MEDICAID PRESCRIPTION DRUG REIMBURSEMENT: WHY THE GOVERNMENT PAYS TOO MUCH

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND
COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

DECEMBER 7, 2004

Serial No. 108–126

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MEDICAID PRESCRIPTION DRUG REIMBURSEMENT: WHY THE GOVERNMENT PAYS TOO MUCH

TUESDAY, DECEMBER 7, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2322, Rayburn House Office Building, Hon. Joe Barton (chairman) presiding.

Members present: Representatives Bilirakis, Walden, Ferguson, Rogers, Barton (ex officio), Waxman, Markey, and Dingell (ex officio).

Also present: Representative Stupak.

Staff present: Mark Paoletta, majority counsel; Andrew Snowdon, majority counsel; Brad Conway, majority counsel; Mike Abraham, legislative clerk; Edith Holleman, minority counsel; and Turney Hall, minority clerk.

Chairman BARTON. The subcommittee will come to order.

Today we are going to hold a hearing on Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much.

We have got a number of panels and a number of witnesses. This is a very important hearing. Medicaid is a program for the poorest and sickest people in our country. We in the Congress have a responsibility to make sure that every possible dollar available under the program goes to those who need it the most. We also have an obligation to make sure that the American taxpayer gets what he or she is paying for.

Unfortunately, the current system by which we reimburse health care providers for prescription drugs under Medicaid flies in the face of both of these principles. The system is broken, and it needs to be fixed. The Government pays far too much for many prescription drugs under Medicaid, primarily because most States continue to use a system that is called average wholesale price, or AWP, as the basis for their reimbursement.

For example, during our investigation, the committee has obtained documents showing that in the summer of 2002 one drug manufacturer's direct sales price of 2,000 20 milligram capsules of Fluoxetine, the generic version of the popular antidepressant Prozac, was $82.62, while the average wholesale price was more than $5,300. Let me repeat that. The generic version, $82.62, but the average wholesale price was $5,300.

I would like to commend the former subcommittee chairman, Mr. Jim Greenwood, and the current vice chairman, Mr. Greg Walden, who is sitting to my right, for their work on this issue over the last year. What they have done is very, very important.

Chairman Greenwood, in particular, was tenacious in the pursuit of average wholesale price reform, first in Medicare where we did change the system, and now in Medicaid where, so far, we have not. In fact, today's hearing is an outgrowth of the committee's prior work on AWP drug-based drug reimbursement under Medicare.

During a hearing back in September 2001, Chairman Greenwood noted that the term AWP could just as easily be an acronym for "ain't what is paid." sadly, this remains true today. As you will hear shortly, the Federal Government and, ultimately, the American taxpayer could save hundreds or millions or even billions of dollars a year if States would bring drug reimbursements more in line with what they actually cost the pharmacy and other health care providers to purchase these drugs.

Today's hearing, which is a culmination of an extensive investigation by the subcommittee staff on a bipartisan basis, will focus on systemic problems with the structure and administration of prescription drug expenditures under Medicaid, as well as abuses of the system.

The committee's prior AWP work ultimately led to important changes in last year's landmark Medicare Modernization Act, MMA, changes that will save the Medicare program $15 billion over the next 10 years. It is my profound hope that this hearing, by exposing some of those same problems and abuses, will set the stage for similar Medicaid reform on a bipartisan basis in the upcoming Congress.

Medicaid is supposed to reimburse pharmacists the estimated acquisition cost of the drugs, plus a reasonable dispensing fee. Over the years, AWP has emerged as a proxy for estimated acquisition costs. Currently, all but eight States rely on AWP as the basis of Medicaid reimbursement. Unfortunately, and all too often, AWP bears little or no resemblance to what these providers really pay, particularly in the generic marketplace where multiple manufactures compete to sell identical drugs that are, for all intents and purposes, a commodity.

During the course of this investigation the committee has uncovered evidence that several manufacturers either inflate their AWPs or actively market their products not based on the lowest price but on the difference between the price and the reimbursement amount, better known in the industry as the spread.

Although the manufacturer's practice of marketing the spread appears to have waned in recent years due in large part to litigation and the heightened scrutiny generated by the work of this committee and others, the existence of substantial spreads remains a fixture of Medicaid prescription drug reimbursement.

Let me say that again. The existence of substantial spreads remains a fixture of Medicaid prescription drug reimbursement.

Generic manufacturers initially set the AWP of their product at 89.9 percent of the brand name's AWP. In the words of one manufacturer, we "set it and forget it." Meanwhile, fierce competition

drives down the actual sales price of these generics, therefore increasing the spread, often dramatically.

I want to be clear here that the price competition is a good thing. Generic drugs have a critical role in play in containing soaring drug costs. Concern, however, is that because of AWP the Medicaid program all too often misses out on these cost savings. Medicaid's use of AWP corrupts the market and turns what would otherwise be a positive development, namely price competition, into abuse that deprives Medicaid of the benefits.

The primary beneficiaries of the current Medicaid reimbursement structure are the retail pharmacies. Data obtained by the committee from five of the largest retail pharmacy chains reveals that during the period of July 1, 2002, to June 30, 2003 the average acquisition cost for seven widely prescribed generic drugs was 22 cents, while the average Medicaid reimbursement just for those drugs alone was 56 cents, more than double the cost; and you can see that on the chart that is up on the overheads.

Indeed, evidence gathered by the committee suggests that Medicaid reimbursement is more generous than that of most private payors. The pharmacies do not generally deny that they reap substantial margins on certain prescription drugs under Medicaid. Their argument is that any overpayments for prescription drugs are necessary to offset Medicaid dispensing fees, which they assert do not cover the true cost of the services that they provide to the Medicaid population.

This situation is analogous to physician-administered drugs in Medicare. In the new Medicare law, we have attempted to make significant changes to the way that physician-administered drugs are reimbursed, scrapping AWP in favor of a new market-based average sales price and increasing payments for physician services.

A recent Government Accountability Office study released just last week shows that, the appropriateness of the new payments here as is in Medicare.

I believe that we should pay providers fairly for their services. I have got absolutely no problem with increasing dispensing fees, if that is what we need to do. But we should pay them accurately so that we can achieve cost savings while ensuring that Medicaid beneficiaries will continue to have access to critically important drugs.

In this context, I am especially pleased to welcome David Balland from the Texas Health and Human Services Commission and Patrick O'Connell from the Texas Attorney General's Office.

Texas is one of the States on the forefront of Medicaid reform; and the approach that the State of Texas Medicaid program has taken to address these problems, an approach that should serve as a model to other States, in my opinion, is one of flexibility, transparency and fairness.

Texas has imposed an aggressive reimbursement formula and requires manufacturers to provide transaction data as a means of verifying acquisition costs, while at the same time having one of the highest dispensing fees of any State. These reforms have resulted in substantial cost savings for both the State and to the Federal Government, yet not one pharmacy has left the program as a result of underpayment.

This is work that was begun under then Attorney General John Cornyn, who is now one of our Senators from Texas. I want to commend him for his work in that area.

As the Texas Attorney General in 1999, Senator Cornyn identified Medicaid fraud as a priority and created a special section devoted entirely to this issue. Senator Cornyn was invited to testify here today, but, due to a scheduling conflict, he is not available.

I want to thank all of our witnesses at today's hearings. I think that with the amount of money that we are spending on prescription drugs under our Medicaid program it is very important that we identify reforms to get the biggest bang for the buck.

I want to think the committee staff on both sides of the aisle for the strong work that they have done over the last year and a half on this issue, and I look forward to this being one of the landmark hearings of this subcommittee.

[The prepared statement of Hon. Joe Barton follows:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Medicaid is a program for the poorest and sickest people in this country, and we in Congress have a responsibility to make sure that every possible dollar available under this program goes to those who need it the most. We also have an obligation to make sure that the American taxpayer gets what he or she pays for. Unfortunately, the current system by which we reimburse health care providers for prescription drugs under Medicaid flies in the face of both of these principles. The system is broken, and it needs to be fixed.

The government pays far too much for many prescription drugs under Medicaid, primarily because most states continue to use Average Wholesale Price, or AWP, as the basis of reimbursement. For example, during this investigation, the Committee obtained documents showing that in the summer of 2002 one drug manufacturer's direct sales price of 2000 20-milligram capsules of fluoxetine—the generic version of the popular antidepressant Prozac—was $82.62, while the AWP was more than $5,300.

I would like to commend former Subcommittee Chairman James Greenwood and current Vice Chairman Greg Walden for the tremendous work that they have done on this very important issue. Chairman Greenwood, in particular, has been tenacious in the pursuit of AWP reform, first in Medicare and now in Medicaid. In fact, today's hearing is largely an outgrowth of the Committee's prior work on AWP-based drug reimbursement under Medicare. During a hearing back in September 2001, Chairman Greenwood noted that the term AWP could just as easily be an acronym for "ain't what's paid." Sadly, this remains true today. As you will hear shortly, the federal government—and ultimately the American taxpayer—could save hundreds of millions of dollars per year if states would bring drug reimbursements more in line with what it actually costs pharmacies and other health care providers to purchase these drugs.

Today's hearing, which is the culmination of an extensive investigation by Subcommittee staff, will focus on systemic problems with the structure and administration of prescription drug expenditures under Medicaid, as well as abuses of the system. This Committee's prior AWP work ultimately led to important changes in last year's landmark Medicare Modernization Act, changes that will save the Medicare program approximately $15 billion over the next ten years. It is my profound hope that this hearing, by exposing some of these problems and abuses, will set the stage for similar Medicaid reforms in the 109th Congress.

Medicaid is supposed to reimburse pharmacists the estimated acquisition cost of the drugs, plus a reasonable dispensing fee. Over the years, AWP has emerged as a proxy for estimated acquisition cost: currently, all but eight (8) states rely upon AWP as the basis of Medicaid reimbursement. Unfortunately, all too often AWP bears little or no resemblance to what these providers really pay, particularly in the generic marketplace, where multiple manufacturers compete to sell identical drugs that are, for all intents and purposes, a commodity. During the course of its investigation, the Committee uncovered evidence that several manufacturers either inflated their AWP's or actively marketed their products not based on the lowest price,

but on the difference between the price and the reimbursement amount—better known as the "spread."

Although the manufacturers' practice of marketing the spread appears to have waned in recent years, due in large part to litigation and the heightened scrutiny generated by the past work of this Committee and others, the existence of substantial spreads remains a fixture of Medicaid prescription drug reimbursement. Generic manufacturers initially set the AWP of their products at 89.9% of the brand-name drug's AWP, and, in the words of one manufacturer: "We set it and forget it." Meanwhile, fierce competition drives down the actual sales prices of these generics, thereby increasing the spread, often dramatically.

I want to be clear here that price competition is a good thing, and generic drugs have a critical role to play in containing soaring drug costs. My concern, however, is that because of AWP, the Medicaid program all too often misses out on these cost savings. Medicaid's use of AWP corrupts the market and turns what would otherwise be a positive development—namely price competition—into an abuse that deprives Medicaid of the benefits.

The primary beneficiaries of the current Medicaid reimbursement structure are the retail pharmacies. Data obtained by the Committee from five of the largest retail pharmacy chains reveals that during the period July 1, 2002 to June 30, 2003, the average acquisition cost for seven widely-prescribed generic drugs was $0.22, while the average Medicaid reimbursement, just for the drugs alone, was $0.56—more than double the cost. Indeed, evidence gathered by the Committee suggests that Medicaid reimbursement is more generous than that of most private payors.

The pharmacies do not generally deny that they reap substantial margins on certain prescription drugs under Medicaid. Rather, they argue that any overpayments for prescription drugs are necessary to offset Medicaid dispensing fees, which they assert do not cover the true cost of the services that they provide to the Medicaid population. This situation is analogous to physician-administered drugs in Medicare. In the new Medicare law, we made significant changes to the way that physician-administered drugs were reimbursed, scrapping AWP in favor of a new market-based Average Sales Price and increasing payments for physician services. A recent Government Accountability Office study released just last week by this Committee confirmed the appropriateness of the new payments. Here, as in Medicare, I believe that we should pay providers fairly, but accurately, so that we can achieve cost savings while ensuring that Medicaid beneficiaries will continue to have access to critically important drugs.

In this context, I am especially pleased to welcome David Balland, from the Texas Health and Human Services Commission and Patrick O'Connell, from the Texas Attorney General's Office. Texas is one of the states on the forefront of Medicaid reform, and the approach that the Texas Medicaid program has taken to address these problems—an approach that should serve as a model to other states—is one of flexibility, transparency, and fairness. Specifically, Texas has imposed an aggressive reimbursement formula and requires manufacturers to provide transaction data as a means of verifying acquisition costs, while at the same time having one of the highest dispensing fees of any state. These reforms have resulted in substantial cost savings for both the state and the federal government, yet not one pharmacy has left the program as a result of underpayment.

Much of the good work done by Texas Medicaid and the Attorney General's Office is due, in no small part, to the foresight and dedication of Senator John Cornyn, and I would like to pay Senator Cornyn a special tribute here this morning. As the Texas Attorney General in 1999, Senator Cornyn identified Medicaid fraud as a priority and created a special section devoted entirely to this issue. I invited Senator Cornyn to testify here today, but, due to a scheduling conflict, he was unfortunately not available. Senator Cornyn did submit a written statement for the record that I would like to attach to these remarks.

I want to thank all of the witnesses at today's hearing for taking the time to attend today's hearing. Given the tremendous amount of money spent on prescription drugs under the Medicaid program, I think that this is an issue worthy of the Committee's attention, and I hope that this hearing will help to reform a system that is plainly in a state of disrepair.

Chairman BARTON. Senator Cornyn has submitted a written statement for the record, and we will put that into the record.

[The prepared statement of Hon. John Cornyn follows:]

PREPARED STATEMENT OF HON. JOHN CORNYN, A UNITED STATES SENATOR FROM THE STATE OF TEXAS

Thank you, Mr. Chairman, for inviting me to testify today before the Subcommittee on Oversight and Investigations concerning government payments for Medicaid prescription drug reimbursement. I was disappointed my schedule did not permit me to appear in person, but I am deeply appreciative of the opportunity to submit these written remarks.

I would also like to thank Patrick O'Connell, Chief of the Civil Medicaid Fraud Section of the Texas Attorney General's Office, for his comments. I share Mr. O'Connell's pride that Texas was the first state to move from AWP based reimbursement to wholesaler cost and that the Texas Vendor Drug Program is one of the best Medicaid programs in the country, if not the best. I especially applaud the dedication and enthusiasm that the current Texas Attorney General Gregg Abbott and Chief O'Connell have shown in continuing the work we initiated during my tenure as Texas Attorney General combating Medicaid fraud and abuse.

As you are aware, suspicions of overpayments for prescription drugs in Medicaid programs across the nation have been alleged since the programs were first implemented. In 1977, the U.S. Congress enacted the federal Medicare/Medicaid Anti-Fraud and Abuse Act, which provided federal funding to states that established Medicaid fraud and abuse control units. In 1997, Texas' ability to combat Medicaid fraud improved when the Texas Legislature enacted Senate Bill 30, which provided for implementing fraud detection technology, additional monitoring of service providers along with administrative penalties, civil remedies, and criminal sanctions for fraudulent and abusive actions.

I was sworn in as Texas Attorney General in 1999 and became increasingly concerned about overpayments for prescription drugs in the Texas Medicaid Program and other specific instances of fraud and abuse. In August of 1999, I created the Civil Medicaid Fraud Section within my Elder Law Division. Prior to that time, few investigations, and no lawsuits, regarding civil Medicaid fraud had been pursued. With the creation of this special Section, we dedicated resources and efforts to fighting fraud, waste, and abuse in the Medicaid system.

I was deeply troubled by some of our discoveries. While there are several examples upon which I could draw, there is one that continues to resonate. In September of 2000, we filed a landmark case against three drug companies—DEY, Inc., Roxane Laboratories, Inc., and Warrick Pharmaceuticals Corporation—for civil Medicaid fraud as part of a complicated scheme to corner the market in respiratory disease medications.

Typically, when a doctor prescribes medication for a Medicaid patient, a pharmacy dispenses the medication and then bills Medicaid for reimbursement. In order for the drug to be eligible for Medicaid reimbursement, the drug manufacturer must certify the prices at which it sells the drug in writing with the Texas Department of Health (TDH). TDH uses that certification to calculate the amount of reimbursement pharmacies will receive. Texas at the time was the only state that required drug manufacturers to certify their prices in order to be eligible for Medicaid reimbursement.

These drug companies falsely reported inflated prices for their respiratory medications to TDH. Then, they turned around and sold these drugs to pharmacies at drastically reduced prices while the pharmacies were reimbursed at the inflated price. This scheme ensured that pharmacies would dispense the defendants' drugs over other less profitable medications. All of this was part of a strategy by the drug companies to increase their market share and "capture" the market. To be blunt, this was tantamount to stealing from taxpayers. Medicaid funds should be spent only to provide necessary medical care and prescription medications to those who need it. Instead, elaborate schemes such as these steal scarce tax dollars to finance corporate market strategies and to inflate illegally the bottom line. Plain and simple: it is wrong

Two of the defendants ultimately settled for $45.5 million collectively, and the third is set for trial. This lawsuit sent a clear signal to participants in Medicaid programs across the country that those who try to steal from the Medicaid program may be prosecuted with a heavy price inflicted.

This is but one example. However, it effectively emphasizes the importance of remaining vigilant in our efforts for those of us charged with protecting the public trust. I commend you, Mr. Chairman, and the members of this Subcommittee, for continuing to examine these important issues. And, I appreciate the opportunity to share with you some of my experiences.

Thank you.

Chairman BARTON. Now I want to recognize my distinguished friend from Massachusetts, one of the members who has been a real watchdog on this subcommittee, Mr. Markey of Massachusetts, for an opening statement.

Mr. MARKEY. Thank you, Mr. Chairman, very much and thank you for having this very important hearing today.

We are going to hear from the Department of Health and Human Services Inspector General, indicating that the Federal Government is paying far too much for prescription drugs under the Medicaid program.

This is not the first time that such concerns have been raised. We have been getting reports of these overpayments since the early 1990's. Yet the Centers for Medicare and Medicaid Services have continually failed to address their international mismanagement and the systematic problems that enable drug companies and pharmacies to commit fraud and inflate the prices of their drugs.

Prescription drugs are one of the fastest growing expenses for Medicaid. Between 1992 and 2002, expenditures for prescribed drugs increased by 19 percent per year, and by 2003 the Medicaid program spent over $31 billion on prescription drugs alone. If we do not address the rising costs of prescription drugs, it will drain the Medicaid program of the funds needed to provide health care to our Nation's most vulnerable populations.

There are three problems with the current system that I hope to hear more about in today's hearing. The first is that CMS has been slow to implement simple cost-saving measures within the agency. The second problem is that the price the States pay for prescription drugs has nothing to do with the actual cost of the drug. The third problem is that the Federal Government is not allowed to use its market power to negotiate lower prices for consumers.

The Inspector General has identified several simple ways that CMS could save money if they were more diligent in their administration of the problem. Putting qualified drugs on the Federal upper limits list as soon as they are approved, for example, could save over $100 million.

Unfortunately, not all of Medicaid's problems can be solved so easily. We also have to address the fact that the current reimbursement system practically begs to be exploited.

The fact that numerous pharmacies and drug companies have pled guilty to overcharging Medicaid, lying about their costs, taking kickbacks and submitting false claims show the vulnerability of the system. We currently have a system where companies are asked to simply make up the price that the States will pay for their drugs. This price, called the average wholesale price, has no relationship to the actual cost of the drug, and the companies that set that price do not have to provide the States any information about the real costs of manufacturing the drugs.

It is like being asked to pay $50 for a T-shirt without having access to any information about what others have paid for the same T-shirt. If the vendor tells you that it is a fair price but doesn't have to give you any evidence that it is reasonable, you have no choice but to trust that seller, that that seller is being honest.

When it comes to spending taxpayer money, we cannot base our decisions on trust. We need to base them on evidence. In order to

ensure that States are not overpaying for prescription drugs, they should have access to pricing information and the actual costs of the drugs.

We will hear today about the new program that has been successful in actually reducing spending on prescription drugs. In April, HHS allowed Michigan, Vermont, New Hampshire, Alaska and Nevada to form a purchasing pool. By combining their programs, they were able to increase their market power and to negotiate better drug prices. At a time when drug prices were rising at a rate of almost 20 percent per year, Michigan's drug prices actually declined about 1 percent in the first year of their pooling program. In response to their success, Administrator Mark McClelland stated that pools are a proven legal and safe way to lower drug costs.

However, if evidence suggests that pools work, and CMS acknowledges that they are an effective way to lower costs, then why is the Federal Government forbidden from creating one large pool and using its market power to negotiate the best price for Medicaid and Medicare beneficiaries with the drug companies across our country?

Today, we are going to hear from Wal-Mart about how they are reducing costs through the purchasing power of their Sam's Clubs. But why can't we establish an Uncle Sam's Club that can link up all of the States to pool their enormous purchasing power of the Federal and State governments to further drive down the costs of prescription drugs for every ordinary American in our country? Why are they forbidden from pooling their resources in order to help those most dependent upon prescription drugs who are in fact being tipped upside down and having money shaken out of their pockets to pay for prescription drugs that every American knows is overpriced to those vulnerable consumers of needed prescription drugs?

In order to preserve this critical health care program, we need to find ways to curb the costs of prescription drugs. Instead of wasting taxpayers' dollars on overinflated drug prices, Medicaid funds could be spent on providing better health care to our country's most vulnerable populations, the children, the elderly, the poor and the disabled.

I look forward to hearing from the recommendations of the IG, the States and other witnesses, and I am compliment you on having this hearing, Mr. Chairman.

Chairman BARTON. Thank you, Mr. Markey.

We now ask our distinguished vice-chairman of the subcommittee, Mr. Walden, for an opening statement.

Mr. WALDEN. Thank you very much, Mr. Chairman.

Let me begin by saying that I, too, share the concerns that the States and the Federal Government are paying too much for drugs dispensed to our Nation's poorest individuals under the Medicaid program. I look forward to learning more about what we can do to remedy this situation.

In September 2001, as you have mentioned, this committee held a hearing that addressed similar problems with the prescription drug reimbursement under Medicare. The systemic problems and abuses brought to light during that hearing helped pave the way

for significant reforms under the Medicare Modernization Act, scrapping Medicare's reliance on the flawed average whole price, or AWP.

And I note in your committee about Mr. Greenwood saying "ain't what is paid." I think it is maybe always worst price, at least when it comes to the Government.

We now turn our attention to Medicaid. Despite differences between the two programs, there is one common denominator, and that is AWP. We have allowed a system to develop where AWP, a number not defined by statute or regulation, has become the reimbursement standard for the vast majority of Medicaid prescription drug programs.

Because AWP is not, in many cases, reflective of actual market prices, it opens the door for the abuses that we will hear about today. At the very least, it serves to deny the taxpayer the full benefit of price competition in the generic marketplace. Let me give you an example.

Ipratropium Bromide is a popular inhalation drug used to treat patients with respiratory problems like bronchitis, emphysema, and asthma. Data obtained by this committee during this investigation reveals that between 1998 through 2003 the AWP for most generic manufacturers in the marketplace for a particular size and strength of the drug remained constant at $44, while the sales price dropped from the mid teens to the low single digits. In mid 2000, however, another competitor entered the market with an AWP of $56 for that same drug; and internal drug company documents show that the existing manufacturers immediately began to lose business because pharmacies could make more money off of the higher AWP.

Data obtained by the committee from five of the largest retail pharmacy operations also show how the Medicaid program failed to capture the cost savings. In fiscal year 2000, the average cost to these pharmacies for a single unit of this particular Ipratropium Bromide product was roughly 20 cents, while their average Medicaid reimbursement was 41 cents for the same product, not including any dispensing fees. And by 2002 the average cost had dropped to 13 cents, but average Medicaid reimbursement remained at 41 cents.

We will hear today from the Department of Health and Human Services Office of Inspector General about the substantial cost savings, perhaps totaling hundreds of millions of dollars, that could be achieved by eliminating AWP as a reimbursement standard, as well as by placing drugs on the Federal upper limit in a more timely fashion.

I am also pleased that Edward Stratemeier, former Vice President of Legal, Government Relations and Public Policy at Aventis Pharmaceuticals, a manufacturer of brand name drugs, has agreed to appear before the committee to discuss problems that he and his former employer had identified with the use of AWP as a reimbursement standard and the need for AWP reform.

Medicaid prescription drug costs are enormous. We all know that. And they continue to rise. In fiscal year 2002, total Medicaid expenditures for prescription drugs exceeded $23 billion; and the Office of the Actuary at CMS projects that Medicaid expenditures

will increase at an average of 12.7 percent per year through 2011. A recent report from the National Association of State Budget Officers predicts that in 2004 States will, for the first time, spend more on Medicaid than any other program, including education.

In light of these soaring drug costs under Medicaid, it is imperative that the Federal and State governments do everything possible to ensure that drug reimbursement is adequate and fair not only to the taxpayers but also to the pharmacies dispensing the drugs. To date, the solution adopted by many State Medicaid programs to the problem of bloated AWPs has been to modify their reimbursement formulas with larger discounts off of AWP. This is a band-aid, not a long-term solution.

A discount off of a bad number is still a bad number, and at what point does it simply become nonsensical? AWP minus 15 percent? AWP minus 50 percent? AWP minus 80 percent? As in the case of Medicare, I recognize that, as we consider how to reform prescription drug reimbursement under Medicaid, we must also consider the impact on the service providers.

So let me say up front that no one expects pharmacies, or any other health care providers, for that matter, to serve the Medicaid population at a loss. If the pharmacies are, in fact, underpaid for their services, then let's examine that issue more fully, analyze the relevant data and take steps to ensure they are reimbursed fairly for their services and expenses.

The answer is not to proceed with the status quo, however, making up shorts in one area through overpayments in another and hoping at the end of the day everything comes out in the wash.

I would point out, however, that, according to figures obtained by the committee, Medicaid dispensing fees are far more generous than the pharmacies receive from their largest private payors.

I would also like to thank all of the witnesses for appearing here today, and I hope this hearing will serve as a springboard for meaningful Medicaid reform in the near future. AWP is a convention that has long outlived its usefulness, and it is time for us to adopt a reimbursement standard for Medicaid that is more reflective of actual market cost.

AWP, we are told, has been described as the devil we know. But I guess I would prefer not to dance with this devil at all.

Thank you, Mr. Chairman.

[The prepared statement of Hon. Greg Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Let me begin by saying that I too share the concern that the States and the federal government are paying too much for drugs dispensed to our nation's poorest individuals under the Medicaid program. I look forward to learning about what we can do to help remedy this situation while still maintaining the quality of care that Medicaid beneficiaries deserve.

In September 2001, this Committee held a hearing that addressed similar problems with prescription drug reimbursement under Medicare. The systemic problems and abuses brought to light during that hearing helped pave the way for significant reforms under the Medicare Modernization Act, scrapping Medicare's reliance on the flawed Average Wholesale Price, or AWP.

We now turn our attention to Medicaid. Despite differences between the two programs, there is one common denominator: AWP. We have allowed a system to develop where AWP—a number not defined by statute or regulation—has become the reimbursement standard for the vast majority of Medicaid prescription drug pro-

grams. Because AWP is not, in many cases, reflective of actual market prices, it opens the door for the abuses that we will hear about today. At the very least, it serves to deny the taxpayer the full benefit of price competition in the generic marketplace.

Ipratroprium bromide—a popular inhalation drug used to treat patients with respiratory problems (bronchitis, emphysema, and asthma)—serves as an excellent example. Data obtained by the Committee during this investigation reveals that from 1998 through 2003, the AWP of most generic manufacturers in the marketplace for a particular size and strength of the drug remained constant at $44, while the sales price dropped from the mid-teens to low single digits. In mid-2000, however, another competitor entered the market with an AWP of $56 for the same drug, and internal drug company documents show that the existing manufacturers immediately began to lose business because pharmacies could make more money off of the higher AWP.

Data obtained by the Committee from five of the largest retail pharmacy operations also shows how the Medicaid program failed to capture these cost savings. In Fiscal Year 2000 (7/1/00-6/30/01), the average cost to these pharmacies for a single unit of this particular ipratroprium bromide product was roughly $0.20, while their average Medicaid reimbursement was $0.41 for the same product, not including any dispensing fees. By FY 2002, the average cost had dropped to $0.13, but the average Medicaid reimbursement remained at $0.41.

We will hear today from the Department of Health and Human Services Office of Inspector General about the substantial cost savings—perhaps totaling hundreds of millions of dollars per year—that could be achieved by eliminating AWP as a reimbursement standard, as well as by placing drugs on the Federal Upper Limit in a more timely fashion. I am also pleased that Edward Stratemeier, former Vice President of Legal, Government Relations and Public Policy at Aventis Pharmaceuticals, a manufacturer of brand-name drugs, has agreed to appear before the Committee to discuss problems that he and his former employer had identified with the use of AWP as a reimbursement standard and the need for AWP reform.

Medicaid prescription drug costs are enormous, and they continue to rise. In Fiscal Year 2002, total Medicaid expenditures for prescription drugs exceeded $23 billion, and the Office of the Actuary at CMS projects that Medicaid prescription drug expenditures will increase at an average of 12.7% per year through 2011. A recent report from the National Association of State Budget Officers predicts that in 2004, states will, for the first time, spend more on Medicaid than any other program, including education.

In light of these soaring drug costs under Medicaid, it is imperative that the federal and state governments do everything possible to ensure that drug reimbursement is adequate and fair, not only to the taxpayers but to the pharmacies dispensing the drugs. To date, the solution adopted by many state Medicaid programs to the problem of bloated AWPs has simply been to modify their reimbursement formulas with larger discounts off of AWP. This is a band-aid, not a long-term solution. A discount off of a bad number is still a bad number, and at what point does it simply become nonsensical: AWP minus 15 percent? 50 percent? 80 percent?

As in the case of Medicare, I recognize that as we consider how to reform prescription drug reimbursement under Medicaid, we must also consider the impact on the service providers. Let me say up front that no one expects pharmacies, or any other health-care providers for that matter, to serve the Medicaid population at a loss. If the pharmacies are, in fact, underpaid for their services, then let's examine that issue more fully, analyze the relevant data, and take steps to ensure that they are reimbursed fairly for their services and expenses. The answer is not to proceed with the status quo, making up for shortfalls in one area through overpayments in another and hoping that, at the end of the day, everything comes out in the wash. I would point out, however, that according to figures obtained by the Committee, Medicaid dispensing fees are far more generous than those that the pharmacies receive from their largest private payors.

I too would like to thank all of the witnesses for appearing here today, and I hope that this hearing will serve as a springboard for meaningful Medicaid reform in the near future. AWP is a convention that has long outlived its usefulness, and it is time for us to adopt a reimbursement standard for Medicaid that is more reflective of actual market cost. AWP has been described by some as "the devil we know," but I guess I would prefer not to dance with the devil at all.

Chairman BARTON. Thank you, Mr. Walden.

The Chair would note that we have, in order of appearances, the distinguished Member from California, Mr. Waxman, and the equally——

Mr. WAXMAN. The more distinguished gentleman.

Chairman BARTON. They are both equally distinguished. One is the ranking member of the full committee, however. We will recognize Mr. Dingell for an opening statement.

Mr. DINGELL. Thank you, Mr. Chairman; and I thank my colleague. I think he is overly kind to me. And I want to express my respect and appreciation to him and also to you, Mr. Chairman.

This morning, we are having a very interesting hearing in which we are trying now to figure out what is going to happen in the future with regard to drug prices under the legislation enacted during the past Congress with regard to Medicare and Medicaid and prescription pharmaceuticals. The situation is not one in which we can look forward with any particular comfort.

This committee has been addressing the use of AWP, or the average wholesale price, as the basis of reimbursement for Federal and State prescription drug programs for several years. As we will learn today, the drug reimbursement system for Medicaid is built on layers of artificial price structures, most of which in no way reflect actual costs.

It has also created an environment that puts providers in situations where they can charge higher drug prices to Federal and State governments and also to private insurers. There have been piecemeal efforts to address this flawed system and to reduce prices. There is a rebate program which covers $7 billion a year of the $30 billion spent for Medicaid prescriptions.

Since 2001, aggressive U.S. Attorneys and State Attorneys General, with the assistance of whistle-blowers such as the ones we will hear from today, have uncovered efforts to game the system and have recovered over $1 billion in Medicare and Medicaid overcharges and fines. These lawsuits will continue, with New York City and the State of Pennsylvania filing the most recent ones.

The States are taking their own steps to reduce drug prices. My own State of Michigan has been a leader in pooling its bargaining power with other States to get lower prices. I welcome Paul Rinehart, head of Michigan's Medicaid program, to this hearing; and I look forward to his testimony.

The Texas Vendor Drug program, which obtains actual drug acquisition prices from vendors, was recently recommended by an expert panel as one that the Centers for Medicare and Medicaid Services should consider implementing nationwide. I would ask, Mr. Chairman, at this time that the report be placed in the record.

Chairman BARTON. Without objection, so ordered.

Mr. DINGELL. Thank you, Mr. Chairman.

[The information referred to follows:]

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Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices

Final Report

Contract #500-00-0049
Task Order 1

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Contents

1.0 Introduction and Background

In both the Medicaid and the Medicare Part B prescription drug programs, there is a need for a payment methodology that accurately reflects the costs of products and services from efficient providers. One essential component of any drug payment methodology is payment for the costs of acquiring the drug product. Many state Medicaid programs and the Medicare Part B program currently base their prescription drug payment on the term known as average wholesale price (AWP), a list price from manufacturers. Other state Medicaid programs pay based on an amount labeled as wholesale acquisition costs (WAC), also a list price. However, both AWP and WAC are list prices, not transaction prices, and are widely viewed as inflated relative to actual acquisition costs.

This report provides background on current Medicaid and Medicare policy and the structure of the pharmaceutical marketplace and of pharmaceutical prices and payments, highlighting implications for the estimation of acquisition costs and for payment policy. Alternative approaches for estimating pharmacies' and physicians' acquisition costs for prescription drugs are then described and evaluated. After review and evaluation of the options, the authors recommend that actual acquisition costs be estimated by using manufacturer-supplied data on average selling prices by class of trade. The proposed approach would be similar to that used by the Texas Medicaid Vendor Drug program, but might incorporate more precise definition of terms, more classes of trade, and other differences. Given that additional primary data collection may not be efficient or feasible at this time, the authors propose to further analyze the Texas program and the data it collects in order to refine our recommended approach and to understand its potential value to public payers, either as a point of comparison for existing payment policies or as the basis of a new policy.

This report is based on the authors' experience, research, and analysis. In addition, it is based on the experience and insights of an expert panel. These 15 experts and one observer were selected in consultation with CMS to provide a range of perspectives. Experts came from a variety of sectors including CMS, vendors of drug utilization and pricing information, the pharmacy sector, oncologists and other physicians, researchers, the State Medicaid sector, drug wholesalers, and individuals with expertise in drug pricing gained via participation in, and observation of the current drug pricing environment. Appendix A lists the panel members. Each member of the panel was interviewed individually in November 2003 and attended a one and a half day panel meeting in January 2004. After the meeting, panel members were invited to further comment on key topics either in writing or by phone. Of the 15 panel members, 12 chose to provide additional comments. Themes from the panel meeting and the individual interviews are incorporated into the discussion below. Appendix B offers a summary of key points made during the January meeting.

2.0 Overview of Recent Drug Pricing Issues and Current Medicaid and Medicare Policy

2.1 Overview of Recent Drug Pricing Issues

Several essential contextual issues have implications for estimating acquisition costs in the Medicaid and Medicare context.

- Why are there concerns about drug prices and expenditures in these programs?
- What are the sources of growth in drug prices and expenditures?

- How does drug product payment fit into the total compensation to pharmacies, physicians and other providers?
- What is the structure of the pharmaceutical market both in terms of the flow of product (channels of distribution) and in terms of the flow of funds (sources of payment)?
- What are the meanings of various drug product pricing terms and how are these prices set in the market?
- Do pricing patterns differ by class of trade or type of provider (e.g., community pharmacies versus physicians versus others)?
- Do pricing patterns differ by type of drug (e.g., brand versus generic)?

Each of these issues is addressed in later portions of this report, and each bears on the appropriate method for estimating actual acquisition costs.

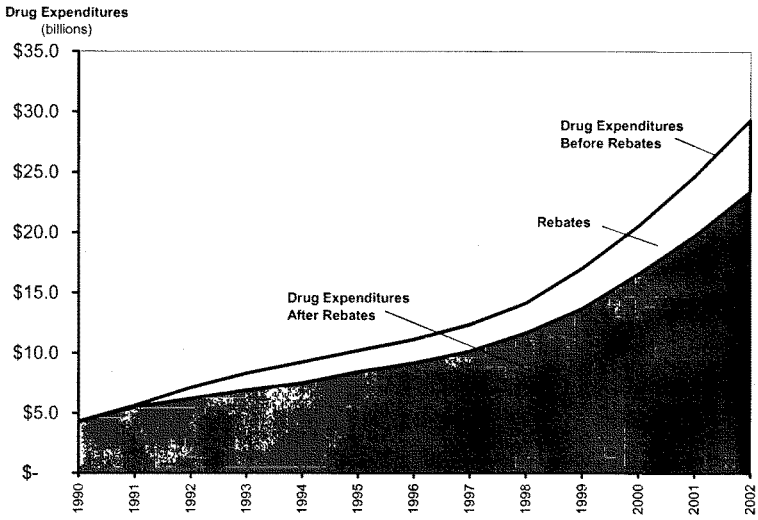
2.2 Signals of a Need for Change

A number of signals in the market have raised concern about prescription drug prices and expenditures to the top of the public policy agenda. First, outpatient drug expenditures in both public and private programs have been growing at an annual rate of 15 to 20 percent since the mid-1990s—a rate that is more than double the rate of growth in total health spending (i.e., Medicaid total expenditures grew 7.7 percent per year from 1997 to 2000).[12] Second, prescription drugs are the fastest growing sector of Medicaid programs, which, in turn, are one of the largest segments of state spending at a time when states are facing record deficits.[3] Third, the prices paid for prescription drugs by the Medicaid and Medicare programs have come under question compared to the prices paid by other sectors of the market.[4] For example, most other government programs (i.e., the Veterans Administration, and the 340B program for federally qualified facilities) pay less for prescription drugs than do the Medicaid or Medicare Part B programs, even after accounting for rebates.[5] Fourth, there is evidence that drug manufacturers have 'gamed' the pricing policies of both Medicare Part B and the Medicaid drug rebate program in a manner that creates economic incentives that lead to increased rather than decreased drug expenditures.[6,7,8] Fifth, legislation to cover outpatient prescription drugs under Medicare has recently been passed by the U.S. Congress and is set for an ambitious implementation schedule over the next year and one-half.[9]

2.3 Medicaid Drug Program and Expenditures

The Medicaid drug program grew from $7.1 billion in 1992 to $29.3 billion in 2002—more than a four-fold increase in ten years; (see Exhibit 1). Even after accounting for the rebates received by the Medicaid program (federal and state levels), the drug expenditures grew from $6.2 billion to $23.4 billion—still nearly a four-fold increase over ten years. Both legislative changes and specific trends within the drug program have contributed to the growth in drug program expenditures.

Exhibit 1: U.S. Medicaid Drug Expenditures Before and After Rebates: 1990 to 2002 (Current $)



SOURCE: Compiled by Stephen W. Schondelmeyer, PRIME Institute, University of Minnesota from data found in CMS/HCFA-2082 Reports (adjudicated & paid claims), CMS/HCFA-64 Reports (budgeted and expended funds), CMS/HCFA Medicaid Drug Utilization public use files, and the annual volumes of Pharmaceutical Benefits Under State Medical Assistance Programs (Reston, VA: National Pharmaceutical Council, 1990 to 2002).

Legislative and Regulatory History

Historically, the Medicaid drug program has been guided by legislation and regulation that encouraged states to base their payments for the drug product cost on the concept of 'estimated acquisition cost' (EAC). A HCFA memo from 1977 described that "The intent of the final Medicaid regulations on drug payment is to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to see that their ingredient cost levels are as close as possible to actual acquisition cost."[10] More recent reports on the Medicaid drug program describe 'Actual Acquisition Cost' (AAC) as "the pharmacist's net payment made to purchase a drug product, after taking into account such items as purchasing allowances, discounts, rebates, and the like."[11] Since the early 1980s state Medicaid programs have based their EAC upon Average Wholesale Price (AWP) or AWP minus a specific percentage to reflect the prices pharmacists actually pay for the drug products.[12]

At the same time that the Medicaid drug program intended to pay the actual, or estimated acquisition cost, incurred by the pharmacy for a specific drug product, Medicaid regulations also specified that pharmacies were to be paid a 'reasonable dispensing fee.' Medicaid program materials further describe a 'reasonable dispensing fee' as "an established dispensing fee to cover the pharmacy's overhead and profit."[13]

The Medicaid Drug Rebate Program was established by Congress with the passage of the Omnibus Reconciliation Act of 1990 and began operation January 1, 1991. After several legislative revisions

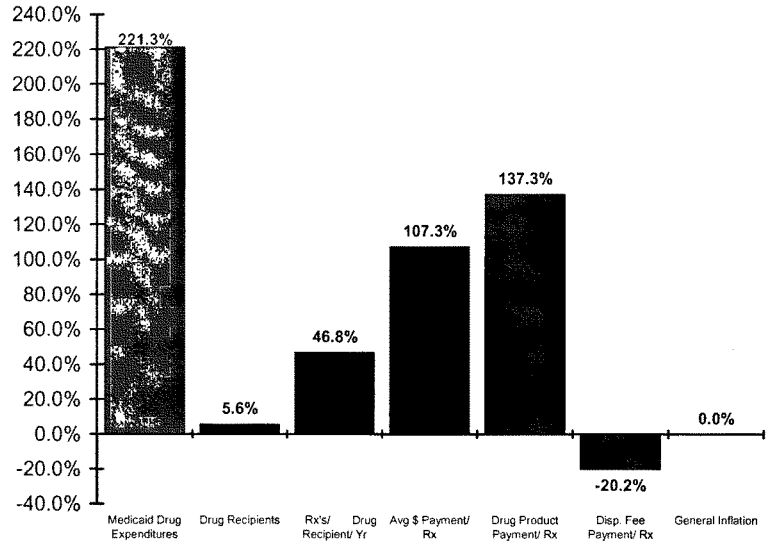
to the program in the early 1990s, the rebate program has remained unchanged for nearly a decade. Drug firms must voluntarily agree to participate in this program in order to have their drug products covered by the Medicaid program. The rebate agreement obligates the drug firm to report to CMS its average manufacturer price (AMP) and its best price for each drug product (by NDC number) on a quarterly basis. State Medicaid programs, then, have to report to CMS and each participating drug firm the quantity of each drug product (by NDC) paid for by the state's Medicaid program in a given quarter. This unit volume is used to calculate the amount of rebate due based on the rebate formulae specified in the statute. Simplistically, drug firms selling single source or innovator multiple source drug products (off-patent brands) must pay a rebate which is the greater of: (1) 15.1 percent of the AMP; (2) or the AMP less the best price offered to certain classes of trade. In addition, an inflation adjustment rebate factor is also due. Non-innovator multiple source drugs (off-patent generics or non-originator brands) pay a fixed percentage rebate of 11% of AMP. These generic drug products are not subject to either the best price calculation or the inflation adjustment rebate.

States' Medicaid programs may, at their discretion, develop state rebates in addition to the federally mandated rebates. Only a handful of states took advantage of the additional state rebate option prior to 2000 (most notably California), but many states have initiated or are exploring how to develop a state rebate above and beyond the federally mandated rebates. The Drug Rebate Program in 1992 provided payments of about $1 billion dollars versus overall drug program costs of $7.1 billion. By 2002 the Drug Rebate Program produced nearly $6 billion in revenue that is shared by the states and the federal Medicaid program to offset the almost $30 billion spent on total Medicaid drug expenditures. The rebate revenue is shared in proportion to the state and federal contributions to each state's Medicaid program costs. The rebate program produces revenue representing more than 20-percent of total Medicaid drug program expenditures. States would not easily make up the revenue produced by the Medicaid Drug Rebate program if the rebate program were to be reduced substantially or removed.

Sources of Growth in Medicaid Drug Expenditures

Between 1992 and 2002, Medicaid drug program expenditures (adjusted for constant dollars) increased 221 percent.[14] This rapid growth is one driver of the interest in revisiting Medicaid payment policy and ensuring that it is optimally designed. In this same period, the number of drug recipients decreased about 6 percent, while the drug utilization rate (prescriptions per person per year) increased nearly 46.8 percent. The average payment per prescription grew more than 107 percent with the manufacturer's drug product cost accounting for a 137 percent increase while pharmacy dispensing fees actually decreased 20 percent, in constant dollars, over the last decade (see Exhibits 2 and 3).

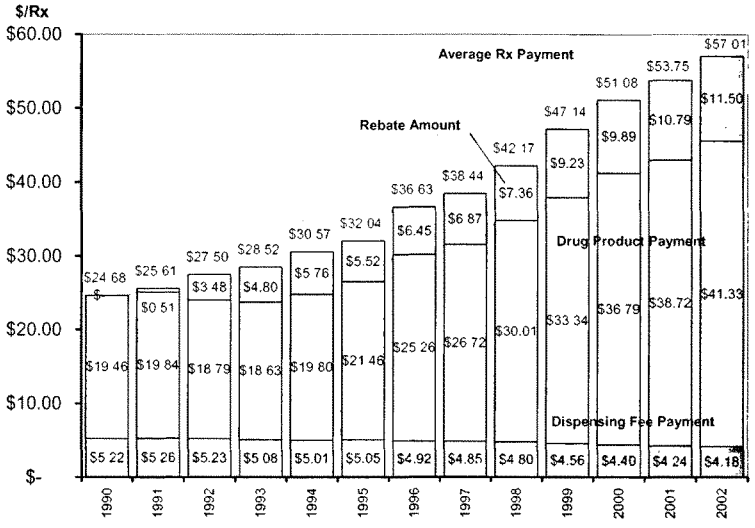
Exhibit 2: U.S. Medicaid Drug Expenditures Percent Change in Major Components: 1992 to 2002 in Inflation Adjusted $



SOURCE: Compiled by Stephen W. Schondelmeyer, PRIME Institute, University of Minnesota from data found in CMS/HCFA-2082 Reports (adjudicated & paid claims), CMS/HCFA-64 Reports (budgeted and expended funds), CMS/HCFA Medicaid Drug Utilization public use files, and the annual volumes of Pharmaceutical Benefits Under State Medical Assistance Programs (Reston, VA: National Pharmaceutical Council, 1990 to 2002).

There are two lessons here. First, drug product prices at the manufacturer level are the major source of increase in Medicaid drug program expenditures. Thus, it is important to focus on this component of the payment policy. Second, these data suggest that pharmacy dispensing fees have not been a source of growth in drug program expenditures and that reductions to pharmacy dispensing fees have not been an effective way to reduce prices at the manufacturer level. Medicaid programs do not purchase drug products directly from manufacturers, but rather prescriptions are purchased through local pharmacies. If management of growth in drug product costs is the desired outcome, the efforts to manage this cost must be focused primarily at the manufacturer level.

Exhibit 3: U.S. Medicaid Average Prescription Payment, Drug Product Payment, and Dispensing Fee: 1990 to 2002 (Constant 2002 $)



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Drug Prices and Pharmacy Payment

The payment amount for drug products to pharmacies and other providers under Medicaid and Medicare cannot be viewed in isolation from the other payments to such providers for storage, handling, counseling, dispensing, billing, record-keeping, and administration. In both the Medicaid and the Medicare program, drug payment policy incorporates two components: a component directly representing the cost of professional services and a component representing drug product costs. Note that, deliberately or not, the drug cost component of the payment has typically offered a margin relative to acquisition costs. This may be appropriate since certain other costs (such as drug inventory and storage, accounts receivable, uncollectible claims and copays, and the cost of capital) vary in proportion to the cost of the drug. In the Medicaid case, many other components of dispensing costs, such as pharmacist time, may be more appropriately viewed as varying according to the number of prescriptions dispensed rather than the cost of the drug product. For these components, a per-unit dispensing fee is appropriate. In addition, as pharmacists provide collaborative services with physicians and other health care providers that assure appropriate medication therapy management a service fee component may also be appropriate.

The drug cost component of the Medicaid and Medicare Part B drug payment systems has historically been based on the publicly available price known as the "Average Wholesale Price" (AWP). This price, however, has become controversial because it is only a suggested (or list) price, but not an actual transaction price. Medicaid programs typically reduce the payment to pharmacies for a drug product by an amount ranging from 5 to 15 percent (varies by state) off of AWP.[15] Certain other drug products under Medicaid, i.e., non-innovator multiple source (NMS) drugs (i.e., generics) are paid

based on a Federal upper limit (FUL), also known as a maximum allowable cost (MAC) limit and some states have state MACs on many more drug products than included on the federal FUL list. This FUL or MAC is not directly based on AWP, but is almost always substantially less than AWP for most generic drug products.

Most experts agree that AWP, or even the typical discounts to AWP, exceed actual acquisition costs for both pharmacies and physicians.[16] This is particularly true for generic drugs. At the same time, these experts agree that Medicaid dispensing fees are low relative to actual dispensing costs. One panel member commented, "If it weren't for the AWP spread, the pharmacies would be out of business." Payments based on the cost structure experienced by pharmacies may warrant payment of a reasonable and managed spread (an amount paid above the actual acquisition cost), in addition to a fixed dispensing fee and an appropriate service fee for medication therapy management. Therefore, reform of the drug product cost component of the payment system must be considered in association with reform of other components of the payment system.

2.4 Medicare Part B Drug Program and Expenditures

Currently, Medicare Part B generally covers drugs that are "incident to" a physician's service, durable medical equipment (DME) drugs, and drugs specifically covered by statute (for example, oral immunosuppressive drugs). Drugs that fall under the category of "incident to a physician's service" include drugs that cannot be self-administered such as injectible and intravenous agents for oncology, rheumatoid arthritis, and nausea. Part B drug expenditures grew from $3.3 billion in 1998 to $8.4 billion in 2002—nearly a three-fold increase in four years. Both payment method and trends for specific drugs within the Medicare Part B drug program have contributed to the growth in drug program expenditures.

Legislative and Regulatory History

From 1991 to 1998, the method of payment for drugs under Medicare Part B was based on the lower of: (1) estimated acquisition cost (EAC) or (2) average wholesale price (AWP) for a drug. If a drug was available from multiple sources, the payment was based on the median of the national average wholesale prices for generic equivalents. The estimated acquisition costs were defined as the "actual invoice prices paid by the providers furnishing the drug" and were to be determined based on provider surveys.[17] In addition to the drug cost, the survey was to include indirect costs such as inventory, waste, and spoilage. Practically, the fiscal intermediaries set the payment limit as AWP according to the Red Book or First Databank's Blue Book. In contrast, in the early 1990s the Medicaid program was using EAC defined by most states as AWP –X percent, with the reduction to AWP ranging from 5 to 15 percent. The statutory basis for Medicare drug payments changed to AWP – 5 percent beginning on January 1, 1998. Another change known as 'least costly alternative' (LCA) developed through certain fiscal intermediaries as early as mid-1997. The LCA approach reasoned that when there were two or more similar or equivalent therapeutic alternatives, the Medicare Part B payment could be limited to the cost of the least costly alternative. This LCA approach started in just a few states, but by 2002 had spread to more than 40 states.

Beginning January 1, 2004, the payment amount for drugs administered by physicians was revised based on statutory language contained in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA; Pub.L. 108-173). The new payment method was to be 85 percent of the AWP as of April 1, 2004 for most physician-administered drugs with certain exceptions. The MMA further described payment rules to be implemented January 1, 2005 based on manufacturer submission of data on a drug's average sale price (ASP). The ASP is defined in the MMA as the amount of the manufacturer's sales revenue to all purchasers divided by the total number of units sold in a given quarter. The manufacturer should include the effect of "volume discounts, prompt pay

discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid program)."[18]

At the same time that the MMA altered its payment policy for the drugs covered by Part B, it also specified new procedures for calculating the practice expense relative value units (RVUs) associated with drug administration services for certain physician specialties and for clinical oncology nurses.[19]

Sources of Growth in Medicare Part B Expenditures

As in the Medicaid case, there has also been rapid growth in Medicare Part B drug expenditures. Analysis of the sources of this growth reveals that only a few of the approximately 450 covered drugs account for most of the spending. As noted earlier, drug expenditures in 1998 were about $3.3 billion and this amount grew to more than $8.4 billion by 2002.[20] During the same period (1998 to 2002), the Medicare enrollment grew only 1.4 percent per year while the drug spending grew an average of 27 percent per year. The vast majority (77 percent) of the Medicare Part B drug expense is paid to oncologists and urologists. Oncologist-based drug expenditures grew from $1.2 billion in 1998 to $3.8 billion in 2002 with the spending growth from 2001 to 2002 at 41 percent. The spending on drugs under Medicare Part B is highly concentrated with 7 of the approximately 450 drugs accounting for 49 percent of the spending ($4.0 billion out of $8.4 billion). Nineteen drugs accounted for 75 percent of the total drug spend and 33 drugs accounted for 86 percent of the total. Both drug product price increases at the manufacturer level and increases in utilization appear to have been the major contributors to growth in drug expenditures for the Medicare Part B program.

Drug Payment and Provider Expenses

Panel members agreed that, under the 1998-2003 payment methodology, the administration of prescription drugs covered by Part B generated high profit margins for oncologists, urologists, and other physicians. In addition, they commented that the financial incentives created by this profitability played a large and problematic role in prescribing decisions, i.e., prescribers responded to these high margins by tending towards administering more (and more expensive drugs) than might be medically necessary or optimal for the health of the patient.

If physicians' profits are a function of quantities administered and the spread between the AWP and the transaction price, manufacturers' profits are a function of quantities administered and transaction prices. Thus, manufacturers' rational response in this setting is to set transaction prices high (to increase their profits directly) and AWPs even higher (to increase physician profits and thereby the demand for their drug). Particularly in the Medicare setting, where the payment accrues to the prescriber, the ideal is for the third party payment system to create neutral incentives regarding the amount and nature of drugs administered.[21] A payment system based on actual acquisition costs accomplishes this goal. Note that the ASP-based payment policy, which Medicare Part B will use beginning in 2005, is such a system.

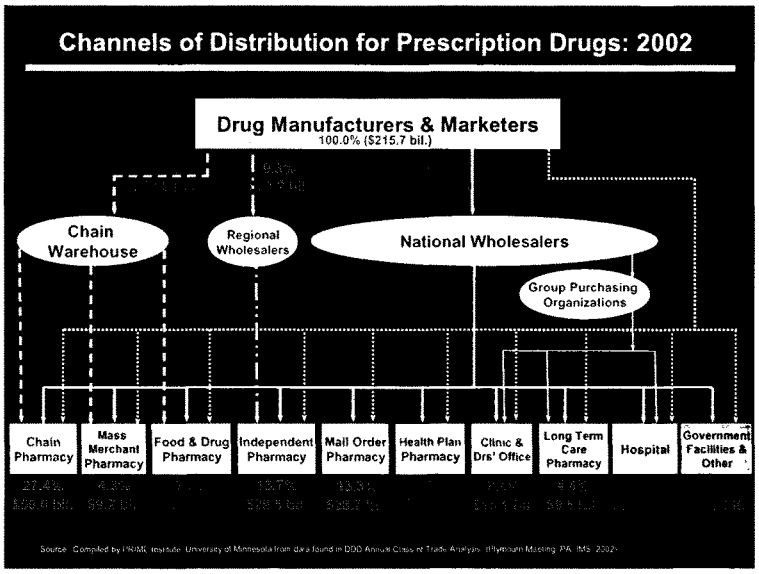
Now that drug payments are being revised downwards, the affected physicians are raising concerns about the level of payments to physicians and nurses for drug administration.[22] The oncologists' position is an acknowledgement that drug cost payments should be reduced, but at the same time the fee for drug administration needs to be evaluated and increased.

3.0 Structure of the Pharmaceutical Market

3.1 Channels of Distribution

Channels of distribution for prescription drug products are the pathways that drug products follow from the pharmaceutical manufacturer to the patient who ultimately uses the medication. There are three primary levels in the distribution channel: (1) manufacturers, (2) wholesalers, and (3) providers. Manufacturers and marketers reported $215.7 billion in revenue from prescription drugs in 2002. The flows of these drug products through various channels of distribution are depicted in Exhibit 4.

Exhibit 4: Channels of Distribution for Prescription Drugs: 2002



Manufacturers and Marketers

The manufacturer level is the starting point for prescription drugs as they begin their movement through the various channels of distribution. Any firm that manufactures or sells a prescription drug in the United States must hold a new drug application (NDA) or an abbreviated new drug application (ANDA) issued by the U.S. Food & Drug Administration (FDA). However, other firms may market a prescription drug without holding either an NDA or an ANDA, if such a firm has entered into a licensing agreement with an NDA or ANDA holder.

Every firm that markets a prescription drug in the United States must register with the FDA to obtain a unique national drug code (NDC) number (11-digits) for each drug product marketed. The first part of the NDC, the labeler code (5-digits), uniquely identifies the firm marketing the drug product. The

second segment, the product code (4-digits), identifies a specific strength, dosage form, and formulation for a given drug product. The third segment, the package code (2-digits), identifies package sizes and package types (e.g., bulk, unit dose, or unit of use). Both the product and package codes are assigned by the firm and not by the FDA.

Manufacturers or marketers, who want to be assured that the Medicaid program will cover their drug products, must sign a national drug rebate agreement with the Secretary of the Department of Health and Human Services in order for states to receive federal funding for outpatient drugs dispensed to Medicaid patients. Not all NDC holders participate in the Medicaid Drug Rebate program. Approximately 544 pharmaceutical companies (or labelers) currently participate in the Medicaid Drug Rebate Program.

Wholesalers and Distributors

Manufacturers or marketers of prescription drugs most often sell their drug products to a middleman, or intermediate level, before the drug product reaches the pharmacy or physician that will provide the drug to the patient. National wholesalers are the primary intermediate level in the channel of distribution process accounting for 45.7 percent of prescription drugs ($98.5 billion) in 2002, (see Exhibit 4). Other intermediate channels of distribution include chain warehouses with 32.3 percent ($69.8 billion) of the market, regional and specialty wholesalers with 9.3 percent ($20.2 billion) of the market, and group purchasing organizations that usually contract with a wholesaler to perform the distribution function on their behalf. About 12.6 percent of prescription sales by drug manufacturers are made directly to providers (e.g., physicians or hospitals) or pharmacies.

The principal trade organization representing wholesalers in the United States is the Healthcare Distribution Management Association (HDMA). In 2002, the HDMA reported that there were more than 72 distributor companies operating approximately 242 distribution centers.[23] On average, these distribution centers handle more than 21,000 different healthcare items. More than one-half of the items distributed (about 11,000) are prescription pharmaceuticals and biologics, and the additional items include "over-the-counter and herbal products, health and beauty aids, medical and hospital supplies, durable medical equipment and home healthcare items."[24] The three largest wholesalers (Cardinal Health, AmeriSource Bergen, and McKesson) each have about 32 percent of the national market and collectively account for 97 percent of the drug sales that flow through national wholesalers and 83 percent of all wholesalers (national, regional, and specialty). Wholesalers add a markup and fees to the manufacturer's drug product cost to cover the cost of distribution and other services they provide. The total wholesaler gross margin averaged about 4.3 percent in 2002 with a range from 3.7 to 5.5 percent for the 25th and 75th percentile. These costs are added to the manufacturer's drug product cost and passed on to the pharmacy or provider purchasing through a wholesaler.

In addition to full-line national wholesalers, there are also regional and specialty wholesalers that handle just under 10 percent of manufacturer drug sales. Regional wholesalers are usually similar to the national full-line wholesalers, but they typically have only one or a few distribution centers limited to a relatively small geographic region. Specialty wholesalers, in contrast, may have a national market presence, but instead limit the types of drug products stocked to a very narrow set. Specialty wholesalers may focus on generic drugs, biological agents, or drugs for a specific therapeutic purpose such as oncology, dialysis, or HIV therapy. Specialty wholesalers may also focus on serving certain facility types such as long term care pharmacies, home health agencies, or hospice facilities.

Group purchasing organizations (GPOs) may act on behalf of a group of providers to negotiate price with drug manufacturers. Most group purchasing organizations, however, do not ever take possession

of, or handle, the drug product. Instead, GPOs often will contract with a traditional wholesaler to perform the wholesaling and distribution function on behalf of the GPO and its members.

A number of large chain pharmacies have developed and operate their own distribution centers rather than purchasing drug products through traditional wholesalers. Chain warehouses accounted for 32.3 percent ($69.8 billion) of all prescription drug sales by drug manufacturers in 2002. Chains that operate their own warehouses incur expenses similar to those seen by traditional wholesalers (range from 3.7 to 5.5 percent). When a chain pharmacy performs the warehousing function in addition to the retail distribution and counseling functions, the chain does have additional costs similar to those that a wholesaler would have added to the manufacturer's drug product cost.

Pharmacies and Providers

The final step in the channel of distribution for pharmaceuticals comes when the pharmacist or physician provides the drug to the patient. In most cases, except for mail order pharmacies, this provision of the drug to the patient results from a face-to-face encounter with the patient. In addition to providing the drug product, the pharmacist is also responsible for taking steps to assure safe and effective drug use such as: development of a patient profile to screen for drug interactions, contraindications, and duplicate therapy; counseling the patient on appropriate use; and other similar activities. The physician has similar responsibilities and, in most Part B cases, administers the drug in conjunction with other services.

There are a number of types of pharmacies and providers as shown in Exhibit 4. Community-based pharmacies accounted for the largest share (52.6 percent or $113.3 billion) of manufacturer prescription drug sales in 2002. Community pharmacy includes traditional chain pharmacies (e.g., Walgreen's or CVS), mass merchant pharmacies (e.g., Wal-Mart or K-Mart), food and drug pharmacies (e.g., Kroger or Safeway), and independent pharmacies (i.e., locally-owned corner drug stores). Mail order pharmacies accounted for 13.3 percent ($28.7 billion) of manufacturer prescription drug sales in 2002.

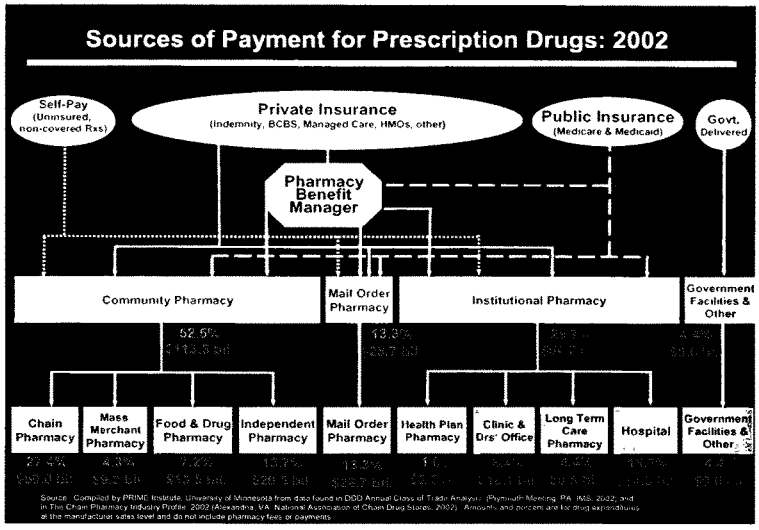
Health plan pharmacies purchased only 1.0 percent ($2.3 billion) of all prescription drugs sold by manufacturers. These purchases were made by managed care plans (HMOs and PPOs) with their own in-house pharmacies where the health plan takes possession of drug product inventory and dispenses prescriptions directly to patients. The vast majority of managed care plans contract with a network of community pharmacies for provision of prescription drugs or with a pharmacy benefit manager (PBM) to administer the benefit for the managed care plan.

Other endpoints to the channels of distribution include: clinics and physicians' offices (1.0 percent; $2.3 billion); long term care pharmacies (4.4 percent; $9.5 billion); hospital pharmacies (15.9 percent; $34.3 billion); and government facilities and other government programs (4.4 percent; $9.6 billion).

3.2 Sources of Payment for Pharmaceuticals

Payments for prescription drug products may come from one, or more, sources including: the patient as an individual (termed "self-pay" or "cash-pay"); private insurance; public insurance (Medicaid and Medicare); or government delivered and financed health care. Various prescription drug programs are managed by Pharmacy Benefit Managers (PBMs) and engage networks of pharmacies and providers to deliver prescription drugs. (See Exhibit 5.)

Exhibit 5: Sources of Payment for Prescription Drugs: 2002



Self-Pay

Self-pay, or cash, prescriptions represent a shrinking part of the outpatient prescription market. In 1992, more than one-half (55.6 percent) of all outpatient prescriptions were self-pay. By 1997, self-pay prescriptions had shrunk to 29.1 percent and in 2002 and 2003 they represent less than 15 percent of outpatient prescriptions. The dramatic reduction in cash pay prescriptions has also greatly reduced the pharmacy's pricing flexibility. The pharmacy has some control over setting the price for cash pay prescriptions, but it has little control over the prices paid by public and private third party programs. Although mail order programs, private PBMs and drug discount cards all claim to compare their prices against usual and customary retail prices, the disappearance of the cash pay retail prescription market renders the concept of "usual and customary retail price" almost meaningless.

Private Third Party (Insurance and Managed Care)

The share of outpatient prescriptions covered in part, or in whole, by private third party programs has grown substantially over the past decade from 30.1 percent in 1992 to 73.0 percent in 2002 and 2003. Most of these third party prescriptions are managed through PBMs and networks of pharmacies that have contracted to participate in these networks. Most pharmacists report that PBMs have most of the negotiating power in these networks, especially given their growing market share and the dominance of a few large PBMs.

Public Third Party (Medicare and Medicaid)

The Medicaid program is the single largest third party program (public or private) for prescription drug coverage. In 1992, Medicaid paid for 14.3 percent of all outpatient prescriptions and by 1997 the Medicaid share had dropped to 11.7 percent. The Medicaid share of outpatient prescription has

grown again over the last five years to 13.0 percent of outpatient prescriptions. Medicaid recipients in some states may pay modest co-payments. However, under certain circumstances if the patient cannot pay the copay the pharmacy may still be required to dispense the prescription and the pharmacy may not be able to recover the lost copay from either the patient or the Medicaid program.

Part B of Medicare paid for approximately 4 percent of total prescription drug expenditures in 2002. Once the MMA prescription drug benefit is implemented (January 1, 2006), Medicare (Parts B and D) will become the single largest third party program easily surpassing the Medicaid program. Medicare Part B beneficiaries are currently responsible for 20 percent of the cost of their covered medication, a sum that may be a substantial burden in cases in which beneficiaries do not have other insurance.

Pharmacy Benefit Managers

Pharmacy benefit managers are a key part of most third party drug benefit plans. In 2001, the top three PBMs processed more than one billion of the three billion outpatient prescriptions filled nationally, and all PBMs together processed 1.5 billion of these prescriptions. The PBMs serve many functions including: benefit design and contracting, pharmacy network formation and management, prescription claims processing, formulary management and rebate negotiation, drug utilization screening and review, operation of mail order pharmacies, and other functions. PBMs are a central part of the third party drug benefit system, but, in general, PBMs do not directly purchase prescription drug products from the drug manufacturer, take possession of the drug product, or provide the drug product to the patient. If, however, the PBM owns a mail order pharmacy, then the PBM's mail order pharmacy may perform in-house each of the functions in the distribution of a drug product. Although certain PBMs and third party programs may receive rebates, such rebates provide a modest decrease in drug price—about 2 to 5 percent of total drug spending by a drug benefit plan.[25] Examination of the sources of revenue for PBMs reveals that PBMs make more money from manufacturer revenue than they make from employer/client fees.[26] Other major sources of revenue include revenue from pharmacy discounts not passed on to the end payer. Some analysts have raised concerns about the potential conflict of interest faced by PBMs with more revenue from drug manufacturers than from the employer or client. Another potential conflict of interest results from a PBM promoting their own pharmacy (a mail order pharmacy) while at the same time reviewing prices and processing prescription claims of community pharmacies. This issue has been described in other publications.[27]

4.0 Structure of Pharmaceutical Prices and Payments

The terms for describing drug prices have changed over the past four decades. New terms have emerged and old terms have developed new meanings. Careful definition of drug pricing terms is important to assure consistency and confidence in the prices reported and to assure propriety and accuracy when establishing payment and public policy.

4.1 Pricing Terms and Definitions

Important and essential elements in the definition of a drug product price term are:

- ***list or transaction***: list prices are published by manufacturers; transaction prices stem from actual transactions and hence represent both the supply and the demand side of the market;
- ***level of the market involved*: drug product transactions occur at different levels in the market such as** the manufacturer, wholesaler, or provider (e.g., pharmacy, physician, hospital, etc.) levels;

- ***classes of trade eligible for the price***: providers are grouped by each manufacturer into various classes of trade based on the structure of the pharmaceutical market (e.g., independent pharmacies, chain pharmacies, mail order pharmacies, long term care pharmacies, hospitals, physicians, etc) and the manufacturer's average selling price usually varies across classes of trade;

- ***type of drug product***: drug products may be grouped by their patent and exclusivity status into three broad groups that have different pricing patterns such as single source (patent and exclusivity protected brands), innovator multiple source (off-patent brands), and non-innovator multiple source (generics or branded generics) drug products;

- ***adjustments to price that have or have not been taken into account***: the invoice price for drug products may not reflect all adjustments to prices such as discounts, rebates, purchasing allowances or other forms of economic consideration;

- ***source of the price information***: price information can be collected from different sources such as the manufacturer, wholesaler, provider, or a third party program;

- ***effective time when price is available***: manufacturers determine when and how much the price of a drug product will change and the providers' costs are affected by price changes immediately upon implementation of a price change. The timing of when third party programs update their price reimbursement files (e.g., immediately or based on retrospective data) can have a substantial impact on providers; and

- ***relationship to other prices***: AWP and WAC are primarily used as benchmark prices rather than as actual transaction prices, but most other types of prices, discounts, rebates, and methods of third party reimbursement are expressed in relationship to one of these benchmark prices (AWP or WAC);

Wholesale Acquisition Cost (WAC). The Wholesale Acquisition Cost (WAC) is a *list price* used for *invoices between drug manufacturers and wholesalers* and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The WAC is set and published by drug manufacturers with an effective date and remains in effect until a change in price is published. Some drug manufacturers have other names for this price such as list price, catalog price, or book price. In the past decade, WAC was a term that typically included adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration.[28] More recently, WAC has come to mean a list price before any form of price adjustment. WAC is closer to wholesaler's actual acquisition cost than is AWP. However, due to different levels of discounts across drug products and specific classes of trade, the WAC does not generally have a reliable relationship to the actual acquisition cost. Within a specific class of trade, WAC may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products. If WAC is to be used to estimate a price from wholesaler to provider (i.e., pharmacy, physician, or others), an adjustment must be made to account for the wholesaler (or chain warehouse) operating cost and a reasonable profit.

Average Wholesale Price (AWP). The Average Wholesale Price (AWP) is a *list price* used for *invoices between drug wholesalers and pharmacies or other appropriate drug purchasers* and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is set directly, and published, by most drug manufacturers with an effective date and remains in effect until a change in price is published. Some drug manufacturers argue that they do not set the AWP, but instead either

the wholesaler or the drug price databases set the AWP. Even when the AWP is actually calculated by a wholesaler or a drug price database, these sources typically calculate the AWP as a fixed percentage above the WAC (i.e., typically 20 or 25 percent above WAC for brand name drugs) so that, in effect, by setting the WAC the drug manufacturer also sets the AWP for a drug product. AWP has been a term that typically does not include adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is typically 20 to 25 percent above the WAC[29] for brand name drugs, but may be considerably higher (20 to 70 percent) than WAC for generic drugs. Because of different levels of discounts across drug products and specific classes of trade, the AWP does not generally have a reliable relationship to the actual acquisition cost. Within the retail class of trade, AWP may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products.

Direct Price (DP). The Direct Price (DP) is a *list price* used for *invoices between drug manufacturers and pharmacies or providers* and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The DP is set and published by drug manufacturers with an effective date and remains in effect until a change in price is published. Many drug manufacturers have a wholesale only policy and do not sell directly to pharmacies or providers, while other drug firms establish a direct price and do sell drug product directly. Direct purchases are often subject to minimum order quantities and, therefore, direct purchases may not be practical or economically efficient for many purchasers.[30]

Certain direct purchasers (i.e., physicians, but typically not pharmacies) may benefit from delayed invoice dating (e.g., payment is not due for 60 or 90 days) from the manufacturer. The DP for some manufacturers is the same as the WAC, while for others the DP may be slightly higher (by 3 to 5 percent) than WAC. Because of different levels of discounts across drug products and specific classes of trade, the DP does not generally have a reliable relationship to the actual acquisition cost. Within the retail class of trade, DP may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products. However, use of direct price to estimate pharmacy or provider acquisition cost must take into account the added cost of acquisition.

A larger share of generic drugs, than of brand-name drugs, is sold direct from the manufacturer. Because of different levels of discounts, the DP does not have a reliable relationship to the actual acquisition cost, in general, or for specific classes of trade.

Earned Discounts. Earned discounts are transactional discounts based on efficient business practices of the pharmacy or physician purchasing drug products from either a wholesaler or a drug manufacturer. The earned discount is usually expressed in terms such as '2-10 Net 30', meaning 2 percent discount off of the total invoice amount if paid within 10 days and the full invoice amount is due if paid between 11 and 30 days. Earned discount terms are set by the wholesaler or the manufacturer and are usually stated on the invoice. In some cases, manufacturers offer substantially greater delayed invoice payment to certain classes of trade (e.g., direct physician purchasers) that allow the purchaser to sell and collect for the drug product before the payment to the manufacturer is due (e.g., payment is not due for 60 or 90 days). These greatly delayed invoice terms would not typically be called 'earned discounts'. Different levels of 'earned discounts' and 'other delayed term discounts' are available to different classes of trade. The earned discounts will usually have a reliable relationship to actual acquisition cost, but not necessarily to AWP or WAC. The treatment of earned discounts in estimating actual acquisition costs of a pharmacy or provider should be consistent with the actual payment terms of a given third party when reimbursing pharmacies or providers.

Actual Acquisition Cost (AAC). The Actual Acquisition Cost (AAC) is a *transaction price* used to describe *the price paid by a pharmacy or provider* when purchasing a drug product from either a drug manufacturer or wholesaler. The invoice price and all on-invoice, as well as off-invoice, adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration are taken into account. **This price is the appropriate conceptual basis for the payment policy.**

The AAC is set by the drug manufacturer, but, historically, has not been published or made public. Some drug manufacturers may have a variety of terms for specific discounts that are based on class of trade, volume of purchase, market share movement, preferred formulary status, terms of payment, bundling of products, and other criteria. AAC is meant to be the net price after all forms of discount, rebate, purchasing allowances or any other forms of economic consideration have been taken into account. Arguably, drug manufacturers consider the discounts that contribute to AAC proprietary and confidential. Consequently, the relationship of AAC to either AWP or WAC is not predictable from public data sources in general, or for specific classes of trade. For single source brand name drugs that do not typically have discounts beyond on-invoice 'earned discounts', the AAC may have a reasonably predictable relationship to AWP or WAC.

4.2 Price Variation in the Market

In order to consider options for payment policy, it is necessary to understand some of the key dimensions of price variation in the pharmaceutical marketplace.

Class of Trade Variations

Nearly all drug manufacturers divide the channels of distribution into groups known as 'classes of trade'. The 'classes of trade' at the broadest level are the groups identified on the pharmacy-provider level of the channels of distribution chart (Exhibit 4) including: chain pharmacies, mass merchant pharmacies, food and drug pharmacies, independent pharmacies, mail order pharmacies, health plan and HMO (in-house) pharmacies, long term care pharmacies, hospital pharmacies, physicians and clinics, government facilities, and other settings. The structural differences in actual prices charged to each of these 'classes of trade' can differ considerably and appear to be arbitrary and are usually unrelated to volume of drug product purchased.

In most markets, when one buyer can purchase a product at a lower price than other purchasers, there is the potential for arbitrage. That is, the buyer with access to the lower price is able to purchase the product at the low price and resell it, at a profit, to the party without access to the lower price. This drives down the price differentials both directly (because the high-price buyers get lower prices) and indirectly (because manufacturers no longer gain from the differential pricing and hence desist from the practice). This practice of arbitrage across classes of trade is explicitly prohibited by re-sale limitations established in the pharmaceutical marketplace by the Prescription Drug Marketing Act of 1988.

Both the monopoly position of patent (or exclusivity) protected drug products and the prohibition on arbitrage enable drug firms to use 'discriminatory pricing', which seeks to maximize the price to each individual buyer or group of similarly situated buyers. There are sometimes volume discounts within a class of trade, but volume does not usually explain the difference in price across classes of trade. A physician purchasing drug product direct from the manufacturer will usually get one of the lowest prices in the market, especially for drug products administered in the physician's office, while independent and chain community pharmacies often pay the highest prices in the market. This pattern occurs even when the chain pharmacy purchases far more volume (millions of dollars) nationally than an individual physician purchases in a year (i.e., hundreds or thousands of dollars). Volume may get one physician a better price than another physician. Volume, however, does not

explain why a chain pharmacy pays a higher price, even though it purchases a substantially larger volume of a drug product than an individual physician typically purchases. The structural barriers of monopoly position and statutory prohibitions on price arbitrage mean that the purchasers who get the lowest price in the market are not necessarily the most efficient purchasers in the market. Because class-of-trade differentials exist and are outside of the control of the purchaser, an accurate approach to estimating actual acquisition costs must take into account the class of trade pricing practices of drug firms. The practice of class of trade pricing is not usually disclosed directly by drug manufacturers and could experience change as the dynamics of the pharmaceutical marketplace evolve during the implementation and operation of the new Medicare outpatient drug benefit.

Drug Product Type Variations

The pricing patterns of brand name drug products and generic drug products can be quite different. For most brand name drug products that are still covered by patent or exclusivity terms, the price relationship between list prices (AWP and WAC) and actual transaction prices (actual acquisition cost or average selling price) for a given class of trade is reasonably predictable. That is, the WAC is equal to, or very close to (+ or – 5%) the actual acquisition cost for the community pharmacy class of trade and the AWP is typically 20 to 25 percent above the WAC or, alternatively, WAC is 16.67 or 20 percent below AWP. In such cases, a payment policy based on AWP (i.e.; usually AWP minus a certain percent) may be relatively accurate. This pricing pattern holds for community pharmacy classes of trade (independents, chains, and food & drug stores), but not necessarily for other classes of trade (i.e., mail order pharmacies, HMOs and health plan pharmacies, long term care, physicians or clinics, hospitals, or state and federal facilities or programs). Some of these other classes of trade control the demand (i.e., prescribe or influence the drug prescribed) and are reimbursed by a third party based on a percent off of AWP or a percent above WAC. When these other providers can actually purchase the drug product from the manufacturer, and when the manufacturer deliberately creates a large and hidden spread between actual acquisition cost and the reimbursement amount, then the physician or other provider has a very strong financial incentive to prescribe their drug. This non-transparent spread leads to a financial incentive to prescribe more often and to prescribe higher-priced drugs over lower-priced drugs even when they are not necessarily the most cost-effective alternative. These financials incentives from the hidden spreads may be one factor contributing to the rapid growth of Medicare Part B drug program expenditures over the past four years.

Once a brand name drug product loses its patent and market exclusivity, the brand name drug may face price competition from generic versions of the drug product. Usually the brand manufacturer does not compete on price with generics for the community pharmacy class of trade. This means that the AWP and WAC relationship to actual acquisition cost discussed earlier for brand name drugs still holds. However, brand manufacturers sometimes offer substantial discounts relative to WAC to certain classes of trade (i.e., hospitals, long term care, health plans, and physicians). This may keep the actual acquisition cost of the brand drug somewhat price competitive in non-community pharmacy settings, and particularly when the provider receives payments keyed to list prices may result in excessive financial incentives to prescribe or use the brand name rather than a generic equivalent.

Price competition begins when the market is entered by the first generic drug product that is a therapeutically equivalent version of a brand name drug product made by the drug firm that holds the original NDA for a given chemical entity. When two or more generic drug products enter the marketplace they typically compete on price with each other even though the brand name product usually does not compete on price. The first generic will typically enter the market at a list price (both AWP and WAC, if a WAC is reported) that is 10 to 30 percent below the originator brand price. Often the price competition among generic versions of a drug product will be reflected by one or two decreases in list prices (AWP and WAC) in the first six to twelve months after generic entry, but after that time it is rare to see generic list prices change and at some point in time the generic list prices for some drugs may even begin to rise again.

The relationship between list prices (AWP and WAC) is much less predictable for generic drugs than it is for brand name drugs. Some generic drug products will have AWPs that are the typical 20 to 25 percent above the WAC, but it is not unusual to see generic drug products with an AWP that is 50 to 100 percent, or more, above the WAC. Even more volatile is the relationship between the list prices (AWP or WAC) and actual acquisition cost for generics. Generic firms often discount their actual net price to the pharmacy to compete with other generics, but they do not always reflect these discounts in lower AWP or WAC list prices. Generic prices are also relatively volatile, because the market for generic drugs is effectively a commodity market. Thus, AWP-based payment policy is much less accurate for these drugs than it is for the branded drugs. Medicaid drug payment policy reflects the lower market prices for generic drugs by placing a FUL (a federal MAC or a state MAC) on many generic products.

Geographic Variations

Geographical variations in the actual drug cost at the manufacturer level are not common. Once one has accounted for class of trade differentials, most drugs have the same list prices (AWP and WAC) regardless of where they are purchased or used. In the few cases where a specific drug may have prices that vary by region, the variation is often in response to certain third party payment methods (i.e., the Least Costly Alternative (LCA) method) of paying for therapeutic alternates under Medicare Part B by certain fiscal intermediaries.

In contrast; to the general uniformity of prescription drug prices, the cost of professional services (i.e., physician fees or pharmacy fees) usually varies by geographic region. Both physician and pharmacy costs of providing the required services that accompany prescription drugs vary by geographic region due to differences in rent, salaries, general cost of living, insurance, and other factors. To the extent that the drug cost component of the payment policy is intended to also cover part, or all, of other costs associated with drug provision (e.g., storage and handling, or counseling and medication therapy management), there may be a need for this component to vary by region. Also, for the reasons above, changes in drug product payment policy may have different impacts upon providers and pharmacies across regions. These same factors may also vary across geographic locations (rural versus urban) within the same region.

5.0 Options for Estimating Acquisition Costs

5.1 Evaluation Criteria

The previous sections described essential background issues for the estimation of actual acquisition costs. This section lays out criteria for evaluating potential estimation methods and discusses the data that are available and potentially available for this purpose. Several options are then described and evaluated for their strengths and weaknesses with respect to these criteria. The criteria presented below emerged from the authors' analysis and from the Expert Panel's discussion. Because the estimation method would ultimately be used in the context of drug payment, some of the criteria bear on payment policy as well as on estimation approaches *per se*. Similar criteria have previously been applied to evaluation of alternative payment methods for multi-source prescription drugs.[31]

Accurate and Reliable

The Medicaid and Medicare programs should have access to accurate and reliable information regarding the actual acquisition costs for prescription drugs for each channel of distribution. Based on such accurate and reliable cost data, these programs may decide that the payment rate to pharmacies or physicians should include a percent markup on brand name drug product costs, and an

even greater markup for generic drugs, but this practice should be an explicit decision of the policy maker and not an implicit and hidden factor left in the control of the pharmaceutical manufacturer. In this context, 'accuracy' concerns the degree to which the price used in payment policy is close to, or the same as, the amount actually paid by a pharmacy or physician for a given drug product. 'Reliability' is the degree to which the price used in payment is consistent for similar prescription claims.

Based on Markets: Estimated acquisition costs are more likely to be accurate if they are based on actual transaction prices in the market (i.e., the average selling price). Market or actual prices can be contrasted both to list prices, set by manufacturers, and to administered prices, set by the government. This approach, however, requires transparency of transaction prices.

Generally and Widely Available

Any price list used by the Medicaid or Medicare program should reflect 'generally and widely available prices,' that is, any provider paid according to the payment policy should be able to procure drugs at the published payment amount.

Estimated Separately by Class of Trade: Because actual acquisition costs vary by class of trade, the estimation methodology must take into account these differentials in order to generate drug product payments that are both accurate and reflect generally and widely available prices. For example, when a drug manufacturer sets lower prices for one class of trade (e.g., physicians) versus another class of trade (e.g., community pharmacies), the result is that the average of the prices across these two classes of trade will overpay the class with the lower price (physicians) and will under pay the class with the higher price (pharmacies). In addition to class of trade differences, drug product prices may differ for other reasons such as geographic or regional (urban versus rural) variations. A payment policy that does not account for different acquisition costs by class of trade, or other factors, may preclude certain providers from the market for reasons beyond their control. For providers within the same class of trade, the concept of 'generally and widely available prices' is appropriate and helpful to assure that a wide spectrum of physicians or pharmacies will be willing to participate in the program.

Current and Up-to-Date

An effective price list must be based on current prices that are updated regularly. Drug prices are set by drug manufacturers and can change whenever the manufacturer decides to adjust the price (usually an increase). Most manufacturers change drug product prices every 6 to 12 months with the average interval being about 10 to 11 months, however, some drug products may change their prices much more frequently. Claritin, for example, in the last three years before being switched to over-the-counter status raised its price every three months and had a cumulative annual price increase in 2002 of 21.2 percent. If provider payments for prescription drugs were being revised only once a year, a pharmacy would be losing as much as 20 percent on each Claritin prescription dispensed near the end of the year.

An effective payment policy should not set drug product payment amounts that consistently result in an underpayment due to delayed updates of prices. The drug product payment database needs to be electronically available using the standard electronic data interchange protocols in the prescription marketplace, and it needs to be updated on a virtual basis with a minimum of time delay (1 week or less) in updating price changes.

Transparent and Accessible

The price list and payment policy must be readily available to, and clearly understood by, market participants. Those covered by the payment policy should understand the source of data and how those data are translated into the payment policy. In addition, any price list to be used in payment for prescription drug products must be in an easily accessible and usable format. This format must be compatible with pharmacy and claims processor computer and software systems. Obviously, an electronic database is essential for both efficient publication and use. Pharmacy and physician providers must be able to easily confirm current payment at the time of prescribing, or dispensing, a prescription.

Adequate Compensation to Providers and Pharmacies

While the drug product component of the payment policy should be based on actual acquisition costs, the payment policy as a whole should adequately compensate providers for the storage, handling, dispensing, and administration of prescription drugs and for their professional services. This is essential to ensure that beneficiaries have access to quality care, without triggering perverse incentives. At present, the margins, or spreads, between drug product payment amount and actual acquisition cost may compensate providers (physicians and pharmacies) for deficiencies elsewhere in the payment system. If and when the method for estimating acquisition costs is altered, it may be desirable to reconsider the payment policy as a whole.

Incentives for Pharmacies and Providers to Supply Drugs

Any payment scheme creates financial incentives for providers. Ideally, these incentives foster quality and cost-effectiveness. Two main dimensions of provider incentives have already been discussed. First, adequate compensation gives providers incentives to participate in the program and supports beneficiary access. Second, payment based on actual acquisition costs creates neutral incentives for providers regarding the choice of drug therapy with the result that providers are more likely to focus on the choice of therapy that is optimal for the patient and economically efficient for the program.

Incentives for Key Parties to Provide Data

Pricing data will be needed from various levels in the market to determine appropriate payment amounts. If the program establishes fair, but not excessive prices, providers will be more likely to participate in good faith than if the program tries to implement below-market prices that overly squeeze the provider's margins. In addition, terms must be clearly defined so that firms understand what data they are expected to submit and so that analysts understand what data they have received.

Authority to conduct audits of drug manufacturers and of all provider types may provide some incentive for firms to participate in reasonable requests for data. Other incentives need to be identified and examined. If manufacturer data submission is chosen as a viable alternative, the drug firm can be asked to certify the data provided in a manner similar to that specified in the corporate integrity agreements (CIAs) developed by the Department of Justice for use by those drug firms that have settled fraud allegations related to Medicaid and Medicare drug pricing.

The consequences of inaccurately or incompletely defined pricing terms and concepts can be seen in the case of certain drug manufacturers who may have underpaid the Medicaid drug rebate program through various methods that are questionable and possibly illegal. For example, a drug firm may charge a managed care pharmacy the regular price for a drug product for one-half of the year and then charge less than 10 percent of the regular price (i.e., a 'nominal' price) for the other half of the year. In this way the drug firm has effectively given the managed care pharmacy a 45 percent discount, but

this discount, arguably, does not have to be reported as a 'best price' discount. The sale of drug product at less than 10 percent of the regular price is considered a 'nominal price' (intended to benefit free clinics and groups like Planned Parenthood) and is exempt from the best price calculation. In this case the definition of a 'nominal price' has been gamed to allow passing on an effective discount arguably without having to declare the discount as a best price for purposes of calculating the Medicaid best price rebate.

Other Considerations

In addition to meeting the criteria above, any payment policy must be politically acceptable and feasible to implement. Payment policy may need to vary to account for acquisition cost differences across: (1) provider types (i.e., classes of trade), (2) program types (i.e., Medicaid, Medicare Part B, and Medicare Part D), (3) drug product types (i.e., single source brands, innovator multiple source brands, and generics), and (4) geographic locations. For example, policies may seek to acknowledge the greater volatility of generic prices or promote competition among therapeutic alternates, as the least costly alternative (LCA) policy does. Finally, a regional adjustment to the payment for storage, handling and dispensing of a drug product may be necessary to address regional variations in rent, labor, and distribution costs.

5.2 Sources for Drug Price Data

A method for estimating acquisition costs must be based on data. In theory, one could capture data on all market transactions and use it to estimate the prices being paid for each and every drug product at each and every point in the market. However, this is not possible given the complexity and volume of market transactions. There are four basic sources of accessible data: (1) primary data from supply chain transactions; (2) secondary data on list prices from drug price and clinical information data firms; (3) secondary data on invoice prices from drug market and utilization data firms; and (4) legislative and regulatory price databases. The basic sources of primary and secondary data are briefly outlined and then discussed below.

Primary Data from Supply Chain Transactions

There are five potential sources of electronic transaction data from the supply side: (1) manufacturer sales transactions to direct purchasers (mostly wholesalers and large chains); (2) wholesaler sales to pharmacies and other purchasers; (3) pharmacy purchase invoices from wholesalers and manufacturers; (4) pharmacy sales transaction data submitted to payers; and (5) third-party payment transactions for prescriptions provided by pharmacies or other providers (i.e., physicians). Only the first three of these transactions are actual purchase prices at the manufacturer or wholesaler level that could be used to establish appropriate payments to pharmacies or physicians. In fact, these electronic transaction data sources are used by various drug price database firms (i.e., IMS Health, Verispan, First Data Bank, MediSpan, and Red Book) to collect and aggregate drug pricing and utilization data.

Secondary Data on List Prices

Three commercially available drug price databases track list prices of drug products in the U.S. market at the AWP and WAC levels. These databases are: (1) the Blue Book (First DataBank, Hearst Publishing Co., Palo Alto, CA); (2) MediSpan Master Drug DataBase and PriceChek PC (Facts & Comparisons, Wolters Kluwer Health, Inc., Indianapolis, IN); and (3) the Red Book (Thomson-Medical Economics, Montvale, NJ). Historically, each of these firms published a price list in printed format once a year with quarterly updates. Since the mid-1980s, however, the electronic version of these databases has been the primary format for price list publication. These databases are updated on a continuous (daily) basis. In addition to price data, these databases also contain or link to

other databases that provide descriptive and clinical information on drug products including therapeutic class and uses, drug interactions, patent and regulatory status, therapeutic equivalence and generic alternatives, and many other useful data elements.

The principal users of these drug price databases are pharmacies and third party programs. Pharmacies use the drug price and clinical information database on their in-store computers for pricing, filling prescriptions, drug interaction screening, and submission of third party prescription claims. Third party payers (public and private) use these databases to screen, adjudicate, and determine payment for covered prescriptions. Virtually every third party program (public or private), or its claims processor, use one of these drug price databases as the source for AWP, or WAC, values that serve as the basis for calculating the price that a pharmacy will be paid for each drug product based on the NDC number. This price information is then used according to the contractual pricing formula to pay the pharmacy for the prescriptions dispensed to eligible recipients. The vast majority (more than 40) of the state Medicaid programs use First DataBank's drug price information as the basis for prescription drug payments to pharmacists and other providers.[32]

Secondary Data on Invoice Prices

Several commercial drug market and utilization databases are available with fairly comprehensive data on revenue, units sold, and price per unit for each prescription drug product on the market. These databases are: (1) National Sales Perspectives (NSP) and National Prescription Audit (NPA) (IMS Health, Plymouth Meeting, PA); (2) Source Prescription Audit (SPA) (Scott Levin, a Division of Verispan); and (3) NDC Prescription Price Analyzer and NDC Prescription Price Reporter (NDC Health, Inc). Each of these databases was developed primarily as a source of market intelligence information for drug manufacturers to track how their drug products are performing in the market compared with other similar drug products. Since these databases are based on transaction invoice data from the market there is a brief lag time from actual transaction to availability of data. For certain database products the lag time may be as short as one or two weeks, but for most market databases there is a lag of six to eight weeks.

The IMS NSP database is transaction data from wholesaler and manufacturer sales invoices into pharmacies and other purchasers. The IMS NPA database is based on retail pharmacy sales of prescriptions to patients by various methods of payment including cash, private third party, and Medicaid. The Scott Levin SPA database and the NDC Health databases are similar to the IMS NPA database in that they obtain their data from retail pharmacy sales of prescriptions to patients by various methods of payment including cash, private third party, and Medicaid. Each of these retail sales databases captures their data from pharmacy transactions on computer systems in each pharmacy. All sources claim to obtain data from 35,000 to 45,000 out of the total 53,000 community pharmacies in the United States.

The principal users of these drug market and utilization databases are pharmaceutical manufacturers who want to track how their drug product is selling compared to other similar drugs. Purchasing reports from these databases can be quite expensive---tens of thousands of dollars to millions of dollars. Manufacturers use these databases to track market shares, sales volume, new and total prescriptions, generic substitution, therapeutic switching, amount and effect of promotional activities, impact of formulary preferences and restrictions, impact of copays and co-insurance, compliance and persistence of drug therapy, and other issues.

Legislative and Regulatory Drug Price Databases

There are several databases with price information that have been created for statutory or regulatory purposes related to various government programs. These government databases include: (1) the Medicaid drug rebate database; (2) the Medicaid drug utilization database; (3) the Texas Vendor Drug

Program manufacturer price database; (4) the federal supply schedule for prescription drugs; (5) the VA price database; (6) the 340B program price schedule for prescription drugs; (7) the federal ceiling price for prescription drugs; (8) the TriServices Support Center price schedule for prescription drugs; and (9) the Medicare Part B average selling price (ASP) database authorized under the newly passed MMA.

The first three of these databases collect data on manufacturer's prices to community pharmacies (items 1 and 3) or from community pharmacies to Medicaid recipients (item 2). As such these databases hold potential for use in setting or evaluating payment amounts for prescription drug products provided to Medicaid and Medicare Part B recipients. The prices reported in the other government databases (e.g., VA, FSS, or 340B prices) are prices that are not generally and widely available to community pharmacies or physicians and, therefore, these price databases hold little utility in setting payment rates for prescription drugs in the private market. Description of these government programs and how their prices are determined has been described elsewhere.[33]

CMS provides national administrative services that support the operation of the Medicaid drug rebate program created by the Omnibus Reconciliation Act of 1990 (OBRA 90). A manufacturer must voluntarily participate in the Medicaid drug rebate program in order for their drug products to be covered in the Medicaid program. To facilitate the implementation of the Medicaid drug rebate program, CMS (formerly HCFA) collects pricing data from all participating drug manufacturers for all drug products sold by that manufacturer including the average manufacturer price (AMP) and the 'best price' to any non-exempt purchaser. This information, however, by statute is consider proprietary and confidential and cannot be publicly released by CMS.

5.3 Description and Evaluation of Options

This section describes and evaluates options for estimating acquisition costs for drugs covered under Medicaid and Medicare Part B programs. These options are categorized according to the primary source of the data.

Option 1. Primary Data from Manufacturers

One broad option for estimating acquisition costs is to collect data on average selling prices from manufacturers or to work with existing sources of such data, such as data used for the Medicaid drug rebate program, the Texas Vendor Drug Program, or the Medicare Part B program (ASP). Average selling prices, with adjustment for a wholesaler margin, provides a reasonable estimate of acquisition costs, if collected and reported by class of trade.

There are barriers to using the existing Medicaid database for pricing in the Medicaid and Medicare Part B programs. First, the OBRA 90 Act that created the drug rebate program includes provisions, at the manufacturers' insistence, which specify that the AMP and best price data are to be treated as proprietary and confidential. While this data might be very useful in creating a price list, to date it has not been released or used for purposes other than operation of the drug rebate program.

A feasible alternative is to work with the data from the Texas Drug Vendor (VDP) program. Based on statutorily authority at the state level, the Texas VDP requires submission of pricing data by the manufacturer of every drug product desiring to be covered by Texas Medicaid. While there are certain concerns regarding how prices and classes of trade are defined, these data have already been collected and are potentially available for research. For the Texas VDP, manufacturers are responsible for providing the data on each drug product to be covered and for updating those prices in a timely manner as they change periodically. The data are entered into a database based on each drug

product's unique NDC number. The resulting database is updated when notice of price changes arrive or within a few days of that time.

A third alternative is original data collection, following the Texas approach, but using enhanced processes and definitions. While this alternative may represent the ideal, it also requires significant effort and may require new legislation or regulations in other states or at the federal level.

Advantages and Disadvantages. Data from manufacturers could be used to price the entire list of drugs covered by both Medicaid and Medicare Part B and can be applied to both brand and generic drugs. Different prices for various classes of trade could be accommodated (e.g., community pharmacies, long term care, physicians, hospitals, and others). The database could be updated on a virtual basis, which essentially means changes on any given business day with a processing time lag of less than one week. In addition, transaction data from manufacturers has the potential to incorporate all forms of discounts, rebates, and other forms of economic incentives.

The disadvantages of this approach are that it does not technically generate providers' acquisition costs, but manufacturers' net revenue and wholesaler cost. An adjustment to account for wholesaler markup (operating margin) is required to convert this price into a pharmacy or physician acquisition cost. In addition, this approach may require new regulation or legislation in order to enable CMS to gather this data from manufacturers (beyond what is being gathered for AMP under Medicaid or ASP under Medicare) as they are unlikely to submit it voluntarily. However, national implementation of manufacturer data collection is far more cost-efficient for both the government and for drug firms than having each state set up its own system, as Texas has. If a national data collection is used, there should be coordination between efforts related to Medicaid and Medicare.

Option 2. Careful Analysis of List Prices

A second option to be explored is tracking the AWP:WAC ratio over time in one of the existing drug price databases (e.g., First DataBank or MediSpan). Medicaid and most other third parties currently pay based on AWP or a function of AWP. This means that if the AWP increases, even if the WAC or the actual price to the pharmacy or provider does not increase, the payment to the pharmacy or the provider will increase. Most drug products have had a constant AWP:WAC ratio over time and as long as the ratio stays constant, then AWP – X percent or WAC + X percent will function similarly in terms of effect on total payment for a drug product. If however, the AWP:WAC ratio changes (i.e., the gap gets wider), the third party payer using AWP minus as the basis for drug product payments will then be paying a larger markup on the drug product cost than a third party payer basing payments on WAC plus.

There is evidence to suggest that a number of major drug manufacturers increased the AWP:WAC ratio for the vast majority (90 percent or more) of their drug products between October 2001 and July 2002.[34] The shift resulted in most drug products of these firms moving their AWP from 20 percent to 25 percent above the WAC. This move means that for drug products reimbursed by Medicaid or private third party programs based on a percent off of AWP, these programs paid 5 percent more for each prescription. This change was initiated and driven by drug manufacturers, even though most of the benefit may accrue to the pharmacy. This is an example of the type of 'gaming' that a payment system should be routinely monitoring. Under this option an assessment will be made of the economic impact of the AWP:WAC change that occurred in late 2001 and early 2002. A possible change in the payment method to a WAC + X percent may be warranted and would help to avoid this particular form of 'gaming.'

Another gaming issue can be addressed using the existing drug price databases. This issue is concerned with relabeling of single source drug products (patent protected brands) under a relabeler's new NDC number and setting a new and higher AWP. Most third party payers have pricing formulas

and methods that assume that there is only one AWP price for a single source drug. Actually, nearly all of the most prescribed single source brand name drug products have several relabelers who have established their own NDC numbers and have set their own AWPs for the originator brand product. Often these relabeler NDCs are not sold to, or available to all purchasers, but they are sold only to a special class of trade such as physician dispensers, mail order pharmacies, or long term care facilities. The originator brand may have a price of $2 per tablet while the relabeler may have set the new AWP at $3 per tablet. Using the payment method of most third party programs including most Medicaid programs, the higher price will be paid and the program won't even know that it was an inflated AWP. This phenomenon is not a small matter, the number of relabeler NDCs in the MediSpan drug price database grew from 791 in 1990 to more than 20,000 in 2002.[35]

The existing drug price databases can also be used to efficiently identify drugs that should have a federal upper limit (FUL) or MAC established and to calculate that MAC. The method for establishing and updating the FUL amount could be reviewed and alternative formulae for calculating the FUL can be examined according to established criteria.[36]

Advantages and Disadvantages. This approach could be used for the entire list of drugs of both Medicaid and Medicare Part B and can be tailored to special problems with both brand name single source drugs and generic off-patent drugs. Specific prices to certain structural classes of trade (e.g., long term care, physicians, hospitals, and mail order) could be isolated and filtered out or taken into account. With list price data, it is not possible to analyze class of trade differences directly; one must determine whether certain relabelers sell only to specific classes of trade and not to others. The database and pricing amounts could be updated on a virtual basis which essentially means changes on any given business day with less than one week processing time lag. The disadvantage of this approach is that both the AWP and the WAC are list prices and not actual transaction prices. Also, the standard drug databases have only one AWP and one WAC for all buyers, despite the fact that certain classes of trade may routinely receive substantial discounts off of AWP or WAC. Even though the methods described in this section may move the payment closer to the actual price, there is no direct link to actual prices.

Option 3. IMS Invoice Data

The third option is to use a drug marketing and utilization database, IMS' National Sales Perspectives (NSP - formerly Retail and Provider Perspectives, RPP). This database comes from wholesaler and manufacturer invoices of pharmacy and other provider purchasers. Consequently, the data is broken down by class of trade for each drug product at the NDC level. The price most often used by wholesalers on their invoices is the WAC. IMS does take into account discounts shown on the line item of an invoice, but this type of discount is rarely given to community pharmacies. When price database WACs are compared with the IMS invoice cost per unit, the two are essentially the same. The strength, however, for the IMS NSP data set is that the invoice prices for certain classes of trade do show at least part of the discounts given to these other classes of trade such as clinics (and physicians), long term care facilities, in-house HMOs, hospitals, home health care, mail order pharmacies, and other government programs.

In particular, this approach may be a good way to estimate acquisition costs for Medicare Part B drugs provided by clinics and physician offices or by hospital outpatient facilities. While this database still will not capture all discounts, the adjusted invoice price is likely to be closer to the actual price than either AWP or WAC from the standard drug price databases. Other potential uses of the IMS databases in pricing can be explored and evaluated.

Advantages and Disadvantages. This approach will provide price estimates for Medicare Part B drugs that are closer to actual cost for clinics (and physicians) than either the standard WAC or AWP. The IMS NSP database has monthly updates with a 6 to 8 week delay in reporting. If CMS had

access to this data, little additional data processing would be necessary and the actual analysis would be fairly straightforward.

The disadvantage of this approach is that even the net invoice price reported does not take into account rebates or all forms of discounts or other forms of economic consideration. Also, the IMS database does not maintain its list of drug products with the NDC number attached to each drug product record. A database bridge will need to be created from IMS data to a drug price database such as MediSpan's Master Drug Data Base. In addition, IMS data is typically quite expensive, and IMS may be reluctant to allow its data to be used to set payment policy. IMS may be concerned either that such use would alienate its data suppliers (i.e., wholesalers, pharmacies, and other providers) and thus compromise its data products or that such use would cause its suppliers to manipulate their data to game the price list and thus compromise its product. Also, IMS may be concerned that use of this data for payment policy may alienate the major purchasers of their data (i.e., drug manufacturers).

Option 4. Wholesaler Survey

The fourth option is to survey wholesalers to determine either the wholesaler's actual cost from the manufacturer and/or the pharmacy's (or other provider's) actual cost from the wholesaler. Wholesaler data is the basis for secondary commercial data sources such as IMS Health. Also, the wholesalers would be able to break down sales into class of trade to identify price differences that are based on the structural factors in the pharmaceutical market. Data at pharmaceutical wholesalers is highly automated and electronic data interchange standards would make this process fairly efficient. As noted above, only three wholesalers account for greater than 85 percent of wholesale activity and about one-half of total manufacturer sales of prescription drug products. Wholesaler surveys could capture not only list and invoice prices from manufacturer to wholesaler and from wholesaler to pharmacy or provider, but also data on various discounts, certain types of rebates, chargebacks, and payment terms (e.g., delayed billing). Nearly all drug products in the prescription market would be in wholesaler databases, except for drugs that are mostly or exclusively sold direct from manufacturer to the provider or pharmacy.

In order to create a price list from a wholesaler survey, the contractor or entity organizing the data will have to acquire and match the data to a drug database (i.e., First DataBank or MediSpan) to obtain other drug product identifiers and information for describing and grouping drug products. A database bridge will need to be created from wholesaler data to a drug price database such as MediSpan's Master Drug Data Base.

Advantages and Disadvantages. This approach will provide price estimates for nearly all drugs in the market, although the data on branded drugs would be stronger than the data on generic drugs. In addition to AWP and WAC, the types and levels of discounts and other forms of economic consideration can be captured. Also, a wholesaler survey would enable estimation of the average selling price by class of trade. Wholesale data could be updated on a daily or weekly basis with little delay. Wholesaler survey data could be organized to serve as the basis for payment, but that would require public disclosure of the data used as the basis for payment. An alternative use of the wholesaler survey data would be as a validity check against other price data sources.

The disadvantages of this approach are that the wholesalers may be reluctant to co-operate because of the desire to maintain the confidentiality of their business practices. Wholesalers' data will miss certain rebates. Also, in certain key markets, such as the market for injectible drugs, many transactions go around the wholesaler.

In addition, a new wholesaler survey may be burdensome and redundant given that much of the information from wholesalers has already been collected and organized by the commercial database at

IMS Health, and the IMS database has the additional advantage of supplemental data from manufacturers and pharmacies.

Option 5. Provider Survey

The fifth option is to survey providers (primarily pharmacies and physicians) to determine amounts actually paid for specific drugs. On invoice prices and discounts or allowances could be identified by this approach. The sheer numbers of providers (100,000 or more administering drugs in office) and pharmacies (55,000) here are quite large; however, scientific sampling would be possible. Separate surveys would be needed for each class of trade, such as independent pharmacies, chain pharmacies, clinics (and physicians), long-term care facilities, in-house HMOs, hospitals, home health care, mail order pharmacies, and other government programs. Moreover, surveys would need to be administered frequently (at least quarterly) in order to capture price changes.

This option would impose significant burden on providers given the sizes of the samples necessary and the number of individual drug products. Providers and pharmacies are less likely than wholesalers to have purchase and invoice data in an electronic form. Also, the compatibility of electronic formats is likely to be low due to the large numbers of competing pharmacy and practice management software products. Data would need to be converted to a common format, and a database bridge would need to connect the survey data to a major drug price database such as MediSpan's Master Drug Data Base.

Advantages and Disadvantages. This approach would provide price estimates for Medicare Part B drugs that would be closer to actual cost for clinics (and physicians) than either the standard WAC or AWP. It would have the potential to capture all rebates and discounts, though with a significant delay. However, it is not feasible to use provider surveys as the primary source of price data because of the burden of data collection. The potential value of this approach lies in generating confirmation of actual market prices for a very select set of drugs such as top drugs under Medicare Part B. In addition, these data could be used to spot check for price gaming behavior by manufacturers or providers.

The strengths and weaknesses of these data sources are summarized below:

Exhibit 6:

Summary of Strengths and Weaknesses of Data Sources for Estimation of Acquisition Costs

Manufacturer data	*Strengths*: Actual price, includes all discounts and rebates, available by class of trade, reasonable effort
	Weaknesses: May need legislation or regulation, not technically an acquisition cost
	***Conclusion*: Strongest base data**
List prices	*Strengths*: Widely used standard, minimum effort
(e.g., AWP & WAC from MediSpan or First DataBank)	*Weaknesses*: List prices (AWP and WAC) not actual prices, not class of trade specific
	***Conclusion*: Essential point of comparison**

Exhibit 6:

Summary of Strengths and Weaknesses of Data Sources for Estimation of Acquisition Costs

IMS invoice data	*Strengths*: Existing source of discounted invoice prices (list less invoice discounts), available by class of trade
	Weaknesses: Misses certain discounts and rebates, must be publicly available to serve as basis of payment
	***Conclusion*: Very helpful point of comparison**
Wholesaler survey	*Strengths*: Potential source of invoice data, available by class of trade, moderate effort
	Weaknesses: Does not capture direct sales to chains or physicians, duplicative of IMS
	***Conclusion:* Helpful point of comparison, especially if IMS data not available**
Provider survey	*Strengths*: Potential source of actual acquisition costs, can spot check for price gaming
	Weaknesses: Very burdensome for providers and surveyor
	***Conclusion:* Potential point of comparison, esp. for key drugs and markets**

6.0 Recommendations and Directions for Further Work

6.1 Recommendation

There is no simple method of estimating acquisition costs. Based on our research and the comments of the Expert Panel, the authors recommend that CMS consider an approach to estimating acquisition costs that is based on collecting primary data from manufacturers. Members of the expert panel strongly favored this approach at the meeting and in their individual comments after the meeting.

In particular, in addition to list prices, manufacturers would be asked to supply average selling prices by class of trade. These classes of trade might include independent pharmacies, chain warehouses, long term care pharmacies, physicians (direct sales), and hospitals. If these data are to be used as a basis for payment under Medicare Part D which begins in January of 2006, then prices to the mail order class of trade should also be collected. Manufacturers would also be asked to note other major provider types that might be purchasing on behalf of Medicaid and Medicare beneficiaries, to explain the situation, and to provide the associated average selling prices. All terms would be carefully defined including pricing terms, as well as discounts and rebates to be included and excluded[37], and the channels of distribution. Manufacturers would be required to certify that the prices supplied were true and accurate.

The strengths of this approach are that it: (1) yields actual transaction prices, (2) incorporates all discounts and rebates, (3) incorporates class of trade differentials, (4) provides an efficient method (relative to a provider survey), and (5) represents a feasible approach to estimating actual acquisition cost. Similar methods are in place in the Medicaid rebate program and in the Texas Vendor Drug Program. One conceptual shortcoming of this approach is that it generates a manufacturer's sales price as opposed to a provider's acquisition cost. The authors believe that if the data are gathered by precisely defined classes of trade and channels of distribution, the manufacturers' sales costs can be accurately adjusted to produce an estimate of the providers' acquisition costs. A second practical

shortcoming is that CMS may need new regulation or legislation in order to gather this data on a national basis from manufacturers, as they are unlikely to supply it voluntarily.

The authors also recommend that before considering additional primary data collection, CMS undertake a careful evaluation of the existing Texas Vendor Drug Program (VDP) and the price data that it collects. The Texas approach is very similar to our recommended approach. Below, we offer additional information regarding the Texas VDP, followed by a brief description of the proposed evaluation.

6.2 The Texas Vendor Drug Program

In the 1980s the Texas Vendor Drug Program studied "ways to achieve more accurate payment for the drug product portion of claims paid to pharmacy providers."[38] Texas VDP recognized that the list price (AWP) in the commercial price databases was greater than the amount pharmacies actually paid the wholesaler for a drug product. The state of Texas, therefore, established statutory authority to collect the drug price information from manufacturers.

The Texas VDP set up a system to survey drug manufacturers who choose to participate in the Medicaid program. Initially each manufacturer was asked to submit a list of all drug products, at the NDC level, that it wished to have covered under the Medicaid drug program. Along with each NDC number and product description, the manufacturer was asked to provide several price points including:

- Average wholesale price;
- Price to wholesaler and/or distributor;
- Direct price to pharmacy;
- Price to chain warehouse;
- Institutional or other contract price (e.g., nursing home, home health care); and
- Other prices.

See Appendix C for examples of the standard cover letter and survey that are sent to manufacturers to request this information. The Texas VDP has also developed standard response letters to drug manufacturers for various situations (also in Appendix C).

Another important feature of the Texas price survey system is the requirement that an official of the drug company certify that the prices sent are correct. This requires the drug firm to take ownership of all price information submitted and avoids the drug firm hiding behind the wholesaler or the drug price database as the source of their prices. Also, the initial application contains a statement requiring the drug firm to report any changes in information about their products within 15 days of such change. Drug firms must report changes in formulation, product status, price or availability.

Once survey forms are received by the Texas VDP, the drug product descriptions and related price variables are entered into a single database system. This data is compared to standard price data and the manufacturer is contacted if discrepancies are observed, including cases in which the manufacturer appears to have submitted a list price in place of a market price. Even though drug firms are responsible for reporting changes in product or price information within 15 days of such a change, the Texas VDP also contacts each manufacturer annually with a copy of the product and price information on file and requests that the manufacturer review this information and make any appropriate and necessary updates.

The Texas VDP uses the data submitted by manufacturers to calculate several classes of trade-specific "estimated acquisition costs" (e.g., retail-wholesale, direct, chain warehouse, nursing home). When pharmacies submit a drug claim to Texas Medicaid for payment, they include information concerning the channel of distribution through which they purchased the drug. Texas Medicaid payment is then the lowest of: (1) the AWP less a percentage; (2) WAC plus a percentage; (3) MAC, if a multiple source drug; or (4) the class of trade specific "estimated acquisition cost" reported by the manufacturer.

6.3 Directions for Further Work

The authors propose to conduct a case study of Texas' current approach to estimating acquisition costs and to secure and analyze the data that the Texas VDP already collects from manufacturers. Such an effort could maximize the national value of what Texas is already doing. This case study could give CMS, and other states, a perspective on what would be gained from instituting such a system in other settings where the current drug product reimbursement system is based on a function of either AWP or WAC. Moreover, it could provide valuable lessons relevant to the implementation of reimbursement based on alternative price measures such as ASP.

A thorough case study would fully document the Texas VDP's process and key stakeholders' perceptions of the strengths and weaknesses of that process. The stakeholder analysis would include manufacturers, wholesalers, pharmacies, other providers, and the Texas Medicaid program. Among other things, this case study would review the definitions of all pricing terms and propose definitions that would be applicable for use on a national basis. The potential value and impact of calculating prices at more detailed "class of trade" levels will be explored. The analysis would describe and evaluate the process by which the Texas VDP collects and uses the price information provided by manufacturers and converts these prices into estimated acquisition costs to determine drug product payment amounts.

In addition, the case study will analyze the costs of establishing and maintaining the Texas VDP process and price list, including data collection and analysis. Levels of staffing and skills that are necessary to support this undertaking will be determined. Finally, current and potential approaches to identifying and resolving pricing discrepancies, errors, fraud, and abuse will be examined and evaluated.

In the data analysis component, the authors would acquire the Texas VDP data and compare them to readily available price data from other sources, possibly including:

- AWP, WAC, and other list prices;
- transaction prices captured in drug market and utilization data bases, such as IMS;
- transaction prices collected via a survey of selected wholesalers;
- the maximum allowable cost (MAC) at federal and state levels for certain generics; and
- the Medicare Part B ASP (if permissible).

The comparison with the AWP and WAC is most relevant to understanding the potential savings to the Medicaid program of a new method, relative to the current methods of reimbursement. The comparison with transaction prices, either from drug market and utilization databases or from selected wholesalers, is valuable to confirm the validity of the data that Texas receives. The comparison with ASP would be highly relevant to the Medicare Part B program, especially if it emphasized potential differences by class of trade or if it emphasized potential differences between a price list that is updated continuously and a price list that is updated quarterly, with a two-quarter lag.

Based on these analyses, the authors would develop and describe insights and the best options for the implementation of a similar data collection and payment policy in another setting such as another State Medicaid program, the Medicare Part B ASP program, or a national Medicaid resource, administered by CMS. The Expert Panel might be invited to comment on initial evaluation findings and various proposals for best options. These comments could be incorporated into the final report.

Endnotes

[1]

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[5] Schondelmeyer, Stephen W. "Estimated Relative Price Compared to AWP for Prescription Drugs at Manufacturer Level," Chart 4, p.10 as found in von Oehsen, William H., III, Ashe, Marice and Duke, Kathryn, Pharmaceutical Discounts Under Federal Law: State Program Opportunities, Public Health Institute, Pharmaceuticals and Indigent Care Program, Oakland, CA, May 2001.

[6] "2 Drug Makers to Pay $875 Million to Settle Fraud Case," New York Times, Oct. 4, 2001.

[7] "AstraZeneca Pleads Guilty in Cancer Medicine Scheme," New York Times, June 21, 2003.

[8] "Bayer Agrees to Pay U.S. $257 Million in Drug Fraud," New York Times, April 17, 2003.

[9] "Medicare Bills Would Add Drug Benefits: Prescription Drug Benefit Is Key To Biggest Changes in 38 Years," Washington Post, June 27, 2003, p. A01.

[10] HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: "Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)." as reproduced in National Pharmaceutical Council, Pharmaceutical Benefits Under State Medical Assistance Programs, 1980, p. 14.

[11] National Pharmaceutical Council, Pharmaceutical Benefits Under State Medical Assistance Programs, 1994, p. 45.

[12] National Pharmaceutical Council, Pharmaceutical Benefits Under State Medical Assistance Programs, 1985, p. 34-36.

[13] National Pharmaceutical Council, Pharmaceutical Benefits Under State Medical Assistance Programs, 1991, p. 14.

[14] Analysis conducted by Stephen W. Schondelmeyer, PRIME Institute, University of Minnesota and presented at "Understanding the Drug Benefit Debate: How Will It Affect Your Organization?", National Managed Health Care Congress, 7th Annual Congress on Medicare and Medicaid, Washington, DC, March 10, 2003.

[15] National Pharmaceutical Council, Pharmaceutical Benefits Under State Medical Assistance Programs, 2001, p. 4-57.

[16] Studies analyzing the adequacy of current drug payment include: (1) Adams, Kathleen and Kreling, David, Assessment of Adequacy of Reimbursement Rates to Pharmacies and Its Impact on the Access to Medication and Pharmacy Services by Medicaid Recipients, Systemetrics, Inc., (National Technical Information Service, PB94-187689), August 1993. (2) US General Accounting Office, Medicare: Payment for Covered Outpatient Drugs Exceed Providers' Cost, GAO-01-1118, September 2001. (3) US General Accounting Office, Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices, GAO-02-531T, March 14, 2002.

[17] Department of Health and Human Services, Health Care Financing Administration, "Medicare Program; Fee Schedule for Physicians' Services," Federal Register, Nov. 25, 1991, 59502-59524.

[18] Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Changes to Medicare Payment for Drugs," Federal Register, Jan. 7, 2004, 1084-1116.

[19] Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Changes to Medicare Payment for Drugs," Federal Register, Jan. 7, 2004, 1084-1116.

[20] Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Payment Reform for Part B Drugs; Proposed Rule," Federal Register, Aug. 20, 2003, 50428-52.

[21] If anything, incentives should promote cost containment, as the LCA incentives do.

[1] American Society of Clinical Oncologists, "Reform of the Medicare Payment Methods for Cancer Chemotherapy," May 2001.

[1] Healthcare Distribution Management Association, "2002 HDMA Industry Profile and Healthcare Factbook," 2002, p. xi.

[1] Ibid., p. xi.

[1] PriceWaterhouseCoopers, *Study of Pharmaceutical Benefit Management*, HCFA Contract No. 500-97-0399/0097, June 2001, p.131; Patrick Holjo and Matthew Kamm. *Pharmacy Benefit Managers: Keeping a Lid on Drug Costs*, Banc of America Securities, February 20, 2002, p. 29.

[1] Patrick Holjo and Matthew Kamm. *Pharmacy Benefit Managers: Keeping a Lid on Drug Costs*, Banc of America Securities, February 20, 2002.

[1] Langenfeld, James and Maness Robert, The Cost of PBM "Self-Dealing" Under a Medicare Prescription Drug Benefit, September 9, 2003.

[1] Adams, Kathleen, Gavin, Norma and Kreling, David, Assessment of Adequacy of Reimbursement Rates to Pharmacies and Its Impact on the Access to Medication and Pharmacy Services by Medicaid Recipients, Systemetrics, Inc., (National Technical Information Service, PB94-187689), August 1993,p. 4.

[1] The relationship between AWP and WAC is sometimes expressed as a percentage off of AWP (e.g., 16.67% or 20% off of AWP) rather than as a percentage above WAC (e.g., 20% to 25% above WAC).

[1] Even though a direct purchase price may be marginally below a wholesaler purchase price, direct purchases may not be the most efficient or appropriate purchase decision or estimate of actual acquisition cost. If the direct purchase option requires a minimum order quantity that is greater than a one to two month supply requirement for a pharmacy, then the pharmacy's stocking and distribution costs (e.g., inventory turnover rate and inventory carrying costs) may increase to a point that the marginal benefit of direct prices is outweighed. Additionally, if a pharmacy is ordering direct from many manufacturers instead of ordering from one or two wholesalers, the pharmacy's acquisition cost (e.g., increased volume and complexity of order processing and number of accounts) may increase to a point that the marginal cost of direct prices is outweighed.

[1] Schondelmeyer, Stephen W., "Impact of Alternative Reimbursement Limits for Coverage of Multisource Prescriptions Under Medicare," Journal of Research in Pharmaceutical Economics, Vol.1 (3), 1989, pp. 27-47.

[1] National Pharmaceutical Council, Pharmaceutical Benefits Under State Medical Assistance Programs, 2001, p. 4-61.

[1] von Oehsen, William H., III, Ashe, Marice and Duke, Kathryn, Pharmaceutical Discounts Under Federal Law: State Program Opportunities, Public Health Institute, Pharmaceuticals and Indigent Care Program, Oakland, CA, May 2001.

[1] Based on analysis conducted by Stephen W. Schondelmeyer, PRIME Institute, University of Minnesota using PriceChek PC data from MediSpan.

[1] "Bayer Agrees to Pay U.S. $257 Million in Drug Fraud," New York Times, April 17, 2003.

[1] Schondelmeyer, Stephen W., "Impact of Alternative Reimbursement Limits for Coverage of Multisource Prescriptions Under Medicare," Journal of Research in Pharmaceutical Economics, Vol.1 (3), 1989, pp. 27-47.

[1] Certain rebates payable to PBMs might be excluded.

[1] Letter from Marilyn Johnston, Texas Commissioner of Human Resources, Subject: Agenda Item No. 6, Vendor Drug Product Acquisition Cost Proposals, November 13, 1984.

Appendix A: Members of the Expert Panel

Lowell Anderson, President, Bel-Air Pharmacy

James Boyd, Senior Vice President, Network Services, Rx.com/PDX

Phil Burgess, National Director, Pharmacy Affairs, Walgreen's

Paul Deutsch, Carrier Medical Director, Empire Medicare Services Part B (NY)

Deirdre Duzor, Co-Leader, Medicaid Pharmacy Team, CMS (Also the Project Officer)

David Kreling, Professor, College of Pharmacy, University of Wisconsin

John Lockwood, Venacare

Martha McNeill, Director, Texas Medicaid/CHIP Product and Prescriber Management

Lynn Mitchell, Director, Oklahoma Medicaid

Mark Pulido, Independent, (formerly Chief Executive Officer, McKesson)

Paul Saatsoglou, Practice Leader, Global Portfolio Optimization, IMS

Bruce Stuart, Professor, School of Pharmacy, University of Maryland

Bill Sullivan, Curative Health Services

Don Thompson, Director, Center for Medicare Management, Division of Ambulatory Services, Centers for Medicare and Medicaid Services (CMS)

Robert Vito, Regional Inspector General, Office of Evaluation and Inspections, Office of the Inspector General (observer)

Richard Weininger, Oncometrix

Appendix B: Themes from Expert Panel Meeting

This summary is based on notes taken on flip charts during the Expert Panel Meeting for the Medicaid and Medicare Drug Pricing Project, held on January 26 and 27, 2004. Fifteen experts were in attendance, bringing knowledge from various segments of the healthcare community in the US, including: physicians, chain drug stores, community pharmacies, state Medicaid agencies, wholesalers, data base organizations, academia, and CMS. Discussion points have been reworded and reorganized for clarity.

Desirable Features of Payment Methodology and Policy

(This section encompasses both Medicaid and Medicare Part B; some of these issues are common to both programs and some are unique to one program or the other.)

Desirable Features of Price List that Will Serve as the Basis for Payment

- Transparent
  - Source and creation well-understood
  - Publicly available
- Accurate and reflective of market
- Current and updated regularly
  - Known to providers before they agree to participate (if used for payment)
- Acknowledges different prices in different channels of distribution or classes of trade
  - Retail pharmacies and physicians' offices are two different worlds
    - Texas also distinguishes between chain and community pharmacies

Desirable Features of Estimation Methodology

- Concepts must be well-defined
- Minimizes gaming, to the extent possible
  - Based on objective data that is difficult to manipulate
  - Ultimate use of data does not penalize "telling the truth"
  - Includes efforts and processes to identify and manage gaming
- Politically acceptable
- Process easily able to be audited
- Not cost prohibitive and feasible to implement and maintain

- Argues for electronic database, especially for Medicaid

- Mean, median, variance – need to carefully select appropriate price point for government

- Based on market (actual transaction prices)– not list prices, not administered prices

Desirable Features of Payment Policy

- Adequate but not excessive
  - Preserves access ("widely available market prices")
- Comprehensible to participants
- Acknowledges different prices in different channels
- Avoids perverse incentives for payers, e.g., under current system states may seek to maximize rebates rather than to minimize outlays
- Should *follow*, not *lead* market
- Impacts
  - Preserves access and quality of care for patients
  - Maintains incentives for innovation in the pharmaceutical industry
  - Creates incentives for quality and cost-effectiveness in prescribing

Issues Specific to Medicaid

- Agreement that dispensing fees are lower than actual dispensing costs and that drug payment generally exceeds actual acquisition costs.
  - The spread in drug payment compensates for the low dispensing fees.
  - "If it weren't for spread, pharmacies would be out of business."
- Some aspects of dispensing cost (e.g., inventory and accounts receivable) vary with the cost of the drug
  - Other aspects of dispensing costs are closer to a fixed amount per-prescription.
  - One possibility is to have part of the dispensing fee based on a percentage of drug cost but that is capped.
- We often focus on paying for dispensing the medication without consideration of the cost of professional services related to dispensing the medication.
  - Perhaps a pharmacist should be paid for *not* dispensing a medication that would cause harm rather than the current system, which pays a pharmacist a dispensing fee only when the medication is dispensed

Issues Specific to Medicare

- Agreement that the payment is generous and that there is a considerable spread between product cost and the payment
  - These generous financial incentives are problematic
  - The perverse incentives may result in over-prescribing expensive medications
  - A new, higher priced drug will be prescribed more than current medications, even if the new medication does not have safety or efficacy advantages
  - This also results in physicians prescribing poly-therapy when not indicated by evidence-based medicine (e.g., chemotherapy)
- Comments re: ASP
  - The role of the price list emerging from this project would be as a point of comparison for ASP
    - "Keep ASP honest"
  - ASP includes multiple classes of trade
    - Participants believe that physicians may receive lower pricing than other classes of trade, such as home health
    - If this is the case, then ASP-based payment may overpay certain Part B providers
  - There are other opportunities to manipulate ASP
    - Examples:
      - Discretion in unbundling "bundles"
      - Discretion in allocation of free goods and samples
      - Manipulation of units: vial size, dosing, and J codes
    - There is a need for manufacturer accountability for samples and provider billing for samples
    - Recommendation that CMS seek to characterize and monitor these potential abuses and loopholes
- Important to monitor utilization at provider level to encourage responsible behavior.
- Use of HCPCs is problematic (i.e., should consider using NDC codes)
  - But, in designing a payment methodology, CMS may wish to preserve some incentives for cost-effective prescribing.

- When multiple drugs are subsumed under one HCPCs code, then HCPCs-based payment does reward the low-cost choice.

- A level playing field benefits all.
  - Manufacturers may be open to reasonable reforms of drug payment methodology.

Issues Related to Brand /Generic Distinction

- General agreement that the markets for branded and generic drugs are very different
  - Also there are differences between branded drugs in more and less competitive markets
  - And between branded drugs in settings where prescribers have incentives (i.e., Medicare) and in retail setting.
- Spread is generally uniform and narrow for brand name
  - Stable and known relationship to AWP
  - For Medicaid, reliance on pricing reference lists may be a satisfactory strategy for brand-name drugs.
- Spread wider and more variable for generics
  - Most of the profit is here
  - But these are also lower cost drugs
  - May wish to preserve incentives for generic prescribing and dispensing
  - Generic markets are more like commodity markets than markets for branded drugs.

Comments Related to Private Markets for Prescription Drugs

- Price, market share, and volume are components of a multidimensional discussion in the private sector, especially if formularies are in play
- Competition and price sensitivity do help to hold down prices in private markets
  - This is more true for generic than for brand
- Managed care is able to come up with a fair price
  - The Medicaid MACs are generally fair as well

Comments Related to the Pharmaceutical Manufacturers

- Agreement that manufacturers should have an obligation to be reasonable in reporting AWP
  - AWP needs to be better defined
- Agreement that major cost issues reside at manufacturer level

- Some participants felt manufacturers should have an obligation to be more reasonable in pricing
- Manufacturers may or may not face price pressure depending on the level of competition for other therapies (drug and not drug)
- Important to distinguish between estimating acquisition costs (bringing government in line with other payers) and reforming pricing at the manufacturer level

Estimation of Acquisition Costs

The Expert Panel discussed criteria for evaluating the utility of various sources for acquiring data to determine actual acquisition costs. Four options were examined, and the strengths and weaknesses of each were identified and discussed.

Data from Manufacturers: Strengths and Weaknesses	
Strengths	***Weaknesses***
❖ Original source of most data ➢ Only place to capture rebates and additional incentive programs ▪ May impose burden to fully account for rebates ❖ Possible to have prices by channel of distribution / class of trade ➢ Would be very helpful to request ASP by channel of distribution / class of trade	❖ Requires manufacturer cooperation ➢ May require change in law ❖ Retrospective system, not real-time

Data from Wholesaler Survey: Strengths and Weaknesses	
Strengths	***Weaknesses***
❖ Good quality data ➢ Fairly transparent ➢ Includes all contract data on branded drugs ➢ Generic data more difficult to capture ❖ Few touch points (3 to 6 wholesalers) ❖ Possible to have data by class of trade and by	❖ Requires wholesaler cooperation ➢ May require change in law ❖ May not reflect rebates ❖ In the case of injectibles and generics, many transactions go around the wholesaler

geographic area ❖ Attractive in terms of time and cost to implement	

Data from Provider Survey: Strengths and Weaknesses	
Strengths	***Weaknesses***
❖ Providers could supply this data ➢ Could draw on claims processing data is available ❖ May reveal some rebates (although not in a timely manner) ❖ Best used for auditing or check and balance purpose	❖ Requires provider cooperation ➢ Time consuming ➢ No incentive to cooperate ➢ CMS attempted this and the American Society of Clinical Oncologists (ASCO) halted it as burdensome ❖ Very time-consuming for CMS / contractor ➢ Large sample size required ➢ Very high cost

Data from Secondary Sources: Strengths and Weaknesses	
Strengths	***Weaknesses***
❖ Available ❖ Quick and easy ❖ May be able to observe price comparisons here	❖ Requires participation of secondary data provider ❖ By extension, requires cooperation of primary data providers (wholesalers, chains) ➢ These providers may stop working with secondary data provider if unhappy with how their data are used Secondary data providers cannot risk alienating these source data providers because the quality of their product depends on them

Ranking of Options

Based on Cost (Data Acquisition and Analysis)

- Lowest cost: Wholesaler survey
- Closely followed by: Manufacturer survey
- Midpoint: Secondary data (price compendia)
- Much more expensive: Provider survey

Time to Implement

- Shortest time: Secondary data
- Closely followed by: Wholesaler survey
- Midpoint: Manufacturer survey (?? Medicare only)
- Most time: Provider survey

Appendix C: Texas Correspondence

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

Don A.Gilbert, M.B.A.
COMMISSIONER

Since Federal and State regulations require the Texas Vendor Drug Program to pay contracted pharmacies our best estimate of the cost of a pharmaceutical product to the pharmacies, the State relies upon information provided by manufacturers in setting price reimbursement. To ensure Texas' ability to continue to price products accurately, it is critically important that you report information which accurately reflects the market prices paid within the classes of trade for which pricing information is requested. A form is included so that all necessary information from the manufacturer will be available for pricing and dosing recommendations. Questionnaires should be limited to no more than 20 per submittal request for any one month period. A separate questionnaire is to be submitted for each drug and strength. Please supply a cover sheet listing all products, strengths and package sizes for which you are submitting applications. Questions must be answered in full. If you leave a pricing category blank, you are representing to the State of Texas that you DO NOT sell this product to entities in that category. This form may be reproduced.

All inquiries regarding this questionnaire and revisions are to be directed to:

Texas Department of Health
Vendor Drug Program
1100 West 49th Street.
Austin, Texas 78756-3174

Drugs are listed using the NDC number of the manufacturer or distributor who is holding the drug forth as it's own and has the company's name on the label of the container that is sold to the pharmacy. If your company has a product to which the "New Drug Coverage" applies, please add the FDA approval date of the New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA), or Antibiotic Drug Approval (ADA) to the questionnaire.

Martha McNeill, R.Ph.
Director of Product Management
Vendor Drug Program
(512)338-6965
(512)338-6462-Fax
(512)338-6932-Secretary

REQUEST FOR INFORMATION FOR NEW DRUG PRODUCT OR FOR
ADDITIONAL INFORMATION OF PRODUCTS CURRENTLY
INCLUDED IN TEXAS MEDICAID

Please fill out the following information for consideration in Texas Medicaid
An altered form will not be accepted

1. DRUG DESCRIPTION

NDC. NO: (multiple package size of same strength	PACKAGE QTY: products may be included)	
PRODUCT BRAND NAME:_____ GENERIC NAME:_____ THERAPEUTICALLY SIMILAR DRUGS:_____		
COLOR:	FLAVOR:	
DOSAGE FORM:	IS THIS DRUG LEGEND OR OTC?	DEA SCHEDULE OF THE DRUG:
DRUG STRENGTH:		
MAXIMUM DAILY DOSE:		
RECOMMENDED DAILY DOSE:		
INGREDIENTS/DESCRIPTION:		
LIST SHELF LIFE:		
ESTIMATED AVG. DURATION OF THERAPY:		
MAXIMUM DURATION OF TREATMENT:		

ORANGE BOOK RATING:

A - Drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products.

B - Drug products that FDA at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products.

C - Not listed in Orange Book

Revised - May 1, 2002

FOR PURPOSES OF PROVIDING THE PRICE INFORMATION BELOW, THE FOLLOWING DEFINITIONS SHALL APPLY:

a) Except as otherwise defined in law (e.g. Average Manufacturer Price), price is the net price after all chargebacks, discounts and rebates to wholesalers/distributors or pharmacies are applied, other than commercially reasonable prompt pay discounts.

b) "Pharmacy" includes all entities with an approved Class A or Class C pharmacy license issued by the State Board of Pharmacy.

2. PRICE INFORMATION

AVERAGE OF SUGGESTED WHOLESALE PRICE TO PHARMACY (AWP)	$
AVERAGE MANUFACTURER PRICE (AMP)	$
PRICE TO WHOLESALER AND/OR DISTRIBUTOR	$
DIRECT PRICE TO PHARMACY	$
CENTRAL PURCHASE PRICE TO CHAIN (SUCH AS WAREHOUSE PRICE)	$
INSTITUTIONAL OR OTHER CONTRACT PRICE (Nursing Home, Home Health Care)	$
OTHER PRICE	$

IF YOU DO NOT SELL AT A SINGLE PRICE, YOU MAY PROVIDE US WITH A RANGE OF PRICES

INCLUDE A COPY OF FILE CARD, PACKAGE INSERT AND OR MATERIAL FOR PHYSICIANS

3. Please circle the companies to whom you report pricing information.

FIRST DATA BANK PRICE ALERT RED BOOK

MEDI-SPAN BLUE BOOK

OTHER:_____

4. Do you sell to distributors, repackagers, or relabelers, other than full-service drug wholesalers, who in turn sell your product to the retail trade bearing your NDC number?

If yes, attach a listing.

P. O. Box 13247 • Austin, Texas 78711 • 4900 North Lamar, Fourth Floor, Austin, Texas 78751

5. Attach a copy of your Vendor Liability Insurance:

   a. Included or

   b. Previously submitted or unchanged. (Do not need to resubmit)

6. Available date through WHOLESALERS_____

7.

Name of firm:		
Address:		
City:	State:	Zip:
Name and address of Manufacturer of drug:		
City:	State:	Zip:
Name and Address of representatives/government affairs persons covering the Texas area; if applicable:		
City:	State:	Zip:
Phone:		

8. Is this product now marketed under an approved NDA or ANDA?

   Submit a copy of the FDA letter of approval of the NDA or ANDA, or, if not applicable, a copy of the FDA letter of approval for marketing.

9. Please circle DESI classification of this product.

   2 Non-DESI/IRS: safe and effective

   3 DESI/IRS under review

   4 LTE DESI/IRS for some indications

   5 Non-Covered - LTE DESI/IRS for all indications

   6 Non-Covered - LTE DESI/IRS withdrawn form the market

A product added to the Texas Vendor Drug Program must bear the labeler code, as defined by the FDA, of the party, with the exception of a licensed full-service drug wholesaler, marketing the final sale to the provider.

Manufacturers or distributors having one or more of their pharmaceuticals included in the program are responsible for submitting notification of any changes pertaining to any of the above information not later than such revisions are scheduled to occur to:

Health & Human Services Commission
Vendor Drug Program
Attn: Martha McNeill, R.Ph.
Director of Product Management
1100 West 49th Street
Austin, Texas 78756-3174

The Vendor Drug Program adheres to the confidentiality requirements of 42 USC § 1396r-8(b)(3)(D) concerning drug pricing information.

I certify that the information submitted is correct to the best of my knowledge and that this product is not now in violation of either Federal or State Law. I also agree to inform the Health & Human Services Commission, in writing, of any changes in formulation, product status, price or availability as herein describe, within fifteen (15) days of such change.

Responsible Person (Type or Print) _____ Signature _____

Title _____ Date _____

Address _____ City _____ State _____ Zip _____

Company Name _____ ( ) Telephone _____

TDCI CAN BE FOUND AT: WWW.HHSC.STATE.TX.US/HCP/VDP/PRODUCTENROLL.HTML

5

TEXAS DEPARTMENT OF HEALTH
RULES RELATING TO (TDCI)
TEXAS DRUG CODE INDEX PRODUCTS
CAN BE FOUND IN 25 TAC, CHAPTER 35 SUBCHAPTER H

Information Necessary for Addition of Drugs to the Texas Drug Code Index

(A) Any drug company that has a valid rebate agreement under section 1927 of Social Security Act may submit a completed questionnaire to the Texas Department of Health for addition of a drug not currently listed in the Texas Vendor Drug Index (TVDI). Drug companies include any manufacture, own label distributor or relabeler.

(B) The drug company must complete the questionnaire form provided by the department. All questions on the form must be answered and all statements must be complete. For a multi-source drug, the drug company may reference the actual manufacturer's data, if the manufacturer's drug is listed in the Texas Vendor Drug Index.

(C) Sources other than drug companies may request the addition of a drug not currently listed in the TVDI. If the request is not from a drug company, the department requests the manufacturer to complete a questionnaire in subsection (B) of the section

(D) The drug company and other sources, if applicable, are entitled to receive notification of status of the questionnaire. If, the form is unacceptable or incomplete, the department, will state the reason.

Review and Evaluation

(A) The department reviews each questionnaire to determine if there is a need for the drug to be added to the Texas Vendor Drug Index and what restrictions, if any are appropriate. In determining need, the department considers the following:

(1) expansion of the prescriber's armamentarium by a new drug or an additional multi-source drug.

(2) predominate use of the drug in our patient setting.

(3) The cost of the drug to pharmacies compared to:

(a) wholesale estimated acquisition cost (WEAC) or direct estimated acquisition cost (DEAC) listed in the Redbook (Annual Pharmacist's Reference), and other generically equivalent drug products.

(B) The department may return a questionnaire for any of the following reasons:

(1) discovery of false, erroneous or incomplete information or documentation on the questionnaire form:

(2) failure of the drug company to provide the department with documentation of the:

(a) approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA), if applicable.
(b) Food and Drug Administration (FDA) approval for marketing.

(3) failure of the drug company to provide the department with the National Drug Code (NDC), as defined by and filed with FDA, for the drug product as shown on the drug product container sold to the pharmacy

(4) failure of the drug company to provide the department with the current DEAC to the pharmacy, cost to a wholesaler, or estimated wholesale cost to a pharmacy. The allowable WEAC and/or DEAC are the cost t a pharmacy, as determined by review of published or non-published prices resulting from routine marketing practices.

(C) The department may deny coverage of a product if it determines that the drug: NOTE: NUTRITIONAL (FOOD & FOOD SUBSTITUTES) PRODUCTS ARE NOT DRUGS. Is included in one or more of the following classes:

(a) Amphetamines when used for weight loss and obesity control drugs.
(b) Appliances
(c) Cosmetics
(d) DESI-ineffective products
(e) Diagnostic aids
(f) Durable medical Equipment (rental or purchase)
(g) Elastic stockings
(h) Experimental drugs
(i) Fertility drugs
(j) First Aid supplies
(k) Immunizing agents
(l) Irrigating sets
(m) IV sets
(n) Medical devices
(o) Medical supplies
(p) Oxygen
(q) Products unsuitable for use outside of physician offices or health care facilities
(r) Shampoos, unless medicated for parasite control
(s) Skin lotions and creams (non-legend cosmetic types)
(t) Soaps and soap substitutes
(u) Supports and suspensories
(v) Convenience packaging or more expensive unit-dose
(w) Vitamin and anti-anemia combinations

Resubmittal of an unacceptable Questionnaire

(A) If a questionnaire for an addition is determined to be unacceptable, the drug company may request reconsideration of the decision. The department, retains the right to make the final decision.

(B) If a questionnaire and/or a request for reconsideration of a questionnaire for an addition is determined to be unacceptable, the drug company may not resubmit the questionnaire for six months. The department, may reconsider it's decision on the questionnaire during the six month period.

Retention and Deletion of Drugs

(A) The department reviews the TVDI to evaluate the need for retaining or deleting drugs according to the following criteria:

(1) If the drug company fails to remove from pharmacies any drug recalled by the FDA or fails to meet other federal requirements, the department may request the HHS allow deletion of the drug. If the drug company repeatedly fails to meet FDA or other federal requirements, the department may request permission to delete all drugs manufactured by the company.

(2) If the drug company fails to provide the department the current drug costs including the direct estimated acquisition cost (DEAC) to the pharmacy, the cost to a wholesaler, and the estimated wholesale cost to a pharmacy. The department may request that HHS allow deletion of the drug. If the department retains a drug for which the cost was not reported, the department establishes the cost. The allowable WEAC and DEAC are t le cost to a pharmacy, as determined by review of published or non-published prices resulting from routine marketing practices.

(3) The department deletes a legend drug if the same drug becomes available as an over-the-counter drug.

(4) Effective upon notification, the department deletes discontinued or permanently recalled drugs. This provision applies to:
(a) drugs permanently recalled by the manufacturer
(b) drugs permanently recalled by the FDA
(c) drugs no longer manufactured

(5) The department deletes drugs for which federal matching funds are no longer available. Federal matching funds are not available for:
(a) drugs for which a rebate is not available under public law 101-503
(b) drugs for which notice of opportunity for hearing has been published in the Federal Register.

(B) If a drug is deleted, the drug company is entitled to be notified and given the opportunity to request reconsideration of the decision unless the deletion is based on criteria in subsection (A)(3)-(5) of this section. The department, retains the right to make the final decision.

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

http://www.tdh.state.tx.us

1100 West 49th Street
Austin, Texas 78756-3199
512/458-7111

Paul J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

Dear :

This will advise you that your application(s) for inclusion of the drug(s) on the list of drug products for which the Texas Vendor Drug Program will reimburse pharmacies on Medicaid prescriptions has been approved. All claims should be submitted under product NDC number. The effective date for this approval is

Thank you for your submission of these products. Your cooperation in keeping me informed of any changes to your product line, including changes in cost to wholesalers and retail/chain pharmacies, is hereby requested and required.

Sincerely,

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug

MM:jto

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

http://www.tdh.state.tx.us

1100 West 49th Street
Austin, Texas 78756-3199
512/ 458-7111

Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

Dear

This will advise you that your application(s) for drug(s) for inclusion of drugs on the list of drug product for which the Texas Vendor Drug Program will reimburse pharmacies on Medicaid prescriptions has been denied

is a non-covered item. Therefore, your application is being returned.

If you have any questions, please feel free to call me at (512)338-6965, between the hours of 8-5, Monday thru Friday.

Sincerely,

Martha McNeill,R.Ph.
Director of Product Management
Bureau of Vendor Drug

MM:jto

Enclosures

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

http://www.tdh.state.tx.us

1100 West 49th Street
Austin, Texas 78756-3199
512/458-7111

Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

Dear :

We have already approved in If you have any questions, please feel free to call me at (512) 338-6965, between the hours of 8-5, Monday thru Friday.

Sincerely,

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug

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1100 West 49th Street
Austin, Texas 78756-3199
512/458-7111

Paul J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

Dear :

The attached application(s) are being returned. According to our latest communication with your company these products were not approved for marketing by the U.S. Food and Drug Administration. The Texas Vendor Drug Program can't add these to the Texas Vendor Drug Formulary for Medicaid Reimbursement until there is FDA approval.

Please resubmit these applications when the products have been signed up with the HCFA Rebate Agreement and the marketing is approved by the FDA. I would advise, to attach a copy of the HCFA approval letter with your applications.

Sincerely,

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug

MM: jto

Enclosures

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

http://www.tdh.state.tx.us

1100 West 49th Street
Austin, Texas 78756-3199
512/458-7111

Patti J. Patterson, M.D., M.P.H
Executive Deputy Commissioner

Dear :

We received your correspondence concerning the addition of new products to the Texas Vendor Drug Program. However, as explained in the cover letter attached to the enclosed application, it is a requirement that we receive complete information on each drug and strength before inclusion in the Texas Drug Code Index (TDIC).

Enclosed is an application(s) and also a copy of the regulations pertaining to addition of drugs to theTexas Drug Code Index. Please complete, sign and return the application(s) to:

Martha McNeill, R.Ph.
Bureau of Vendor Drug
The Department of Health
1100 West 49th Street
Austin, TX 78756-3174

Sincerely,

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug
(512)338-6965

MM: jto

Enclosures

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

http://www.tdh.state.tx.us

1100 West 49th Street
Austin, Texas 78756-3199
512/458-7111

Patti J. Patterson, M.D., M.P.H
Executive Deputy Commissioner

Dear :

I am returning your request for your drug products, because it needs to have Direct Prices and/or prices to Wholesalers.

Once you receive our application back, please send it back with the requested information so we can process it. If you have any questions feel free to call me at (512) 338-6965, between the hours of 8-5, Monday thru Friday.

Sincerely,

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug

MM: jto

Enclosures

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

http://www.tdh.state.tx.us

1100 West 49th Street
Austin, Texas 78756-3199
512/458-7111

Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

Dear :

The attached application(s) are being returned. According to our latest communication with your company you have not signed up your labeler _____ with HCFA. The Texas Vendor Drug Program can't add products to the Texas Vendor Drug Formulary for Medicaid Reimbursement until the labeler is signed up with HCFA for rebates .

Please resubmit these applications when the company has been signed up with a HCFA Rebate Agreement. I would send a copy of the HCFA approval letter with your application(s).

Sincerely,

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug

MM: jto

Enclosures

Texas Department of Health

William R. Archer III, M.D.
Commissioner of Health

http://www.tdh.state.tx.us

1100 West 49th Street
Austin, Texas 78756-3199
512/ 458-7111

Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

Dear :

The Bureau of Vendor Drug does routine maintenance reviews of The Texas Vendor Drug Index. While monitoring usage of pharmaceutical products listed in the formulary during this process we found that the size of your product , has had no usage. The size is showing reimbursements.

Let us know if your company has reason to request continued product coverage of . If we have not heard from you by , we will delete this product size from our payment files.

If you have any questions, please feel free to call me at (512)338-6965, between the hours of 8-5, Monday thru Friday.

Sincerely,

Martha McNeill, R.Ph.
Director of Product Management
Bureau of Vendor Drug

MM:jto

Mr. DINGELL. We also look forward to learning more about this program and hearing from our witnesses from Texas.

But these measures alone are not going to solve the health care problems of our poorest citizens. Nor will taking away health insurance from the poor to reduce the Medicaid rolls.

Medicaid is now an essential part of the Nation's health care system. In 2003, there were 40.4 million persons covered by Medicaid for their health needs, or 13.6 percent of our population. If this program did not exist, almost one-third of this Nation's total population would be totally uninsured. We need to be stepping up our assistance, and billions of dollars in tax cuts should not come at the expense of the health of our most vulnerable citizens.

We also need to look at what the Medicare Modernization Act will do to the States and the elderly poor. Mr. Rinehart will tell us that Michigan may pay more under MMA for drugs than it ever did before.

On Sunday, the New York Times ran a disturbing article about the unworkability of the new Medicare drug plan for the 1.5 million Americans who live in nursing homes, many of them in different stages of dementia are receiving drugs through feeding tubes, people obviously unable to come to a judgment about what plan it is that will serve their interests best.

These people are not on the Internet studying the various drug cards, nor are they able to. It appears that CMS has no strategy for serving these people, and I look forward to inquiring of CMS about these matters at a suitable time. We must address this critical issue then in the next Congress at the earliest time.

Mr. Chairman, I commend you and I thank you for continuing to focus on the Medicaid drug pricing issues; and I look forward to the testimony from all of our witnesses.

Chairman BARTON. We thank the distinguished gentleman from Michigan.

We would ask our distinguished subcommittee chairman of the Health Subcommittee, Mr. Bilirakis of Florida, for an opening statement.

Mr. BILIRAKIS. Thank you, Mr. Chairman. Good morning to all.

Today's hearing, obviously by now, focuses on an issue of great importance, Medicaid prescription drug reimbursement. Prescription drug payments are one of the fastest growing health care costs. In 2001 alone, Medicaid spent approximately $20 billion on drugs; and from 1997 through 2001, Federal Government Medicaid expenditures, Federal Medicaid expenditures, I emphasize, grew at more than twice the rate of total Medicaid spending.

The Medicaid program is the largest payor for prescription drugs nationally, representing about 14 percent of the market. The Federal Government contribution ranges from, as we know, from 50 to 83 percent in matching payments, depending on the State's per capita income.

Examining the amount of money the Federal Government pays for drugs is not an issue—is not a new issue for the Energy and Commerce Committee. In both the Medicare and Medicaid programs there have been concerns that the Federal Government is paying too much for drugs. Congress addressed some of those concerns, hopefully, in the Medicare Modernization Act that was

signed into law last year. But there is still more work to be done to ensure that prescription drugs are reimbursed at an accurate rate.

Medicaid reimbursement for prescription drugs is complicated, as is already obvious to all of us, and as we will see here today varies greatly from State to State. The Federal Government sets the maximum drug reimbursement limit.

But within those Federal parameters each State establishes its own estimated acquisition cost formula. This calculation is based on data from published drug prices, average wholesale price info, and wholesale prices. However, States do not necessary have access to the actual price paid for drugs, as has already been stated.

According to a recent Department of HHS Inspector General report, the difference between the highest and lowest State Medicaid drug payments ranged between 12 to 4,073 percent. At a glance, this definitely seems odd, doesn't it? However, there are many complicated factors as to why State reimbursement policies vary, the most visible being the acquisition price formula, but there are other factors as well.

This subject is, as I think, again, obvious to all of us, will be a top priority for this committee in the 109th Congress. We all look forward to hearing what our witnesses have to say. I believe and hope that the information they share with us will help us move forward in the next Congress.

Thank you, Mr. Chairman. I yield back.

Chairman BARTON. Mr. Waxman,the distinguished gentleman from California is recognized for an opening statement.

Mr. WAXMAN. Thank you very much. I am pleased that the subcommittee is holding this hearing today on issues involving Medicaid prescription drug reimbursement.

Medicaid, as you know, is a critical program for over 52 million low-income families and children and aged, blind and disabled people who rely on it for their health care services. It is a program that is costly, and it is a program that strains the budgets of the States who are struggling to meet the needs of their citizens. It is a program that needs better tools to control costs and spend dollars efficiently, and it is a program that, frankly, needs increased fiscal support from the Federal Government.

While members of this subcommittee might disagree on the best ways to improve and strengthen Medicaid, what surely all of us can agree on is that our scarce dollars be spent effectively. We should not be wasting dollars by overpaying for prescription drugs.

First, of course, in this program as in Medicare, we should be taking all of the steps we can to lower the price for prescription drugs. We should be using the bargaining power of negotiation in order to get better prices. Medicare represents millions of people, Medicaid represents millions of people, as does private insurance. We ought to be using that collective buying clout to get better prices for the prescription drugs in both programs.

Interestingly enough, Medicaid in some ways has been a leader in this effort. In fact, it was in 1990 when we established that Medicaid would be given the more favorable of the best price for brand name drugs or a minimum rebate of dollars off the average manufacturer's price, or AMP.

Years before Medicare took similar action, we broke away from the concept of accepting the average wholesale price, or AWP, as the price the program should pay. It was an early recognition that the AWP was an essentially bogus price that bore little relationship to the actual acquisition police of drugs.

Further, we attempted to ensure competition if there were three or more generics on the market by limiting the price the program would pay. But we made a critical mistake when these policies were developed. Even then, the drug industry was powerful, and they succeeded in securing a provision in the basic legislation that kept the best price and the AMP information a secret.

Can you imagine that? The Federal Government knew this information, but we kept it a secret from the States. This has proved to be a costly error. Without this crucial piece of information, States who are, after all, responsible for establishing the reimbursement rates for prescription drugs could not set their reimbursement rates appropriately.

As a result, they continued to rely on the average wholesale price minus some arbitrary amount simply because they did not have the information they needed to set a more appropriate reimbursement rate. Well, we at the Federal level bear responsibility for this, but we can remedy it. We need to make the information on the AMP and the best price available to the States.

I would hope this administration would ask for the authority to do this and that Members of the majority party would support it, even though the pharmaceutical companies might well oppose it. It might mean taking on these drug companies who seem opposed to transparency, but it makes a lot more sense to save money this way than to slash the Federal commitment to the people who depend on Medicaid.

As we will learn today, some States have been very aggressive in attempting to get this information and require drug companies to provide it. Too often, they have found that the Federal Government has undercut their ability to do this.

There is a further irony in the fact that the so-called claw-back provision of the recently passed Medicare prescription drug bill is designed so that the States that have spent the last few years in aggressive efforts to control increases in prescription drug expenditures will be disadvantaged for their efforts. They will have their fiscal obligation to the Federal Government grow at a higher rate than would have been the case if their prescription drug price control efforts had continued. This is also wrong, and we should fix it.

I hope this hearing today will shed some light on these issues and help show us a way to save money in Medicaid that will, in the end, benefit not hurt the millions of Americans this program is designed to serve.

Thank you, Mr. Chairman.

Chairman BARTON. Thank you, Mr. Waxman.

Not seeing any other members who have not yet made a statement, the Chair would ask unanimous consent that all members of the subcommittee not present have the requisite number of days to put their written statement in the record.

Hearing no objection, so ordered.

We now want to welcome our first panel. We have Mr. Mark Jones, who is President of Ven-A-Care in Florida, and we have Dr. John Lockwood, who is Vice President of that same company also in Florida.

Gentlemen, we welcome you. Your statements are in the record in their entirety. We will recognize you, Mr. Jones, and then Dr. Lockwood for 7 minutes to elaborate on your statement. Welcome to the subcommittee.

TESTIMONY OF T. MARK JONES, PRESIDENT, VEN-A-CARE OF THE FLORIDA KEYS, INC.; AND JOHN LOCKWOOD, VICE PRESIDENT, VEN-A-CARE OF THE FLORIDA KEYS, INC.

Mr. JONES. Mr. Chairman, members of the committee, good morning. My name is Mark Jones. I am President——

Chairman BARTON. Excuse me. This is an oversight hearing. I am not used to doing hearings where I have to swear people in.

It is the tradition of this subcommittee, since it is an oversight and investigation subcommittee, to take all testimony under oath. Do either of you gentlemen oppose testifying under oath?

Mr. JONES. No.

Chairman BARTON. You also have the right, under the Constitution, to be represented by counsel during your testimony. Do either of you have counsel here that you wish to advise you during your testimony?

Mr. JONES. No.

Chairman BARTON. Would you then each of you stand and raise your right hand.

[Witnesses sworn.]

Chairman BARTON. Now we can start with you, Mr. Jones, for 7 minutes.

Mr. JONES. My name is Mark Jones. I am the President of Ven-A-Care of the Florida Keys. I wish to thank you for the opportunity to appear before you today to discuss a matter of vital importance to the government health care benefit programs such as Medicaid.

Before I go on, this is Dr. John Lockwood, he is the Vice President of Ven-A-Care as well.

Today's hearing focuses on excessive reimbursement for pharmaceutical products by the States' Medicaid programs. Deceptive price reports by some drug manufacturers are causing hundreds of millions in damages to our country's joint State and Federal health care programs for the poor. The inflated reimbursements resulting from deceptive reports of prices have a corruptive effect on our health care system.

Ven-a-Care has learned this firsthand when it suffered economic retaliation for its refusal to enter into a business arrangement where inflated reimbursements were used to enrich the physicians in order to induce them to increase orders of expensive drugs.

Many Federal and State health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers.

The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent or misleading information is actionable.

The difference between the amount a provider is reimbursed for a drug and the provider's cost is known as the spread. In the context that we are addressing today, it means the difference between the cost of the drug to the pharmacy or other provider and the amount Medicaid reimburses for the cost of the drug. The greater the spread the greater the profit.

When a manufacturer reports a price that exceeds the price at which its drug is selling for in the marketplace, the States' Medicaid programs determine a reimbursement amount that are higher than the government intends. The participating manufactures then engage in conduct known as marketing the spread, by means such as the following:

Some manufacturers take action to increase reimbursement by further inflating their reported prices in order to persuade customers to buy their drugs. Some manufacturers train their sales personnel to pitch the higher reimbursement spreads on their drugs as compared to their competitors' drugs.

Reimbursement spreads on manufacturers' drugs are routinely marketed through software programs and data provided by wholesalers and group purchasing organizations that show the pharmacy the comparative spreads on different manufacturers' drugs so that pharmacy can choose the drug with the greatest spread.

Notwithstanding the explicit warnings from the OIG, the drug manufacturer executives who report inflated drug prices and direct their subordinates to market the spread often contend that their deceptive conduct should be blamed on the government reimbursement programs themselves. They argue that their reported prices are no more than list prices and need not be good faith representation of what their drugs actually sell for in the marketplace. Executives and other representatives from these companies have actually contended that it is the industry standard for them to make up any price they choose and report it for use by government reimbursement programs, even if the reported prices are more than 10 time the true prices they know are generally and currently available in the marketplace.

Such assertions have been rejected by the courts. For example, in a recent case involving the drug Lupron, United States District Court Judge Stearns spoke directly to such preposterous assertions by the drug company defendants.

Judge Stearns wrote, "Defendants repeatedly assert that they had no duty to disclose what was publicly known to everyone, that is, that the Lupron AWP was a sticker price and never intended to reflect the drug's true average wholesale price. In support of this argument, defendants cite a number of government reports acknowledging that published AWPs for prescription drugs often exceed their acquisition cost. The argument is ultimately unpersuasive. There is a difference between a sticker price and a sucker price."

Judge Stearns then addressed an argument often made by drug manufacturers who are caught reporting inflated prices. They argue that the U.S. Congress actually condones and even encourages such deception. Judge Stearns wrote again, "The suggestion that Congress would deliberately condone a bribery scheme using

public funds to enrich drug manufacturers and physicians is, to say the least, unusual."

It is my hope that my testimony as well as the information gathered through this committee's investigation will eliminate certain factors and concerns which I believe are critical to understanding the Medicaid reimbursement problem. They are: Drug manufacturers choose to have their drugs covered by Medicaid; they are not required to do so.

Drug manufacturers know that State Medicaid programs rely on the prices that the manufacturer reports directly or through their price reporting compendia. As with any system of government reimbursement, pharmaceutical reimbursement is based upon trust, in this case trust that the drug companies will report their prices in good faith.

The root of the problem of excessive Medicaid reimbursement for pharmaceuticals lies with those drug manufacturers who choose to deceive rather than tell the truth about their prices.

The excuse that a company will lose market share if it reports prices truthfully should not be accepted from pharmaceutical manufacturers. Other industries such as banking, communications, electrical power and defense manufacturers have been faced with similar integrity issues.

Any legislation directed at improving the Medicaid reimbursement system should not inadvertently create a potential defense through which manufactures may argue that Congress has somehow absolved them from their past defalcations.

Judge Stearns' decision quoted above illustrates that the manufacturers who have participated in this scheme seek to misconstrue the intent of Congress as somehow approving their deceptive conduct.

In closing, I would ask that this committee consider the insidious damage which such deceptive practices have on our free market system. The contention by drug manufacturers that deception is somehow justified when it becomes widespread in their industry reveals a serious and fundamental integrity flaw that, if left unaddressed, threatens the taxpayer, the patient and the industry itself.

Mr. Chairman and members, thank you for the chance to appear before your committee. Dr. Lockwood and I are happy to answer questions.

[The prepared statement of T. Mark Jones follows:]

PREPARED STATEMENT OF T. MARK JONES, PRESIDENT, VEN-A-CARE OF THE FLORIDA KEYS

Mr. Chairman and Members of the Committee, good morning. I am T. Mark Jones, President of Ven-A-Care of the Florida Keys. I wish to thank you for the opportunity to appear before you today to discuss a matter of vital importance to government health care benefit programs such as Medicaid: The diversion of hundreds of millions of taxpayer dollars because some pharmaceutical manufacturers report falsely inflated prices, knowing that government programs use those reports in setting reimbursement amounts. Ven-A-Care's past president, Zachary Bentley, appeared before this Committee on September 21, 2001 and testified about the impact of the same deceptive practices on the Medicare Program. Due in large part to the hard work of this Committee, protections against such drug manufacturer misconduct were included in the Medicare Modernization Act. I would draw the Committee's attention to the extensive evidence presented during the September 2001 hearing that exposes how drug manufacturers' deceptive reports of prices has dam-

aged the Medicare Program and its elderly and disabled beneficiaries. Today's hearing focuses on excessive reimbursement for pharmaceutical products by the States' Medicaid Programs, where the same kinds of deceptive price reports, by some drug manufacturers, are causing wide scale financial harm to our country's joint state and federal healthcare program for our poor.

As the information from this Committee's prior investigations revealed, Medicare reimburses pharmacies directly for a limited number of drugs, such as the inhalant drug Ipratopium Bromide when administered with a nebulizer. However, a very large portion of Medicare Part B drug expenditures directly reimburse physicians who administer the drug and may receive a direct financial benefit from their decision to use a particular drug. State Medicaid Programs, on the other hand, reimburse all providers for a much larger number of drugs than does Medicare Part B, and the vast majority of Medicaid drug expenditures are paid to pharmacies that dispense the drug to the Medicaid beneficiary. Accordingly, the manufacturers' marketing of the financial inducements, made possible by their false price reports, is usually directed at pharmacies when Medicaid reimbursement is at issue. As the cost of the War On Terror climbs and our national deficit grows, Congress faces increasing pressure to reduce federal contributions to State Medicaid Programs. Congressional and Executive Branch scrutiny of deceptive price reporting practices by drug manufacturers will do much to insure that the scarce dollars remaining are no longer diverted from their intended purpose of caring for our poor. Federal and State Medicaid funds must not be used as financial incentives that support individual drug companies' marketing efforts.

A brief discussion of Ven-A-Care's history will help put my remarks in the proper context. Ven-A-Care is a very small specialty pharmacy that was created in the late 1980s to provide infusion, inhalation and injectible pharmaceuticals to seriously ill patients, outside of the hospital setting, in the Florida Keys. We immediately experienced a high demand for our services due to the large numbers of patients suffering from HIV related illnesses in Key West. Our early success attracted the attention of National Medical Care, then the health care subsidiary of WR Grace Corporation, that organized the referring physicians in the community into a single venture and attempted to recruit Ven-A-Care's principals with promises of making us multi-millionaires within a few short years. Our examination of the NMC business plan revealed what appeared to be an unlawful arrangement where excessive reimbursement for pharmaceuticals would be used to generate exorbitant profits. Our concerns about the propriety of the venture were elevated by then recent experiences. In one instance, we received from Medicare a payment for a cancer therapy in an amount many times our cost as a very small pharmacy. Assuming that a mistake had been made, we voluntarily returned the money to Medicare. In another instance, we became concerned that the Florida Medicaid Program was paying excessive amounts for certain infusion therapies and we informed the program supervisors. The organizers of the NMC venture made it very clear to us that "success" would result from using funds generated by inflated pharmaceutical reimbursements to financially induce the participating physicians to increase their prescriptions, of expensive pharmaceutical therapies, many fold beyond that which had previously resulted from their best medical judgment. We did not believe that we could properly participate and we declined. As a result, the participating physicians redirected their referrals to the new venture in which they had an economic interest and Ven-A-Care soon lost virtually its entire market. After reporting our concerns to the appropriate federal authorities and assisting them in their investigations of NMC's business practices, Ven-A-Care brought its first action under the Federal False Claims Act which ultimately led to the United States recovering nearly $500,000,000 and WR Grace divesting itself of its healthcare businesses.

Our experience with the NMC venture was soon followed by other opportunities to share in other business arrangements where excessive government reimbursement for pharmaceuticals was used to fund kick-back arrangements and increase utilization of expensive drug therapies. Again we reported these situations to the government, gathered evidence through our own investigations and took other actions to assist the United States Department of Justice, the HHS OIG and later the States' Attorneys General in their efforts to identify and address the causes of the inflated reimbursement that was fueling the kinds of kick-back arrangements to which Ven-A-Care had been exposed.

As an industry insider, Ven-A-Care has had access to information that the federal and state governments needed to understand the root cause of the inflated Medicaid drug reimbursements. The following summarizes what we discovered:

a.) The United States government's policy has been that Medicaid reimbursement for drugs should be based upon the cost of the drug to the pharmacy, or other health care provider, who purchases the drug in the free marketplace and must

not be based upon government price controls or government negotiating power. This is significantly different from the situation where the government agency buys the drug directly, such as for the public health service, and gets the benefit of the much lower Federal Supply Schedule Prices.

b.) Medicaid programs pay pharmacies a dispensing fee over and above the amount reimbursed for the cost of the drug itself. The drug manufacturers' deceptive price reports cause the Medicaid Programs to pay excessive reimbursement for the drugs' cost to the pharmacy or other provider. All state Medicaid Programs as required to limit their reimbursement for the cost of the drug itself to an amount no greater then that based upon the program's estimate of the acquisition cost (EAC) which in turn is to be based upon prices "generally and currently available" in the marketplace.

c.) Therefore, "reimbursement" in the context of the Medicaid pharmacy benefit, is the amount that a state Medicaid Program pays the pharmacy, or other provider, for the cost of the drug that it dispenses or otherwise provides to a Medicaid beneficiary.

d.) State Medicaid programs look to prices reported directly to them by the manufacturer, as in the case of the Texas Program, or indirectly through prices the manufacturer causes to be reported by the three recognized drug price compendia; Red Book, First Data Bank and Medi-Span.

e.) The manufacturers report prices, and cause prices to be reported by the compendia, in three basic formats: Average Wholesale Price (AWP)—a representation of the price of the drug from the wholesaler to the pharmacy or other provider. Wholesaler Acquisition Cost (Cost)—a representation of the cost of the drug to the wholesaler from the manufacturer. Direct Price (DP)—a representation of the price the manufacturer charges the pharmacy when it buys the drug directly from the manufacturer.

f.) The term "spread" denotes the difference between one price or cost and another. In the context that we are addressing today, it means the difference between the cost of the drug to the pharmacy or other provider and the amount Medicaid reimburses for the cost of the drug. The greater the spread, the greater the profit.

g.) When the manufacturer of a drug reports, or causes the reporting of, an AWP, WAC or DP that is materially and deceptively greater than the actual prices in the marketplace, it causes the Medicaid Programs to calculate an estimated acquisition cost that is higher than the cost at which the drug is generally and currently available in the marketplace and thus reimburse at an inflated amount that causes the spread on the drug to be inflated.

h.) The manufacturers who have chosen to provide deceptive price reports have actively, albeit surreptitiously, taken steps to counteract government efforts to better estimate drug acquisition costs of prudent purchasers in the marketplace.

—Medicaid reimbursement at a discount off of AWP (eg AWP-15%) is counteracted by companies who report AWPs resulting in spreads of hundreds and even thousands of a percent.

—Medicaid reimbursement based upon WAC plus a percent, such as that paid by Florida and Massachusetts, is counteracted by companies that report, or cause the reporting of, false inflated WACs.

—Medicaid reimbursement based upon DP, such as that paid for some drugs by California, is counteracted by companies that report, or cause the reporting of, false inflated DPs.

—Efforts by states that require direct reporting of prices, such as Texas are counteracted by companies that report false prices directly to the state program.

—Efforts by CMS to set caps based on the Federal Upper Limit (FUL), are similarly counteracted because FULs are based upon 150% of the lowest publicly available price for a generic and FULs are inflated when the underlying reported prices are false.

i.) The participating manufacturers then engage in conduct known as "marketing the spread" by means such as the following.

—Some manufacturers will have direct discussions with large customers after which they will take action to increase reimbursement by further inflating their reported prices in order to persuade the large customers to buy their drugs.

—Some manufacturers will train their sales personnel to pitch the higher reimbursement spreads on their drugs, as compared to their competitors', directly to the pharmacies.

—The reimbursement spread on manufacturers' drugs is routinely marketed through software programs and data provided by wholesalers and group purchasing organizations that show the pharmacy the comparative spreads on different manufacturers' drugs so that the pharmacy can choose the drug with the greatest spread.

Over the last several years, Ven-A-Care has been vigilant in reporting industry insider information to the United States Department of Justice, the HHS OIG and the States' Attorneys General that has enabled them to identify and begin to address pharmaceutical pricing fraud by drug manufacturers. I am only at liberty to discuss a small portion of those efforts in this open proceeding; however, they are instructive:

1.) *The United States ex rel. Ven-A-Care v. Bayer:* Settled in 2001, the "Bayer 1" case resulted in the recovery of $14,000,000 by the Medicaid program and set the stage for similar actions throughout the United States, as well as more focused Congressional interest such as this Committee's September 21, 2001 hearing. The concept of reimbursement based upon Average Selling Price ("ASP") was included in the Bayer settlement agreement and later incorporated into the Medicare Modernization Act.

2.) *Texas ex rel Ven-Care v. DEY Laboratories and Schering-Plough/Warrick:* Ven-A-Care brought the first case under the Texas False Claims Act against drug manufacturers for reporting falsely inflated pricing information in order to cause the Texas Medicaid Program to pay inflated reimbursement which was in turn used as a marketing tool to induce pharmacies and other health care providers to select the manufacturers' drug over their competitors. Then Texas Attorney General, now United States Senator, John Cornyn, joined with Ven-A-Care and became the first State Attorney General to pursue action against pharmaceutical manufacturers for such deceptive price reports that cause Medicaid to overpay for drugs. To date, DEY Laboratories has paid $18,500,000 and Schering Plough has paid $27,000,000 to compensate the Texas Medicaid Program.

3.) *Texas ex rel. Ven-Care v. Roxane and Bohringer Ingelheim:* In this case the Texas Attorney General has joined with Ven-A-Care to pursue recoveries of excessive Medicaid reimbursements allegedly caused by deceptive pharmaceutical manufacturer price reports. This case is currently in active litigation.

4.) *Texas ex rel. Ven-Care v. Abbott Laboratories, Baxter, B. Braun McGaw:* In this case the Texas Attorney General has joined with Ven-A-Care to pursue recoveries of excessive Medicaid reimbursements allegedly caused by deceptive pharmaceutical manufacturer price reports. This case is currently in active litigation.

5.) *California ex rel. Ven-A-Care v. Abbott Laboratories:* In this case the California Attorney General has joined with Ven-A-Care to pursue recoveries of excessive Medicaid reimbursements allegedly caused by deceptive pharmaceutical manufacturer price reports. This case is currently in active litigation.

6.) *Florida ex rel. Ven-A-Care v. DEY, Schering-Plough and Roxane Laboratories:* In this case the Florida Attorney General has joined with Ven-A-Care to pursue recoveries of excessive Medicaid reimbursements allegedly caused by deceptive pharmaceutical manufacturer price reports. This case is currently in active litigation.

In addition to the above, the following states have brought similar actions against drug manufacturers for deceptively reporting drug prices resulting in their Medicaid Programs paying excessive reimbursement: New York, Massachusetts, Connecticut, Minnesota, Kentucky, Wisconsin, Arkansas, Ohio, Montana, and Nevada.

Since the settlement of the Bayer 1 case in 2001, approximately $2,400,000,000 has been recovered from drug manufacturers in cases, brought under the federal and various states' False Claims Acts, seeking recovery of excessive reimbursements paid by the Medicare and Medicaid Programs or recoveries of amounts underpaid to the Medicaid Rebate Program. (See, "The Role of the False Claims Act in Reducing Medicare and Medicaid Fraud by Drug Manufacturers: An Update", prepared for Taxpayers Against Fraud Education Fund by Andy Schneider, Principal Medicaid Policy, LLC, November 2004.) Perhaps more importantly, the industry insider information provided by Ven-A-Care has assisted the HHS OIG to better understand how drug manufacturers' deceptive price reports cause immense damage to the Medicare and Medicaid Programs. The HHS OIG addressed this in the OIG Compliance Program Guidelines for Pharmaceutical Manufacturers, 68 Federal Register No. 89, pages 23731-23743 (May 5, 2003). The OIG has made it clear that it considers such conduct to be fraudulent and to violate the False Claims Act and the anti-kickback laws. I have attached a full copy of the OIG's Guidelines. However, the following excerpts are directly relevant to today's proceedings:

> "*Integrity of Data Used To Establish or Determine Government Reimbursement.* Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expec-

tation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti-kickback statute."

Average Wholesale Price. The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit."

"Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u (o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers."

"If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product."

"In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product."

Notwithstanding such explicit warnings from the OIG, the drug manufacturer's executives, who report inflated drug prices, often contend that their deceptive conduct should be blamed on the government reimbursement programs themselves. They argue that their reported prices are no more than "list" prices and need not be good faith representations of what their drugs actually sell for in the marketplace. Executives and other representatives from these companies have actually gone so far as to represent that it is "the industry standard" for them to make up any price they choose and report it for use by government reimbursement programs no matter how many hundreds or, in many cases, thousands of a percent that their represented prices exceed the true prices that they know are generally and currently available in the marketplace. Such assertions have been rejected by the courts. For example, in a recent case, *In re Lupron Mktg. & Sales Practices Litig.,* 295 F. Supp. 2d 148 (D. Mass. 2003), brought to recover such price fraud damages for Medicare beneficiaries whose 20 per cent co-payment had been inflated, United States District Court Judge Stearns spoke directly to such preposterous assertions by the drug company defendants:

"But this is not a case of nondisclosure. Defendants did not stand mute. As alleged in the Amended Complaint, defendants trumpeted a lie by publishing the inflated AWPs, knowing (and intending) them to be used as instruments of fraud." Id at 647.

"Defendants repeatedly assert that they had no duty to disclose what was publicly known to everyone, that is, that the Lupron® AWP was a "sticker

price" and never intended to reflect the drug's true average wholesale price. In support of this argument, defendants cite a number of government reports acknowledging that the published AWPs for prescription drugs often exceed their acquisition cost. The argument is ultimately unpersuasive. **There is a difference between a sticker price and a sucker price.** If one were confronting a modest markup of the actual AWP for Lupron ® (which 300% is not), intended to make sales of the drug for the treatment of Medicare patients commercially viable (given the 95% of AWP reimbursement rate), it is unlikely that there would have been a government investigation of TAP's marketing practices. Similarly, if the same inflated AWP had not been used to set reimbursement rates for private purchasers and insurers, the Amended Complaint would not have been filed. The Blues, in their response to defendants' argument, have it exactly right: "[I]f everything [about Lupron ®] was known to everybody, why did [d]efendants emphasize secrecy?" Blues Memorandum, at 7. Finally, the recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct. (Emphasis added) Id at 648.

"...As defendants portray the Congressional purpose in setting the reimbursement rate at 95% of AWP, Congress meant to turn a blind eye to the inflated AWPs as a means of enticing physicians to treat Medicare patients. In other words, Congress deliberately invited the very fraud of which defendants are accused. As defendants describe it, "a determination that AWP must be set at the actual cost to providers would result in lower Medicare payment levels to physicians, prompting many of those physicians to stop treating Medicare patients because it is not cost-effective for them to do so." Defendants' Memorandum, at 32. The suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual." Id at 648.

The above excerpts from Judge Stearn's decision illustrate the following corrupted logic underlying certain drug companies' rationalization that they have no duty to tell the truth about prices: government reimbursement systems that trust price representations by drug companies are easy to cheat; therefore many companies cheat; therefore cheating is the industry standard; therefore cheating isn't really cheating. After Judge Stearns rejected the proposition that such a complete lack of integrity is somehow excused, if it occurs within the pharmaceutical industry, the drug companies in question agreed to pay $150,000,000 in damages.

Like the Defendants in the Lupron case, the manufacturers, who choose to have their drugs covered by Medicaid, know that state Medicaid Programs are relying on their price reports to estimate the drug's cost for reimbursement purposes. For a significant portion of the dollars expended by the states' Medicaid Programs, reimbursement is based upon reported prices that fairly and reasonably reflect the price at which the drug is generally and currently available in the marketplace. It is only where the manufacturers choose to falsely report their prices that Medicaid pays an inflated amount. This inflated "spread" is what enables the manufacturers participating in this scheme to use the taxpayers' money to arrange financial inducements which are then used to persuade customers to purchase their drug instead of a competitor's. Moreover, in many cases, the government dollars that are diverted in this manner encourage excessive utilization of the drug therapy and otherwise have a corruptive influence on the healthcare delivery system.

Testimony and documents secured from employees of pharmaceutical companies merely corroborate that the drug manufacturers participating in this deceptive practice are fully aware that they are misleading the States' Medicaid Programs. We understand that the Committee has also been provided with some of this evidence. We hope that it will be carefully considered, because it reveals scenarios such as:

1.) A drug company executive suggesting further inflation of price reports, but presented with subordinates' concerns about the increased government scrutiny of price reporting practices in 2000, articulated his conscious decision to risk government sanctions in order to maximize sales for as long as he could get away with it.

2.) A drug company executive presented with a competitor, who had caused a greater spread on WAC based reimbursement in Florida and other states reported admittedly false inflated WAC prices to the compendia in an effort to gain greater market share.

3.) The four most senior executives of a drug company crafted a written marketing plan directly based upon creating and marketing financial incentives to their customers arising from the company's manipulation of Medicare and Medicaid reimbursement through false price representations.

4.) Drug company executives choose to inflate the reported AWPs for many of their drugs by several hundred percentage points in order to create greater financial incentives for their customers and thus avoid price reductions that would otherwise occur due to natural market forces.
5.) Competing drug companies each inflate their price reports for generic versions of the same drug and thus cause the FULs set by CMS to be themselves inflated because they are based upon 150% of the lowest publicly available price.
6.) After a branded drug comes off patent, competing drug companies each continually decrease their true price due to competition while continually increasing the spread through their inflated reported price reports, while utilization of the drug increases exponentially.
7.) Drug company executives testify that they never change the AWP for a drug once it is established. The evidence shows that they routinely increase AWPs to gain or retain market share.
8.) Some, but not all, manufacturers fail to report declining AWPs even though they know the market price of the drug, to all customers, is falling precipitously in the competitive marketplace and that their deceptive price reports will deprive the Medicaid Program of the benefits of declining prices.

It is my hope that my testimony, as well as the information gathered through this Committee's investigation, will illuminate certain factors which I believe are critical to an understanding the Medicaid reimbursement problem. They are:

a.) Drug manufacturers choose to have their drugs covered by Medicaid. They are not required to so.
b.) Drug manufacturers know that Medicaid Programs must estimate the acquisition costs of drugs in setting reimbursement. Millions upon millions of claims are paid by Medicaid programs each year and scarce dollars cannot, and should not, be taken away from benefits in order to investigate and determine the individual cost of each prescription.
c.) Drug manufacturers know that the State Medicaid Programs rely on the prices the manufacture reports directly or through the price reporting compendia.
d.) As with any system of government reimbursement, pharmaceutical reimbursement is based upon trust, in this case trust that drug companies will report their prices in good faith.
e.) The root of the problem of excessive Medicaid reimbursement for pharmaceuticals lies with those drug manufacturers who choose to deceive rather than tell the truth about their prices.
f.) Dissembling excuses, such as protestations that a company will lose market share if it reports prices truthfully, should not be accepted from pharmaceutical manufacturers. Other industries, such as banking, communications, electrical power, and defense manufacturers have all been faced with similar integrity issues.
g.) Congress addressed the evil of drug manufacturers' false price representations in the Medicare Modernization Act by requiring manufacturers to report the Average Selling Price for their drugs. These prices are in turn published by CMS. Unfortunately, similar tools have not been provided to the Medicaid Program as evidenced by a comparison of Medicaid FULs with Medicare ASPs for certain drugs, such as Ipratopium Bromide which are reimbursed by both programs. The drug's Medicaid FUL, which is still based on inflated price reports by manufacturers, is several times greater than the ASPs now reported to Medicare.
h.) Any legislation directed at improving the Medicaid reimbursement system, should not inadvertently create a potential defense through which manufacturers may argue that Congress has somehow absolved them from their past defalcations. Judge Stearns' decision quoted above illustrates that the manufacturers who have participated in this scheme seek to misconstrue the intent of Congress as somehow approving their deceptive conduct.
i.) Insuring now that drug manufacturers, that have reported inflated prices in the past, face the full consequences of their actions under the law, will provide the best assurance that drug manufacturers will not misrepresent ASP or other price information vital to reimbursement decisions in the future.

In closing, I would ask that this Committee consider the insidious damage that such deceptive practices have on our free market system. The contention by drug manufacturers, that deception is somehow justified when it becomes widespread in their industry, reveals a serious and fundamental integrity flaw that, if left unaddressed, threatens the taxpayer, the consumer and the industry itself. The noble effort to generate profits must never be permitted to subjugate the higher duty to tell the truth.

Mr. Chairman and Members, thank you for the chance to appear before your Committee. I am happy to answer any questions that you may have.

Chairman BARTON. Dr. Lockwood, you don't have a statement that you——

Mr. LOCKWOOD. No, I don't.

Chairman BARTON. Okay. The Chair would recognize himself for 10 minutes.

Dr. Lockwood or Mr. Jones, explain in layman's terms what average wholesale price should be. What should it mean?

Mr. LOCKWOOD. Average wholesale price has been a benchmark for the industry for over 30 years, and for brand drugs AWP is a fairly reliable benchmark. About 80 percent—at least based on our studies and government studies and talking to Medicaid program directors, about 80 percent of the Medicaid dollars are paid on brand drugs and are fairly accurately reimbursed.

Chairman BARTON. But I want to—I don't want to know what the tradition is. I want, in layman's terms, average wholesale—I am trying to think, if I go out and I grow cotton, I know what it costs me for the seed. I know what it costs me for the tractor. I know what it costs me to own the land, if I am paying on it, or to rent the land if I don't own it.

And when I—when that cotton crop is ready to go to market, I have got a pretty good idea what my costs are. And I add some profit margin, which is a little bit based on the market and demand and supply, and that is my average wholesale price, I think.

So, in drugs, all of these different manufacturers who tend to be running around like we didn't know what average wholesale price is, it is some number that we can stick out there, and the higher the better, because it increases the spread that we can then discount to encourage the pharmacies to use our drug, because they get a bigger markup on it.

What should it be? I mean, how—if we wanted to set some sort of a Federal standard in law for average wholesale price, what should it be? That is my question.

Mr. LOCKWOOD. We believe that average wholesale price should be a number that is reflective of the underlying marketplace that the drug manufacturer sees when they look at their own books.

Chairman BARTON. It is——

Mr. LOCKWOOD. Some people interpret it—because AWP is not defined—but they have sometimes interpreted average to mean usual, meaning the average or usual wholesale price.

Traditionally, it has been 20 percent higher than the invoice price that the wholesaler gets. So that when a drug manufacturer sells to a wholesaler, there is an invoice price.

Chairman BARTON. It is not a cost-based price? It is not based on the cost of the manufacturer of the drug to actually produce and market that drug? It is not a cost-based price? It is a market-based demand price?

Mr. LOCKWOOD. It is a marked-based price. In this country, we have never instituted price controls. And my partner and I are certainly capitalists, and we don't believe in price controls. We believe drug companies should be able to set their own prices. But we think those prices should be reflective of their underlying marketplace.

We don't want to get into the business of manufacturers. If they can produce something for $1 and sell it in the market for $10, that

is their business. But they shouldn't report to the government that when they are selling—actually selling it for $10 that they are selling it for $100. And that is what is happening with AWP, is that they are saying that this drug costs a hundred dollars, while everyone in the market is buying it for $10.

Chairman BARTON. So we ought to do away—I mean, if it is okay for the manufacturers to set the price wherever they want, what we should do from the Federal Government perspective is whatever you actually sell it for is what you report it for? You sell it for $1,000, you report it. If you sell it for 10 cents, you report it. But don't say I am going to sell it for $1,000, and I am really selling it for $10.

Mr. LOCKWOOD. Correct. We believe in capitalism. We think that drug companies should be able to set their prices. They just need to report them in an accurate, fair and responsible way, much like the OIG has recommended in their compliance guidelines.

Chairman BARTON. Are the people that are setting this average wholesale price, is that the manufacturer or is that a middleman that sets that price?

Mr. LOCKWOOD. Well, there has been argument about that. But I don't think anyone argues that compendia certainly use prices they get directly from manufacturers to calculate AWP.

In some circumstances, manufacturers send the AWP directly to the compendia and tell them that is their price. In other circumstances, they send a price that they know the compendia are going to mark up 20 percent, for instance, which has been a common industry amount. So they know that when they send a price of $100 that the compendia are going to make an AWP of $120. There is no confusion there.

What is more, our investigations have shown that all of the compendia send a report to the drug manufacturers every year and ask them to verify that the prices they are reporting are, in fact, correct, accurate, appropriate, and if they are not right, they need to be changed.

Chairman BARTON. Well, if we have some manufacturers testify later and I ask them what is wrong with reporting what you really—what your true selling price is, what is wrong with that? What is it that is so scary or so negative toward their continued existence as a for-profit entity that they can't report what the real selling price is?

Mr. LOCKWOOD. Transparency seems to scare them dramatically. Exactly why, you may need to ask them. I can speculate, but——

Chairman BARTON. Well, speculate.

Mr. LOCKWOOD. We believe that the real market prices may actually become lower as a result of transparency. My point being that if you have a drug that you are selling at a high AWP, you may actually be able to sell that drug for more money than your competitor because you have a better spread.

Look, I don't want to confuse you, but if you are selling a drug for $10 and your spread, your AWP is $100, you might be able to get $10; whereas another company might be selling the drug for $5, but because their AWP is $50, nobody is buying their drug, so that high AWPs help drag up, in some circumstances, the transaction prices.

Chairman BARTON. But if we switch to a system where they actually report real selling price and document and verify it, not price controls, but some sort of—like we have in the natural gas market or the oil market or any other market where there is buy and sell and some sort of a commodity function, over time, everybody is going to know what the true prices are, at least at the selling price, not the proprietary cost, but the actual selling price, and the best win. Right?

Mr. LOCKWOOD. Absolutely. We believe that is fair and appropriate. We think they have that obligation now. There is some disagreement on that. But we believe that the government should be benefiting from transparency in price transactions. That will lead to a true marketplace. Currently, Medicaid, Medicare—until your recent bill—and consumers are price-shielded from true competition that's occurring in the marketplace. We are seeing these AWPs but not seeing the real marketplace.

Chairman BARTON. But if we did that, if we went to a requirement for true price reporting, gave some flexibility on the dispensing fee for pharmacies so that, if their cost of dispensing the prescription for Medicaid is truly high or something, they get reimbursed for that; implement that, have a transition period, a year, 2 years, to go from the old system to the new system, is there any reason that that wouldn't work and result in significant savings to both State and Federal coffers for Medicaid and to the consumers from the copayment side if they have a Medicaid co-payment?

Mr. LOCKWOOD. We believe it would work, and we believe it's ideal. It preserves capitalism in the marketplace, and it fosters competition, and it's what should be happening in this market.

Chairman BARTON. Is there anything I haven't asked you that I should in the next 10 seconds before my time expires?

Mr. LOCKWOOD. We need more than 10 seconds probably.

Chairman BARTON. Okay. My time has expired.

I recognize the gentleman from Massachusetts, Mr. Markey, for 10 minutes.

Mr. MARKEY. Thank you, Mr. Chairman, very much.

So what you have got here is a situation where a drug company makes a drug, they are selling 100 pills for $100 wholesale to a company, and so it looks like the price is $100 for 100 pills. But, actually, there's a 10 percent discount to the wholesaler, so it's really only $90 for 100 pills to the wholesaler, and then the wholesaler can further try to make a profit as a wholesaler on their sale down the chain.

Meanwhile, the report to Medicaid is that it actually costs $125 for the 100 pills, which is then the price which the Federal Government and the taxpayer has to pay, although we know that the actual price is $90 for 100 pills, because that is the real world. The made-up number, the average wholesale price, is the price that we have to pay, Americans have to pay for these pills.

Now, how do they make up this average wholesale price, which is perhaps 35 percent higher than the actual cost to an actual wholesaler to purchase these drugs? How do they make up that number?

Mr. JONES. I think more importantly than how they make it up is what they are doing with it. Basically, in the generic market-

place right now, manufacturers are—they are always in control of their prices. They own every price that is ever published; it's theirs. They are taking those published prices, using the difference between what they are selling them for and what the end buyer that is going to build a program gets reimbursed for as their marketing tool to sell their drugs. So that is called the spread. A manufacturer reports price; $125 is the AWP. Medicaid uses that $125 to reimburse whomever is billing it, yet they sell it for $90. Well, the difference between $90 and $125 is the spread. That is the financial incentive that these companies use to sell their drugs, because you are talking about a generic market. You are talking about a marketplace in general where this is 7 or 8 different manufacturers of the same drug.

Mr. MARKEY. Okay. Well, we held our first hearing on average wholesale price in 2001. The drug companies have paid over $2 billion in fines, penalties, reimbursements to the Federal and State governments. Now, that's a lot of money. But has anything really changed in the marketing of prescription drugs to the retailer since 2001?

Mr. JONES. Well, I think, for those manufacturers that have participated in paying that money, it has changed.

Mr. MARKEY. Okay. How about for the marketplace in general?

Mr. JONES. I think the marketplace obviously has an awareness of what they are doing. I mean, maybe a little anecdotal evidence here: Over the time period that we have been investigating this, we have heard drug manufacturers first claim that they didn't know where AWP came from; it wasn't their number. And then that evolved into, yes, we set the AWPs. And then we heard drug manufacturers say, we don't know anything about marketing the spread. We are not interested in marketing the spread; we are only interested in the price that we charge our customer. But we finally evolved into, yes, there is a spread out there, and, yes, we do market it. And, now, we are at the point with this industry where they are saying, look, it is so messed up, everybody wants to buy drugs based solely on the spread value, and we can't stop it even if we want to.

Mr. MARKEY. So has the spread between the average wholesale price paid by the retailers been reduced, or is the average wholesale price as false as it always was?

Mr. JONES. Well, obviously, depending on the drugs, because different drugs have different methods of being—you know, pricing. But I think——

Mr. MARKEY. Which drugs still have a false price?

Mr. JONES. The generic industry drugs. Basically, your generic drugs. That's how they are marketing them in this country right now.

Mr. MARKEY. So the industry argues that they still need a very high average wholesale price whether it is openly marketed or not. Is that correct?

Mr. JONES. Yes.

Mr. MARKEY. That's their argument. Now, is it a justified argument?

Mr. JONES. Absolutely not.

Mr. MARKEY. Why not?

Mr. JONES. Because they are using precious government funds as the incentive for selling their drugs, to market their drugs with.

Mr. MARKEY. So one of the witnesses on the third panel will testify that the real acquisition costs for wholesalers is the reported wholesale acquisition cost plus 5 percent. Is that a good base price to use for reimbursements?

Mr. LOCKWOOD. Well, for some brand drugs, that is an accurate number. But for a whole host of other drugs, the wholesale acquisition cost has been altered over time and is no longer an accurate number. We discovered that in Texas certainly. Texas has paid off of a price to the wholesaler, and we have found essentially that there is fraud in the WAC marketplace as well.

Mr. MARKEY. So what is your view of the Federal upper limits set on drugs by CMS, by the Federal Government? Do they reflect the real cost of the drug?

Mr. LOCKWOOD. The Federal upper limit has been an attempt by the government to ensure prudent purchasing in generic drugs, and they essentially are saying, this is a ceiling price, we are not going to pay anything more than this. The problem with the FUL is that it is based on reported prices and that, if a manufacturer or a whole host of manufactures are reporting inflated prices, whether it be WAC, direct price or average wholesale price, if those are inflated, the resulting FUL is inflated.

Mr. MARKEY. FUL means?

Mr. LOCKWOOD. Federal upper limit. It's an upper limit price that CMS creates to limit reimbursement on generics. So that the lowest generic price reported, if it's $100, the FUL basically says, we are not going to ever pay more than $150.

Mr. MARKEY. Well, a markup of a spread of 25 to 35 percent seems incredibly high and unreasonable to me for a markup in a commodity marketplace. Don't you agree?

Mr. LOCKWOOD. We agree with that. We are proponents of average sales price.

Mr. MARKEY. So if every wholesaler is able to reap a 25 to 35 percent spread, doesn't that suggest that there isn't real price competition in the prescription drug market?

Mr. LOCKWOOD. Well, in fact, wholesalers don't receive those kind of benefits. Generally speaking, wholesalers are probably making 1 or 2 or 3 percent.

Mr. MARKEY. How about the pharmacies? The pharmacists are then taking advantage of their spreads. And, you know, we are not against paying pharmacists appropriately and fairly. Do the pharmacies deserve to get a 25 to 35 percent markup in the price of drugs to grandma who is standing there in front of the counter? Do they deserve that kind of markup?

Mr. JONES. Medicaid is trying to estimate acquisition cost; 30 percent markups over acquisition costs are not realistic in the Medicaid program.

Mr. MARKEY. So what is the fix then? How do you make sure that grandma isn't digging through her pocketbook standing there to pay a 25 to 35 percent markup for a drug that we all know is nowhere near that cost in terms of its manufacture and delivery right to that counter? Why should she, knowing she should have

to take that pill in a half an hour, have to pay that money? And how do we fix that problem at that counter?

Mr. LOCKWOOD. In fact, your 25 and 30 percent is very low. If we could bring up slide number 6, perhaps, this will give you an idea. And it is in your binder under number 4. If you will look at it, you can see that there are huge, huge spreads involved in some of these common generic drugs. In the case of Fluoxetine, we are talking about an AWP of $259.85, and the current cost last week is $4.25 for that bottle, for the whole thing. And even the FUL isn't capturing this.

Mr. MARKEY. So we have got a situation here where the pharmacist is saying that, for grandma, she has to pay—that is, the Federal Government or the States have to pay—25 to 35 percent more for the drugs. But the States could be using that money to lower the cost for grandma to be in a nursing home, to lower the cost for more children to be covered by a medical program that would increase the health of the children in that State. And yet the pharmacy is saying, we won't give this drug to grandma unless you give us this 25 to 35 percent markup.

So what we need from you in 30 seconds is, how do you fix that? What do you recommend to fix that at that counter to make sure that the drugs are what—are a price that they should be, so that all the rest of the money could then be used to help grandma and the children in that community to have a higher level of health care?

Chairman BARTON. And the gentleman's time has expired. We will let the witnesses answer the question, and then we are going to have to go to Mr. Walden.

Mr. LOCKWOOD. I think we like average sales price. The GAO study that just came out I think 6 days ago, I think, has verified that average sales price is an effective way of estimating drug costs. And then, by all means, taking care of the pharmacies, paying them a reasonable dispensing fee for their services. They have to make a profit. They have to stay in business. They have to help distribute our drugs.

Mr. MARKEY. In other words, use the Medicare system to determine the price, rather than this system that Medicaid is now using, because the Medicaid system allows for the taxpayer and grandma to get ripped off in terms of the benefits they receive. Is that correct?

Mr. LOCKWOOD. We like the ASP system.

Mr. MARKEY. You like the Medicare system better than the Medicaid system.

Mr. LOCKWOOD. The new Medicare system, yes, sir. Yes, sir.

Mr. MARKEY. Thank you.

Chairman BARTON. I would like to point out before we recognize Mr. Walden that we have changed in Medicare to the average sales price in this MMA, the Medicare Modernization Act. CBO says that should save about $15 billion over the next, I think, 10 years. So I am not saying we have got it right in Medicare, but we are moving in the right direction. And the purpose of this hearing is to see if we can't do a similar thing in Medicaid. And we obviously see that there are lots of areas we can improve in.

With that, we would recognize Mr. Walden for 10 minutes.

Mr. WALDEN. Thank you, Mr. Chairman. And before I start asking questions, I would just like to move that the documents that are contained in the exhibit binder be made a part of the official record.

Chairman BARTON. Without objection, so ordered.

Mr. WALDEN. Thank you, Mr. Chairman.

You know, gentlemen, it seems to me like this is the proverbial $500 toilet seat of Medicaid, the AWP is. And I am wondering what the FUL is, because if you look at your chart there, the Federal upper limit doesn't seem to be a standard that works either, compared to the price that is being paid. Is that correct?

Mr. JONES. Unfortunately, it's a price that is determined off of the manufacturer's reported prices. So it is as vulnerable to price manipulation as any other.

Mr. LOCKWOOD. Could we bring up slide 8?

Mr. WALDEN. I was just going to go to slide 8. Indeed. There you are. All right. Go ahead.

Mr. LOCKWOOD. This slide is based on current prices, and the ASP plus 6 from the second quarter of 2004. So I don't—we are mixing apples and oranges a little bit here. The current cost price is listed in the column that is highlighted.

Mr. WALDEN. Okay. So let us take Ipatropium; $3.50 is the current price?

Mr. LOCKWOOD. Yes, sir.

Mr. WALDEN. As of when?

Mr. LOCKWOOD. About 3 days ago.

Mr. WALDEN. And the Federal upper limit is as of a year ago?

Mr. LOCKWOOD. Yes.

Mr. WALDEN. And why is that price from November 2, 2003?

Mr. LOCKWOOD. Well, that was the date the FUL was changed.

Mr. WALDEN. And isn't that another issue that we face, is updating the FUL list?

Mr. LOCKWOOD. Yes, we do. But I don't know if the reported prices have changed or not. In fact, they may not have changed in the past year. If the manufacturers are continuing to report the same prices they did at that time, the FUL won't change.

Mr. WALDEN. Well, I think there is also an issue in the IG's report about how often these prices get adjusted, once it is determined there are generics on the market, that there is a continuing problem there that may date back a decade it seems like or at least a half a decade if not more. Well, how current is the AWP? Is that the same issue?

Mr. LOCKWOOD. The AWPs are current now.

Mr. WALDEN. So the $44.10 AWP for Ipatropium is a current price?

Mr. LOCKWOOD. Yes, sir.

Mr. WALDEN. So you are looking at more than 10 times the price. The spread is more than 10 times the actual price.

Mr. LOCKWOOD. Yes, sir.

Mr. WALDEN. And who is pocketing that difference?

Mr. LOCKWOOD. In general, the pharmacies, the providers.

Mr. JONES. And manufacturers are also benefiting by market share.

Mr. WALDEN. Getting market share. So there is a marketplace working here. Isn't there?

Mr. LOCKWOOD. Absolutely.

Mr. WALDEN. It's just not to the benefit of the person paying the bill. And generally, in America, marketplaces we like are the ones that benefit the buyer. Isn't that how you foster competition?

Mr. JONES. The consumer is not benefiting here.

Mr. WALDEN. The consumers are losing. The States are losing. The Federal Government is losing, and the people in between are making at least what would appear to be a tidy profit.

Now, we also have to recognize that this AWP isn't necessarily the price being paid. Right?

Mr. LOCKWOOD. That's correct.

Mr. WALDEN. Because they will discount off of that.

Mr. LOCKWOOD. And it would default to the FUL for most State Medicaid programs.

Mr. WALDEN. And are these FUL current cost AWP prices, are they fairly representative of all the drugs, or are these the worst-case examples?

Mr. LOCKWOOD. These are not the worst cases. In fact, I have—I've included a couple of charts over a wide range of drugs.

Mr. WALDEN. Do you want to reference those?

Mr. LOCKWOOD. It's in your binder under number 4. And these represent drugs that are antidepressants, inhalant drugs, antibiotics, cancer drugs, such as tamoxifen used in breast cancer, and high blood pressure drugs. So this is over virtually the entire drug marketplace; it's not just one little niche where this is occurring.

Mr. WALDEN. Now, you are seeing some—I will probably not pronounce this correctly, but Ranididine.

Mr. LOCKWOOD. Ranididine.

Mr. WALDEN. I got that wrong.

Mr. LOCKWOOD. It's a drug used to control stomach acid that is now actually over-the-counter.

Mr. WALDEN. And we're paying $44.90; well, the current cost is $44.92 over-the-counter?

Mr. LOCKWOOD. That's for a bottle of 1,000 pills, the current cost is $44.92.

Mr. WALDEN. And the AWP is $1,480?

Mr. LOCKWOOD. Yes, sir.

Mr. WALDEN. And that is a current AWP?

Mr. LOCKWOOD. Yes, sir.

Mr. WALDEN. All right. Have you done any analysis of how good a job these Federal upper limits do in capturing cost savings?

Mr. LOCKWOOD. Well, they certainly reduce, as you can see in that drug. If the government is paying $341 instead of $1,480, that's a significant cost savings. But when you compare the FUL, if you look at the FUL spread on that column, you can still see that there is a huge, huge profit involved there. And it is because the FUL is based on reported prices that manufacturers do what—seem to do what they want with.

Mr. WALDEN. What I have struggled with is why this isn't considered some sort of fraudulent billing practice.

Mr. LOCKWOOD. I believe we consider it fraud.

Mr. WALDEN. Why?

Mr. LOCKWOOD. Because of—actually, the OIG probably did a much better job of explaining it than I could. I am not an attorney. But the OIG really set down the guidance to manufacturers in 2003, and they point out that these type behaviors may be actionable under the False Claims Act and under the Anti-kickback Statute. And I am no attorney, but I am relying on them.

Mr. WALDEN. Can you—well, several drug manufacturers have asserted in their written statements that the current Medicaid reimbursement system effectively puts them between a rock and a hard place. They can't lower their AWP to make it more reflective of actual market prices without losing all of their business. How do you respond to that argument? And I have got some e-mail traffic from one agency that indicates very clearly there is enormous market pressure to raise the AWP or you lose market share.

Mr. JONES. Certainly they use the reported prices to gain market share in the generic marketplace. Off the top of my head, when I think about that statement, they corrupted the system. They are the ones that are responsible for reporting the prices. Those prices come from them, and the selling prices come from them. So, now, they find themselves in that untenable position of not being able to adjust or correct a system that they have already corrupted.

Mr. LOCKWOOD. They can't stop the fraud.

Mr. JONES. They did too good of a job educating the consumers who are going to build the programs, the pharmacists or the doctors or whomever is receiving the benefit of selling that drug. They have educated them so well, they have——

Mr. WALDEN. They are marketing the spread.

Mr. JONES. Absolutely.

Mr. WALDEN. And the idea is that the bigger spread, the more the take.

Mr. JONES. The higher the utilization in certain circumstances.

Mr. LOCKWOOD. Manufacturers will tell you they can't quit doing this unless everyone stops at once.

Mr. WALDEN. Which is why it is up to us to make that change. Isn't it?

Mr. LOCKWOOD. Because if there is a half a dozen companies in the market and one of them stops——

Mr. WALDEN. They are out of business.

Mr. LOCKWOOD. They are out of business. Now, Abbott Laboratories did some significant price changes in 2001 that significantly lowered their prices in the marketplace, and I think they should be commended for it.

Mr. WALDEN. And what was the impact of that? How are they doing?

Mr. LOCKWOOD. Well, they lowered AWPs on a whole host of drugs enormously. Now, I don't have that information in front of me, but they made a substantial change in their price reporting on a whole host of drugs.

Mr. WALDEN. Can you turn to tab 5 in your binder there, please, sir, in the final minute and a half I have here. This exhibit is information on pricing from a company called Innovatix—is that right? Innovatix, your home infusion specialists. And I am intrigued, because this would seem to be a document available—how? Through prescription service or something?

Mr. LOCKWOOD. To members, it's available over the Internet.

Mr. WALDEN. Members of?

Mr. LOCKWOOD. Innovatix.

Mr. WALDEN. Okay. And it lists the AWP spread, the AWP. It's pretty hard to read on this graph. And then the contract price, right?

Mr. LOCKWOOD. Yes, sir.

Mr. WALDEN. Doesn't this give us the data where we could make more informed decisions about actual costs of drugs being sold out on the market?

Mr. JONES. These reflect prices in the marketplace.

Mr. WALDEN. And isn't that what Medicaid and Medicare and other consumers should be paying based on that?

Mr. JONES. Absolutely.

Mr. LOCKWOOD. We believe that.

Mr. WALDEN. Now, there are some who would make an argument that, if you just add a percentage to this price, say contract price plus 6 percent for overhead, you are going to distort the market as well and just continue to try and drive up price to get the higher percentage. How do we wrestle with that?

Mr. LOCKWOOD. Those are difficult issues. It's hard unless you have a prospective payment program like Medicare has for hospitals to control every cost. I think our effort has been to try to get to real market prices and then deal with that.

Mr. WALDEN. Because what we don't want to do here is create another AWP, another system that functions in an inverted way, if you will. So, appreciate your testimony today. Thank you, Mr. Chairman.

Chairman BARTON. Before we go to the next panel, the key though is the government reimbursement rate has got to be based on an actual price that somebody pays, not on some artificial posted price.

Mr. LOCKWOOD. Yes, sir.

Chairman BARTON. We have got to change like we have in Medicare from some sort of a, I won't say a made-up price, but a—just a sticker price to what somebody who is actually going to use the drug is paying.

Mr. JONES. Something that has a basis in reality in the marketplace.

Chairman BARTON. And that has to be transparent. It has got to be verifiable, and there has to be some ability for willing buyers and willing sellers to have some degree of certainty that that is a real price that is available to anybody that meets the terms and conditions of quantity and deliverability and things like that.

We want to thank you for your testimony. There may be some written questions for the record, and we would ask that you reply as quickly as possible because we are going to attempt to legislate in this area in the next Congress.

Mr. WALDEN. Trust but verify, Mr. Chairman.

Chairman BARTON. Trust but verify. I have heard that somewhere. But thank you, gentlemen. You are excused.

We would now like to have our second panel come forward. We have Mr. George Reeb, who is the assistant inspector general, Centers for Medicare & Medicaid Audits. He is accompanied by Mr.

Robert Vito, regional inspector general for evaluations and inspections, from the Philadelphia region.

We also have Mr. Dennis Smith, who is the director of the Center for Medicaid & State Operations, Center for Medicare and Medicaid Services here in Washington.

We have Mr. Patrick O'Connell, who is the assistant attorney general for civil Medicaid fraud in the Texas Attorney General's Office in Austin, Texas.

Mr. David Balland, who is the associate commissioner for Medicaid and CHIP, the Texas Health and Human Services Commission in Austin.

And Mr. Paul Reinhart, who is the Medicaid director for the State of Michigan in Lansing, Michigan.

Welcome, gentlemen. It is the tradition of this subcommittee to take all testimony under oath. Do any of you object to testifying under oath?

You also have the right to be advised by counsel during your testimony. Do any of you have counsel with you that you wish to also swear in?

Will you all please rise and raise your right hand.

[Witnesses sworn.]

Chairman BARTON. Your testimony is in the record in its entirety. We are going to start with you, Mr. Reinhart, and we are just going to go right down the row and give each of you gentlemen that wish to elaborate on your testimony 7 minutes to do so. So welcome to the subcommittee, Mr. Reinhart.

TESTIMONY OF PAUL REINHART, MICHIGAN MEDICAID DIRECTOR; DENNIS SMITH, DIRECTOR, CENTER FOR MEDICAID AND STATE OPERATIONS, CENTERS FOR MEDICARE AND MEDICAID SERVICES; GEORGE M. REEB, ASSISTANT INSPECTOR GENERAL, CENTERS FOR MEDICARE AND MEDICAID AUDITS, ACCOMPANIED BY ROBERT VITO, REGIONAL INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, PHILADELPHIA; DAVID J. BALLAND, ASSOCIATE COMMISSIONER FOR MEDICAID AND CHIP, TEXAS HEALTH AND HUMAN SERVICES COMMISSION; AND PATRICK J. O'CONNELL, TEXAS ATTORNEY GENERAL'S OFFICE

Mr. REINHART. Thank you. Good morning, Mr. Chairman, and members of the subcommittee.

Chairman BARTON. Pull that microphone directly toward you, sir, please. Thanks.

Mr. REINHART. Good morning, Mr. Chairman, and members of the subcommittee. Thank you for this opportunity to discuss Medicaid prescription drug policies. My name is Paul Reinhart, and I am the director of the Michigan Medicaid program.

While we work very hard to constrain cost increases in all areas of the Medicaid program, Michigan's pharmacy cost containment efforts have been particularly effective. Unfortunately, one aspect of the Medicare Modernization Act will increase Medicaid pharmacy costs, at least in the short term.

The Michigan Medicaid program utilizes many strategies to hold down the cost of the pharmacy benefit. The three major initiatives we have used in Michigan are: Preferred drug lists; the multi-State

prescription drug purchasing pool; and limiting reimbursements to pharmacists to their actual acquisition drug costs. These strategies have been quite successful and have produced savings not only for Michigan but also for the Federal Government. In fiscal year 2003, the first year of our preferred drug list program, per script cost increases declined to 4 percent from the 11 percent increases that routinely occurred in prior years.

Similarly, in fiscal year 2004, the first year of our multi-State purchasing initiative, per beneficiary costs for prescription drugs actually declined by about 1 percent. We believe our aggressive cost containment programs saved us $130 million in fiscal year 2004.

The Michigan Medicaid program, like a growing number of States, uses a preferred drug list or PDL to discourage physicians from prescribing high-cost drugs when lower-cost but equally effective drugs are available. Here is how the PDL works.

A committee of physicians and pharmacists and Medicaid staff use evidence-based information and cost to decide which drugs will be included on the preferred list. Drugs not on the list are available, but the prescribing physician must secure prior authorization from our pharmacy benefit manager. This program has substantially increased the use of low-cost generic drugs.

The ability of the preferred drug list to generate savings is greatly enhanced by our multi-State pharmacy purchasing program. When Governor Granholm began her term in January 2003, she directed the Medicaid agency to develop a multi-State pharmaceutical purchasing program. She believed that manufacturers would be willing to give State Medicaid programs a better price for their products in exchange for access to a larger market. And she was right. In mid 2003, Michigan and Vermont began a joint purchasing program for Medicaid prescription drugs and asked the Centers for Medicare and Medicaid Services for permission to add additional States to the program.

After a series of delays, in April 2004, CMS finally authorized Michigan, Vermont, Nevada, Alaska and New Hampshire to create an even larger pool and jointly negotiate better prices from pharmaceutical manufacturers. This larger pool will save Michigan an additional $13 million this year. CMS has also recently authorized Minnesota and Hawaii to join the pool, which should increase savings even more.

We have also generated substantial savings in Michigan by limiting Medicaid payments to pharmacists to their actual acquisition costs. We do this by significantly discounting payments for brand-name drugs and through daily adjustments of our payments for generic drugs to the best price available that day from pharmaceutical distributors.

Finally, while the Medicare Modernization Act certainly has many positive aspects, one component of that act is likely to increase costs for States that have effectively managed the drug benefit for dual eligibles. Michigan has been able to hold down the rate of growth in pharmacy spending to well below 5 percent, but the MMA's mandatory State contribution will be determined using much higher inflation factors. Even after adjusting for the declining contribution percentage, we estimate that the clawback will in-

crease Michigan's costs by about $20 million in fiscal year 2006 and $30 million in fiscal year 2007.

Conclusion: I hope my remarks today demonstrate that, at least in Michigan, we are not paying too much for the pharmaceutical products used by Medicare beneficiaries.

[The prepared statement of Paul Reinhart follows:]

PREPARED STATEMENT OF PAUL REINHART, REPRESENTING THE STATE OF MICHIGAN

Good morning Mr. Chairman and distinguished members of the Subcommittee. I want to thank you for this opportunity to discuss the Michigan Medicaid pharmacy program. My name is Paul Reinhart and I am the director of the Michigan Medicaid program. Prior to working in this capacity in Governor Granholm's Administration, I served as the Director of the Office of Health and Human Services in Governor Engler's Department of Management and Budget.

While we work very hard to constrain cost increases in all areas of the Medicaid program, our pharmacy cost containment efforts have been particularly effective and I appreciate the opportunity to tell you about them. I would also like to discuss the effect the Medicare Modernization Act will have on our ability to constrain Medicaid costs.

Pharmacy Cost Containment Programs

As you know, each state chooses a reimbursement methodology for its Medicaid program. The Michigan Medicaid program utilizes many strategies to hold down the costs of the pharmacy benefit, but the three major initiatives we have used in Michigan are:

- A preferred drug list;
- The multi-state prescription drug purchasing pool; and
- Limiting reimbursements to pharmacists to their actual drug acquisition costs

These initiatives have been extremely successful in constraining our prescription drug costs, producing savings not only for Michigan, but also for the federal government..

In fiscal year 2003, the first year of our preferred drug list program, our per-script cost increase declined from 11% to only 4%. In fiscal year 2004, the first year of the multi-state purchasing initiative, per-beneficiary costs for prescription drugs actually declined about 1%. We believe our aggressive cost containment programs reduced pharmacy spending in fiscal year 2004 from $770 million to $640 million, a savings of $130 million.

I have attached some charts at the back of this presentation that detail these trends.

Preferred Drug List

The Michigan Medicaid program, like a growing list of states, uses a preferred drug list (PDL) to discourage physicians from prescribing high cost drugs when lower cost, but equally effective, drugs are available. Michigan instituted the PDL in the last quarter of fiscal year 2002. A "Pharmacy and Therapeutics Committee" of physicians and pharmacists appointed by the Governor uses evidence-based information to decide which drugs will be included on the preferred list. Drugs not on the list are, of course available, but the prescribing physician must secure prior authorization from our pharmacy benefit manager or from one of the physicians employed by the Medicaid agency. This program has substantially increased the use of generic drugs. Generic drugs now account for well over 50% of the drugs paid for by the Michigan Medicaid program.

Multi-State Prescription Drug Purchasing Pool

The ability of the preferred drug list to generate savings is greatly enhanced by our multi-state pharmaceutical purchasing program. When Governor Jennifer Granholm began her term in January of 2003, she directed the Michigan Medicaid agency to develop a multi-state pharmaceutical purchasing program. She felt that manufacturers would be willing to give state Medicaid programs a better price for their products in exchange for access to a larger market. And she was right.

In mid-2003, Michigan and Vermont began a joint purchasing program for Medicaid prescription drugs and asked the Centers for Medicare and Medicaid Services (CMS) for permission to add additional states to the program. After a frustrating series of delays, in April of 2004, CMS finally authorized Michigan, Vermont, Nevada, Alaska and New Hampshire to create an even larger pool and jointly negotiate better prices from pharmaceutical manufacturers. This new larger pool generated

price discount proposals from over 40 manufacturers (when only two states were involved in FY03, 26 pharmaceutical manufacturers submitted discounted price proposals). These new prices are estimated to save Michigan an additional $13 million per year on prescription drugs. CMS has also recently authorized Minnesota and Hawaii to join the pool, which should produce further savings when prices are renegotiated with pharmaceutical manufacturers next year.

We strongly encourage CMS to expedite approvals of additional states that want to enter the pool. This will allow additional cost savings to both state and federal governments.

Limiting Product Reimbursements to Pharmacists

In addition to the efforts just discussed, we have generated substantial savings in Michigan by limiting product reimbursements paid to pharmacists to the pharmacist's actual product acquisition cost.

We accomplish this in two ways. First, our payment for brand name drugs is set at the AWP, or "average wholesale price" less 13.5%-15.5% depending on the size of the pharmacy. Any pharmacist who is willing to accept this level of reimbursement is able to participate in the Medicaid program. This practice has been in place since fiscal year 2000.

Second, we use a contractor to adjust payments for generic drugs on a daily basis to the actual acquisition costs for that day. This is a practice also known as "maximum allowable cost, or "MAC" pricing. Michigan began aggressive daily MAC pricing in October 2004.

Michigan's successful program was recognized by the 2004 Department of Health and Human Services' Office of Inspector General report that concluded Michigan had the lowest product reimbursement costs in the country.

Medicare Modernization Act

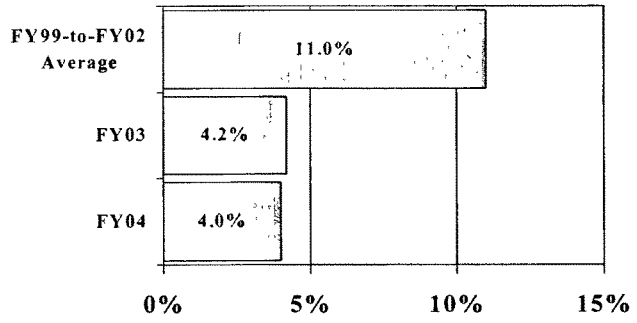
I would now like to briefly discuss how the Medicare Modernization Act (MMA) will impact state Medicaid programs' ability to constrain prescription drug cost increases. Not surprisingly, we had hoped that a Medicare pharmacy benefit would relieve states of the responsibility of paying for the drugs used by Medicaid-Medicare dual eligibles—or at the very least that the benefit would not increase our pharmacy costs for these dual eligibles. While the MMA certainly contains many positive aspects, we have concluded that it, unfortunately, will increase our costs in Michigan.

The MMA requires states to continue subsidizing the pharmacy benefit for dual eligibles. While prescription drug costs for dual eligibles will be covered by Medicare Part D, states will be responsible for making monthly payments back to the Department of Health and Human Services for a large portion of the drug expenditures for these individuals. This financing mechanism is also known as the "clawback," or what some call a "reverse block grant." States will be required to pay the federal government for 90 percent of the state portion of dual elgibles' pharmacy costs in 2006, 88.333 percent in 2007, and this amount continues to gradually decline to 75% in 2014. The Department of Health and Human Services (HHS) will determine the state payment amount and base part of the formula on double digit growth factors (National Health Expenditures and then average per-capita expenditures for Part D drugs) which will be considerably higher than the low, single digit growth rates we have been able to achieve in Michigan for prescription drugs. We estimate that the clawback will increase state costs by $20 million in fiscal year 2006 and $30 million in fiscal year 2007 (see attached chart). In Michigan, this is quite a blow because we have been so effective managing these costs.

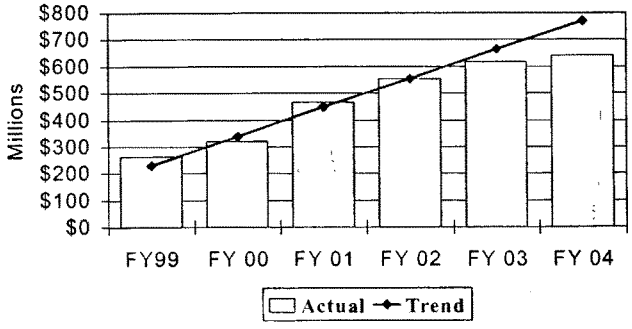
Additionally, since Medicare will manage the pharmacy benefit for dual eligibles, the size of our multi-state purchasing pool will be significantly reduced, which means our ability to leverage better Medicaid pharmaceutical prices from manufacturers will be reduced. The other states in our pool will find that their Medicaid savings will be greatly affected too.

I hope my remarks today demonstrate that, at least in Michigan, we are not paying too much for the pharmaceutical products used by our beneficiaries, but rather, we have been very proactive, aggressive, and successful in our cost containment initiatives. Thank you for the opportunity to share our experiences. I would be happy to answer any questions.

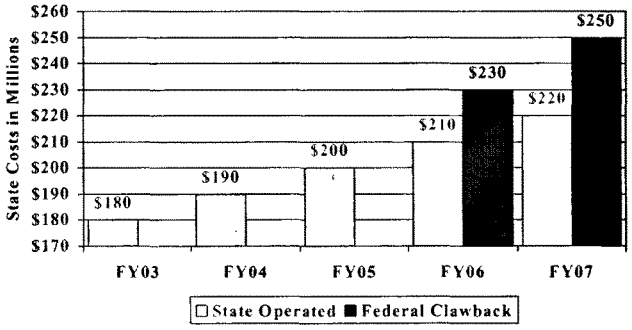
Annual Cost Per Script Increase



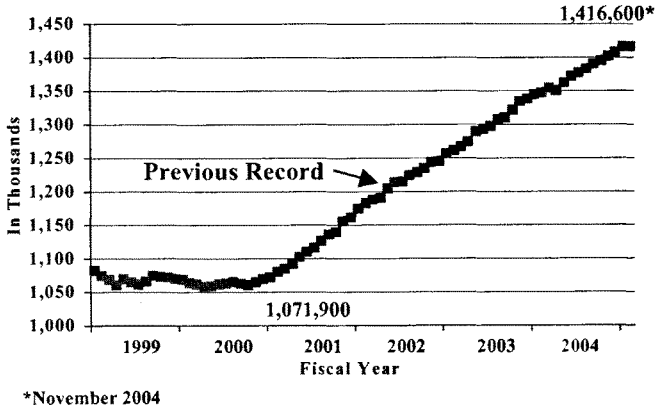
Estimated Pharmacy Cost Containment Savings



"Clawback" Will Increase Michigan's Costs



Michigan Medicaid Caseload



*November 2004

Mr. WALDEN [presiding]. Thank you.
Mr. Smith.

TESTIMONY OF DENNIS SMITH

Mr. SMITH. Thank you, Mr. Chairman. I appreciate the opportunity to appear before the subcommittee today.

I will have a full statement for the record. I did also want to provide for the subcommittee a broader picture of Medicaid drug purchasing as a whole. We are providing to the subcommittee a number of charts that show that, indeed, there is variation State by State within drug classes, et cetera. We hope this information will be helpful to the subcommittee as it is looking at the issues of Medicaid prescription drugs.

There are a number of underlying assumptions that we all are faced with in terms of looking at the cost of prescription drugs in the Medicaid program.

First, that the States themselves operate within a Federal reimbursement framework. But just as States set reimbursement for hospitals, nursing homes, and physicians, they also are the ones at the front line to set reimbursement levels for prescription drugs. We have a large number of pharmacies that participate in the Medicaid program. States are looking at guaranteeing access to coverage for low-income individuals, many of them with special needs. We have great participation rates among the Nation's pharmacies in the Medicaid program. So the States and the Federal Government are looking at balancing different interests between access for the Medicaid beneficiary and being prudent purchasers of the services themselves.

So, first, we start off with the fact that Medicaid is a matching program, a shared cost between the States and the Federal Government. And as the first line of that program the States, when they have their dollars at risk, indeed have a basic incentive to be prudent purchasers for the Medicaid program. The framework sort of broadens from there in terms of the different options that the Medicaid program has to set prices for prescription drugs, including the Federal upper limit, which we have focused on a lot here this morning already, and that I know is something the subcommittee is very much interested in.

But States also have an option to adopt what is called the "maximum allowable costs" or a MAC. And a number of States do that. Those MACs are generally more stringent than the Federal upper limits. So, again, we are looking at a Federal framework that says a State cannot pay more than this amount, but the States have great flexibility underneath those amounts as I mentioned, again, in relationship to other types of payers as well.

The Federal statute that was adopted, I believe was alluded to earlier, back in 1990. The statute requires manufacturers who want coverage of their products to enter into an agreement with CMS to provide rebates for the prescription drugs paid for through the rebate plan. So we have a different way of looking at getting the best price and the lowest price, and best value for the taxpayers for the Medicaid program. The acquisition of the drug itself is part of it, but the rebate is another part of it as well.

Obviously, in the Medicaid program, there are a number of different types of purchasers and providers involved in the decision-making itself when you are looking at the overall cost of the Medicaid program. Pharmacies, physicians, and the consumers themselves all have a role in ultimately determining what the price that Medicaid will pay for a prescription. Approximately 550 pharmaceutical companies participate in the rebate program and in fiscal year 2003, the manufacturers paid rebates of about $6.4 billion for outpatient drugs.

In terms of the focus over the last few years of how CMS is helping States to find ways to be more prudent purchasers of prescription drugs, our focus has been through the various State plan amendments which Mr. Reinhart alluded to. States have adopted a variety of different approaches with the help of CMS. We have more States than ever before negotiating supplemental rebates with the manufacturers. There is the national rebate, and States are negotiating further rebates on top of that. More States than ever before are doing those supplemental rebates. Other tools, such as prior authorization, are an important key at the point of access with the physician to help educate physicians about being price-sensitive in the Medicaid program. A number of States have adopted prior authorization in recent years as well. So the focus has been on several different areas, not just one particular area, to help States negotiate lower prices for the Medicaid program.

Mr. Reinhart referred to the purchasing pool that had never existed before this administration approved it and expanded it to help States pool the lives that are involved in order to get deeper discounts for the programs. I think that a lot of the discussion this morning is about information, and I think we are taking further steps, steps that had not been taken ever before, about making that information available to the general public as a whole.

With the prescription discount card under Medicare, the administration took the unprecedented step of actually putting on the Web site price comparisons to give the general public access to information. We believe that information is indeed an important component. In the marketplace, people having access to that information is obviously a very important part of making marketplace work successfully.

I see my time is ready to expire. I appreciate the opportunity to appear before this subcommittee and ask that my entire statement be included in the record.

[The prepared statement of Dennis Smith follows:]

PREPARED STATEMENT OF DENNIS SMITH, DIRECTOR, CENTER FOR MEDICAID AND STATE OPERATIONS CENTERS FOR MEDICARE AND MEDICAID SERVICES

Mr. Chairman, members of the subcommittee, thank you for your invitation to appear this morning to discuss Medicaid prescription drug reimbursement. Coverage of outpatient prescription drugs is an optional benefit for Medicaid programs. All states currently provide prescription drug coverage, which is critically important to Medicaid beneficiaries. However, this benefit is one of the greatest costs for the states. In fiscal year 2002, Medicaid drug expenditures were $29.3 billion out of $258.2 billion in total Medicaid spending or 11.3 percent. In addition, Medicaid drug spending increased at an annual average rate of 19 percent from fiscal years 2000 to 2002, while Medicaid spending as a whole grew 12 percent annually during that period. In 2003, Medicaid spent more than $34 billion on prescription drugs (See Chart 1). Of this amount, 23 percent was spent on drugs commonly prescribed to treat mental health conditions (See Chart 2). Furthermore, spending varies based

on the specific medication prescribed. For example, under analgesics and anesthetics, the mean reimbursement for Celebrex is $112 per prescription, compared to $12 for ibuprofen (See Chart 3). In addition, the 29 most commonly prescribed drugs account for 25% of Medicaid spending on prescription drugs (Chart 4). Spending on prescription drugs claims varies by state. The average claim ranges from approximately $40 to more than $60 (See Chart 5). Therefore, it is important that both the Federal government and the states ensure that Medicaid programs pay for prescription drugs appropriately.

States Determine Payment to Providers

Medicaid operates as a provider payment program. States may pay health care providers directly on a fee-for-service basis, or states may pay for Medicaid services through various prepayment arrangements, including payments to managed care plans. Within Federally imposed upper limits and specific restrictions, each State has broad discretion in determining the payment methodology and payment rate for prescription drugs, and what to pay pharmacists in dispensing fees. Generally, payment rates must be sufficient to enlist enough providers to ensure covered services are available at least to the extent that comparable care and services are available to the general population within a geographic area. Providers participating in Medicaid must accept Medicaid payment rates as payment in full. It also is important to note that prices have increased between 5 percent and 7 percent in recent years. An increase in utilization, as well as an increase in the Medicaid population has helped to increase the mean reimbursement per prescription (See Chart 6).

CMS Involvement with Medicaid Drug Pricing

While the States are largely responsible for managing their prescription drug benefit, Federal law authorizes CMS to ensure the Federal government receives a good price for prescription drugs. For example, the Medicaid Drug Rebate Program affords Medicaid programs the opportunity to pay for drugs at discounted prices, which are similar to those offered by pharmaceutical manufacturers to other large purchasers. In addition, Medicaid programs have a number of options to set prices for prescription drugs, including the Federal Upper Limit (FUL), maximum allowable cost (MAC), and wholesale acquisition cost (WAC) programs.

Medicaid Drug Rebate Program Controls Costs

Federal statute requires manufacturers to enter into an agreement with the Secretary of Health and Human Services, on behalf of the states, to provide rebates for covered outpatient prescription drug products paid for by Medicaid through the Medicaid Drug Rebate Program. Manufacturers that do not sign an agreement are not eligible for Federal Medicaid coverage of their product(s). Except for some statutory limitations, if a Medicaid program opts to cover prescription drugs for their beneficiaries, it must provide coverage and reimbursement for all covered outpatient drug products manufactured by companies that have entered into a rebate agreement with CMS, as Congress has guaranteed access to the Medicaid market for those drug manufacturers that provide rebates. Approximately 550 pharmaceutical companies participate in this program. Currently, 49 states and the District of Columbia participate in the Medicaid Drug Rebate Program (Arizona has an 1115 waiver that exempts it from participating in the Medicaid Drug Rebate Program).

Manufacturers submit their Average Manufacturer Price (AMP) and Best Price (BP) to CMS. Using the AMP and BP, CMS calculates the rebate amount and informs the states. The rebate is calculated differently depending on the type of drug. For generic drugs, the rebate is 11 percent of AMP. For brand-name prescription drugs, the rebate is calculated in two ways. Basic rebates for brand-name drugs are the greater of 15.1 percent of the AMP or AMP minus BP. In addition, if the price of a drug increases at a rate faster than the consumer price index from a base year, the manufacturer would owe the state the difference dollar for dollar. States receive rebates from manufacturers based on states' quarterly data on the utilization of the manufacturers' drugs. The Drug Rebate Program was enacted out of concern for the costs the Medicaid program was paying for outpatient drugs. In FY 2003, manufacturers paid rebates to states of about $6.4 billion for covered outpatient drugs. The program gives Medicaid programs the opportunity to obtain discounted prices similar to those offered by pharmaceutical manufacturers to other large purchasers.

States that wish to pursue Medicaid supplemental rebates in addition to rebates already received under the National Drug Rebate Agreement have the option to negotiate such rebates with drug manufacturers as specified in Federal law. In recent years, CMS has approved plan amendments that allow states to negotiate additional state-specific supplemental rebates for their Medicaid population or participate in a multi-state pooling supplemental rebate agreement. Rebates received under state

supplemental agreements are shared with the Federal government at the same rate as the national rebates.

Currently, 33 states have Medicaid supplemental rebates, including those states in multistate pooling arrangements. Twenty-six states have negotiated rebates on their own. For example, Florida began collecting state-only supplemental rebates in 2001 in conjunction with the establishment of its Preferred Drug List (PDL). Currently, the state receives supplemental rebates on brand name drugs, but not on generics. The state received rebates of $51 million in FY 2003 and does not expect to lose participation from any of the approximately 80 manufacturers that currently pay supplemental rebates.

Medicaid Federal Upper Limit Cuts Costs

One proven method to reduce drug costs for States and to ensure the government is a prudent purchaser of prescription medications is the use of generic medications instead of more expensive brand name pharmaceuticals. As you know, Mr. Chairman, generic drugs are typically significantly less expensive than their brand-name counterparts (See Chart 7). This is achieved through the use of the Federal Upper Limit (FUL), a program that caps Medicaid payments for brand name drugs that have therapeutically equivalent generic medications available. As a result, the FUL program, which achieves savings by taking advantage of current market prices, helps to significantly reduce pharmacy costs for both the states and the Federal government.

Through the FUL program, CMS sets an upper limit reimbursement amount for drugs that meet certain criteria. However, not all drugs are subject to the FUL pricing. To establish the FUL for a drug, CMS examines the FDA's Orange Book data to determine whether all the formulations of a drug product approved by the FDA are therapeutically equivalent. When all of the versions of that drug are not therapeutically equivalent, there must be at least three therapeutically equivalent drug products. Once a product has met the FDA criteria, CMS verifies that it meets the necessary compendium criteria by consulting the national drug-pricing compendium (Red Book, First Data Bank, and Medi-Span) to verify that there are at least three suppliers of the drug listed. If there are three suppliers, CMS sets the FUL at 150 percent of the lowest price (Average Wholesale Price, Wholesale Acquisition Cost, or Direct Price). A state's aggregate payment for all Medicaid prescription drugs with a FUL must not exceed, in the aggregate, the payment levels established by the FUL program. The aggregate cap allows states to increase or decrease the cost of individual prescription drugs in accordance with state or local markets while maintaining the overall savings created by the FUL program. States may exceed the FUL price for individual prescription drugs as long as their aggregate expenditures do not exceed the amounts that would have otherwise been spent by applying the FUL limit plus a reasonable dispensing fee.

CMS uses a 150 percent mark-up so that FUL prices are high enough to ensure that pharmacists can stock an equivalent product without a loss on acquisition costs. The mark-up also assures that FUL prices are low enough so that Medicaid will not pay too much for a prescription drug that is included on the list. The 150 percent mark-up is intended to balance the interests of both pharmacists and the government in achieving efficiency, economy, and quality of care. In addition, to ensure the most accurate prescription drug pricing data, CMS has actively worked with the publishers of the compendium to resolve FUL pricing issues and to encourage the collection of accurate data. Because of the complexity and volatility of the drug marketplace, it is impossible to be certain that pricing or the inclusion of a drug on the FUL list is 100 percent accurate. CMS has an on-going process in place to ensure that any necessary revisions to the list can be identified and completed. As new information becomes available, CMS compiles a list of changes that is released periodically to the agency's regional offices. The regions provide the information to the states, which notify providers. CMS also posts the changes on its website at www.cms.hhs.gov/medicaid/drugs/drug10.asp.

We greatly appreciate the various reports of the Office of Inspector General on its review of prescription drug prices and the FUL program. While we value their work, in regards to the FUL program, it must be examined in its entirety. Specifically CMS must establish a drug product's eligibility for the FUL list that includes verification with the suppliers of the drugs that are necessary to assure availability.

Utilizing Maximum and Wholesale Costs

Maximum Allowable Cost (MAC) programs are designed to ensure Medicaid programs pay appropriate prices for generic and multi-source brand drugs. Typically, States administering the MAC programs will publish lists of selected multi-source and generic drugs with the maximum price at which Medicaid will reimburse for

those medications. Pharmacies generally will not receive payments that are higher than the MAC price. These programs differ from the FUL list, as states have more discretion in determining what drugs to include on the MAC list. Instead of the MAC, some states use wholesale acquisition costs (WAC), which is the listed price supposedly paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug.

Additional Tools Are Available to States to Address High Prescription Drug Costs

In addition to the rebate program, and as a result of increasing prescription drug costs, State Medicaid programs have implemented a variety of cost-containment mechanisms in their drug programs over the past few years. These mechanisms have allowed States to reduce their pharmacy expenditures and maintain beneficiary access to a vital part of their overall health care. While some of the pharmacy techniques employed by the States represent prudent management of program costs, the Medicaid drug benefit remains a State option with benefits and limitations that vary from State to State. CMS can provide consultation and support to assist states in using these and other methods to lower their drug costs without compromising quality of care. However, aside from federal regulations, most Medicaid cost containment decisions ultimately are made at the state level. States use a variety of methods to pay for prescription drugs. In addition, they use a variety of cost control measures. For example, the use of copayments, generic substitution, and disease management programs are handled at the state level (See Chart 8).

Copayments Contribute to Cost Containment

At their discretion, states may impose nominal deductibles, coinsurance, or copayments on some Medicaid beneficiaries for certain services. Nominal copayments are a tool available to states as a cost containment measure. The use of copayments for prescription drugs varies from state to state. Nineteen states have no copayment, and the vast majority of the remaining states require a copayment ranging from 50 cents for generic drugs to $3.00 for brand-name prescriptions. Cost sharing limits are set by Federal regulation and have not changed in many years. In addition, some groups are totally exempt from cost-sharing by law. Pregnant women, children under age 18, and hospital or nursing home patients who are expected to contribute most of their income to institutional care are exempt from cost-sharing.

States' Aggressive Generic Substitution Saves Money

Generic drugs account for more than half of all prescriptions in the United States. Many private health plans have generic drug use rates of more than 90 percent, but generics are not as widely used in some Medicaid programs. The low prices of generic drugs in the United States are an important potential source of savings for states. The potential cost-savings by the use of generic drugs has prompted 39 states to require that the generic version of a drug be dispensed to Medicaid beneficiaries when available. Under these mandatory generic substitution policies, the brand name drug remains available to beneficiaries through prior authorization. Examples of "best practices" involving generic drugs include Minnesota and Idaho. For example, Minnesota has had a mandatory generic substitution policy in place for nearly a decade. This saves the State $10 million annually. Idaho also has a mandatory generic substitution policy, which increased the percentage of generic drugs dispensed from 46.7 percent in fiscal year 2002 to 53 percent in fiscal year 2003. Idaho's policy saved $11.7 million in State and Federal funds.

Drug Utilization Review Protects Patients and Reduces Costs

Congress created the Medicaid Drug Utilization Review (DUR) Program through the Omnibus Budget Reconciliation Act of 1990. The program promotes patient safety by an increased review and awareness of outpatient prescribed drugs. Under the law, states are required to complete annual reports, which provide an excellent measurement tool to assess how well states have implemented the DUR program and the effect DUR has had on patient safety, provider prescribing habits and dollars saved. In addition to promoting patient safety and positive health outcomes, the DUR program serves as a cost savings strategy by avoiding problems such as adverse drug interactions, drug-disease interactions, therapeutic duplication and overprescribing by providers.

State Medicaid Disease Management Programs Reduce Expenses

Disease management programs are an emerging strategy for states to improve care and are designed to reduce overall expenditures, including drug expenditures, through more appropriate medication use for Medicaid beneficiaries with chronic illnesses. Both North Carolina and Washington have instituted successful disease

management programs. For instance, North Carolina's Pharmacy Management Initiative has lowered drug costs of participants by 22 percent through use of a preferred drug list and is expected to save $9 million in 2004 through its pharmacy program that reviews the drug regime of nursing home residents and recommends changes consistent with appropriate prescribing practices.

States' Additional Techniques to Control Costs

States use a number of additional techniques to control Medicaid prescription drug costs.

- Approximately 9 states have strict limits on the number of brand name prescriptions that can be filled.
- About 37 states employ refill and/or monthly or annual prescription limits.
- Virtually all states (50 with the exception of Tennessee but including DC) report using day supply limits ranging from about a 30 to 100 day supply.
- About 32 states have fail-first or step therapy programs in place. Fail-First policies require that the patient fail on at least one other medication as a prerequisite for authorization of a specific, often non-formulary, medication. Step Therapy is a prescription pattern based on the state of illness that involves using the drug believed to be the most cost-effective first, followed by more expensive therapies.

Approaches for Cost Containment in Medicaid and the Private Sector Differ

The private sector utilizes a number of techniques to control their prescription drug costs, including significant consumer cost sharing, which would not be appropriate in the Medicaid setting. For example, private health plans use tiered copayments, which vary depending on whether the drug is generic, preferred, brand-name, or not included on a plan's formulary. Utilizing a range of copayments encourages patients to select lower-cost options. State Medicaid programs, however, may institute only a nominal copayment or coinsurance for prescription drugs, as Federal regulation sets a mandated $3 limit or a 5 percent coinsurance limit. Furthermore, as mentioned above, by law states cannot require prescription drug copayments for pregnant women, children under age 18, and hospital or nursing home patients who are expected to contribute most of their income to institutional care.

Some private insurers also require their members to obtain their prescriptions solely through mail-order pharmacies to control costs. In Medicaid, there is freedom of choice of provider and any willing provider. While Medicaid programs could apply for a waiver to use mail-order pharmacies to dispense medications to those with chronic conditions, states do not have the authority to restrict people with Medicaid to mail-order pharmacies for all their prescriptions.

Private insurers use formularies with tiered cost sharing and exclusion of certain drugs as a cost saving strategy. However, Medicaid must cover all FDA-approved drugs for every manufacturer that has a national rebate agreement, with some exceptions. States may utilize a preferred drug list, which would exclude certain drugs, but Federal law requires these excluded drugs be made available through prior authorization. In addition, private insurers may not cover particular drugs, such as oral contraceptives and antihistamines, topical nasal products, and cough/cold products. These drugs account for 4 percent of Medicaid spending on prescription drugs (See Chart 9).

Conclusion

Mr. Chairman, members, thank you again for the opportunity to testify. CMS will continue to assist all states in adopting safe, proven approaches to lowering drug costs while providing access to prescription drugs and quality care. In addition, CMS will fulfill its role as a partner through the Federal Upper Limit and Medicaid Drug Rebate programs to ensure the government is a prudent purchaser of prescription medications. Thank you again for hearing my testimony, and I am happy to answer any questions you might have.

Chart 1

Table 1: Total Number of Prescriptions and Amount Reimbursed, (1994-2003)

Year	Number of Rx (in millions)	Amount Reimbursed (in $ millions)	Average Price Per Prescription
1994	332.9	$8,435.4	$25.34
1995	330.1	$8,994.2	$27.25
1996	340.1	$10,606.4	$31.19
1997	340.5	$11,574.7	$34.00
1998	350.2	$13,587.2	$38.80
1999	368.0	$16,177.2	$43.95
2000	404.9	$19,988.6	$49.37
2001	476.7	$25,351.2	$53.18
2002	520.8	$29,639.1	$56.91
2003	573.1	$34,298.3	$59.85

Source: Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, State Drug Utilization Data, 1994-2003.

Chart 2

2003 Medicaid Prescriptions and Reimbursements by Drug Group			
GROUP	Number Rx	Amount Reimbursed	Mean Reimbursement
ANTI-INFECTIVE AGENTS	46,509,187	$ 3,403,663,559	$ 73.18
BIOLOGICALS	243,546	$ 320,850,342	$ 1,317.41
ANTINEOPLASTIC AGENTS	1,982,937	$ 428,876,537	$ 216.28
ENDOCRINE AND METABOLIC DRUGS	54,556,435	$ 2,778,079,944	$ 50.92
CARDIOVASCULAR AGENTS	102,503,877	$ 4,128,003,331	$ 40.27
RESPIRATORY AGENTS	60,786,865	$ 2,837,901,907	$ 46.69
GASTROINTESTINAL AGENTS	38,926,954	$ 2,712,783,203	$ 69.69
GENITOURINARY PRODUCTS	8,045,177	$ 466,983,390	$ 58.05
CENTRAL NERVOUS SYSTEM DRUGS	81,693,758	$ 7,302,883,398	$ 89.39
STIMULANTS/ANTI-OBESITY/ANOREXIANTS	6,709,833	$ 520,613,909	$ 77.59
MISC.PSYCHOTHEAPEUTIC AND NEUROLOGICAL AGENTS	3,305,209	$ 561,514,396	$ 169.89
ANALGESICS AND ANESTHETICS	62,775,245	$ 2,853,284,118	$ 45.45
NEUROMUSCULAR DRUGS	33,125,583	$ 2,427,417,306	$ 73.28
NUTRITIONAL PRODUCTS	18,096,550	$ 245,085,656	$ 13.54
HEMATOLOGICAL AGENTS	15,938,287	$ 1,706,717,131	$ 107.08
TOPICAL PRODUCTS	31,933,433	$ 1,237,125,236	$ 38.74
MISCELLANEOUS PRODUCTS	1,374,319	$ 239,355,332	$ 174.16
Total	568,507,195	$ 34,171,138,695	$ 60.11
Source: Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, State Drug Utilization Data, 1994-2003.			
Note: Above payments are not net of rebates (avg. rebate =20%). Totals do not reflect those of Chart 1 because there was no NDC data match during the data merge for some drug groups.			

Chart 3

2003 Top Volume Medicaid Drugs: Number Rx, Reimbursements, Mean Reimbursement				
GROUP	BRAND NAME	Number Rx	Amount Reimbursed	Mean Reimbursement
ANTI-INFECTIVE AGENTS	LEVAQUIN	1,648,517	$ 134,336,626	$ 81.49
	ZITHROMAX Z-PAK	2,380,008	$ 102,548,251	$ 43.09
	Total	4,028,525	$ 236,884,878	$ 58.80
ENDOCRINE AND METABOLIC DRUGS	FOSAMAX	1,878,839	$ 137,414,148	$ 73.14
	ORTHO EVRA	1,421,774	$ 65,800,882	$ 46.28
	Total	3,300,613	$ 203,215,030	$ 61.57
CARDIOVASCULAR AGENTS	FUROSEMIDE	2,144,032	$ 12,933,620	$ 6.03
	HYDROCHLOROTHIAZIDE	1,830,532	$ 9,845,024	$ 5.38
	LIPITOR	5,955,009	$ 512,348,991	$ 86.04
	NORVASC	3,925,630	$ 240,834,862	$ 61.35
	TOPROL XL	1,352,352	$ 35,232,043	$ 26.05
	Total	15,207,555	$ 811,194,540	$ 53.34
RESPIRATORY AGENTS	ALBUTEROL	4,113,227	$ 75,084,164	$ 18.25
	CLARINEX	1,518,137	$ 95,834,320	$ 63.13
	COMBIVENT	1,712,690	$ 104,053,469	$ 60.75
	FLONASE	1,875,761	$ 114,521,839	$ 61.05
	NASONEX	1,184,769	$ 78,305,307	$ 66.09
	SINGULAIR	1,544,434	$ 133,634,141	$ 86.53
	ZYRTEC	2,154,515	$ 126,243,612	$ 58.59
	Total	14,103,533	$ 727,676,853	$ 51.60
GASTROINTESTINAL AGENTS	NEXIUM	1,775,089	$ 235,506,162	$ 132.67
	OMEPRAZOLE	1,213,695	$ 147,953,298	$ 121.90
	PREVACID	4,430,988	$ 588,356,248	$ 132.78
	PROTONIX	3,379,484	$ 348,632,334	$ 103.16
	Total	10,799,256	$ 1,320,448,042	$ 122.27
CNS DRUGS	AMBIEN	2,279,123	$ 164,414,071	$ 72.14
	CELEXA	1,743,470	$ 133,700,697	$ 76.69
	LEXAPRO	1,512,294	$ 97,397,808	$ 64.40
	PAXIL	1,368,409	$ 119,881,195	$ 87.61
	SEROQUEL	2,588,630	$ 338,572,008	$ 130.79
	WELLBUTRIN SR	1,656,769	$ 155,129,411	$ 93.63
	ZOLOFT	4,051,009	$ 349,741,104	$ 86.33
	ZYPREXA	2,679,100	$ 775,105,862	$ 289.32
	Total	17,878,804	$ 2,133,942,155	$ 119.36
ANALGESICS AND ANESTHETICS	CELEBREX	3,089,190	$ 347,565,912	$ 112.51
	HYDROCODONE/ ACETAMINOPHEN	4,341,191	$ 31,849,197	$ 7.34
	IBUPROFEN	1,180,716	$ 14,119,958	$ 11.96
	Total	10,336,495	$ 548,220,283	$ 53.04
NEUROMUSCULAR DRUGS	NEURONTIN	2,279,440	$ 259,884,235	$ 114.01
	Total	2,279,440	$ 259,884,235	$ 114.01
HEMATOLOGICAL AGENTS	PLAVIX	1,870,425	$ 219,197,936	$ 117.19
	Total	1,870,425	$ 219,197,936	$ 117.19
	Grand Total	79,804,646	$ 6,460,663,952	$ 80.96
Source: Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, State Drug Utilization Data, 2003				
Note: The 34 brand name drugs in this table comprised the top 40 NDCs in terms of total prescriptions for 2003.				
Some drugs listed had more than one NDC because of different drug strengths.				

Chart 4

2003 Top Reimbursed Medicaid Drugs			
Brand Name	Number Rx	Amount Reimbursed	Mean Reimbursement
ZYPREXA*	4,746,284	$ 1,514,229,675	$ 319.03
RISPERDAL	3,094,449	$ 682,271,982	$ 220.48
SEROQUEL	3,423,046	$ 607,288,028	$ 177.41
PREVACID	4,430,988	$ 588,356,248	$ 132.78
LIPITOR	5,955,009	$ 512,348,991	$ 86.04
ZOLOFT	4,051,009	$ 349,741,104	$ 86.33
PROTONIX	3,379,484	$ 348,632,334	$ 103.16
CELEBREX	3,089,190	$ 347,565,912	$ 112.51
NEURONTIN	2,279,440	$ 259,884,235	$ 114.01
NEXIUM	1,775,089	$ 235,506,162	$ 132.67
PLAVIX	1,870,425	$ 219,197,936	$ 117.19
SYNAGIS	142,108	$ 196,902,396	$ 1,385.58
COMBIVIR	285,816	$ 168,058,372	$ 587.99
AMBIEN	2,279,123	$ 164,414,071	$ 72.14
DEPAKOTE	1,129,201	$ 162,681,355	$ 144.07
OXYCONTIN	229,698	$ 162,145,821	$ 705.91
ADVAIR DISKUS	1,116,273	$ 155,146,684	$ 138.99
WELLBUTRIN SR	1,656,769	$ 155,129,411	$ 93.63
VIOXX	1,725,398	$ 154,685,217	$ 89.65
NORVASC	2,274,355	$ 153,863,962	$ 67.65
OMEPRAZOLE	1,213,695	$ 147,953,298	$ 121.90
KALETRA	236,464	$ 145,758,674	$ 616.41
TOPAMAX	616,836	$ 140,486,767	$ 227.75
EFFEXOR XR	1,150,936	$ 139,907,572	$ 121.56
PROCRIT	94,902	$ 138,770,788	$ 1,462.25
FOSAMAX	1,878,839	$ 137,414,148	$ 73.14
TRIZIVIR	143,132	$ 135,994,934	$ 950.14
LEVAQUIN	1,648,517	$ 134,336,626	$ 81.49
CELEXA	1,743,470	$ 133,700,697	$ 76.69
TOTAL	57,659,945	$ 8,392,373,399	$ 145.55

Source: Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, State Drug Utilization Data, 2003.

Note: The 29 brand name drugs in this table comprised the top 40 NDCs in terms of total reimbursements for 2003. Some drugs listed had more than one NDC because of different drug strengths and/or administration forms. Above figures are not net of rebates (avg. =20%).

* The total reimbursement for this drug differs from that in Table 3, because the top 40 NDCs on the basis of reimbursement did not include some of the NDCs that comprised the top 40 NDCs on the basis of volume.

Chart 5

2002 PRESCRIBED DRUG PAYMENTS, AVERAGE PAYMENTS, AND AVERAGE PER MEDICAID BENEFICIARY

SOURCE: MSIS STATE SUMMARY DATA MART 2002
NOTE: Hawaii, New Mexico, and Washington State have not submitted data yet.

STATE		Payments	# Claims		Avg/Claim	# Benes.	Avg/Bene
AK	$	83,324,085	1,475,339	$	56.48	70,550	1,181.06
AL	$	454,370,478	10,617,210	$	42.80	500,789	907.31
AR	$	279,644,642	5,632,026	$	49.65	356,233	785.00
AZ	$	4,338,712	68,583	$	63.26	7,805	555.89
CA	$	3,402,508,001	52,578,967	$	64.71	2,651,229	1,283.37
CO	$	202,286,461	3,616,322	$	55.94	153,520	1,317.66
CT	$	356,980,484	5,725,416	$	62.35	123,704	2,885.76
DC	$	68,050,981	1,074,508	$	63.33	45,216	1,505.02
DE	$	100,112,623	1,763,028	$	56.78	125,461	797.96
FL	$	1,736,991,594	34,209,477	$	50.78	1,245,841	1,394.23
GA	$	749,552,199	18,210,905	$	41.16	1,076,904	696.03
IA	$	277,753,942	6,620,995	$	41.95	245,711	1,130.41
ID	$	121,780,793	2,275,749	$	53.51	125,537	970.08
IL	$	1,222,947,241	27,209,290	$	44.95	1,199,933	1,019.18
IN	$	636,357,519	13,294,116	$	47.87	490,386	1,297.67
KS	$	220,800,602	4,566,112	$	48.36	157,618	1,400.86
KY	$	661,409,737	15,195,290	$	43.53	489,416	1,351.43
LA	$	682,557,080	15,073,042	$	45.28	689,973	989.25
MA	$	952,790,939	17,772,200	$	53.61	659,626	1,444.44
MD	$	320,313,995	5,337,463	$	60.01	181,101	1,768.70
ME	$	250,331,526	5,640,548	$	44.38	224,664	1,114.25
MI	$	674,898,273	13,950,622	$	48.38	577,785	1,168.08
MN	$	294,838,630	5,570,944	$	52.92	190,577	1,547.08
MO	$	799,910,014	16,952,594	$	47.19	493,230	1,621.78
MS	$	568,084,274	10,595,910	$	53.61	526,923	1,078.12
MT	$	77,980,883	1,613,517	$	48.33	67,365	1,157.59
NC	$	1,069,140,895	20,349,044	$	52.54	949,795	1,125.65
ND	$	51,749,961	1,245,002	$	41.57	44,428	1,164.81
NE	$	196,526,107	4,670,105	$	42.08	194,889	1,008.40
NH	$	98,836,636	2,112,896	$	46.78	78,861	1,253.30
NJ	$	686,301,522	11,344,446	$	60.50	296,059	2,318.12
NV	$	90,134,969	1,505,800	$	59.86	71,950	1,252.74
NY	$	3,413,404,507	57,227,232	$	59.65	2,567,595	1,329.42
OH	$	1,330,569,382	28,492,906	$	46.70	997,246	1,334.24
OK	$	267,549,002	5,434,476	$	49.23	276,111	968.99
OR	$	269,936,847	5,402,946	$	49.96	242,865	1,111.47
PA	$	719,243,402	13,635,640	$	52.75	464,848	1,547.27
RI	$	126,331,040	2,138,403	$	59.08	53,729	2,351.26
SC	$	456,976,916	9,088,832	$	50.28	576,136	793.18
SD	$	63,654,623	1,277,159	$	49.84	64,948	980.09
TN*	$	-	-		#DIV/0!	-	#DIV/0!
TX	$	1,591,828,224	36,991,211	$	43.03	2,153,316	739.25
UT	$	140,520,420	3,025,689	$	46.44	152,268	922.85
VA	$	453,663,058	8,881,985	$	51.08	319,196	1,421.27
VT	$	115,623,970	2,397,281	$	48.23	112,227	1,030.27
WI	$	455,720,622	13,289,815	$	34.29	309,795	1,471.04
WV	$	274,613,136	6,372,794	$	43.09	276,338	993.76
WY	$	38,008,542	822,223	$	46.23	42,652	891.13
TOTAL	$	27,111,249,489	532,346,058	$	50.93	22,851,799	1,186.39

Note: The above payments are not net of rebates which average about 20% of the reimbursed amounts.
* This is a "managed care state" with no reported fee-for-service drug data in MSIS.

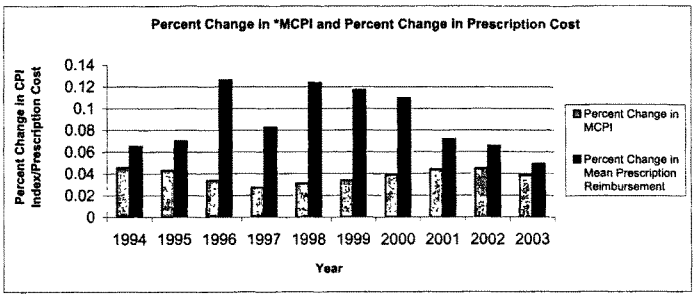
Chart 6

Table 3: Mean Prescription Reimbursements Vs. Medical Consumer Price Index (MCPI)

Year	*MCPI	Percent Change in MCPI	Mean Prescription Reimbursement	Percent Change in Mean Prescription Reimbursement	Mean Prescription Reimbursement (2003 Dollars)
1994	211.0	4.55%	$25.34	6.51%	$35.68
1995	220.5	4.31%	$27.25	7.01%	$36.72
1996	228.2	3.37%	$31.19	12.63%	$40.61
1997	234.6	2.73%	$34.00	8.26%	$43.06
1998	242.1	3.10%	$38.80	12.37%	$47.61
1999	250.6	3.39%	$43.95	11.72%	$52.11
2000	260.8	3.91%	$49.37	10.98%	$56.24
2001	272.8	4.40%	$53.18	7.16%	$57.92
2002	285.6	4.48%	$56.91	6.55%	$59.20
2003	297.1	3.87%	$59.85	4.91%	$59.85

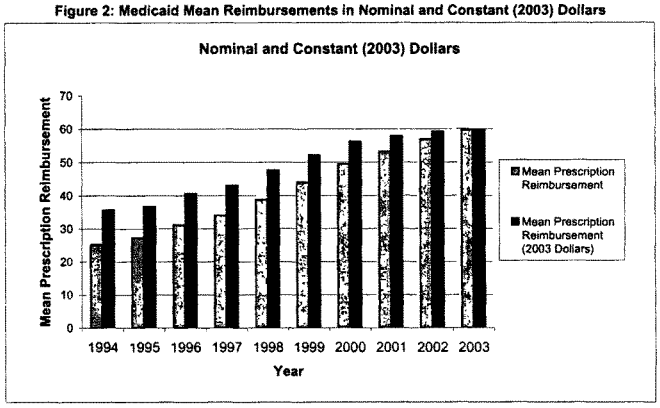
Source: Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, State Drug Utilization Data, 1994-2003.
*U.S. Bureau of Labor Statistics, Base year 1982-1984, http://www.bls.gov

Figure 1: Change in Medical Consumer Price Index (MCPI) and Mean Prescription Reimbursement



Source: Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, State Drug Utilization Data, 1994-2003.
*U.S. Bureau of Labor Statistics, Base year 1982-1984, http://www.bls.gov

Figure 2: Medicaid Mean Reimbursements in Nominal and Constant (2003) Dollars



Source: Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, State Drug Utilization Data, 1994-2003.

Chart 7

DRUG PRICE COMPARISON

BRAND/GENERIC EQUIVALENTS - MEDICAID PAYMENT PER UNIT

	BRAND	PAYMENT/UNIT	GENERIC EQUIVALENT	PAYMENT/UNIT	STRENGTH
DRUG USE	***GLUCOPHAGE*** BLOOD SUGAR REGULATION (ANTI-HYPERGLYCEMIC)	***$0.72***	***METFORMIN HCL***	***$0.33***	500 MG
	XANAX CENTRAL NERVOUS SYSTEM DEPRESSANT (BENZODIAZEPINE)	***$1.10***	***ALPROZALAM***	***$0.12***	0.5MG
	VASOTEC BLOOD PRESSURE REGULATION (ACE INHIBITOR)	***$0.60***	***ENALAPRIL***	***$0.32***	2.5MG
	LOPID CHOLESTEROL LOWERING AGENT	***$0.85***	***GEMFIBROZIL***	***$0.36***	600MG
	HYTRIN MUSCLE RELAXER USED FOR PROSTATE CONDITIONS	***$0.93***	***TERAZOSIN***	***$0.56***	1MG
	LASIX FLUID REGULATOR (DIURETIC)	***$0.24***	***FUROSEMIDE***	***$0.14***	40MG

BRAND DRUG PRODUCTS WITH THERAPEUTIC SUBSTITUTION (ADJUSTED FOR COST BASED ON AVERAGE RECOMMENDED DAILY DOSE EQUIVALENTS) (AAD=AVERAGE ADULT DOSE)

BEXTRA 10MG ANTI-INFLAMMATORY (NSAIDS)	***$2.94 AAD-1X/DAY***	***IBUPROFEN 800 MG***	***$0.64 AAD-4X/DAY X .16***
NEXIUM 20MG STOMACH ACID INHIBITOR	***$4.32 AAD-1X/DAY***	***RANITIDINE 150MG***	***$0.52 AAD-2X/DAY X.26***
ZOLOFT 50MG ANTIDEPRESSANT	***$2.51 AAD-1X/DAY***	***FLUOXETINE 20MG***	***$0.38 AAD-1X/DAY***

SOURCE: 2004, QUARTERS 1 AND 2 SELECTED DRUG REIMBURSEMENTS - DRUG REBATE FILE
UTILIZATION AND MEAN REIMBURSEMENT PER PRESCRIPTION - CMS

Medicaid Prescription Reimbursement Information By State - Quarter Ending December 2004

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAY	STATE MAC
Alabama	WAC +9.2% then AWP-10%	$5.40	$.50-$3.00*	Yes
Alaska	AWP-5%	$3.45-$11.46 (based on pharmacy/Medicaid volume)	$2.00	No
Arizona	AWP-15%	$2.00 (FFS only)	none	No
Arkansas	AWP-20% (generic); AWP-14% (brand)	$5.51	$.50-$3.00*	Yes
California	AWP-10%	$4.05	$1.00	Yes
Colorado	AWP-35% (generic); AWP-13.5% (brand)	$4.00 (retail pharmacy); $1.89 (institutional pharmacy)	$.75 (generic); $3.00 (brand)	Yes
Connecticut	AWP-40% (generic); AWP-12% (brand)	$3.60	$1.00	Yes
Delaware	AWP-14% (traditional - retail independent & retail chain pharmacies); AWP-16% (non-traditional - long term care & speciality pharmacies)	$3.65	none	Yes
DC	AWP-10%	$4.50	$1.00	No
Florida	Lower of AWP-13.25% or WAC+7%	$4.23; $4.73 (NH-long term care)	2.5% of payment up to $300	Yes
Georgia	AWP-11%	$4.63 (brand for profit pharm); $4.33 (brand not for profit); $5.13 (generic for profit pharm); $4.63 (generic not for profit)	$.50 (generic); $.50-$3.00*(brand); $.50 (preferred brand)	Yes
Hawaii	AWP-10.5%	$4.67	none	Yes
Idaho	AWP-12%	$4.94 ($5.54 for unit dose)	none	Yes
Illinois	AWP-25% (generic); AWP-12% (brand)	$4.60 (generic); $3.40 (brand)	$0.00 (generic); $3.00 (brand)	Yes
Indiana	AWP-20% (generic); AWP-13.5% (brand)	$4.90	$3.00	Yes
Iowa	AWP-12%	$4.26	$1.00	Yes
Kansas	AWP-27% (generic); AWP-13% (single source)	$3.40	$3.00	Yes
Kentucky	AWP-12%	$4.51	$1.00	Yes
Louisiana	AWP-13.5% (AWP-15% for chains)	$5.77	$.50-$3.00*	Yes
Maine	AWP-15%; direct supply drug list-usual & customary charge or AWP-17% plus $3.35 professional fee or FUL or MAC plus $3.35 professional fee (Mail order lowest of usual & customary charge, AWP-20% plus $1.00 professional fee-for exceptions see State plan, FUL or MAC plus $1.00 professional fee)	$3.35; $4.35 & $5.35 (compounding); $12.50 (insulin syringe)	$2.50 (generic & brand) (not to exceed $25 per mo.) (Mail order not subject to co-pay) $3 per day RHC (max of $30 per mo., per individual)	Yes
Maryland	Lower of AWP-12% or WAC+8%, direct price+8% or distributor price when available	$3.69 (generic); $2.69 (brand); $4.69 (generic-NH); $3.69 (brand-NH); $7.25 (home IV therapy)	$1.00-$2.00	Yes
Massachusetts	WAC+6%	$3.50 (single source), $5 (multiple source)	$1.00 (multi-source & non-legend OTC); $3.00 (non-exempt)	Yes
Michigan	AWP-13.5% (independ pharm (1-4 stores)); AWP-15.1% (chain (5+ stores))	$3.77	$1.00	Yes

Chart 8

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAY	STATE MAC
Minnesota	AWP-11%	$3.65	none	Yes
Mississippi	AWP-12%	$3.91; allows for a reasonable dispensing fee for OTC	$1.00 (generic); $2.00 (preferred brand); $3.00 (brand)	No
Missouri	Lower of AWP-10.43% or WAC+10%	$4.09	$.50-$2.00*	Yes
Montana	AWP-15%	$4.70	$1.00	No
Nebraska	AWP-11%	$3.27-$5.00 (based on service delivery, unit dosage or 3rd party payors)	$2.00	Yes
Nevada	AWP-15%	$4.76	$1.00 (generic); $2.00 (brand)	No
New Hampshire	AWP-16%	$1.75	$1.00 (generic); $2.00 (brand & compound)	Yes
New Jersey	AWP-12.5%	$3.73; $4.07 (addt'l services)	none	No
New Mexico	AWP-14%	$3.65	none	Yes
New York	AWP-12%	$4.50 (generic); $3.50 (brand)	$.50 (generic); $2.00 (brand)	No
North Carolina	AWP-10%	$5.60 (generic); $4.00 (brand)	$1.00 (generic); $3.00 (brand)	Yes
North Dakota	AWP-10%	$5.60 (generic); $4.60 (brand)	$3.00 (brand)	No
Ohio	Lower of WAC+9% or AWP-12.8%	$3.70	$3.00 (if not on PDL)	Yes
Oklahoma	AWP-12%	$4.15	$1.00-$2.00*	Yes
Oregon	AWP-11% (institutional), AWP-15% (noninstitutional)	$3.50 (retail); $3.91 (institutional)	$2.00 (generic); $3.00 (brand)	Yes
Pennsylvania	AWP-10%	$4.00	$1.00	No
Rhode Island	WAC+5%	$3.40 (outpatient), $2.85 (long term care)	none	No
South Carolina	AWP-10%	$4.05 (independ pharm); $3.15 (institutional)	$3.00	Yes
South Dakota	AWP-10.5%	$4.75 ($5.55 for unit dose)	$2.00	Yes
Tennessee	AWP-13%	$2.50 (long term care dual eligib); $5.00 (NH only-if 28 days+)	N/A	Yes
Texas	Lower of AWP-15% or WAC+12%	$5.14	None	Yes
Utah	AWP-15%	$3.90 (urban); $4.40 (rural)	$3.00	Yes
Vermont	AWP-11.9%	$4.25	$1.00-$3.00*	Yes
Virginia	AWP-10.25%	$3.75; $5.00 (unit dose drugs)	$1.00	Yes
Washington	AWP-14% (single source & multiple source (w/2-4 manufact)), AWP-50% (multiple source from 5+ manufact), AWP-19% (brand-mail order), AWP-15% (generic-mail order)	$4.20-$5.20 (based on 3-tiered pharmacy volume); $3.25 (mail order)	none	Yes
West Virginia	AWP-12%	$3.90 (+$1.00 for compounding)	$.50-$3.00*	No
Wisconsin	AWP-11.25%	$4.88	$.50 (over-the-counter); $3.00 (brand); $1.00 (generic)	Yes
Wyoming	AWP-11%	$5.00	$2.00	No
(AWP=avg wholesale price, WAC=wholesaler acquisition cost, NH=nursing home)				
*Co-pay varies by cost of prescription.			REVISED 11/23/04	
SOURCE: CMS Approved State Plans				

Chart 8

Chart 9

2003 Medicaid Payments for "Everyday" Drugs

GROUP	Number Rx	Amount Reimbursed	Mean Reimbursement
Oral Contraceptives	3,985,630	$ 171,561,252	$ 43.04
Antihistamines	14,844,865	$ 592,711,833	$ 39.93
Systemic and Topical Nasal Products	5,397,737	$ 289,338,405	$ 53.60
Cough/Cold/Allergy Products	13,754,444	$ 265,470,988	$ 19.30
Total	37,982,676	$ 1,319,082,478	$ 34.73

Source: Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, State Drug Utilization Data, 2003.

Mr. WALDEN. It will be. Thank you, Mr. Smith.
Mr. Reeb, thank you for being with us.

TESTIMONY OF GEORGE M. REEB

Mr. REEB. Good morning, Mr. Chairman. I am George Reeb; I am assistant inspector general for the Centers of Medicare and Medicaid Audits within the HHS Office of Inspector General. Robert Vito, regional inspector general for evaluations and inspections in Philadelphia, accompanies me. We appreciate the opportunity to appear before you today.

In short, the Medicaid program continues to pay too much for prescription drugs. My written statement describes the OIG's work, showing that the Medicaid drug program could save money if it is improved on four particular fronts.

First, States need better methods for estimating pharmacy acquisition costs. Second, CMS must ensure that qualified drugs are placed on the Federal upper limit lists in a timely manner. Third, States must do a better job of accounting for their billing and collections of the rebates from the rebate collection process. And, fourth, CMS, we believe, should seek legislation to correct the inconsistencies which exist between the rebate and the reimbursement calculations.

Most States have used and continue to use the average wholesale price to estimate pharmacies' acquisition costs of drugs. The published AWPs that States use to establish their Medicaid drug reimbursements generally bear little resemblance to the prices incurred by retail pharmacies to purchase drugs. In prior audit reports that we issued in 2001 and 2002, we estimated that pharmacies' actual acquisition costs for brand-name drugs in 1999 was an average of 21 percent below AWP and for generic drugs was an average of 65 percent below AWP. The effect of the difference between the pharmacy invoice costs and the amount Medicaid would have paid for those drugs was about $1.5 billion, a spread from which the States could have derived savings through better reimbursement methods.

After additional analyses based on both State and industry interests, we recommend that, if States continue to use a reimbursement system based on AWP, they should consider adopting a four-tiered payment system that is described in my written statement.

Next, I would like to mention our findings with regard to the Federal upper limit program. For multiple-source drugs, Medicaid limits reimbursement to Federal upper limit amounts if at least three generic equivalents are available and certain other requirements are met. Medicaid misses savings opportunities when qualified drugs are not placed on the Federal upper limit list in a timely manner. In a report we issued in February of this year, we estimated that Medicaid could have saved $123 million in 2001 if CMS had added just 55 more products to the Federal upper payment list.

As a follow-up to that report, your committee requested that OIG conduct additional work on this subject. Today, we are releasing the results of that work. Again, we found that qualified drugs needed to be added more timely to the Federal upper limit list. Delays in adding the drugs we reviewed cost the Medicaid program an estimated $167 million between 2001 and 2003.

Another area we reviewed is the extent to which States vary in their Medicaid reimbursements for the same drugs. We estimated that, overall, Medicaid could have saved as much as $86 million in fiscal year 2001 if the 42 States that we reviewed had reimbursed at the same price as the lowest paying price—lowest paying State for each of the selected drugs. Overall, we believe that States could reduce their spending on prescription drugs by adopting various strategies that other States have successfully used to contain costs.

States also spend too much on prescription drugs because they do not adequately manage their Medicaid rebate billings and collections process. We recently completed audits at the rebate programs in 48 States and the District of Columbia. We found that rebate accounting systems were inadequate, and information submitted to CMS was unreliable, thereby undermining CMS' ability to oversee the drug reimbursement rebate process.

My written statement also describes concerns we have about the negative effect of inconsistencies between the key values that are used for calculating rebates and reimbursements. We estimate that, if rebates and reimbursements had been calculated using the same value, Medicaid would have achieved a substantial increase in added rebates. Audit work in progress confirms that Medicaid continues to overspend because of this inconsistency in the rebate and the reimbursement processes. Medicaid reimbursement should reliably reflect the actual cost of the drugs to the pharmacy. We do not believe that occurs now, and States need assistance in strengthening their ability to make reasonable payments for the drugs they do cover.

Mr. Chairman, this concludes my testimony, and we welcome any questions you may have.

[The prepared statement of George M. Reeb follows:]

PREPARED STATEMENT OF GEORGE M. REEB, ASSISTANT INSPECTOR GENERAL FOR THE CENTERS FOR MEDICARE AND MEDICAID AUDITS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning, Mr. Chairman. I am George M. Reeb, Assistant Inspector General for the Centers for Medicare and Medicaid Audits at the U.S. Department of Health and Human Services' Office of Inspector General (OIG). Robert Vito, Regional Inspector General for Evaluation and Inspections in Philadelphia, accompanies me. We appreciate the opportunity to appear before you today to present information regarding Medicaid's payments to pharmacies for prescription drugs.

In short, the Medicaid program continues to pay too much for prescription drugs. My testimony provides a brief overview of OIG's body of work over the last several years related to Medicaid-covered drugs that provides the basis for our belief that Medicaid is paying too much for prescription drugs and offers suggestions for controlling Medicaid spending.

The testimony describes OIG's findings regarding (1) pharmacy acquisition costs and average wholesale price, (2) the Federal upper limit program, (3) State variations in reimbursements for the same drugs, and (4) the Medicaid drug rebate program. I am also providing additional analytical information on pharmacy acquisition costs, highlights of Medicaid-related settlements with pharmaceutical manufacturers and chain drug stores, and a list of selected OIG reports and other guidance that are available on our Web site at http://www.oig.hhs.gov.

The Centers for Medicare & Medicaid Services estimated that calendar year 2003 Medicaid expenditures for prescription drugs totaled more than $31 billion, triple the $9.4 billion spent in 1994. Both the States and the Federal Government share these expenditures. Under Federal law, States have wide latitude in setting their reimbursement rates for prescription drugs. Federal regulations require that each State's reimbursement for a drug not exceed, in the aggregate, the lower of estimated acquisition cost plus a reasonable dispensing fee or the providers' usual and customary charge to the public for the drug. For certain multiple-source (generic)

drugs, Medicaid regulations set Federal upper limits that are contained on a list published by CMS. Within this general framework, the States use a variety of different pricing mechanisms when setting reimbursement amounts.

States must reasonably reimburse pharmacies for prescription drugs provided to Medicaid beneficiaries; yet, they lack access to pharmacies' actual acquisition costs. Due to this lack of data, they rely on estimates to determine Medicaid reimbursement. These estimates include formulas for estimating pharmacy acquisition cost, pharmacies' "usual and customary" charges, Federal upper limits, and State maximum allowable costs.

PHARMACY ACQUISITION COSTS AND AVERAGE WHOLESALE PRICE

Most States have used and continue to use the average wholesale price (AWP) to estimate pharmacies' acquisition costs of drugs. For the most part, AWP's (which are not clearly defined by law or regulation) are compiled in drug compendia such as Medical Economics' *Red Book*. As our audit findings have demonstrated, the published AWPs that States use to establish their Medicaid drug reimbursements generally bear little resemblance to the prices incurred by retail pharmacies to purchase drugs.

Until the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare also used AWP as the basis for most drug reimbursements. Although the Congress recently took action to help lower excessive payment levels for Medicare, Medicaid's reimbursement methodology continues to be based largely on the same inflated AWPs that had plagued Medicare.

To compare actual pharmacy acquisition costs to AWP, for calendar year 1999 we obtained from 217 pharmacies in 8 States pricing information that included thousands of invoice prices for both brand and generic drug products. We compared each invoice drug price to the AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. We estimated that pharmacy acquisition costs for brand name drugs in 1999 were an average of 21.8 percent below AWP and for generic drugs were an average of 65.9 percent below AWP. Both estimates were higher than our previous studies of 1994 data that showed 18.3 percent below AWP for brands and 42.4 percent below AWP for generics.

Our comparisons of pharmacy acquisition costs to AWP for 1999 did not adjust the invoice prices for the net effect of discounts available to most pharmacies, such as volume discounts, prompt pay discounts, and related rebates provided to pharmacies by manufacturers and/or wholesalers that would further lower the total pharmacy acquisition costs. For that one year, 1999, we estimated that the combined pharmacy invoice costs alone for brand name and generic drugs may have been as much as $1.5 billion lower than Medicaid would have paid for those drugs using the States' national average discount from AWP of 10.3 percent. This $1.5 billion constitutes a spread from which States could have derived savings through better reimbursement methods. We used a single average discount in the calculation because, in 1999, most States used the same discount for brand name drugs as they did for the generics that did not have an upper limit.

In the audit of 1999 data, we did not attempt to assess the adequacy of dispensing fees paid by the States to pharmacies. Based on information available from CMS, it appears that States have significantly varying amounts of dispensing fees.

In 2002, in response to requests by the industry and the States' interest in having more information on pharmacy purchase prices for additional categories of drugs, the OIG conducted an additional analysis of the 1999 data. That analysis provided a more comprehensive breakdown of percentages for a variety of drug categories. The analysis demonstrated a wide range of discounts from AWP for pharmacy purchases, depending on the category of drug that was being purchased. We concluded that the common method of reimbursing for brand name drugs and certain generic drugs using a single percentage discount does not adequately consider the large fluctuations in actual discounts between brands and generics. We recommended that, if States continue to use a reimbursement system based on AWP, they should consider adopting a four-tiered payment system. More information about the additional analysis and the recommended four-tiered payment system is provided in Appendix A.

States continue to use a discounted AWP for estimating pharmacy acquisition costs. However, many have established separate discounts for brand name and generic drugs. CMS estimated that for the year 2003, for brand drugs, the States' discounts from AWP ranged from 5 percent to 16 percent. For generic drugs, CMS estimated that the States' discounts from AWP ranged from 5 percent to 50 percent. A small number of States use wholesale acquisition cost rather than AWP when estimating the acquisition cost.

One reason States continue to rely on AWP, despite its widely recognized deficiencies, is that States lack access to alternative, more accurate price information. One option that could be studied is the feasibility of developing a base payment methodology that uses actual pharmacy invoice prices adjusted, if necessary, for a profitability factor after netting post-invoice discounts and other considerations.

FEDERAL UPPER LIMITS

For multiple-source (generic) drugs, Medicaid limits reimbursement to Federal upper limit amounts if at least three generic equivalents are available and certain other requirements are met. The Federal upper limits restrict the amount that Medicaid can reimburse for drugs that have available generic equivalents (42 CFR § 447.332). Medicaid misses savings opportunities when qualified drugs are not placed on the Federal upper limit list in a timely manner.

To quantify the missed savings opportunities, we obtained a list of the top 200 multiple-source drugs based on retail sales for the year 2001 and determined whether the drugs were on CMS's November 2001 Federal upper limit list. In a report issued in February 2004, we reported that 90 drugs were not included on the list despite meeting the established criteria. We estimated that Medicaid could have saved $123 million in 2001 if CMS had added just 55 of these 90 products to the Federal upper limit list. Four products alone accounted for 71 percent of the $123 million in potential savings. Subsequently, CMS added 9 of the 90 products to the Federal upper limit list. Seven of the nine products accounted for $94 million of the $123 million in savings we calculated for 2001.

As a follow-up to this report, your Committee requested that OIG conduct additional work to answer the following questions:

- Since 2001, how many generic drugs have met the criteria for inclusion on the Federal upper limit list?
- How many of these drugs have been included on the Federal upper limit list?
- How long, on average, did it take CMS to add newly qualified drugs to the list?
- How much does lag time between when a drug meets the criteria and its inclusion on the Federal upper limit list cost the Medicaid program?

Today, we are releasing the results of our work related to the Committee's request. Again, we found that CMS does not consistently add qualified drugs to the Federal upper limit list in a timely manner. Of the 252 first-time generic drugs approved between 2001 and 2003, 109 products met the statutory and regulatory criteria for inclusion on the list. CMS had added only 25 of the 109 drugs to the list as of July 15, 2004 (date of analysis), and very few of these were included in a timely manner. It took CMS an average of 36 weeks to place these products on the list once they met the statutory and regulatory criteria for inclusion. Only 3 of the 25 drugs were included on the list when they first became qualified. The longest delay was for two versions of Metformin Hydrochloride, which were qualified for 102 weeks before being added in March 2004.

An additional 84 of the 109 drugs we reviewed had still not been added to the Federal upper limit list as of July 15, 2004. The delay in adding these 84 drugs averaged 55 weeks as of that date.

Delays in adding the reviewed drugs cost the Medicaid program an estimated $167 million between 2001 and 2003. A majority of the losses were attributable to delays in adding just eight drugs, which accounted for 85 percent ($143 million) of the estimated losses. The product with the highest losses for Medicaid, Fluoxetine 20 mg capsules (brand name Prozac), illustrates the potential effect of not adding drugs to the Federal upper limit list in a timely manner. Fluoxetine met all criteria for inclusion on the Federal upper limit list by April 1, 2002. However, CMS did not place Fluoxetine on the list until December 1, 2002. We estimate that this delay in adding the 20 mg dosage size of Fluoxetine capsules cost Medicaid an estimated $57 million dollars. The Federal share of the loss on Fluoxetine was approximately $32.6 million. The Federal share of the $167 million loss on all the drugs we reviewed was approximately $95.5 million.

Based on the findings of this report, we recommended that CMS establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits. We also suggested that CMS focus its resources on ensuring that high-volume drugs that have recently come off patent are added to the list expeditiously. The report is available on OIG's Web site today under "What's New," and I have provided the report to the Committee.

STATE VARIATIONS IN REIMBURSEMENTS FOR THE SAME DRUGS

As previously mentioned, States have wide latitude in setting their reimbursement amounts for prescription drugs. In September 2004, we issued a report of a

study in which we assessed the extent to which States vary in their Medicaid reimbursement for the same drugs. We analyzed fiscal year 2001 State Medicaid prescription drug reimbursement data for a sample of 28 national drug codes. A national drug code is a numeric identifier issued by the Food and Drug Administration (FDA) for each drug. The code indicates the manufacturer of the drug, the product dosage amount, and the package size. Forty-two States agreed to participate in our review and provided us with their total ingredient reimbursement amount (excluding dispensing fees) and the total units reimbursed for each of the 28 national drug codes. Using the data supplied by States, we calculated an average unit price per drug and found substantial variations in States' payments for the same drugs. These variations translate into overspending by Medicaid.

Based on State data, we estimated that, overall, Medicaid could have saved as much as $86.7 million in fiscal year 2001 if all 42 States had reimbursed at the same price as the lowest paying State for each of the drugs reviewed. In fact, Medicaid could have cut its spending by more than half if all States had paid the same price as the lowest paying State for just 9 of the 28 drugs. These savings estimates derive from only 28 national drug codes that were randomly selected from 600 national drug codes for which there were substantial Medicaid outlays. Medicaid covers over 50,000 national drug codes, implying a potential for even greater program savings.

We believe savings could be achieved if CMS would: (1) share with the States the various types of price data it collects to help States develop better estimates of pharmacy acquisition costs, (2) conduct further research on the factors that affect States' drug prices to be able to advise States more effectively on ways to set their reimbursement levels, and (3) annually review the States' drug prices in order to share comparative State prices and methods to reduce costs.

MEDICAID DRUG REBATE PROGRAM

State Accounting for Rebate Billings and Collections

In addition to paying too much up front for Medicaid prescription drugs, States exacerbate their overspending of State and Federal funds by poor management of their rebate billings and collections. Pursuant to the Medicaid Drug Rebate Statute, States collect rebates from drug manufacturers for drug purchases made under the Medicaid program. The drug rebate program allows Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs.

The statutory drug rebate program became effective in January 1991. After a start-up period, we audited the effectiveness of the new program in eight States. In June 1993, we reported that CMS had not ensured that States had established proper accountability and controls over the billing and collection of drug rebates. In addition, CMS could not develop a nationwide total of the uncollected portion of Medicaid drug rebates because States were only required to report the rebates that were collected. We replicated our review recently on a national scale, using 2002 information, and found that, while accountability had improved since our 1993 report, improvements are needed in most States. Weaknesses included the following:

- Rebate accounting systems were inadequate.
- Information submitted to CMS was unreliable, undermining CMS's ability to oversee the program.
- Accounting for interest on late rebate payments was improper.
- The dispute resolution and collection processes were inadequate.

We are in the process of developing a national roll-up report. The individual final reports for each State and the District of Columbia are currently available on our Web site.

Drug Rebate Calculations

Additional Medicaid overspending occurs because of an inconsistency between the key values used for calculating rebates and reimbursements. Currently, Medicaid requires that rebates be based on a specifically designated value, average manufacturer price (AMP), while, at the same time, allowing reimbursements to be calculated using other values (usually a discounted AWP). This creates a situation whereby fluctuations in reimbursements do not result in a corresponding adjustment in the associated rebates. When a State increases its payments for a drug, it would not receive a correspondingly higher rebate on that drug purchase because there is currently no connection between the reimbursement and rebate calculations. Legislation is needed to establish a connection.

In a 1998 audit report, we recommended that CMS seek legislation requiring drug manufacturers to pay Medicaid drug rebates on the same basis that States deter-

mine reimbursements. The recommendation was supported by our review of data for calendar years 1994 through 1996 for 100 brand name drugs that had the greatest amount of Medicaid reimbursement in that period. We estimated that if rebates had been based on AWP (instead of on the statutorily required AMP) for that period, Medicaid would have achieved over $1 billion in added rebates. We used AWP to calculate the rebates for the period because most States were basing drug reimbursements on AWP minus a percentage discount. According to information States have reported to CMS, most States continue to use AWP in their reimbursement methodologies. Audit work in progress confirms that Medicaid continues to overspend because of the inconsistent bases used for reimbursement and rebates.

Manufacturers' Calculation of AMP

AMP is supposed to represent the price at which the manufacturers sell their drugs to wholesalers for use in the retail class of trade. In addition to the situation described above, our work at selected manufacturers has shown they are making inconsistent interpretations as to what components are included in AMP. The inconsistencies have included how to treat Medicaid sales and accounting for sales and price concessions that flow through organizations that represent both retail and non-retail customers. It is important that all manufacturers report consistent and accurate information in order for the rebate process to work as intended. We therefore suggest that additional clarification of the definition of AMP be provided by CMS. This would both improve the rebate process and assist States that may consider the use of AMP data in estimating pharmacy acquisition costs for reimbursement purposes.

CONCLUSION

All States could reduce their spending on prescription drugs by adopting various strategies that other States have successfully used to contain costs. The savings could be even greater if states had better access to accurate pricing information. Reimbursement should reliably reflect the actual costs of the drug to the pharmacy and be grounded in information that can be validated. There is an urgent need for the Medicaid policymaking community to assist States in strengthening their ability to make reasonable payments for the drugs they cover. This concludes my testimony, and I welcome your questions.

APPENDIX A

ADDITIONAL ANALYSIS OF PHARMACY ACQUISITION COSTS AND AVERAGE WHOLESALE PRICE

OIG collected brand name and generic drug acquisition costs for calendar year 1999 and compared those costs to the average wholesale price (AWP) for each drug. After issuing separate reports on brand name and generic drugs, we conducted an additional analysis that provided a more comprehensive breakdown of percentages for a variety of drug categories. We found that:

- For single source innovator drugs, pharmacies purchased the drugs at an estimated discount of 17.2 percent below AWP.
- For all drugs without Federal upper limits (single source innovator, multiple source innovator, and multiple source non-innovator), pharmacies purchased the drugs at an estimated discount of 27.2 percent below AWP.
- For multiple source drugs without Federal upper limits, pharmacies purchased the drugs at an estimated discount of 44.2 percent below AWP. A further breakdown of these drugs showed the estimated discount for innovator multiple source drugs to be 24.4 percent and 54.2 percent for non-innovator multiple source drugs.
- For multiple source drugs with Federal upper limits, pharmacies purchased the drugs at an estimated discount of 72.1 percent below AWP.

These percentages do not consider discounts available to most pharmacies, such as volume discounts, prompt pay discounts, and related rebates that would further reduce acquisition costs.

The analysis shows that there is a wide range of discounts from AWP for pharmacy purchases depending on the category of drug that is being purchased. We concluded that, if States continue to use a reimbursement system based on AWP, CMS should encourage States to consider adopting a four-tiered payment system consisting of a percentage discount off AWP for:

(1) single source brand name drugs;
(2) innovator multiple-source drugs without a Federal upper limit; and
(3) non-innovator multiple-source drugs without a Federal upper limit.

(4) The fourth tier would be to pay the Federal upper limit price for qualified multiple source drugs.

As in the audits on which this additional analysis was based, we focused our efforts on evaluating the pharmacy's acquisition costs for the drugs and offer no opinion on the adequacy of the dispensing fees being paid.

APPENDIX B

MEDICAID-RELATED PRESCRIPTION DRUG SETTLEMENTS

Settlements with Pharmaceutical Manufacturers

Recent Federal investigations of pharmaceutical manufacturers that led to settlements involving Medicaid prescription drug cases serve to illustrate weaknesses and vulnerabilities in the Medicaid drug reimbursement arena. Following are descriptions of some, but not all, relevant cases. Both the United States and individual States have negotiated other settlements that are not mentioned here.

The OIG's "Compliance Program Guidance for Pharmaceutical Manufacturers" is available on the OIG Web site at http://www.oig.hhs.gov/fraud/complianceguidance.html.

Schering-Plough Corporation. Recently, ScheringPlough Corporation agreed to pay $345.5 million as part of a global settlement with the Government and entered a 5year corporate integrity agreement (CIA) with the OIG. As part of the settlement, Schering-Plough agreed to pay $293 million to resolve its civil and administrative liabilities in connection with illegal and fraudulent pricing of its allergy drug Claritin under the Medicaid drug rebate program. The civil portion of the case focused on ScheringPlough's alleged failure to include the value of certain incentives offered to two managed care organizations in Schering-Plough's determination of the best price reported for purposes of the Medicaid drug rebate program. By failing to include the value of the incentives in its determination of best price, ScheringPlough allegedly underpaid rebates due to the States and overcharged entities (such as community health centers) that purchased drugs at ceiling prices that are based on Medicaid drug rebate prices. With regard to the criminal portion of the case, a subsidiary of ScheringPlough, the Schering Sales Corporation, pled guilty to a kickback charge and was sentenced to pay a $52.5 million criminal fine. Schering Sales Corporation was charged with paying a kickback of almost $2 million in order to keep Claritin on the formulary of a managed care organization.

Pfizer Inc. As part of a fiscal year 2004 global settlement of $430 million plus interest, Pfizer Inc. (Pfizer), Warner-Lambert Company LLC (Warner-Lambert), and the Parke-Davis Division agreed to pay $190 million in a civil False Claims Act settlement relating to Warner-Lambert's promotion of the drug Neurontin. Pfizer acquired Warner-Lambert and its Parke-Davis Division in June 2000. Between July 1995 and June 2001, Neurontin was approved by FDA only for use in treating epilepsy, but Warner-Lambert allegedly engaged in a wide-ranging program to promote Neurontin for other uses. The Government alleges that these activities caused the submission of false and/or fraudulent claims to Medicaid. To resolve its criminal liability, Warner-Lambert pled guilty to violating the Federal Food, Drug and Cosmetic Act and agreed to pay a $240 million criminal fine. Pfizer entered a comprehensive 5-year corporate integrity agreement with OIG.

AstraZeneca Pharmaceuticals, LP and Zeneca Inc. In June 2003, the United States announced a global settlement with AstraZeneca. The company agreed to pay a total of almost $355 million and enter a 5-year CIA with OIG to resolve its criminal and civil liabilities relating to the marketing and pricing of its prostate cancer drug, Zoladex. AstraZeneca pled guilty to conspiracy to violate the Prescription Drug Marketing Act by causing the submission of reimbursement claims for Zoladex that had been provided free of charge as samples. The Government also alleged that AstraZeneca paid illegal remuneration (in various forms including grants, travel, and entertainment) to induce the purchase of Zoladex; that AstraZeneca created and marketed an average wholesale price (AWP) spread between the Medicare reimbursement for Zoladex and its cost; and that AstraZeneca misreported and underpaid Medicaid rebates for Zoladex. AstraZeneca also agreed to enter separate settlements with the States.

Bayer Corporation. In April 2003, Bayer Corporation agreed to pay $257.2 million in criminal fines and civil assessments to settle a False Claims Act case relating to the Medicaid drug rebate program. Bayer agreed to plead guilty to charges that it violated Federal law by failing to report certain information to FDA. The case focused on Bayer's failure to include certain sales to Kaiser Permanente Medical Care (an HMO) in its calculation of Best Price reported for purposes of the Medicaid drug rebate program. The Medicaid drug rebate program requires drug manufacturers to

report their Best Prices to CMS and to pay rebates to the State Medicaid programs based on those reported prices.

GlaxoSmithKline. Also in April 2003, GlaxoSmithKline settled a Medicaid drug rebate case for almost $88 million, based on facts similar to the Bayer matter discussed above. In connection with the settlement, GlaxoSmithKline entered a 5-year CIA with OIG. GlaxoSmithKline also agreed to enter into separate settlement agreements with the States.

Pfizer, Inc. In October 2002, the United States settled a Medicaid drug rebate case with Pfizer, Inc., Warner-Lambert Company and the Parke-Davis Division. The Government alleged that Warner-Lambert failed to include the value of certain unrestricted educational grants in the best price reported for purposes of the Medicaid drug rebate program and, as a result, underpaid rebates due. The government alleged that Warner-Lambert paid the grants to a managed care organization in order to obtain unrestricted formulary status for the cholesterol-lowering drug, Lipitor. As part of the settlement, Pfizer paid $49 million and entered a five-year CIA with OIG.

TAP Pharmaceutical Products, Inc. In October 2001, the United States announced a major global health care fraud settlement with TAP Pharmaceutical Products Inc. TAP agreed to pay a total of $875 million to resolve its Medicare and Medicaid liability. TAP agreed to plead guilty to violating Federal law governing the use of drug samples. In addition, TAP allegedly set and reported AWPs for its prostate cancer drug, Lupron, at levels far higher than the actual acquisition cost of the majority of its customers (such as physicians) and caused those customers to receive excess reimbursement from Medicare and Medicaid. TAP also allegedly underpaid rebate amounts due to the States under the Medicaid drug rebate statute.

Bayer Corporation. In February 2001, the United States entered a $14 million settlement with Bayer Corporation in connection with Bayer's AWP pricing and Medicaid drug rebate practices relating to six drugs. The Government alleged that Bayer set and reported AWPs for the drugs at levels far higher than the actual acquisition costs of the products; that Bayer made misrepresentations to the Medicaid programs of certain States; and knowingly misreported and underpaid Medicaid rebates for the drugs. As part of the settlement, Bayer entered a five-year CIA with OIG.

Settlements with Chain Drug Stores

Rite Aid Corporation. In 2004, Rite Aid Corporation agreed to pay $7 million and enter a 4year CIA to resolve its civil and administrative liability relating to the submission of claims to Medicaid and other Government health care programs for partially-filled prescriptions for drugs that were not delivered to the beneficiaries and, in some instances, were ultimately returned to stock. In addition to the settlement with the Federal Government, Rite Aid entered settlements with 28 States and the District of Columbia to resolve alleged liability to the States for the Medicaid damages.

Wal-Mart Stores, Inc. In 2004, Wal-Mart Stores, Inc., agreed to pay almost $2.87 million and enter a 4-year CIA to resolve alleged civil and administrative liabilities relating to the submission of claims for partially filled prescriptions between 1990 and 2000. The settlement resolved a False Claims Act qui tam suit alleging that Wal-Mart submitted false claims each time it dispensed only a portion of a prescription to a customer yet billed Medicaid, TRICARE, or the Federal Employee Health Benefits Program for the full amount of the prescription.

Eckerd Corporation. In May 2002, Eckerd Corporation entered a settlement with the United States and a group of States for $9 million. Eckerd also entered into a 5-year CIA with OIG. The Government alleged that Eckerd submitted false claims each time it dispensed only a portion of a prescription to the customers but billed for the full amount of the prescription. The claims at issue were submitted to Medicaid, TRICARE, and the Federal Employee Health Benefits Program between 1986 and 2000. Previously, ECK M.D., Inc., an affiliate of Eckerd, pled guilty to submitting false claims to Medicaid and to violating certain record-keeping requirements of the Controlled Substances Act.

CVS Corporation. In July 2001, the U.S. Department of Justice and the OIG, working jointly with representatives of the States, reached settlement in a qui tam action against CVS Corporation, involving allegations that the company submitted claims for partially filled prescriptions to Medicaid, TRICARE, and the Federal Employee Health Benefits Program. In addition to paying $4 million to the Government, CVS also agreed to a 4-year CIA.

Walgreen Co. In 1999, the Federal and State governments (through the Medicaid Fraud Control Units) entered the first settlement with a major retail pharmacy chain for conduct involving partially filled prescriptions billed to Medicaid and other

Federal health care programs. Walgreen Co. paid $7.6 million and entered a 4-year CIA to resolve its liability.

APPENDIX C

SELECTED MEDICAID DRUG REPORTS AVAILABLE ON THE OIG WEB SITE (HTTP://WWW.OIG.HHS.GOV)

A-06-91-00092: HCFA Needs to Provide Additional Guidance to Drug Manufacturers To Better Implement the Medicaid Drug Rebate Program. 1992. (Inconsistencies in manufacturers methods used to determine AMP.)
A-06-91-00102: Improvements Needed in HCFA's Procedures To Implement the Medicaid Drug Rebate Program. 1992. (Errors in AMP and best price.)
A-06-92-00029: Management Controls Over the Medicaid Drug Rebate Program. 1993. (Inadequate State controls and accountability over billing and collection of rebates.)
A-06-96-00030: Medicaid Pharmacy: Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs. 1997. (Based on invoices, in 1994 pharmacy acquisition costs for brand name drugs averaged 18.3 percent below AWP.)
A-06-97-00011: Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products. 1997. (Based on invoices, in 1994 pharmacy acquisition costs for generic drugs averaged 42.5 percent below AWP.)
A-06-97-00052: Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs. 1998. (Increases in reimbursement do not trigger corresponding increases in rebates.)
A-06-00-00023: Actual Acquisition Cost of Brand Name Prescription Drug Products. 2001. (Based on invoices, in 1999 pharmacy acquisition costs for brand name drugs averaged 21.84 percent below AWP.)
A-06-01-00053: Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products. 2002. (Based on invoices, in 1999 pharmacy acquisition costs for generic drugs averaged 65.93 percent below AWP.)
A-06-02-00041: Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products. 2002. (A 4-tier discounting methodology would bring reimbursement more in line with acquisition costs.)
OEI-05-99-00611: Containment of Medicaid HIV/AIDS Drug Expenditures. 2001. (Comparison of Medicaid payments to other pricing methods.)
OEI-03-01-00010: Medicaid's Use of Revised Average Wholesale Prices. 2001. (States' use of price revisions by First Databank.)
OEI-05-02-00080: Medicaid's Mental Health Drug Expenditures. 2003. (Comparison of Medicaid payments to 4 other Federal payers.)
OEI-05-02-00680: State Strategies to Contain Medicaid Drug Costs. 2003. (Review of States' methods to control spending on drugs.)
OEI-03-02-00670: Omission of Drugs from the Federal Upper Limit List in 2001. 2004. (CMS did not ensure timely placement of drugs on the FUL list.)
OEI-03-02-00660: Medicaid Rebates for Physician-Administered Drugs. 2004. (Some States' systems are inadequate to ensure rebate collections.)
OEI-05-02-00681: Variation in State Medicaid Drug Prices. 2004. (States' reimbursements vary widely for the same drugs.)
OEI-03-04-00320: Addition of Qualified Drugs to the Medicaid Federal Upper Limit List. 2004. (CMS did not ensure timely placement of drugs on the FUL list.)

Mr. WALDEN. Thank you, Mr. Reeb.

Mr. Vito, do you have any comments? No.

Mr. O'Connell, or Mr. Balland.

TESTIMONY OF DAVID J. BALLAND

Mr. BALLAND. Good morning, Mr. Chairman. Mr. O'Connell has agreed to allow me to go first as his statement will follow logically after mine.

Good morning, Mr. Chairman. Thank you for having Texas attend this very important hearing. I am David Balland, the associate commissioner for the Medicaid and Children's Health Insurance Program for the State of Texas, and I appreciate this opportunity to be with you today.

Mr. WALDEN. Thank you for being here.

Mr. BALLAND. Our main goal in setting reimbursement for the Texas Medicaid Prescription Drug Program, referred to as the Vendor Drug Program, is to make the reimbursement formula as fair as possible to all parties involved by reimbursing as close as possible to the pharmacy's actual cost and the pharmacies—allowing the pharmacies to set an adequate fee to cover their costs to dispense that product and working with the pharmacies. We do this in a proactive and transparent manner.

In Texas, we spend approximately $2 billion a year on prescription drugs for Medicaid clients. Most States currently use private companies to access prescription drug pricing information by drug in order to set reimbursement levels for their pharmacies for prescription drugs dispensed in their Medicaid programs. These companies request pricing information from manufacturers by drug, and then make this unregulated pricing information available to their clients for a fee. Unlike most other States, Texas does not solely rely on the pricing information provided by these private companies to set our reimbursement for prescription drug products. We take the proactive approach and do this due to the potential inaccuracy of the reported information and the actual cost of the product to the pharmacies.

Texas Medicaid used similar pricing services as most States until the early 1980's when the Texas Vendor Drug Program studied ways to more accurately pay for drug products paid to pharmacy providers since we were having problems obtaining accurate pricing information. Once we recognized that the average wholesale price was greater than the amount that Texas pharmacies paid the wholesaler for a drug product, we decided to do this. In other words, Texas Medicaid was reimbursing our pharmacies at a higher amount than the pharmacies' actual price to purchase the drug product.

Texas started requiring drug manufacturers to fill out an application and questionnaire in the early 1980's for their products to be considered for the Texas Medicaid list of covered prescription drugs. We required drug manufacturers to provide pricing information on a number of different kinds of actual prices for each prescription drug product in order to determine the appropriate reimbursement level for those products purchased from different sources, including the average wholesale price, the wholesale acquisition cost, the chain warehouse price, the direct price to the pharmacy, and similar pricing information. Our Vendor Drug Program took specific steps to further refine the reimbursement amount paid to our pharmacies, including putting into place targeted prescription drug audits and pharmacy invoice audits and requesting additional pricing information directly from drug manufacturers.

Based on information from some out-of-State pharmacies and our Texas Medicaid regional pharmacists, Texas Medicaid Vendor Drug Program initiated two targeted audits—drug invoice, one in early 2000 and one in early 2001. We selected drug products with the greatest estimated discrepancy in pricing from drug manufacturers to review during these audits, including over 300 brand-name and generic prescription drug products. The audits found significant discrepancies between Texas Medicaid vendor drug reimbursement

to our pharmacies and the amount the pharmacies were actually paying for most of the 300-plus products reviewed.

As a result of these two targeted audits, we updated the base reimbursement amount for most of these specific drug products. The reimbursement updates to pharmacies for most of the products reviewed saves Texas Medicaid an estimated annual $20 million in all funds.

Additionally, we completed an invoice audit of more than 674 pharmacies in 2001 through 2002. This audit also indicated that Texas was reimbursing the pharmacies at a significantly higher amount than the pharmacies' costs. We proposed to change the prescription drug reimbursement formula after this audit. Unfortunately, the program was unable to proceed with the proposed changes due to legal challenges by the pharmacy association. This proposed rule was estimated to save Texas Medicaid millions of dollars annually due to setting more accurate reimbursement levels for prescription drugs.

In addition to moving toward a more accurate reimbursement for product cost, we are working to determine the most accurate dispensing fee that our program should pay the pharmacy. An August 2002 study completed by Myers and Stauffer L.C. Indicated that the actual statewide median cost of dispensing a drug in Texas Medicaid is estimated at about 90 cents higher than the current dispensing expense.

Texas will continue to develop tools and request additional pricing information that will assist us in setting the most accurate reimbursement fee for our pharmacies. We will proceed with the following activities: One, continue developing aggressive State maximum allowable costs; two, require drug manufacturers to also report average manufacturer price; three, further define the accuracy of the price the wholesaler pays the manufacturer; and, four, analyze the feasibility of implementing a more accurate dispensing fee.

These additional price points will allow Texas to cross-check all the reported pricing information to reach the most accurate product cost and dispensing fee for a product.

In conclusion, Mr. Chairman, again, thank you, members of the committee, for giving Texas Medicaid an opportunity to be a part of this important panel. Texas Medicaid works very closely with our partners, drug manufacturers and pharmacies in a transparent manner, in a proactive way, and has tried to establish a fair process that works for all parties involved.

[The prepared statement of David J. Balland follows:]

PREPARED STATEMENT OF DAVID J. BALLAND, ASSOCIATE COMMISSIONER FOR MEDICAID AND THE CHILDREN'S HEALTH INSURANCE PROGRAM, TEXAS HEALTH AND HUMAN SERVICES COMMISSION

My name is David J. Balland, Associate Commissioner for Medicaid and the Children's Health Insurance Program (CHIP) at the Texas Health and Human Services Commission.

Before I begin my testimony, I would like to thank you, Mr. Chairman, and the members of the Committee for inviting Texas to speak on such an important topic. We look forward to sharing our prescription drug reimbursement best practices with our federal and state partners.

Our main goal in setting reimbursement for the Texas Medicaid prescription drug program, referred to as the Vendor Drug Program, is to make the reimbursement formula as fair as possible to all parties involved by reimbursing as close as possible to the pharmacies' actual cost of buying prescription drugs. Texas then

works with the pharmacies to set an adequate fee to cover their costs to dispense that product to Medicaid recipients. In Texas, we spend about two billion dollars a year on prescription drugs for Medicaid clients (in state and federal dollars).

Current Pricing System: Most states currently use private companies to access prescription drug pricing information by drug in order to set reimbursement levels for their pharmacies for prescription drugs dispensed in their Medicaid programs. These companies request pricing information from drug manufacturers by drug and then make this unregulated pricing information available to their clients for a fee.

Unlike most other states, Texas does not solely rely on the pricing information provided by these private companies to set our reimbursement for prescription drug products due to the potential inaccuracy of the reported information and the actual cost of the product to the pharmacies.

Problems with Earlier Pricing Systems: Texas Medicaid used similar pricing services as most states until the early 1980's when the Texas Vendor Drug Program studied ways to more accurately pay for drug products paid to pharmacy providers. The Texas Vendor Drug Program had long recognized that the average wholesale price in the commercial price database was greater than the amount that Texas pharmacies actually paid the wholesaler for a drug product. In other words, Texas Medicaid was reimbursing our pharmacies at a higher amount than the pharmacies actual price to purchase the drug product.

In the early 1980's, Texas started requiring drug manufacturers to fill out an application (later referred to as a questionnaire) for their products to be considered for the Texas Medicaid list of covered prescription drugs (otherwise known as a formulary). In the questionnaire, drug manufacturers are asked to provide pricing information on a number of different kinds of actual prices for each prescription drug product in order to determine the appropriate reimbursement level for products purchased from different sources including:

- Average price pharmacies paid for product from a wholesaler, known as Average Wholesale Price;
- Price paid for product by the wholesaler and/or prescription drug distributor, known as Wholesaler Acquisition Cost;
- Chain warehouse price;
- Direct price to the pharmacy; and
- Similar pricing information.

Steps Taken to Further Refine Pricing: The Texas Vendor Drug Program took specific steps to further refine the reimbursement amount paid to our pharmacies including:

1. We put into place targeted prescription drug audits and pharmacy invoice audits; and
2. We requested additional pricing information directly from drug manufacturers.

Based on information from some out of state pharmacies and our Texas Medicaid regional pharmacists, who gather acquisition cost information in the public sector out-patient pharmacy market, Texas Medicaid Vendor Drug Program initiated two targeted drug invoice audits, one in early 2000 and the other in early 2001. Texas selected drug products with the greatest estimated discrepancy in pricing from drug manufacturers to review during the audits, including over 300 brand name and generic prescription drug products.

The audits found significant discrepancies between Texas Medicaid Vendor Drug Program reimbursement to our pharmacies and the amount the pharmacy was actually paying for most of the 300-plus products reviewed.

Texas Medicaid Vendor Drug Program Targeted Audit Savings: As a result of these two targeted audits, the Texas Medicaid Vendor Drug Program updated the base reimbursement amount for most of these specific drug products. The reimbursement updates to pharmacies for most of the products reviewed saved Texas Medicaid an estimated annual savings of over $20 million in state and federal funds.

In addition to the targeted specific product audits, Texas Medicaid Vendor Drug Program also completed an invoice audit of more than 670 pharmacies in 2001-2002. This audit also indicated that Texas was reimbursing the pharmacies at a significantly higher amount than the pharmacies' cost to purchase their products from drug manufacturers or prescription drug wholesalers. Even though Texas Medicaid Vendor Drug Program proposed to change the prescription drug reimbursement formula after this audit, the program was unable to proceed with proposed changes due to legal challenges by the pharmacy association. This proposed rule was estimated to save Texas Medicaid millions of dollars annually due to setting more accurate reimbursement levels for prescription drugs.

Dispensing Fee: In addition to moving towards a more accurate reimbursement for product cost, the Texas Medicaid Vendor Drug Program is also working to determine the most accurate dispensing fee that our program should pay the pharmacy.

An August 2002 study completed by Myers and Stauffer L.C. indicated that the actual statewide median cost of dispensing a drug in Texas Medicaid is estimated at about 90 cents higher than the current dispensing expense. The dispensing costs were especially higher with specialty and urban pharmacies.

Next Steps: Texas will continue to develop tools and request additional pricing information that will assist us in setting the most accurate reimbursement for our pharmacies. Texas Medicaid Vendor Drug Program will proceed with the following activities:

- Continue with developing aggressive state maximum allowable cost (MAC) on certain products;
- Require drug manufacturers to also report average manufacturer price (AMP) for products in the Texas questionnaire;
- Further define the accuracy of the price the wholesaler pays the manufacturer, known as Wholesaler Acquisition Cost, and
- Analyze the feasibility of implementing a dispensing fee that reflects actual cost to pharmacies in Texas.

These additional price points will allow the Texas Medicaid Vendor Drug Program to cross check all the reported pricing information to reach the most accurate product cost and dispensing fee for a product.

Conclusion: Thank you, Mr. Chairman and members of the Committee, for giving Texas Medicaid and opportunity to be part of this important panel. Texas Medicaid works very closely with our partners, drug manufacturers and pharmacies, and has tried to establish a fair process that works for all parties involved.

In addition, we will proceed to be as flexible as possible while maintaining the best prescription drug prices for the state and federal government in the Texas Medicaid program. We must continue to seek the best value in order to be able to sustain this program that is so essential to the health of our vulnerable clients.

Mr. WALDEN. Thank you. And I always try and do whatever I can to help Texas. It is important. My chairman appreciates that, too.

Mr. O'Connell, thanks for being here.

TESTIMONY OF PATRICK J. O'CONNELL

Mr. O'CONNELL. Thank you, Mr. Chairman. My name is Patrick O'Connell; I am an assistant attorney general and chief of the civil and Medicaid fraud section of the Texas Attorney General's Office. We thank you very much for giving us the opportunity to testify today.

In 1999, then Texas Attorney General, now United States Senator John Cornyn, became concerned about fraud against the Texas Medicaid program and created a special Civil Medicaid Fraud Section within our Attorney General's Office. Our section utilizes the Texas Medicaid Fraud Prevention Act to initiate civil litigation to recover funds wrongfully taken from Texas Medicaid.

One of the first cases we received was filed by a small Florida pharmacy, Ven-A-Care of the Florida Keys, whom you heard from today. Ven-A-Care brought information to us showing that certain drug manufacturers—not all—but certain drug manufacturers violated Texas law by intentionally reporting prices to the Medicaid program that did not remotely equal the prices they really charged for their products. As Mr. Balland has indicated, unlike most other States which derive their pricing information from third parties, Texas requires the manufacturers who want their products to be eligible for Medicaid reimbursement in Texas to fill out this questionnaire for each drug they wish placed on the formulary. When Texas relies upon an inflated price report in calculating a pro-

vider's estimated acquisition cost, the resulting reimbursement to providers is well above the provider's actual acquisition cost, thus providing pharmacies with unintended windfall profits.

Based on the information that we received from Ven-A-Care as well as information we discovered in our own preliminary investigations, General Cornyn authorized us to intervene against three defendants in September 2000. This Texas lawsuit was the first ever State intervention in a qui tam case involving pharmaceutical manufacturer pricing fraud.

The evidence we discovered in our lawsuits and investigation shows that some manufacturers make conscious deliberate business decisions to create enhanced spreads and to market the sale of their products based on those spreads. For example, we found that some manufacturers have engaged in the following activities: Purposefully reporting false and inflated wholesale prices to the Medicaid program in Texas; deliberately failing to report prices to certain classes of trade in violation of Texas law; instructing their sales personnel to market spreads to customers; creating spread sheets showing pharmacies how much more profit they can make off of Medicaid when purchasing one manufacturer's product over another; and tying sales personnel compensation to success in marketing the spread.

We also found that some manufacturers actually kept two sets of computer records with prices, one with the inflated prices that were reported to their price reporting services and to Texas Medicaid, and another with their real contract prices that are used in their everyday business transactions with the manufacturers' customers.

As of May 2004, we have settled with two defendants in our lawsuit for a recovery for the State and the Federal Government of $45.5 million. In both cases, Texas recovered more than two times the actual damages to the Medicaid program plus our costs, our attorneys' fees, and the attorneys' fees of the relater. It's important for the committee to remember that these were Texas State settlements only. Texas is approximately 8 percent of the national Medicaid budget. So if you multiply it by 10 or 12, I think you can see the numbers involved.

Our office continues to provide assistance to those authorities in other jurisdictions who are pursuing these defendants and other companies. We have developed close and cooperative working relationships with the United States Department of Justice and with the other State attorneys general who have initiated similar litigation. So far, 13 other States have followed Texas' lead and have sued various drug companies for false price reporting.

The litigation in Texas is still pending against one of the three defendants we sued in 2000, and we are scheduled to go to trial against that manufacturer in the fall of next year. We have also intervened against three new additional defendants. The cases against those three defendants is in the discovery phase, and we anticipate trial in those cases to be reached in the spring of 2006.

Despite our efforts, some unscrupulous manufacturers continue to devise ways to defraud our Texas Medicaid program, and we are doing everything in our power to bring those companies to justice.

Our current Texas Attorney General Greg Abbott has committed the resources of the agency to these efforts.

I would like to make clear that while Texas is pleased to have recovered these significant sums of money in the qui tam cases, litigation is clearly not the most efficient way to run this system. Our Texas Medicaid program has been required to spend thousands of man hours responding to discovery requests and preparing for hearings and preparing for and attending depositions in our litigation. The program could have used those hard earned tax dollars to provide more and better services if the Vendor Drug Program personnel were not tied up in the litigation caused by the very manufacturers who have been gaming our system. Thank you for your attention, and I will be available for questions.

[The prepared statement of Patrick J. O'Connell follows:]

PREPARED STATEMENT OF PATRICK J. O'CONNELL, CHIEF, CIVIL MEDICAID FRAUD SECTION, OFFICE OF THE ATTORNEY GENERAL OF TEXAS

Mr. Chairman and members of the Subcommittee: Good morning. My name is Patrick O'Connell. I am an Assistant Attorney General and Chief of the Civil Medicaid Fraud Section of the Texas Attorney General's Office. Thank you for inviting us to testify this morning. In my remarks, I will describe for you the efforts undertaken by the Texas Attorney General to identify and vigorously litigate against those persons and companies that defraud the Medicaid system in Texas.

As you are aware, the federal False Claims Act has been in place since the Civil War. Texas adopted our version of the FCA in 1995. Our statute, the Texas Medicaid Fraud Prevention Act, is specific to fraud against the Medicaid Program. In 1999, then Texas Attorney General, now United States Senator, John Cornyn became concerned about fraud against the Texas Medicaid Program and created a special Civil Medicaid Fraud Section within the AG's office. Our Civil Medicaid Fraud Section utilizes the Texas statute to initiate civil litigation to recover funds defrauded from Texas Medicaid. One of the first cases we received was filed by a small Florida pharmacy, Ven-A-Care of the Florida Keys, Inc., who you heard from earlier today.

Ven-A-Care brought information to us showing that certain drug manufacturers violated Texas law by intentionally reporting prices to the Texas Medicaid Program that did not bear a reasonable relationship to the prices for their products that were generally and currently available in the market place. Unlike most other states which derive pricing information from third party price reporting services like First Data Bank, Texas requires manufacturers who want their products to be eligible for Medicaid reimbursement to fill out a questionnaire for each drug they wish placed on the Texas Medicaid formulary. For each drug, the manufacturer must report its prices to various classes of trade: e.g., its AWP; its price to wholesaler and/or distributor; its direct price; special price to chain warehouse, etc. A drug company representative is required to sign the form and certify that the information included in it is accurate. Texas law also requires drug companies to update the Medicaid Program with any changes in reported pricing within 15 days of the change.

When Texas relies upon an inflated price report in calculating a provider's estimated acquisition cost ("EAC"), the resulting reimbursement to providers is well above the providers' actual acquisition cost, thus providing pharmacies with windfall profits. The information brought to us by Ven-a-Care indicated that certain drug companies may have knowingly and purposefully misrepresented their reported prices to Texas in order to enhance or drive up the reimbursement to their provider customers.

Under the Texas statute, we have broad powers to compel document production and testimony of potential witnesses. In 1999 and 2000, we used these civil investigative demand powers to require several manufacturers to produce documents. We also took examinations under oath of several industry representatives. Based on the information that we received from Ven-a-Care, as well as the information we received pursuant to the CID process, General Cornyn authorized us to intervene against threeVAC defendants in September 2000. The Texas lawsuit was the first state intervention in a qui tam case involving pharmaceutical manufacturer pricing fraud.

The evidence we have discovered in our investigations shows that some manufacturers make conscious, deliberate business decisions to create enhanced spreads and

to market the sale of their products based on the spreads. For example, we found that some manufacturers engaged in the following activities:

- purposefully reported false and inflated prices to Texas Medicaid—as well as to third party price reporting services—in order to create enhanced spreads;
- deliberately failed to report prices to certain classes of trade in violation of Texas law;
- instructed their sales personnel to market spreads to customers;
- created spread sheets showing pharmacies how much more profit they can make off Medicaid when purchasing one product over another;
- tied sales personnel compensation to success in marketing the spread.

We also found that some manufacturers actually kept two sets of computer records with prices: one, with inflated prices that are reported to the price reporting services like First Data Bank, or in Texas' case, directly to the Medicaid Program; and another with real contract prices that are used in every day business transactions with the manufacturer's customers.

In June 2003, we settled our case with one defendant drug company for $18.5 Million, and in May 2004, we settled with another for $27 Million. The total recovery in both settlements was $45.5 Million. In both cases, Texas recovered more than two times the actual damages to the Medicaid Program, plus our costs and attorneys' fees. Since the federal government supplies approximately 62 cents of every dollar spent on Medicaid in Texas, so approximately 62% of the net settlements went to the United States Treasury.

It is important to remember that these were Texas State settlements only. My office continues to provide assistance to those authorities in other jurisdictions who are pursuing these and other companies. We have developed close and cooperative working relationships with the United States Department of Justice and with other state attorneys general who have instituted similar litigation. So far, California, Kentucky, Florida, Minnesota, Connecticut, New York, Ohio, Arkansas, Wisconsin, West Virginia, Massachusetts, and Nevada have sued drug companies for false price reporting.

Litigation in Texas is still pending against one of the defendants we sued in September 2000, and we are scheduled to go to trial against that manufacturer in the fall of next year. We have also intervened against three additional defendants. The case against these three defendants is in the discovery phase where we are taking depositions and exchanging documents. That trial is scheduled to begin in the Spring of 2006.

I would like to briefly follow-up on the remarks from the Texas Medicaid Program. We have consistently found over the last five years of litigation that our Vendor Drug Program in Texas is one of the best, if not the best, program in the country. Texas is the only state thus far to require drug companies to report and certify their prices directly to our Medicaid administrators. This distinguishes Texas from all other Medicaid programs, which derive their pricing information from third party publishing services like First Data Bank. In addition, as you heard, Texas was the first state to move from AWP based reimbursement to wholesaler cost and the first to differentiate payments to chain pharmacies. In addition to these efforts, our Texas Program continues to search for new ways to improve. They have passed a law requiring drug companies to report their AMP to Texas Medicaid, and they intend to use the AMP as another benchmark for comparison with the prices reported by manufacturers. Unfortunately, to date, only 16% of manufacturers are reporting their AMPs.

Despite our efforts, some unscrupulous manufacturers continue to devise ways to defraud Texas Medicaid, and we are doing everything in our power to bring those companies to justice. Our current Texas Attorney General, Greg Abbott, has committed the resources of the agency to these efforts. Through his leadership and vision, we have obtained the funding to increase our staffing to 8 lawyers plus support staff. With this additional staffing, we will be pursuing every manufacturer that we find has engaged in this type of activity.

I would like to make clear that, while Texas is pleased to have recovered significant sums of money in these qui tam cases, litigation is not the most efficient way to run this system. The Texas VDP has been required to spend thousands of man hours responding to discovery requests and preparing for and attending depositions in our litigation. The program could have used our hard earned tax dollars to provide more and better services if VDP personnel were not tied up in litigation caused by manufacturers who game the system. In addition, without the help of relators like Ven-A-Care, who took great personal and financial risks to present their allegations, we would not have been able to obtain the significant recoveries in the DEY and Schering. We hope that you will ensure that, in whatever system implemented

in the future by Congress, the States and the Department of Justice continue to have laws with strong penalties to force compliance.

My time is about up. Thank you for your attention. I am happy to answer any questions.

Mr. WALDEN. Thank you very much, Mr. O'Connell. I want to thank all of the panelists. Your testimony has been very helpful in our process here.

Mr. Reinhart, I want to start with you with a question, because I think I heard you say in your testimony that Michigan updates its list of prices on a daily basis?

Mr. REINHART. For generic drugs, we do.

Mr. WALDEN. And how do you do that?

Mr. REINHART. Well, our agency has significant staff constraints, so we have hired an outside entity that also is a pharmacist, and they monitor the market, they—each of the distributors, and they will adjust prices accordingly. If a pharmacist—and we do this all over the Internet. So if a pharmacist indicates that they couldn't find the drug for that price, our consultant will send them back and tell them two places where they can get it.

Mr. WALDEN. And is this a nationwide service that you subscribe to, or is this a Michigan-only creation?

Mr. REINHART. This is a Michigan firm.

Mr. WALDEN. Do you know if they work in other States?

Mr. REINHART. Not to my knowledge.

Mr. WALDEN. All right. But you are able to update your pricing, then, on a daily basis?

Mr. REINHART. Well, we do that for generic drugs.

Mr. WALDEN. Right.

Mr. REINHART. We still have the more traditional—for brand-name drugs, we do use the average wholesale price.

Mr. WALDEN. And do you know what cost that is to the State to have that service, to utilize that service?

Mr. REINHART. It is minor. I think that component of—you know, I mentioned a $130 million savings. That component contributes about $40 million, and this service is less than a half a million.

Mr. WALDEN. Per year?

Mr. REINHART. It's very modest. Right.

Mr. WALDEN. Mr. Smith, why does it take CMS so long in some cases, as identified by Mr. Reeb and his colleague Mr. Vito, to update these lists when these generics come out? And how many people do you have dedicated and at what cost?

Mr. SMITH. Right now, there are about 700 drugs on the Federal upper limit. The last full update, I believe, was in 2001. We have updated on a specific basis when drugs come on. And it is not just one drug, but we have to assure that there are three.

Mr. WALDEN. Right.

Mr. SMITH. That is part of it. We have done 13 updates since 2001 to advise that these drugs would be put on the FUL.

I think part of the delay is waiting for three. Part of the intensity is that we actually have to go back and do a verification ourselves to make sure that those prices are indeed available at that price.

Mr. WALDEN. Would you admit that the system that's being used today or has been in use up until today simply isn't functioning as well as it should for the taxpayers?

Mr. SMITH. I would agree that we have done it on a historical basis, and it's time to update what we are doing and how we are doing it. And, as I said in my opening statement, a lot of our activity has been involved with providing other tools to the States. Obviously, this is an operational one. But we appreciate——

Mr. WALDEN. I know. But I go back to—I've read through the IG's draft report and the testimony today, and it just seems that the problem remains, despite repeated suggestions. And I am not picking on you, but it is just something we all need to get involved in and figure out from our end what we need to fix, and I think from CMS's end, specifically Fluoxetine—there were 8 or 9 generics in the market the day that the exclusivity period ended, and yet it took a considerable length of time to update the list. Right?

Mr. SMITH. Again, that update was our own verification that those prices——

Mr. WALDEN. And how long did it take to update?

Mr. SMITH. It took approximately a year to do that verification.

Mr. WALDEN. And do you know how much loss to the taxpayer occurred during that period?

Mr. SMITH. I have not calculated it.

Mr. WALDEN. Compared to if an update had been done quicker?

Mr. SMITH. I think this has shown us that we need to update our internal procedures.

Mr. WALDEN. One of the findings in the OIGs report—or recommendations—is that there is a new group of generics about to come onto the market that could have—there are substantial costs associated with them. And so it seems clear to me as a business owner that it is going to be important from a business standpoint that your agency be ready to go to put those on the upgraded list. What assurance can you give our committee that that will happen short of a year or 10 months?

Mr. SMITH. We are looking at that in itself and understand windows will be coming into the market, and we will move quickly. But again, it is incumbent on us to do that verification that they are available as well. But we will do that.

Mr. WALDEN. Do you need better notification from FDA when generics are going to come on the market? Do you get that today?

Mr. SMITH. I think we use the same resources that all purchasers have available to them. This information is available. We look at three different commercial products that are available just as other purchasers and insurers do as well.

Mr. WALDEN. I want to go to that. Mr. Reeb, Mr. Vito, maybe you can tell me. I am told that some of the big purchasers on the private side, on the insurance side, move pretty rapidly when generics come to market in terms of adjusting their price structures. Are you familiar with that?

Mr. VITO. We are not, sir.

Mr. WALDEN. Do you agree with what Mr. Smith says in terms of the problems associated with trying to update? I mean, I have read your recommendations. It seems like there is a real issue here in terms of being able to move swifter than we are; is that correct?

Mr. VITO. We believe there is a problem. We believe that it can be resolved by having a dedicated effort on CMS's part. We understand the amount of significant work that is involved in maintain-

ing the list, adding the products to the list and deleting them. But it is certainly manageable if the FTEs are applied to it, the resources are applied to it that are necessary. It is our estimation that if you put these resources to that goal, the savings to the program, both the Medicaid and the Federal Government, will far exceed the cost that you would——

Mr. WALDEN. That is what seems obvious to me is, wow, you are talking about literally hundreds of millions, if not billions of dollars, and we have got a big hole in the bucket draining out all those savings quickly. How difficult would it be to update this on a more timely basis? How many people do you think it would take?

Mr. VITO. In our estimation, I think that would be better answered by CMS. However we can say that if it is 1, 2, 3 FTEs, whatever those numbers are, the cost of those FTEs will be certainly outweighed by the savings that can be achieved to the program.

Mr. WALDEN. I want to make sure I am not mixing the proverbial apples and oranges here. Is the price updating information that Michigan is doing using this outside service comparable to what we are talking about for updating these lists?

Mr. VITO. I am not familiar with what Michigan is using. I could tell you, though, that it appears that they are doing more than just looking at the red book and the blue book and the MediSpan, the drug compendiums; is that correct?

So it would be different.

Mr. WALDEN. It would be different in terms of their resources to identify the prices?

Mr. VITO. I believe that the Medicaid program, they are required to use the drug compendiums to identify the lowest-priced product and then add 150 percent to that. I believe that is what CMS does.

Mr. WALDEN. Is that correct, Mr. Smith?

Mr. SMITH. That is correct. The rebate provision of the Medicaid law itself, established the parameters that we work with.

Mr. WALDEN. So that is where we need to come into focus here to fix that if that is indeed the problem.

Let me ask about the rebates AWP versus AMP because it looks like we are paying at one schedule and reimbursing based on a different price. Is that correct, Mr. Reeb and Mr. Vito?

Mr. REEB. We issued a report a couple of years ago exactly saying that. We estimated that about a billion dollars could have been saved over a 3-year period had the rebates been paid using AWP. We don't like AWP, but if you are going to reimburse under AWP, then it doesn't seem to make sense to us to have a rebate process that uses average manufacturers price. You are using two different sets of numbers to basically try to bring a little bit more——

Mr. WALDEN. So how much are we losing as a result of this mismatched pricing?

Mr. REEB. We estimated about a billion dollars for a 3-year period ending around 1997 or so, but we are updating the data presently, and it is at least that much in present day——

Mr. WALDEN. I would think with the growth in the percentage of Medicaid that is prescription drugs, it would be at least that, if not significantly more, when you look at the rapid escalation in costs in the last few years.

Mr. REEB. We believe—and again, we are not supporting AWP as necessarily being a good basis, but if you are going—most States use that in some form in their reimbursement process. Then, if in the rebate process you use that, it would at least bring another pressure point on the system, the industry, as to—if you are going to raise AWP, then you run the risk of making the spread greater to the best price which is how the rebate calculation uses those two sets of numbers.

Mr. WALDEN. And just quickly, in your report from a couple of years ago, you also looked at Oregon's Medicaid system and found that it wasn't operating appropriately and some $20 million in problems there. Do you know if they have responded in a positive way to your recommendations?

Mr. REEB. I don't know specifically, sir.

Mr. WALDEN. Okay. I will get back to you on that.

Mr. Stupak, I would like to turn to you now for 10 minutes.

Mr. STUPAK. Thank you, Mr. Chairman. I am sorry, most of this hearing I was in another hearing. But it is good to be here and to welcome Mr. Rinehart from Michigan. I did read your testimony.

A couple of questions, Mr. Rinehart, if I may. How much do you estimate that Michigan saves each year under the preferred drug list that you have been using?

Mr. RINEHART. It's difficult to precisely partition—the preferred drug list and the multi-State work hand in hand. I said it earlier that our pricing strategies save about $40 million. So this other component will be about $90 million.

Mr. STUPAK. Has anyone lost their prescription drug benefit as you saved this money?

Mr. RINEHART. No. No one has lost money.

Mr. STUPAK. Michigan has been very aggressive in cutting their Medicaid prescription drug costs, particularly in the generic area. Do you think that your maximum allowable cost or MAC is more aggressive than most States?

Mr. RINEHART. I think it is. I think the daily component and the use of technology to convey those prices to pharmacists is a little more aggressive.

Mr. STUPAK. The daily component, you said you MAC change your prices every day?

Mr. RINEHART. We do.

Mr. STUPAK. In your testimony you outlined how Michigan has benefited from prescription drug pooling purchase. The purchasing pool plan was approved in April; correct?

Mr. RINEHART. April 22.

Mr. STUPAK. Okay. And I know you have explained the clawback in your testimony as part of your Medicare prescription drug bill. Can you please briefly explain it again? Specifically what does it mean to Michigan, the clawback prevision in the Medicare bill?

Mr. RINEHART. Sure. States are required to help finance the drug benefit for dual eligibles. And our contribution will be calculated using our 2003 per person expenditures, per capita expenditures, inflated through 2006, and the index that most people cite, it's an 11 or 12 percent annual increase. And as I tried to argue earlier, our annual increases are below 5 percent currently because we have been so aggressive in managing the benefit. So even though

in 2006, when the declining percentage will pay 90 percent of that per capita amount, it is still more than we think we could have managed the benefit to because of our lower growth rates.

Mr. STUPAK. Sure. Because you are below that 11 percent, and making an assumption on 11, you are doing it at 4; therefore, you are going to have to pick up that 6, if you will?

Mr. RINEHART. Yes.

Mr. STUPAK. How does this compare to other items in Michigan's Medicaid budget?

Mr. RINEHART. The pharmacy expenditure line grew at a much lower rate than the balance of the program. I included a chart in my written testimony that shows the caseload. The caseload has dramatically increased in Michigan. So everything is growing, but this particular line grew at a rate somewhat below the balance of the program.

Mr. STUPAK. Is it fair to see that the clawback provision is going to cost Michigan about $30 million in 2007?

Mr. RINEHART. On a full-year basis, in 2007, $30 million State resources, yes.

Mr. STUPAK. What about other States? Do you have any idea what will happen there?

Mr. RINEHART. In talking to my colleagues, States that have been aggressive in constraining the growth in pharmacy spending, if they started in 2002, 2003, and I think it is likely they will also increase, my colleague from Ohio was talking about an $80 million figure.

Mr. STUPAK. So the States that have been aggressive in trying to provide prescription drug coverage underneath the Medicaid plan, but still trying to save taxpayers money underneath the so-called Medicare reform bill that was passed are actually going to be punished now with the clawback provision?

Mr. RINEHART. At least initially. The State percentage declines to 75 percent. So at some point, perhaps we will reach a break-even point, but certainly initially, we feel costs will exceed what we would have spent.

Mr. STUPAK. Mr. Balland, you are a much bigger State than Michigan. Do you agree with that that the clawback provision will cost States money, and if so, how much in your State?

Mr. BALLAND. Yes, sir. I do agree it will cost—the estimate in Texas, I am not certain what that figure is.

Mr. STUPAK. Mr. Rinehart, Michigan's annual increases in prescription drug expenditures are below the national average than the other States. So when you get to this clawback, the only thing we can do to relieve you of that is to repeal that part of the bill?

Mr. RINEHART. You could—I would have——

Mr. STUPAK. Are there any other ways you can think of——

Mr. RINEHART. You could accelerate immediately to the 75 percent.

Mr. STUPAK. As opposed to the 90?

Mr. RINEHART. As opposed to the 90. That would be very helpful. Or 100 percent.

Mr. STUPAK. 100 percent, I am sure, would be better. Let me ask you in a different area, Sunday there was an article in The New York Times that CMS has no plan for moving elderly nursing home

patients on Medicaid to the new Medicare drug benefit program, and that it is possible for these patients to select a drug card. How is Michigan going to do that, because that is that dual eligible again?

Mr. RINEHART. Sure. That is very important and we are very concerned about that. We are working hard. Michigan was one of the States that did receive a grant from CMS for education and outreach. Recently, I know Mr. Smith has indicated, that there will be an open enrollment period prior to December. But in December, States will be allowed for those that haven't selected—I think this is true—States would be allowed to automatically enroll beneficiaries into a card. So that at least should avoid an interval with no coverage, but it will be a fair amount of work.

Mr. STUPAK. Mr. Balland, do you care to comment on that aspect of it about selecting the card there?

Mr. BALLAND. I am sorry. Say that again, sir.

Mr. STUPAK. Sure. The article—I don't know if you saw it—in The New York Times this past Sunday. It was about that CMS has no plan for moving the elderly nursing home patients on Medicaid to the new Medicare drug benefit program, and that it is impossible for these patients to select drug cards. So how would Texas approach this? You have no longer dual eligibility underneath the Medicare reform bill that has passed.

Mr. BALLAND. No. And we would have to analyze that further to see exactly what the impact would be on Texas.

Mr. STUPAK. Mr. Reeb, if I can ask you a question. In a 2001 report on Medicaid's use of the average wholesale price, the OIG concluded that the reliance on the reported average wholesale price as a basis for drug reimbursement was fundamentally flawed and CMS said it would look for solutions. In its October 2003, report, the OIG recommended that CMS—and I am quoting now—"review the current reimbursement methodology, work with States to find a method that more accurately estimates pharmacies' acquisition costs and initiate a review of Federal Medicaid rebates." Did CMS ever do this?

Mr. REEB. I don't think any action, as such, directly has been taken, but I believe CMS has brought the issue up to the States as a part of normal operations. I don't believe, as such, a fundamental change in the process has a occurred yet, but perhaps, Mr. Smith——

Mr. STUPAK. I was going was going to say, Mr. Smith, could you comment on that? Can you tell us why CMS has not worked to develop a more accurate acquisition cost for the States to work with?

Mr. SMITH. I think we have provided updates to the full list. I think much of our attention has been on helping States find other ways, such as the purchasing pools and prior authorization, et cetera. So I think we have had a great deal of activity with the States in helping them to find ways to save money in the Medicaid program.

Mr. STUPAK. But the report which said it was fundamentally flawed really looked at CMS and the way the drug reimbursement was done, and they said it was fundamentally flawed, and you said you would look for solutions. Other than working with States have you come up with any solutions?

Mr. SMITH. Wgain, we have to work within a framework of making certain that there are at least three alternatives and to validate that they are available at those prices. That is an intensive process. And as I stated earlier, we are looking internally at how we can improve the way we do update the FUL on a quicker basis.

Mr. STUPAK. Yes. But the way you base it upon they said was fundamentally flawed. So even if you are doing all of this, unless you take care of the fundamental basis of it—I mean, is there any logic to States reimbursing on the average wholesale price while the rebates are actually based on the average manufacturing price, and that is not really shared with the States? So, I mean, where is the logic here?

Mr. SMITH. Mr. Stupak, in terms of that basis, that comes from Title XIX itself. That comes from the law wherein Congress established how we do it back in 1990, in terms of having those two different standards.

Mr. STUPAK. So wouldn't CMS recommend to the Congress having to change the law so you would have a real good basis, not an average wholesale price, but the average manufacturing price which would save everyone a lot of money?

Mr. SMITH. I believe we have twice put in the President's budget recommendations to address the pricing. On the pricing itself also I would like to——

Mr. STUPAK. But in the President's budget that won't change it unless we change the law.

Mr. SMITH. That is correct.

Mr. STUPAK. So shouldn't you really come to Capitol Hill and ask us to change the law on that so you could use the average price?

Mr. SMITH. Certainly Congress has to take that action itself.

Mr. STUPAK. Did CMS recommend that——

Mr. SMITH. We did not submit legislation, no.

Mr. STUPAK. Did you recommend that they do it in the Medicare reform bill last August?

Mr. SMITH. In Medicare, I believe it went to the average sales price instead. In terms of the consideration of changing Medicaid at the same time, I don't know to what extent that——

Mr. STUPAK. And we should do it for Medicare and Medicaid; right? We shouldn't have two different systems?

Mr. SMITH. We do have two different systems. We do have different systems on acquisition and in the rebate programs. I don't think that Medicare has the rebate program that Medicaid does. I know we have focussed a lot on the manufacture side, but I do want to at least bring to the subcommittee's attention, when you talk about AWP, it has an impact on the pharmacy as well. The pharmacy is being paid not only for its acquisition, but also storage and counseling the Medicaid patient as well. Most States price their purchase on an AWP minus 10 percent to AWP minus 15 percent but they also add on a dispensing fee. That dispensing fee has large variation among the States. So when you look at the price that a State says in its State plan, "This is what I want to reimburse our pharmacies for," they are looking not just at the cost of acquisition, but also counseling that Medicaid patient. Many argue that the Medicaid recipient needs additional time at the pharmacy,

and you are compensating the pharmacy for that as well. And in addition, again, how Medicaid differs——

Mr. WALDEN. I understand the gentleman has one more question.

Mr. STUPAK. Yes, one more question if I can. While I have you here, the CHIPS program, as you know, back on September 30, 2004, more than a billion dollars of funding under the CHIPS program was reverted back to Treasury. This money is money that States could have used for coverage. A number of States have insufficient funding this year, and over the next 3 years, more than 17 States are projected to have inadequate funds to cover their current children population. There is bipartisan legislation in the House and Senate to address this matter, but the way I understand it, the administration objected, publicly stating he wanted to spend the money to do more outreach instead. My question is if the State doesn't have enough money to cover the kids they currently cover, what good does it do to do more outreach to bring more people in a program when you don't have enough money to cover the kids to start with?

Mr. SMITH. Sure. First, the money that expired, that money expired when Congress created S-CHIP. We created it on the basis that States would have 3 years to spend their allotments. The authority to spend the money dated back to 1998, 1999, and 2000. That money was unspent because the States themselves didn't have enough kids covered so that they needed those resources.

In terms of 2005, Congress gave the Secretary the authority to redistribute unspent allotments. You are taking from one State that didn't use the money to give it to another State. That, in itself, we project and the States project, will be sufficient funding through the end of 2005, because you are adding that money plus 3 years of allotments including the new 2005 allotments.

In terms of the legislation that was introduced that was based on a formula, that formula, in itself, would have left States with shortfalls in the long term. It did not solve all the problems.

Mr. STUPAK. We are not saying it is going to solve all the problems. We are saying States that don't have enough money to cover the kids, we wanted the money—a bipartisan group wanted the money to go back to the States to cover kids. Instead, the administration said no, we are going to use it for outreach to bring more kids in the program. We don't have enough money to cover the kids in the program. Why bring more kids in? A lot of us saw it as sort of the way of administration saying we will give it to you next year but only if we can block grant the Medicaid program back to the States, which would leave the States even further underfunded.

Mr. SMITH. Well, I think what the President announced was that we should use money that the States themselves said "We aren't going to use this money based on coverage." The first step to increasing insurance is to actually enroll kids for programs they are already eligible for. And the second part of that was that Congress should come back and reauthorize the S-CHIP program. It has done great things. We are at record levels in coverage for kids and we want to do more.

Mr. WALDEN. Thank you, Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. WALDEN. I am going to turn now to the chairman of the full committee, Mr. Barton, for questions.

Chairman BARTON. Thank you, Mr. Chairman. Before I go into questions, I have got a point of personal privilege. I would like to introduce my wife, Terry Barton, who is right behind me; my district director, Ron Wright from Arlington, Texas; and his wife, Susan Wright. I introduce them to the committee. Just a little bit of a personal break.

I am going to direct most of my questions to our two friends from Texas who have testified. And I am going to start by reading part of the statement that Mr. O'Connell has already put into the record. On Page 3 of his statement he talks about some of the things that the State of Texas did in their investigation, and I am going to read a part of it and then ask Mr. O'Connell a question.

"the evidence that we discovered in our investigation shows that some manufacturers made conscious, deliberate business decisions to create enhanced spreads and to market the sale of their products based on these spreads.

For example, we found that some manufacturer engaged in the following practices: One, purposefully reported false and inflated prices to Texas Medicaid as well as to third-party price reporting services in order to create enhanced spreads; two, deliberately failed to report prices to certain classes of trade in violation of Texas law; three, instructed their sales personnel to market spreads to customers; four, created spreadsheets showing pharmacies how much more profit they can make off Medicaid when purchasing one product over another; five, tied sales personnel compensation to success in marketing the spread.

We also found that some manufacturers actually kept two sets of computer records with prices. One with inflated prices that are reported to the price reporting services like First DataBank or, in Texas's case, directly to the Medicaid program and another with real contract prices that are used in everyday business transactions with the manufacturers' customers." Mr. O'Connell, because of these results of the investigations that Texas attorney general's office found, what was the result of the lawsuits that were brought by the Texas Attorney General?

Mr. O'CONNELL. As I indicated earlier Mr. Chairman, so far we have collected $45.5 million, and that is more than twice the amount of what we believe were the damages incurred by the Texas Medicaid program. And in addition, we recovered the attorneys' fees and costs of the Attorney General as well as related——

Chairman BARTON. Are there any lawsuits that are still pending?

Mr. O'CONNELL. Yes. We have one still pending against Roxane Pharmaceuticals, which will be taking place in fall of 2005, and then we have also sued three other manufacturers: Abbott Laboratories, Braun/McGaw Pharmaceuticals, as well as Baxter.

Chairman BARTON. So the only lawsuits that have been concluded that the State of Texas has won, and you've got four other pending lawsuits?

Mr. O'CONNELL. And we have settled two. One with DEY Laboratories; one with Warwick, a division of Schering. And we have four others. And then Senator Cornyn, when he was Attorney General,

made clear that there were other investigations going on, and we are proceeding as quickly as we can with the staffing that we have.

MChairman BARTON. Is it reasonable to expect that the lawsuits that haven't been settled that are still pending, the outcome is going to be similar to what has already occurred?

Mr. O'CONNELL. We certainly expect so, yes, sir.

Chairman BARTON. That would be obvious—that is what I would think. What has Texas done to change its Medicaid system as a result of these same investigations? Have there been changes in the way Texas administers its part of Medicaid that deals with prescription drug reimbursement?

Mr. O'CONNELL. Absolutely. And Mr. Balland may be able to speak to it more than I. But I do know that because of the prices that we have found in our investigations, they have conducted audits, spent significant sums of money to conduct these audits, which I don't believe they should have had to do, in order to get the real pricing that the pharmacies and wholesalers are paying for these products. They then lowered the reimbursement rates in Texas for those particular prices. And in addition, and more importantly, the maximum allowable cost that was referred to earlier that Texas maintains in those MACs were lowered significantly as well. And in most cases, my understanding is the Texas MAC is significantly lower than the Federal upper limit that is currently in place.

Chairman BARTON. Mr. Balland, do you want to elaborate on the changes that Texas has made in its system?

Mr. BALLAND. Yes, sir. Thank you, Mr. Chairman. That is correct. We—75 percent of the time, Texas pays lower than the Federal upper limit. Also, we have refined the pricing methodology in the State to make it much more accurate. We also have three points that we feel makes the vendor drug program in Texas unique, and that is, No. 1, we have a pricing system that is proactive and transparent in determining the most accurate prices; No. 2, we have within our vendor drug program a formulary unit which is dedicated and focused to determining the most accurate of prices; and then No. 3, we are the only State that has a questionnaire that we require the manufacturers to answer with specific pricing points that help us refine those true prices.

Chairman BARTON. Is there any manufacturer or distributor that because of the changes that Texas has made or because of these lawsuits has chosen to not serve Texas? Has somebody backed out and said we don't want to play in that market anymore?

Mr. BALLAND. No.

Mr. O'CONNELL. Not only that, Mr. Chairman, the number of pharmacies that are participating in the Medicaid program have gone up over the last number of years instead of gone down.

There was one thing that the Medicaid program did that I think was particularly important, I think, and that is that a rule was passed requiring manufacturers to report their AMPs directly to Texas. The rule required that the AMPs maintain confidential—as you know, CMS gets those AMPs but they are not provided to the States. So far, only 16 percent of the manufacturers have complied with that rule and we have a problem when——

Chairman BARTON. The AMP is the average manufacturing product——

Mr. O'CONNELL. The actual manufacture price for the previous quarter, which would be akin to the average sale price that you have instituted in Medicare. Only 16 percent of the manufacturers have cooperated with us so far in that regard.

Chairman BARTON. I just want to recapitulate because I am about to run out of time. The Texas Attorney General, who is now the United States Senator from Texas, decided that there was reason to believe that fraud or corruption was occurring in the Medicaid program in terms of prescription drug payments in Texas; so he instigated an investigation that has so far resulted in several lawsuits being successfully concluded and the State and the Federal Government have recouped over $45 million. We have got 3 or 4 lawsuits that are currently pending. In addition, the State of Texas has changed the way it administers the Medicaid program. Because of those changes, there are significant cost savings. No provider has chosen not to provide so that so far it is a win-win for everybody in terms of honesty and good government.

My last question is, is there any reason to believe that some system similar to what the State of Texas has instigated would not work at the Federal level if we did something similar?

Mr. O'CONNELL. In my opinion, no. Obviously the concern that we have is Texas has spent a tremendous amount of money to institute this system, and I think most States, certainly the smaller States, probably don't have the funds to do that. And the more money you spend trying to get the number right, the less money you have to spend on your beneficiaries.

Chairman BARTON. But the two representatives from Texas think that what Texas is doing in a similar way, obviously would have to be massaged to some extent, could be used in other States?

Mr. BALLAND. Absolutely.

Chairman BARTON. All right. I want to ask Mr. Rinehart, who I think is from Michigan, do you agree with that? Do you think that what Texas is doing might be useful in Michigan?

Mr. RINEHART. Yes, I do.

Chairman BARTON. Mr. Smith, Mr. Reeb, Mr. Vito, do you all see any reason to believe that something similar to what we're doing in Texas couldn't be used at the Federal level and other State levels? Anybody?

Mr. SMITH. I think, Mr. Chairman, it goes back to part of the fundamentals of Medicaid. The Federal Government is working with upper limits and frameworks. You've heard two good examples today, of how the States themselves are involved in getting prices lower than what the Federal upper limits would have allowed. So that's the way Medicaid works.

Chairman BARTON. But I mean does anybody on this panel, before we turn it back because I have got about a minute left, fundamentally think we ought to just maintain the status quo? Is everybody in agreement that we ought to change the status quo and if it is necessary to do that by Federal statute that we ought to do that, we ought to actually change the Federal law? And I'm not saying we go to exactly what Texas is doing, but to go to some system that really is based on actual sales prices with auditing and

backup so that we have a transparency in the system so that anybody that has an interest can find out what's really going on? Is there anybody that disagrees with that? Let the record show that all the heads are saying they——

Mr. SMITH. I think everybody wants better than what we have.

Chairman BARTON. All right. With that, Mr. Chairman, I yield back the balance of my time.

Mr. WALDEN. The gentleman yields back the balance of his time.

The Chair now recognizes the gentleman from Michigan, Mr. Rogers.

Mr. ROGERS. Thank you, Mr. Chairman. I want to commend Chairman Barton for holding the hearing. One thing I have found through this whole process is when you look at the monumental occasion that happened here not so long ago, the first time ever under Medicaid trying to provide a prescription drug benefit, and hopefully apply some common sense, it was so big, we have some problems. And I know my good friend, Mr. Stupak from Michigan, was talking about why don't we fix the Medicaid portion of it. We're still trying to figure out if we exactly got reimbursement right for oncology, and we're really talking about pharmacies in the Medicaid and trying to figure that out. We still have issues that we have to work out. It is a complicated, complicated—too complicated obviously. I think we have decided that. Better transparency, better availability for information.

Mr. Rinehart, I want to congratulate you in the State of Michigan. You have been aggressive and you have certainly given credence to the old saying that no good deed goes unpunished, at least in the first couple of years. But I want to make sure we are comparing apples and apples. I think you have acknowledged that when it gets down to that 75 percent mark, that is going to be a true savings for Michigan that is in this bill.

And as I understand your numbers, you didn't add in that 28 percent subsidy that is being paid to a State like Michigan to its retiree benefits. So there is a big chunk of money that is being able to be applied to Medicaid or any other issue the State decides.

Mr. RINEHART. That is true. No, I did not. I just focussed on Medicaid——

Mr. ROGERS. So it's not really a true loss. What is really deceptive here is we have got the two best, I think, in the State. I think you are No. 1 and No. 2 for keeping your costs down. I have imagined if we put all the States in a hat and drew two out, we'd have a whole different story here about cost containment on Medicaid prescription drugs. This has kind of given us a bit of a distorted view on why we're at and I think why that formula was there.

I will offer you this commitment, that I will work with Chairman Barton to make sure that we institute at least a little fairness and not punish the States that have been aggressive about keeping their costs down. But I would caution that next year's an estimate for you. You've done a great job. You've come down. The numbers over the last few years were very impressive. That is wonderful. We just want to make sure that number continues, because it is a guess right now, and you are making a best guess, and we want to make sure we're accurate. We don't want to punish you for doing

great things, but we don't want to give you extra money for having a little bit of progress and falling back either.

So as you can imagine, with 48 States in the mix, it is pretty complicated for us to get to the right conclusion. These hearings are incredibly important for us to understand how we tweak this thing and make it better and more service-oriented, especially in cases exactly like this.

And just to CMS, I'll throw you under the bus. I am hoping—you've really enjoyed that today. I can tell by that expression and the sweat on your brow that you love that. I mean I hope that we are going to allow—and my understanding and reading of this and through staff consultations is that there is a little wiggle room that is not hard, fast, and certain, that CMS will have some ability to make some judgments to look at how their costs—how they're charging back on that clawback provision; is that correct?

Mr. SMITH. Offhand, I'm not certain what wiggle room you might be referring to. But I think overall, the way the State contribution, as we call it, is calculated, is off of a base year. Congress enacted this a year ago. They had to establish something as a base so 2003 was the calendar year that they used because that way the expenditures were what they were. It was set, instead of basing it on estimates. And then it was indexed by national health expenditures.

That, in itself, historically, is of benefit to States because the growth in prescription drugs in the Medicaid program is generally higher and historically higher than national health expenditures. So right off the bat, Congress provided a way for the States to save money by doing a lower rate of growth.

When you get States like Michigan and Texas that then have become more aggressive than what the national health expenditures have been, that is to the good on both sides because then they are saving that much money for the rest of the Medicaid program as well. So I don't see——

Mr. ROGERS. You mean projected growth sayings is what you are saying over time?

Mr. SMITH. Correct. Because they are saving that for the entire population, not just——

Mr. ROGERS. So even States like Michigan and Texas, and I heard Ohio mentioned, at the end of the day at the 10-year—they are all reaping rewards from this bill.

Mr. SMITH. Yes. They all, compared to the baseline, will be spending less than what they would be doing.

Mr. ROGERS. Which is a benefit. And, Mr. Rinehart, again, I congratulate what you are doing. I know in November you went to this outside contractor. I think that's a great way to do it. As I looked at it, and I would just be interested in your thoughts on it, but one of the immediate issues I guess that I looked at that raised my eyebrow was that you are only dealing with distributors. So there may be even a better way to do it. And I'm not condemning what you did. I think it's a great thing. But have you look at other ways to try to do that? Because you are contracting with a firm who is taking distributor prices. As you sat through the net and through other places, can you tell me cost savings, can you tell me a better way to do it?

Mr. RINEHART. The savings on this firm we estimate that about $40 million in 2004. I have learned a lot today about—we are dealing with a distributor, and there's a step before that that I think could be done. I don't know how Michigan could do it by itself, but get better pricing information at that level. We still use the average wholesale price for brand name drugs, and that's half of our spending. So any attempts to—any efforts to improve the accuracy of that, that would be very helpful as well.

Mr. ROGERS. I appreciate it. Mr. Smith, I just want to go back to this New York Times article, and I didn't get a chance to read the whole thing, but my understanding is they are not ineligible, they are just worried about their capacity in order to have access; is that correct?

Mr. SMITH. That's correct. Most definitely they are eligible, and most definitely they will be enrolled. The issue is really trying to take the overarching concept of competition among plans and applying it to a specialty market in long-term care. So, this is something that we believe we are making great progress on, and when the final rule is developed, I think people will see that the concern has been alleviated. But most definitely we are going to be auto-enrolling all these individuals who are dual-eligibles so they will become eligible and matching them up with a plan that will do what they do today for low-income seniors. It's kind of a specialty market with the long term-care pharmacy providers themselves and helping them to work with the plan sponsors, developing the product that will meet the needs of low-income citizens.

Mr. ROGERS. And as I understand it, please correct me if I'm wrong, but there was kind of a loose framework there under Medicaid that they hope will have a better management structure under Medicare, just getting an understanding of the cost. It doesn't mean it is going to diminish the services, doesn't mean it's going to diminish what they are certainly eligible for. But it is forcing us to go through an understanding of exactly how we implement it, which means we will have a better idea of what cost and what it truly and accurately costs us to take care of those patients.

Mr. SMITH. I think you are correct, yes, sir.

Mr. ROGERS. Is that correct?

Mr. SMITH. Yes.

Mr. ROGERS. So this isn't—we're not pulling a rabbit out of a hat. There is already a system under Medicaid. Now we have some transfer, some mechanism to Medicare; is that correct?

Mr. SMITH. That's correct.

Mr. ROGERS. So this isn't an insurmountable the sky is falling——

Mr. SMITH. We do not believe it is insurmountable at all. And we believe that we will come up with models that guarantee access and provide quality of treatment that people in nursing homes need at a competitive price. It's a specialty market and I think that when the final rule comes up people will be very pleased with what we come out with.

Mr. ROGERS. Thank you. I don't have too much further other than I just want to thank you so much. If we can be of any assistance as we move forward on this, again, I'd like to see States like Texas and Michigan get rewarded. Being that you are from Michi-

gan, it is easy to say I think all those other 48 ought to pay for the difference. I'm sure I have a lot of help here from that.

Mr. WALDEN. The gentleman's time has expired.

Mr. ROGERS. But we do appreciate—especially Oregon. We do appreciate your efforts. I think we need to be cautious sometimes about some of what we have heard from the State administration. At the end of the day, this will save Michigan money in a very large way. And I think it is counterproductive for this sparring, I think even with the administration, about the cost of this. There are some things that we can fix and make it better. Absolutely no doubt. And this is a good thing for Michigan and they will save significant amounts of money, and I look forward to working with you. Thank you, and I yield back.

Mr. WALDEN. I thank the gentleman from Michigan.

Mr. STUPAK. Mr. Chairman, in response to Mr. Rogers' questions, Mr. Smith said they have a plan that they have ready to fix this nursing home thing. Could he submit that to the committee for the record so we would have it so we can look at it.

Mr. WALDEN. I'm sure we can ask him for that.

Mr. STUPAK. This plan that you have in response to Mr. Rogers' questions?

Mr. SMITH. The final rule on how the long-term care pharmacies and the plan sponsors themselves will be working together to deliver the benefit.

Mr. STUPAK. But when you have that plan ready, could you submit it to the committee before the final rule?

Mr. SMITH. Before the final rule?

Mr. STUPAK. Yes.

Mr. SMITH. The proposed regs are already out. We are going through all the comments, et cetera, and expect to publish the final regs in early January.

Mr. STUPAK. Send those proposed rules up, would you please?

Mr. SMITH. The proposed, absolutely. Absolutely.

[The material referred to appears in the Federal Register of Tuesday, August 3, 2004, Parts II and III.]

Mr. STUPAK. Thank you.

Mr. WALDEN. Thank you. I'm going to dismiss this panel now. Thank you very much for your testimony and for your good work. It is most helpful in our committee's deliberations. We appreciate your sticking with us today. I know other committee members may have questions they may want to submit to you for a response along the way.

Now I would like to call forward our final panel of witnesses today. Mr. Edward H. Stratemeier, former Vice President and General Counsel of Aventis Pharmaceuticals; Ms. Pamela R. Marrs, Senior Vice President and CFO of DEY, Inc.; Ms. Lesli Paoletti, Roxane Laboratories, Inc.; Mr. Timothy Catlett, Senior Vice President of Sales and Marketing, Barr Laboratories, Incorporated; David Marshall, R.Ph., director of Category Management for Generics, CVS Corporation; John Ziebell, R.Ph., Category Manager for Pharmacy, Health & Wellness, Walgreen Company; and Frank Seagrave, Vice President of Pharmacy, Wal-Mart Stores, Incorporated.

You are all aware the committee is holding an investigative hearing and when doing so, has had the practice of taking testimony under oath. Do any of you have an objection to providing your testimony under oath? Let's start with Mr. Seagrave. Do you have any objection to——

Mr. SEAGRAVE. No.

Mr. WALDEN. Mr. Ziebell?

Mr. ZIEBELL. No.

Mr. WALDEN. Mr. Marshall?

Mr. MARSHALL. No.

Mr. WALDEN. Mr. Catlett?

Mr. CATLETT. We need one more chair.

Mr. WALDEN. If we can get you a chair, that would be helpful. We need one more chair at the witness table.

Ms. Paoletti, do you object?

Ms. PAOLETTI. I have no objections.

Mr. WALDEN. Ms. Marrs?

Ms. MARRS. No objection.

Mr. WALDEN. Mr. Stratemeier?

Mr. STRATEMEIER. No objection.

Mr. WALDEN. Okay. The Chair then advises you that under the rules of the House Rules Committee, you're entitled to be advised by counsel. Do any of you desire to be advised by counsel?

Mr. Seagrave? Counsel? Do you want to be advised by counsel?

Mr. ZIEBELL. Yes, I do.

Mr. WALDEN. You do? Could you identify your counsel, please?

Mr. ZIEBELL. Mr. Frederick Robinson. Mr. WALDEN. Mr. Frederick Robinson, right there. Okay. Mr. Marshall?

Mr. MARSHALL. No counsel.

Mr. WALDEN. Mr. Catlett?

Mr. CATLETT. Mr. Mark Young.

Mr. WALDEN. Mr. Mark Young. Okay, thank you.

Ms. Paoletti?

Ms. PAOLETTI. Yes. Ed Miller.

Mr. WALDEN. Ed Miller is your counsel.

Ms. Marrs?

Ms. MARRS. Yes. Paul Doyle.

Mr. WALDEN. Paul Doyle. And Mr. Stratemeier?

Mr. STRATEMEIER. No, your honor.

Mr. WALDEN. "Chairman" is okay, as opposed to "your honor."

[Witnesses sworn].

Mr. WALDEN. You're now under oath and you may give a 5-minute summary of your written statement.

I'm going to have Mr. Rogers take over the Chair for just a moment, but please proceed, and Mr. Stratemeier, we will begin with you. Thank you again for being here.

TESTIMONY OF EDWARD H. STRATEMEIER, FORMER VICE PRESIDENT AND GENERAL COUNSEL OF AVENTIS PHARMACEUTICALS; PAMELA R. MARRS, SENIOR VICE PRESIDENT AND CFO, DEY, INC.; LESLI L. PAOLETTI, ROXANE LABORATORIES, INC.; TIMOTHY P. CATLETT, SENIOR VICE PRESIDENT OF SALES AND MARKETING, BARR LABORATORIES, INCORPORATED; DAVID MARSHALL, DIRECTOR OF CATEGORY MANAGEMENT FOR GENERICS, CVS CORPORATION; JOHN ZIEBELL, CATEGORY MANAGER FOR PHARMACY, HEALTH & WELLNESS, WALGREEN COMPANY; AND FRANK SEAGRAVE, VICE PRESIDENT OF PHARMACY, WAL-MART STORES, INCORPORATED

Mr. STRATEMEIER. Thank you, Mr. Chairman, Members of Congress. My name is Edward Stratemeier. Until recently, I was senior Vice President of Aventis Pharmaceuticals. My responsibilities included legal matters, government relations, and public policy in North America.

Aventis is a global pharmaceutical company that has just been acquired by Sanofi-Synthelabo to form Sanofi-Aventis. As a result of that merger, I left the company. I'm here today at the committee's request as a private citizen. I understand that the purpose of today's hearing is to address issues relating to AWP-based reimbursement of prescription drugs under Medicaid.

I have been asked to discuss with the committee the policy positions developed by Aventis during my tenure with respect to AWP reimbursement for prescription drugs. And as much as I am no longer employed by Sanofi-Aventis, I cannot say whether the company still supports the policy positions taken during my tenure, nor can I speak to what the company will do in the future with respect to these matters. I joined Marion Laboratories, one of the predecessor companies of Aventis, in 1982. Over the past 20 years, I've been actively engaged in the prescription pharmaceutical industry as an attorney and a senior executive. It was in my capacity as head of government relations and public policy that I oversaw the development of Aventis's position on reimbursement for pharmaceuticals under Medicare and Medicaid.

The pharmaceutical industry has seen many changes since I joined Marion. The complexity, potency, and value of the products the industry develops have changed as had the entire distribution system for those products. One thing, however, has not changed: the reliance on AWP as a reimbursement benchmark by both government and private payors. To understand this reliance, one has to look back nearly 40 years. In the late 1960's, about the only people who did not pay for prescription drugs out of their own pockets were employees of the pharmaceutical companies and people who qualified for Medicaid.

Therefore, it fell to Medicaid to try to build systems to meet the task of paying for these drugs. I think it is important to remember that in the 1960's, a computer with as much computing power today as today's notebooks had not been built and would have filled an entire building. Medicaid needed simple manual systems. As a result, the concept of average wholesale price, or AWP, was created by the director of Medical, the California Medicaid Agency. The idea was that rather than having a pharmacist report what he had

paid to purchase a product and then going through some type of audit procedure to make sure that that was in fact the case, it would be administratively simpler to always pay the same amount for a given drug. At the time it was established, AWP was not intended to be what was actually paid by the pharmacist to the wholesaler, but it was a good surrogate for administrative efficiency.

Beginning in 1969, Medical reimbursed pharmacies for Medicaid patients' prescriptions by paying AWP plus a dispensing fee. As third-party coverage of prescription drug costs became more widespread by both government and private payers, the reliance on AWP became more invasive.

Let me fast forward through two of the major trends in the pharmaceutical industry that have made AWP a problematic reimbursement benchmark. These trends are consolidation in the wholesale drug industry and the rise of managed care, including pharmacy benefit managers. For branded prescription drugs, AWP typically reflects a 20 to 25 percent markup over the wholesale acquisition cost, the manufacturer's list price to wholesalers, also known as WAC. This markup roughly corresponded to the wholesalers' markup in early days of AWP. However, drug wholesalers have seen technological change that has dramatically increased the efficiency of scale in that industry. The change fostered incredible competition and led to consolidation of the industry. Three companies now account for over 90 percent of the wholesale drug business and they do it on gross margins of less than 5 percent. That means that an AWP that remains static at a 20 to 25 markup over WAC began to overstate the price paid by the retail pharmacist.

The 1980's saw the rise of managed care and PBMs. Whatever else they may have done, they forced big pharmaceutical companies to aggressively compete on price. They did this by limiting the number of drugs a drug plan would pay for and then negotiating with the manufacturers for rebates to be on the preferred known as a formulary. They also forced pharmacies to compete on price by requiring pharmacists to sign contracts if they wanted to serve the population covered by the plan.

I should point out that all of these agreements used AWP as a benchmark price. While these trends were occurring, there was tremendous pressure to maintain AWP at a fixed markup from WAC. AWP had been codified as the benchmark price by statute or regulation in the public sector and by contract in the private sector. As the difference between AWP and real prices paid by pharmacists and providers began to increase, that difference was used to compensate for lack of payment for services. A change in the current well-known relationship of AWP to WAC would have had far-reaching effects on the provision of health care services.

In 1990, Congress recognized that private sector payers were able to negotiate substantial discounts from pharmaceutical manufacturers. To take advantage of these negotiations for Medicaid, Congress included provisions in the Omnibus Budget Reconciliation Act, requiring pharmaceutical manufacturers to pay a rebate on Medicaid purchases that was based on the best price negotiated by private sector payers.

The 2002 policy document which was provided by Aventis to the committee reflects the result of an effort to point out the problems associated with relying on AWP benchmarking and government reimbursement of prescription drugs given the reality of the changed environments in which those products were used. It was Aventis's view that appropriate methodology needed to reimburse providers for the drugs they dispensed at or near their cost to acquire those drugs while also fully and appropriately paying them for the professional services they provided in connection with dispensing those products.

I appreciate the opportunity to appear before the committee today and would be happy to answer your questions regarding the use of AWP as a basis for reimbursement.

[The prepared statement of Edward H. Stratemeier follows:]

PREPARED STATEMENT OF EDWARD H. STRATEMEIER, ESQ.

Mister Chairman, Members of Congress, my name is Edward Stratemeier. Until recently I was Senior Vice President of Aventis Pharmaceuticals. My responsibilities included legal matters, government relations and public policy in North America. Aventis is a global pharmaceutical company that has just been acquired by Sanofi-Synthelabo to form Sanofi-Aventis. As a result of the merger I left the company.

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In the late 1960's, about the only people who did not pay for prescription drugs out of their own pockets were employees of pharmaceutical companies and people who qualified for Medicaid. Therefore it fell to Medicaid to try to build systems to meet the task. I think it is important to remember that in the 60's, a computer with as much computing power as today's notebooks had not been built and would have filled a large building. Medicaid needed simple manual systems.

As a result, the concept of Average Wholesale Price or AWP was created by the director of Medi-Cal, the California Medicaid Agency. The idea was that rather than having a pharmacist report what he had paid to purchase a product (and then going through some type of audit procedure to verify that he had truly paid such a price) it would be administratively simpler to always pay the same amount for a given drug. At the time it was established, AWP was not intended to be what was actually paid by the pharmacist to the wholesaler, but it was a good surrogate for administrative efficiency. Beginning in 1969, Medi-Cal reimbursed pharmacies for Medicaid patients' prescriptions by paying AWP plus a dispensing fee. As third party coverage of prescription drug costs became more widespread—both by government and private payers—the reliance on AWP became more pervasive.

Let me fast-forward through two of the major trends in the pharmaceutical industry that have made AWP a problematic reimbursement benchmark. These trends are consolidation in the wholesale drug industry and the rise of managed care including Pharmacy Benefit Managers (PBM's.)

For branded prescription drugs, AWP typically reflects a 20% to 25% mark up over the Wholesale Acquisition Cost (the manufacturer's list price to wholesalers also known as WAC.) This mark up roughly corresponded to the wholesaler's mark up in the early days of AWP. However, drug wholesalers have seen technological change that has dramatically increased the efficiency of scale in that industry. That

change fostered incredible competition and led to consolidation of the industry. Three companies now account for over ninety percent of the wholesale drug business and they do it on gross margins of less than five percent. That means that an AWP that remained static at a twenty to twenty-five percent markup over WAC began to overstate the price paid by the retail pharmacist.

The 1980's saw the rise of managed care and PBM's. Whatever else they may have done, they forced big pharmaceutical companies to aggressively compete on price. They did this by limiting the number of drugs that a drug plan would pay for and then negotiating with the manufacturers for rebates to be on the preferred list (known as a formulary.) They also forced pharmacies to compete on price by requiring pharmacists to sign contracts if they wanted to serve the population covered by the plan. I should point out that all of these agreements used AWP as the benchmark price.

While these trends were occurring, there was tremendous pressure to maintain AWP at a fixed markup from WAC. AWP had been codified as the benchmark price, by statute or regulation in the public sector and by contract in the private sector. As the difference between AWP and the real prices paid by pharmacists and providers began to increase, the difference was used to compensate for lack of payments for services. A change in the current, well-known relationship of AWP to WAC would have far reaching effects on the provision of health care services.

In 1990, Congress recognized that private sector payers were able to negotiate substantial discounts from pharmaceutical manufacturers. To take advantage of these negotiations for Medicaid, Congress included provisions in the Omnibus Budget Reconciliation Act requiring pharmaceutical manufacturers to pay a rebate on Medicaid purchases that was based on the "Best Price" negotiated by private sector payers.

In 2001, the Office of the Inspector General of the Department of Health and Human Services and the General Accounting Office both issued reports that found that Medicare providers were paying substantially less than AWP to obtain the drugs they dispensed to patients and recommended government reimbursements to providers for drugs be brought more in line with acquisition costs. As committee staffs were considering the question, Aventis met with them to recommend adopting acquisition cost as the amount for reimbursement. This recommendation was formally adopted by Aventis management in 2002.

The 2002 Aventis policy document, which was provided by Aventis to the Committee, reflects the result of an effort to point out the problems associated with relying on AWP benchmarking in government reimbursement of prescription drugs given the realities of the changed environment in which those products are used. It was Aventis' view that an appropriate reimbursement methodology needed to reimburse providers for the drugs they dispensed at or near their cost to acquire those drugs, while also fully and appropriately paying them for the professional services they provided in connection with dispensing those products.

I appreciate the opportunity to appear before the Committee today, and will be happy to answer your questions regarding the use of AWP as a basis for reimbursement.

Mr. ROGERS [presiding]. Thank you for your testimony.

Ms. Marrs.

TESTIMONY OF PAMELA R. MARRS

Ms. MARRS. Good morning, Mr. Chairman and distinguished members of this committee. Thank you for the opportunity to appear before you today.

For the past 15 years, I have been the Chief Financial Officer of DEY LP. Founded in 1978 and located in Napa California, DEY is a specialty pharmaceutical company focused on the development, manufacturing, and marketing of prescription drugs for the treatment of respiratory diseases and respiratory-related allergies. In addition to our facility in Napa, we also have a distribution center in Allen, Texas.

Last year Congress and the administration took important steps to reform and improve Medicare reimbursement policy when it passed the Medicare Modernization Act. As you know, the system of reimbursement using a percentage of AWP badly needed to be

reformed and many in the pharmaceutical industry including DEY supported reform. Medicaid reimbursement has typically had a spread between the cost of the drug paid by the provider and the reimbursement amendment. That spread goes to the provider, not to the manufacturer. Until the mid 1990's, my understanding is that it was not unusual for salespeople when speaking to customers to compare their spreads with those of their competitors. Beginning in the late 1990's as a result of litigation, government investigations, and the OIG compliance program guidance, my understanding is that the industry has become sensitive to this practice and has largely stopped. At DEY we have developed and implemented a major compliance program over the last few years designed to ensure that our sales force is compliant with the OIG guidance.

Is the spread still meaningful to providers? Yes. Because they often depend on the spread to cover their cost of dispensing which often exceeds the dispensing fees they receive from Medicaid.

How does DEY set AWP for generics? At DEY, our historical practice for generic drugs has been to set the generic AWP as a percentage off of the brand's AWP when the product is launched. Usually that percentage has been around 10 percent. After that, our practice has been not to change AWP on generics.

Why doesn't DEY lower its AWP on generic drugs? The simple answer is that given the system that now exists, our customers won't buy from us if we lower our AWP. This was confirmed about a year and a half ago when a reporting service lowered their published AWP for our drugs without consulting. Our customers told us they would stop buying from us with the lower AWP. This could have put many of our employees out of work overnight. So we went to court and the court issued a temporary restraining order.

Why do we need AWP at all? At this point the current system is based on AWP, and customers rely on it and won't buy a product without it. As evidence of this, about 2 years ago, because of the litigation, we tried to market a new drug with no AWP. Our customers said they would not buy it. So we set an AWP which happened to be lower than those of our competitors. As a direct result of this lower AWP, we sold almost nothing of a drug for which we had projected to have sales of $6 million.

These experiences taught us that reimbursement reform has to come from the government and be applied to the whole industry. If a generic company, especially a small one like ours, tries to buck the AWP system on its own, it can being be forced out of a whole business line.

Do our profits on generic drugs increase as the spread increases? In DEY's case, the answer is no. First, it is important to keep in mind that the drugs manufacturers don't get the money from the spread. The money realized from the spread goes to providers. Second, in the case of generic drugs, a larger spread actually means a lower profit for the manufacturer.

Because generic drugs are a commodity, price competition is fierce. If the spread for a particular generic drug is getting larger, it almost always is because AWP is remaining the same while the actual selling price is getting lower. At the same time, our costs are increasing and our margins declining. This situation has shown

dramatically in the case of Albuterol, which has been repeatedly cited in CMS reports as having some of the largest spreads of any drug. For the last 10 years, the spread on Albuterol, which is one of DEY's biggest generic products in terms of volume, has been getting larger and larger as the price drops because of competition.

Have our profits increased as the spread has grown? No. At the current time, we are actually close to breaking on Albuterol due to the continuing erosion of the market price.

As I said at the outset, I am the Chief Financial Officer of DEY. I have held that position since 1989. Most of the documents I was asked about and my staff interview or that came to me afterwards came out of our sales and marketing department, and with some exceptions where I was copied or was the addressee, I saw them for the first time during this litigation. Having said that, I hasten to add that I have learned a lot about AWP in these documents from the litigation and I will try to be as helpful as I can when answering questions. Thank you for your time and I'd be pleased to answer any questions.

[The prepared statement of Pamela Marrs follows:]

PREPARED STATEMENT OF PAMELA MARRS, CHIEF FINANCIAL OFFICER, DEY, LP

Good morning, Mr. Chairman and distinguished members of this Committee. Thank you for the opportunity to appear before you today. For the past 15 years, I have been the Chief Financial Officer of DEY, L.P. Founded in 1978 and located in Napa, California, DEY is a specialty pharmaceutical company focused on the development, manufacturing and marketing of prescription drug products for the treatment of respiratory diseases and respiratory-related allergies. In addition to our facility in Napa, we also have a distribution center in Allen, Texas.

Last year Congress and the Administration took important steps to reform and improve Medicare reimbursement policy when it passed the Medicare Modernization Act.

As you know, the system of reimbursement using a percentage of average wholesale price, or AWP, badly needed to be reformed and many in the pharmaceutical industry, including DEY, supported reform.

Medicaid reimbursement has typically had a spread between the cost of the drug paid by the provider and the reimbursement amount. That spread goes to the provider, not the manufacturer. Until the mid 1990's, my understanding is that it was not unusual for sales people, when speaking to customers, to compare their spreads with those of their competitors. Beginning in the late 1990's, as a result of litigation, government investigations and the OIG Compliance Program Guidance for Pharmaceutical Manufacturing issued in 2003, my understanding is that the industry has become sensitive to this practice and it has largely stopped. At DEY, we have developed and implemented a major compliance program over the last few years designed to ensure that our sales force is compliant with the OIG Guidance.

We have also seen many changes on the government side that are reducing the emphasis on AWP. Last year's Medicare law will, by 2006, virtually eliminate AWP as a basis for Medicare reimbursement under Part B. The new Medicare Part D drug benefit will not use AWP as a basis for government payment for drugs. So, both by industry practice and government action, the situation is changing.

Is the spread still meaningful to providers?

Yes, because they often depend on the spread to cover their costs of dispensing, which often exceed the small dispensing fees they receive from Medicaid.

How does DEY set AWP for generics?

At DEY, our historical practice for generic drugs has been to set the generic AWP as a percentage off of the brand's AWP when the product is launched. Usually that percent has been about 10%. After that, our practice has been not to change AWP on generics.

Why doesn't DEY lower its AWP on generic drugs?

The simple answer is that, given the system that now exists, our customers won't buy from us if we lower our AWP. This was confirmed about a year and a half ago when a reporting service lowered their published AWP for our drugs without consulting us. Our customers told us they would stop buying from us with the lower

AWP. This could have put many of our employees out of work overnight. So we went to court and the court issued a temporary restraining order stopping the service's action.

Why do we need an AWP at all?

At this point, the current system is based on AWP and customers rely on it and won't buy a product without it. As evidence of this, about two years ago, because of the litigation, we tried to market a new drug with no AWP. Our customers said they wouldn't buy it so we set an AWP which happened to be lower than those of our competitors. As a direct result of the lower AWP, we sold almost nothing of a drug for which we had projected to have sales of $6 million. These experiences taught us that reimbursement reform has to come from the government and be applied to the whole industry. If a generic company—especially a small one like ours—tries to buck the AWP system on its own, it can be forced out of whole business lines.

Do our profits on generic drugs increase as the spread increases?

In DEY's case, the answer is no.

First, it is important to keep in mind that the drug manufacturers don't get the money which comes from the spread. Money realized from the spread goes to the providers.

Second, in the case of generic drugs, a larger spread actually means a lower profit margin for the manufacturer. Because generic drugs are a commodity, price competition is fierce. If the spread for a particular generic DEY drug is getting larger, it is almost always because the AWP of the drug is remaining the same, while the actual selling price is getting lower. At the same time, our costs are increasing and our margins are declining.

This situation is shown dramatically in the case of albuterol, which has been repeatedly cited in CMS reports as having some of the largest spreads of any drug.

For the last ten years, the spread on albuterol, which is one of DEY's biggest generic products in terms of volume sold, has been getting larger and larger as the price drops because of competition. Have our profits increased as the spread has grown? No. At the current time, we are close to breakeven on albuterol due to continuing erosion of the market price.

Why doesn't the industry get together and agree on a solution to the AWP problem?

It is not within the purview of the industry to make such a change. We at DEY are anxious to provide information and assistance so we can help the government bodies that will effect such changes. We have provided written comments on multiple occasions to CMS as that body has worked toward reform of the current AWP-based system in an effort to assist with this process.

As I said at the outset, I am the Chief Financial Officer of DEY. I've held that position since 1989. Most of the documents I was asked about in my staff interview or afterwards came out of the sales and marketing department and, with some exceptions where I was copied or was the addressee, I saw them for the first time during the litigation.

Having said that, I hasten to add that I have learned a lot about AWP and these documents from the litigation and I'll try to be as helpful as I can in answering your questions about them. q

Thank you for your time. I would be pleased to answer any questions you may have.

Mr. WALDEN. Thank you, Ms. Marrs. We appreciate you being here.

Ms. Paoletti. Thank you.

TESTIMONY OF LESLI L. PAOLETTI

Ms. PAOLETTI. Mr. Chairman and members of the subcommittee, my name is Leslie Paoletti. I am appearing today on behalf of Roxane Laboratories, where I am senior product manager. I am here today at your request to assist you in your efforts to examine Medicaid reimbursement.

Roxane is a leader in the development, manufacture and marketing of generic pharmaceutical products. We are proud to produce medicines that extend and improve the quality of patient lives while reducing reliance on more expensive alternative treatment

options, including hospitalization stays, invasive medical procedures, and more expensive prescription products. We are committed to continuing to provide lower cost pharmaceuticals to meet the health care needs of Americans.

As you know, Roxane is one of 26 manufacturers from whom the subcommittee requested documents in connection with its investigation into reimbursements and rebates under Medicaid. Roxane voluntarily produced several thousand pages of documents and provided witnesses for informal interviews on two separate occasions.

Roxane understands the importance of the congressional oversight process in determining the need for, and establishing a basis for, legislation improving the Medicaid system. We therefore agreed to the subcommittee's request that we appear today to answer any questions on which members believe we can provide useful information.

We have been advised that the Energy and Commerce Committee may develop legislative recommendations to reform Medicaid reimbursement policies, which we understand currently are established on a State-by-State basis under a variety of complex formulas. As you know, as a manufacturer of multisource products, our revenues come exclusively from purchases by our customers who, in turn, sell to parties or patients. We do not sell prescription pharmaceutical products directly to patients, nor do we receive any payments from Medicaid. However, we would support any effort by Congress to bring greater efficiencies and simplicity to the system, including much-needed guidance from the government.

We believe any reform should maintain an incentive for using generic drugs and ensure that an appropriate and viable economic framework remains in place for health care providers to serve patients.

I would be pleased to answer any of the questions on issues you have identified and on the materials we have previously provided to you. Roxane looks forward to working with you as you address these issues.

[The prepared statement of Lesli L. Paoletti follows:]

PREPARED STATEMENT OF LESLI L. PAOLETTI, ROXANE LABORATORIES, INC.

Chairman Barton and Members of the Subcommittee, my name is Lesli Paoletti. I am appearing today on behalf of Roxane Laboratories, Inc., where I am Senior Product Manager. I am here today at your request to assist you in your efforts to examine Medicaid reimbursement.

Roxane is a leader in the development, manufacture and marketing of generic pharmaceutical products. We are proud to produce medicines that extend and improve the quality of patient lives while reducing reliance on more expensive alternative treatment options, including hospital stays, invasive medical procedures, and more expensive prescription products. We are committed to continuing to provide lower cost pharmaceuticals to meet the health care needs of Americans.

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I would be pleased to answer any questions on the issues you have identified and on the materials we previously have provided to you.

Roxane looks forward to working with you as you address these issues.

Mr. WALDEN. Thank you for being here today.

Mr. Catlett, thank you for being here.

TESTIMONY OF TIMOTHY P. CATLETT

Mr. CATLETT. Thank you, Mr. Chairman and members of the subcommittee. I am Tim Catlett, Senior Vice President of Sales and Marketing of Barr Laboratories. We are a leading manufacturer of generic pharmaceuticals.

Mr. Chairman, I know that you and others want to reduce the cost of prescription drugs for Medicaid patients. Your goal and Barr's business objectives are well aligned. Barr's generic drug business is designed to offer the same medicines as branded companies, but at a lower cost.

The products we manufacture and sell are mostly in tablet and capsule form. They are dispensed to patients by others, not Barr. Barr does not receive reimbursements under Medicaid.

Like other generic manufacturers, Barr does offer a vehicle for reducing Medicaid costs. When a pharmacy dispenses a generic drug to a Medicaid patient, the reimbursement to Medicaid is usually lower, and often substantially lower, than it would be for a branded product. In that way, promoting the use of generic products helps to reduce Medicaid costs. For any drug reimbursement system, providing incentives to pharmacies to dispense generic drugs is vital to achieving cost reductions.

Generic drugs, by definition, are second to market, not first. Pharmacies must be convinced to stock and dispense our products as the alternative to a branded product which has been on their shelves for years. If the drug reimbursement systems, including Medicaid, do not create incentives to dispense generic drugs, substantial cost savings will be lost.

I know the subcommittee has questions about AWP, or average wholesale price. As HHS found years ago, AWP does not represent an actual wholesale price or an average of actual prices. Instead, as set out in my written testimony, AWP is simply a publicly available reference price.

Many drug reimbursement systems, including some State Medicaid agencies, use AWP in certain instances as a reference point to calculate reimbursement levels for those who dispense drugs to patients. Because they recognize that AWP is not an actual acquisition price, these agencies reimburse at a percentage off AWP.

If a generic manufacturer lowered its AWP unilaterally in a multisource generic environment, pharmacists might choose to dispense a competitor's generic product.

I would be pleased to answer any questions the subcommittee may have, and thank you for your consideration.

[The prepared statement of Timothy P. Catlett follows:]

PREPARED STATEMENT OF TIMOTHY P. CATLETT, SENIOR VICE-PRESIDENT OF SALES AND MARKETING, BARR LABORATORIES, INC.

Mr. Chairman, thank you for inviting me to testify today. My name is Tim Catlett, and I am Senior Vice-President of Sales and Marketing at Barr Laboratories, Inc. Barr is pleased to have the opportunity to answer any questions the Subcommittee may have on the company's role as a manufacturer of generic pharmaceuticals in the context of the Medicaid program.

I would like to make two key points:

First, Barr is in business to offer its customers the *same* medicines as brand name drug manufacturers but at a significantly *lower* cost, and we do. As a result, when Medicaid patients receive a generic prescription product, they receive the same medicine as the counterpart branded product, but at a cost to the Medicaid system that usually is substantially lower.

Second, Medicaid and other prescription drug reimbursement programs should encourage the maximum utilization of lower-cost generic drugs. Any proposed changes must be carefully examined to ensure that they include appropriate incentives for pharmacies to stock and dispense generic products.

AN INTRODUCTION TO BARR LABORATORIES, A GENERIC PHARMACEUTICAL MANUFACTURER.

Barr is one of America's leading manufacturers of generic drugs.[1] A generic drug is a product determined by the Food and Drug Administration ("FDA") to contain the same active ingredients, and provide the same therapeutic value, as its brand-name counterpart. The FDA bases its sameness determination on detailed scientific criteria, including clinical studies. These criteria include showing that the generic product is pharmaceutically equivalent to the branded product (*i.e.*, contains the same amount of the same active ingredient); and that the generic product is bioequivalent to the branded product (*i.e.*, has the same rate and extent of absorption in the human body).

When the FDA determines that a generic product is therapeutically equivalent to its branded counterpart, the FDA grants the generic what is called an "AB" rating. The rating means that the generic product is interchangeable with the branded counterpart. Once an AB rating is granted, the generic product can be substituted for the brand at the pharmacy level, even in response to a prescription written for the branded product, unless the physician writes "dispense as written." When a pharmacy dispenses a generic prescription product to a Medicaid patient, the pharmacy provides the patient with the same medicine as the branded product, but usually at a significantly lower cost to the Medicaid system.

Barr's generic pharmaceutical research, development, and marketing efforts focus on specialty products that are difficult to manufacture or otherwise require our unique development skills. Often, Barr makes available the first low-cost generic alternative for a pharmaceutical product, either by developing generic pharmaceuticals to compete with branded drugs no longer under patent, or by challenging patents on branded products under the Hatch-Waxman Act when those patents appear to be invalid, unenforceable, or not infringed by our product.[2]

Patent challenges brought by generic manufacturers under the Hatch-Waxman Act have resulted in $27 billion in prescription drug cost savings.[3] Barr brought several of these cost-saving patent challenges, including the one that resulted in the first marketing of a lower-cost generic form of Prozac more than two years prior to patent expiry. When Barr successfully develops a generic substitute, other manufacturers are thereby encouraged to bring generic products to market when allowed by law. The resulting vigorous generic pharmaceutical competition brings even lower prices and greater cost-savings for consumers and their insurers.

Currently, Barr manufactures and distributes more than 70 generic products in core therapeutic categories, including oncology, female healthcare (including hor-

[1] More information about Barr and its role in the development of the generic drug industry can be found at http://www.barrlabs.com.

[2] Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 (1999 & Supp.).

[3] *See* Kathleen D. Jaeger, Presentation to the HHS Task Force of Drug Importation, April 5, 2004, *available at* http://www.gphaonline.org/policy/pdf/2004-04-05-testimony.pdf.

mone therapy and oral contraceptives), cardiovascular, anti-infective, pain management, and psychotherapeutics. All of Barr's generic products are in tablet, capsule or oral suspension dosage form. We do not sell our generic pharmaceutical products directly to physicians or their patients. Rather, our "customers" for these products are pharmaceutical wholesalers, who in turn sell to pharmacies; large chains with distribution centers and pharmacy operations; mail-order pharmacies; federal, state, and local government institutions; and managed care organizations. Our customers then either dispense our products to patients or sell our products to pharmacies, which then dispense our products to patients pursuant to prescriptions written by physicians.

The growth of generic pharmaceutical manufacturers over the last thirty years has resulted in substantial prescription drug cost savings for consumers, private insurers, and public insurers. For example, during the third quarter of 2004, the average prescription cash price to a consumer of a branded pharmaceutical medication was $97.52, as compared with an average price of only $26.35 for a generic prescription.[4]

Congress and federal agencies recognize that use of generic pharmaceuticals should continue to be promoted, given the magnitude of savings that already have been realized. According to the Centers for Medicare & Medicaid Services ("CMS"), generic substitution is a "best practice" for lowering prescription drug costs.[5] When Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, Title IX §§1101-1104, it closed loopholes in Hatch-Waxman that delayed the development and marketing of generic products. According to the Congressional Budget Office, these statutory reforms "would accelerate the availability of generic versions of prescription drugs" and "result in lower total drug spending within the United States by $7 billion over the 2004-2013 period."[6]

Pharmaceutical Price Data.

Brand and generic manufacturers provide pricing data to independent publishers, including Red Book, First DataBank, and others, which compile the data for drug manufacturers, wholesalers, retailers, and third-party payors, including state governments and the federal government. These data are used as reference points for numerous purposes, including calculating reimbursement levels under Medicaid and other public and private health insurance programs.

Average Wholesale Price. It is generally known in the pharmaceutical industry and related government agencies that average wholesale price ("AWP") is a reference price only, and does not represent the actual selling price charged by a manufacturer for its products. The Department of Health and Human Services has repeatedly recognized that AWP does not reflect an actual wholesale price.[7] A recent General Accounting Office report confirms that "AWP is not necessarily the price paid by a purchaser," and that it is "often described as a 'list price' [or] 'sticker price.'"[8] A generic manufacturer typically establishes the AWP for the generic product at 90% of the corresponding brand AWP.

Wholesale Acquisition Cost. Wholesale acquisition cost ("WAC") is the price that wholesalers and distributors pay on the invoice for a given product, although discounts may be provided after invoice, for prompt-pay or periodic volume purchasing incentives, or as rebates.

Average Manufacturer Price. Average manufacturer price ("AMP") is the average per tablet price for a product sold to a CMS-designated class of purchasers including wholesalers, retail chains, and mail order pharmacies for resale in the retail pharmacy market after all discounts and rebates to customers are taken into account. Manufacturers report AMP to CMS on a quarterly basis. For generic products, the manufacturer then pays a unit rebate amount of 11% of the AMP to the state Medicaid programs based on utilization of the product by each state Medicaid program.

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[4] IMS Health, National Prescription Audit, November 2004.

[5] Centers for Medicare and Medicaid Services, Safe and Effective Approaches to Lowering State Prescription Drug Costs: Best Practices Among State Medicaid Drug Programs, *available at* http://www.cms.hhs.gov/medicaid/drugs/strategies.pdf.

[6] *See,* Congressional Budget Office, Analysis of Changes to the Hatch-Waxman Act, August 27, 2003, *available at* http://www.cbo.gov/ftpdocs/45xx/doc4513/Hatch-WaxmanLtr.pdf.

[7] *See* Report, Title XIX of the Social Security Act, Limitation on Payment or Reimbursement for Drugs, Medicaid Transmittal No. 84-12, *reprinted in* Medicare & Medicaid Guide (CCH0 ¶34,157, at 10,193 (Sept. 1984); Report, Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program, A-06-89-0037 (Oct. 1989), reprinted in Medicare & Medicaid Guide (CCH) ¶38,215 (1990).

[8] United States General Accounting Office, Report to Congressional Committees GAO-01-1118, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost,* 9 (September 2001).

States can readily calculate AMP for a generic product from the unit rebate data they receive from CMS.

Prescription Reimbursements Under Medicaid.

Pharmaceutical manufacturers, including Barr, do not seek or receive any reimbursements under the Medicaid program. It is pharmacies that are reimbursed, under the contracts they negotiate with state Medicaid agencies, for the Medicaid prescriptions they fill.

Because CMS "note[s] the shortcomings of using AWP as a basis for reimbursement," the agency has agreed to "strongly encourage states to reevaluate their reimbursement methodology for drugs' and to "continue to encourage states to look for an alternate basis for reimbursement."[9] Despite these admonitions, many States, like many private insurers, choose to use AWP to establish the reimbursement formula for Medicaid prescriptions that they negotiate with retailers during each contract period. Notably, these formulae usually subtract a percentage "off" of AWP (different States negotiate different percentages), reflecting the understanding that AWP is a reference price.[10]

CMS can and sometimes does cap the reimbursement of Medicaid prescriptions with a Federal Upper Limit ("FUL"). Because CMS does not always move to set a FUL when additional competitors enter the market, thirty-eight states have established maximum allowable cost ("MAC") programs to cap reimbursement under Medicaid even absent a FUL. As soon as a FUL or a MAC is set, other reimbursement methods and reference price data—including AWP and WAC—diminish in significance.

THE IMPORTANCE OF INCENTIVES FOR GENERIC DRUG USE

In order for Barr and other generic manufacturers to continue providing these dramatic cost-savings, generic medicines must be stocked and dispensed by pharmacies. As a practical matter, wholesalers, drug chains with distribution centers, and pharmacies stock or maintain access to essentially all branded pharmaceutical products. If a physician writes a prescription for a branded product for which no generic exists, or if a physician writes "brand medically necessary," the pharmacy must be able to dispense the branded product.

Because a full catalogue of brand products already must be stocked or accessible, pharmacies incur extra costs when they stock any generic products. Consequently, pharmacies must have an economic incentive to carry and dispense generic products. Such an incentive exists when the pharmacy can purchase the generic product for sufficiently less than the branded product and then dispense the generic product at a lower price than the branded product and still make a "profit" on the generic product that is greater than the pharmacy could make on the branded product. If the profit to the pharmacy is greater on the branded product than on the generic product, the pharmacy is not likely to stock or sell the generic product. Moreover, because prices on generic products are almost always lower than prices on the equivalent branded products, third-party payors (including Medicaid) will almost always pay a lower reimbursement amount for the generic product even though the pharmacy makes a larger "profit" on that generic product.

As long as Medicaid agencies or other third party reimbursers continue to use AWP-based reimbursement systems, AWP could be a factor in a pharmacy's decision as to which generic manufacturer's product to purchase and dispense. If a generic manufacturer unilaterally reduced its AWP for a given product relative to the AWPs of other generic manufacturers for the same product, pharmacies would have an incentive to purchase another manufacturer's drug that did not reduce its AWP.

If any changes to Medicaid prescription reimbursement are considered, these changes must maintain Medicaid's practice of promoting the use of lower cost, therapeutically equivalent, generic drugs by providing pharmacies with financial incentives to carry and dispense generic drugs.

Barr's Fluoxetine Product.

Barr incurred millions of dollars in costs and years of patent infringement litigation in order to bring a low-cost Prozac substitute to market. When Barr ultimately prevailed in the litigation, we were entitled to 180 days of exclusivity for our

[9] Letter from Thomas A. Scully, Administrator to Janet Rehnquist, Inspector General (March 7, 2002) (Commenting on Department of Health and Human Services Office of Inspector General, Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products, A-06-01-00053 (March 2002)).

[10] Quarterly reports of state reimbursement formulae are available at http://www.cms.hhs.gov/medicaid/drugs/prescriptions.asp.

fluoxetine product under the Hatch-Waxman Act, because we were the first to file an Abbreviated New Drug Application challenging the patents on Prozac.[11] Barr brought this important generic medication to market more then two years prior to patent expiry.

As is customary for generic products, Barr's fluoxetine was a lower-cost alternative to the brand, Prozac. This provided pharmacies with an incentive to purchase and dispense generic fluoxetine. The incentive Barr provided was effective: by the end of the exclusivity period, generic fluoxetine products had gained more then 80% of the prescription market for 20 mg Prozac. The early introduction of a generic fluoxetine, and the incentives provided to pharmacies through a lower purchase price for the generic medication, encouraged substitution of the generic for the brand.

The day that Barr's fluoxetine exclusivity period ended, nine other generic manufacturers entered the market, each establishing virtually the same AWP for fluoxetine as Barr's. Prices for generic fluoxetine dropped quickly and dramatically. Of course, the establishment of a FUL or a MAC for fluoxetine immediately following the launch of multiple generics (January 29, 2002) would have effectively eliminated the use of AWP as a reference point for reimbursement. Notably, this is exactly what did happen with private third party payors (which account for approximately 87% of the market), almost all of which placed a MAC on generic fluoxetine either before or immediately after January 29, 2002. CMS did set a FUL for Prozac on December 1, 2002.[12]

Conclusion.

Barr is proud to be part of a highly competitive industry that offers generic products at a lower cost than the brands. In 2003, through the enactment of Hatch-Waxman reforms, Congress recognized the importance of generic drugs and their role in easing the financial strain that prescription drug costs often impose on the budgets of many in our society, including federal and state budgets under Medicaid. For the very same reasons, Congress should ensure that any potential changes to Medicaid reimbursement will encourage, rather than discourage, the continued substitution of generic drugs.

Mr. WALDEN. Thank you, Mr. Catlett. We appreciate your being here.

Mr. Marshall.

TESTIMONY OF DAVID MARSHALL

Mr. MARSHALL. Mr. Chairman and distinguished Representatives, on behalf of CVS Corporation I would like to thank the committee for inviting CVS to appear today to participate in this important hearing.

CVS shares the committee's goal of reducing the cost of prescription drugs for all of our customers. The single most effective action that can be taken to achieve that goal is to promote the use of generic drugs wherever possible. It is my responsibility at CVS to purchase generic drugs at the lowest possible cost.

I am pleased to have the opportunity to answer your questions to the best of my ability today. Thank you.

Mr. WALDEN. Thank you, Mr. Marshall.

Mr. Ziebell, your comments.

TESTIMONY OF JOHN ZIEBELL

Mr. ZIEBELL. I have no comment, but I am ready to answer any questions you may have.

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[11] Press Release, Indiana District Court Clears Way for Barr's Generic Prozac(R) Launch, available at http://www.barrlabs.com/pages/nprpr.html.

[12] Centers for Medicare and Medicaid Services, Federal Upper Limit (FUL) Changes to Transmittal No. 37 at 17. (showing that CMS added fluoxetine hydrochloride to the FUL product list for implementation on December 1, 2002). *See also* Department of Health and Human Services Office of Inspector General, Ommission Of Drugs From The Federal Upper Limit List in 2001, OEI-03-02-00670 (discussing delays in establishing FULs in a timely manner.)

Mr. WALDEN. Thank you for being here.
Mr. Seagrave.

TESTIMONY OF FRANK SEAGRAVE

Mr. SEAGRAVE. Thank you, Mr. Chairman.

My name is Frank Seagrave. I am a registered pharmacist in Louisiana, Colorado, and Mississippi. I am currently the Vice President of Pharmacy for Wal-Mart Stores, Incorporated.

I am familiar with the struggle that many States are currently having with their Medicaid expenditures. The Medicaid business at Wal-Mart represents about 11 percent of our prescription business. I believe that Wal-Mart and our 11,500 pharmacists are part of the solution.

Currently, retail pharmacy Medicaid reimbursement is based on a formula consisting of two parts, estimated acquisition costs, plus a dispensing fee. Everyday low price, or EDLP as we call it, is a core belief of our company. It greatly benefits the Medicaid program in many States because our EDLP is often below the Medicaid allowable price. When this happens, the State gets charged the lower price. Wal-Mart's EDLP, therefore, is a value to the Medicaid program.

I believe that generic drugs are the best opportunity for savings in the Medicaid program. The average price of a Medicaid prescription that was filled with a brand name drug at Wal-Mart in 2002 was $88.53. When a Medicaid prescription was filled with a generic drug, the average price was $20.25, a savings of $68.28. Therefore, the average Medicaid price of a prescription filed with a brand name drug was 439 percent higher.

Generics are deemed to be bioequivalent and therapeutically equivalent and should be mandatory when they are available. At Wal-Mart, we dispense generic drugs over 94 percent of the time when one is available. Wal-Mart is able to effectively negotiate good costs on generic drugs because generics are available from multiple manufacturers and are therefore commodities.

This is not the case with brand name drugs. Wal-Mart has no greater leverage for branded drug products than any other retail class of trade pharmacy provider. There is great disparity between what brand name drug manufacturers charge retail pharmacies and the lower prices they charge other classes of trades, such as hospitals, mail order pharmacies and HMOs. Thus, an average sales price, or ASP, model for drugs dispensed to Medicaid recipients would be inequitable for retail pharmacies.

Wal-Mart currently accepts all endorsed Medicare discount cards. We have been aggressive in providing educational literature regarding the discount cards to our customers. The program has been a success at Wal-Mart. We look forward to the opportunity to serve the needs of our Medicare customers when the Medicare drug benefit starts.

Wal-Mart pharmacists and all retail pharmacists are a valuable part of the health care system and the communities that we serve. Pharmacists routinely consult with customers and answer questions about prescription and over-the-counter drugs as well as general health care issues. Pharmacists are consistently regarded as the one of the Nation's most trusted professionals.

In summary, Wal-Mart is committed to continue to provide the best service to our Medicaid customers in any reimbursement system as long as it provides fair payment for the service and product delivered, protects the customer's safety, and allows the Nation's retail pharmacies to fairly participate. Thank you.

[The prepared statement of Frank Seagrave follows:]

PREPARED STATEMENT OF FRANK SEGRAVE, WAL-MART STORES, INC.

INTRODUCTION

Mr. Chairman and members of the Committee, your efforts to gain more information about pharmaceutical reimbursements under Medicaid are well advised.

I am a registered pharmacist. I joined Wal-Mart Stores, Inc. (Wal-Mart) in 1986, and after various roles in operations and merchandising, became Vice Presidents of Wal-Mart's Pharmacy Division based in Bentonville, Arkansas. Part of my role includes ensuring that "Everyday Low Price" (EDLP) is practiced within the Pharmacy Division. In its purest form EDLP is as it sounds: the same low price every time you visit the store. EDLP begins with "Everyday Low Cost" (EDLC). Purchasing at the best cost along with being a low cost operator and using technology to be efficient allows us to sell at EDLP.

As a Medicaid pharmacy provider in 49 states, our job is to get the right medications to the patients who need them. As a retail pharmacy provider, we must stock and dispense the majority of medications that are commonly prescribed. It is noteworthy that "pharmacies" do not practice pharmacy; it is the face-to-face interaction with the 11,500 Wal-Mart pharmacists that benefit Medicaid recipients.

Our pharmacies operate in large urban locations and small rural towns across America. Of our nearly 3,500 pharmacies, over 1,200 operate in rural areas with a population of less than 50,000. Medicaid patients in both rural and urban areas value their relationship with their Wal-Mart or Sam's Club pharmacist. Wal-Mart's focus is on our retail pharmacy patients and their healthcare outcomes. To this end, our pharmacists are advocates for the Medicaid patients they serve. This advocacy includes: working with prescribers to select less expensive alternative medications; immediate conversion of brand medications to lower cost generics when they become available; and treatment with less expensive OTC medications. Wal-Mart pharmacists seek to limit "preventable" events by maximizing patient adherence to prescribed treatments. "*Pharmacy is about relationships*" has become the unofficial mantra of the Pharmacy Division's Associates.

Wal-Mart purchases most drugs centrally through its own pharmacy distribution centers. We are described as a "self-warehousing" chain. Whenever possible, Wal-Mart buyers order directly from manufacturers, who ship products directly to Wal-Mart pharmacy distribution centers.

Wal-Mart's purchasing decisions for generic products are straightforward. If "AB rated" generic products—which mean products determined by the FDA to be identical to the brand drug—are available from multiple manufacturers, Wal-Mart will purchase the drug product with the lowest acquisition cost. Product availability is also a factor, because a reliable supply of product is essential to satisfy our patients.

Wal-Mart does not take into account the amount of Medicaid reimbursement, known or anticipated, in determining whether to stock or sell any particular branded or generic drug product. We first and foremost follow our core tenet—"ALWAYS LOW PRICES." Lower drug product prices to patients are made possible through lower acquisition costs and operational efficiencies.

State Medicaid program beneficiaries represent an important patient population to Wal-Mart. These patients represent 11% of our pharmacy business revenue. Wal-Mart values its role as a Medicaid provider and has never withdrawn from participation in any program, in the Medicaid system, or threatened to do so. Wal-Mart competes for Medicaid patients based on service. While we never provide a blanket waiver of Medicaid co-payments for our patients, we do not collect the nominal co-payment when a Medicaid patient is unable to pay it.

We do not sponsor a Medicare Discount Card Program, but accept all Medicare-endorsed drug discount cards. Wal-Mart has been aggressive in providing educational literature regarding these discount cards and these approved discount cards have been a success at Wal-Mart. The Pharmacy Division also strongly supports and participates significantly in manufacturer-sponsored patient assistance programs, such as TogetherRx.

My testimony today addresses two issues. First, the importance of ensuring access to Wal-Mart's retail pharmacies by America's most needy, the elderly and the poor.

Second, how can Wal-Mart partner with the states to have an effective Medicaid drug program?

The importance of ensuring access to Wal-Mart's retail pharmacies.

On a daily basis, our 11,500 pharmacists take care of patients in the Medicaid program, fill their prescriptions that are subject to complex rules and regulations, and provide the best patient-focused care.

When prescription-only products move to the over-the-counter (OTC) market, their prices drop sharply. Wal-Mart pharmacists routinely consult with patients who have OTC medication questions. This includes options such as our cost-effective private label Equate® brand OTC products, for patients when therapeutically appropriate. Wal-Mart's private label diabetic testing and treatment products sold under the ReliOn® diabetes brand are considered the best value brand in the United States. All state Medicaid programs should include these products on their formularies and provide reimbursement for them. Many states do this today.

Usual and Customary Charges (U&C)

Revenue from Wal-Mart's "cash" pharmacy business for drug products is significantly larger than its revenue from Medicaid. Retail cash price or "U&C" is defined as the usual and customary charge for a drug product offered to cash paying patients. Because this U&C is often lower than the reimbursement formula for Medicaid, this benefits both cash-paying patients and the Medicaid programs. Individual Wal-Mart pharmacies have the ability to lower, but not increase, drug product prices (U&C) within their marketplace as they see fit. Thus, Wal-Mart's U&C (EDLP) is often lower than the formula driven payment set by the state Medicaid programs. Our estimates indicate that many times Medicaid prescriptions were reimbursed at Wal-Mart's lower U&C. The impact of our aggressive lowering of U&C is represented on the attached graphs and Fact Sheet.

Generic Utilization at Wal-Mart

When a generic is available for a prescribed branded product, Wal-Mart pharmacies dispense that generic over 94% of the time. This is true for all payers. Consumers need to know when generic options are available and that they are as safe and effective as brand name drugs, but at a fraction of the cost. Wal-Mart pharmacists play an important role in educating patients about their drug treatment. Our pharmacists help patients understand generic options and whether more affordable generics might be right for them.

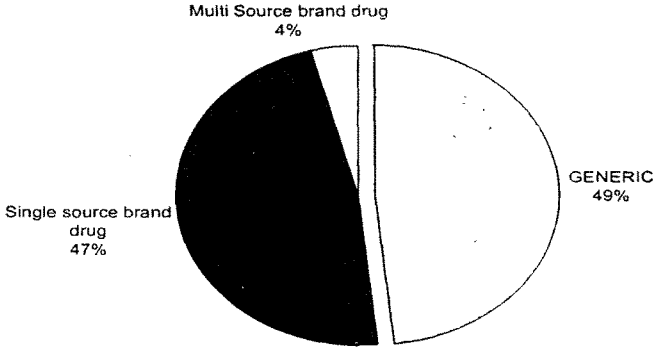
In summary, Wal-Mart has low prescription and OTC drug prices everyday for cash-paying patients and Medicaid benefits directly from this. Our pharmacists also recommend generic drugs and shift patients to more cost-effective drug therapies.

How can the Wal-Mart partner with the states to have an effective Medicaid drug program?

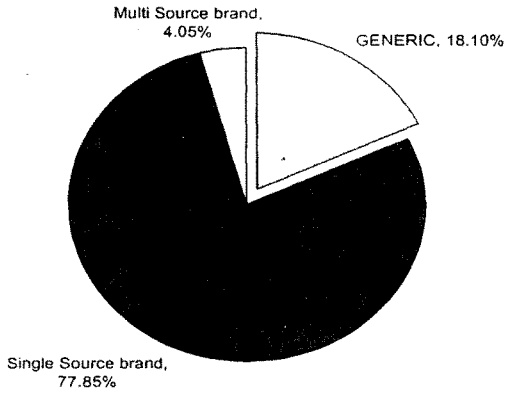
One of the main reasons for the continuing rise in Medicaid drug expenditures and the failure of cost-containment measures, is the introduction of new, more expensive brand name drugs. Drugs within a therapeutic class may be similar, but their prices often vary substantially. Several state Medicaid programs took a major step in passing legislation mandating a permanent commission to research and report on the comparative effectiveness of medications and prices. Wal-Mart encourages other states to implement similar tools.

Reimbursement mechanisms for generics should aim for price competition as the main priority. To Wal-Mart, multi-source generics represent a commodity. Generics save everyone money. The following charts demonstrate Wal-Mart's experience in Medicaid reimbursement for 2002.

% of Medicaid prescriptions by type of drug

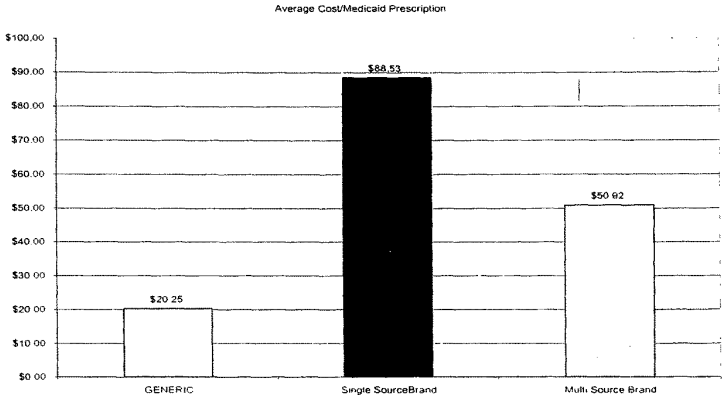


% of Medicaid Revenue by type of drug



Wal-Mart Stores, Inc. data, 2002

While almost *half* of the prescriptions are written for generic drugs, they account for less than *20%* of total Medicaid expenditures. Switching from expensive brand drugs to lower cost generics can help alleviate this problem. Wal-Mart is strongly committed to encouraging the use of AB rated generics—the exact same drugs at a much lower cost. Generic substitution provides tremendous savings at the same time. Generic drugs mean competition, and competition means lower prices, both to the pharmacy and to the patient. Focusing on generics to reduce Medicaid prescription drug costs is not the answer, because the largest expense lies in the over-utilization and high cost of single source brand drugs. The chart below provides the average total reimbursement received by Wal-Mart from Medicaid programs for each type of drug.



Wal-Mart Stores, Inc., 2002

Wal-Mart endorses the continued adoption maximum allowable cost (MAC), with frequent audits/updates, for multi-source generic drugs under Medicaid.

For branded drug products, Wal-Mart has little or no ability to negotiate discounts below the published wholesale acquisition cost (WAC). Wal-Mart has no greater leverage for branded drug products than any other retail class of trade pharmacy provider.

There is a great disparity between what drug manufacturers charge retail pharmacies and the significantly lower prices they charge other classes of trade such as hospitals, mail order pharmacies, and health maintenance organizations. Thus, an average sales price (ASP, as defined in the Prescription Drug Improvement and Modernization Act (PDIM)) reimbursement model for drugs dispensed to Medicaid beneficiaries would be inequitable for retail pharmacies. ASP is intended to represent volume-weighted, average selling price to *all* purchasers, excluding certain federal purchasers.

Conclusion

Wal-Mart supports any reimbursement system that provides fair payment for the service and product delivered, protects the patient's safety, and permits the nation's retail pharmacies to fairly participate. Wal-Mart's motto—Always low prices—is carried out in its pharmacy operations. Actual substantial savings come from market shifts to more cost-effective therapies. Wal-Mart and its pharmacists, as a low cost pharmacy provider, are on the front line to effectuate such shifts.

Thank you for the opportunity to appear today. As always, Wal-Mart is willing to work with state Medicaid programs to be part of the solution.

Mr. WALDEN. Thank you. I appreciate your comments, Mr. Seagrave.

I just want to say at the outset that we don't want to do anything here that would create a disincentive to generic use. I think we all agree that that is an important component of holding down costs and giving consumers choice. But we do need to make sure that the taxpayer benefits from the savings, and I think—so we can take care of those who need help that today are, frankly, robbed

of that help because, in some cases, of lack of funds. So I want to start by getting at this issue of the AWP with this panel. Do each of you believe that the AWP reflects the actual selling price that you charge for your products?

If we can get kind of a yes-or-no answer. Mr. Stratemeier.

Mr. STRATEMEIER. No, it does not.

Ms. MARRS. No.

Ms. PAOLETTI. No.

Mr. CATLETT. No.

Mr. MARSHALL. No.

Mr. ZIEBELL. No.

Mr. SEAGRAVE. No.

Mr. WALDEN. So all of you agree that it is not a legitimate selling price, reflection of your selling price.

Do you adjust the AWPs of your products after you have set them; and, if so, under what circumstances? Mr. Stratemeier.

Mr. STRATEMEIER. Well, in the brand industry, AWP generally reflects a 20 to 25 percent markup over wholesale acquisition cost, WAC. So as WAC is increased, AWP goes up accordingly.

Mr. WALDEN. You do adjust your AWP then on a regular basis?

Mr. STRATEMEIER. I can't say that companies adjust the AWP. The reported AWP by the reporting services, put out the AWP. Most companies, including Aventis do not set an—most brand companies do not set an AWP.

Mr. WALDEN. Okay. Ms. Marrs.

Ms. MARRS. In our case, in the case of generics, we historically have not had a practice of raising AWP. For the brand products, we have increased AWP as the WAC has increased.

Mr. WALDEN. Okay.

Ms. PAOLETTI. Generally, we do not change our AWPs once they are established. We have changed some AWPs for one reason or another.

Mr. WALDEN. Why wouldn't you adjust them to reflect the market?

Ms. PAOLETTI. Why wouldn't we?

Mr. WALDEN. Yes.

Ms. PAOLETTI. It is generally a standard in the generic industry that you set your price for AWP and you don't adjust it.

Mr. WALDEN. All right. Mr. Catlett.

Mr. CATLETT. An instance where I can think that AWPs are increased in our business would be in a sole-source generic situation. We are the only generic on the market. If there was a brand price increase and we felt there might be an opportunity and we would make a decision to raise our generic price, we would raise both our AWP and our price to maintain.

I think we heard earlier today that generally there is a 90 percent difference between the brand and the generic price. That is the incident I can think where AWP might increase, sir.

Mr. WALDEN. Let me go to your testimony. I am going quote it here, Mr. Catlett. You said, "It is generally known in the pharmaceutical industry and related government agencies that average wholesale price, AWP, is a reference price only and does not represent the actual selling price charged by the manufacturer for its products."

I would like you to—they don't have the notebook, do they—to turn to Tab 1. Do we have—we don't have that. They can't turn to Tab 1. There you go.

In our exhibit binder there, you will see OIG compliance program guidelines for pharmaceutical manufacturers. And on the bottom of page 23,733, it says, "The government sets reimbursement with the expectation that the data provided are complete and accurate, and, where appropriate, manufacturer's reported prices should accurately take into account price reductions, cash discounts and free goods," et cetera.

In light of these ongoing—these OIG guidelines, if you report an AWP, aren't you required to make sure that it is up to date and accurate?

Mr. CATLETT. Are you directing that question to me?

Mr. WALDEN. To you and Ms. Paoletti and Ms. Marrs.

Mr. CATLETT. I will take the question first, sir.

The practice in the industry is to report AWP as a reference price. I believe what is reported that is updated is we do provide our AMP, which is our average manufacturer's price, which does take into account all of those.

Mr. WALDEN. But given that AWP is also used as a reimbursement mechanism, shouldn't it be accurate to the market? I mean, to—shouldn't it represent something?

Mr. CATLETT. It has been industry practice and the practice at Barr that it is strictly a reference price and it is in relation to the branded price.

Mr. WALDEN. Ms. Paoletti.

Ms. PAOLETTI. I would agree with that. And there really is no clear guidance for us to follow that tells us how to calculate that number.

Mr. WALDEN. Ms. Marrs.

Ms. MARRS. I would agree with my colleagues.

I think we have heard many times here today the system is broken. There is no statutory definition of AWP. To the extent that there is clear guidance, as the gentleman from Barr said, we have been reporting AMP. But the industry practice as it is and the lack of statutory guidance, industry practice has prevailed.

Mr. WALDEN. All right. I want to go—turn to Tab 37, if you would, Ms. Paoletti. This is document number 01999-02002. The second page of the document, 02000, states that Roxane's bids for Furosomide business were rejected not because the sales price was too high but solely because the AWP was too low. Our AWP and reimbursement factors in negotiations with retail customers.

Do you want to talk about that, that document?

Ms. PAOLETTI. Furosomide was a very unique situation for us in that there were some changes in the market that allowed opportunities for us to potentially gain new business.

When we tried to gain the new business, we were repeatedly told that our AWPs were out of line with our competitors and, upon looking at that, discovered that they were significantly below our competitors such that, regardless of how low our contract price was, no one would buy the product.

Mr. WALDEN. So AWP—I mean, okay. I guess what I see here is that AWP is how you get market share. The higher it is, the better

chance you have to get market share. Because somebody is making money on the spread, and the people making the money are the purchasers. Right?

Ms. PAOLETTI. I would disagree with that. I think it is in—in our experience, it has been a rare occasion that customers have discussed any of that with us; and, in this occasion, it is my impression that the only reason it was discussed was because we were out of line. They weren't asking us to increase the spread over where the current market was. They were just asking us to be on a level playing field.

Mr. WALDEN. Okay. We will try and tell you what tab this one is.

But there is—Tab 39, if you will go to that. And it says here—this is to Judy Waterer from Anthony Tavolero. It says, Judy, as you know, Caremark had shown interest with our Furosomide back in April. After review of our AWPs on the product, the opportunity was dead. Our AWPs are 78 percent below the rest of the industry. I am not aware of any competitor where the AWP is below $100 for bottles of 40 milligram thousands. Miline and Zenith are approximately $120, ours is $29. Caremark has commented that they could not possibly award the product to us unless we increased our AWPs. Janet Miller also added that Roxane has a history of having AWPs out of sync with the rest of the industry.

I don't know why we have to wait until our customers complain before we adjust an AWP. Major customers—Walgreen, Wal-Mart, CVS, MEDCO, Caremart—expect their leading suppliers to maintain their AWPs. Not executing this core competency reflects negatively on Roxane and promotes a perception of Roxane not understanding industry dynamics. I hope this helps.

This would appear to me to reference more than just Furosomide. Does it appear that way to you?

Ms. PAOLETTI. Well, he does say that we have a history. I am not sure what he is basing that on. Typically, we set our pricing and we don't monitor it. We don't monitor AWPs once they are set.

Mr. WALDEN. Then why would he say, I don't know why we have to wait until our customers complain until we adjust an AWP?

Ms. PAOLETTI. In this case, he is referencing Furosomide. And we aren't able to get business. Actually, we were on the verge of discontinuing the product because we couldn't gain customers, and it was based on the fact that our AWP was so far out of line with where the rest of the market was.

Mr. WALDEN. Okay. And then if you would turn to Tab 38 in the binder. This document also notes that when AWP is out of line with the rest of the market it a bigger issue than a straight price. But this e-mail goes on to mention concerns associated with the decision to raise AWP, including scrutiny and consumer backlash. Can you discuss those concerns?

Ms. PAOLETTI. Any time pharmaceutical companies do a price increase, it is scrutinized, AWP in particular, because that is one of the prices that is publicly available for every one to see.

Mr. WALDEN. But it appears, in this case at least, in order to get market share—am I missing it? In order to get market share, you are having to increase your AWP?

Ms. PAOLETTI. We were having to bring it in line with our competitors, yes. They weren't asking us to raise it above our competitors. That was not my impression.

Mr. WALDEN. What effect does raising the AWP have on the price that they pay for that product?

Ms. PAOLETTI. That the customers pay? It would not have an impact on the price that they paid.

Mr. WALDEN. What is the benefit to them of a higher AWP set by you, which I assume would be an arbitrarily set AWP?

Ms. PAOLETTI. Well, in this case, they weren't buying our product. They were buying another competitor's product, who was much higher. So, in that case, there would not have been an impact on what they were currently buying versus what——

Mr. WALDEN. No, my point is, your incentive to raise the AWP is to get market share, is it not?

Ms. PAOLETTI. In this case, it was to bring ourselves in line so that we could actually compete on a contract price basis.

Mr. WALDEN. Right. To get more market share.

Ms. PAOLETTI. Sure.

Mr. WALDEN. It doesn't cost the purchaser any more and it doesn't cost you anything to have a higher AWP?

Ms. PAOLETTI. True.

Mr. WALDEN. So the loser in this is the government, right, the taxpayers?

Ms. PAOLETTI. Well, I wouldn't agree with that.

Mr. WALDEN. Why?

Ms. PAOLETTI. Because at the time they were already buying one of our competitor's products that was already at that—at that level. My changing that price didn't advantage——

Mr. WALDEN. Right. Okay. But your company would benefit by changing if it allowed you to get market share.

I guess the point is not to pick on Roxane specifically. I don't mean to do that necessarily, other than as an example of the pressures within the marketplace that drive a higher AWP in order to get market share. The actual price paid by the purchaser is no more. You have indicated that. The AWP, you just all are competing up here to see who has got the highest, because that creates the biggest spread?

Ms. PAOLETTI. I am not sure that is the way that it is really done.

Mr. WALDEN. How is it done?

Ms. PAOLETTI. In our case, we set the AWP and we don't monitor AWPs of our competitors. We typically don't change our AWPs.

Mr. WALDEN. In this case, you were monitoring and had all of the data. It is in the e-mail.

Ms. PAOLETTI. Well, in this case, we weren't monitoring it. It was so far out of line that our competitors were bringing it to our attention that, hey, even if you have the best supply and the lowest contract price, I can't pay your product because you are not in line on this other reference price.

Mr. WALDEN. The other reference price does what for them?

Ms. PAOLETTI. It would have put us in line with——

Mr. WALDEN. No, it creates the spread, right? The AWP creates the spread with the actual purchase price. Correct?

Ms. PAOLETTI. It would be one of the factors that their reimbursement is based on, yes.

Mr. WALDEN. All right. My time has expired. Thanks for the patience of the committee.

Mr. Stupak.

Mr. STUPAK. Thanks, Mr. Chairman.

Well, going along that line, Exhibits 37, 38, 39, Mr. Catlett, your testimony on page 8 says, if a generic manufacturer unilaterally reduces its AWP for a given product relative to the AWPs of other generic manufacturers for the same product, pharmacies would have an incentive to purchase another manufacturer's drug that did not reduce its AWP.

So basically what is going on here, if you keep the AWP high, then the pharmacies make more money off it, right?

Mr. CATLETT. I believe what I tried to say in my written testimony is that the AWPs are set as a reference price. If a—in a multi-source situation, if there are multiple competitors, I believe that if a company such as Barr was to unilaterally reduce its AWP and if we are still in a situation where it is not an FUL or not a MAC in place and we are dealing with AWP reimbursement formulas, while I have no example or any experience and could you give you an example of it, my fear might be that it would put a situation in place where we may have that type of decision.

Mr. STUPAK. Well, Ms. Marrs, you testified that you had a product and you lowered your AWP and you couldn't get any customers to buy it, right?

Ms. MARRS. We have had a couple of situations. We tried to launch a product without AWP.

Mr. STUPAK. You established an AWP. It was lower than the rest, and your customers wouldn't buy it?

Ms. MARRS. That is correct.

In the other situation, we did not lower our AWP, but one of the reporting services chose to do so without our knowledge. And, as a result of that, we got many calls from pharmacists basically saying that they wouldn't be able to buy our products in the future if that situation was not changed.

Mr. STUPAK. So if we lower the AWP, why won't the pharmacies buy the drugs? If there is a lower AWP, you are paying a lower price, you could pass that savings on to your customers, as you claim you like to do. So why wouldn't you buy a drug at a lower AWP? Mr. Marshall? Mr. Ziebell? Mr. Seagrave?

Mr. MARSHALL. As I stated earlier, my responsibility to CVS is to purchase the lowest-possible-cost generic product. I do not focus on the AWP value in negotiations. The market is very fluid and dynamic and a highly competitive marketplace.

Mr. STUPAK. That is not what these people are saying. They are all saying you keep your AWP at the market standard. It is not fluctuating. If you would bring it lower, you don't get customers. You are the customers. You are the pharmacists. Isn't it true the reason why you don't want to lower AWP is if you have a lower AWP your reimbursement from the government and from the insurance companies is discounted off of that AWP? So, therefore, if the AWP is lower, your profit is lower on that drug. Isn't that true?

Mr. MARSHALL. Again, I don't focus on the AWP. My initiative or my——

Mr. STUPAK. How about just a yes or no? I don't care if you focus on it or not. Doesn't it stand to logic if you have a lower AWP and you are reimbursed—and that AWP is discounted by Medicaid and by the big insurance companies, the lower the AWP, the lower the profit for the pharmacy? Yes or no?

Mr. MARSHALL. Yes, if the reimbursement were based on AWP. Correct.

Mr. STUPAK. Are you telling me it is not?

Mr. MARSHALL. No, I am agreeing with you, that that would be the case.

Mr. STUPAK. Sure.

How about Mr. Ziebell? Would you agree with that? Lower AWP means lower profit to—who do you represent? CVS or Walgreens?

Mr. ZIEBELL. It would depend on whether or not the product is reimbursed based on AWP. If it were, than the profit would——

Mr. STUPAK. Well, Medicaid is reimbursed based on AWP?

Mr. ZIEBELL. In some situations, yes. There are Federal upper limit and MAC situations put on by the Federal Government and the individual States. But if it was based strictly on AWP, if you lower AWP, the reimbursement would be lower.

Mr. STUPAK. Well, we are looking at the list right here. Medicaid prescription reimbursement information by State. It is all based upon an AWP, plus a little bit more. So the lower the AWP, the lower the profit to you. So if you are really concerned about the price the customer pays, wouldn't you want to buy your drugs from these manufacturers here who have a lower AWP to pass that savings on to your customers?

Mr. ZIEBELL. I haven't had a situation presented to me where the AWP has been lower.

Mr. STUPAK. Well, not you personally. But I mean to your company.

Mr. ZIEBELL. Well, I am the purchaser of generic pharmaceuticals. And that is the case, that no one has been——

Mr. STUPAK. You represent what company?

Mr. ZIEBELL. Walgreens.

Mr. STUPAK. So this e-mail then that they referred to, I believe Exhibit 38: I don't know why we have to wait until our customers complain before we adjust an AWP. Major customers—Walgreens, Wal-Mart, CVS, MEDCO, Caremart—expect their leading suppliers to maintain their AWPs.

I guess you are mentioned in this one.

Mr. ZIEBELL. Well, from the manufacturer's standpoint. I have never indicated that direction to any manufacturer.

Mr. STUPAK. Okay. Mr. Seagrave, do you care to comment? If you lower your AWP, you could lower the price for the customer, right?

Mr. SEAGRAVE. I would agree with the other two gentlemen. If reimbursement is based upon the AWP only, then our reimbursement would be less if it was based on AWP.

I would comment, though, that we heard testimony on the previous panel from some gentlemen from Michigan and in Texas where they indicated that they do have maximum allowable costs

in place, and they base their reimbursement off of that and not off of AWP.

Mr. STUPAK. Well, how can this side of the table over here—Mr. Stratemeier, Ms. Marrs, Ms. Paoletti, Mr. Catlett—be saying they can't sell any unless it is based on a stable AWP, which is higher price? You are saying that is not the only reason? I mean, what side of the table is right here, left or right?

Ms. MARRS. I think the issue is there needs to be a level playing field. I don't think the manufacturer is as concerned with exactly what the reimbursement rate is. The issue is it has to be the same for all manufacturers competing with that specific product.

Mr. STUPAK. Well, a manufacturer wouldn't be concerned, because you are trying to get part of market share. It makes sense, you would lower your AWP to get a bigger market share. But if the customers, the pharmacies won't buy it unless you maintain a higher AWP, because that is what their profit is based upon—so the system really is broken.

Ms. MARRS. The system is broken. There really needs to be a reimbursement rate set by somebody outside of manufacturing so it is a level playing field for all of the manufacturers.

Mr. STUPAK. Let me ask you this question, and go right down the line. We have known for years and we have heard again today that the average wholesale price, or AWP, and the WAC, or wholesale acquisition cost, on which most States base their Medicaid drug reimbursement formulas are fictitious numbers. You know it, Congress knows it, CMS knows it, and the States know it. As the $2 billion in fines and settlement indicate, the manufacturers have benefited from an AWP system, but so have the providers. The big losers been the taxpayers and the poor who are most vulnerable to losing their health care when there are budget crunches. Sicker, uninsured, and untreated people don't benefit any of us. The systems need to be changed. But any changes, any change needs to be fair, transparent, efficient and effective.

The CMS expert panel recommends that reimbursement be based on actual acquisition costs to the pharmacies. Aventis made this recommendation in 2002. So I would like to hear from each of you how would you change the system. Mr. Stratemeier.

Mr. STRATEMEIER. Well, as we said in our policy statement, that we think that actual acquisition cost is the best way to start your structure, your reimbursement system.

Mr. STUPAK. Then you can still put in a dispensing fee and a copay?

Mr. STRATEMEIER. If a pharmacist dispenses drugs, there would be a dispensing fee. For physician office drugs, there would be a physician services fee. That needs to be adequately dealt with in its own right. But the key is the actual acquisition.

Mr. STUPAK. The key is for the pharmaceuticals to use the actual acquisition cost.

Ms. Marrs.

Ms. MARRS. I agree that it should be cost based, and a reasonable service fee should be provided.

In the case of getting the cost from the manufacturer, I just would caution the committee that, in our case, most of our sales are to wholesalers and distributors. So when we report an average

selling price that may not be reflective of what the pharmacy is actually paying. That needs to be considered in developing the methodology.

Ms. PAOLETTI. I would agree that any system that is put in place needs to encourage the use of generic, lower cost generics, and it needs to take into account all of the issues that impact all of the parties—the manufacturers, the pharmacies, the patients, and the government.

I am not sure that we can sit here today and put forth a proposal.

Mr. CATLETT. I think the important issue here and what you are getting at is, in a situation where we have many competitors entering the market and we are seeing a dramatic decrease in acquisition price by our customers, that an AWP-based reimbursement system may not be the best solution.

I think that is the really the key issue here there needs to be reliance upon.

Mr. MARSHALL. We would, at CVS, be open to dialog to discuss a program that would provide coverage for Medicaid patients, would offer a program that covered the cost and adequately covered the dispensing fees associated with filling a prescription; and, again, just to reiterate, that would promote the lower cost generics.

Mr. ZIEBELL. I think that is the most important part, is you don't want to take away the incentive to dispense the generic over the brand. The focus here has really been on the markups on generic pharmaceuticals, but not much attention has been paid to the small markup that results from the calculations based on brand-name pharmaceuticals. So I think you have to keep that in mind, also.

Mr. STUPAK. Mr. Seagrave.

Mr. SEAGRAVE. Well, I think there are a lot of possibilities and a lot of things that we can talk about and ways to fix the system.

I think primarily what we would want to do is focus on the increased use of generic drugs, and then I think we need to come up with a fair and equitable formula where we address the adequate dispensing fee, the adequate cost of goods and services, and we will offer our support into finding that solution.

Mr. WALDEN. Thank you.

The gentleman from Michigan, Mr. Rogers.

Mr. ROGERS. Thank you, Mr. Chairman.

Wow, was it a great day when I got the health care committee in Energy and Commerce. You know, I went to a reference point to make sure we were taking about the same rule of law. I went to page 23,733. I don't know how you all do it.

And when I look at the fact that there is really no guidance in this AWP, if we have found an enemy in this whole thing, it is us, the U.S. Congress. To create a system that has a perverse incentive in it for the customers of these manufacturers to try to establish a price point that says, look, I know they are not going to cover my proper dispensing costs so I have got to build that in, and I am going to make sure that obviously we make a little bit on the drug itself and the dispensing costs. So I have got to try to figure out how to bump up this AWP to make sure, of which they are not giv-

ing me credit for, I get credit for when I am building in my profit margin on running a pharmacy. Holy mackerel.

I don't know how we got here. But this is broke. I appreciate you all being here. Where there is profit, there is normally confusion—or where there is confusion, there is normally profit.

I would venture to guess that most of you have been subject to lawsuits on pricing. Has any of you experienced a lawsuit on pricing?

Let the record reflect that I think everybody on the panel has been shaking their head. The only people smiling are your counselors on the other side of you.

I mean, this thing is absolutely amazing. And, Ms. Paoletti, can you explain to me—I mean, what—when this lawsuit happens to your company, based on confusion of which I think the Federal Government is a big part of this problem, what does that do? What does that cost structure do to the cost of your product, to your time and talents dedicated to trying to run a business and getting low-cost drugs to the market?

Ms. PAOLETTI. It takes a tremendous amount of our resources, both time and money, that, frankly, would be much better spent reducing our prices and our costs.

Mr. ROGERS. Do you have any idea—probably not a fair question, but do you have any idea—I mean, what percentage cost—is there any way I can get anywhere close to a figure of what—the lawsuit problem of your cost structure? You build it in every year, I imagine.

Ms. PAOLETTI. I am sure that we can provide it for you.

Mr. ROGERS. That would be helpful.

Anyone else? Obviously, some of even the bigger pharmacies, have you been subject to these suits as well?

Mr. ZIEBELL. I am not personally aware of that. I am in the purchasing department, and I try to keep the costs as low as possible. I am not aware of pricing lawsuits.

Mr. ROGERS. I think we all know the answer to the question. This is a significant cost. It is a confusion that we have created for you to try to have to deal with. And I agree. I appreciate you all being here. We are going to have to do something about this. This is absolutely nuts.

Let me ask you this. Could you go to a Medicare pricing system, ASP plus 6, fill in the blank? I mean, this—is this something that is a structure that seems to be a little bit closer to taking into account your costs of distribution and the costs of the drug and the ability for you to keep your doors and lights on and pay people? Any thoughts?

Nobody wants to commit to a pricing structure. That is very smart. I can see your lawyers tugging on the back of you. If you do, don't do that. That means no bonus this year.

Quite obviously, this pricing structure thing is a problem. Let me ask you this other question. You can sense my frustration. I certainly sense yours, and trying to go through this and understand it.

By the way, that first 22,000 pages was riveting. Loved it.

Would it be—what problem would it cause for you—and I will address this to Ms. Paoletti—to provide your pricing structure to the States? Is that a problem?

Ms. PAOLETTI. We would provide whatever information was required by the States, as we currently do.

Mr. ROGERS. For DEY as well?

Ms. MARRS. We would be fine with providing pricing information to the States. We would hope that it would be kept confidential from our customers.

Mr. ROGERS. Obviously. I am not sure that is the right answer. But if I have learned nothing today, that we have got, A, a transparency problem, availability of information problem, and this god-awful system of which we have created to build in these perverse incentives for people to start dealing against each other, not for lowering prices in a free market competition but to try to jack them up a little bit to cover costs that we haven't recognized at the Federal Government, is a real issue for you and your operations.

That is an issue that I hope, if nothing else, that we walk away from this hearing today and try to deal with that very, very serious issue. And I, again, I appreciate you all being here and your forthrightness, and trying to get us to this answer.

Again, I have found this out in this oncology issue that we have created a really bad system, and then we blamed people for trying to participate in applying any business sense that they could possibly muster in this god-awful system that we created, and then we come back a few years later and said, how could do you that? That is awful. It is a system that we created.

Thanks for having the patience to hang in there and trying to offer low-cost drugs to your customers. Hopefully, we will have some relief on this lawsuit side of it as well. I know that is just an absolute waste of money in our healthcare system. We have got to fix it.

And hopefully, Mr. Chairman, we can work to eliminate what is obviously a very confusing, large, ugly system, trying to develop and implement rules and regulations so you all know what you doing.

With that, I yield back, Mr. Chairman.

Mr. WALDEN. The Chair now recognizes the gentleman from New Jersey, Mr. Ferguson, for questions.

Mr. FERGUSON. Thank you, Mr. Chairman. I appreciate you holding this hearing. I don't have any questions at this time, but I share many of my colleagues' concerns about AWP.

Clearly, this is an issue that is going to continue to draw a lot of attention from folks on this panel, folks on our committee. And I really look forward to engaging in that debate, because clearly there are many problems which need to be addressed, and I thank the chairman and the committee for holding this hearing.

Mr. WALDEN. Appreciate your participation.

Mr. Marshall, I want to come back on some questions. I would like to turn your attention to Tab 37. In the exhibit binder, pages 2001, 2002, purportedly quote a voice mail left by a CVS buyer, Matt Leonard. Do you know who Mr. Leonard is, Mr. Marshall?

Mr. MARSHALL. Yes.

Mr. WALDEN. Who is he?

Mr. MARSHALL. I replaced Matt Leonard. He was the person in my position prior to me taking the current role.

Mr. WALDEN. Is he still with the company?

Mr. MARSHALL. Yes, he is.

Mr. WALDEN. And what role does he have now?

Mr. MARSHALL. He is the Vice President of Pharmacy Merchandising.

Mr. WALDEN. So where is he in the hierarchy with you?

Mr. MARSHALL. I report to Matt.

Mr. WALDEN. So you report to Mr. Leonard.

This is a voice mail supposedly left by him in June, July 2000, concerning Furosomide. And it says, and I quote, CVS would award Roxane the product if we, Roxane, would adjust our AWPs to reflect where the other generic companies are. Otherwise, CVS would award to Zenith Gold Line.

Does CVS emphasize AWP or reimbursement when negotiating with these folks?

Mr. MARSHALL. Okay. I have not seen this document prior to this time, and it was my understanding that counsel had spoken with counsel for the committee, that documents that had not been reviewed previously would not be reviewed today. I would just like to verify that.

Mr. WALDEN. Who did your counsel speak to on the committee about that?

Mr. MARSHALL. I believe it was Mr. Stone.

Mr. WALDEN. My understanding is there was not an agreement like that. They tried to show you all of the documents that we got.

Mr. MARSHALL. I would be more than willing to review this document and come back to you with a response.

Mr. WALDEN. Why don't you take your time right now to take a look at it, if you don't mind.

Because it says: CVS is looking for a Furosomide vendor. Apparently, the HICFA MACs are changing shortly, and they are not happy with the margins. And their current supplier—they did not have the new MACs available to share with me, but, being public record, I am sure that we should have them somewhere. In fact, I think Bob has them on his desk.

In the past, CVS has asked for AWP less 55 percent to be competitive on generics. I am not sure how the MAC impacts this. I would like to discuss this with Bob or Anthony before we bid. For now, I have listed the requested bid price, AWP less 50.

And then it says: ML, CVS would award Roxane the product if we would adjust our AWPs to reflect where other generic companies are. Otherwise, would award it to Zenith Gold Line.

If you look at Tab 38——

Mr. MARSHALL. Okay.

Mr. WALDEN. [continuing] Tab 38, you will see that the document there, which I am told you have been made aware of prior to this hearing, is almost identical in its language or reference points to this issue.

Have you seen that document before, Tab 38? It is a set of e-mails. My counsel indicates that you were made aware of this document.

Mr. MARSHALL. I have seen the lower portion of that page. Yes.

Mr. WALDEN. And for the record, this is an e-mail from Steve Snyder to Judy Waterer at Roxane, right? It says: Gang, CVS is looking for a Furosomide vendor. Apparently, the HICFA MACs are changing shortly. And I just read most of this. That goes on to say, can I request that we discuss this Thursday or Friday, et cetera, et cetera, which is very similar to the document on page Tab 36.

So I guess the issue is, do you know if Mr. Leonard or you—do you ever look at AWPs?

Mr. MARSHALL. As I mentioned earlier, regarding negotiation of lowest cost, to the extent that a manufacturer provides me with a published AWP or their AWP and references that AWP in a conversation or in a proposal, very often I will use that AWP value as a point of negotiation, not to instruct or ask that the value be changed in any way, shape or form, but, to the extent that I am offered a discount off of AWP, for example, that a manufacturer indicates they would sell it to CVS for AWP less 40 percent, I may say, well, gee, I would like to have it at AWP minus 60 percent as a good negotiating tool, all within the context of that value having been provided to me but for no other purpose other than to derive a lower cost of goods.

Mr. WALDEN. I thought earlier you testified that you didn't look at AWP as a negotiating point?

Mr. MARSHALL. I believe I testified that I do not consider AWP as far as requesting any changes to that value. But to the extent that it is presented to me by a manufacturer, I will use that as a point of leverage to try to get a lower——

Mr. WALDEN. Do you ever inquire about AWP, what it is and what—how much off you are being offered?

Mr. MARSHALL. As a standard, the AWP is provided when a proposal is provided to me for a new product.

Mr. WALDEN. So it is something that you look at then?

Mr. MARSHALL. I am aware of it.

Mr. WALDEN. Do you require it to be provided to you when you are looking at purchasing a product?

Mr. MARSHALL. We require it to put in into our systems.

Mr. WALDEN. Okay. So you are asking for AWP, the pricing on AWP, right?

Mr. MARSHALL. Yes, I am asking for the value.

Mr. WALDEN. Why do you ask for that?

Mr. MARSHALL. We need it to set up an item in our current systems at CVS.

Mr. WALDEN. What purpose does it serve in your current system then? It is to determine the spread?

Mr. MARSHALL. No. I am not certain, But it may have some role in third-party processing downstream. But I am not sure as to the purpose we need it.

Mr. WALDEN. You don't know what use it has in your company?

Mr. MARSHALL. I need to have that value to set up a new item. Correct.

Mr. WALDEN. I guess I am—but you don't know why you need it? You just know you need it?

Mr. MARSHALL. It is a value that I need to populate in our purchasing system.

Mr. WALDEN. But you don't know what role it plays in the purchasing system?

Mr. MARSHALL. I believe that downstream it may be used in our third-party processing systems.

Mr. WALDEN. And that third-party processing system does what? Is that the billing system to the government?

Mr. MARSHALL. The third-party system would be responsible for managing our third-party claims.

Mr. WALDEN. And who are third-party claims?

Mr. MARSHALL. Private as well as Medicaid.

Mr. WALDEN. So this does play a relationship then in the billing to Medicaid?

Mr. MARSHALL. Yes, as far as me populating that value, and ultimately downstream it may be used for that purpose.

Mr. WALDEN. But you are telling me you don't negotiate that AWP value——

Mr. MARSHALL. That is correct.

Mr. WALDEN. [continuing] when you are making a purchase.

Mr. MARSHALL. That is correct. I may negotiate a discounted purchase price.

Mr. WALDEN. Let me be clear. I realize that you don't necessarily set the AWP. But you negotiate a percentage off of that AWP, is that right?

Mr. MARSHALL. In some instances when I am presented with a price by a manufacturer and it is referenced as a discount off of an AWP. For example, the price we are willing to sell this to CVS is at 40 percent off of our established AWP. As a good negotiator, I may ask for 50 percent of AWP in that circumstance.

Mr. WALDEN. But you have never asked them to raise an AWP or said it is hard to buy your product because your AWP is so low?

Mr. WALDEN. That is correct.

Mr. WALDEN. Ms. Paoletti, I am curious then—hold on just a minute. I am sorry.

Mr. Marshall, can you go to Tab 42? You should have seen this, I am told by counsel.

This is an e-mail—is that correct? I will let you get there.

Mr. MARSHALL. Yes.

Mr. WALDEN. This is e an e-mail to Matthew J. Leonard, subject Roxane, cyclofosfamide.

It says, Matt, I thought an e-mail might be a little quicker and easier than trying to exchange voice mails on this. We spoke about cyclofosfamide a week or so ago. You indicated that our spread was not significant enough to pique your interest.

I would like to approach by company about what it might take to get CVS on board. Can you provide me with CVS's annual volume of the 25 milligram and 50 milligram product? Also, pass me the volume that you believe CVS would sway to the generic if I can bring you a 50 to 60 percent spread via a contract price. Thanks, Steve Snyder, National Account Manager, Eastern Midwest.

Does this not also reference the spread being important, AWP versus what you pay?

Mr. MARSHALL. Yes. In this case, just to clarify, my interpretation is the spread here is the established AWP of the manufacturer and a requested price to CVS.

Again, I can't comment on something that was written by another individual. But my interpretation would be it would be similar to what I had described earlier as far as a lever in negotiating a lower purchase price when you are presented with an AWP value.

Mr. WALDEN. All right. Ms. Paoletti, if you could turn to Tab 36. This is an e-mail to Judy Waterer from Robert Socora, I believe. And it lists the AWPs for, I assume, your competitors. Is that correct?

Ms. PAOLETTI. That is correct.

Mr. WALDEN. They are like 151.90, 141, 151, 140. And then Roxane is at 45.

Ms. PAOLETTI. Correct.

Mr. WALDEN. How did your AWP get so out of line with the others?

Ms. PAOLETTI. Again, we set our pricing, typically, when we launch the product, and then we don't revisit the AWP. It is typically set as a standard off of the brand in the generic industry, and we wouldn't typically readdress it. In this case, I can't say why the other competitors were higher.

Mr. WALDEN. Sure. Did you readdress it in this case, Furosomide?

Ms. PAOLETTI. We had to.

Mr. WALDEN. Why?

Ms. PAOLETTI. Because our AWP was so far out of line, as you can see with our competitors, that they wouldn't want the product.

Mr. WALDEN. I am confused between you and Mr. Marshall here. Because he says AWP—he doesn't set it. He is going to negotiate off of it for your purchase price, right? And you are saying it is not high enough. We are talking about CVS here in the middle.

Ms. PAOLETTI. I think we are talking about a very rare occasion. You know, we might talk about——

Mr. WALDEN. But I think it is indicative of a practice in the industry.

Ms. PAOLETTI. I am not sure that it is. This is a situation where it was so far out of line with our competitors that——

Mr. WALDEN. What would be the purpose being of raising it?

Ms. PAOLETTI. Our purpose was to just put us on a level playing field.

Mr. WALDEN. And for what purpose did you need to be on a level playing field?

Ms. PAOLETTI. Because the——

Mr. WALDEN. To get market share?

Ms. PAOLETTI. Absolutely.

Mr. WALDEN. For market share you needed to raise your AWP, which you said you didn't normally do once it is set?

Ms. PAOLETTI. That is true. Again, this is a very unique situation. We were faced with discontinuing the product because nobody would buy it, because no matter—even if our contract price was on a level playing field with our competitors and our service level and we were a-graded, the AWP, which is one additional factor, was so far out of line, again, that——

Mr. WALDEN. Right. It was out of line because the spread matters to those buying the product.

Ms. PAOLETTI. In some cases, I would assume that is true.

Mr. WALDEN. I would assume in every case, although it may not be as dramatic as this. If spread plays into it here, tell me why it wouldn't play into it everywhere else?

Ms. PAOLETTI. I think as long as you are relatively in the same ballpark, it hasn't been our experience that it is something that is dwelled on. AWP is generally a reference price that is sometimes, primarily in new launch products, used as a—just as a reference point in contract negotiations.

Mr. WALDEN. But it is a reference point that is used?

Ms. PAOLETTI. Yes.

Mr. WALDEN. So, I mean—I am having trouble believing that it is not an important part of this discussion.

Ms. PAOLETTI. I am sure it is an important factor in some decisions. I don't know that it is something that is dwelled on in every case.

Mr. WALDEN. So you don't think it is a big deal, AWP?

Ms. PAOLETTI. Absolutely. I think AWP and the issues need to be addressed. Is it something—is reimbursement something that we discuss in normal discussions with our customers? No.

Mr. WALDEN. All right. This will be a question to the representatives from the various pharmacies. Medicaid dispensing fees vary fairly widely from State to State. I think we have heard the national average for Medicaid dispensing fees appears to be somewhere in the neighborhood of $4 per prescription.

By way of comparison, the committee obtained data showing what the pharmacies receive in the way of dispensing fees from some of their larger third-party payors. One pharmacy chain also submitted data showing the average dispensing fees for all of its retail customers. These data showed an average of approximately $2.25 per prescription on the private side.

Why should Medicaid being paying more in the way of dispensing fees than private payors? Mr. Marshall, shall we start with you?

Mr. MARSHALL. Sure. I understand the data that you have presented to me. My understanding, there are two components to reimbursement. There is a negotiated formula component, which may involve the AWP or Federal upper limit or a MAC price. There is also the dispensing fee.

So I take your information at face value, but I really couldn't come to a conclusion as to, you know, whether we would be paying for Medicaid versus the private plans, other than on that absolute value of the dispensing fee.

Mr. WALDEN. Are the numbers correct, from your perspective, on the dispensing fee?

Mr. MARSHALL. I believe. I am not as closely tied to this in my current role. I knew that it was, you know, that Medicaid was a little higher than $3 and on the private a little higher than $2.

Mr. WALDEN. So we are in the ballpark here, from your historical background?

Mr. MARSHALL. Yes.

Mr. WALDEN. You can't comment as to why Medicaid should be paying more as a dispensing fee than other third-party payors?

Mr. MARSHALL. No. Again, I think you need to consider the entire equation as far as the overall reimbursement.

Mr. WALDEN. Mr. Ziebell.

Mr. ZIEBELL. I am not really familiar with the figures presented or how they apply to Walgreens, but I would agree you have to—you can't look just at the dispensing fee. You have to figure the cost component and how that figures in the calculation also.

Mr. WALDEN. All right. Mr. Seagrave.

Mr. SEAGRAVE. I think your numbers are fairly accurate. But I will tell you that when we look at reimbursement, we don't look at one segment of the formula. We look at the ingredient costs as well as the dispensing fee. We look at the total reimbursement. We don't look at one component or the other.

I will mention that, with respect to our Medicaid and Medicare business, it is not a business that we would negotiate as we do with the commercial payors such as the PBMs and the HMOs. So when we are looking at the business we look at it in total. We look at total reimbursement.

Mr. WALDEN. I appreciate that.

In fact, based upon the data provided by the pharmacies, Medicaid actually pays slightly more for ingredient costs, I am told.

And I guess—what I want to make sure of is that, as we move forward on the policy side here, is that we do the best we can to get it right, that we don't have a situation where we are paying more for drugs than we should and more than private payors are paying or others. We ought to pay what is fair. I don't believe AWP is fair. Then we are just guessing off of a percentage off AWP. There is all of these different systems.

I also want to make sure, though, that pharmacists are properly compensated so that if we change how you are being paid or how this system functions that we don't shortchange it and pharmacists suddenly write to all our constituents and say we are not going to dispense any more because those miserly turkeys in Congress changed the formula.

But I don't think it's right, either, to have a formula that ends up overcompensating on the drug side and undercompensating on dispensing or overcompensating on both. We need to try and figure out how to get it right, because the costs are exploding around us, and I would like to see a marketplace work, work honestly, work ethically.

I think Aventis got at this issue a bit when they realized AWP was going to become a tar baby for the industry. And I commend you for noticing that and for taking action, because I am amazed that AWP prior to this hasn't been blown out of the water and, after seeing what we went through on Medicare, that something didn't change for Medicaid prior to this.

Turn to the gentleman from Michigan, Mr. Stupak.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. Catlett, if I can go back to you. The statement you made in your testimony states that, again, if a generic manufacturer unilaterally reduced its AWP for a given product relative to the AWPs of other generic manufacturers for the same product, pharmacies would have an incentive to purchase another manufacturer's drug that did not reduce its AWP. Why did you say in your testimony?

Mr. CATLETT. I believe that potentially could happen. I mean, I could not think of an instance where it has happened. I think I

mentioned that earlier. But my fear, if there was a great disparity, that—between AWPs of generic products, that potentially the company that had the lowest AWP may not be in a position to sell their product in a system where there is AWP-based reimbursement in terms of how that's how the system's being based.

Mr. STUPAK. Has your company ever had the lowest AWP and had it purchased by the pharmacies? Have you lowered your AWP to be lowest and had that happen, where they had purchased your AWP?

Mr. CATLETT. No, I have no recollection of that.

Mr. STUPAK. Ms. Marrs, if the pharmacies would purchase at a lower AWP, could you lower your AWPs on your products and stay in business?

Ms. MARRS. As I mentioned before, I think key to this, and similar to what Ms. Paoletti said, there has to be a level playing field. The manufacturer has no incentive to keep their AWPs high. We are just trying to compete in a fair market. So whatever the government chooses as their reimbursement system, we want there to be a level playing field for all manufacturers of the same product.

Mr. STUPAK. Sure. But the point is, you could lower all your AWPs and still stay in business, couldn't you?

Ms. MARRS. Probably not. As I've testified, we had a similar experience to Ms. Paoletti.

Mr. STUPAK. And the reason why you couldn't, because they wouldn't purchase it, right?

Ms. MARRS. I don't believe they would.

Mr. STUPAK. Okay.

Ms. MARRS. In fact, the product I mentioned when we had a lower AWP, we did not raise our AWP. We no longer sell the product because we could not compete.

Mr. STUPAK. And only because no one would purchase it.

Ms. MARRS. Correct.

Mr. STUPAK. But if they would purchase at a lower AWP, you could probably lower all your AWPs of the products you sell and still stay in business as long someone would purchase your product. Right?

Ms. MARRS. Correct.

Mr. STUPAK. And in your testimony—and why wouldn't they purchase your product?

Ms. MARRS. Well, because they are being reimbursed at a much lower rate for our product than somebody else's in this particular case.

Mr. STUPAK. Correct. So the company wouldn't make as much money; and, again, the taxpayer/customers wouldn't have to pay, right?

Ms. MARRS. Correct.

Mr. STUPAK. Thank you.

I have nothing further, Mr. Chairman.

Mr. WALDEN. Thank you, Mr. Stupak.

We don't have anything else at this time for the committee. We greatly appreciate your insights and your patience, and we will look forward to staying in communication with all of you.

With this, the third panel is dismissed. The record will remain open for ample opportunity for members to submit other questions or testimony; and, with that, the subcommittee is adjourned.

[Whereupon, at 2:02 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
Medical Services Administration

MEMORANDUM

DATE: January 3, 2005

TO: Michael Abraham
Voncille Hines
Committee on Energy and Commerce
U.S. House of Representatives

FROM: Paul Reinhart, Director
Medical Services Administration

SUBJECT: Medicaid Prescription Drug Reimbursement Question

In a December 21, 2004 letter to me, Rep John Dingell asked me to respond to a question regarding my testimony at the Subcommittee on Oversight and Investigations' December 7, 2004 hearing.

Rep. Dingell asked, "Please explain in detain the financial impact of the clawback provision of the Medicare Modernization Act on Michigan overall, particularly since Michigan, as you testified, has been particularly aggressive in cutting its prescription drug costs under Medicaid, and Congress agreed to "do no harm" to the states in that legislation."

Here's my response:

The clawback provision of the Medicare Modernization Act is likely to increase Michigan's costs because the Michigan Medicaid program has been able to hold the rate of growth in pharmaceutical costs for dual eligibles to a level considerably below the growth factor that will be used by the federal government to determine state clawback payment amounts.

Michigan's aggressive pharmacy cost containment program - - the preferred drug list, the multi-state pharmaceutical pooling initiative, daily maximum allowable cost pricing, and steeply discounted average wholesale prices - - have reduced the rate of growth in pharmacy costs for dual eligibles to 4 to 5 percent per year. According to statements from CMS, initial state clawback payments to the federal government will be calculated using national annual drug cost inflation factors that are typically around 12 percent. Even after adjusting the 12 percent per year growth factors for the 10 percent discount for 2006 (i.e., the "declining state percentage"), Michigan's cost will still be greater then they would have been under the our much lower state-managed 4 percent growth rate.

As I indicated in my testimony, it's likely that Michigan's general fund clawback costs will be $20 million greater than they would have been under the current state-managed program in FY06 and $30 million greater in FY07.

I hope this information answers Rep. Dingell's question, but, if not, feel free to ask for additional detail.

Thank you again for the opportunity to discuss this issue with the subcommittee.

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

ALBERT I AWKINS
EXECUTIVE C IMMISSIONER

January 6, 2005

Via FAX/E-Mail

The Honorable John D. Dingell
U.S. House of Representatives
Committee on Energy and Commerce
2322 Rayburn House Office Building
Washington, D.C. 20515-6115

Dear Representative Dingell:

Thank you for the opportunity to provide additional information to the Committee. In your letter, you requested a response to the following question:

> Please explain in detail the financial impact of the clawback provision of the Medicare Modernization Act on Texas overall, particularly since Texas, as you testified, has been particularly aggressive in cutting its prescription drug costs under Medicaid, and Congress agreed to "do no harm" to the states in that legislation.

When the Medicare Modernization Act federalized drug benefits for dual eligible (Medicare and Medicaid) beneficiaries, it created an undesirable federal financial precedent for states. State governments (through the clawback provision) will now be required, for the first time, to provide direct financing for a federal Medicare benefit.

Little in the way of near-term state savings will be realized, due to the structure of the clawback formula. The formula uses 2003 Medicaid drug expenditures as the base year for determining state payments. Texas, like many other states, has since implemented a number of initiatives to bring down the costs of prescription drugs such as a preferred drug list, prior authorization of some drugs, supplemental rebates, and an evaluation of pharmacy benefit management. Using 2003 as the base year will fail to recognize aggressive state efforts to reduce the rate of growth on drug spending. States, at their option, should be allowed to use later base years that reflect fuller drug spending controls.

The formula also phases in the reduction in state spending very slowly. For example, in 200 6, states will be required to pay an amount equal to 90 percent of the clawback formula's calculation. The states' payment does not decline to 75 percent of the clawback estimate un il 2015. This slow decline in the state's new financing obligation combined with the base yeai problem and dual eligible caseload growth resulting from the MMA will mean questionable "savings" for state Medicaid programs. Texas estimates that clawback payments will total a bout $175 million in FY 2006 and climb to $290 million in FY 2007.

I hope this information adequately addresses the issue regarding the clawback provision of t ie Medicare Modernization Act and its financial impact on Texas. Please let me know if you v ould like any additional information.

Sincerely,

David J. Balland
Associate Commissioner for Medicaid and CHIP

DJB:GS:la

Attachment

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Greg Walden, Vice Chairman
Subcommittee on Oversight and Investigations

The Honorable Peter Deutsch, Ranking Member
Subcommittee on Oversight and Investigations

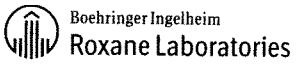
Question for Mr. David J. Balland
Associate Commissioner for Medicaid and CHIP
Texas Health and Human Services Commission
From the Honorable John D. Dingell
Committee on Energy and Commerce
Regarding the December 7, 2004, Subcommittee on Oversight and Investigations Hearing entitled "Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much"

1. Please explain in detail the financial impact of the clawback provision of the Medicare Modernization Act on Texas overall, particularly since Texas, as you testified, has been particularly aggressive in cutting its prescription drug costs under Medicaid, and Congress agreed to "do no harm" to the states in that legislation.

   When the Medicare Modernization Act federalized drug benefits for dual eligible (Medicare and Medicaid) beneficiaries, it created an undesirable federal financial precedent for states. State governments (through the clawback provision) will now be required, for the first time, to provide direct financing for a federal Medicare benefit.

   Little in the way of near-term state savings will be realized, due to the structure of the clawback formula. The formula uses 2003 Medicaid drug expenditures as the base year for determining state payments. Texas, like many other states, has since implemented a number of initiatives to bring down the costs of prescription drugs such as a preferred drug list, prior authorization of some drugs, supplemental rebates, and an evaluation of pharmacy benefit management. Using 2003 as the base year will fail to recognize aggressive state efforts to reduce the rate of growth on drug spending. States, at their option, should be allowed to use later base years that reflect fuller drug spending controls.

   The formula also phases in the reduction in state spending very slowly. For example in 2006, states will be required to pay an amount equal to 90 percent of the clawback formula's calculation. The states' payment does not decline to 75 percent of the clawback estimate until 2015. This slow decline in the state's new financing obligation combined with the base year problem and dual eligible caseload growth resulting from the MMA will mean questionable "savings" for state Medicaid programs. Texas estimates that clawback payments will total about $175 million in FY 2006 and climb to $290 million in FY 2007.



The Honorable Chairman Joe Barton
U.S. House of Representatives
Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

January 18, 2005

Dear Chairman Barton:

This letter is in response to a series of questions Congressman Mike Rodgers (R-MI) asked me during the December 7, 2004 hearing before the House Energy and Commerce Oversight and Investigation Subcommittee. Congressman Rodgers asked that I outline on behalf of Roxane Laboratories, Inc. the cost broad based class action and state law suits have had on the company.

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It is important to note at the outset that Roxane complies fully with all applicable laws and regulations, including all requirements of the State Medicaid programs. As a generic pharmaceutical company Roxane strives to provide high value products that extend and improve people's lives while at the same time saving state and federal government's money by avoiding more expensive alternative treatment options.

Despite Roxane's commitment to full compliance with all laws and regulations, Roxane has, like numerous other pharmaceutical manufacturers, been named in a host of lawsuits that Roxane believes are without merit.

- Roxane had been called into a series of "cookie cutter" class action suits. Nation wide, there are well over 50 proposed class action and "whistleblower" lawsuits on the same topic brought by trial lawyers seeking, among other things, hundreds of millions of dollars in attorneys' fees – money that will go to the lawyers and not to the governmental and non-governmental health care programs that pay for prescription drugs.
- Defending these lawsuits has forced Roxane to spend literally millions of dollars and thousands of hours of employee time – money and time that could be spent developing and marketing generic products that save lives and reduce Medicaid budgets. In the end, the hidden tax of this meritless litigation ultimately harms the American consumer.
- Roxane has had to produce tens of thousands of documents, in hard copy and electronic form, in multiple fora, at great expense and effort.

The Plaintiff's bar has found yet another way to take advantage of lack of clarity with government regulation. We support reforming the Medicaid system and call on Congress and State governments to provide much needed guidance so generic companies like Roxane can continue to operate within the law without fear of excessive and meritless law suits that ultimately harm the American consumer. We also strongly support any form of reasonable tort reform as a beginning to reeling in what is clearly a legal system out of control.

Thank you for the opportunity to respond to these questions in writing.

Sincerely,

Lesli Paoletti
Senior Product Manager

cc: The Honorable Mike Rodgers (R-MI)

Aventis Pharmaceuticals

24	Policy Decision Memorandum re: Average Wholesale Price (AWP)	11/12/02	263-272

Dey Laboratories

25	Robert Mosak Memo re: Albuterol Pricing Strategies	02/24/92	90851-855
26	Reimbursement Comparison Worksheet	01/31/95	170961
27	Memo from Covay to Tipton re: Achievement of Objectives for 1995 Commissions	05/08/95	
28	Memo from Burnham to Sales & Marketing re: Albuterol WAC Pricing	05/30/95	122497
29	Voice Mail from Dan Maloney to Mike Wilson re: Ipratropium	06/28/00	8488
30	Dey Bid Price Worksheets w/ E-Mail from Mike Wilson re: Caremark	07/10/01	5808-5811
31	E-Mails re: DuoNeb Proposal	08/01/02	145847
32	E-Mail from Pam Marrs to Klaus Rueth re: 2001 Cash Flow Projections	03/12/01	164080-081
33	Fax Cover Sheet re: DuoNeb Agreement with CVS	05/12/00	153225

Roxane Laboratories

34	Letter from Paoletti to First Data Bank re: Product Listing for Roxane	10/20/99	879
35	Graph Prepared by Committee Staff re: Furosemide Pricing		
36	E-Mail from Robert Sykora re: Furosemide AWP	04/14/00	1793
37	E-Mail from Waterer to Paoletti re: Furosemide AWP Adjustment and Attached Memo	07/26/00	1999-2008
38	E-Mail Exchange between Waterer and Snyder re: CVS Furosemide Opportunity	06/28/00	1788
39	E-Mail Chain between Waterer and Tavolaro re: Furosemide	07/24/00	381
40	E-Mail Exchange re: Albuterol and Ipratroprium Update	07/13/01	1446
41	Graph Prepared by Committee Staff re: Ipratroprium Pricing	1998-2003	
42	E-Mail Exchange re: CVS Cyclophosphamide	04/20/00	1896-1897
43	E-Mail from Dawn Gordon to Judy Waterer re: CCP Issues	05/03/00	1906

Barr Laboratories

44	Fluoxetine 20mg Capsules Agreement with Wal-Mart	02/06/01	210-211
45	Letter from Barr Acct. Manager to Buyer re: Fluoxetine Price [Redacted]	07/29/02	CC 000078
46	Red Book Product Information for Fluoxetine	06/03/04	
47	Graph Prepared by Committee Staff re: Fluoxetine Pricing	2001-2003	

Pricing Graphs

48	Graph Prepared by Committee Staff re: Pharmacy Pricing for 7 Select Generic Drugs		
49	Graph Prepared by Committee Staff re: Pharmacy Pricing for Buspirone - 20mg		
50	Graph Prepared by Committee Staff re: Pharmacy Pricing for Ipratroprium Bromide		
51	Graph Prepared by Committee Staff re: Pharmacy Pricing for Fluoxetine - 20mg		

Other

52	Kaiser Commission - Medicaid Outpatient Prescription Drug Benefits Survey Results	12/01/03	

Dated: April 18, 2003.
Elizabeth M. Duke,
Administrator.
[FR Doc. 03-10934 Filed 5-2-03; 8:45 am]
BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Pharmaceutical Manufacturers developed by the Office of Inspector General (OIG). Through this notice, the OIG is setting forth its general views on the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.

FOR FURTHER INFORMATION CONTACT: Mary E. Riordan or Nicole C. Hall, Office of Counsel to the Inspector General, (202) 619-2078.

SUPPLEMENTARY INFORMATION:

Background

Compliance program guidance is a major initiative of the OIG in its effort to engage the health care community in preventing and reducing fraud and abuse in federal health care programs. The purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements. In the last several years, the OIG has developed and issued compliance program guidance directed at the following segments of the health care industry: the hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; Medicare+Choice organizations offering coordinated care plans; hospices; nursing facilities; individual and small group physician practices; and ambulance suppliers.

Copies of these compliance program guidances can be found on the OIG Web site at *http://oig.hhs.gov/fraud/complianceguidance.html.*

Developing the Compliance Program Guidance for Pharmaceutical Manufacturers

On June 11, 2001, the OIG published a solicitation notice seeking information and recommendations for developing compliance program guidance for the pharmaceutical industry (66 FR 31246). In response to that solicitation notice, the OIG received eight comments from various outside sources. We carefully considered those comments, as well as previous OIG publications, such as other compliance program guidances and Special Fraud Alerts. In addition, we have taken into account past and ongoing fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration). In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, draft compliance program guidance for the pharmaceutical industry was published in the **Federal Register** on October 3, 2002 (67 FR 62057) for further comments and recommendations.

Elements for an Effective Compliance Program

This compliance program guidance for pharmaceutical manufacturers contains seven elements that have been widely recognized as fundamental to an effective compliance program:

- Implementing written policies and procedures;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems and undertaking corrective action.

These elements are included in previous guidances issued by the OIG. As with previously issued guidances, this compliance program guidance represents the OIG's suggestions on how pharmaceutical manufacturers can establish internal controls to ensure adherence to applicable rules and program requirements. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program. The document is intended to present voluntary guidance to the industry and not to represent binding standards for pharmaceutical manufacturers.

Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services is continuing in its efforts to promote voluntary compliance programs for the health care industry. This compliance guidance is intended to assist companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products (pharmaceutical manufacturers) in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care programs[1] and in evaluating and, as necessary, refining existing compliance programs.

This guidance provides the OIG's views on the fundamental elements of pharmaceutical manufacturer compliance programs and principles that each pharmaceutical manufacturer should consider when creating and implementing an effective compliance program. This guide is not a compliance program. Rather, it is a set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one. For those manufacturers with an existing compliance program, this guidance may serve as a benchmark or comparison against which to measure ongoing efforts.

A pharmaceutical manufacturer's implementation of an effective compliance program may require a significant commitment of time and resources by various segments of the organization. In order for a compliance program to be effective, it must have the support and commitment of senior management and the company's governing body. In turn, the corporate leadership should strive to foster a culture that promotes the prevention, detection, and resolution of instances of problems. Although an effective compliance program may require a reallocation of existing resources, the long-term benefits of establishing a compliance program significantly outweigh the initial costs.

In a continuing effort to collaborate closely with the pharmaceutical industry, the OIG published a notice in

[1] (Endnotes appear at end of document)

the **Federal Register** soliciting comments and recommendations on what should be included in this compliance program guidance.[2] Following our review of comments received in response to the solicitation notice, we published draft compliance guidance in the **Federal Register** in order to solicit further comments and recommendations.[3] In addition to considering the comments received in response to that solicitation notice and the draft compliance guidance, in finalizing this guidance we reviewed previous OIG publications, including OIG advisory opinions, safe harbor regulations (including the preambles) relating to the federal anti-kickback statute,[4] Special Fraud Alerts, as well as reports issued by the OIG's Office of Audit Services and Office of Evaluation and Inspections relevant to the pharmaceutical industry. (These materials are available on the OIG Web page at *http://oig.hhs.gov.*) In addition, we relied on the experience gained from investigations of pharmaceutical manufacturers conducted by OIG's Office of Investigations, the Department of Justice, and the state Medicaid Fraud Control Units. We also held meetings with four groups of industry stakeholders—Pharmaceutical Research and Manufacturers of America (PhRMA) and pharmaceutical manufacturer representatives; health plan and health plan association representatives; representatives of pharmacy benefit managers (PBMs) and representatives of the American Medical Association (AMA) and its member organizations.

A. Benefits of a Compliance Program

The OIG believes a comprehensive compliance program provides a mechanism that addresses the public and private sectors' mutual goals of reducing fraud and abuse; enhancing health care provider operational functions; improving the quality of health care services; and reducing the cost of health care. Attaining these goals provides positive results to the pharmaceutical manufacturer, the government, and individual citizens alike. In addition to fulfilling its legal duty to avoid submitting false or inaccurate pricing or rebate information to any federal health care program or engaging in illegal marketing activities, a pharmaceutical manufacturer may gain important additional benefits by voluntarily implementing a compliance program. The benefits may include:

- A concrete demonstration to employees and the community at large of the company's commitment to honest and responsible corporate conduct;
- An increased likelihood of preventing, or at least identifying, and correcting unlawful and unethical behavior at an early stage;
- A mechanism to encourage employees to report potential problems and allow for appropriate internal inquiry and corrective action; and
- Through early detection and reporting, minimizing any financial loss to the government and any corresponding financial loss to the company.

The OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from the operations of a pharmaceutical manufacturer. However, a good faith effort by the company to comply with applicable statutes and regulations as well as federal health care program requirements, demonstrated by an effective compliance program, significantly reduces the risk of unlawful conduct and any penalties that result from such behavior.

B. Application of Compliance Program Guidance

Given the wide diversity within the pharmaceutical industry, there is no single "best" pharmaceutical manufacturer compliance program. The OIG recognizes the complexities of this industry and the differences among industry members. Some pharmaceutical manufacturers are small and may have limited resources to devote to compliance measures. Conversely, other companies are well-established, large multi-national corporations with a widely dispersed work force. Some companies may have well-developed compliance programs already in place; others only now may be initiating such efforts. The OIG also recognizes that pharmaceutical manufacturers are subject to extensive regulatory requirements in addition to fraud and abuse-related issues and that many pharmaceutical manufacturers have addressed these obligations through compliance programs. Accordingly, the OIG strongly encourages pharmaceutical manufactures to develop and implement or refine (as necessary) compliance elements that uniquely address the areas of potential problems, common concern, or high risk that apply to their own companies (or, as applicable, to the U.S. operations of their companies).

For example, although they are not exhaustive of all potential risk areas, the OIG has identified three major potential risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and federal governments to establish payment; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples. The risk areas are discussed in greater detail in section II.B.2. below. The compliance measures adopted by a pharmaceutical manufacturer should be tailored to fit the unique environment of the company (including its organizational structure, operations and resources, as well as prior enforcement experience). In short, the OIG recommends that each pharmaceutical manufacturer should adapt the objectives and principles underlying the measures outlined in this guidance to its own particular circumstances.[5]

II. Compliance Program Elements

A. The Basic Compliance Elements

The OIG believes that every effective compliance program must begin with a formal commitment by the pharmaceutical manufacturer's board of directors or other governing body. Evidence of that commitment should include the allocation of adequate resources, a timetable for the implementation of the compliance measures, and the identification of an individual to serve as a compliance officer to ensure that each of the recommended and adopted elements is addressed. Once a commitment has been undertaken, a compliance officer should immediately be chosen to oversee the implementation of the compliance program.

The elements listed below provide a comprehensive and firm foundation upon which an effective compliance program may be built. Further, they are likely to foster the development of a corporate culture of compliance. The OIG recognizes that full implementation of all elements may not be immediately feasible for all pharmaceutical manufacturers. However, as a first step, a good faith and meaningful commitment on the part of the company's management will substantially contribute to the program's successful implementation. As the compliance program is implemented, that commitment should filter down through management to every employee and contractor of the pharmaceutical manufacturer, as applicable for the particular individual.

At a minimum, a comprehensive compliance program should include the following elements:

(1) The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that verbalize the company's commitment to compliance (e.g., by including adherence to the compliance

program as an element in evaluating management and employees) and address specific areas of potential fraud and abuse, such as the reporting of pricing and rebate information to the federal health care programs, and sales and marketing practices;

(2) The designation of a compliance officer and other appropriate bodies (*e.g.*, a corporate compliance committee) charged with the responsibility for developing, operating, and monitoring the compliance program, and with authority to report directly to the board of directors and/or the president or CEO;

(3) The development and implementation of regular, effective education and training programs for all affected employees;

(4) The creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process (such as a hotline or other reporting system) to receive complaints or questions, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;

(5) The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems;

(6) The development of policies and procedures addressing the non-employment or retention of individuals or entities excluded from participation in federal health care programs, and the enforcement of appropriate disciplinary action against employees or contractors who have violated company policies and procedures and/or applicable federal health care program requirements; and

(7) The development of policies and procedures for the investigation of identified instances of noncompliance or misconduct. These should include directions regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action and preventive measures and processes to report the offense to relevant authorities in appropriate circumstances.

B. Written Policies and Procedures

In developing a compliance program, every pharmaceutical manufacturer should develop and distribute written compliance standards, procedures, and practices that guide the company and the conduct of its employees in day-to-day operations. These policies and procedures should be developed under the direction and supervision of the compliance officer, the compliance committee, and operational managers. At a minimum, the policies and procedures should be provided to all employees who are affected by these policies, and to any agents or contractors who may furnish services that impact federal health care programs (*e.g.*, contractors involved in the co-promotion of a manufacturer's products).

1. Code of Conduct

Although a clear statement of detailed and substantive policies and procedures is at the core of a compliance program, the OIG recommends that pharmaceutical manufacturers also develop a general corporate statement of ethical and compliance principles that will guide the company's operations. One common expression of this statement of principles is the code of conduct. The code should function in the same fashion as a constitution, *i.e.*, as a document that details the fundamental principles, values, and framework for action within an organization. The code of conduct for a pharmaceutical manufacturer should articulate the company's expectations of commitment to compliance by management, employees, and agents, and should summarize the broad ethical and legal principles under which the company must operate. Unlike the more detailed policies and procedures, the code of conduct should be brief, easily readable, and cover general principles applicable to all employees.

As appropriate, the OIG strongly encourages the participation and involvement of the pharmaceutical manufacturer's board of directors, CEO, president, members of senior management, and other personnel from various levels of the organizational structure in the development of all aspects of the compliance program, especially the code of conduct. Management and employee involvement in this process communicates a strong and explicit commitment by management to foster compliance with applicable federal health care program requirements. It also communicates the need for all employees to comply with the organization's code of conduct and policies and procedures.

2. Specific Risk Areas

This section is intended to help prudent pharmaceutical manufacturers identify areas of their operations that present potential risk of liability under several key federal fraud and abuse statutes and regulations.[6] This section focuses on areas that are currently of concern to the enforcement community and is not intended to address all potential risk areas for pharmaceutical manufacturers. Importantly, the identification of a particular practice or activity in this section is not intended to imply that the practice or activity is necessarily illegal in all circumstances or that it may not have a valid or lawful purpose underlying it.

This section addresses the following areas of significant concern for pharmaceutical manufacturers: (1) Integrity of data used by state and federal governments to establish payment amounts; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.

This guidance does not create any new law or legal obligations, and the discussions that follow are not intended to present detailed or comprehensive summaries of lawful and unlawful activity. Rather, these discussions should be used as a starting point for a manufacturer's legal review of its particular practices and for development of policies and procedures to reduce or eliminate potential risk.

a. Integrity of Data Used To Establish or Determine Government Reimbursement. Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act[7] if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti-kickback statute.

Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or

other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

Given the importance of the Medicaid Rebate Program, as well as other programs that rely on Medicaid Rebate Program benchmarks (such as the 340B Program [8]), manufacturers should pay particular attention to ensuring that they are calculating Average Manufacturer Price and Best Price accurately and that they are paying appropriate rebate amounts for their drugs.[9]

In sum, pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes.

b. Kickbacks and Other Illegal Remuneration—*A. General Considerations.* Pharmaceutical manufacturers, as well as their employees and agents, should be aware of the federal anti-kickback statute and the constraints it places on the marketing and promotion of products reimbursable by the federal health care programs, including, but not limited to, Medicare and Medicaid. In the health care sector, many common business activities, including, for example, sales, marketing, discounting, and purchaser relations, potentially implicate the anti-kickback statute. Pharmaceutical manufacturers and their employees and agents should be aware that the anti-kickback statute prohibits in the health care industry some practices that are common in other business sectors. In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business.

The anti-kickback statute is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of federal health care business. The anti-kickback statute addresses not only the offer or payment of anything of value for patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal health care program. The statute extends equally to the solicitation or acceptance of remuneration for referrals. Liability under the anti-kickback statute is determined separately for each party involved. In addition to criminal penalties, violators may be subject to civil monetary sanctions and exclusion from the federal health care programs. Under certain circumstances, a violation of the anti-kickback statute may give rise to liability under the False Claims Act.

Although liability under the anti-kickback statute ultimately turns on a party's intent, it is possible to identify arrangements or practices that may present a significant potential for abuse. Initially, a manufacturer should identify any remunerative relationship between itself (or its representatives) and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly. Persons or entities in a position to generate federal health care business include, for example, purchasers, benefit managers, formulary committee members, group purchasing organizations (GPOs), physicians and certain allied health care professionals, and pharmacists. The next step is to determine whether any *one* purpose of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program. Importantly, a lawful purpose will not legitimize a payment that also has an unlawful purpose.

Although any arrangement satisfying both tests requires careful scrutiny from a manufacturer, the courts have identified several potentially aggravating considerations that can be useful in identifying arrangements at greatest risk of prosecution. In particular, manufacturers should ask the following questions, among others, about any problematic arrangements or practices they identify:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Does it have a potential to undermine the clinical integrity of a formulary process? If the arrangement or practice involves providing information to decision-makers, prescribers, or patients, is the information complete, accurate, and not misleading?
- Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees? Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

Manufacturers that have identified problematic arrangements or practices can take a number of steps to reduce or eliminate the risk of an anti-kickback violation. Detailed guidance relating to a number of specific practices is available from several sources. Most importantly, the anti-kickback statute and the corresponding regulations establish a number of "safe harbors" for common business arrangements, including personal services and management contracts, 42 CFR 1001.952(d), warranties, 42 CFR 1001.952(g), discounts, 42 CFR 1001.952(h), employment, 42 CFR 1001.952(i), GPOs, 42 CFR 1001.952(j), and certain managed care and risk sharing arrangements, 42 CFR 1001.952(m), (t), and (u). *Safe harbor protection requires strict compliance with all applicable conditions set out in the relevant safe harbor.* Although compliance with a safe harbor is voluntary and failure to comply with a safe harbor does not mean an arrangement is illegal, many arrangements can be structured to fit in safe harbors, and we recommend that pharmaceutical manufacturers structure arrangements to fit in a safe harbor whenever possible. Other available guidance includes special fraud alerts and advisory bulletins issued by the OIG identifying and discussing particular practices or issues of concern and OIG advisory opinions issued to specific parties about their particular business arrangements. Parties may apply for an OIG advisory opinion using the procedures set out at 42 CFR part 1008. The safe harbor regulations (and accompanying **Federal Register** preambles), fraud alerts and bulletins, advisory opinions (and instructions for obtaining them), and other guidance are available on the OIG web site at *http://oig.hhs.gov.*

B. Key Areas of Potential Risk. The following discussion highlights several known areas of potential risk. The propriety of any particular arrangement can only be determined after a detailed examination of the attendant facts and circumstances. *The identification of a given practice or activity as "suspect" or as an area of "risk" does not mean it is necessarily illegal or unlawful, or that it*

cannot be properly structured to fit in a safe harbor. Nor does it mean that the practice or activity is not beneficial from a clinical, cost, or other perspective. Rather, the areas identified below are those areas of activity that have a potential for abuse based on historical law enforcement experience and that should receive close scrutiny from manufacturers. The discussion highlights potential risks under the anti-kickback statute arising from pharmaceutical manufacturers' relationships with three groups: purchasers (including those using formularies) and their agents; persons and entities in a position to make or influence referrals (including physicians and other health care professionals); and sales agents.

(1) Relationships with Purchasers and their Agents—(a) Discounts and Other Remuneration to Purchasers. Pharmaceutical manufacturers offer purchasers a variety of price concessions and other remuneration to induce the purchase of their products. Purchasers include direct purchasers (*e.g.*, hospitals, nursing homes, pharmacies, some physicians), as well as indirect purchasers (*e.g.*, health plans). Inducements offered to purchasers potentially implicate the anti-kickback statute if the purchased products are reimbursable to the purchasers, in whole or in part, directly or indirectly, by any of the federal health care programs. Any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the anti-kickback statute and should be carefully reviewed.

Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, manufacturers have a strong financial incentive to hide *de facto* pricing concessions to other purchasers to avoid passing on the same discount to the states. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized.

Discounts. Public policy favors open and legitimate price competition in health care. Thus, the anti-kickback statute contains an exception for discounts offered to customers that submit claims to the federal health care programs, if the discounts are properly disclosed and accurately reported. *See* 42 U.S.C. 1320a–7b(b)(3)(A); 42 CFR 1001.952(h). However, to qualify for the exception, the discount must be in the form of a *reduction in the price* of the good or service based on an arms-length transaction. In other words, the exception covers only reductions in the product's price. Moreover, the regulations provide that the discount must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (*i.e.*, a rebate).

Manufacturers offering discounts should thoroughly familiarize themselves, and have their sales and marketing personnel familiarize themselves, with the discount safe harbor at 42 CFR 1001.952(h) (and, if relevant, the safe harbors for price reductions in the managed care context, 42 CFR 1001.952(m), (t), and (u)). In particular, manufacturers should pay attention to the discount safe harbor requirements applicable to "sellers" and "offerors" of discounts. Under the safe harbor, sellers and offerors have specific obligations that include (i) informing a customer of any discount and of the customer's reporting obligations with respect to that discount, and (ii) refraining from any action that would impede a customer's ability to comply with the safe harbor. To fulfill the safe harbor requirements, manufacturers will need to know how their customers submit claims to the federal health care programs (*e.g.*, whether the customer is a managed care, cost-based, or charge-based biller). Compliance with the safe harbor is determined separately for each party.

Product Support Services. Pharmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product. Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns. For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal health care program.

Educational Grants. Pharmaceutical manufacturers sometimes provide grant funding for a wide range of educational activities. While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchasers, GPOs, PBMs and similar entities raise concerns under the anti-kickback statute. Funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate. Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes.

To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions. Effective separation of these functions will help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate. Manufacturers should establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are *bona fide.* The manufacturer should have no control over the speaker or content of the educational presentation. Compliance with such procedures should be documented and regularly monitored.

Research Funding. Manufacturers often contract with purchasers of their products to conduct research activities on behalf of the manufacturer on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. Post-marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug. Prudent manufacturers will develop contracting procedures that

clearly separate the awarding of research contracts from marketing. Research contracts that originate through the sales or marketing functions—or that are offered to purchasers in connection with sales contacts—are particularly suspect.

Pharmaceutical manufacturers sometimes provide funding to their purchasers for use in the purchasers' own research. In many cases, the research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes better delivery of health care, or otherwise benefits patients. However, as with educational grants, if linked directly or indirectly to the purchase of product, research grants can be misused to induce the purchase of business without triggering Medicaid Best Price obligations. To reduce risk, manufacturers should insulate research grant making from sales and marketing influences.

Other remuneration to purchasers. As already noted, any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the anti-kickback statute and should be carefully reviewed. Examples of remuneration in connection with a sale include, but are not limited to, "prebates" and "upfront payments," other free or reduced-price goods or services, and payments to cover the costs of "converting" from a competitor's product. Selective offers of remuneration (*i.e.*, offers made to some but not all purchasers) may increase potential risk if the selection criteria relate directly or indirectly to the volume or value of business generated. In addition, manufacturers may contract with purchasers to provide services to the manufacturer, such as data collection services. These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be fair market value for legitimate, reasonable, and necessary services.

(b) Formularies and Formulary Support Activities. To help control drug costs while maintaining clinical appropriateness and quality of patient care, many purchasers of pharmaceutical products, including indirect purchasers such as health plans, have developed drug formularies to promote rational, clinically appropriate, safe, and cost-effective drug therapy. Formularies are a well-established tool for the effective management of drug benefits. The formulary development process—typically overseen by a committee of physicians, pharmacists, and other health care professionals—determines the drugs that are covered and, if tiered benefit levels are utilized, to which tier the drugs are assigned. So long as the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs, the development of a formulary is unlikely to raise significant issues under the anti-kickback statute.

Formulary support activities, including related communications with patients and physicians to encourage compliance, are an integral and essential component of successful pharmacy benefits management. Proper utilization of a formulary maximizes the cost-effectiveness of the benefit and assures the quality and appropriateness of the drug therapy. When provided by a PBM, these services are part of the PBM's formulary and benefit management function—a service provided to its customers—and markedly different from its purchasing agent/price negotiator role. Most importantly, the benefits of these formulary support activities inure directly to the PBM and its customers through lower costs.

To date, Medicare and Medicaid involvement with outpatient drug formularies has been limited primarily to Medicaid and Medicare managed care plans. In light of the safe harbors under the anti-kickback statute for those managed care arrangements, the financial arrangements between health plans and pharmaceutical manufacturers or, where the pharmacy benefit is managed by a PBM, the arrangements among the three parties, have received relatively little scrutiny. However, as federal program expenditures for, and coverage of, outpatient pharmaceuticals increase, scrutiny under the anti-kickback statute has also increased. Several practices appear to have the potential for abuse.

• *Relationships with formulary committee members.* Given the importance of formulary placement for a manufacturer's products, unscrupulous manufacturers and sales representatives may attempt to influence committee deliberations. Any remuneration from a manufacturer or its agents directly or indirectly to person in a position to influence formulary decisions related to the manufacturer's products are suspect and should be carefully scrutinized. Manufacturers should also review their contacts with sponsors of formularies to ensure that price negotiations do not influence decisions on clinical safety or efficacy.

• *Payments to PBMs.* Any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM's customers' purchases *potentially* implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j). That safe harbor requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer. In addition, arrangements with PBMs that assume risk may raise different issues; depending on the circumstances, protection for such arrangements may be available under the managed care safe harbors at 42 CFR 1001.952(m), (t) and (u).

• *Formulary placement payments.* Lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized.

In addition, some manufacturers provide funding for purchasers' or PBMs' formulary support activities, especially communications with physicians and patients. While the communications may indirectly benefit the manufacturer, the primary economic beneficiary is typically the formulary sponsor. In other words, the manufacturer's dollars appear to replace dollars that would or should be spent by the sponsor. To the extent the manufacturers' payments are linked to drug purchases directly or indirectly, they potentially implicate the anti-kickback statute. Among the questions that should be examined by a manufacturer in connection with these activities are: Is the funding tied to specific drugs or categories? If so, are the categories especially competitive? Is the formulary sponsor funding similar activities for other drug categories? Has funding of PBM activities increased as rebates are increasingly passed back to PBM customers?

(c) Average Wholesale Price. The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

(2) Relationships with Physicians and Other Persons and Entities in a Position to Make or Influence Referrals. Pharmaceutical manufacturers and their agents may have a variety of remunerative relationships with persons or entities in a position to refer, order, or prescribe—or influence the referral, ordering, or prescribing of—the manufacturers' products, even though the persons or entities may not themselves purchase (or in the case of GPOs or PBMs, arrange for the purchase of) those products. These remunerative relationships potentially implicate the anti-kickback statute. The following discussion focuses on relationships with physicians, but the same principles would apply when evaluating relationships with other parties in a position to influence referrals, including, without limitation, pharmacists and other health care professionals.

Manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions. There is no substantive difference between remuneration from a pharmaceutical manufacturer or from a durable medical equipment or other supplier—if the remuneration is intended to generate any federal health care business, it potentially violates the anti-kickback statute.

Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. For example, if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (*i.e.*, have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer. Moreover, under the anti-kickback statute, neither a legitimate purpose for an arrangement (*e.g.*, physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (*i.e.*, the purposeful inducement of business).

In light of the obvious risks inherent in these arrangements, whenever possible prudent manufacturers and their agents or representatives should structure relationships with physicians to fit in an available safe harbor, such as the safe harbors for personal services and management contracts, 42 CFR 1001.952(d), or employees, 42 CFR 1001.952(i). *An arrangement must fit squarely in a safe harbor to be protected.* In addition, arrangements that do not fit in a safe harbor should be reviewed in light of the totality of all facts and circumstances, bearing in mind the following factors, among others:

- *Nature of the relationship between the parties.* What degree of influence does the physician have, directly or indirectly, on the generation of business for the manufacturer? Does the manufacturer have other direct or indirect relationships with the physician or members of the physician's group?
- *Manner in which the remuneration is determined.* Does the remuneration take into account, directly or indirectly, the volume or value of business generated (*e.g.*, is the remuneration only given to persons who have prescribed or agreed to prescribe the manufacturer's product)? Is the remuneration conditioned in whole or in part on referrals or other business generated? Is there any service provided other than referrals?
- *Value of the remuneration.* Is the remuneration more than trivial in value, including all gifts to any individual, entity, or group of individuals?[10] Do fees for services exceed the fair market value of any legitimate, reasonable, and necessary services rendered by the physician to the manufacturer?
- *Potential federal program impact of the remuneration.* Does the remuneration have the potential to affect costs to any of the federal health care programs or their beneficiaries or to lead to overutilization or inappropriate utilization?
- *Potential conflicts of interest.* Would acceptance of the remuneration diminish, or appear to diminish, the objectivity of professional judgment? Are there patient safety or quality of care concerns? If the remuneration relates to the dissemination of information, is the information complete, accurate, and not misleading?

These concerns are addressed in the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"), adopted on April 18, 2002, which provides useful and practical advice for reviewing and structuring these relationships. (The PhRMA Code is available through PhRMA's Web site at *http://www.phrma.org.*) Although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.

The following paragraphs discuss in greater detail several common or problematic relationships between manufacturers and physicians, including "switching" arrangements, consulting and advisory payments, payments for detailing, business courtesies and other gratuities, and educational and research activities.

• *Switching" arrangements.* As noted in the OIG's 1994 Special Fraud Alert (59 FR 65372; December 19, 1994), product conversion arrangements (also known as "switching" arrangements) are suspect under the anti-kickback statute. Switching arrangements involve pharmaceutical manufacturers offering physicians or others cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product. This activity clearly implicates the statute, and, while such programs may be permissible in certain managed care arrangements, manufacturers should review very carefully any marketing practices utilizing "switching" payments in connection with products reimbursable by federal health care programs.

Consulting and advisory payments. Pharmaceutical manufacturers frequently engage physicians and other health care professionals to furnish personal services as consultants or advisers to the manufacturer. In general, fair market value payments to small numbers of physicians for *bona fide* consulting or advisory services are unlikely to raise any significant concern. Compensating physicians as "consultants" when they are expected to attend meetings or conferences primarily in a passive capacity is suspect.

Also of concern are compensation relationships with physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities, such as speaking, certain research, or preceptor or "shadowing" services. While these arrangements are potentially beneficial, they also pose a risk of fraud and abuse. In particular, the use of health care professionals for marketing purposes—including, for example, ghost-written papers or speeches—implicates the anti-kickback statute. While full disclosure by physicians of any potential conflicts of interest and of industry sponsorship or affiliation may reduce the risk of abuse, disclosure does not eliminate the risk.

At a minimum, manufacturers should periodically review arrangements for physicians' services to ensure that: (i) The arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are provided; (iv) the compensation is at fair market value; and (v) all of the preceding facts are documented prior to payment. In addition, to further reduce their risk, manufacturers should structure services arrangements to comply with a safe harbor whenever possible.

Payments for detailing. Recently, some entities have been compensating physicians for time spent listening to sales representatives market pharmaceutical products. In some cases, these payments are characterized as "consulting" fees and may require physicians to complete minimal paperwork. Other companies pay physicians for time spent accessing web sites to view or listen to marketing information or perform "research." All of these activities are highly suspect under the anti-kickback statute, are highly susceptible to fraud and abuse, and should be strongly discouraged.

Business Courtesies and Other Gratuities. Pharmaceutical companies and their employees and agents often engage in a number of other arrangements that offer benefits, directly or indirectly, to physicians or others in a position to make or influence referrals. Examples of remunerative arrangements between pharmaceutical manufacturers (or their representatives) and parties in a position to influence referrals include:

• Entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations; and

• Gifts, gratuities, and other business courtesies.

As discussed above, these arrangements potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company. While the determination of whether a particular arrangement violates the anti-kickback statute depends on the specific facts and circumstances, compliance with the PhRMA Code with respect to these arrangements should substantially reduce a manufacturer's risk.

Educational and Research Funding. In some cases, manufacturers contract with physicians to provide research services on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. Research contracts that originate through the sales or marketing functions—or that are offered to physicians in connection with sales contacts—are particularly suspect. Indicia of questionable research include, for example, research initiated or directed by marketers or sales agents; research that is not transmitted to, or reviewed by, a manufacturer's science component; research that is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business; and post-marketing research used as a pretense to promote product. Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing or promotion of their products.

In addition, pharmaceutical manufacturers also provide other funding for a wide range of physician educational and research activities. Manufacturers should review educational and research grants to physicians similarly to educational and research grants to purchasers (described above). As with grants to purchasers, the OIG recognizes that many grant-funded activities are legitimate and beneficial. When evaluating educational or research grants provided by manufacturers to physicians, manufacturers should determine if the funding is based, in any way, expressly or implicitly, on the physician's referral of the manufacturer's product. If so, the funding plainly implicates the anti-kickback statute. In addition, the manufacturer should determine whether the funding is for *bona fide* educational or research purposes. Absent unusual circumstances, grants or support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty.

Pharmaceutical manufacturers often provide funding to other sponsors of continuing medical education (CME) programs. Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program.[21] In addition, manufacturers and sponsors of educational programs should be mindful of the relevant rules and regulations of the Food and Drug Administration. Codes of conduct promulgated by the CME industry may provide a useful starting point for manufacturers when reviewing their CME arrangements.

(3) Relationships with Sales Agents. In large part, a pharmaceutical manufacturer's commitment to an effective fraud and abuse compliance program can be measured by its

commitment to training and monitoring its sales force. A pharmaceutical manufacturer should: (i) Develop a regular and comprehensive training program for its sales force, including refresher and updated training on a regular basis, either in person or through newsletters, memoranda, or the like; (ii) familiarize its sales force with the minimum PhRMA Code standards and other relevant industry standards; (iii) institute and implement corrective action and disciplinary policies applicable to sales agents who engage in improper marketing; (iv) avail itself of the advisory opinion process if it has questions about particular practices used by its sales force; and (v) establish an effective system for tracking, compiling, and reviewing information about sales force activities, including, if appropriate, random spot checking.

In addition, manufacturers should carefully review their compensation arrangements with sales agents. Sales agents, whether employees or independent contractors, are paid to recommend and arrange for the purchase of the items or services they offer for sale on behalf of the pharmaceutical manufacturer they represent. Many arrangements can be structured to fit in the employment or personal services safe harbor. Arrangements that cannot fit into a safe harbor should be carefully reviewed. Among the factors that should be evaluated are:

- The amount of compensation;
- The identity of the sales agent engaged in the marketing or promotional activity (*e.g.*, is the agent a "white coat" marketer or otherwise in a position of exceptional influence);
- The sales agent's relationship with his or her audience;
- The nature of the marketing or promotional activity;
- The item or service being promoted or marketed; and
- The composition of the target audience.

Manufacturers should be aware that a compensation arrangement with a sales agent that fits in a safe harbor can still be evidence of a manufacturer's improper intent when evaluating the legality of the manufacturer's relationships with persons in a position to influence business for the manufacturer. For example, if a manufacturer provides sales employees with extraordinary incentive bonuses and expense accounts, there may well be an inference to be drawn that the manufacturer intentionally motivated the sales force to induce sales through lavish entertainment or other remuneration.

c. Drug Samples. The provision of drug samples is a widespread industry practice that can benefit patients, but can also be an area of potential risk to a pharmaceutical manufacturer. The Prescription Drug Marketing Act of 1987 (PDMA) governs the distribution of drug samples and forbids their sale. 21 U.S.C. 353(c)(1). A drug sample is defined to be a unit of the drug "that is not intended to be sold * * * and is intended to promote the sale of the drug." 21 U.S.C. 353(c)(1). Failure to comply with the requirements of PDMA can result in sanctions. In some circumstances, if the samples have monetary value to the recipient (*e.g.*, a physician) and are used to treat federal health care program beneficiaries, the improper use of samples may also trigger liability under other statutes, including the False Claims Act and the anti-kickback statue.

Pharmaceutical manufacturers should closely follow the PDMA requirements (including all documentation requirements). In addition, manufacturers can minimize their risk of liability by: (i) Training their sales force to inform sample recipients in a meaningful manner that samples may not be sold or billed (thus vitiating any monetary value of the sample); (ii) clearly and conspicuously labeling individual samples as units that may not be sold (thus minimizing the ability of recipients to advertently or inadvertently commingle samples with purchased product); and (iii) including on packaging and any documentation related to the samples (such as shipping notices or invoices) a clear and conspicuous notice that the samples are subject to PDMA and may not be sold. Recent government enforcement activity has focused on instances in which drug samples were provided to physicians who, in turn, sold them to the patient or billed them to the federal health care programs on behalf of the patient.

C. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every pharmaceutical manufacturer should designate a compliance officer to serve as the focal point for compliance activities.[12] This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the company and the complexity of the task. If the individual has additional management responsibilities, the pharmaceutical manufacturer should ensure that the individual is able to dedicate adequate and substantive time and attention to the compliance functions. Similarly, if the compliance officer delegates some of the compliance duties, he or she should, nonetheless, remain sufficiently involved to fulfill the compliance oversight function.

Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official with direct access to the company's president or CEO, board of directors, all other senior management, and legal counsel. The compliance officer should have sufficient funding, resources, and staff to perform his or her responsibilities fully. The compliance officer should be able to effectuate change within the organization as necessary or appropriate and to exercise independent judgment. Optimal placement of the compliance officer within the organization will vary according to the particular situation of a manufacturer.[13]

Coordination and communication with other appropriate individuals or business units are the key functions of the compliance officer with regard to planning, implementing or enhancing, and monitoring the compliance program. The compliance officer's primary responsibilities should include:

- Overseeing and monitoring implementation of the compliance program;[14]
- Reporting on a regular basis to the company's board of directors, CEO or president, and compliance committee (if applicable) on compliance matters and assisting these individuals or groups to establish methods to reduce the company's vulnerability to fraud and abuse;
- Periodically revising the compliance program, as appropriate, to respond to changes in the company's needs and applicable federal health care program requirements, identified weakness in the compliance program, or identified systemic patterns of noncompliance;
- Developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeking to ensure that all affected employees and management understand and comply with pertinent federal and state standards;
- Ensuring that independent contractors and agents, particularly those agents and contractors who are involved in sales and marketing activities, are aware of the requirements of the company's compliance program with respect to sales and marketing activities, among other things;
- Coordinating personnel issues with the company's Human Resources/

Personnel office (or its equivalent) to ensure that the List of Excluded Individuals/Entities [15] has been checked with respect to all employees and independent contractors;

- Assisting the company's internal auditors in coordinating internal compliance review and monitoring activities;
- Reviewing and, where appropriate, acting in response to reports of noncompliance received through the hotline (or other established reporting mechanism) or otherwise brought to his or her attention (e.g., as a result of an internal audit or by corporate counsel who may have been notified of a potential instance of noncompliance);
- Independently investigating and acting on matters related to compliance. To that end, the compliance officer should have the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and any resulting corrective action (e.g., making necessary improvements to policies and practices, and taking appropriate disciplinary action) with various company divisions or departments;
- Participating with the company's counsel in the appropriate reporting of any self-discovered violations of federal health care program requirements; and
- Continuing the momentum and, as appropriate, revision or expansion of the compliance program after the initial years of implementation.[16]

The compliance officer must have the authority to review all documents and other information relevant to compliance activities. This review authority should enable the compliance officer to examine interactions with government programs to determine whether the company is in compliance with federal health care program reporting and rebate requirements and to examine interactions with health care professionals that could violate kickback prohibitions or other federal health care programs requirements. Where appropriate, the compliance officer should seek the advice of competent legal counsel about these matters.

2. Compliance Committee

The OIG recommends that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program.[17] When developing an appropriate team of people to serve as the pharmaceutical manufacturer's compliance committee, the company should consider a variety of skills and personality traits that are expected from the team members. The company should expect its compliance committee members and compliance officer to demonstrate high integrity, good judgment, assertiveness, and an approachable demeanor, while eliciting the respect and trust of company employees. These interpersonal skills are as important as the professional experience of the compliance officer and each member of the compliance committee.

Once a pharmaceutical manufacturer chooses the people who will accept the responsibilities vested in members of the compliance committee, the company needs to train these individuals on the policies and procedures of the compliance program, as well as how to discharge their duties. The OIG recognizes that some pharmaceutical manufacturers (e.g., small companies or those with limited budgets) may not have the resources or the need to establish a compliance committee. However, when potential problems are identified at such companies, the OIG recommends the creation of a "task force" to address the particular issues. The members of the task force may vary depending upon the area of concern. For example, if the compliance officer identifies issues relating to improper inducements to the company's purchasers or prescribers, the OIG recommends that a task force be organized to review the arrangements and interactions with those purchasers or prescribers. In essence, the compliance committee is an extension of the compliance officer and provides the organization with increased oversight.

D. Conducting Effective Training and Education

The proper education and training of officers, directors, employees, contractors, and agents, and periodic retraining of personnel at all levels are critical elements of an effective compliance program. A pharmaceutical manufacturer must take steps to communicate effectively its standards and procedures to all affected personnel by requiring participation in appropriate training programs and by other means, such as disseminating publications that explain specific requirements in a practical manner. These training programs should include general sessions summarizing the manufacturer's compliance program, written standards, and applicable federal health care program requirements. All employees and, where feasible and appropriate, contractors should receive the general training. More specific training on issues, such as (i) the anti-kickback statute and how it applies to pharmaceutical sales and marketing practices and (ii) the calculation and reporting of pricing information and payment of rebates in connection with federal health care programs, should be targeted at those employees and contractors whose job requirements make the information relevant. The specific training should be tailored to make it as meaningful as possible for each group of participants.

Managers and employees of specific divisions can assist in identifying specialized areas that require training and in carrying out such training. Additional areas for training may also be identified through internal audits and monitoring and from a review of any past compliance problems of the pharmaceutical manufacturer or similarly situated companies. A pharmaceutical manufacturer should regularly review its training and, where appropriate, update the training to reflect issues identified through audits or monitoring and any relevant changes in federal health care program requirements. Training instructors may come from outside or inside the organization, but must be qualified to present the subject matter involved and sufficiently experienced in the issues presented to adequately field questions and coordinate discussions among those being trained. Ideally, training instructors should be available for follow-up questions after the formal training session has been conducted.

The pharmaceutical manufacturer should train new employees soon after they have started working. Training programs and materials should be designed to take into account the skills, experience, and knowledge of the individual trainees. The compliance officer should document any formal training undertaken by the company as part of the compliance program. The company should retain adequate records of its training of employees, including attendance logs, descriptions of the training sessions, and copies of the material distributed at training sessions.

The OIG suggests that all relevant personnel (*i.e.*, employees as well as agents of the pharmaceutical manufacturer) participate in the various educational and training programs of the company. For example, for sales representatives who are responsible for the sale and marketing of the company's products, periodic training in the anti-kickback statute and its safe harbors should be required. Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities.

The OIG recognizes that the format of the training program will vary depending upon the size and resources of the pharmaceutical manufacturer. For example, a company with limited resources or whose sales force is widely dispersed may want to create a videotape or computer-based program for each type of training session so new employees and employees outside of central locations can receive training in a timely manner. If videos or computer-based programs are used for compliance training, the OIG suggests that the company make a qualified individual available to field questions from trainees. Also, large pharmaceutical manufacturers may find training via the Internet or video conference capabilities to be a cost-effective means of reaching a large number of employees. Alternatively, large companies may include training sessions as part of regularly scheduled regional meetings.

The OIG recommends that participation in training programs be made a condition of continued employment and that failure to comply with training requirements should result in disciplinary action. Adherence to the training requirements as well as other provisions of the compliance program should be a factor in the annual evaluation of each employee.

E. Developing Effective Lines of Communication

1. Access to Supervisors and/or the Compliance Officer

In order for a compliance program to work, employees must be able to ask questions and report problems. Supervisors play a key role in responding to employee concerns and it is appropriate that they serve as a first line of communications. Pharmaceutical manufacturers should consider the adoption of open-door policies in order to foster dialogue between management and employees. In order to encourage communications, confidentiality and non-retaliation policies should also be developed and distributed to all employees.[18]

Open lines of communication between the compliance officer and employees are equally important to the successful implementation of a compliance program and the reduction of any potential for fraud and abuse. In addition to serving as a contact point for reporting problems and initiating appropriate responsive action, the compliance officer should be viewed as someone to whom personnel can go to get clarification on the company's policies. Questions and responses should be documented and dated and, if appropriate, shared with other staff so that compliance standards or polices can be updated and improved to reflect any necessary changes or clarifications. Pharmaceutical manufacturers may also consider rewarding employees for appropriate use of established reporting systems as a way to encourage the use of such systems.

2. Hotlines and Other Forms of Communication

The OIG encourages the use of hotlines, e-mails, newsletters, suggestion boxes, and other forms of information exchange to maintain open lines of communication. In addition, an effective employee exit interview program could be designed to solicit information from departing employees regarding potential misconduct and suspected violations of company policy and procedures. Pharmaceutical manufacturers may also identify areas of risk or concern through periodic surveys or communications with sales representatives about the current marketing environment. This could provide management with insight about and an opportunity to address conduct occurring in the field, either by the company's own sale representatives or those of other companies.

If a pharmaceutical manufacturer establishes a hotline or other reporting mechanism, information regarding how to access the reporting mechanism should be made readily available to all employees and independent contractors by including that information in the code of conduct or by circulating the information (*e.g.*, by publishing the hotline number or e-mail address on wallet cards) or conspicuously posting the information in common work areas. Employees should be permitted to report matters on an anonymous basis.

Reported matters that suggest substantial violations of compliance policies or applicable Federal health care program requirements should be documented and investigated promptly to determine their veracity and the scope and cause of any underlying problem. The compliance officer should maintain a detailed log that records such reports, including the nature of any investigation, its results, and any remedial or disciplinary action taken. Such information, redacted of individual identifiers, should be summarized and included in reports to the board of directors, the president or CEO, and compliance committee. Although the pharmaceutical manufacturer should always strive to maintain the confidentiality of an employee's identity, it should also make clear that there might be a point where the individual's identity may become known or need to be revealed in certain instances. The OIG recognizes that protecting anonymity may be infeasible for small companies. However, the OIG believes all employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know to whom to turn for a meaningful response and should be able to do so without fear of retribution.

F. Auditing and Monitoring

An effective compliance program should incorporate thorough monitoring of its implementation and an ongoing evaluation process. The compliance officer should document this ongoing monitoring, including reports of suspected noncompliance, and provide these assessments to company's senior management and the compliance committee. The extent and frequency of the compliance audits may vary depending on variables such as the pharmaceutical manufacturer's available resources, prior history of noncompliance, and the risk factors particular to the company. The nature of the reviews may also vary and could include a prospective systemic review of the manufacturer's processes, protocols, and practices or a retrospective review of actual practices in a particular area.

Although many assessment techniques are available, it is often effective to have internal or external evaluators who have relevant expertise perform regular compliance reviews. The reviews should focus on those divisions or departments of the pharmaceutical manufacturer that have substantive involvement with or impact on federal health care programs (such as the government contracts and sales and marketing divisions) and on the risk areas identified in this guidance. The reviews should also evaluate the company's policies and procedures regarding other areas of concern identified by the OIG (*e.g.*, through Special Fraud Alerts) and federal and state law enforcement agencies. Specifically, the reviews should evaluate whether the: (1) Pharmaceutical manufacturer has policies covering the identified risk areas; (2) policies were implemented and communicated; and (3) policies were followed.

G. Enforcing Standards Through Well-Publicized Disciplinary Guidelines

An effective compliance program should include clear and specific disciplinary policies that set out the consequences of violating the law or the pharmaceutical manufacturer's code of

conduct or policies and procedures. A pharmaceutical manufacturer should consistently undertake appropriate disciplinary action across the company in order for the disciplinary policy to have the required deterrent effect. Intentional and material noncompliance should subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension, termination or other sanctions, as appropriate. Disciplinary action also may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct. Each situation must be considered on a case-by-case basis, taking into account all relevant factors, to determine the appropriate response.

H. Responding to Detected Problems and Developing Corrective Action Initiatives

Violation of a pharmaceutical manufacturer's compliance program, failure to comply with applicable federal or state law, and other types of misconduct threaten the company's status as a reliable, honest, and trustworthy participant in the health care industry. Detected but uncorrected misconduct can endanger the reputation and legal status of the company. Consequently, upon receipt of reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred and, if so, take decisive steps to correct the problem.[19] The exact nature and level of thoroughness of the investigation will vary according to the circumstances, but the review should be detailed enough to identify the root cause of the problem. As appropriate, the investigation may include a corrective action plan, a report and repayment to the government, and/or a referral to criminal and/or civil law enforcement authorities.

Reporting

Where the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the company should promptly report the existence of misconduct to the appropriate federal and state authorities[20] within a reasonable period, but not more than 60 days,[21] after determining that there is credible evidence of a violation.[22] Prompt voluntary reporting will demonstrate the pharmaceutical manufacturer's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (*e.g.*, penalties, assessments, and exclusion), if the reporting company becomes the subject of an OIG investigation.[23]

When reporting to the government, a pharmaceutical manufacturer should provide all information relevant to the alleged violation of applicable federal or state law(s) and the potential financial or other impact of the alleged violation. The compliance officer, under advice of counsel and with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the operation of the applicable federal health care programs or their beneficiaries.

III. Conclusion

In today's environment of increased scrutiny of corporate conduct and increasingly large expenditures for prescription drugs, it is imperative for pharmaceutical manufacturers to establish and maintain effective compliance programs. These programs should foster a culture of compliance that begins at the executive level and permeates throughout the organization. This compliance guidance is designed to provide assistance to all pharmaceutical manufacturers as they either implement compliance programs or re-assess existing programs. The essential elements outlined in this compliance guidance can be adapted to the unique environment of each manufacturer. It is the hope and expectation of the OIG that the resulting compliance programs will benefit not only federal health care programs and their beneficiaries, but also pharmaceutical manufacturers themselves.

Dated: April 23, 2003.

Janet Rehnquist,

Inspector General.

Endnotes

1. The term "Federal health care programs," as defined in 42 U.S.C. 1320a-7b(f), includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government or any state health plan (*e.g.*, Medicaid or a program receiving funds from block grants for social services or child health services). In this document, the term "federal health care program requirements" refers to the statutes, regulations and other rules governing Medicare, Medicaid, and all other federal health care programs.

2. *See* 66 FR 31246 (June 11, 2001), "Notice for Solicitation of Information and Recommendations for Developing a Compliance Program Guidance for the Pharmaceutical Industry."

3. *See* 67 FR 62057 (October 3, 2002), "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers."

4. 42 U.S.C. 1320a-7b(b).

5. In addition, the compliance program elements and potential risk areas addressed in this compliance program guidance may also have application to manufacturers of other products that may be reimbursed by federal health care programs, such as medical devices and infant nutritional products.

6. In addition, pharmaceutical manufacturers should be mindful that many states have fraud and abuse statutes—including false claims, anti-kickback and other statutes—that are not addressed in this guidance.

7. The False Claims Act (31 U.S.C. 3729–33) prohibits knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the federal government or its agents, like a carrier, other claims processor, or state Medicaid program.

8. The 340B Program, contained as part of the Public Health Services Act and codified at 42 U.S.C. 256b, is administered by the Health Resources and Services Administration (HRSA).

9. 42 U.S.C. 1396r–8. Average Manufacturer Price and Best Price are defined in the statute at 42 U.S.C. 1396r–8(k)(1) and 1396r–8(c)(1), respectively. CMS has provided further guidance on these terms in the National Drug Rebate Agreement and in Medicaid Program Releases available through its Web site at *http://www.hcfa.gov/medicaid/drugs/drug.mpg.htm.*

10. In this regard, pharmaceutical manufacturers should note that the exception for non-monetary compensation under the Stark law (42 U.S.C. 1395nn; 42 CFR 411.357(k)) is not a basis for protection under the anti-kickback statute.

11. CME programs with no industry sponsorship, financing, or affiliation should not raise anti-kickback concerns, although tuition payments by manufacturers (or their representatives) for persons in a position to influence referrals (*e.g.*, physicians or medical students) may raise concerns.

12. It is also advisable to designate as a compliance officer an individual with prior experience or knowledge of compliance and

operational issues relevant to pharmaceutical manufacturers.

13. The OIG believes it is generally not advisable for the compliance function to be subordinate to the pharmaceutical manufacturer's general counsel, or comptroller or similar financial officer. Separation of the compliance function helps to ensure independent and objective legal reviews and financial analysis of the company's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the pharmaceutical manufacturer make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

14. For companies with multiple divisions or regional offices, the OIG encourages coordination with each company location through the use of a compliance officer located in corporate headquarters who is able to communicate with parallel compliance liaisons in each division or regional office, as appropriate.

15. As part of its commitment to compliance, a pharmaceutical manufacturer should carefully consider whether to hire or do business with individuals or entities that have been sanctioned by the OIG. The List of Excluded Individuals and Entities can be checked electronically and is accessible through the OIG's Web site at: *http://oig.hhs.gov.*

16. There are many approaches the compliance officer may enlist to maintain the vitality of the compliance program. Periodic on-site visits of regional operations, bulletins with compliance updates and reminders, distribution of audiotapes, videotapes, CD ROMs, or computer notifications about different risk areas, lectures at management and employee meetings, and circulation of recent articles or publications discussing fraud and abuse are some examples of approaches the compliance officer may employ.

17. The compliance committee benefits from having the perspectives of individuals with varying responsibilities and areas of knowledge in the organization, such as operations, finance, audit, human resources, legal, and sales and marketing, as well as employees and managers of key operating units. The compliance officer should be an integral member of the committee. All committee members should have the requisite seniority and comprehensive experience within their respective departments to recommend and implement any necessary changes to policies and procedures.

18. In some cases, employees sue their employers under the False Claims Act's *qui tam* provisions after a failure or apparent failure by the company to take action when the employee brought a questionable, fraudulent, or abusive situation to the attention of senior corporate officials. Whistleblowers must be protected against retaliation, a concept embodied in the provisions of the False Claims Act. *See* 31 U.S.C. 3730(h).

19. Instances of noncompliance must be determined on a case-by-case basis. The existence or amount of a *monetary* loss to a federal health care program is not solely determinative of whether the conduct should be investigated and reported to governmental authorities. In fact, there may be instances where there is no readily identifiable monetary loss, but corrective actions are still necessary to protect the integrity of the health care program.

20. Appropriate federal and state authorities include the OIG, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in relevant districts, the Food and Drug Administration, the Federal Trade Commission, the Drug Enforcement Administration and the Federal Bureau of Investigation, and the other investigative arms for the agencies administering the affected federal or state health care programs, such as the state Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, HRSA, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

21. In contrast, to qualify for the "not less than double damages" provision of the False Claims Act, the provider must provide the report to the government within 30 days after the date when the provider first obtained the information. 31 U.S.C. 3729(a).

22. Some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. By way of example, the OIG believes a provider should report misconduct that: (1) Is a clear violation of administrative, civil, or criminal laws; (2) has a significant adverse effect on the quality of care provided to federal health care program beneficiaries; or (3) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on federal health care programs.

23. The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude an individual or entity from program participation pursuant to 42 U.S.C. 1320a–7(b)(7) for violations of various fraud and abuse laws. *See* 62 FR 67392 (December 24, 1997).

[FR Doc. 03–10949 Filed 5–2–03; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program: Phase Three—(OMB No. 0930–0209, revision)—SAMHSA's Center for Mental Health Services is conducting Phase III of the national evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program. Phase III collects data on child mental health outcomes, family life, and service system development and performance. Data are being collected on 22 funded systems of care, and approximately 5,100 children and families. Data collection for this evaluation will be conducted over a 5½-year period.

The core of service system data are currently collected every 18 months throughout the evaluation period. Service delivery and system variables of interest include the following: Maturity of system of care development, adherence to the system of care program model, and client service experience. The length of time that individual families will participate in the study ranges from 18 to 36 months depending on when they enter the evaluation.

Child and family outcomes of interest will be collected at intake and during subsequent follow-up sessions at six-month intervals. The outcome measures include the following: Child symptomatology and functioning, family functioning, material resources, and caregiver strain. In addition, a treatment effectiveness study will examine the relative impact of an evidence-based treatment within one system of care.

The average annual respondent burden is estimated below. The estimate reflects the average number of respondents in each respondent category, the average number of responses per respondent per year, the average length of time it will take for each response, and the total average annual burden for each category of respondent, and for all categories of respondents combined.

This revision to the currently approved information collection activities involves: (1) Extension of the data collection period for an additional 18 months to cover an additional sixth year of grant funding in the 22 currently funded systems of care (and a six-month no-cost extension for the evaluation), (2) the addition of a family-driven study to assess the extent of family involvement in service planning, (3) the elimination of the longitudinal comparison study and the addition of a treatment effectiveness study in two sites

Figure 2

The Role of the False Claims Act in Reducing Medicare and Medicaid Fraud by Drug Manufacturers:` An Update

prepared for

Taxpayers Against Fraud Education Fund

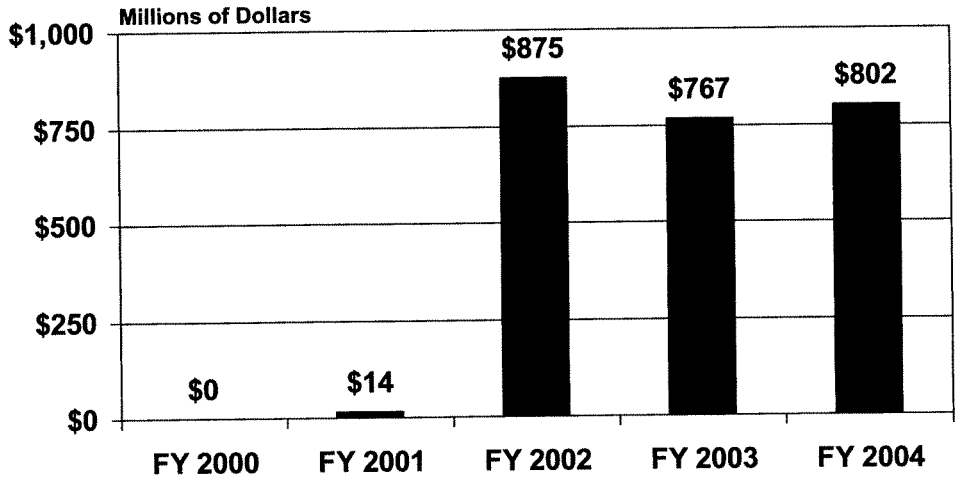
by

Andy Schneider, Principal
Medicaid Policy, LLC

November 2004

Figure 1

Recoveries in Whistleblower Cases for Drug Pricing Fraud in Medicare and Medicaid
FY 2000 – FY 2004



Source: DOJ press releases and settlement agreements.

Summary

In November 2003, Taxpayers Against Fraud Education Fund issued a report highlighting the emergence of the False Claims Act and its whistleblower provisions as the federal government's most important weapon in protecting the Medicare and Medicaid programs against fraud by drug manufacturers. The report found that as of September 2003, six pharmaceutical manufacturers, including three of the top five U.S. drug companies by sales volume, had settled cases with the Department of Justice (DOJ) involving allegations by whistleblowers of pricing or marketing fraud against Medicare and Medicaid. The settlements resulted in total recoveries of nearly $1.66 billion, including criminal fines of $360 million, about $1.1 billion in civil penalties and damages to the Federal government, and over $200 million to state governments to compensate them for losses incurred by their Medicaid programs. The November 2003 report speculated that additional settlements would follow.[1]

This report is the next chapter in an unfolding story. During FY 2004—that is, between October 1, 2003 and September 30, 2004—three more whistleblower cases against drug manufacturers were settled for a total of just over $800 million, raising the total recoveries in such cases by nearly 50 percent to $2.46 billion (Figure 1). The recoveries in the most recent settlements included $290 million in criminal fines, $275 million in penalties and damages to the Federal treasury and Federal grantees, and nearly $235 million to state governments. All three of these settlements involved allegations of fraud against Medicaid, the federal-state health care program for low-income Americans. None of these settlements involved allegations of fraud against Medicare, the federal health care program for elderly and disabled Americans (as discussed in the November 2003 report, two of the prior settlements involved allegations of Medicare fraud).

[1] A. Schneider, *Reducing Medicare and Medicaid Fraud by Drug Manufacturers: The Role of the False Claims Act* (November 2003), www.taf.org.

Ipratropium Bromide 0.02% Sol.

HCPCS code J7645 & (K0518)

YEAR	MEDICARE REIMBURSEMENT AMOUNT PER UNIT*	VenACare COST PER MEDICARE UNIT	"SPREAD" (PROFIT) $	"SPREAD" (PROFIT) %	MEDICARE EXPENDITURES $
1995	$ 3.11 mg. ($0.62/ml)	$3.11	$0.00	0%	$14,426,108
1996	$ 3.75 mg. ($0.75/ml)	$3.26	$0.49	15%	$47,388,622
1997	$ 3.50 mg. ($0.70/ml)	$2.15	$1.35	63%	$96,204,639
1998	$ 3.34 mg.	$1.70	$1.64	94%	$176,887,868
1999	$ 3.34 mg.	$1.60	$1.74	108%	$253,400,414
2000	$ 3.34 mg.	$0.94	$2.40	255%	$347,527,960
2001	$ 3.34 mg.	$0.82	$2.52	307%	$373,076,026
2002	$3.34 mg	$0.64	$2.70	422%	$437,330,544

TAB 3

DRUG	NDC	AWP	FUL FUL Date	CURRENT COST	AWP SPREAD	FUL SPREAD
FLUOXETINE 10mg	00378-4210-01	$259.85	$58.50 12/1/02	$4.25	$254.05	$54.25
DOXAZOSIN 1mg	00172-3685-60	$91.92	$59.18 1/22/02	$7.15	$84.77	$52.03
ALBUTEROL INH 17gm	59930-1560-01	$21.41	$15.00 3/11/03	$4.25	$17.16	$10.75
BUSPIRONE HCL 10mg	00378-1150-01	$134.50	$39.42 12/1/02	$7.95	$126.55	$31.47
IPRATROPIUM BROMIDE .02%,2.5ml,25's	49502-0685-24	$44.10	$14.625 11/2/03	$3.50	$40.60	$11.13

DRUG	NDC	AWP	FUL FUL Date	CURRENT COST	AWP SPREAD	FUL SPREAD
RANITIDINE 150mg, 1000	00781-1883-10	$1480.00	$341.10 1/22/02	$44.92	$1435.08	$296.18
TAMOXIFEN 20mg	00054-4834-13	$113.77	$58.27 10/28/04	$8.13	$105.64	$50.14
CEFACLOR 500mg	00172-4771-60	$389.45	$129.00 1/22/02	$42.10	$347.35	$86.90
AZATHIOPRINE 50mg	00054-4084-25	$131.08	NONE	$32.99	$98.09	N/A
ATENOLOL 50mg	00781-1506-01	$83.42	$8.85 12/1/02	$4.65	$78.77	$4.20

COMPARISON OF CURRENT PRICES TO ASP FROM SECOND QUARTER 2004

DRUG	NDC	AWP	FUL FUL Date	CURRENT COST	ASP + 6 2004 Q2
IPRATROPIUM BROMIDE 0.02%, 2.5ml, 25's	49502-0685-24 (J 7644)	$44.10	$14.625 11/2/03	$3.50	$5.75 (J 7644)
ALBUTEROL 0.083% 3ML, 25'S	49502-0697-03 (J 7619)	$30.25	$10.88 1/22/02	$3.00	$3.1125 (J 7619)

[redacted] log out

Search Results (back to PowerCat Search page)

You entered the following search criteria:
Generic Name: **IPRATROPIUM**

Displaying products 1 to 10

Add Item to Formulary	ndc number	catalog number	generic name	trade name	form/strength/size	contract price +mark-up	contract price	awp	awp spread	manufacturer	class of trade
☐	49502-0685-24		IPRATROPIUM	IPRATROPIUM BROMIDE	PLAS CONT 3ML x 25 UD	NA	$3.50	$44.10	$40.60	Dey Laboratories, L.P.	Home Healthcare
☐	00472-0751-30		IPRATROPIUM	IPRATROPIUM BROMIDE	PLAS CONT 3ML x 30 UD	NA	$11.83	$67.80	$55.97	Alpharma USPD	Home Healthcare
☐	49502-0685-29		IPRATROPIUM	IPRATROPIUM BROMIDE	PLAS CONT 3ML x 30 UD	NA	$4.20	$52.80	$48.60	Dey Laboratories, L.P.	Home Healthcare
☐	49502-0685-61		IPRATROPIUM	IPRATROPIUM BROMIDE	PLAS CONT 3ML x 60 UD	NA	$8.40	$105.60	$97.20	Dey Laboratories, L.P.	Home Healthcare
☐	38779-0230-05	24085	IPRATROPIUM	IPRATROPIUM BROMIDE	POWDER 100GM x 1	NA	$1,402.50	$1,711.05	$308.55	Medisca Inc.	Home Healthcare
☐	38779-0230-06	24085	IPRATROPIUM	IPRATROPIUM BROMIDE	POWDER 1GM x 1	NA	$38.25	$46.67	$8.42	Medisca Inc.	Home Healthcare
☐	38779-0230-04	24085	IPRATROPIUM	IPRATROPIUM BROMIDE	POWDER 25GM x 1	NA	$595.00	$725.90	$130.90	Medisca Inc.	Home Healthcare
☐	38779-0230-03	24085	IPRATROPIUM	IPRATROPIUM BROMIDE	POWDER 5GM x 1	NA	$136.00	$165.92	$29.92	Medisca Inc.	Home Healthcare
☐	00172-6407-44		IPRATROPIUM	IPRATROPIUM BROM .02% INH/SOLN	PLAS CONT .02 % 3ML x 25 UD	NA	$5.99	$44.10	$38.11	IVAX Pharmaceuticals	Home Healthcare
☐	00172-6407-49		IPRATROPIUM	IPRATROPIUM BROM .02% INH/SOLN	PLAS CONT .02 % 3ML x 60 UD	NA	$13.99	$105.60	$91.61	IVAX Pharmaceuticals	Home Healthcare

PHARMACEUTICAL MANUFACTURERS WARRICK AND DEY's USE OF THE "SPREAD" TO CAPTURE THE STATE OF FLORIDA'S MEDICAID MARKET FOR ALBUTEROL 0.083%

Manufacturer	True Cost per ml	Florida Medicaid Reimbursement per ml	The "Spread"	# of claims	Reimbursement paid by Florida Medicaid
Warrick	$0.1065	$0.3590	$0.2525	12,673	$763,595.42
Dey	$0.1125	$0.3531	$0.2406	9,792	$707,220.50
Zenith/Goldline	N/A	$0.2138	**	102	$4,981.86
Geneva	N/A	$0.1787	**	19	$1,278.08
TOTAL REIMBURSEMENT BY THE STATE OF FLORIDA MEDICAID PROGRAM (January 1 through March 31, 1997)					$1,477,075.86

** THE USE OF THE "SPREAD" TO CAPTURE MARKET SHARE IS EVIDENCED BY THE FACT THAT WARRICK'S AND/OR DEY'S CUSTOMERS WILL RECEIVE MORE PROFIT BY PURCHASING WARRICK'S AND/OR DEY'S ALBUTEROL THAN IF ZENITH/GOLDLINE OR GENEVA GAVE THEIR CUSTOMERS THEIR ALBUTEROL FOR FREE.

Ven-A-Care# 7

University of Texas report on wholesale cost accuracy in estimating acquisition costs.

Conclusion

The results of this study indicate that acquisition cost estimates based on either a wholesaler price discounting method or a cost-plus pricing method would be similar for products purchased from wholesalers by pharmacists in independent Texas pharmacies. Initiating either type of estimating method would enhance the accuracy of drug program reimbursement. Applying even the

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Estimating Pharmacy Level Prescription Drug Acquisition Costs for Third-Party Reimbursement

DAVID H. KRELING, PhD.* AND KENNETH W. KIRK, PhD†

Accurate payment for the acquisition costs of drug products dispensed is an important consideration in a third-party prescription drug program. Two alternative methods of estimating these costs among pharmacies were derived and compared. First, pharmacists were surveyed to determine the purchase discounts offered to them by wholesalers. A 18.00% modal and 21.35% mean discount resulted for 73 responding pharmacists. Second, cost-plus percents derived from gross profit margins of wholesalers were calculated and applied to wholesaler product costs to estimate pharmacy level acquisition costs. Cost-plus percents derived from National Median and Southwestern Region wholesaler figures were 9.27% and 18.19%, respectively. A comparison showed the two methods of estimating acquisition costs would result in similar acquisition cost estimates. Adopting a cost-plus estimating approach is recommended because it avoids potential pricing manipulations by wholesalers and manufacturers that would negate improvements in drug product reimbursement accuracy. Key words: costs; prescription drugs; reimbursement; third-party; Medicaid; drug prices. (Med Care 1986, 24:590–600)

An administrative concern in third-party prescription drug programs is having a drug product reimbursement scheme that provides pharmacists accurate payment for the acquisition costs of products dispensed. Therefore, a means of estimating price levels of prescription drug products purchased by pharmacists is needed. This study investigates two approaches for estimating pharmacy-level acquisition costs of products obtained from wholesalers for applying to a state Medicaid drug program. The two approaches incorporate marketplace information from two relevant components in the prescription drug distribution channel, wholesalers and pharmacies.

One pharmacy acquisition cost-estimating approach is based on traditional wholesaler pricing methods, discounting list prices to arrive at pharmacy-level "net" prices. The second approach is based on a newer method of pricing used in the wholesale drug industry, a "cost-plus" approach. In cost-plus pricing, an amount (typically a percentage) is added to the cost of a product that a wholesaler realizes to yield a pharmacy level price (pharmacy acquisition cost).

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This research was conducted while under contract with the Texas Department of Human Services.

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8/93 Dept. of Commerce Assessment…

Table 1.1
Definitions of Terms Specific to the Pharmaceutical Industry

TERM	DEFINITION
Actual Acquisition Cost (AAC)	Pharmacist's net payments made to purchase a drug from any source (e.g., manufacturer, wholesaler) net of discounts, rebates, etc.
Estimated Acquisition Cost (EAC)	An estimate of pharmacies' actual acquisition costs that are made by the States and other third-party payers.
Maximum Allowable Cost (MAC)	A maximum dollar amount for which the pharmacist is reimbursed for selected products.
Average Manufacturer's Price (AMP)	The average price paid by wholesalers to manufacturers for products to be distributed to retailers.
Average Wholesale Price (AWP)	The manufacturer's suggested wholesale price to the retailer which is listed in either the Red or Blue Book.
Wholesale Acquisition Cost (WAC)	The wholesaler's net payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts.

Table 1

Definitions of Terms Specific to Pharmaceutical Payment Policy

Term	Definition
Actual Acquisition Cost (AAC)	Pharmacist's net payments made to purchase a drug from any source (e.g., manufacturer, wholesaler) net of discounts, rebates, etc.
Estimated Acquisition Cost (EAC)	An estimate of pharmacies' actual acquisition costs that are made by the States and other third-party payers.
Maximum Allowable Cost (MAC)	A maximum dollar amount the pharmacist is paid for selected products.
Average Manufacturer's Price (AMP)	The average price paid by wholesalers to manufacturers for products to be distributed to retailers.
Average Wholesale Price (AWP)	The manufacturer's suggested wholesale price to the retailer, listed in either the Red or Blue Book.
Wholesale Acquisition Cost (WAC)	The wholesaler's net payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts.

SOURCE: Adams, E.K., Emory University School of Public Health, Atlanta, GA, and Gondek, K., Health Care Financing Administration, Baltimore, MD, 1993.

TAB 10

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

SEP 16 2002 — Washington, D.C. 20201

TO: Thomas Scully
Administrator
Centers for Medicare & Medicaid Services

FROM: Janet Rehnquist
Inspector General

SUBJECT: Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products (A-06-02-00041)

As a follow-up to our previous work on Medicaid drug reimbursement, attached are two copies of the Department of Health and Human Services, Office of Inspector General's final report entitled, "Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products." This report provides extended analyses of information previously reported to you.[1] Our previous reports estimated the discounts below average wholesale price (AWP) commonly available to pharmacy purchasers of brand name drugs and generic drugs. The estimate for brand name drugs included both single source and multiple source innovator drugs. The estimate for generic drugs was for all non-innovator multiple source drugs, including those on the Centers for Medicare & Medicaid Services' (CMS) federal upper-limits (FUL) list as well as those drugs not on the FUL list.

The objectives of this report were to develop estimates of the discount below AWP available for single source drugs, all drugs without FULs, multiple source drugs without FULs, and multiple source drugs with FULs. We believe that these additional estimates will provide states with more information that will be useful in evaluating their drug reimbursement methodologies. Our current analyses were based on the data obtained from the previous reviews. We found that:

- ***For single source innovator drugs:*** pharmacies purchased the drugs at an estimated discount of 17.2 percent below AWP.
- ***For all drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 27.2 percent below AWP.
- ***For multiple source drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 44.2 percent below AWP. A further breakdown of multiple source drugs without FULs showed the estimated discount for innovator multiple source drugs to be 24.4 percent and 54.2 percent for non-innovator multiple source drugs.
- ***For multiple source drugs with FULs:*** pharmacies purchased the drugs at an estimated discount of 72.1 percent below AWP.

[1] "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023) dated August 10, 2001 and "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-01-00053) dated March 14, 2002.

The above analyses show that there is a wide range of discounts from AWP for pharmacy purchases depending on the category of drug that is being purchased. Based on the results of our additional analyses, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider using a four-tiered reimbursement methodology. This four-tiered system would consist of (1) **tier one** – a percentage discount off AWP for single source brand name drugs; (2) **tier two** – a percentage discount off AWP for innovator multiple source drugs without FULs; (3) **tier three** – a percentage discount off AWP for non-innovator multiple source drugs without FULs; and (4) **tier four** – the FUL price for those FUL multiple source drugs. The current method of reimbursing for brand name drugs and those non-FUL generic drugs using a single percentage discount does not adequately consider the large fluctuations in actual discounts between brands and generics that we found during our additional analyses.

Accordingly, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider adopting a four-tiered payment system in order to bring pharmacy reimbursement more in line with the actual acquisition cost of drug products. We also recommend that CMS share this report with the states.

In response to the recommendations in our draft report, CMS suggested that the OIG recommend a four-tiered reimbursement methodology, rather that the three-tiered system recommended in our draft report in order to differentiate branded generics (innovator multiple source drugs) and generics (non-innovator multiple source drugs). We agreed with the changes suggested by CMS and revised our final report to reflect CMS's comments.

We would appreciate your views and information on the status of any action taken or contemplated on our recommendations within the next 60 days. If you have any questions, please contact me or have your staff contact George M. Reeb, Assistant Inspector General, Centers for Medicare and Medicaid Audits, at (410) 786-7104.

Your formal response to the report is summarized in the body of our final report, as well as attached as an Appendix. In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, Office of Audit Services, reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR part 5.) As such, within 10 business days after the final report is issued, it will be posted on the world wide web at http://oig.hhs.gov.

Please refer to Common Identification Number A-06-02-00041 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID PHARMACY – ADDITIONAL ANALYSES OF THE ACTUAL ACQUISITION COST OF PRESCRIPTION DRUG PRODUCTS

JANET REHNQUIST
INSPECTOR GENERAL

SEPTEMBER
A-06-02-00041

EXECUTIVE SUMMARY

The objective of this report is to provide extended analyses of Office of Inspector General (OIG) audit work related to actual acquisition costs by pharmacies for drugs reimbursed by the Medicaid program. This report enhances the discussion of the Medicaid drug reimbursement issues included in recently issued OIG reports to the Centers for Medicare & Medicaid Services (CMS) on the actual acquisition cost of Medicaid prescription drugs, and reports issued to individually reviewed states. The report for brand name drugs, entitled "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023) dated August 10, 2001, showed that pharmacies purchased such drugs at an estimated average discount of 21.8 percent below average wholesale price (AWP) during Calendar Year (CY) 1999 as compared to 18.3 percent from our review in CY 1994. This estimate for brand name drugs included both single source as well as multiple source brand name drugs.[1] The reports we issued to the states showed the results for the sample pharmacies in those states.

We also issued a report for generic drugs, entitled "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-01-00053) dated March 14, 2002, which showed that the actual generic drug acquisition cost was a national average of 65.9 percent below AWP. Our previous estimate, based on CY 1994 pricing data, showed a discount of 42.5 percent below AWP for generic drugs.

Subsequent to the issuance of our brand name drug report and the state reports, some states included in our review, as well as industry groups, expressed interest in additional information on the discount calculation. Specifically, there was considerable interest in obtaining the discount below AWP for just the single source innovator drugs included in our estimate for brand name drugs. Accordingly, we have provided the results for single source innovator drugs in this report. Because of the reimbursement methodologies used by most states, we also estimated the discount for all drugs (including single source and multiple source innovators as well as multiple source non-innovator drugs) that do not have federal upper limits (FUL).[2] Additionally, we calculated separate estimates for multiple source drugs (both innovators and non-innovators) with and without FULs. We believe that these estimates will provide states with information that will be useful in evaluating their present drug reimbursement methodologies.

Medicaid drug reimbursement to pharmacies for the ingredient cost of drugs is generally based on the estimated acquisition cost (EAC) unless an upper-limit amount has been established. Most states calculate EAC by using the AWP for a drug less a percentage discount. A pharmacy's usual and customary charge to the general public is also a limiting factor in reimbursement. Nationally, we estimated that the average discount was 10.3 percent below

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[1] A single source innovator drug is under patent protection and is produced by only one manufacturer. Upon expiration of the patent, an innovator drug can be produced by other manufacturers, resulting in the drug being categorized as an innovator multiple source drug.

[2] The FULs are developed by CMS for use by state Medicaid programs in reimbursing for drugs that have at least three generic equivalents available.

AWP for all brand name drugs and those generic drugs that are not on FUL drug list developed by CMS. Many states currently use a two-tiered reimbursement methodology to reimburse pharmacies for drugs: (1) a percentage discount off AWP for all brand name drugs and those non-FUL multiple source drugs and (2) an upper-limit price for those multiple source drugs identified as having FUL prices.

Our current analyses provide a more comprehensive breakdown of percentages for a variety of drug categories: single source innovator drugs; all drugs without FULs (single source innovator, multiple source innovator, and multiple source non-innovator); non-FUL multiple source drugs only; and multiple source drugs with FULs. Specifically, we found that:

- ***For single source innovator drugs:*** pharmacies purchased the drugs at an estimated discount of 17.2 percent below AWP.

- ***For all drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 27.2 percent below AWP.

- ***For multiple source drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 44.2 percent below AWP. A further breakdown of multiple source drugs without FULs showed the estimated discount for innovator multiple source drugs to be 24.4 percent and 54.2 percent for non-innovator multiple source drugs.

- ***For multiple source drugs with FULs:*** pharmacies purchased the drugs at an estimated discount of 72.1 percent below AWP.

The above analyses show that there is a wide range of discounts from AWP for pharmacy purchases depending on the category of drug that is being purchased. Based on the results of our additional analyses, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider using a four-tiered reimbursement methodology. This four-tiered system would consist of (1) **tier one** – a percentage discount off AWP for single source brand name drugs; (2) **tier two** – a percentage discount off AWP for innovator multiple source drugs without FULs; (3) **tier three** – a percentage discount off AWP for non-innovator multiple source drugs without FULs; and (4) **tier four** – the FUL price for those FUL multiple source drugs. The current method of reimbursing for brand name drugs and those non-FUL generic drugs using a single percentage discount does not adequately consider the large fluctuations in actual discounts between brands and generics that we found during our additional analyses.

Accordingly, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider adopting a four-tiered payment system in order to bring pharmacy reimbursement more in line with the actual acquisition cost of drug products. We also recommend that CMS share this report with the states.

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INTRODUCTION

BACKGROUND

Medicaid regulations limit the reimbursement of multiple source drugs to upper-limit amounts, if they meet certain criteria. Multiple source drugs include innovator as well as non-innovator drugs, with innovator meaning the brand name version of a drug and non-innovator indicating a generic version. The federal upper-limit (FUL) amounts are established by the Centers for Medicare & Medicaid Services (CMS) and can only be established when certain criteria are met. The criteria require that there be a certain number of drugs, depending on the therapeutic equivalency, published in the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations and at least three suppliers of the drug. All other drugs, including single source drugs and multiple source drugs without FULs, are reimbursed at the estimated acquisition cost (EAC) of the drug plus a dispensing fee. State agencies are responsible for determining the EAC. Reimbursement is also limited by the pharmacist's usual and customary charge to the general public.

The EAC for most states is calculated by using the average wholesale price (AWP) for a drug less a percentage discount. The AWP is the price assigned to the drug by its manufacturer and is compiled by commercial organizations - **Red Book, First DataBank**, and **Medi-Span** - for use by the pharmaceutical community.

In 1997, the Office of Inspector General (OIG) issued separate reports on the actual acquisition cost of brand name and generic drugs. The 1997 reports were based on Calendar Year (CY) 1994 data and included comparisons of 18,973 invoice prices for brand name products and 9,075 invoice prices for generic products. The reports showed average discounts of 18.3 percent below AWP and 42.5 percent below AWP, respectively. The brand name discount estimate included single source as well as innovator multiple source drugs. The methodology utilized in these reviews was collaboratively developed with assistance from the sampled state agencies and CMS.

The OIG also issued reports to CMS on the actual acquisition cost of Medicaid prescription drugs based on CY 1999 data. The report for brand name drugs entitled, "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023) dated August 10, 2001, showed that pharmacies purchased such drugs at an estimated average discount of 21.8 percent below AWP during CY 1999. This estimate for brand name drugs again included both single source as well as multiple source brand name drugs and the review used the same methodology developed for the 1997 reviews. The report for generic drugs entitled, Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-01-00053) dated March 14, 2002, showed a discount of 65.9 percent below AWP.

The cost of the Medicaid drug program has increased significantly in recent years. Drug expenditures in CY 1994 totaled about $9.4 billion. In CY 1999, drug expenditures increased to about $17.9 billion.

OBJECTIVES, SCOPE, AND METHODOLOGY

Our review was performed in accordance with generally accepted government auditing standards. The objective of this report was to provide additional analyses of the data compiled for our earlier reviews.[3] Specifically, our objectives were to develop estimates of the discount below AWP for single source drugs, all drugs without FULs, multiple source drugs without FULs, and multiple source drugs with FULs for Medicaid pharmacy providers. Our objectives did not require that we identify or review any internal control systems. Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription for instances such as therapeutic intervention, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid-specific administrative costs, and general overhead.

To accomplish our current objectives, we used the data that was obtained for the two prior reports as a basis for this report. We used a multistage sampling procedure (a detailed description of our sample design is included as **APPENDIX 1** to this report). State Medicaid agencies were designated as the primary sample units and Medicaid pharmacy providers as the secondary sample units. We selected a stratified random sample of 8 states from a universe of 48 states and the District of Columbia. Arizona was excluded from the universe of states because its Medicaid drug program was a demonstration project using prepaid capitation financing. Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. Of the 8 states, 2 states (Montana and Florida) were selected from a universe of 10 states and the District of Columbia that were included in our previous review. The other 6 states (Colorado, Indiana, Texas, Washington, West Virginia, and Wisconsin) were selected from the remaining 38 states.

We obtained a listing of all Medicaid pharmacy providers from each sample state. The state agencies were responsible for classifying each pharmacy as a chain, independent, or non-traditional (nursing home pharmacies, hospital pharmacies, home intravenous feeding (IV), etc.). For purposes of these reviews, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a 1999 listing of the metropolitan statistical areas and their components. We selected a stratified random sample of 40 pharmacies from each state with 8 pharmacies selected from each of 5 strata -- urban-chain, rural-chain, urban-independent, rural-independent, and non-traditional. We sampled the non-traditional category separately so it could be excluded from our estimates. We excluded the non-traditional category because we believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and those discounts would inflate our estimates.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1999. Supply sources included wholesalers, chain

[3] "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023) dated August 10, 2001 and "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-01-00053) dated March 14, 2002.

warehouse distribution centers, generic distributors, and manufacturers. Each pharmacy was initially assigned a month from January 1999 to December 1999 in order to provide a cross-section of this 12-month time period. However, we permitted some pharmacies to provide invoices from other months in 1999 if invoices were not available for the requested period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which were needed to obtain AWP for the drug. We used the **2000 Red Book**, a nationally recognized reference for drug product and pricing information, to obtain NDCs or identify over-the-counter items. Two prominent wholesalers, as well as four chain stores, whose invoices contained the wholesaler item numbers rather than NDCs, provided us with a listing that converted their item numbers to NDCs.

To identify single source drugs, we used information available on a pricing file supplied by **First DataBank**. The state of Florida provided the **First DataBank** file. To identify the drugs with FULs, we obtained a listing of FUL drugs from CMS that was effective on September 1, 1998. We also obtained a listing from CMS of the subsequent changes to the September list. From these listings, we identified the generic code numbers for the drugs on the FUL listing and compared those generic code numbers to the drugs on the invoices.

We obtained the AWP that was in effect as of the invoice date for each NDC on the invoices from the **First DataBank** pricing file. If a drug from an invoice was not on the pricing file, we eliminated that drug. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which the invoice price was discounted below AWP.

We also calculated a discount below AWP for each pharmacy based on the total invoice dollars on the pharmacy invoice(s). This discount was computed by summing all invoice prices for a pharmacy and comparing that total to the sum of all the AWPs for the pharmacy. The estimates calculated using these weighted pharmacy discounts are included in the detailed sample results reported in **APPENDIX 2**.

We used Office of Audit Services (OAS) statistical software to calculate all estimates, as well as to generate all random numbers. We obtained the total number of pharmacies in the universe from the National Council for Prescription Drug Programs. We did not independently verify any information obtained from third-party sources. Additionally, we did not attempt to identify any special discounts, rebates, or other types of special incentives not reflected on the invoices. The results of our additional analyses were developed by our Little Rock, Arkansas OAS field office from January to May 2002.

FINDINGS AND RECOMMENDATIONS

Based on our findings, we recommend that CMS encourage states to consider changing the Medicaid reimbursement methodology that is normally used to reimburse pharmacies for outpatient prescription drugs. States on average paid AWP minus 10.3 percent in 1999, which represented reimbursement for all brand name drugs and those generic drugs that are not on the

FUL drug list developed by CMS. Multiple source drugs that were included on the CMS FUL list[4] must meet set criteria and are reimbursed at the FUL price. Thus, Medicaid used a two-tiered reimbursement methodology to reimburse pharmacies for drugs: (1) a percentage discount off AWP for all brand name drugs and those non-FUL multiple source drugs and (2) an upper-limit price for those multiple source drugs identified as having FUL prices.

Based on the results of our additional analyses, if states continue to reimburse for drugs based on AWP, we recommend that CMS encourage states to consider using a four-tiered reimbursement methodology. This four-tiered system would consist of (1) **tier one** – a percentage discount off AWP for single source brand name drugs; (2) **tier two** – a percentage discount off AWP for innovator multiple source drugs without FULs; (3) **tier three** – a percentage discount off AWP for non-innovator multiple source drugs without FULs; and (4) **tier four** – the FUL price for those FUL multiple source drugs. The current method of reimbursing for brand name drugs and those non-FUL multiple source drugs using a single percentage discount does not adequately consider the large fluctuations in actual discounts between brands and multiple source drugs that we found during our additional analyses.

Our review of CY 1999 Medicaid drug reimbursements showed that for brand name drugs, pharmacy invoice prices were discounted an average of 21.8 percent below AWP. We included in this calculation all single source innovator drugs and multiple source innovator drugs. The percentage discounts off AWP for all generic drugs reimbursed in CY 1999 (including those generics on the FUL) was 65.9 percent.

Our additional analyses of this data, however, provide a more comprehensive breakdown of discount percentages for single source innovator drugs, all drugs without FULs (single source innovator and multiple source drugs), non-FUL multiple source drugs only, and multiple source drugs with FULs. Specifically, we found that:

- ***For single source innovator drugs:*** pharmacies purchased the drugs at an estimated discount of 17.2 percent below AWP.

- ***For all drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 27.2 percent below AWP.

- ***For multiple source drugs without FULs:*** pharmacies purchased the drugs at an estimated discount of 44.2 percent below AWP. A further breakdown of multiple source drugs without FULs showed the estimated discount for innovator multiple source drugs to be 24.4 percent and 54.2 percent for non-innovator multiple source drugs.

- ***For multiple source drugs with FULs:*** pharmacies purchased the drugs at an estimated discount of 72.1 percent below AWP.

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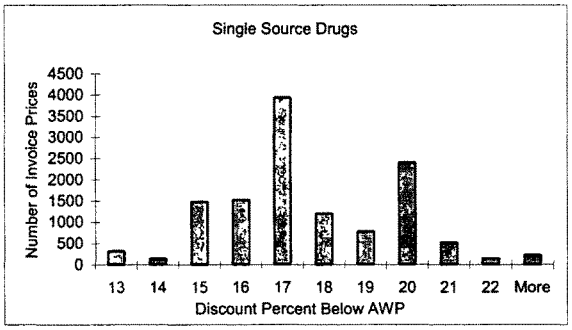
[4] Many states have established their own programs for limiting reimbursement for generic drugs. These programs are often referred to as state maximum allowable cost (MAC) programs. Reimbursement for generic drugs on these state MAC programs is limited to the MAC price for a given generic drug. When we refer to FUL generic drugs, we are also considering these to include those drugs covered by state MAC programs.

The above analyses show that there is a wide range of discounts depending upon the category of drug that is being purchased. The following provides the details of those findings.

SINGLE SOURCE INNOVATOR DRUGS

As part of our expanded analyses, we developed an estimate of the average discount below AWP for **tier–one** type drugs (single source innovator drugs) at which pharmacies were able to purchase these drugs. We estimated that pharmacies purchased single source innovator drugs at a discount of 17.2 percent below AWP.[5] The estimate was based on a comparison to AWP of 12,685 invoice prices with a standard error of 0.25 percent. Our previous estimate (included in report A-06-00-00023), which included innovator multiple source drugs, was 21.8 percent below AWP with a standard error of 0.35 percent.

As discussed above, the results presented in our original report on brand name drugs included both single source and multiple source innovator drugs. We presented our prior work as a combination because that was how CMS accounted for innovator multiple source drugs and that was how drug manufacturers paid rebates under the Medicaid rebate program. The rebate percentage is greater for brand name drugs than for generic drugs. However, there was considerable interest in having us break down single source innovator and multiple source innovator drugs into the two categories. While the estimate of the discount fell to 17.2 percent when multiple source innovator drugs were removed from our calculations, the discount remains considerably higher than the discount used by most states in their determination of EAC (which was an average of 10.3 percent). The following chart provides a distribution of the 12,685 invoice price discounts and shows that most single source innovator drugs are discounted between 15 and 20 percent.

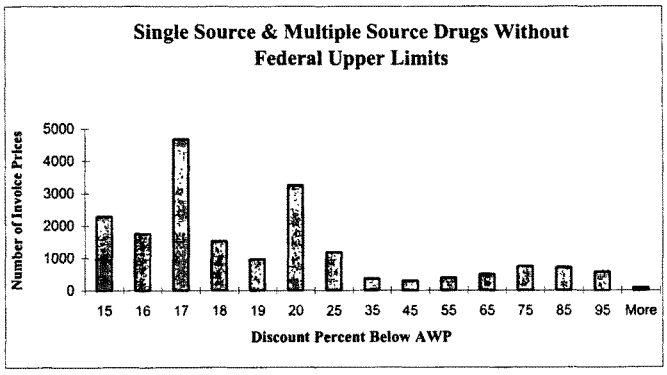


[5] The lower limit and upper limit at the 90 percent confidence level were 16.8 and 17.6 percent, respectively.

ALL DRUGS WITHOUT FULS

In order to develop a discount estimate that could be compared to the single discount percentage (on average 10.3 percent nationally in CY 1999) that was used by states to reimburse pharmacies for prescription drugs, we included all drugs from the invoices in our review except those innovator multiple source and non-innovator multiple source drugs that were on the FUL listings. We calculated this total average discount estimate to be 27.2 percent below AWP compared to the 10.3 percent used on average by the states. The estimate was based on a comparison to AWP of 19,357 invoice prices with a standard error of 0.34 percent.

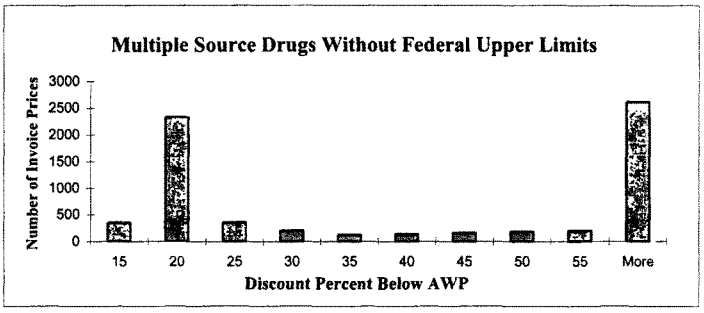
As the following chart shows, most of the invoice prices fall below the average estimate of 27.2 percent. Therefore, we would not recommend establishing a discount percentage as high as 27.2 percent for this category of drugs because of the concern that many pharmacies may not be able to purchase certain brand name drugs at these discounts. However, we are providing this information to show a comparison to the single discount percentage that is, on average, currently used by most states. The following chart shows the distribution of the discounts below AWP for the 19,357 invoice prices.



MULTIPLE SOURCE DRUGS WITHOUT FULS

As previously stated most states used the same single percentage discount (on average 10.3 percent) for single source, multiple source innovator, and multiple source non-innovator drugs that were not on the CMS FUL list. However, we estimated that pharmacies purchased multiple source drugs that did not have FULs at a discount of 44.2 percent below AWP. The estimate was based on a comparison of 6,672 invoice prices to AWP with a standard error of 0.61 percent.

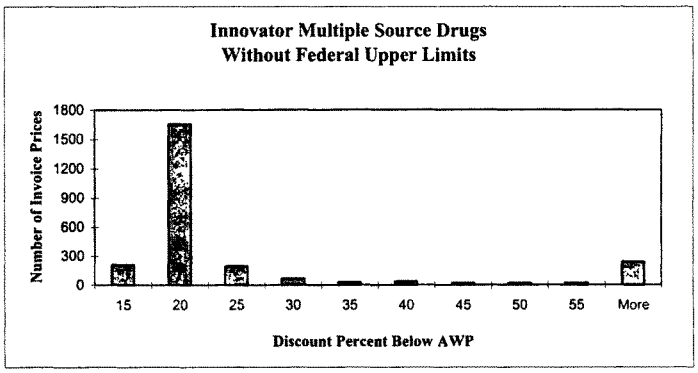
This average discount estimate from our review is significantly greater than what states, on average, paid during the period reviewed. The following chart shows the distribution of the discounts for the 6,672 invoice prices.



Discount for Innovator Multiple Source Drugs Without FULs

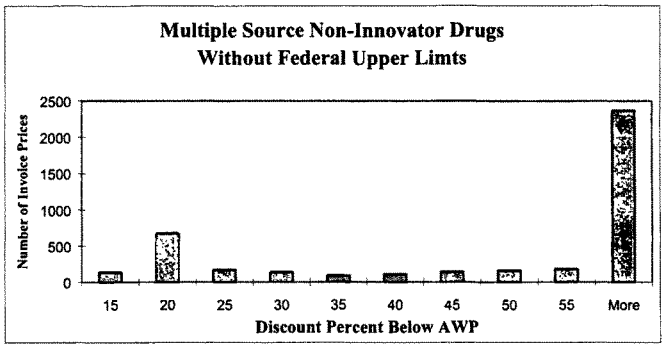
We believe the use of only one EAC, or one discount from AWP, for multiple source drugs without FULs is not the best method for reimbursing these drugs. If the results of our review (an average discount of 44.2 percent) were used as the EAC for multiple source drugs that are not on the CMS FUL list, some drugs would be reimbursed at a level far below a pharmacy's cost for those drugs. As the distribution chart above shows, there were a large number of invoice price discounts that fell in the 20 percent range. These drugs represented, for the most part, innovator multiple source drugs.

As a result, we calculated a separate estimate for the innovator multiple source drugs that are not on the CMS FUL list. We estimated that discount to be 24.4 percent below AWP. The estimate was based on 2,503 invoice prices with a standard error of 0.92 percent. The following chart provides a distribution of the invoice price discounts for innovator multiple source drugs that are not on the CMS FUL list.



Discount for Non-Innovator Multiple Source Drugs Without FULs

As the chart above shows, most of the innovator multiple source drugs fell in the 20 percent discount range. The effect of removing the innovator multiple source drugs from our analyses of multiple source drugs without FULs resulted in increasing the estimated discount for non-innovator multiple source drugs without FULs to 54.2 percent. The estimate was based on 4,169 invoice prices with a standard error of 0.89 percent. The following chart provides a distribution of the invoice price discounts.

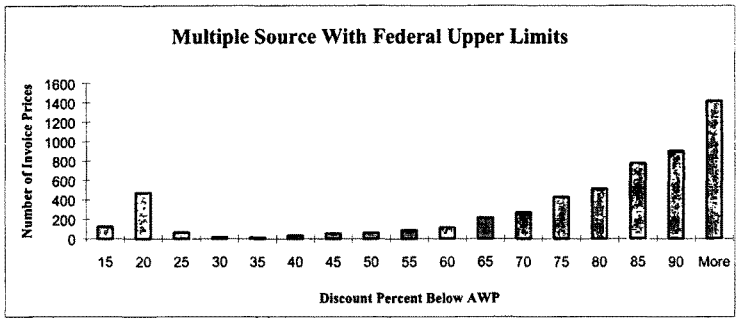


The discount below AWP for non-innovator multiple source drugs not on the CMS FUL list was significantly greater than the innovator multiple source drugs. This difference and the results of our review of the discounts available on innovator multiple source drugs without FULs would support the use of a separate EAC for those multiple source drugs that are not on the CMS FUL list. The establishment of such an EAC should take into consideration the wide range in the discounts for innovator multiple source and non-innovator multiple source drugs, 24.4 and 54.2 percent, respectively. We believe that the results from our review will be useful for states that are considering reimbursing for drugs using one EAC for innovator single source drugs and another EAC for multiple source drugs that are not on the CMS FUL list.

MULTIPLE SOURCE DRUGS WITH FULS

There are a large number of drugs reimbursed by states following the FULs established by CMS. We estimated that the invoice price for multiple source drugs with FULs was 72.1 percent below AWP. The estimate was based on a comparison of 5,575 invoice prices to AWP with a standard error of 0.95 percent.

The following chart shows the distribution of the discounts for the individual invoice prices.



We did not evaluate the FUL prices established by CMS. However, as shown in the above chart, it appears drug manufacturers were providing deeper discounts on purchases of those drugs that were on the CMS FUL listings as compared to those multiple source drugs that were not listed. We are especially interested in the fact that about 1,400 of the 5,575 invoice prices were greater than 90 percent below AWP for those drugs. We will be further reviewing this area in consultation with CMS.

INDIVIDUAL STATE RESULTS

All of our work reported in this current report and our two prior reports involved eight sampled states. We issued individual reports detailing the results of our reviews on brand name and generic drugs to those states. As a result of the extended analyses included in this current report, we plan to share with these eight states their individual results based on this analyses. However, for CMS's use, we have included the results of the additional analyses for the individual states in **APPENDICES 3** through **10**.

CONCLUSIONS AND RECOMMENDATIONS

The results of our additional analyses included in this report provide further support for the recommendation contained in our earlier reports that CMS require the states to bring pharmacy drug reimbursement more in line with the actual acquisition cost of brand name and generic drugs. Our estimate of the discount below AWP for single source innovator drugs, 17.2 percent, was significantly greater than the discount used by most states for reimbursing drugs not on the FUL list (an average discount of 10.3 percent) even after removing multiple source innovator drugs from our calculations.

We also estimated that pharmacies purchased all drugs without FULs at a discount of 27.2 percent below AWP. When this 27.2 percent figure is compared to the national state average discount of 10.3 percent, it appears that states were paying substantially higher

reimbursement rates for drugs than necessary. However, we would not recommend the use of a single discount for drugs without FULs, such as the 27.2 percent value we determined. Rather than using one EAC for reimbursing drugs without FULs, states should consider using different EACs – one for single source drugs, one for innovator multiple source drugs without FULs, and another for non-innovator multiple source drugs without FULs. If states used these three EACs for certain categories of drugs and reimbursed for FUL drugs using the FULs developed by CMS, they would have a four-tiered reimbursement system. One state already uses a three-tiered system and three states are currently considering similar reimbursement methodologies. (See **APPENDIX 11**.)

We believe that the three-tiered approach already being used by one state and the proposed changes to reimbursement by three other states represent a significant advancement in ensuring that Medicaid reimburses drugs more in line with the actual acquisition costs of drugs and provides support for all other states to consider using a four-tiered reimbursement methodology. Accordingly, if states continue to use a reimbursement system based on AWP, we recommend that CMS encourage states to consider adopting a four-tiered payment system in order to bring pharmacy reimbursement more in line with the actual acquisition cost of drug products. Such a four-tiered system would provide for separate discount percentages for (a) single source innovator drugs, (b) multiple source innovator drugs not on the FUL listing, (c) non-innovator multiple source drugs not on the FUL listing, and (d) all drugs on the FUL listing. We also recommend that CMS share this report with the states.

CMS'S COMMENTS

In response to the recommendations in our draft report, CMS agreed to share our report with the states. However, CMS suggested that the OIG recommend a four-tiered reimbursement methodology, rather than the three-tiered system recommended in our draft report in order to differentiate branded generics (innovator multiple source drugs) and generics (non-innovator multiple source drugs). In addition, CMS offered a technical comment regarding the criteria for the establishment of FUL prices. The full text of CMS's comments is included as **APPENDIX 12** to this report.

OIG'S RESPONSE

We agreed with the changes suggested by CMS and revised our final report to reflect CMS's comments.

OTHER MATTERS

The CMS recently developed a legislative proposal that was included as part of the President's fiscal year 2003 budget that proposes to change the basis for calculating Medicaid outpatient prescription drug rebates. This change would substitute AWP in place of the average manufacturer's price in the rebate formula. We previously issued a report[6] to CMS that recommended such a change and detailed several advantages of doing so. We support CMS's proposed change and agree with CMS that connecting the rebate amount to AWP could result in AWPs that more closely reflect the actual acquisition cost of a given drug. If this change is approved and implemented, states may, at some point, have to re-evaluate their reimbursement methodology to see if further changes are needed.

[6] "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" (A-06-97-00052).

SAMPLE DESCRIPTION[7]

Sample Objectives:

Develop a nationwide estimate of the extent of the discount below AWP of actual invoice prices paid by Medicaid pharmacies for prescription drugs.

Population:

The primary sampling population was all states providing coverage of prescription drugs as an optional service under section 1905 (a) (12) of the Social Security Act (the Act). Section 1903 (a) of the Act provides for federal financial participation in state expenditures for prescription drugs.

Sampling Frame:

The primary sampling frame was a listing of all states and the District of Columbia, participating in the Medicaid prescription drug program except for Arizona and Tennessee. Arizona was excluded because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was also excluded because of a waiver received to implement a managed care program for Medicaid.

Sample Design:

A stratified multistage sample was designed with states as the primary sample units and Medicaid pharmacy providers within those states as the secondary sample units. A stratified random sample of states was selected for the primary sample and a stratified random sample of pharmacies was selected for the secondary sample. A sample of eight pharmacies was selected from each of five strata. The five strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). Each pharmacy was assigned a month from 1999 for which to provide invoices. All pharmacies were initially assigned a month from January 1999 to December 1999 in a method designed to provide a cross-section of the 12-month period. However, some pharmacies were permitted to submit invoices from other months in 1999, as invoices were not available for the month originally assigned. The largest invoice from each of four different sources of supply

[7] This sample was used for both of our original reports involving brand name and generic drugs (A-06-00-00023 and A-06-01-00053). The results of this sample then became the basis for the additional analyses we performed on drug reimbursement and reported in this current report.

was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. All invoice prices were compared to AWP.

Sample Size:

Eight states were selected for review from our primary sampling frame. Eight pharmacies were selected from each stratum of our secondary sample frame. Therefore, a maximum of 40 pharmacies was selected from each state. Of the 8 states, 2 states were selected from the universe of 10 sampled states plus the District of Columbia in our previous review. The remaining 6 states were selected from the remaining universe of 38 states.

Source of Random Numbers:

OAS statistical sampling software was used to generate the random numbers.

Characteristics to be Measured:

From our review of the pharmacy invoices, we calculated the percentage of the discount below AWP of actual invoice prices for all drugs on the invoices submitted.

Treatment of Missing Sample Items:

No spare was substituted for a pharmacy that refused to provide the requested information. If a stratum had eight or fewer pharmacies, we reviewed all pharmacies in that stratum. Spares were substituted for pharmacies that were not providers during the review period and for misclassified pharmacies. If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that supplier type during the assigned month.

Estimation Methodology:

We used OAS statistical software for stratified multistage variable sampling to project the percentage difference between actual invoice prices and AWP for each stratum, as well as an overall percent difference.

Other Evidence:

We obtained AWP from a pricing file received from the state of Florida.

DETAILED SAMPLE RESULTS

SINGLE SOURCE DRUGS

Category	Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP	Percent Below AWP (Weighted)*
Rural-Chain	1,008	52	2,707	16.63	16.60
Rural-Independent	1,243	55	2,043	17.85	17.71
Urban-Chain	5,745	56	6,109	16.97	16.91
Urban-Independent	2,398	53	1,826	17.64	17.64
Non-Traditional	1,123	58	1,194	26.26	25.39
Overall (Exc. Non-Trad.)	10,394	216	12,685	17.19	17.15

ALL DRUGS WITHOUT FEDERAL UPPER LIMITS

Category	Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP	Percent Below AWP (Weighted)*
Rural-Chain	1,008	52	4,175	27.38	22.24
Rural-Independent	1,243	55	3,033	26.24	23.27
Urban-Chain	5,745	56	9,470	28.22	23.96
Urban-Independent	2,398	54	2,679	24.98	22.95
Non-Traditional	1,123	62	2,096	41.95	34.86
Overall (Exc. Non-Trad.)	10,394	217	19,357	27.16	23.48

* Weighted based on total dollars on each pharmacy's invoice(s).

DETAILED SAMPLE RESULTS

MULTIPLE SOURCE DRUGS WITHOUT FEDERAL UPPER LIMITS

Category	Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP	Percent Below AWP (Weighted)*
Rural-Chain	1,008	52	1,468	43.63	37.87
Rural-Independent	1,243	54	990	42.35	38.38
Urban-Chain	5,745	56	3,361	47.03	45.56
Urban-Independent	2,398	54	853	38.68	37.10
Non-Traditional	1,123	58	902	56.75	56.49
Overall (Exc. Non-Trad.)	10,394	216	6,672	44.23	42.03

MULTIPLE SOURCE DRUGS WITH FEDERAL UPPER LIMITS

Category	Universe of Pharmacies	Sample Pharmacies	Drug Prices Reviewed	Percent Below AWP	Percent Below AWP (Weighted)*
Rural-Chain	1,008	51	1,431	69.36	73.56
Rural-Independent	1,243	55	737	71.06	75.97
Urban-Chain	5,745	56	2,740	73.08	78.70
Urban-Independent	2,398	53	667	71.56	76.63
Non-Traditional	1,123	48	617	76.00	79.55
Overall (Exc. Non-Trad.)	10,394	215	5,575	72.13	77.41

* Weighted based on total dollars on each pharmacy's invoice(s).

SAMPLE RESULTS BY STATE
SINGLE SOURCE DRUGS **APPENDIX 3**

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	254	16.61	1.79	15.57	17.66
	Rural-Independent	73	6	189	17.38	0.94	16.78	17.99
	Urban-Chain	357	4	638	17.15	0.86	16.45	17.85
	Urban-Independent	128	6	218	16 85	0 64	16 43	17.27
	Non-Traditional	65	7	115	27 67	10 94	21 25	34 10
	Overall (Excl. Non-Trad.)	617	23	1,299	17.06	0.26	16.63	17.50
FLORIDA	Rural-Chain	137	7	195	15 83	2 56	14.28	17 38
	Rural-Independent	68	8	449	17.96	0.37	17.76	18.17
	Urban-Chain	2,052	8	986	17.81	0.34	17.62	18.01
	Urban-Independent	656	8	220	16 94	1 10	16 30	17 58
	Non-Traditional	363	8	84	29 75	14 56	21 38	38 12
	Overall (Excl. Non-Trad.)	2,913	31	1,850	17.53	0.13	17.31	17.74
INDIANA	Rural-Chain	187	7	414	17.13	2 18	15 80	18 46
	Rural-Independent	105	8	293	17.09	1.11	16.47	17.71
	Urban-Chain	608	7	949	17.60	1.61	16.60	18.60
	Urban-Independent	183	5	217	20 74	8 43	14 62	26 86
	Non-Traditional	178	8	159	26 13	9 17	20 91	31 34
	Overall (Excl. Non-Trad.)	1,083	27	1,873	18.00	0.73	16.80	19.20
MONTANA	Rural-Chain	57	6	255	15 65	1 70	14 57	16 73
	Rural-Independent	104	4	130	16.73	0.62	16.22	17.23
	Urban-Chain	37	8	753	16.34	0.98	15.84	16.84
	Urban-Independent	31	7	183	17.93	3 23	16 16	19.69
	Non-Traditional	47	8	179	26.23	7 67	22 16	30 29
	Overall (Excl. Non-Trad.)	229	25	1,321	16.56	0.26	16.12	16.99
TEXAS	Rural-Chain	225	7	236	16.21	1 68	15 19	17 24
	Rural-Independent	398	8	253	17.56	0.79	17.11	18.02
	Urban-Chain	1,682	8	514	15.96	3.82	13.75	18.18
	Urban-Independent	778	8	260	17 29	0 99	16 71	17 86
	Non-Traditional	214	7	158	23 86	12 98	15 92	31 79
	Overall (Excl. Non-Trad.)	3,083	31	1,263	16.52	0.74	15.30	17.74
WASHINGTON	Rural-Chain	81	6	232	16 65	1 12	15 93	17.37
	Rural-Independent	137	5	104	21.28	8.36	15.25	27.31
	Urban-Chain	512	6	359	15.97	0.91	15.36	16.58
	Urban-Independent	272	5	183	18 14	0 86	17 51	18 77
	Non-Traditional	123	6	92	24 62	5 52	21 00	28.23
	Overall (Excl. Non-Trad.)	1,002	22	878	17.34	0.55	16.44	18.24
WEST VIRGINIA	Rural-Chain	160	6	601	18 03	1 30	17 18	18.89
	Rural-Independent	119	8	292	17.45	0.48	17.18	17.72
	Urban-Chain	137	8	865	17.88	0.77	17.44	18.31
	Urban-Independent	62	7	307	17 77	0 89	17 25	18 29
	Non-Traditional	18	6	180	24 12	11 21	17 97	30 26
	Overall (Excl. Non-Trad.)	478	29	2,065	17.81	0.20	17.48	18.14
WISCONSIN	Rural-Chain	102	6	520	16.22	2 41	14 64	17.79
	Rural-Independent	239	8	333	17.54	0.59	17.20	17.87
	Urban-Chain	360	7	1,045	16.33	2.16	15.00	17.66
	Urban-Independent	288	7	238	18 13	1 32	17 32	18 94
	Non-Traditional	115	8	227	26 15	8 46	21 41	30 89
	Overall (Excl. Non-Trad.)	989	28	2,136	17.13	0.34	16.57	17.70

SAMPLE RESULTS BY STATE
SINGLE SOURCE DRUGS – WEIGHTED BY INVOICE DOLLARS **APPENDIX 4**

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	254	16.10	1.51	15.22	16.98
	Rural-Independent	73	6	189	17.28	1.23	16.49	18.07
	Urban-Chain	357	4	638	17.05	0.95	16.28	17.82
	Urban-Independent	128	6	218	16.75	0.72	16.28	17.22
	Non-Traditional	65	7	115	25 90	9 79	20 15	31 65
	Overall (Excl. Non-Trad.)	617	23	1,299	16.92	0.29	16 45	17.40
FLORIDA	Rural-Chain	137	7	195	15.63	2 62	14 04	17 22
	Rural-Independent	68	8	449	17.79	0.45	17.54	18.03
	Urban-Chain	2,052	8	986	17.79	0.34	17.59	17.98
	Urban-Independent	656	8	220	17.00	1.14	16.34	17.66
	Non-Traditional	363	8	84	27 69	14 44	19 38	35.99
	Overall (Excl. Non-Trad.)	2,913	31	1,850	17.51	0.13	17.29	17.72
INDIANA	Rural-Chain	187	7	414	17 29	2 25	15 91	18 66
	Rural-Independent	105	8	293	16.95	1.09	16.34	17.56
	Urban-Chain	608	7	949	17.57	1.66	16.54	18.60
	Urban-Independent	183	5	217	21.10	9.57	14.16	28.04
	Non-Traditional	178	8	159	26 93	9 91	21 29	32 56
	Overall (Excl. Non-Trad.)	1,083	27	1,873	18.06	0.81	16.73	19.39
MONTANA	Rural-Chain	57	6	255	15 83	2 11	14 50	17 17
	Rural-Independent	104	4	130	17.05	0.70	16.48	17.62
	Urban-Chain	37	8	753	16.40	1.07	15.85	16.95
	Urban-Independent	31	7	183	18.19	3.82	16.10	20.27
	Non-Traditional	47	8	179	24 71	8.00	20 47	28 95
	Overall (Excl. Non-Trad.)	229	25	1,321	16.80	0.31	16.28	17.31
TEXAS	Rural-Chain	225	7	236	16.21	1 76	15 14	17 29
	Rural-Independent	398	8	253	17.13	0.72	16.71	17.54
	Urban-Chain	1,682	8	514	15.98	3.53	13.93	18.02
	Urban-Independent	778	8	260	17 20	1.08	16.58	17.82
	Non-Traditional	214	7	158	22 70	12 03	15 34	30 06
	Overall (Excl. Non-Trad.)	3,083	31	1,263	16.45	0.69	15.32	17.58
WASHINGTON	Rural-Chain	81	6	232	16 63	0 85	16 09	17.18
	Rural-Independent	137	5	104	21.32	8.34	15.29	27.35
	Urban-Chain	512	6	359	15.62	0.50	15.29	15.95
	Urban-Independent	272	5	183	18 34	1 15	17.50	19.18
	Non-Traditional	123	6	92	22 95	5 43	19 39	26 51
	Overall (Excl. Non-Trad.)	1,002	22	878	17.22	0.53	16.35	18.09
WEST VIRGINIA	Rural-Chain	160	6	601	17 95	1 16	17 18	18 72
	Rural-Independent	119	8	292	17.31	0.55	17.00	17.62
	Urban-Chain	137	8	865	17.78	0.73	17.37	18.18
	Urban-Independent	62	7	307	17 81	0 95	17 26	18.37
	Non-Traditional	18	6	180	23 55	11 49	17 25	29 85
	Overall (Excl. Non-Trad.)	478	29	2,065	17.72	0.18	17.42	18.02
WISCONSIN	Rural-Chain	102	6	520	16 15	2 35	14 62	17 68
	Rural-Independent	239	8	333	17.58	0.51	17.28	17.87
	Urban-Chain	360	7	1,045	16.24	1.87	15.09	17.40
	Urban-Independent	288	7	238	17 86	1.17	17.14	18.57
	Non-Traditional	115	8	227	26 81	11 36	20 44	33 19
	Overall (Excl. Non-Trad.)	989	28	2,136	17.03	0.30	16.53	17.53

SAMPLE RESULTS BY STATE
ALL DRUGS WITHOUT FULS

APPENDIX 5

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	370	22.50	4.25	20.02	24.98
	Rural-Independent	73	6	284	23.00	3.87	20.51	25.49
	Urban-Chain	357	4	1,040	29.60	2.64	27.44	31.76
	Urban-Independent	128	7	322	25 01	3 20	23 08	26 95
	Non-Traditional	65	8	190	42 90	19 53	32 27	53 53
	Overall (Excl. Non-Trad.)	617	24	2,016	27.19	0.83	25.82	28.55
FLORIDA	Rural-Chain	137	7	334	32 03	12 60	24 40	39.66
	Rural-Independent	68	8	600	23.41	3.30	21.61	25.22
	Urban-Chain	2,052	8	1,574	29.71	5.64	26.44	32.98
	Urban-Independent	656	8	317	24 36	2 74	22 78	25 94
	Non-Traditional	363	8	159	43 52	14 49	35 19	51 86
	Overall (Excl. Non-Trad.)	2,913	31	2,825	28.47	1.43	26.11	30.83
INDIANA	Rural-Chain	187	7	639	31 40	9 83	25 41	37 39
	Rural-Independent	105	8	455	24.51	3.72	22.43	26.59
	Urban-Chain	608	7	1,451	26.83	2.51	25.28	28.38
	Urban-Independent	183	5	340	28.54	9 04	21 98	35 10
	Non-Traditional	178	8	293	41 24	13 87	33 36	49 12
	Overall (Excl. Non-Trad.)	1,083	27	2,885	27.68	1.07	25.92	29.44
MONTANA	Rural-Chain	57	6	417	27 70	3 75	25 32	30 08
	Rural-Independent	104	4	186	24.58	3.15	22.03	27.12
	Urban-Chain	37	8	1,139	24.93	2.32	23.73	26.12
	Urban-Independent	31	7	270	26 41	5 67	23 31	29 51
	Non-Traditional	47	8	316	41.54	17 41	32 31	50 76
	Overall (Excl. Non-Trad.)	229	25	2,012	25.66	0.84	24.28	27.04
TEXAS	Rural-Chain	225	7	352	23 47	4.80	20.53	26 41
	Rural-Independent	398	8	398	26.08	2.81	24.46	27.69
	Urban-Chain	1,682	8	810	27.98	4.15	25.57	30.38
	Urban-Independent	778	8	397	26 08	5 18	23 08	29 07
	Non-Traditional	214	7	251	42 27	12 57	34 58	49 96
	Overall (Excl. Non-Trad.)	3,083	31	1,957	26.92	0.94	25 38	28.47
WASHINGTON	Rural-Chain	81	6	322	23 15	1 65	22 08	24 22
	Rural-Independent	137	5	153	30.72	10.96	22.81	38.63
	Urban-Chain	512	6	526	24.52	2.40	22.91	26.12
	Urban-Independent	272	5	240	22 76	2 30	21 08	24 44
	Non-Traditional	123	7	219	42 29	13 20	34 31	50 26
	Overall (Excl. Non-Trad.)	1,002	22	1,241	24.78	0.87	23.34	26.21
WEST VIRGINIA	Rural-Chain	160	6	951	29.22	3 11	27 17	31 27
	Rural-Independent	119	8	446	27.23	3.50	25.26	29.19
	Urban-Chain	137	8	1,333	28.94	2.64	27.45	30.43
	Urban-Independent	62	7	462	23 03	3 37	21 06	25 00
	Non-Traditional	18	8	279	32.21	11 05	27 42	37 00
	Overall (Excl. Non-Trad.)	478	29	3,192	27.84	0.59	26.86	28.82
WISCONSIN	Rural-Chain	102	6	790	25 00	6 98	20 46	29.54
	Rural-Independent	239	8	511	26.85	5.81	23.53	30.17
	Urban-Chain	360	7	1,597	26.59	2.62	24.97	28.20
	Urban-Independent	288	7	331	23.61	2 76	21 92	25.31
	Non-Traditional	115	8	389	40 45	8 70	35 57	45.33
	Overall (Excl. Non-Trad)	989	28	3,229	25.62	0.73	24.42	26.83

SAMPLE RESULTS BY STATE
ALL DRUGS WITHOUT FULS – WEIGHTED BY INVOICE DOLLARS APPENDIX 6

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	370	18.50	2.24	17.19	19.81
	Rural-Independent	73	6	284	20.65	3.64	18.31	22.99
	Urban-Chain	357	4	1,040	26.28	3.36	23.53	29.02
	Urban-Independent	128	7	322	21 76	2 89	20 01	23 51
	Non-Traditional	65	8	190	37.84	22 21	25 74	49 93
	Overall (Excl. Non-Trad.)	617	24	2,016	23.93	1.01	22.27	25.59
FLORIDA	Rural-Chain	137	7	334	24 84	7 37	20 38	29.31
	Rural-Independent	68	8	600	20.18	2.08	19.04	21.31
	Urban-Chain	2,052	8	1,574	26.29	4.72	23.55	29.03
	Urban-Independent	656	8	317	22.41	4.29	19.93	24 89
	Non-Traditional	363	8	159	35 58	16 96	25 82	45 33
	Overall (Excl. Non-Trad.)	2,913	31	2,825	25.20	1.23	23.18	27.23
INDIANA	Rural-Chain	187	7	639	25.51	9 01	20 02	31 01
	Rural-Independent	105	8	455	21.30	3.30	19.46	23.14
	Urban-Chain	608	7	1,451	23.06	3.07	21.16	24.96
	Urban-Independent	183	5	340	25.08	10.48	17.47	32 69
	Non-Traditional	178	8	293	35.20	13 10	27 76	42 64
	Overall (Excl. Non-Trad.)	1,083	27	2,885	23.65	1.17	21.72	25.58
MONTANA	Rural-Chain	57	6	417	20 73	1 57	19 74	21 73
	Rural-Independent	104	4	186	22.35	3.62	19.43	25.27
	Urban-Chain	37	8	1,139	21.34	1.91	20.36	22.32
	Urban-Independent	31	7	270	23.16	4.76	20.55	25.76
	Non-Traditional	47	8	316	34 95	18 09	25 37	44 53
	Overall (Excl. Non-Trad.)	229	25	2,012	21.89	0.85	20.49	23.30
TEXAS	Rural-Chain	225	7	352	19 37	2 04	18 12	20 62
	Rural-Independent	398	8	398	21.78	1.74	20.78	22.77
	Urban-Chain	1,682	8	810	21.79	2.56	20.30	23.28
	Urban-Independent	778	8	397	24.40	5.85	21.01	27.79
	Non-Traditional	214	7	251	32.23	9 19	26 61	37 85
	Overall (Excl. Non-Trad.)	3,083	31	1,957	22.27	0.72	21.08	23.46
WASHINGTON	Rural-Chain	81	6	322	18 97	1.12	18 24	19.69
	Rural-Independent	137	5	153	25.18	8.59	18.98	31.38
	Urban-Chain	512	6	526	20.35	1.98	19.03	21.67
	Urban-Independent	272	5	240	20.68	1.64	19.49	21.87
	Non-Traditional	123	7	219	36 89	15 83	27 33	46 44
	Overall (Excl. Non-Trad.)	1,002	22	1,241	20.99	0.69	19.86	22.12
WEST VIRGINIA	Rural-Chain	160	6	951	24 10	2 77	22 27	25 93
	Rural-Independent	119	8	446	23.88	4.89	21.13	26.62
	Urban-Chain	137	8	1,333	25.88	5.58	22.73	29.02
	Urban-Independent	62	7	462	20.71	2.29	19.38	22.05
	Non-Traditional	18	8	279	25 05	10 55	20 48	29 62
	Overall (Excl. Non-Trad.)	478	29	3,192	24.11	0.79	22.81	25.41
WISCONSIN	Rural-Chain	102	6	790	21 57	5 06	18 27	24 86
	Rural-Independent	239	8	511	27.44	12.09	20.53	34.35
	Urban-Chain	360	7	1,597	23.77	2.39	22.30	25.25
	Urban-Independent	288	7	331	22.07	2.56	20.50	23.64
	Non-Traditional	115	8	389	35 69	12 92	28 44	42 94
	Overall (Excl. Non-Trad.)	989	28	3,229	23.93	1.12	22.09	25.78

SAMPLE RESULTS BY STATE
MULTIPLE SOURCE DRUGS WITHOUT FULS **APPENDIX 7**

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	116	35.73	14.26	27.41	44.05
	Rural-Independent	73	5	95	38.28	7.68	32.83	43.73
	Urban-Chain	357	4	402	49.33	4.81	45.39	53.26
	Urban-Independent	128	7	104	42 41	14 17	33.85	50 98
	Non-Traditional	65	7	75	60 61	14 93	51 85	69 38
	Overall (Excl. Non-Trad.)	617	23	717	45.28	1.86	42.22	48.35
FLORIDA	Rural-Chain	137	7	139	45 84	15 01	36 76	54 93
	Rural-Independent	68	8	151	38.89	11.13	32.81	44.97
	Urban-Chain	2,052	8	588	50.46	10.25	44.52	56.41
	Urban-Independent	656	8	97	39 78	9 19	34 46	45 09
	Non-Traditional	363	6	75	57 25	19 78	44 08	70 42
	Overall (Excl. Non-Trad.)	2,913	31	975	47.57	2.66	43 19	51.95
INDIANA	Rural-Chain	187	7	225	50 01	9 33	44 32	55 71
	Rural-Independent	105	8	162	35.60	6.91	31.74	39.46
	Urban-Chain	608	7	502	45.76	5.62	42.28	49.23
	Urban-Independent	183	5	123	42 18	7 79	36.53	47 83
	Non-Traditional	178	7	134	53 60	13 60	45.32	61.88
	Overall (Excl. Non-Trad.)	1,083	27	1,012	44.90	1.47	42.49	47.32
MONTANA	Rural-Chain	57	6	162	43.58	8 20	38.37	48 79
	Rural-Independent	104	4	56	41.40	7.72	35.17	47.63
	Urban-Chain	37	8	386	42.24	5.59	39.36	45.12
	Urban-Independent	31	7	87	44 30	9 42	39 15	49.45
	Non-Traditional	47	8	137	54 03	18 99	43 97	64 08
	Overall (Excl. Non-Trad.)	229	25	691	42.47	1.96	39.25	45.69
TEXAS	Rural-Chain	225	7	116	38 67	10 91	31 99	45 35
	Rural-Independent	398	8	145	40.76	4.82	37.99	43.54
	Urban-Chain	1,682	8	296	44.04	7.78	39.52	48.55
	Urban-Independent	778	8	137	38.13	6 67	34 27	41 98
	Non-Traditional	214	7	93	57 76	16 75	47 51	68 00
	Overall (Excl. Non-Trad.)	3,083	31	694	41.73	1.65	39 01	44.45
WASHINGTON	Rural-Chain	81	6	90	41.58	5 06	38 31	44 85
	Rural-Independent	137	5	49	50.02	19.38	36.02	64.02
	Urban-Chain	512	6	167	42.50	7.04	37.80	47.20
	Urban-Independent	272	5	57	34.76	2 82	32.71	36 81
	Non-Traditional	123	7	127	55 00	9 93	49 01	60 99
	Overall (Excl. Non-Trad.)	1,002	22	363	41.35	1.90	38.22	44.49
WEST VIRGINIA	Rural-Chain	160	6	350	48.25	7.04	43 61	52 89
	Rural-Independent	119	8	154	45.55	7.65	41.25	49.85
	Urban-Chain	137	8	468	45.66	4.50	43.12	48.20
	Urban-Independent	62	7	155	33.24	8.66	28 17	38 31
	Non-Traditional	18	8	99	43 15	15 09	36 61	49 69
	Overall (Excl. Non-Trad.)	478	29	1,127	44.89	1.29	42.76	47.01
WISCONSIN	Rural-Chain	102	6	270	38 65	11 49	31 16	46 14
	Rural-Independent	239	8	178	44.75	7.79	40.29	49.21
	Urban-Chain	360	7	552	47.31	5.61	43.86	50.77
	Urban-Independent	288	7	93	37 86	7 40	33.31	42 40
	Non-Traditional	115	8	162	61 34	13 76	53 62	69.06
	Overall (Excl. Non-Trad.)	989	28	1,093	43.05	1.37	40.79	45 30

SAMPLE RESULTS BY STATE **APPENDIX 8**
MULTIPLE SOURCE DRUGS WITHOUT FULS – WEIGHTED BY INVOICE DOLLARS

					Percent Below AWP			
					Sample		90% Confidence Level	
ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	116	30.97	15.18	22.11	39.83
	Rural-Independent	73	5	95	34.46	10.41	27.07	41.85
	Urban-Chain	357	4	402	49.40	9.99	41.23	57.57
	Urban-Independent	128	7	104	36 01	11 90	28 82	43 21
	Non-Traditional	65	7	75	56 30	22 87	42 87	69 73
	Overall (Excl. Non-Trad.)	617	23	717	43.09	3.10	37.99	48.20
FLORIDA	Rural-Chain	137	7	139	43 79	20 89	31 13	56 44
	Rural-Independent	68	8	151	32.76	9.01	27.84	37.69
	Urban-Chain	2,052	8	588	50.34	14.31	42.03	58.64
	Urban-Independent	656	8	97	38 54	15 67	29 48	47 59
	Non-Traditional	363	6	75	57 57	23 09	42 19	72 94
	Overall (Excl. Non-Trad.)	2,913	31	975	46.96	3.78	40 74	53.19
INDIANA	Rural-Chain	187	7	225	42 54	13 74	34 16	50 92
	Rural-Independent	105	8	162	31.34	8.29	26.70	35.97
	Urban-Chain	608	7	502	42.46	8.00	37.51	47.40
	Urban-Independent	183	5	123	39.52	11 11	31 46	47 58
	Non-Traditional	178	7	134	55 50	15.29	46 18	64.82
	Overall (Excl. Non-Trad.)	1,083	27	1,012	40.90	2.09	37.45	44.34
MONTANA	Rural-Chain	57	6	162	33 63	6 90	29 25	38 01
	Rural-Independent	104	4	56	41.13	14.13	29.73	52.52
	Urban-Chain	37	8	386	38.10	7.86	34.05	42.15
	Urban-Independent	31	7	87	40.34	14 34	32 50	48 19
	Non-Traditional	47	8	137	52 05	23 88	39 40	64 70
	Overall (Excl. Non-Trad.)	229	25	691	38.67	3.30	33.23	44.10
TEXAS	Rural-Chain	225	7	116	33 37	7 80	28.60	38 15
	Rural-Independent	398	8	145	35.54	5.70	32.26	38.82
	Urban-Chain	1,682	8	296	40.38	10.06	34.54	46.21
	Urban-Independent	778	8	137	37.96	12.84	30.53	45 39
	Non-Traditional	214	7	93	57 63	20 62	45 02	70 24
	Overall (Excl. Non-Trad.)	3,083	31	694	38.63	2.27	34.89	42.37
WASHINGTON	Rural-Chain	81	6	90	32 67	7 86	27 59	37 75
	Rural-Independent	137	5	49	46.08	19.72	31.84	60.32
	Urban-Chain	512	6	167	41.47	9.19	35.33	47.60
	Urban-Independent	272	5	57	30.32	2.72	28.34	32.30
	Non-Traditional	123	7	127	55.29	12 57	47 70	62 87
	Overall (Excl. Non-Trad.)	1,002	22	363	38.36	2.28	34.61	42.11
WEST VIRGINIA	Rural-Chain	160	6	350	40.98	7 94	35 76	46 21
	Rural-Independent	119	8	154	41.84	9.65	36.42	47.26
	Urban-Chain	137	8	468	41.61	4.08	39.31	43.92
	Urban-Independent	62	7	155	30.51	6.95	26.44	34.58
	Non-Traditional	18	8	99	41 54	18 65	33 45	49 62
	Overall (Excl. Non-Trad.)	478	29	1,127	40.02	1.44	37.65	42.38
WISCONSIN	Rural-Chain	102	6	270	36 47	13 25	27 84	45.10
	Rural-Independent	239	8	178	41.70	19.92	30.31	53.09
	Urban-Chain	360	7	552	50.07	5.88	46.45	53.69
	Urban-Independent	288	7	93	37.61	12.74	29 79	45 44
	Non-Traditional	115	8	162	58 79	19 00	48 13	69 45
	Overall (Excl. Non-Trad.)	989	28	1,093	43.02	2.38	39.11	46.93

SAMPLE RESULTS BY STATE **APPENDIX 9**
MULTIPLE SOURCE DRUGS WITH FULS

ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Percent Below AWP			
					Sample		90% Confidence Level	
					Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	97	62.46	13.29	54.70	70.21
	Rural-Independent	73	6	65	74.52	8.65	68.95	80.08
	Urban-Chain	357	4	296	74.70	4.34	71.15	78.25
	Urban-Independent	128	6	78	73.05	7 22	68 32	77 78
	Non-Traditional	65	6	57	72 55	13 43	63 96	81 14
	Overall (Excl. Non-Trad.)	617	23	536	73.17	1.51	70.68	75.65
FLORIDA	Rural-Chain	137	7	145	68 89	7 41	64 40	73 38
	Rural-Independent	68	8	91	67.14	12.91	60.09	74.19
	Urban-Chain	2,052	8	453	73.56	4.85	70.75	76.38
	Urban-Independent	656	8	70	68 91	5 96	65 47	72 36
	Non-Traditional	363	5	31	80 94	9 24	74 19	87 69
	Overall (Excl. Non-Trad.)	2,913	31	759	72.15	1.30	70.00	74.29
INDIANA	Rural-Chain	187	7	237	73 40	6 90	69 19	77 61
	Rural-Independent	105	8	77	58.88	7.00	54.96	62.79
	Urban-Chain	608	7	421	74.80	4.43	72.06	77.54
	Urban-Independent	183	5	95	76 74	5 36	72 85	80 63
	Non-Traditional	178	5	75	72 42	5 30	68 58	76 26
	Overall (Excl. Non-Trad.)	1,083	27	830	73.34	1.13	71 48	75.20
MONTANA	Rural-Chain	57	6	126	56 48	24 80	40 73	72.23
	Rural-Independent	104	4	50	75.80	6.25	70.76	80.84
	Urban-Chain	37	8	338	72.24	5.21	69.56	74.92
	Urban-Independent	31	7	64	81 80	3 40	79 94	83 66
	Non-Traditional	47	7	91	70 77	16 36	61.39	80 16
	Overall (Excl. Non-Trad.)	229	25	578	71.23	2.78	66.66	75.80
TEXAS	Rural-Chain	225	6	138	66 08	7 34	61 22	70 95
	Rural-Independent	398	8	114	65.68	10.87	59.42	71.93
	Urban-Chain	1,682	8	223	70.34	6.59	66.52	74.16
	Urban-Independent	778	8	112	72.19	10 17	66 30	78 07
	Non-Traditional	214	4	57	74 53	12 95	63 97	85 08
	Overall (Excl. Non-Trad.)	3,083	30	587	69.89	1.65	67 18	72.60
WASHINGTON	Rural-Chain	81	6	125	74 48	8 07	69 27	79 70
	Rural-Independent	137	5	52	76.08	5.59	72.04	80.12
	Urban-Chain	512	6	127	73.70	4.93	70.41	76.99
	Urban-Independent	272	5	45	73 30	15 25	62 18	84 42
	Non-Traditional	123	7	87	79 79	2 91	78 03	81 54
	Overall (Excl. Non-Trad.)	1,002	22	349	73.98	2.14	70.46	77.50
WEST VIRGINIA	Rural-Chain	160	6	319	75 50	6 37	71 30	79 70
	Rural-Independent	119	8	108	78.10	3.47	76.15	80.05
	Urban-Chain	137	8	488	77.04	7.73	72.68	81.40
	Urban-Independent	62	7	128	52.70	26 00	37 48	67 92
	Non-Traditional	18	7	101	67 17	18 28	58 29	76 05
	Overall (Excl. Non-Trad.)	478	29	1,043	73.63	1.68	70 86	76.40
WISCONSIN	Rural-Chain	102	6	244	67 85	13.50	59 06	76 64
	Rural-Independent	239	8	180	76.90	5.81	73.58	80.22
	Urban-Chain	360	7	394	76.20	1.98	74.98	77.42
	Urban-Independent	288	7	75	73 61	8 16	68 61	78 62
	Non-Traditional	115	7	118	76 21	5 13	73 12	79 31
	Overall (Excl. Non-Trad.)	989	28	893	74.76	1.18	72.81	76 70

SAMPLE RESULTS BY STATE **APPENDIX 10**
MULTIPLE SOURCE DRUGS WITH FULS – WEIGHTED BY INVOICE DOLLARS

					Percent Below AWP			
					Sample		90% Confidence Level	
ST	Category	Universe Of Pharm.	Sample Pharm.	Drug Prices Reviewed	Mean	Standard Deviation	Lower Limit	Upper Limit
COLORADO	Rural-Chain	59	7	97	65.70	17.46	55.51	75.89
	Rural-Independent	73	6	65	73.07	21.19	59.44	86.70
	Urban-Chain	357	4	296	74.22	5.24	69.94	78.51
	Urban-Independent	128	6	78	81 82	5 34	78 31	85 32
	Non-Traditional	65	6	57	77 08	15 88	66 92	87 24
	Overall (Excl. Non-Trad.)	617	23	536	74.85	1.94	71.65	78.04
FLORIDA	Rural-Chain	137	7	145	72.87	9 67	67 01	78 73
	Rural-Independent	68	8	91	67.26	18.52	57.15	77.38
	Urban-Chain	2,052	8	453	80.24	6.70	76.35	84.13
	Urban-Independent	656	8	70	71.39	9 64	65 82	76 96
	Non-Traditional	363	5	31	86 36	7 18	81 12	91 60
	Overall (Excl. Non-Trad.)	2,913	31	759	77.60	1.85	74.56	80.63
INDIANA	Rural-Chain	187	7	237	73 79	7 13	69.44	78 14
	Rural-Independent	105	8	77	60.13	13.86	52.38	67.87
	Urban-Chain	608	7	421	78.56	6.40	74.60	82.51
	Urban-Independent	183	5	95	82 26	7 24	77 01	87.51
	Non-Traditional	178	5	75	73.24	9 83	66 11	80 37
	Overall (Excl. Non-Trad.)	1,083	27	830	76.57	1.59	73.96	79.19
MONTANA	Rural-Chain	57	6	126	59 42	24 51	43 85	74 99
	Rural-Independent	104	4	50	85.65	4.00	82.42	88.88
	Urban-Chain	37	8	338	77.84	6.88	74.30	81.38
	Urban-Independent	31	7	64	84 63	5 04	81 87	87 39
	Non-Traditional	47	7	91	73 81	22 79	60 74	86 89
	Overall (Excl. Non-Trad.)	229	25	578	77.72	2.55	73.52	81.92
TEXAS	Rural-Chain	225	6	138	72 18	16 14	61 49	82 88
	Rural-Independent	398	8	114	70.70	8.12	66.02	75.38
	Urban-Chain	1,682	8	223	78.66	3.21	76.80	80.53
	Urban-Independent	778	8	112	75.30	14 03	67.18	83 42
	Non-Traditional	214	4	57	78 18	11 89	68 49	87.86
	Overall (Excl. Non-Trad.)	3,083	30	587	76.31	1.51	73.82	78.80
WASHINGTON	Rural-Chain	81	6	125	81 03	8 87	75 30	86 77
	Rural-Independent	137	5	52	85.34	1.13	84.52	86.16
	Urban-Chain	512	6	127	75.07	10.03	68.37	81.76
	Urban-Independent	272	5	45	86.80	4 90	83 23	90 37
	Non-Traditional	123	7	87	81 80	4 10	79 32	84 28
	Overall (Excl. Non-Trad.)	1,002	22	349	80.14	2.18	76.55	83.73
WEST VIRGINIA	Rural-Chain	160	6	319	78 60	9 20	72.54	84 66
	Rural-Independent	119	8	108	83.00	5.24	80.05	85.95
	Urban-Chain	137	8	488	79.96	6.18	76.48	83.45
	Urban-Independent	62	7	128	56.13	27 70	39 91	72 35
	Non-Traditional	18	7	101	74 96	18 88	65 78	84 13
	Overall (Excl. Non-Trad.)	478	29	1,043	77.17	1.93	74.00	80.35
WISCONSIN	Rural-Chain	102	6	244	76 40	12 41	68 32	84 48
	Rural-Independent	239	8	180	81.85	6.57	78.10	85.60
	Urban-Chain	360	7	394	79.00	6.15	75.21	82.79
	Urban-Independent	288	7	75	81 09	9 69	75 13	87 04
	Non-Traditional	115	7	118	81 03	4 51	78 31	83 74
	Overall (Excl. Non-Trad.)	989	28	893	80.03	1.54	77.49	82.56

APPENDIX 11

STATES USING A THREE-TIERED REIMBURSEMENT SYSTEM

One state already uses a three-tiered system and three other states are currently considering a change from their current reimbursement system to a three-tiered reimbursement methodology. The state with the three-tiered system reimburses single source drugs at AWP minus 10 percent and multiple source drugs at AWP minus 12 percent. One state proposed a reimbursement of 14 percent below AWP for single source drugs and a discount of 25 percent below AWP for multiple source drugs. A second state is considering a reimbursement of AWP minus 15 percent for single source drugs and AWP minus 50 percent for all other non-FUL drugs. A third state is considering AWP minus 14 percent and AWP minus 50 percent, respectively. We believe that the change to a three-tiered system already being used by one state and the proposed changes by three other states provide further support for all other states to consider a multi-tiered reimbursement system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
(formerly Health Care Financing Administration)

DATE: AUG 20 2002

TO: Janet Rehnquist
Inspector General
Office of Inspector General

FROM: Thomas A. Scully
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicaid Pharmacy-Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products" (A-06-02-00041)

Thank you for the opportunity to review and comment on the above-referenced draft report regarding additional analyses of the actual acquisition cost of prescription drugs. The Centers for Medicare & Medicaid Services (CMS) appreciates the effort that went into this report.

OIG Recommendation

That CMS encourage states to consider adopting a three-tiered payment system in order to bring pharmacy reimbursement more in line with the actual acquisition cost of drug products.

CMS Response

The CMS suggests that OIG recommend a four-tier reimbursement methodology for the following reason. Tier two, of the suggested three-tier system, represents a 44.2 percent discount from the average wholesale price at which pharmacies purchase multiple source drugs without Federal upper limits (FULs). The term "multiple source drug" includes the branded generics (innovator multiple source drugs) and the generics (non-innovator multiple source drugs). This percentage indicates that the branded generics' discount would be the same as the discount for generic drugs. This conflicts with the findings on pages 7-8 of this report. Pages 7-8 identify the discount for innovator multiple source drugs without FULs as 24.4 percent and the discount for non-innovator multiple source drugs without FULs as 54.2 percent. Your recommendation for a three-tiered reimbursement system, with one tier including all non-FUL multiple source drugs, is not consistent with this finding.

Page 2- Janet Rehnquist

Therefore, we suggest that OIG recommend a four-tiered reimbursement methodology. The four-tiered system would consist of single source innovator drugs, innovator multiple source drugs without FULs, non-innovator multiple source drugs without FULs, and FUL drugs.

OIG Recommendation
That CMS share this report with the states.

CMS Response
We concur. We will share this report with the states.

Attachment

Page 3- Janet Rehnquist

Technical Comment

Page 1, Background- The criteria for the establishment of FUL prices are not completely accurate. We suggest that the report either delete the criteria for the establishment of the FUL amounts or include the following language:

"The criteria require that there be a certain number of drugs, depending on the therapeutic equivalency, published in the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations and at least three suppliers of the drug."

TAB 11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

SEP 10 2004

TO: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: Lewis Morris
Chief Counsel to the Inspector General

SUBJECT: OIG Final Report: "Variation in State Medicaid Drug Prices," OEI-05-02-00681

Attached for your review is our final inspection report that assesses the extent to which States vary in their Medicaid pharmacy reimbursement for the same drugs. The Medicaid program could benefit from substantial savings if all States reimbursed pharmacies at prices closer to the drug reimbursement prices paid by the lowest paying States.

We analyzed fiscal year (FY) 2001 prescription drug reimbursement data for 28 drugs from 42 States. We found that the highest paying State's unit reimbursement price ranged from 12 to 4,073 percent more per drug than the lowest paying State for the 28 drugs. On average, the highest paying State paid almost $200 more per package than the lowest paying State for these drugs. Medicaid could have saved $86.7 million in FY 2001 if all States had reimbursed at the same price as the lowest paying State for each of the 28 drugs. Multiple factors contribute to the differences in drug prices across States. Even States with the same formula for estimating pharmacy acquisition costs demonstrated variation in their average annual reimbursement prices.

We recommend that the Centers for Medicare & Medicaid Services (CMS): (1) share average manufacturer price data with States, (2) conduct further research on the factors that affect States' drug prices, and (3) annually review States' reimbursement data to target technical assistance to higher paying States.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions or comments about this report, please do not hesitate to call me or one of your staff may contact Tricia Davis, Director, Medicare and Medicaid Branch, at (410) 786-3143 or through email [Tricia.Davis@oig.hhs.gov]. To facilitate identification, please refer to report number OEI-05-02-00681 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

VARIATION IN STATE MEDICAID DRUG PRICES

Inspector General

September 2004
OEI-05-02-00681

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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ABSTRACT

To assess the extent to which States' Medicaid pharmacy reimbursement varies for the same drugs, we analyzed fiscal year (FY) 2001 prescription drug reimbursement data for 28 national drug codes (28 drugs) from 42 States. The highest paying State's unit reimbursement price ranged from 12 to 4,073 percent more per drug than the lowest paying State for the 28 drugs. Medicaid could have saved $86.7 million in FY 2001 if all States had reimbursed at the same price as the lowest paying State for each of the 28 drugs. Multiple factors contribute to the differences in drug prices across States. Even States with the same formula for estimating pharmacy acquisition costs demonstrated variation in their average annual reimbursement prices. We recommend that the Centers for Medicare & Medicaid Services share more accurate drug pricing information with States, conduct further research on the factors that affect States' drug prices, and annually review States' reimbursement data to target technical assistance to higher paying States.

EXECUTIVE SUMMARY

OBJECTIVE

To assess the extent to which State Medicaid programs vary in pharmacy reimbursement for the same type of prescription.

BACKGROUND

Medicaid prescription drug coverage is one of the most expensive and fastest growing health care expenditures. In fiscal year (FY) 2001, Medicaid expenditures on prescription drugs totaled approximately $20 billion, or 9 percent of the total Federal Medicaid budget. **From 1997 to 2001, Federal Medicaid expenditures for prescription drugs grew at more than twice the rate of total Medicaid spending.**

The Centers for Medicare & Medicaid Services (CMS) sets maximum drug reimbursement regulations and provides guidelines within the State Medicaid Manual to ensure that the Federal Government acts as a prudent buyer of drugs. Within these Federal parameters, each State determines its own pharmacy reimbursement formula(s).

To assess the variation in drug reimbursement prices across State Medicaid agencies, we requested reimbursement data from all States for FY 2001, based on national drug codes, the unique drug identifiers used by the Medicaid program. Our sample consists of 28 national drug codes (referred to as "28 drugs"). We also obtained contextual information about States' pharmacy reimbursement methodology for FY 2001. Our analysis is based on the 42 States that responded to our data request.

FINDINGS

The highest paying State's unit price ranged from 12 to 4,073 percent more per drug than the lowest paying State for the 28 drugs in our sample. For each of the 28 drugs, we used as a benchmark the State that paid the lowest average annual unit price. The difference between the highest and lowest paying States ranged by drug from 12 to 4,073 percent.

On average, the highest paying State paid 477 percent more per drug than the lowest paying State for each of the 28 drugs in our sample. States' prices varied more for the 10 non-innovator

(generic) drugs in our sample than the 18 innovator (brand name) drugs.

For the 28 drugs sampled, on average, the highest paying State paid approximately $200 more per prescription than the lowest paying State. The reimbursement price differences per prescription ranged from a low of $6 for Combivent to a high of $1,244 for Ranitidine. The median price difference was $65. While a few States ranked consistently high or low on all drugs, for most States, reimbursement did not follow a consistent pattern.

Medicaid could have saved more than $86 million in FY 2001 if all States paid the same price as the lowest paying State for each of the 28 drugs in our sample. These potential savings represent over 13 percent of the $653 million in total Medicaid funds spent for these 28 drugs in the 42 States in FY 2001. The Federal share of the savings would be $50 million, while States' share would be $36 million. For the 28 drugs in our sample, potential Medicaid savings per drug ranged from $141,000 for Zestril to $16.3 million for Depakote.

For 9 of the 28 drugs, Medicaid's potential savings exceeded 50 percent of total expenditures. In other words, for these nine drugs Medicaid expenditures could have been cut in half if all States had paid the same price as the lowest paying State for each drug.

States' drug prices are a product of multiple factors and vary even among States with the same pharmacy reimbursement formula. All States reimburse pharmacies for drugs based on a general reimbursement formula established by CMS, but this formula allows significant State flexibility. One component of the CMS reimbursement formula is the State's estimated pharmacy acquisition cost. The estimated pharmacy acquisition cost is often used as a proxy to gauge State's prices. A widespread assumption is that States with the same estimated acquisition cost formula pay similar prices. However, in our sample of drugs, differences in States' estimated acquisition cost formulas only partially explain price differences. For instance, 15 States had the same estimated acquisition cost formula (average wholesale price minus 10 percent), but paid substantially different prices for the drugs in our sample.

In addition to estimated acquisition cost, State reimbursement differences in defining "usual and customary" charge and setting State maximum allowable costs also affect States' drug prices.

RECOMMENDATIONS

CMS rules limiting Medicaid payments for drugs are intended to ensure that the Federal Government acts as prudent buyer of drugs. Our analysis found that the Federal drug reimbursement limits do not ensure prudent reimbursement for drugs under Medicaid.

State price variation results from several factors, but fundamentally stems from States' lack of access to pharmacies' true acquisition costs. States rely on various proxies to estimate pharmacy acquisition cost, but these proxies are not necessarily related to pharmacies' actual costs.

To ensure that the Federal Government pays for drugs more prudently under the Medicaid program, CMS should:

1. Share average manufacturer price data with States to ensure more accurate estimates of pharmacy acquisition cost.

2. Conduct further research on the factors that affect States' drug prices to more effectively advise States on ways to set their reimbursement level.

3. Annually review the States' drug prices in order to share comparative State prices and methods to reduce costs; and target drug reimbursement technical assistance to higher paying States.

Agency Comments

CMS provided comments on the draft report in which they stated their non-concurrence with the report due to concerns about data problems. In general, CMS had concerns about the magnitude of the price variation and the fact that the prices paid by the highest-paying States for certain drugs are above the Federal upper payment limits. They requested that we validate the data with the States. The full text of CMS's comments is included in Appendix G.

We met with CMS staff to discuss and resolve their concerns. We emphasized that we reported what States paid rather than what States should have paid. We explained how we followed up with States with potentially aberrant prices to verify whether this was what the State actually paid.

CMS staff agreed with us that this report raises serious issues that warrant attention. CMS staff have indicated that they plan to

follow up with States, particularly States with prices above upper payment limits. We plan to send State-specific results of our analysis to each State so that they can review their own Medicaid drug payments. We also plan to conduct a future review of State Medicaid drug prices. We look forward to continued work with CMS to ensure the integrity of Medicaid drug payments.

INTRODUCTION

OBJECTIVE

To assess the extent to which State Medicaid programs vary in pharmacy reimbursement for the same type of prescription.

BACKGROUND

Medicaid Drug Expenditures

All State Medicaid programs have elected to include prescription drug coverage, one of the most expensive Medicaid benefits. In fiscal year (FY) 2001, Medicaid expenditures on prescription drugs totaled approximately $20 billion, representing 9 percent of the annual Medicaid budget.[1] The Medicaid program is the largest payer for prescription drugs nationally, representing 14 percent of the drug market.[2] The Federal Government contributes a matching percentage of State Medicaid outlays, ranging from 50 to 83 percent, depending on the State's per capita income.

Prescription drugs are the fastest growing health care expenditure. Nationally, total spending for prescription drugs rose from $48.2 billion in 1992 to $141.8 billion in 2001.[3] Similarly, Medicaid expenditures for prescription drugs grew at more than twice the rate of overall Medicaid spending from FYs 1997 to 2001.[4] The Centers for Medicare & Medicaid Services (CMS) projects that Medicaid drug expenditures will continue to increase by an average of 12.7 percent per year through 2011.[5]

These expected increases are significant in light of State budget constraints. In FY 2002, 40 States faced budget shortfalls that totaled nearly $40 billion. The gap between State revenue and total spending was expected to widen to $58 billion during FY 2003.[6] At the same time, total Medicaid expenditures have risen 13 percent. In a recent survey, 36 States identified prescription drug costs as the top Medicaid cost driver in FY 2001, and 12 additional States listed drugs as 1 of the top 3 expenditures.[7]

Medicaid Pharmacy Reimbursement

Drug Cost. Under section 1902(a)(30)(A) of the Social Security Act, CMS has the authority to set upper payment limits for services available under the Medicaid program. For Medicaid, CMS sets maximum drug reimbursement limits to ensure that the Federal Government acts as a prudent buyer of drugs.[8] Within these

Federal parameters, each State determines its own pharmacy reimbursement formula(s).

In general, States reimburse pharmacies for drugs at the lower of: (1) estimated [pharmacy] acquisition cost; or (2) the pharmacy's usual and customary charge to the general public.[9] The estimated acquisition cost is the State Medicaid agency's best estimate of the price generally and currently paid by providers for the drug.[10] CMS does not prescribe a method for calculating estimated acquisition cost; instead, each State establishes and specifies its own estimated acquisition cost formula in its Medicaid State plan. States also have flexibility to define their interpretation of a pharmacy's usual and customary charge.

Estimating pharmacy acquisition cost can present a challenge for States. Most often, States rely on published prices, including average wholesale price (AWP) and wholesaler acquisition cost, because they may not have access to the actual prices at which pharmacies purchase drugs. States generally obtain these list prices from a national pricing compendium issued by First Databank, a private company. However, numerous studies and audits by the Office of Inspector General (OIG) and other experts have found that these list prices, particularly AWP, overstate the prices pharmacies pay. For this reason, CMS requires that States using AWP include a significant discount off this price for CMS to consider it an acceptable estimate of pharmacy acquisition cost.[11]

For certain multiple source drugs with a sufficient number of equivalent products and at least three suppliers, CMS sets specific Federal upper limit amounts. Multiple source drugs include generic drugs and brand name drugs for which generic alternatives are available (i.e., the drug's patent has expired). The Federal upper limit equals 150 percent of the lowest published price of the drug listed in national pricing compendia.[12] States may reimburse above the Federal upper limit price if the prescribing physician certifies that the brand name version of the drug is medically necessary.

Additionally, some States establish their own maximum allowable costs for multiple source drugs at a rate below an established Federal upper limit or for drugs for which CMS has not set a Federal upper limit. In a 2002 OIG survey, 24 States identified their maximum allowable cost program as a successful drug cost containment effort. Conceptually, State maximum allowable cost

programs resemble the Federal upper limit program in that they establish maximum reimbursement amounts for groups of equivalent drugs, i.e., a brand name drug and its generic equivalents.

In summary, State Medicaid programs reimburse pharmacies for drugs based upon the following upper limits:

For multiple source drugs, reimbursement is the lowest of: (1) the State's estimated acquisition cost calculation; (2) the pharmacy's usual and customary charge; (3) Federal upper limit, if one has been established; or (4) the State maximum allowable cost, if one has been established.

For single source drugs, reimbursement is the lower of: (1) the State's estimated acquisition cost calculation; or (2) the pharmacy's usual and customary charge.

Dispensing Fees. In addition to reimbursing pharmacies for the cost of the drug (also known as the ingredient cost), States are required to determine "reasonable" dispensing fees.[13] This fee represents the charge for the professional services provided by a pharmacist when dispensing a prescription.

Medicaid Drug Rebate Program

In addition to setting reimbursement limits, the Medicaid program limits expenditures by obtaining rebates from drug manufacturers. Federal statute mandates that in order for their drugs to be reimbursed by Medicaid, drug manufacturers must generally enter into rebate agreements and pay quarterly rebates to the State Medicaid agencies.[14] CMS calculates rebate amounts using a statutory formula based on average manufacturer price (AMP), defined as the average price paid by wholesalers for drugs distributed to the retail class of trade. For innovator (brand name) drugs, this formula also includes a calculation based on best price, defined as the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity, excluding any prices charged to a list of specified entities and an additional calculation based on an inflation factor.[15]

Beneficiary Cost Sharing

Federal law 42 U.S.C. § 1396o(a)(3) allows States to require "nominal" co-payments from certain beneficiaries. By law, States

cannot impose cost sharing requirements on particular populations, including children and pregnant women. [16] For those Medicaid beneficiaries subject to cost sharing requirements, co-payments may not exceed $3 per prescription. [17] Also, pharmacists may not withhold a drug from a beneficiary who cannot afford to pay the co-payment. [18]

Coordination of Third Party Coverage

Some Medicaid beneficiaries have an additional third party (i.e., non-Medicaid) source of coverage for prescription drugs. In most cases, Medicaid is the payer of last resort. This means that, in general, the third party bears primary responsibility for paying that beneficiary's claims. If the Medicaid agency is aware of third party coverage, the agency must reject the claim.[19] If the third party does not cover the full amount of the claim, then Medicaid may be responsible for part or all of the remaining balance.

States use two basic methods for processing Medicaid pharmacy claims when a third party is liable. A State Medicaid agency may require the pharmacy to bill the third party first, and then the State pays only the portion of the claim (if any) which is not covered by the third party, up to the Medicaid reimbursement limit. This is known as "cost avoidance." Or, a State Medicaid agency may pay the full amount that Medicaid reimburses for that claim, and then the State assumes the responsibility for recouping payment from the liable third party. This method is known as "pay and chase."

Related Work by the Office of Inspector General

OIG has issued a significant body of work related to Medicaid drug pricing. Numerous OIG reports have concluded that Medicaid pays more than several other Federal and private purchasers for a wide variety of drugs. Also, a 2002 OIG report "Medicaid Pharmacy - Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products" (A-06-02-00041), found that the data upon which States base pharmacy reimbursement overstate pharmacy acquisition costs. More specifically, AWP overstated acquisition costs of single source drugs by 17.2 percent, multisource brand name drugs (without Federal upper limits) by 24.4 percent, multisource generic drugs (without Federal upper limits) by 54.2 percent, and all drugs with Federal upper limits by 72.1 percent. In these reports, OIG recommends that CMS review the current reimbursement methodology, work with States to find a method

that more accurately estimates pharmacy acquisition cost, and initiate a review of Federal Medicaid rebates.

SCOPE AND METHODOLOGY

This report is limited to Medicaid drug reimbursement prices for outpatient drugs purchased by the fee-for-service component of Medicaid. We excluded drug prices negotiated by Medicaid managed care organizations. This study is focused on the variation in the drug reimbursement States pay to outpatient pharmacies. Our drug cost calculations include only the reimbursement for the drug ingredient cost and exclude the dispensing fee. Therefore, our comparison demonstrates the variation in the cost of the drug itself, distinct from differences in States' reimbursement for pharmacy services.

We excluded consideration of the Federal rebate for purposes of this analysis.[a] States have flexibility in setting their own pharmacy reimbursement methodology; however, the Federal unit rebate amount for each drug is established by CMS and is the same for all States. While we recognize that the Federal rebate program is important to cost containment for all States, it is beyond the scope of this study.

Sampling and Data Collection

In Medicaid, drugs are identified and tracked by 11-digit national drug codes (NDCs). NDCs identify unique formulations of each drug, including the manufacturer, strength, and package size.

We defined our sampling frames as the top 200 NDCs ranked by total FY 2001 Medicaid expenditures for each of the 3 categories of drugs. These three drug categories are: (1) single source drugs (brand name drugs with no generic equivalents), (2) innovator multiple source drugs (brand name drugs with generic equivalents), and (3) non-innovator multiple source drugs (generic drugs).

From the sampling frame for each drug category, we randomly selected 10 NDCs. We later excluded 2 of these NDCs (both were

[a] Excluding Federal rebates does not affect the absolute price difference across States, but it makes our percent difference calculations more conservative. For example, suppose State X reimburses $1.00 per unit for a drug, and State Y reimburses $0.50 per unit, and the unit rebate is $0.10. The absolute price difference between States X and Y is $0.50 for both reimbursement ($1.00 - $0.50) and net price after rebate ($0.90 - $0.40). However, State X pays 100 percent more than State Y when comparing reimbursement price ($1.00 vs. $0.50), but 125 percent more than State Y when comparing net prices after rebate ($0.90 vs. $0.40).

innovator multiple source drugs) from our analysis because many States did not cover these 2 NDCs during FY 2001. We will use the term "28 drugs" to refer to the 28 NDCs included in our analysis. **We analyzed the variation for these 28 selected drugs, but we cannot project the variation to the universe of Medicaid drugs.** The selected drugs are detailed in Appendix A. Also, Appendix B lists the primary indication(s) for each drug.

We requested reimbursement information for our sample of drugs from all 50 States and the District of Columbia for FY 2001. We issued this request to both the Medicaid director and Medicaid pharmacy director in each State. For each drug, we requested States' total drug ingredient cost reimbursement and total units for each quarter of FY 2001 (October 2000 through September 2001). Forty-two States responded.

We also surveyed each State's Medicaid director and Medicaid pharmacy director to collect contextual information on States' pharmacy reimbursement for FY 2001, including States': (1) estimated acquisition cost formula(s); (2) sources of pricing data; (3) definition of usual and customary charge; (4) State maximum allowable costs; and (5) pharmacy dispensing fees.

Analysis

Though 42 States responded to our data request, some States could not provide data from all 4 quarters for all 28 drugs. If a State could not provide complete data for 4 quarters of FY 2001 for a particular drug in our sample, we excluded that State from our analysis for that drug. For 9 of the 28 drugs, we received complete data from all 42 responding States. For 9 additional drugs, our analysis relied on 41 of the 42 States. The drug for which the fewest States provided complete data was Zestril, for which we used data from 35 of the 42 States. Appendix A lists the number of States for which we received complete data for each of the 28 drugs.

We used the States' average annual unit prices as the basis for measuring price variation and potential savings. For each State, we calculated the FY 2001 average annual unit price for each drug by adding together the total reimbursement for each of the 4 quarters and dividing this by the sum of the total units for the 4 quarters.

For each drug, we assessed variation in unit reimbursement prices across States in several ways. Primarily, we measured the percent difference in average annual unit price between the highest paying

State and the lowest paying State for each drug. We used the lowest paying State for each drug as a benchmark. We also calculated the interquartile range, which is the difference between the prices paid by the States at the 25th and 75th percentile for each drug. Finally, we applied several graphical techniques, including scatterplots and stock market charts, to each drug to assess the distribution of State prices. We used similar analyses to measure variation across drug categories.

We measured the potential savings Medicaid could have achieved if all States reimbursed for each drug at the same price as the lowest paying State. For each drug, we determined the difference in annual price per unit between the State with the lowest unit price and each of the other States. We multiplied this unit price difference for each State by the total number of units that the State purchased in FY 2001. Our savings calculation is conservative because for each drug we only included savings for the States from which we received all 4 quarters of data for FY 2001. For some drugs, savings are based on fewer than 42 States.

Additionally, we assessed each State's success at obtaining lower prices, relative to other States. For each drug, the State which obtained the lowest unit price was ranked "one." We then evaluated States' patterns of prices, relative to other States, to determine whether States systematically obtain lower or higher relative prices.

Finally, we synthesized the descriptive information from our survey of States with the reimbursement data to explore how States' differences in reimbursement methodologies and other factors may affect differences in average annual drug prices.

Our review was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

The highest paying State's unit price ranged from 2 to 4,073 percent more per drug than the lowest paying State for the 28 drugs in our sample.

For each of the 28 drugs in our sample, we calculated the difference in annual unit price per drug between the lowest and highest paying States. For each drug, we used as a benchmark the State that paid the lowest average annual unit price. The difference between the highest and lowest paying States ranged by drug from 12 to 4,073 percent. On average, the highest paying State paid 477 percent more per drug than the lowest paying State for the 28 drugs in our sample. Median difference was 49 percent.

The average difference between the highest and lowest paying States is considerably higher than the median difference because four drugs demonstrated a substantially higher level of variation than the rest of the sample. For these 4 drugs, the highest paying State paid over 2,000 percent more than the price paid by the lowest State. For 18 of the 28 drugs in our sample, the highest paying State paid between 12 and 71 percent more than the price paid by the lowest paying State. For the remaining 6 drugs, the highest paying State paid between 120 and 548 percent more than the price of the lowest paying State. Appendix C provides the percent price differences for each drug.

For 4 drugs, the highest paying State paid over 2000 percent more than the price of the lowest paying State

Price variation decreases when measured by interquartile differences because this measurement does not include the States with the highest and lowest reimbursement prices. However, a significant amount of variation remains, indicating that the States in the middle of the distribution also vary from each other. Table A provides the average, median, and range in percent differences between the highest and lowest paying States and between the States at the 25th percentile and at the 75th percentile.

Table A. Measures of Percent Variation in States' Unit Prices per Drug

	Percent Difference between Highest and Lowest States	Percent Difference between Interquartile States
Average	477%	28%
Median	49%	6%
Range	12% to 4073%	3% to 266%

Source: OIG National Survey, 2002

On average, the highest paying State paid approximately $200 more per package than the lowest paying State for the 28 drugs.
To calculate the reimbursement price difference per package, we multiplied the unit price difference by the number of units per package. The highest paying State paid an average of $197 more than the lowest paying State per package for the 28 drugs in our sample. The price differences per package range from $6 for Combivent to $1,244 for Ranitidine HCl 1000. The median price difference was $65. Table B displays the top five drugs by absolute price differences per package between the lowest and highest paying States.

Table B. Drugs with the Greatest Absolute Price Difference per Package

[illegible]	[illegible]	[illegible]	[illegible]
Ranitidine HCl 1000	$51	$1,295	$1,244
Atenolol	$17	$704	$687
Prilosec	$3,221	$3,876	$654
Ranitidine Tablets	$25	$648	$623
Ranitidine HCl 500	$27	$648	$621

Source: OIG National Survey, 2002

Absolute price difference per package is a product of both the level of variation across States and the cost of the drug. For example, Prilosec shows a difference of $654 between the highest and lowest paying States and is ranked third in the absolute dollar difference between the highest and lowest States. Because Prilosec is relatively expensive, this represents only a 20 percent difference in price. Conversely, Albuterol Sulfate, which is relatively inexpensive, demonstrates a much lower absolute price difference per package ($7), but this represents a 227 percent difference between the highest and lowest State prices.

States' prices vary most for non-innovator multiple source drugs.
Of the three drug categories, non-innovator multiple source drugs (generic drugs) demonstrated the widest percentage range of prices between the highest and lowest paying States. Price variation ranged from 20 to 4,073 percent for the 10 non-innovator multisource drugs in our sample. Innovator multisource drugs ranked second in percent differences between the highest and lowest States, and single source drugs demonstrated the least percent variation. The median variation among the 10 non-

innovator multisource drugs was 374 percent, compared to 53 percent for the 8 innovator multisource drugs and 18 percent for the 10 single source drugs. Table C displays the range, average, and median percent differences in price for each of the three drug categories.

Table C. Percent Differences between High and Low States by Drug Category

[illegible]	[illegible]	[illegible]	[illegible]
Single Source	12-71%	23%	18%
Innovator Multisource	33-227%	102%	53%
Non-innovator Multisource	20-4073%	1230%	374%

Source: OIG National Survey, 2002

This wide variation in reimbursement price for non-innovator multisource drugs is not limited to the difference between the highest and lowest of the 42 State prices. If we exclude the States with the highest and lowest prices from our analysis, the non-innovator multisource drugs still demonstrate the most variation in our sample, followed by the innovator multisource drugs, and then the single source drugs. The average difference between the State at the 25th percentile and the State at the 75th percentile (i.e., the interquartile range) was 63 percent for the 10 non-innovator multisource drugs. In contrast, the interquartile range for innovator multisource and single source drugs averaged 14 percent and 4 percent, respectively.

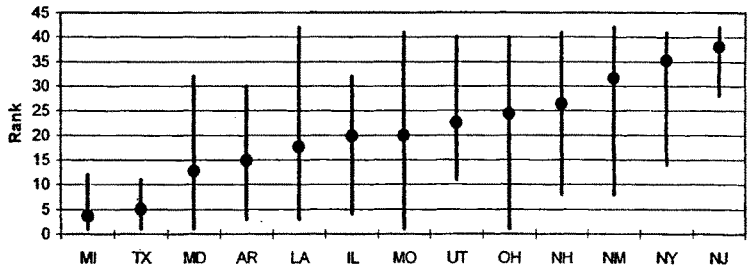
In addition to demonstrating greater percent variation, multiple source drugs (both non-innovator and innovator) display a different pattern of price variation than single source drugs. When the 42 States' prices are ordered from low to high for each drug, prices for the single source drugs in our sample tend to increase at a more consistent rate from the lowest State price to the highest State price. In comparison, prices for multiple source drugs in our sample tend to increase more sharply from one State to the next for several States at the low and/or high ends of the price range. Prices for the States in the middle of the price range, on the other hand, increase more gradually from State to State. To illustrate these different patterns, Appendix D displays the price distributions for a single source and a multiple source drug.

Many States do not pay consistently low or high prices across the 28 drugs in our sample.

To examine State patterns in drug prices, we ranked all States by average annual unit price for each drug for which they provided complete data. A rank of "one" identifies the State that reimbursed at the lowest unit price. Thus, the lower the State's rank, the lower its drug reimbursement prices. We averaged each State's rank across all drugs for which they submitted data.

Chart 1 below displays the high, low, and mean rank across all 28 drugs for selected States and illustrates that several States reimbursed at high relative prices for some drugs and low prices for others. For each State, the top of the line indicates the highest rank that State received for any of the drugs, the bottom of the lines represent the lowest rank, and the dot indicates the mean rank for that State. The longer the line, the greater the difference between a State's highest and lowest rank. For example, across the 28 drugs, Louisiana's ranks ranged from 3 to 42. Missouri's prices ranged from being the lowest (a rank of one) for one drug to one of the highest for another drug.

Chart 1. Highest, Lowest, and Mean Ranks for Selected States



However, as Table D demonstrates, some States displayed consistent patterns in price ranks relative to other States, particularly when States' ranks are assessed by drug category. **Michigan and Texas paid consistently low reimbursement prices relative to other States, while New Jersey and New York ranked consistently high.** Other States, such as Ohio and Nebraska, tended to vary in price rank depending on the type of drug. Both of these States paid relatively high reimbursement prices for single source and multiple source brand name drugs but relatively low reimbursement prices for generic drugs compared to other States.

Table D. Rank (out of 42 States) by Drug Category for Selected States

MI	1	1	1	3
TX	2	4	2	1
NY	41	39	40	40
NJ	42	42	42	42
OH	30	41	31	4
NE	29	36	34	10

Source: OIG National Survey, 2002

States' reimbursement prices for the 28 drugs were not related to their dispensing fees to pharmacies.

For the 28 drugs in our sample, States' dispensing fees were not related to their drug reimbursement prices, relative to other States. A State's total reimbursement to pharmacies for Medicaid prescriptions includes both the drug ingredient reimbursement to cover the cost of the drug itself, plus a dispensing fee to reimburse for the pharmacy's services.[b] For each drug category, we ranked States from the lowest drug reimbursement prices to the highest and then tested whether States' ranks were related to their dispensing fees.[c] **We did not find that States with lower drug ingredient prices were compensating for their lower prices by paying higher dispensing fees.** Appendix E provides details of this analysis.

[b] When States reimburse at the usual and customary charge, the State does not pay a separate dispensing fee.

[c] This analysis is based upon the 33 States with a flat dispensing fee. Nine States with variable fees were excluded.

Medicaid could have saved $86.7 million in FY 2001, if all States paid the same price as the lowest paying State for each of the 28 drugs in our sample

For each drug, we determined the difference in annual unit reimbursement price between the State with the lowest unit price and each of the other States.[d] We multiplied this unit price difference for each State by the total number of units that the State paid for in FY 2001. We found that Medicaid could have saved $86.7 million in FY 2001 for the 28 drugs in our sample. This potential savings represents over 13 percent of the $653 million Medicaid spent for these 28 drugs in the 42 States. The Federal share of the savings would have been $50 million, while States' share would have been over $36 million.

Single source drugs could achieve the greatest potential savings of the three drug categories.

In our sample, potential savings associated with the single source drugs far exceed the potential savings of both types of multiple source drugs in terms of absolute dollar amount. Medicaid could have saved $52.2 million (60 percent of the total savings) on the 10 single source drugs, followed by $25.5 million (30 percent) on the 10 non-innovator multisource drugs, and $8.9 million (10 percent) for the 8 innovator multisource drugs in our sample.

Decreasing the unit reimbursement prices of the single source drugs by even a small percentage would produce substantial savings because single source drugs are the most expensive and the most highly utilized drug category. In our sample, the 10 single source drugs account for 77 percent of the total expenditures on the 28 drugs. Table E provides drug expenditures and potential savings information for the three drug categories.

[d] Our savings calculation is conservative because for each drug we only included savings for the States from which we received all 4 quarters of data for FY 2001. For some drugs, savings are based on fewer than 42 States.

Table E. FY 2001 Expenditures and Potential Savings by Drug Category

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Single Source (10 drugs)	$504 million	77%	$52.2 million	60%
Innovator Multisource (8 drugs)	$34 million	5%	$8.9 million	10%
Non-innovator Multisource (10 drugs)	$116 million	18%	$25.5 million	30%
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Source: OIG National Survey, 2002

Almost half of Medicaid's potential savings would come from 5 of the 28 drugs.

In our sample of 28 drugs, potential Medicaid savings per drug ranged from $141,000 for Zestril to $16.3 million for Depakote. Depakote accounted for 19 percent of the total savings for the 28 drugs. The median potential savings per drug are $2 million. Appendix F provides potential savings associated with each drug.

Five of the 28 drugs produced almost half (49 percent) of the total potential savings. These drugs are Depakote, with $16.3 million in potential savings; Prilosec ($7.4 million); Lipitor ($6.9 million); Avonex Kit ($6.2 million); and Oxycontin ($5.8 million). Potential savings from these 5 drugs total $42.5 million for FY 2001. Spending on these 5 drugs, which account for the highest expenditures in our sample, totaled $376.2 million, representing more than half of the total Medicaid expenditures for the 28 drugs in the 42 States in FY 2001. Because these drugs are costly and highly utilized, any price reduction would have an important impact on Medicaid savings.

Medicaid could have saved more than 50 percent on 9 of the 28 drugs.

For 9 of the 28 drugs, Medicaid's potential savings exceeded 50 percent of total expenditures. In other words, for these drugs Medicaid could have spent less than half of what was spent if all States had paid the same price as the lowest paying State.

For instance, Medicaid could have spent 92 percent less than its FY 2001 expenditures on Atenolol. In FY 2001, the 42 States could have reimbursed pharmacies for the 8 million units of Atenolol for less than $135,000 instead of the $1.8 million actually paid. Michigan and Maryland each paid less than $20 per bottle for

Atenolol, while the average State reimbursement price was $274 per bottle. One State paid over $700 per bottle for the exact same drug. Table F lists the top five drugs by savings as a percentage of expenditures.

Table F. Top 5 Drugs by Savings as a Percentage of Expenditures in FY 2001

Drug	Medicaid Paid	Medicaid Could Have Paid	Savings as a Percent of Medicaid Paid
Atenolol Tablets	$1.8 million	$135,000	92%
Ranitidine HCl 1000	$4.4 million	$506,000	89%
Ranitidine HCl 500	$4.0 million	$522,000	87%
Ranitidine Tablets	$3.6 million	$521,000	86%
Trimox Capsules	$2.6 million	$807,000	69%
Total for 5 Drugs	$16.5 million	$2.9 million	82%

Source: OIG National Survey, 2002

Each State's potential savings depends on the State's unit prices and utilization.

Savings calculations for each State are a product of the State's unit price, relative to the lowest paying State, and the State's utilization. The higher the State's unit reimbursement price compared to the lowest paying State, the larger the per unit difference. This difference per unit is then multiplied by the total units the State reimbursed. Therefore, the more units purchased, the greater potential savings that could be realized by reducing the State's unit price.

The potential Medicaid savings by State ranges from $8,100 for Arizona to $13 million for New York. Potential savings from the median State is $1.1 million. Table G displays the potential savings from the top five States. These 5 States account for almost 42 percent of the total savings for the 42 States. Appendix F provides the potential savings for every State.

Table G. States with the Greatest Potential Savings

State	Potential Savings	% of Total Potential Savings
New York	$13.0 million	15%
Ohio	$7.6 million	9%
New Jersey	$5.6 million	7%
North Carolina	$5.1 million	6%
Illinois	$4.6 million	5%
Total for 5 States	$35.9 million	42%

Source: OIG National Survey, 2002

High utilization contributed to the high potential savings for the top two States. New York, the State with the highest potential savings, had the highest utilization of the 28 drugs in our sample. Ohio could have generated the next highest savings, $7.6 million, and is ranked second in utilization of these drugs.

Comparing Michigan and New Jersey demonstrates how relative reimbursement price also affects savings. Michigan paid consistently low prices relative to other States, including paying the lowest price for 11 of the 28 drugs. New Jersey paid consistently high prices relative to other States, including paying the highest price for 5 of the 28 drugs. In FY 2001, New Jersey ranked 10th in utilization (almost 15 million units) for the drugs in our sample; Michigan ranked 12th (almost 14 million units). However, New Jersey could produce the third highest savings, $5.6 million, while Michigan's potential savings are only $547,000 (less than one-tenth of New Jersey's). Michigan's savings rank 31 out of the 42 States. This substantial disparity in potential savings is a result of unit price differences between the two States.

States' drug prices derive from multiple factors and vary even among States with the same pharmacy reimbursement formula

States' average unit drug prices are a product of multiple factors. These factors stem from States' lack of access to pharmacies' actual acquisition costs, which compels States to rely on proxies to estimate acquisition cost. We present information on how each factor could affect States' drug prices, and where possible, demonstrate this effect within our sample of drugs. However, measurement of the relative impact of each factor on each State's average annual price is beyond the scope of our data and this report.

All States reimburse pharmacies for drugs based on the general upper payment limit formula established by CMS, but this formula allows significant State flexibility. In general, States reimburse at the lowest of: (1) estimated [pharmacy] acquisition cost; (2) the pharmacy's usual and customary charge to the general public; (3) the Federal upper limit amount, if applicable; or (4) the State maximum allowable cost, if applicable.

Additionally, there are factors beyond the drug reimbursement formula that can affect States' reimbursement to pharmacies. One is that States may impose nominal co-payments for prescription

drugs for certain Medicaid beneficiary populations. In this case, the State pays the pharmacy according to its drug reimbursement formula, less the amount of the beneficiary co-payment. Another factor is that States use different methods for processing claims when a third party is liable for payment. These differences can affect States' pharmacy reimbursement.

Differences in States' estimated acquisition cost formulas only partially explain price differences.

Within broadly set Federal regulations and the State Medical Manual guidelines, each State is responsible for determining its own method to estimate pharmacy acquisition cost, since they do not have access to actual acquisition costs. Typically, States base estimated acquisition cost on average wholesale price (AWP) minus a discount. Six of our 42 States base estimated acquisition cost on wholesaler acquisition cost plus an additional percentage or a combination of AWP and wholesaler acquisition cost. Most States apply one estimated acquisition cost formula to all drugs and all pharmacies. In FY 2001, 2 of our 42 States applied different estimated acquisition cost formulas to brand and generic drugs, and 1 State used a different estimated acquisition cost for chain versus independent pharmacies.

In FY 2001, the most common estimated acquisition cost formula, AWP minus 10 percent, was used by 15 of the 42 States in our sample. States' discount off AWP ranged from 5 percent to 16.5 percent. Six States used wholesaler acquisition cost plus a mark-up percentage ranging from 7 to 11 percent.

A State's estimated acquisition cost formula is often used as a proxy by which to gauge that State's reimbursement prices, and it is usually assumed that States with the same estimated acquisition cost formula pay similar prices. However, for the 28 drugs in our sample, States with the same estimated acquisition cost formula paid substantially different prices. Among the 15 States with an estimated acquisition cost formula of AWP minus 10 percent, the highest paying State paid between 6 percent and 1,664 percent more for the 28 drugs in our sample. For these 15 States, the highest paying State paid 187 percent more, on average, for the 28 drugs. The median percent difference was 26 percent.

Comparing these percent differences among the 15 States with the same estimated acquisition cost formula to the price differences among all 42 States indicates that differences in estimated

acquisition cost formulas account for some of the variation in prices across States. These 15 States display less variation than the variation found among all 42 States. The 15 States averaged a price variation of 187 percent for the 28 drugs, while all 42 States averaged a price variation of 477 percent for the 28 drugs. Table H displays the comparison between variation among the 15 States with an estimated acquisition cost formula of AWP minus 10 percent to the variation among all 42 States for selected drugs.

Table H. Percent Price Variation for Selected Drugs among States with Same Estimated Acquisition Cost (EAC) Formula

Drug	Price Variation of EAC among 15 States	Price Variation of EAC among 42 States
Prilosec	13%	20%
Depakote	25%	71%
Clotrimazole	49%	194%
Albuterol Sulfate	103%	227%
Atenolol	1664%	4073%

Source: OIG National Survey, 2002

In particular, States' estimated acquisition cost formulas should explain most of the variation in State unit prices for single source drugs. Because single source drugs are not subject to Federal upper limits or State maximum allowable costs, the reimbursement price should reflect either the estimated acquisition cost or the usual and customary charge to the general public.

However, for the 10 single source drugs in our sample, the price variation among the 15 States with estimated acquisition cost formulas of AWP minus 10 percent does not support this expectation. Although there is less variation among the 15 States than among all 42 States, considerable variation remains. Table I provides average and median differences between the highest and lowest paying States for the 10 single source drugs in our sample.

Table I. Percent Variation in Single Source Drug Prices for States with Same EAC

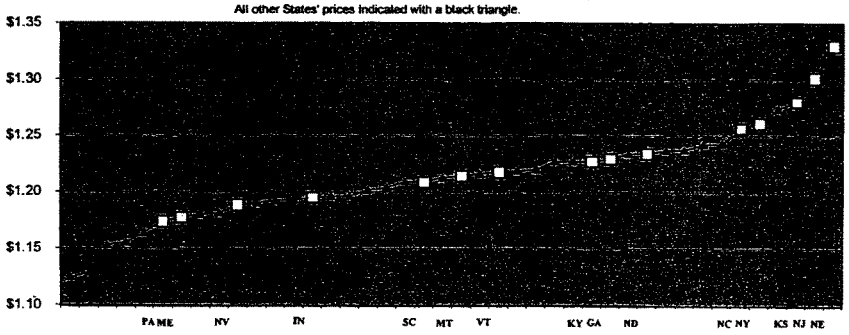
Average Variation among 15 States	Average Variation among 42 States	Median Variation among 15 States	Median Variation among 42 States
23%	12%	18%	12%

Source: OIG National Survey, 2002

Chart 2 below illustrates the extent to which the reimbursement prices of the 15 States with the same estimated acquisition cost formula are dispersed throughout the price distribution of all 42 States. Each of the 42 States' unit prices for Detrol (a single source drug) are arrayed from the lowest paying State to the highest. The unit prices of the States with an estimated acquisition cost of AWP minus 10 are indicated by a white square, and all other States' prices are indicated with a dark triangle. As shown, Pennsylvania has an estimated acquisition cost of AWP minus 10 percent and paid the sixth lowest unit price, while Nebraska has the same estimated acquisition cost, yet paid the highest price of the 42 States for this drug.[8]

Chart 2. States' Unit Prices for Detrol

Prices for States with EAC=AWP-10% are labeled & indicated with a white square.
All other States' prices indicated with a black triangle.



States' differences in usual and customary charge also affect States' average reimbursement prices.

CMS rules require States to reimburse pharmacies for drugs at the pharmacy's usual and customary charge to the public if this price is lower than the estimated acquisition cost, Federal upper limit, and State maximum allowable cost. However, as part of their effort to more closely approximate actual acquistion costs, States define the usual and customary charge differently. Definitions include the pharmacy's charge to the cash-paying customer or the pharmacy's charge to the patient group accounting for the largest number of non-Medicaid prescriptions. Many States exclude prices paid by

[8] No States had a maximum allowable cost for this drug in FY 2001.

third-party payers from usual and customary charges, while a few require pharmacies to include prices they accept from third-party payers as usual and customary charges. Because usual and customary charges are based on the prices the individual pharmacy charges, these amounts can vary among pharmacies within the same State. Further, the extent to which States monitor and enforce pharmacies' billing of usual and customary charges is uncertain.

While it is difficult to measure the effect of differences in usual and customary charge definitions on States' average prices, their impact may be significant. One expert estimated that, nationally, roughly 25 percent of all Medicaid drug claims are paid at the usual and customary charge.[20] Additional evidence suggests that the frequency with which drugs are purchased at the usual and customary charge varies across States. Massachusetts analyzed its Medicaid drug claims for the month of July 2002 and found it paid 34 percent of all claims at the usual and customary charge.[21] In contrast, Vermont paid only 10 percent of its FY 2002 drug claims at the usual and customary charge.[22] Finally, Texas calculated its rate of claims paid at usual and customary charge to be 22 percent.[23]

States' maximum allowable costs contribute to the price variation for multiple source drugs.

States' maximum allowable costs offer another reason why States' reimbursement prices for multiple source drugs vary more than prices for single source drugs. States determine for which multiple source drugs, if any, to set maximum allowable costs. States that set maximum allowable costs may pay lower prices for these drugs than States that base reimbursement exclusively on estimated acquisition cost formulas and usual and customary charge. Twenty of the 42 States reported a maximum allowable cost for at least 1 drug in our sample. On average, the 20 States reported maximum allowable costs for 10 of the 18 multiple source drugs in our sample. For 8 of the 18 multiple source drugs in our sample, the lowest paying States set maximum allowable costs. The highest paying States had not set maximum allowable costs for any of the multiple source drugs.

States vary considerably in the maximum allowable cost prices they set for the same drug. For eight multiple source drugs, the highest reported maximum allowable cost was more than twice as expensive

as the lowest maximum allowable cost. For example, in FY 2001, Oklahoma's maximum allowable cost for Ranitidine was almost $0.38 per pill, a price 371 percent higher than Washington's maximum allowable cost of $0.08 per pill for the same drug.[f]

Finally, while a State's maximum allowable cost generally acts as a ceiling price, States sometimes reimburse at prices above their maximum allowable cost for a particular pharmacy claim. A maximum allowable cost applies to a group of equivalent drugs (i.e., a brand name drug and its generic versions), and the maximum allowable cost amount is commonly based on the least expensive drug in the group. If a physician certifies that a specific drug within a maximum allowable cost group is medically necessary, then a State may reimburse a greater amount for that drug based on its estimated acquisition cost formula or usual and customary charge.

Cost sharing requirements and coordination of third party coverage can also affect States' pharmacy reimbursement.

Beyond drug reimbursement methodologies, differences in States' cost sharing requirements can affect the variation in States' pharmacy reimbursement. States may require "nominal" co-payments from beneficiaries that do not exceed $3 per prescription. For prescriptions with a cost sharing requirement, the State subtracts the amount of the beneficiary co-payment from its reimbursement to the pharmacy.

The potential impact of co-payments on States' average annual price per unit varies by drug. The maximum co-payment is $3 per prescription, so the effect on the unit price depends on the number of units per prescription. In our sample, units per prescription ranged from 4 units, for which a $3 co-payment reduces a State's unit price by $0.75/unit, up to 1,000 units, for which a $3 co-payment reduces a State's unit price by less than one penny ($0.003). These potential reductions in unit price can also be expressed as a percentage of the average unit price for each drug. Table J lists the absolute and percent reductions in unit price resulting from a $3 co-payment for a selection of drugs.

[f] Our sample includes three national drug codes for Ranitidine. These maximum allowable cost amounts are the same for all three.

Table J. Potential Reduction in Unit Price based on $3 Co-payment

Drug	Units per $3 Co-payment	Potential Reduction in Unit Price	Average Unit Price	Potential Percent Reduction in Average Unit Price
Prilosec	1000	$0.003	$3.62	0.1%
Sandimmune	50	$0.060	$5.69	1.1%
Depakote	100	$0.030	$0.80	3.7%
Albuterol Sulfate	20	$0.150	$0.33	46.1%

Source: OIG National Survey, 2002

However, we cannot measure the extent to which co-payments contribute to the variation in average annual drug prices in our sample, because States do not deduct the co-payment amount when reimbursing claims for exempted beneficiaries. For each of the 28 drugs, we have data on total units purchased by each State but do not have data on what percentage of these units went to beneficiaries who are subject to cost sharing requirements.

Additionally, differences in States' processing of claims in which a third party is liable can impact pharmacy reimbursement. Because States that use a cost avoidance method may only reimburse pharmacies for Medicaid's liable portion of claim, their reimbursement data reflect only the amount for which Medicaid is responsible. In contrast, States that use a pay and chase method reimburse the pharmacy the full amount Medicaid reimburses for that claim, which is reflected in their reimbursement data. Even if these States recoup payment from a third party, they do not necessarily update each specific drug claim to reflect the recoupment. Further, a 2001 OIG report, "Medicaid Recovery of Pharmacy Payments from Liable Third Parties" (OEI-03-00-00030) found that in 1999, 32 States were at risk of losing over 80 percent of the pharmacy payments they tried to recover from third parties through the pay and chase method.

We cannot measure the extent to which these different methods of pharmacy claims processing contribute to the variation in drug reimbursement for our sample of drugs. We do not have data on what percentage of claims involved third party liability for each State for the 28 drugs in our sample. Using cost avoidance when a third party is liable could lower a State's average reimbursement for a drug. Michigan primarily used the cost avoidance method and ranked first overall in obtaining the lowest prices for the drugs in our sample. However, New York also used cost avoidance and ranked 41 out of the 42 States for the 28

drugs sampled. Texas used the pay and chase method and achieved the second lowest prices overall for our sample of drugs.

RECOMMENDATIONS

In the State Medicaid Manual, CMS states that "HHS rules [limiting Medicaid payments for drugs] are intended to ensure that the Federal Government acts as a prudent buyer of drugs" under the Medicaid program.[24] Our analysis suggests that the Federal drug reimbursement limits do not ensure prudent buying of drugs by State Medicaid agencies. These limits may not achieve the goal of prudent expenditures for drugs, given the tremendous variability in the amounts States paid for the same set of drugs.

If all States had reimbursed at the same price as the lowest State for each drug in our sample, the Medicaid program could have saved more than $86 million in FY 2001. Again, these potential savings derive from only 28 drugs for the 42 States that provided data. Overall, Medicaid covers almost 60,000 National Drug Codes, using the same reimbursement methods that produced the vast price discrepancies for the 28 drugs in our sample. A clear example of concern is one State's payment of $700 for a specific Medicaid prescription, while two other State Medicaid programs purchase the same prescription for less than $20.

In addition to highlighting the variation in States' drug reimbursement prices and the effect of this variation on Medicaid drug costs, this report provides a starting point for examining why States' drug prices vary greatly. Most examinations of Medicaid drug prices focus on States' estimates of pharmacy acquisition cost. However, our analysis demonstrates that differences in States' estimated acquisition cost formulas only partially explain drug price differences and that several other factors affect States' drug prices.

Most importantly, the factors that drive variability in drug prices across States stem from States' lack of access to pharmacies' true acquisition costs. Because they lack information about such costs, States rely on estimated acquisition costs, usual and customary charges, and maximum allowable costs as proxies for pharmacies' acquisition cost. These proxies are deficient because they are not necessarily linked to the prices at which pharmacies purchase drugs. The wide variation in State Medicaid prices results from the deficiencies in these proxies for estimating pharmacies' acquisition costs.

CMS should share average manufacturer price data with States to ensure more accurate estimates of pharmacy acquisition cost.

Currently, average manufacturer price data may represent the most accurate drug pricing data available to CMS. While pharmacies are not compelled to share their actual acquisition costs with CMS or the States, drug manufacturers are required to submit average manufacturer price data to CMS each quarter as part of the Medicaid rebate program. Average manufacturer price is statutorily-defined and is calculated from actual sales transactions between drug manufacturers and wholesalers.

RECOMMENDATIONS

Previously, OIG has recommended that CMS share average manufacturer price with the States to help improve their estimates of pharmacy acquisition cost.[25] In response, CMS disagreed with the recommendation citing issues associated with average manufacturer price confidentiality.

Further research is needed on the factors that affect States' drug prices.
If States continue to lack accurate price information, CMS should strengthen its work to improve States' ability to optimally reimburse for drugs within the current Medicaid pharmacy reimbursement framework.

To maximize their capacity to assist States, CMS should further examine the determinants of States' drug prices, including (1) States' estimated acquisition cost formulas, (2) usual and customary charges, and (3) maximum allowable cost limits. We recognize that CMS has initiated efforts to further understand the impact of State maximum allowable costs and the Federal upper limit program. We support this effort and encourage CMS to apply the findings from this project and to expand its research on drug pricing and Medicaid reimbursement to include estimated acquisition cost and usual and customary charges. By understanding how each of these factors affects States' drug reimbursement, CMS can more effectively advise States on ways to set their reimbursement levels that help to ensure that the Federal Government pays for drugs more prudently under the Medicaid program.

CMS should annually review the States' drug prices and target technical assistance to States paying the highest reimbursements.
To assess States' relative success in drug reimbursement, CMS should conduct annual analyses of States' prices for a specific sample of drugs using methods similar to those used in this report. States already submit the necessary reimbursement data to CMS. Performing such analysis would allow CMS to target their technical assistance by prioritizing States that pay the highest drug reimbursement prices. Technical assistance would include providing guidance to States on how to improve reimbursement methodologies, based on CMS's enhanced research, as detailed above; ensuring States are aware of how their reimbursement prices compare to other State Medicaid programs; and sharing successful reimbursement strategies from other States.

Annual reviews of States' drug reimbursement also enable CMS to monitor States' improvement over time. Further, State Medicaid reimbursement methods and the larger pharmaceutical marketplace are complex and dynamic. Therefore, ongoing monitoring is essential for CMS to continually target and maximize its resources for improving States' drug reimbursement under Medicaid.

AGENCY COMMENTS

CMS provided comments on the draft report in which they stated that they do not concur with the report because of concerns about problems with the data. CMS provided two specific examples that they considered to be problems in our report. In addition, CMS recommended that we validate the data with the States. The text of CMS's comments is included in Appendix G.

We do not believe that our report contains numerous errors and that either of the two examples CMS cited demonstrate errors or problems in our report. Therefore, we met with CMS staff to discuss these specific examples and any other concerns.

The first example cited in CMS's comments was related to the price of a different package size of Prilosec than the one included in our review. We have included additional language in the finding to clarify our calculation of prescription prices per package for each of the 28 NDCs in our review.

The second example reflected more general concerns. These concerns centered on the magnitude of the price variation that we reported and the prices paid by the highest-paying States for certain drugs. As described in the report, reimbursement for drugs is subject to upper payment limits in which States must pay the lowest of: (1) estimated [pharmacy] acquisition cost; (2) the pharmacy's usual and customary charge to the general public; (3) the Federal upper limit amount, if applicable; or (4) the State maximum allowable cost, if applicable. For some drugs, the prices we report for the highest-paying States are higher than this upper limit formula would dictate. This led CMS staff to question the accuracy of the data that States provided us. This was the central issue in the second example that CMS cited in their comments, i.e., some States reimbursed at prices above the Federal upper limit.

We agreed with CMS staff that some State prices are above the upper payment limit for certain drugs and that this is problematic. We emphasized, however, that we are reporting what States paid rather than what States should have paid. We described our process of reviewing all of the State-reported data, including the fact that we followed up with States whose prices appeared aberrantly high or low to verify whether this was what the State actually paid.

Additionally, at the meeting CMS staff raised some technical considerations, including States' methodology for excluding dispensing fees from ingredient reimbursement cost and States' systems for ensuring that

pharmacies bill for drugs correctly. We also discussed State differences in "usual and customary" charges, State maximum allowable costs, and third party liability, which are addressed in the report.

We agree that all of these factors can affect the magnitude of State drug price variation. In this inspection, we focused on measuring State drug price variation, and while we discussed potential causes of variation, measurement of cause was beyond our scope. We plan to send each State data comparing its Medicaid reimbursement prices to the other States' prices for each of the 28 drugs. We will suggest that each State review its Medicaid drug payments and the factors that affect its prices.

In conclusion, this report raises serious issues concerning Medicaid prescription drug reimbursement that warrant attention and action. We encourage CMS to implement all of our recommendations. We also discussed with CMS staff our plans to conduct another review of State Medicaid drug prices in the future to determine whether the price variation we found for these 28 drugs in FY 2001 is an anomaly or if it is representative of an underlying problem. We will work with CMS to address a variety of their outstanding concerns in that inspection. We look forward to continued work with CMS toward our common goal of ensuring the integrity of prescription drug payments under the Medicaid program.

APPENDIX A

SAMPLE OF 28 DRUGS

Single Source Drugs (10)

NDC	TRADE NAME	STRENGTH	UNITS	States with Complete Data
00009454402	Detrol Tablets	2MG	60	42
50458032050	Risperdal Tablets	2MG	500	41
00002411660	Zyprexa Tablets	7.5MG	60	42
00597001314	Combivent Aerosol Inhalation	103;18MCG;MCG	14.7	41
59627000103	Avonex Kit Administration Pack	30MCG/VIL	4 (kits)	41
00074621413	Depakote Tablets	250MG	100	42
00006007468	Vioxx Tablet	12.5 MG	100	40
00186074282	Prilosec Capsules Delayed Release	20 MG	1000	41
00071015623	Lipitor Tablets	20 MG	90	42
00087606010	Glucophage Tablets	500 MG	500	42

Innovator Multiple Source Sample Drugs (8)*

NDC	TRADE NAME	STRENGTH	UNITS	States with Complete Data
52544023528	Nor-QD	.35 MG	6 X 28	40
00078011022	Sandimmune Oral Solution	100 MG/ML	50 ML	36
59930157003	Clotrimazole Cream	1%	45G	39
00310013034	Zestril Tablets	5MG	1000	35
00032421001	Luvox	100 MG	100	41
00310014510	Zestoretic Tablets	25:20 MG; MG	100	42
59930163601	Normodyne	200 MG	100	39
59930151504	Albuterol Sulfate	0.50%	20 ML	41

Non-Innovator Multiple Source Sample Drugs (10)

NDC	TRADE NAME	STRENGTH	UNITS	States with Complete Data
55953054470	Ranitidine HCl	150 MG	500	41
00228257809	Diltiazem CD Capsules	240 MG	90	41
00003010960	Trimox Capsules	500 MG	500	42
55953054480	Ranitidine HCl	150 MG	1000	39
59011010510	Oxycontin Tablets Controlled Release	40 MG	100	42
00378023110	Atenolol Tablets	50 MG	1000	42
00555090201	Naltrexone Hydrochloride Tablets	50 MG	50	39
00781188305	Ranitidine Tablets	150 MG	500	41
00228271111	Isosorbide Mononitrate Tablets	60 MG	100	40
00364047901	Methylphenidate Hydrochloride	10 MG	100	40

* Two innovator multiple source drugs that were selected in our sampling were excluded from our analysis because many States did not purchase these drugs during FY 2001. They are Nicoderm CQ (NDC 00766145020) and Actiq Lozenge (NDC 00074246524).

APPENDIX B

PRIMARY INDICATIONS FOR SAMPLE DRUGS

The following table lists the primary indications, i.e., the primary conditions that the drugs are intended to treat, for each of the 28 drugs in our sample.

DRUG	PRIMARY INDICATION(S)
Albuterol Sulfate	bronchospasm
Atenolol	hypertension and coronary heart disease
Avonex	multiple sclerosis
Clotrimazole	vaginal yeast infection
Combivent	chronic obstructive pulmonary disease
Depakote	bipolar disorder
Detrol	overactive bladder
Diltiazem CD	hypertension
Glucophage	diabetes
Isosorbide Mononitrate	angina
Lipitor	high cholesterol
Luvox	depression and obsessive compulsive disorder
Methylphenidate Hydrochloride	attention deficit disorder and narcolepsy
Naltrexone Hydrochloride	alcohol dependency
Normodyne	hypertension
Nor-QD	prevention of pregnancy
Oxycontin	pain management
Prilosec	duodenal ulcer, gastric ulcer, gastroesophageal reflux disease (GERD), erosive esophagitis, pathological hypersecretory conditions
Ranitidine HCl	duodenal ulcer, gastric ulcer, gastroesophageal reflux disease (GERD), erosive esophagitis, pathological hypersecretory conditions
Risperdal	schizophrenia and dementia
Sandimmune	prevention of organ rejection following transplants
Trimox	bacterial infection
Vioxx	osteoarthritis, rheumatoid arthritis, acute pain, primary dysmenorrhea
Zestoretic	hypertension
Zestril	hypertension, heart failure, acute myocardial infarction
Zyprexa	schizophrenia and bipolar disorder

APPENDIX C

SELECTED CHARACTERISTICS OF SAMPLE DRUGS

Single Source Drugs

Drug	Percent Difference in Price Between the Two States	Percent Difference in Price Between the Two States	2007 Expenditures in Each State	Percent of Total Expenditures for 20 Drugs	Expenditures for Drug	Percent of Total Expenditures for 20 Drugs
Depakote	70.8%	4.2%	$66,876,204	10.2%	$16,284,584	18.8%
Glucophage	21.0%	4.4%	$20,337,219	3.1%	$1,956,958	2.3%
Avonex	20.4%	5.2%	$53,387,706	8.2%	$6,184,122	7.1%
Prilosec	20.3%	4.8%	$62,221,082	9.5%	$7,367,148	8.5%
Detrol	18.3%	3.1%	$38,415,841	5.9%	$2,800,316	3.2%
Combivent	17.8%	4.7%	$47,000,368	7.2%	$3,544,345	4.1%
Vioxx	16.8%	3.9%	$33,130,383	5.1%	$2,877,104	3.3%
Risperdal	13.5%	2.6%	$23,967,520	3.7%	$1,645,946	1.9%
Zyprexa	13.4%	2.6%	$48,570,362	7.4%	$2,712,454	3.1%
Lipitor	12.1%	3.5%	$109,940,879	16.8%	$6,873,801	7.9%
[illegible]			[illegible]	[illegible]	[illegible]	[illegible]

Innovator Multiple Source Drugs

Drug	Percent Difference in the Low State	Percent Difference in the High State	2007 Expenditures in Each State	Percent of Total Expenditures for 20 Drugs	Expenditures for Drug	Percent of Total Expenditures for 20 Drugs
Albuterol Sulfate	227.0%	52.5%	$3,696,609	0.6%	$1,869,895	2.2%
Clotrimazole	194.4%	10.5%	$1,525,100	0.2%	$848,609	1.0%
Normodyne	164.7%	20.9%	$2,222,774	0.3%	$1,172,316	1.4%
Zestoretic	56.8%	5.9%	$5,379,487	0.8%	$1,415,040	1.6%
Sandimmune	49.5%	5.9%	$2,069,395	0.32%	$544,578	0.6%
Luvox	48.7%	4.1%	$15,608,090	2.4%	$2,581,956	3.0%
Nor QD	42.6%	7.2%	$1,672,834	0.3%	$309,259	0.4%
Zestril	33.3%	3.3%	$1,756,577	0.23%	$141,339	0.2%
[illegible]			[illegible]	[illegible]	[illegible]	[illegible]

SELECTED CHARACTERISTICS OF SAMPLE DRUGS, CONTINUED

Non-innovator Multiple Source Drugs

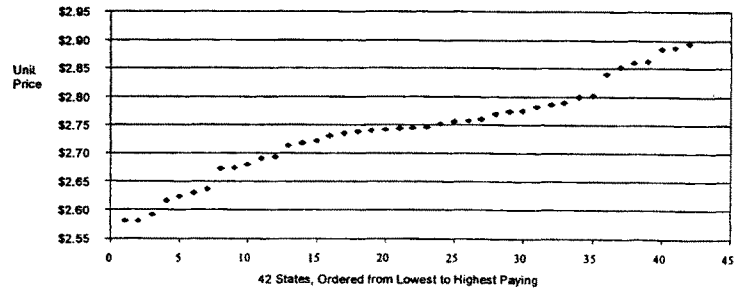
Drug	Percent Difference (High and Low States)	Percent Difference (Excluding High and Low States)	FY 2001 Expenditures (42 States)	Percent of Total Expenditures for 28 Drugs	Potential Savings	Percent of Total Potential Savings for 28 Drugs
Atenolol	4072.7%	266.3%	$1,780,532	0.3%	$1,645,525	1.9%
Ranitidine Tablets	2495.5%	63.6%	$3,637,638	0.6%	$3,116,688	3.6%
Ranitidine (500)	2459.9%	81.3%	$3,961,708	0.6%	$3,438,326	4.0%
Ranitidine (1000)	2274.6%	111.9%	$4,382,270	0.7%	$3,876,220	4.5%
Trimox	547.5%	32.5%	$2,615,314	0.4%	$1,807,883	2.1%
Isosorbide Mononitrate	200.0%	39.7%	$3,693,750	0.6%	$2,045,719	2.4%
Methylphenidate	120.1%	12.0%	$2,913,568	0.5%	$1,275,016	1.5%
Diltiazem	67.6%	10.1%	$5,533,307	0.9%	$1,761,686	2.0%
Naltrexone	43.6%	7.9%	$3,349,813	0.5%	$815,141	0.9%
Oxycontin	20.5%	2.5%	$83,758,577	12.8%	$5,758,943	6.6%
TOTAL			[illegible]	[illegible]	[illegible]	29.5%

APPENDIX D

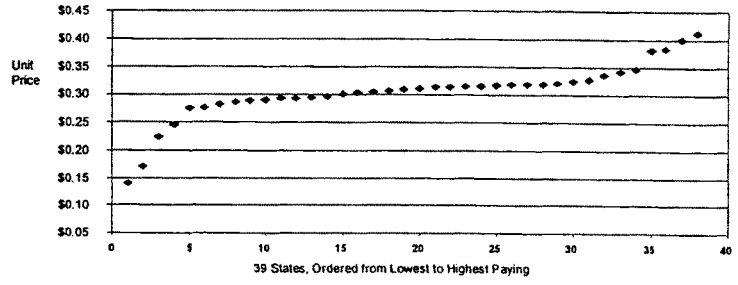
DISTRIBUTION OF STATES' PRICES FOR LIPITOR AND CLOTRIMAZOLE

Multiple source drugs (both non-innovator and innovator) tended to display a different pattern of price variation than single source drugs. When the States' prices are ordered from low to high, prices for the single source drugs generally increased from the lowest to highest State price at a more consistent rate than multiple source drugs. Multiple source drugs tended to increase more sharply from one State to the next at the low and/or high ends of the price range, while prices of States in the middle of the range increased more gradually from State to State. Comparing the States' prices for Lipitor, a single source drug, to Clotrimazole, an innovator multiple source drug, illustrates this pattern.

Distribution of States' Prices for Lipitor



Distribution of States' Prices for Clotrimazole



APPENDIX E

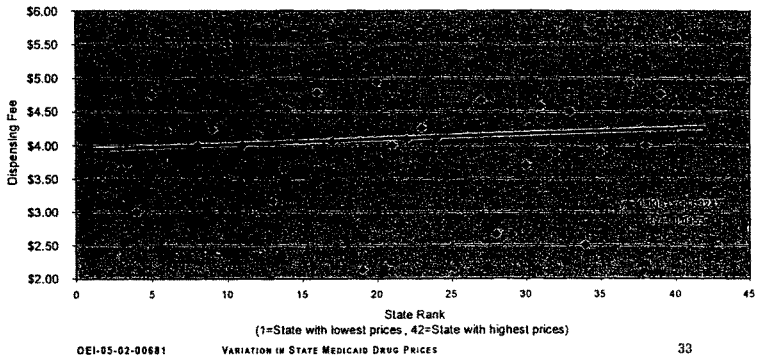
COMPARISON OF DISPENSING FEES TO STATES' PRICES

Though this study focuses on States' reimbursement for the cost of the drug itself, we did collect information on the dispensing fees States paid to pharmacies during FY 2001. Of the 42 States, 33 paid flat dispensing fees (e.g., Indiana paid $4.00 per prescription), and 9 paid variable dispensing fees. For some of these States, variable dispensing fees vary with the price of the drug, such as Texas, which paid a flat fee plus an "inventory management factor" of 2 percent of the drug cost. Other States' fees varied by pharmacy. For example, Utah paid a higher fee to rural pharmacies than urban pharmacies, and Oregon's fee varied by the volume of prescriptions that the pharmacy filled annually. We excluded the nine States with variable fees from our dispensing fee comparison.

For the 33 States with flat fees, we explored whether the States that paid lower relative prices for the drugs in our sample compensated by paying higher dispensing fees. We compared States' dispensing fees to their ranks relative to other States. The State with the lowest prices was ranked "one." We graphed these data points with State rank along the x-axis (independent variable) and State dispensing fee along the y-axis (dependent variable).

If States that paid lower prices compensated pharmacies with higher dispensing fees, then we would expect the graph to show a negative slope, i.e., as the States' ranks (and therefore prices) increased, the dispensing fee would decrease. In fact, as Chart X below displays, these comparisons demonstrated very little relationship at all. The best fit line is almost flat, which would indicate no relationship, and the slight slope is in a positive direction (slope = 0.0081). Further, the very small R^2 (0.0153) indicates that any relationship between dispensing fee and relative drug prices for these 33 States is very weak.

Relationship between States' Relative Drug Prices and Dispensing Fees



APPENDIX F

POTENTIAL SAVINGS BY STATE

State	Potential Savings	Savings as a Percent of State's Expenditures in Sample Drugs	State's Savings as a Percent of Total Potential Savings
AK	$64,264	15.3%	0.1%
AR	$854,018	12.2%	1.0%
AZ	$8,096	16.7%	0.01%
CO	$894,285	13.1%	1.0%
CT	$1,368,736	12.2%	1.6%
FL	$4,513,343	11.7%	5.2%
GA	$3,355,312	14.8%	3.9%
HI	$327,148	11.6%	0.4%
ID	$531,284	13.7%	0.6%
IL	$4,615,653	15.6%	5.3%
IN	$2,037,517	12.7%	2.4%
KS	$1,106,127	15.5%	1.3%
KY	$2,986,066	17.2%	3.5%
LA	$1,887,159	12.9%	2.2%
MA	$2,278,094	7.6%	2.6%
MD	$900,427	12.0%	1.0%
ME	$844,402	9.9%	1.0%
MI	$547,273	2.6%	0.6%
MN	$924,362	8.6%	1.1%
MO	$3,645,740	13.9%	4.2%
MS	$2,484,232	16.7%	2.9%
MT	$386,057	12.9%	0.5%
NC	$5,090,788	15.6%	5.9%
ND	$239,602	16.0%	0.3%
NE	$880,540	15.9%	1.0%
NH	$430,943	13.6%	0.5%
NJ	$5,632,460	18.1%	6.5%
NM	$326,577	16.6%	0.4%
NV	$418,466	17.4%	0.5%
NY	$13,017,331	16.7%	15.0%
OH	$7,573,440	15.0%	8.7%
OK	$1,098,092	16.2%	1.3%
OR	$1,099,746	13.4%	1.3%
PA	$3,091,889	12.4%	3.6%
SC	$1,556,766	11.8%	1.8%
SD	$221,419	12.9%	0.3%
TX	$2,536,669	7.3%	2.9%
UT	$549,730	14.0%	0.6%
VT	$560,638	12.1%	0.7%
WA	$4,288,644	11.3%	5.0%
WV	$1,323,208	14.8%	1.5%
WY	$174,374	14.5%	0.2%
TOTAL	$86,670,918	[illegible]	100%*

* Exceeds 100% due to rounding.

APPENDIX G

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: FEB 12 2004

TO: Dara Corrigan
Acting Principal Deputy Inspector General
Office of Inspector General

FROM: Dennis G. Smith
Acting Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General Draft Report: *"Variation in State Medicaid Drug Prices,"* (OEI-05-02-00681)

Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report entitled, *"Variation in State Medicaid Drug Prices."* We have the following comments.

Medicaid regulations at 42 CFR 447.331 provide that States pay for prescriptions not subject to Federal upper payment limits at the lower of the estimated acquisition cost or the provider's usual and customary charges to the general public. As a means of determining "estimated acquisition cost" States use pricing data published by national drug pricing compendia (Red Book, First Data Bank and Medi-Span). Most States set their rates at a percentage discount off average wholesale price, but some apply a mark up to wholesale acquisition cost. The OIG study reviewed State payments for certain drugs and reported wide variation in these prices. To narrow this variation and improve the relationship of prices to costs the OIG report recommends that the Centers for Medicare & Medicaid Services (CMS) should:

- share average manufacturer price data with states to ensure more accurate estimates of pharmacy acquisition costs;
- conduct research on the factors that affect states drug prices; and
- review the states drug reimbursements for the highest paying states.

We do not concur with the report at this time because we have identified numerous errors in the data. Before using such data, we believe that the OIG should share the data with the States and ask them to explain how it could be accurate or correct the errors. The following are examples of the problems we found.

1. The average cost of a prescription for Prilosec cited in the report exceeds $3000. In contrast, the average wholesale price (AWP) for this drug is in the range of $125 - $150 per prescription.

2. The prescription cost of ranitidine (generic Zantac) cited in the report ranges from $51 to $1295. Yet, the upper payment on this drug is $.34 per tablet. In addition, the strengths used are not available in the market.

Based on these and other clear errors in the data, we suggest that the OIG correct the data on which the report is based before release.

ACKNOWLEDGMENTS

This report was prepared under the direction of William C. Moran, Regional Inspector General for Evaluation and Inspections in the Chicago Regional Office, and Natalie Coen, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

Emily Melnick, Team Leader

Erin Lemire, Lead Analyst

Jennifer Gera, Intern

Linda Frisch, Program Specialist

Tricia Davis, Director, Medicare and Medicaid Branch

Technical Assistance

Barbara Tedesco, Mathematical Statistician

END NOTES

[1] This figure is based on data from Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Financial Management Reports, Fiscal Year 2001. Available at http://www.cms.gov/medicaid/mbes/ofs-64.asp

[2] Bruen, Brian. "States Strive to Limit Medicaid Expenditures for Prescribed Drugs." Prepared for the Kaiser Commission on Medicaid and the Uninsured. Washington, DC; February 2002

[3] Kreling, David H., David A. Mott, Joseph B. Wiederholt, Janet Lundy, Larry Levitt. "Prescription Drug Trends: A Chartbook Update." Kaiser Family Foundation. Washington, DC; November 2001

[4] This figure is based on data from Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Financial Management Reports, Fiscal Year (FY) 2001 and FY 1997. Total Medicaid expenditures (minus drug expenditures) increased 31 percent from FYs 1997 to 2001; total Medicaid drug expenditures increased 94 percent during the same time period. Data available at http://www.cms.gov/medicaid/mbes/ofs-64.asp

[5] Centers for Medicare & Medicaid Services, "National Health Expenditure Projections 2001-2011." March 2002. Available at http://cms.hhs.gov/statistics/nhe/default.asp

[6] Associated Press. "In Budget Crises, State Leaders Call for U.S. Aid." New York Times, Final, Section A, Page 15, Column 1; July 25, 2002

[7] National Association of State Budget Officers. Available at http://www.nasbo.org

[8] State Medicaid Manual, Chapter 6, Section 6305. Available at http://www.cms.gov/manuals/pub45/pub_45.asp

[9] 42 CFR § 447.331

[10] 42 CFR § 447.301

[11] State Medicaid Manual, Chapter 6, Section 6305. Available at http://www.cms.gov/manuals/pub45/pub_45.asp

[12] 42 CFR § 447.332

[13] State Medicaid Manual, Chapter 6, Section 6305. Available at http://www.cms.gov/manuals/pub45/pub_45.asp

[14] 42 U.S.C. § 1396r-8(a)

[15] 42 U.S.C. § 1396r-8

[16] 42 U.S.C. § 1396o(a)(2)

[17] 42 CFR § 447.54

[18] 42 U.S.C. § 1396o(e)

[19] 42 CFR § 433.139

[20] Conversation with Dr. Stephen Schondelmeyer, Director of the PRIME Institute at the University of Minnesota, August 6, 2002

[21] "Reimbursement for Prescribed Drugs." Report to the General Court. Commonwealth of Massachusetts, Executive Office of Health and Human Services, Division of Health Care Finance and Policy. October 3, 2002

[22] "Maximum Allowable Cost Savings Report." State of Vermont, Agency of Human Services. December 2, 2002

[23] Lawson K.A., Hong S.H., Johnsrud M.T., Skrepnek G. "An assessment of cost saving options for the Medicaid Vendor Drug Program." The University of Texas College of Pharmacy, Austin, Texas. May 1995

[24] State Medicaid Manual, Chapter 6, Section 6305. Available at http://www.cms.gov/manuals/pub45/pub_45.asp

[25] Office of Inspector General report "Cost Containment of Medicaid HIV/AIDS Drug Expenditures," OEI-05-99-00611. July 2001

TAB 12

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Omission Of Drugs From The Federal Upper Limit List in 2001

Inspector General

February 2004
OEI-03-02-00670

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees State Medicaid fraud control units which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

OBJECTIVE

This inspection: (1) determined whether drugs that met the criteria established by Federal laws and regulations were included on the Federal Upper Limit list in 2001, and (2) calculated the potential savings that could have resulted in 2001 if additional drugs that met the established criteria had been included on the Federal Upper Limit list.

BACKGROUND

In 1987, 42 CFR § 447.332 authorized the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration) to establish Federal Upper Limits in order to limit the amount that Medicaid could reimburse for multiple-source drugs. A multiple-source drug is defined as "a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name." According to the State Medicaid Manual, these reimbursement limits, commonly known as Federal Upper Limits, were established to ensure that the Federal Government acts as a prudent payer by taking advantage of current market prices for multiple-source drugs.

The regulation required CMS to establish a Federal Upper Limit amount for a drug product (i.e., each specific dosage form and dosage amount of a drug) when: (1) all versions of a drug product had been classified as therapeutically equivalent by the Food and Drug Administration (FDA), and (2) at least three suppliers of the drug product are listed in current editions (or updates) of published compendia of cost information for drugs available for sale nationally. The Omnibus Budget Reconciliation Act of 1990, however, changed this criteria by requiring a Federal Upper Limit when three or more versions of a drug product have been rated therapeutically and pharmaceutically equivalent by FDA, regardless of the ratings of other versions. The Federal Upper Limit amount for a drug is set at 150 percent of the published price for the least costly therapeutically-equivalent product plus a reasonable dispensing fee. CMS publishes the list of drug products for which Federal Upper Limits have been established in the *State Medicaid Manual* and on its website at www.cms.gov/medicaid/drugs/drug10.asp.

We obtained a list of the top 200 multiple-source drugs based on retail sales for the year 2001, and determined if the drugs were on CMS's November 2001 Federal Upper Limit list. For each of the drugs not on the Federal Upper Limit list, we determined if any forms or strengths met the criteria for inclusion on the list. We then calculated a Federal Upper Limit amount for any drug products that met the criteria by multiplying the lowest

price published in the *Red Book for Windows* by 150 percent. We determined each State's average payment for these drug products by obtaining payment and utilization data from CMS. For drug products whose Federal Upper Limit amount would have been less than a State's average payment amount, we calculated potential Medicaid savings by multiplying the price difference by Medicaid utilization. We then aggregated the individual savings for each State to determine the overall potential savings to Medicaid.

FINDING

Ninety drug products met the established criteria but were not included on the Federal Upper Limit list in 2001.

If CMS had included 55 of these drug products on the Federal Upper Limit list, the Medicaid program could have saved $123 million in 2001. This represents 30 percent of the $411 million Medicaid reimbursed for these 55 products that year. Four drug products alone accounted for 71 percent of the $123 million in potential Medicaid savings. The Medicaid program could have saved $88 million in 2001 by placing these 4 products (albuterol aerosol, ipratropium bromide solution, enalapril maleate 20 mg tablets, and clozapine 100 mg tablets) on the Federal Upper Limit list.

The remaining 35 of the 90 drug products met the criteria for inclusion on the Federal Upper Limit list but did not have any associated savings. However, States would pay the Federal Upper Limit amount only if it were less than the estimated acquisition cost or State maximum allowed cost. Therefore, States would not have made higher payments if these products had been included on the Federal Upper Limit list.

After the start of this inspection but prior to the release of the final report, CMS added 9 of the 90 products to the Federal Upper Limit list. Seven of these drug products (albuterol aerosol, ipratropium bromide solution, aspirin/butalbital/caffeine tablets, and 4 strengths of enalapril maleate tablets) accounted for a significant portion ($94 million) of the savings we calculated for 2001.

RECOMMENDATION

Federal Upper Limits were created to help Medicaid save money by taking advantage of lower prices for multiple-source drugs available in the marketplace. Although the Federal Upper Limit list already includes over 400 drug products, there are more that could be added. At a time when Medicaid prescription drug costs are increasing, efforts should be made to include on the Federal Upper Limit list all drugs that meet the requirements. This could result in millions of dollars in savings to both State Medicaid programs and the Federal Government.

We recommend that CMS take steps to ensure that all drugs meeting the criteria set forth in Federal laws and regulations are included on the Federal Upper Limit list.

Agency Comments

CMS states that they do not agree with the Office of Inspector General's (OIG's) savings estimates. Specifically, CMS states that OIG used only the *Red Book* to identify suppliers and prices, and did not subsequently verify the information provided in the *Red Book* with suppliers. In addition, CMS states that three of the products that we identified as leading to the most savings were recently added to the Federal Upper Limit list. Therefore, CMS believes that our savings estimates should be reduced accordingly. CMS also believes that it is nearly impossible to say with certainty that a particular group of products has been incorrectly excluded from the Federal Upper Limit list at any one time since pricing and product information changes frequently. CMS believes that their efforts to add and remove drug products on the Federal Upper Limit list should be recognized by OIG. Finally, CMS states it does not believe that products that would not lead to savings should be included on the Federal Upper Limit list.

While CMS disagrees with our savings estimates, we are unable to determine if they concur with our recommendation that drugs which meet the criteria should be included on the Federal Upper Limit list, as well as what, if any, actions CMS plans to take in response to our report. OIG stands by the drugs identified as meeting the criteria, the subsequent savings estimates, and our recommendation.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVE

This inspection: (1) determined whether drugs that met the criteria established by Federal laws and regulations were included on the Federal Upper Limit list in 2001, and (2) calculated the potential savings that could have resulted in 2001 if additional drugs that met the established criteria had been included on the Federal Upper Limit list.

BACKGROUND

Medicaid Program

Medicaid is a jointly-funded, Federal-State health insurance program for certain low income and medically-needy people. Individual States establish eligibility requirements, benefit packages, and payment rates for their Medicaid program under broad Federal standards set by the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Financing Administration). Federal regulations mandate that States provide basic services to beneficiaries in order to receive Federal matching funds. States may also receive Federal funding if they provide other optional services. One of the most commonly covered optional services that States provide is prescription drug coverage. All 50 States and the District of Columbia currently offer prescription drug coverage under the Medicaid program. In calendar year 2001, Medicaid payments for prescription drugs totaled almost $24 billion.

Medicaid Drug Reimbursement Methodology

Each Medicaid agency is required to submit a State plan to CMS describing its payment methodology for covered drugs. Federal regulations require that each State's reimbursement for a drug not exceed the lower of its estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drug. States have implemented dispensing fees that range from $2.00 to $5.60 per prescription.

CMS allows States flexibility in defining estimated acquisition cost. Most States base their calculation of estimated acquisition cost on a drug's average wholesale price discounted by a certain percentage. This discount ranged from 5 percent to 15 percent in the year 2001. A small number of States use wholesale acquisition costs rather than average wholesale prices when determining estimated acquisition cost. Average wholesale prices and wholesale acquisition costs are reported by companies, such as First DataBank and Medical Economics.

For certain drugs, States also use the Federal Upper Limit and State Maximum Allowable Cost programs in determining reimbursement amounts. CMS has established Federal Upper Limit amounts for over 400 drugs. In addition, more than half of the States have implemented a Maximum Allowable Cost program in order to reduce reimbursement amounts for certain drugs. Individual States determine the types of drugs that are included in their Maximum Allowable Cost program, and the method by which the Maximum Allowable Cost for a drug is calculated.

In summary, States often use a variety of different pricing mechanisms when setting reimbursement amounts. In most cases, States reimburse for a drug at the lower of its estimated acquisition cost, the Federal Upper Limit amount, the Maximum Allowable Cost, or the provider's usual and customary charge.

Federal Upper Limit List

In 1987, 42 CFR § 447.332 authorized CMS to establish Federal Upper Limits in order to limit the amount that Medicaid could reimburse for multiple-source drugs. A multiple-source drug is defined as " . . . a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name." According to the State Medicaid Manual, these reimbursement limits, commonly known as Federal Upper Limits, were established to ensure that the Federal Government acts as a prudent payer by taking advantage of current market prices for multiple-source drugs.

The regulation required CMS to establish a Federal Upper Limit amount for a drug product (i.e., each specific dosage form and dosage amount of a drug) when: (1) all versions of a drug product had been classified as therapeutically equivalent by the Food and Drug Administration (FDA), and (2) at least three suppliers of the drug product are listed in current editions (or updates) of published compendia of cost information for drugs available for sale nationally. The Omnibus Budget Reconciliation Act of 1990, however, changed this criteria by requiring a Federal Upper Limit when three or more versions of a drug product have been rated therapeutically and pharmaceutically equivalent by FDA, regardless of the ratings of other versions. FDA identifies equivalent drug products in their publication *Approved Drug Products with Therapeutic Equivalence Evaluations*. According to FDA, drugs that are therapeutically equivalent are designated as "A-rated."

The regulation sets the Federal Upper Limit amount at 150 percent of the published price for the least costly therapeutically-equivalent product that can be purchased in quantities of 100 tablets or capsules plus a reasonable dispensing fee. If the drug product is not available in quantities of 100 or if the drug product is a liquid, then the Federal Upper Limit amount should be based on a commonly listed size. States are required to meet the Federal Upper Limit requirements only in the aggregate. This means that a State can pay more than the Federal Upper Limit amount for certain products as long as it pays less than the Federal Upper Limit amount for other products.

CMS publishes the list of drug products for which Federal Upper Limits have been established in the *State Medicaid Manual*. The Federal Upper Limit list is also available on CMS's website at www.cms.gov/medicaid/drugs/drug10.asp. Any revisions to the Federal Upper Limit list are typically noted in Medicaid program memoranda and on the CMS website. CMS establishes an upper limit for specific forms and strengths for each multiple-source drug on the list. The Federal Upper Limit list also provides the source of the pricing information used to calculate the upper limit amount for each drug.

METHODOLOGY

Information from CMS

We met with CMS staff to obtain a better understanding of how CMS administers Federal Upper Limits. We discussed with CMS the procedures used to identify drugs that should be placed on the Federal Upper Limit list, as well as the methods used to calculate the Federal Upper Limit amount. CMS also provided documentation of these procedures.

Determining Whether Drugs Met Federal Upper Limit Criteria

Determining Drugs Not Currently on the Federal Upper Limit List. We obtained a list of the top 200 multiple-source drugs based on retail sales for the year 2001 from *Drug Topics* magazine. We compared the *Drug Topics* list to CMS's November 2001 Federal Upper Limit list. In making this comparison:

(1) If *Drug Topics* listed a specific form for a drug, then we determined if this specific form was on the Federal Upper Limit list.

(2) If *Drug Topics* did not list a specific form, then we determined if any form of the drug was on the Federal Upper Limit list.

For example, if *Drug Topics* magazine placed ibuprofen liquid on its list of top 200 multiple-source drugs, then the liquid form of ibuprofen would need to be specifically mentioned on the Federal Upper Limit list. However, had *Drug Topics* simply listed ibuprofen (with no specific form), then we determined if any forms of ibuprofen were part of the Federal Upper Limit list. If any form of the drug appeared on the Federal Upper Limit list, then we concluded that the drug was included. In total, we determined that 64 of the 200 multiple-source drugs from the *Drug Topics* list were not included on the Federal Upper Limit list as of November 2001.

Identifying All Versions of the 64 Drugs Not on the Federal Upper Limit List. Because CMS calculates an upper limit amount for every form and strength of a drug (i.e., each specific drug product) that meets the criteria set forth by Federal laws and regulations, we needed to identify all the forms and strengths for each of the 64 multiple-source drugs not on the Federal Upper Limit list. We used the October 2001 edition of the *Red Book for Windows* (published by Medical Economics) to gather this information.

According to the *Red Book*, these 64 multiple-source drugs were associated with 200 different drug products in various forms and strengths.

We then compiled a list of all the national drug codes (NDCs) associated with each of the 200 drug products. Each individual drug product manufactured or distributed in the United States has a unique NDC. NDC identifies the manufacturer of the drug product, the product dosage form, and the package size. For each NDC, the *Red Book* provides published prices (usually average wholesale prices and wholesale acquisition costs), supplier information, and FDA therapeutic equivalency data. The *Red Book* also lists whether the individual drug product is a brand or generic version.

Determining if the 200 Drug Products Met Federal Upper Limit Criteria. We used the *Red Book* to determine whether each of the 200 drug products met the established criteria for inclusion on the Federal Upper Limit list. We first determined whether each of the drug products had at least three versions deemed therapeutically-equivalent (A-rated) by FDA. For any drug products that met this criteria, we verified that there were at least three suppliers listed in the *Red Book*. In all, 90 of the 200 drug products met the criteria for inclusion on the Federal Upper Limit list. These 90 drug products comprised different forms and strengths of 42 drugs from *Drug Topics'* list of the top 200 multiple-source drugs. Table 1 below illustrates the steps taken to reach this number.

Table 1: Number of Drugs and Drug Products in Each Stage of Methodology

Methodology Step	Number of Drugs	Number of Drug Products
Drug Topics' Top 200 Multiple-Source Drugs	200	Not determined
Drugs on *Drug Topics'* List Not on the Federal Upper Limit List	64	200
Drugs Not on Federal Upper Limit list that Met Federal Upper Limit Criteria	42	90

Calculating Federal Upper Limit Amounts

To calculate a Federal Upper Limit amount for the 90 drug products that met the criteria for inclusion, we used pricing information and therapeutic equivalency data from the *Red Book*. Federal regulations set the upper limit amount at 150 percent of the least costly therapeutically-equivalent product that can be purchased in package sizes of 100 (with certain exceptions). Therefore, we determined which of the A-rated versions available in a package size of 100 had the lowest price listed in the *Red Book*. If a product was not available in a package size of 100, we determined the lowest price for the most common package size listed in the *Red Book*. We then multiplied this price by 150 percent to determine the Federal Upper Limit amount for the drug product. This potential Federal Upper Limit amount would apply to all NDCs

associated with the drug product. We did not verify that the prices published in the *Red Book* were actually available in the marketplace.

Calculating Medicaid Payments

To determine the amount Medicaid reimbursed for the 90 drug products that met the Federal Upper Limit criteria, we downloaded 50 Medicaid payment and utilization files for calendar year 2001 from CMS's website. We did not include Arizona because its drug payment and utilization file was not available. Each file contained variables representing total State payments, number of units reimbursed, and number of prescriptions written for every NDC listed on a paid claim in 2001. We removed NDCs associated with brand versions of the drug product from the file. We excluded brand versions because many State Medicaid agencies require a generic version of the drug product to be dispensed.

The total State payment amount listed in the files included both the payments for the drug product and the dispensing fees paid to the pharmacy. To determine a State's payments for the drug product only, we:

(1) Aggregated total State payments, number of units reimbursed, and number of prescriptions written for all generic NDCs associated with the product

(2) Calculated the total amount the State paid in dispensing fees for the drug product by multiplying the State's dispensing fee by the number of prescriptions written for the product

(3) Subtracted this amount from the total State payments for the drug product

We then calculated the average State payment by dividing the State's payments for the drug product (without the dispensing fee) by the number of units reimbursed. One of the 90 drug products did not have payment data listed in the State files, and was therefore, not included in subsequent calculations.

Calculating Potential Savings

We calculated the difference between the average State payment and the potential Federal Upper Limit amount. If the potential Federal Upper Limit amount for a drug product was less than the average State payment, we multiplied the price difference by the number of units reimbursed in order to determine each State's potential savings for the product. For each of the drug products with potential savings, we added the savings among all States. Finally, we aggregated the savings for all drug products to determine the overall potential savings to the Medicaid program.

This study was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDING

Ninety drug products met the established criteria but were not included on the Federal Upper Limit list in 2001

Each of the 90 drug products had at least 3 versions rated therapeutically equivalent by FDA, and were available from 3 or more suppliers. These 90 drug products accounted for $667 million in Medicaid reimbursement in 2001. Prior to the release of this report, CMS added 9 of the 90 products to the Federal Upper Limit list.

Adding 55 of the 90 drug products to the Federal Upper Limit list could have saved Medicaid $123 million in 2001

Medicaid could have saved $123 million in 2001 by adding 55 drug products to the Federal Upper Limit list. This represents 30 percent of the $411 million Medicaid reimbursed for the 55 products that year. Each of these drug products had at least three versions rated therapeutically equivalent by FDA and were available from three or more suppliers. These 55 products represented various forms and strengths of 25 drugs from *Drug Topics* magazine's list of top 200 multiple-source drugs by retail sales in 2001.

Four drug products accounted for 71 percent of the $123 million in potential Medicaid savings in 2001. **The Medicaid program could have saved $88 million in 2001 by placing these four products (albuterol aerosol, ipratropium bromide solution, enalapril maleate 20 mg tablets, and clozapine 100 mg tablets) on the Federal Upper Limit list.** Albuterol aerosol accounted for 42 percent of overall savings. The State of New York alone could have realized $9.2 million in savings had albuterol aerosol been included on the list in 2001. The total savings attributed to the four products are shown in Table 2 on the following page. A complete list of the 55 drug products and their savings is presented in Appendix A. We did not verify that the prices published in the *Red Book* were available in the marketplace.

An additional 35 drug products met the criteria for inclusion on the Federal Upper Limit list but did not have any associated savings. These 35 drug products represented various forms and strengths of 23 drugs from *Drug Topics* magazine's list of top multiple-source drugs by retail sales. For 34 of these 35 drug products, no State had an average payment amount for the product that was less than the potential Federal Upper Limit amount. Medicaid did not make any payments for 1 of the 35 drug products. Therefore, this product did not have any potential savings. States reimburse for a drug at the lower of its estimated acquisition cost, the Federal Upper Limit amount, the Maximum Allowable Cost, or the provider's usual and customary charge. States would only pay the Federal Upper Limit amount for a drug product if it were the lowest of these options. Therefore, States would not have made higher payments if these 35 products had been included on the Federal Upper Limit list.

Table 2: Drug Products With The Highest Potential Federal Upper Limit Savings

Drug Product	Total Medicaid Reimbursement	Potential Federal Upper Limit Amount	Potential Savings
Albuterol Aerosol, 0.09 mg/inh[1]	$87,481,266	$0.39	$52,299,768
Ipratropium Bromide, 0.02% solution[2]	$65,156,902	$0.34	$19,945,230
Enalapril Maleate, 20 mg tablet[2]	$21,332,860	$0.72	$7,918,226
Clozapine, 100 mg tablet	$83,652,722	$2.48	$7,742,010
Total	$257,623,750		$87,905,234

Source: OIG analysis of 2001 Medicaid drug utilization and payment data and October 2001 *Red Book* pricing data

After the start of this inspection but prior to the release of the final report, CMS added 9 of the 90 products to the Federal Upper Limit list. Seven of these drug products (albuterol aerosol, ipratropium bromide solution, aspirin/butalbital/caffeine tablets, and four strengths of enalapril maleate tablets) accounted for a significant portion ($94 million) of the savings we calculated for 2001. Albuterol aerosol was added to the Federal Upper Limit list on March 11, 2003, ipratropium bromide and enalapril maleate were added on August 24, 2003, and aspirin/butalbital/caffeine was added on November 2, 2003. According to our analysis, adding the other two products (buspirone hydrochloride and oxaprozin) would not have led to any savings that year.

[1] Albuterol aerosol was added to the Federal Upper Limit list on March 11, 2003.

[2] Ipratropium bromide solution and enalapril maleate tablets were added to the Federal Upper Limit list on August 24, 2003.

RECOMMENDATION

Federal Upper Limits were created to help Medicaid save money by taking advantage of lower prices for multiple-source drugs available in the marketplace. Although the Federal Upper Limit list already includes over 400 drug products, there are more that could be added to the list. At a time when Medicaid prescription drug costs are increasing, efforts should be made to include on the Federal Upper Limit list all drugs that meet the requirements. This could result in millions of dollars in savings to both State Medicaid programs and the Federal Government.

We recommend that CMS take steps to ensure that all drugs meeting the criteria set forth in Federal laws and regulations are included on the Federal Upper Limit list.

Agency Comments

CMS states that they do not agree with the the Office of Inspector General's (OIG's) savings estimates. Specifically, CMS states that OIG used only the *Red Book* to identify suppliers and prices, and did not subsequently verify the information provided in the *Red Book* with suppliers. In addition, CMS states that three of the products that we identified as leading to the most savings were recently added to the Federal Upper Limit list. Therefore, CMS believes that our savings estimates should be reduced accordingly. CMS also believes that it is nearly impossible to say with certainty that a particular group of products has been incorrectly excluded from the Federal Upper Limit list at any one time since pricing and product information changes frequently. CMS believes that their efforts to add and remove drug products on the Federal Upper Limit list should be recognized by OIG. Finally, CMS states it does not believe that products that would not lead to savings should be included on the Federal Upper Limit list.

CMS also includes a technical comment stating that four sections of this report do not describe all the potential situations in which Federal Upper Limits may be established. CMS suggests that we revise these sections of the report.

The full text of CMS's comments is presented in Appendix B.

OIG Response

In the report, we recommended that all products that meet the criteria set forth in the statute and regulation be included on the Federal Upper Limit list. The regulatory criteria only require that three suppliers who offer therapeutically-equivalent products be listed in current editions of national pricing compendia, and that the Federal Upper Limit amount be set at 150 percent of the lowest published price. We strictly followed these criteria in identifying the 90 drug products that had not been included in 2001 and in calculating their potential Federal Upper Limit amounts.

CMS believes that drugs that meet the criteria but have no associated savings should not be included on the Federal Upper Limit list. However, the Omnibus Budget Reconciliation Act of 1990 states that "[CMS] shall establish a Federal upper reimbursement limit..." Furthermore, States reimburse for a drug at the lower of its estimated acquisition cost, the Federal Upper Limit amount, the Maximum Allowable Cost, or the provider's usual and customary charge. Therefore, States would only pay the Federal Upper Limit amount for a drug product if it were the lowest of these options, and including a drug on the list would not lead to higher payments.

In response to CMS's technical comment concerning therapeutic equivalency requirements, we point out that the statute explicitly requires the establishment of a Federal Upper Limit when there are at least three therapeutically equivalent products that have been A-rated by FDA. The statute states that "[CMS] shall establish a Federal Upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such..." We believe that this statement is clear in its intent that CMS must set a Federal Upper Limit in situations in which three products have been A-rated by FDA and the other criteria are met. CMS's comments indicate that the agency takes the position that it also has the discretion to set Federal Upper Limits under certain additional circumstances. For the purposes of this report, OIG applied a conservative interpretation of the Federal Upper Limit criteria, but would expect additional savings to result from a broader application of the criteria.

In conclusion, OIG believes that the savings estimates for 2001 presented in this report are correct for the time period we reviewed. OIG also reaffirms its recommendation that CMS should include all products that meet the criteria on the Federal Upper Limit list.

APPENDIX A

Drug Products With Federal Upper Limit Savings

The table below lists the 55 drug products that, if included on the Federal Upper Limit list, could have led to $123 million in Medicaid savings in 2001. Unless otherwise noted, drug information is based on package sizes of 100.

Drug Product	Total Medicaid Reimbursement	Potential Federal Upper Limit	Potential Savings
APAP/Butalbital/Caffeine			
325 mg-50 mg-40 mg, Capsule	$89,384.49	$0.36	$324
325 mg-50 mg-40 mg, Tablet	$3,909,337.28	$0.07	$2,660,418
500 mg-50 mg-40 mg, Capsule	$721,437.87	$0.69	$31,031
500 mg-50 mg-40 mg, Tablet	$2,506,195.89	$0.54	$706,407
Albuterol			
.09 mg/inh, Aerosol, 17 gm[1]	$87,481,265.89	$0.39	$52,299,768
2 mg/5 ml, Syrup, 480 ml	$3,242,419.13	$0.02	$1,111,100
Aspirin/Butalbital/Caffeine			
325 mg-50 mg-40 mg, Capsule	$411,383.11	$0.57	$138
325 mg-50 mg-40 mg, Tablet[2]	$538,594.21	$0.06	$363,022
Aspirin/Butalbital/Caffeine/Codeine			
325 mg-50 mg-40 mg-30 mg, Capsule	$2,188,509.43	$0.84	$179,712
Bupropion HCl			
100 mg, Tablet	$5,106,598.56	$0.80	$173,685
75 mg, Tablet	$4,759,489.74	$0.65	$1,656
Clotrimazole			
1%, Cream, 15 gm	$9,064,256.21	$0.23	$3,501,129
1%, Solution, 30 ml	$605,040.37	$0.61	$148
Clozapine			
100 mg, Tablet	$83,652,722.25	$2.48	$7,742,010
25 mg, Tablet	$7,907,922.22	$0.98	$578,799
Desmopressin Acetate			
10 mg/ml, Solution, 2ml	$6,187,808.53	$0.19	$1,338,246
Desmopressin Acetate			
4 mcg/ml, Solution, 10 ml	$512,170.58	$10.02	$199,539
Diflorasone Diacetate			
05%, Cream, 30 gm	$842,858.89	$1.50	$262
05%, Ointment, 30 gm	$1,016,670.39	$1.54	$315
Dipyridamole			
25 mg, Tablet	$366,648.16	$0.10	$152,414
50 mg, Tablet	$1,015,602.14	$0.13	$491,145
75 mg, Tablet	$339,020.00	$0.14	$6,575
Enalapril Maleate			
2.5 mg, Tablet[3]	$4,782,059.14	$0.41	$1,544,162
5 mg, Tablet[3]	$16,945,321.12	$0.51	$5,648,266
10 mg, Tablet[3]	$20,365,750.25	$0.54	$6,767,074
20 mg, Tablet[3]	$21,332,859.73	$0.72	$7,918,226
Erythromycin Ethylsuccinate			
250 mg, Enteric Coated Tablet	$295,673.48	$0.22	$13,881
Glycopyrrolate Maleate			
25 mg, Tablet	$1,643,208.29	$2.20	$114
50 mg, Tablet	$10,737,096.08	$2.47	$2,370
Haloperidol			
1.5 mg, Tablet	$129,870.76	$0.25	$4,953
3 mg, Tablet	$1,479,788.03	$0.32	$6,346

APPENDIX A

	Total Medicaid Reimbursement	Potential Federal Upper Limit	Potential Savings
Albuterol Solution			
1%-0.35%-10000 U/mL, Solution-Otic, 10 ml	$4,010,585.08	$1.53	$1,061,891
1%-0.35%-10000 U/mL, Suspension-Otic, 10 ml	$6,794,382.04	$1.53	$1,806,367
Lidocaine/Prilocaine			
25 mg, Capsule	$234,076.01	$0.05	$23,200
50 mg, Capsule	$214,407.05	$0.08	$2,334
75 mg, Extended Release Capsule	$1,152,338.18	$0.69	$316,656
Ipratropium Bromide			
0.02%, Solution, 2.5 ml[3]	$65,156,902.28	$0.34	$19,945,230
Methadone HCL			
10 mg/ml, Solution, 946 ml	$70,613.56	$0.10	$19,778
40 mg, Tablet	$301,985.47	$0.37	$64
Methylphenidate HCL			
20 mg, Extended Release Tablet	$7,440,180.34	$1.06	$141
Nicotine Polacrilex			
15 mg, Extended Release Tablet	$1,691,463.24	$0.80	$5,161
Phentermine HCL			
30 mg, Capsule	$136,369.61	$0.18	$104,872
37.5 mg, Capsule	$1,993.44	$0.58	$947
37.5 mg, Tablet	$199,607.09	$0.30	$149,489
Ticlopidine HCL			
80 mg, Tablet	$6,536,421.53	$0.39	$4,947,453
120 mg, Tablet	$1,083,691.05	$0.54	$785,364
160 mg, Tablet	$559,271.45	$0.67	$406,557
240 mg, Tablet	$97,550.50	$0.94	$72,637
Timolol Maleate			
0.25%, Gel Forming Solution, 5 ml	$268,795.65	$4.62	$1
0.5%, Gel Forming Solution, 5ml	$5,062,860.34	$5.50	$242
Warfarin			
2.5 mg, Tablet	$3,601,587.06	$0.58	$1,391
3 mg, Tablet	$2,213,985.36	$0.58	$4,462
4 mg, Tablet	$2,144,529.40	$0.59	$1,741
6 mg, Tablet	$735,396.70	$0.84	$89
7.5 mg, Tablet	$1,071,049.80	$0.86	$87
TOTAL	**$410,935,004.45**		**$123,099,389**

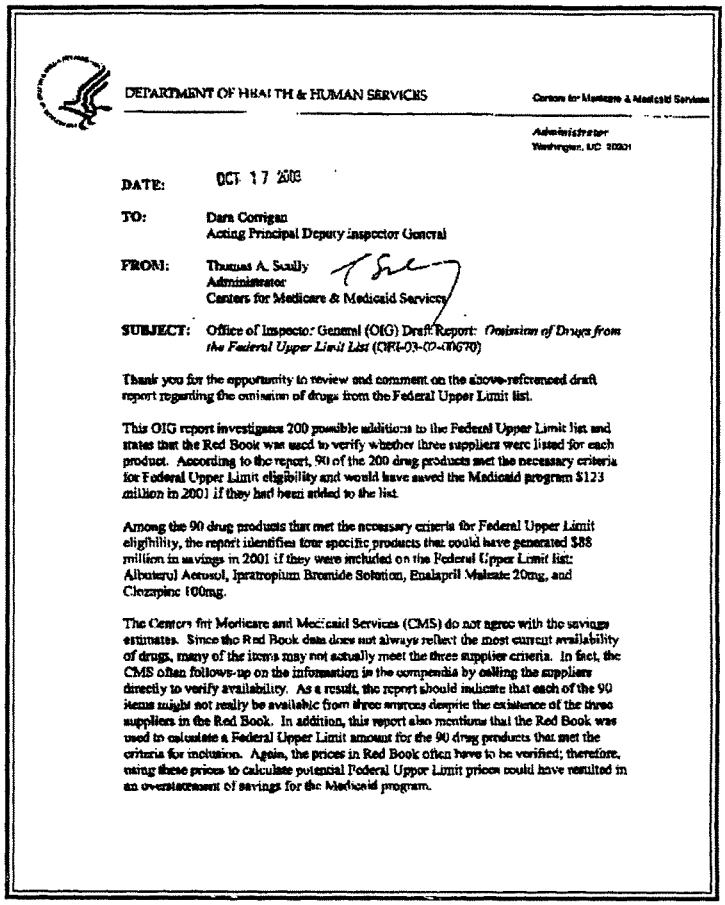
[1] Albuterol aerosol was added to the Federal Upper Limit list on March 11, 2003.

[2] Aspirin/Butalbital/Caffeine tablets were added to the Federal Upper Limit list on November 2, 2003.

[3] Ipratropium bromide solution and enalapril maleate tablets were added to the Federal Upper Limit list on August 24, 2003.

APPENDIX B

Centers for Medicare & Medicaid Services's Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 17 2003

TO: Dara Corrigan
Acting Principal Deputy Inspector General

FROM: Thomas A. Scully
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *Omission of Drugs from the Federal Upper Limit List* (OEI-03-02-00670)

Thank you for the opportunity to review and comment on the above-referenced draft report regarding the omission of drugs from the Federal Upper Limit list.

This OIG report investigates 200 possible additions to the Federal Upper Limit list and states that the Red Book was used to verify whether three suppliers were listed for each product. According to the report, 90 of the 200 drug products met the necessary criteria for Federal Upper Limit eligibility and would have saved the Medicaid program $123 million in 2001 if they had been added to the list.

Among the 90 drug products that met the necessary criteria for Federal Upper Limit eligibility, the report identifies four specific products that could have generated $88 million in savings in 2001 if they were included on the Federal Upper Limit list: Albuterol Aerosol, Ipratropium Bromide Solution, Enalapril Maleate 20mg, and Clozapine 100mg.

The Centers for Medicare and Medicaid Services (CMS) do not agree with the savings estimates. Since the Red Book data does not always reflect the most current availability of drugs, many of the items may not actually meet the three supplier criteria. In fact, the CMS often follows-up on the information in the compendia by calling the suppliers directly to verify availability. As a result, the report should indicate that each of the 90 items might not really be available from three sources despite the existence of the three suppliers in the Red Book. In addition, this report also mentions that the Red Book was used to calculate a Federal Upper Limit amount for the 90 drug products that met the criteria for inclusion. Again, the prices in Red Book often have to be verified; therefore, using these prices to calculate potential Federal Upper Limit prices could have resulted in an overstatement of savings for the Medicaid program.

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Of the four specific products identified by the OIG as potentially generating $88 million in savings in 2001, Albuterol Aerosol was added to the Federal Upper Limit list in February 2003 and Ipratropium Bromide and Enalapril Maleate were added in July 2003. Because these products are included on the Federal Upper Limit list, the amount that Medicaid could have saved should be reduced accordingly. Although the report suggests that products should be added to the Federal Upper Limit list even when a Federal Upper Limit amount exceeds the average Medicaid payment, we continue to believe that placing a Federal Upper Limit on an item that would clearly generate more cost savings by being reimbursed at the Maximum Allowable Cost or Estimated Acquisition Cost level would serve no purpose, and in fact would be detrimental to the program. According to the most recent Federal Upper Limit data that is current through June 2003, Clozapine 100mg tablets would not generate savings because the Federal Upper Limit amount for this product exceeds the Average Wholesale Prices (AWPs) for this item and would therefore exceed the typical Medicaid payment of a percentage discount off of AWP.

OIG Recommendation

The OIG recommends CMS take steps to ensure that all drugs meeting the criteria set forth in Federal laws and regulations are included on the Federal Upper Limit list.

CMS Response

First, it is important to note that pharmaceutical pricing and product information changes almost daily. As a result, because the pharmaceutical marketplace is constantly evolving, it is nearly impossible to say with certainty that a particular group of products has been incorrectly excluded from the Federal Upper Limit list at any one time. The CMS makes every effort to ensure that all drugs meeting the Federal Upper Limit criteria are included on the Federal Upper Limit list. To address the frequent marketplace changes, regular updates to the list are issued to the states and are posted on the Federal Upper Limit website. In fact, since the publication of the last Federal Upper Limit list in 2001, 39 drug products have been added to the list through the release of such updates. At the same time, 64 products have been deleted because they no longer meet the necessary criteria. In addition, CMS continues to welcome information from manufacturers, states, and pharmacy industry representatives regarding drug products that may be eligible for Federal Upper Limit pricing but are not on the current list, as well as those products that may no longer meet the necessary criteria and should be removed from the list. When such information is received, CMS performs a thorough investigation to determine whether adjustments can be made to the Federal Upper Limit list. Because this report only captures one particular period of time and the overall Federal Upper Limit program represents an ongoing process, these continuous updates should be recognized in the OIG draft report findings.

Attachment

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Technical Comment

Four sections of this report incorrectly describe the therapeutic equivalency criteria used to establish Federal Upper Limit prices: the background portion of the Executive Summary, the fourth paragraph on page two, the second paragraph on page four, and the second paragraph of the Findings section on page six. Each of these four sections states that a Federal Upper Limit is established on a product if three or more versions of the product have been classified as therapeutically equivalent by the Food and Drug Administration (FDA). This description is correct in instances where several therapeutically equivalent versions of a product are listed along with a version of the same product that is not therapeutically equivalent. However, a Federal Upper Limit can also be established for a drug product where all of the versions of the drug listed by the FDA are therapeutically equivalent—in those cases, there can be as few as two versions of the product listed by the FDA as long as they are both therapeutically equivalent. To present a more accurate description of the Federal Upper Limit criteria related to therapeutic equivalency, we suggest that each of the above mentioned sections be revised to reflect instances where all versions of the product are therapeutically equivalent versus instances where there are products that are therapeutically equivalent and products that are not therapeutically equivalent mixed together.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in Philadelphia, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

UPDATE: EXCESSIVE MEDICARE REIMBURSEMENT FOR ALBUTEROL

Inspector General

January 2004
OEI-03-03-00510

Office of Inspector General

http://oig.hhs.gov

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EXECUTIVE SUMMARY

OBJECTIVE

To update data provided in a 2002 report comparing Medicare reimbursement for albuterol to prices available to Medicaid, the supplier community, and the Department of Veterans Affairs (VA).

BACKGROUND

Albuterol is an inhalation drug commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Prior to 2004, Medicare's reimbursement methodology for albuterol and other prescription drugs was set forth in section 1842(o) of the Social Security Act, as amended by section 4556 of the Balanced Budget Act of 1997. At the time, reimbursement for a covered drug was set at 95 percent of the drug's average wholesale price (AWP). Recently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 lowered reimbursement for many Part B drugs, including albuterol. In 2004, Medicare reimbursement for albuterol will be 80 percent of AWP.

Medicare beneficiaries are responsible for paying a 20 percent coinsurance payment for covered drugs. In calendar year (CY) 2002, Medicare and its beneficiaries paid $412 million for the unit-dose solution form of albuterol, up from $296 million in CY 2000.

Albuterol is usually provided to Medicare beneficiaries by pharmacies, which then submit claims for reimbursement to Medicare. Medicaid beneficiaries also obtain albuterol through pharmacies. Pharmacies can purchase drug products through group purchasing organizations (GPOs), wholesalers, and directly from manufacturers. Unlike Medicare and Medicaid, VA provides veterans with drugs purchased directly from manufacturers or wholesalers. There are several purchase options available to VA, including the Federal Supply Schedule, blanket purchase agreements, and VA national contracts.

We obtained Medicare's CY 2003 reimbursement amount for albuterol. For comparison, we: (1) obtained Medicaid's 2003 reimbursement amount for albuterol by reviewing the Federal Upper Limit list, (2) estimated 2003 pharmacy acquisition costs

for albuterol by obtaining pricing information from a national wholesaler/distributor and a GPO, and (3) determined the VA's 2003 payment amount for albuterol by accessing pricing data available on its website. We also obtained manufacturer-reported wholesale acquisition costs (WACs) from the January 2003 edition of the *Drug Topics Red Book*. We calculated potential savings by multiplying Medicare's 2002 total payments for albuterol by the percentage difference between the Medicare reimbursement amount and the Medicaid reimbursement amount.

The exact savings estimates presented in this report are for 2002. Because the 2004 reimbursement amount for albuterol was lowered to 80 percent of AWP from 95 percent of AWP, the savings that Medicare would achieve by paying the Medicaid Federal Upper Limit Amount would now be lower. However, the difference in price between Medicare and Medicaid would still be large, and significant savings would still result if Medicare were able to reimburse albuterol at the Federal Upper Limit amount.

FINDINGS

Medicare continues to pay more for albuterol than other payors, costing the program and its beneficiaries millions of dollars a year. In 2003, the Centers for Medicare & Medicaid Services (CMS) set the Medicaid Federal Upper Limit amount for albuterol at $0.17 per milligram (mg), compared to $0.47 per mg for Medicare. If Medicare could reimburse for albuterol at the Federal Upper Limit amount, the program would have saved $263 million in 2002. Approximately $53 million of the savings would have resulted from reduced coinsurance payments.

Data collected from a drug wholesaler/distributor and a GPO showed that pharmacies were able to purchase albuterol for substantially less than the Medicare reimbursement amount. In spring 2003, the median price of albuterol at both the wholesaler/distributor and GPO was $0.06 per mg. Medicare's reimbursement amount of $0.47 per mg was nearly eight times more for the same amount of the drug. We did not collect data from pharmacies regarding any additional costs related to providing albuterol to Medicare beneficiaries.

Furthermore, manufacturer-reported WACs published in the *Red Book* also showed that pharmacies were able to purchase albuterol for prices substantially below the Medicare reimbursement amount. In January 2003, the median WAC reported in the *Red Book* was $0.08 per mg.

If Medicare were able to use prices available to the supplier community as a basis for albuterol reimbursement, the program and its beneficiaries would save millions of dollars a year.

Since our 2002 report, which was based on 2001 data, the price at which albuterol was available to the supplier community had decreased, while the Medicare reimbursement amount had remained the same. In 2001, we calculated that the median price of albuterol through wholesaler/distributors and GPOs was $0.08 per mg, 33 percent higher than the 2003 price of $0.06 per mg. In addition, manufacturer-reported WACs had also decreased, from a median of $0.11 per mg in 2001 to $0.08 in 2003.

The median Federal Supply Schedule price available to VA for generic albuterol was $0.05 per mg. In comparison, Medicare reimbursed over 9 times more ($0.47 per mg) for the same amount of the drug in 2003. However, it should be noted that, unlike Medicare, VA purchases drugs for its health care system directly from manufacturers or wholesalers, rather than reimbursing pharmacies for the drug. Both the VA Federal Supply Schedule price and the Medicare reimbursement amount for albuterol have remained constant since our previous report.

CONCLUSION

Despite numerous attempts by CMS to lower reimbursement amounts for prescription drugs, Medicare still pays a high premium for albuterol. This report is part of a series of reports on albuterol that have consistently found that the published average wholesale prices, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers.

Because of Medicare's reliance on published average wholesale prices, the program's reimbursement remains constant, despite the fact that other purchasers pay significantly less for albuterol

than they did several years ago. In addition, Medicare's total reimbursement for albuterol continues to increase substantially each year. Consequently, the Medicare program loses progressively more money every year.

We understand that, unlike most drugs covered by Medicare, albuterol is usually provided by pharmacies rather than administered by physicians. These pharmacies obviously need to make a profit from the products they supply, yet the spread between what Medicare reimburses for albuterol and the price at which suppliers are able to purchase the drug is significant.

Furthermore, we recognize that the VA acts as a purchaser of drugs, while Medicare reimburses pharmacies for the product. However, the fact that one Government agency is able to purchase a drug for one-ninth of Medicare's reimbursement amount is disconcerting.

Congress has recently passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act). This Act provides for numerous changes in Medicare's reimbursement methodology for drugs covered under Part B, including albuterol. Based on this new Act, Medicare will reimburse albuterol at 80 percent of AWP in 2004. We hope that the data presented in this report is helpful to CMS in determining an appropriate payment amount for the drug beyond 2004.

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INTRODUCTION

OBJECTIVE

To update data provided in a 2002 report comparing Medicare reimbursement for albuterol to prices available to Medicaid, the supplier community, and the Department of Veterans Affairs (VA).

BACKGROUND

Medicare Coverage of Albuterol

Currently, Medicare Part B does not pay for over-the-counter or most outpatient prescription drugs. However, Medicare Part B will cover drugs that are necessary for the effective use of durable medical equipment. One such product, albuterol, is an inhalation solution commonly used with a nebulizer to treat patients suffering from asthma or emphysema. Albuterol is typically provided to Medicare beneficiaries by pharmacies.

Medicare Reimbursement of Albuterol

The Centers for Medicare & Medicaid Services (CMS) contracts with four companies, known as durable medical equipment regional carriers (DMERCs), to process and reimburse medical equipment and supply claims, including albuterol Each DMERC is responsible for determining the reimbursement amount for albuterol in their respective region, based on Medicare's reimbursement methodology.

Prior to 2004, Medicare=s reimbursement methodology for albuterol and other prescription drugs was set forth in section 1842(o) of the Social Security Act, as amended by section 4556 of the Balanced Budget Act of 1997. At the time, the Social Security Act stated that reimbursement for covered drugs was to be set at 95 percent of the drug's average wholesale price (AWP). CMS directed carriers to obtain AWP data from the *Drug Topics Red Book* or similar pricing publications used by the pharmaceutical industry. In 2003, each DMERC reimbursed $0.47 per milligram (mg) for the unit-dose solution form of albuterol.

Recently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act) lowered reimbursement for many Part B drugs in 2004 and beyond by revising section

1842(o) of the Social Security Act. According to the new Act, the payment for a drug contained in the table, "Medicare Part B Drugs in Most Recent GAO and OIG Studies" published in the Federal Register (68 FR 50445) will be the percentage of the AWP indicated in the table. If the percentage in the table is less than 80 percent, then the percentage applied to reimbursement will be 80 percent. Based on the data presented in this table, in 2004, Medicare reimbursement for albuterol will be 80 percent of AWP.

Medicare paid $412 million for the unit-dose solution form of albuterol in calendar year (CY) 2002, up from $296 million in CY 2000. This total represents 5 percent of the $8.2 billion Medicare paid for all prescription drugs in 2002. Medicare payments include both the 80 percent that Medicare reimburses, and the 20 percent coinsurance payment for which beneficiaries are responsible.

CMS Use of Office of Inspector General (OIG) Data

In a proposed rule published in the Federal Register on August 20, 2003, CMS states, "If the OIG performs a new market analysis, we expect to incorporate this information into the Medicare payment limits...Initially, we would use the market analyses available to us from GAO and OIG studies to transition widely available market prices into the Medicare payments." Because of the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the proposed rule did not take effect. However, according to this Act, new pricing data may be useful for setting Medicare reimbursement amounts in the future.

Recent Attempts to Lower Medicare Reimbursement

Inherent Reasonableness. Section 4316 of the Balanced Budget Act of 1997 allows CMS to diverge from Medicare=s statutorily-defined payment method if the method results in payment amounts that are not inherently reasonable. In late 1998, CMS attempted to use this authority to lower what it considered excessive reimbursement for several items. One of these items was albuterol, which was targeted for an 11 percent fee reduction. However, the lower prices were never implemented, as Congress suspended the use of CMS's inherent reasonableness authority through a provision of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

This provision required the General Accounting Office (GAO) to complete a study on the potential effects of using inherent reasonableness measures before CMS could invoke the authority. The GAO report, issued in July 2000, found that inherent reasonableness reductions for some items were justified. However, GAO questioned the methodology that the carriers used in their collection of pricing data for albuterol.

On February 11, 2003, a new interim final rule for the application of inherent reasonableness went into effect. According to the regulation, payment amounts may be considered unreasonable based on a number of criteria, including: (1) payment amounts are grossly excessive when compared to other purchasers in the same locality, or (2) payment amounts are grossly excessive when compared to acquisition costs. According to the regulation, a payment amount is considered grossly excessive if a reduction of at least 15 percent is required to produce a realistic and equitable reimbursement amount.

Competitive Bidding. CMS included albuterol and several other inhalation drugs in a competitive bidding project in the San Antonio, Texas area that sought to use market forces to set accurate prices for durable medical equipment and related supplies. In November 2000, CMS announced the selection of durable medical equipment suppliers who had submitted competitive bids for the included items. New prices for these items went into effect in the bidding area on February 1, 2001. The new reimbursement amount for albuterol set by the competitive bidding process was $0.32 per mg, approximately 32 percent below the usual Medicare price. CMS hopes to use the results from these demonstrations more generally in the Medicare program.

Medicaid Reimbursement of Albuterol

As with Medicare, Medicaid beneficiaries typically receive albuterol from pharmacies. Pharmacies are then reimbursed by the Medicaid program.

Federal regulations require that each State Medicaid agency's reimbursement for a drug not exceed the lower of its estimated acquisition cost plus a reasonable dispensing fee, or the provider's usual and customary charge to the public for the drug. CMS allows States flexibility in defining estimated

acquisition cost. Like Medicare, most States base their calculation of estimated acquisition cost on a drug's AWP discounted by a certain percentage. This discount ranged from 5 percent to 15 percent in the year 2001. A few States use published wholesale acquisition costs (WACs) plus a percentage markup rather than AWPs when calculating estimated acquisition cost.

For certain drugs, States also use the Federal Upper Limit and State Maximum Allowable Cost programs in determining reimbursement amounts. According to CMS, the purpose of Federal Upper Limits is to ensure that the Federal Government acts as a prudent purchaser by taking advantage of current market prices for multiple-source products. CMS has established Federal Upper Limit amounts for over 400 drugs. In addition, more than half of the States have implemented a Maximum Allowable Cost program in order to reduce reimbursement amounts for certain drugs. Individual States determine the types of drugs that are included in their Maximum Allowable Cost program, and the method by which the Maximum Allowable Cost for a drug is calculated.

Acquisition Sources of Albuterol for Pharmacies

Pharmacies can purchase drug products through several sources, including group purchasing organizations (GPOs), wholesalers/distributors, and directly from manufacturers. GPOs provide their members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or from a wholesaler/distributor who accepts GPO's price. Wholesalers/distributors purchase large volumes of drugs from manufacturers and sell them directly to physicians, suppliers, and pharmacies.

VA Payments for Albuterol

Unlike Medicare and Medicaid, VA purchases drugs for its health care system directly from manufacturers or wholesalers. There are several options available to VA when purchasing drugs, with the most common being the Federal Supply Schedule. The Federal Supply Schedule provides agencies like VA with a simple process for purchasing commonly-used products in any quantity while still obtaining the discounts associated with volume buying. Using competitive procedures,

contracts are awarded to companies to provide supplies over a given period of time at the Federal Supply Schedule price. However, VA is sometimes able to negotiate prices lower than Federal Supply Schedule amounts through other avenues, such as blanket purchase agreements and VA national contracts.

Related Work on Albuterol

OIG has consistently found that Medicare's usual reimbursement amount for albuterol (based on AWP) is excessive. For example, in our report *Excessive Medicare Reimbursement for Albuterol* (March 2002), we calculated that the Medicare reimbursement amount for albuterol in 2000 was more than 9 times higher than the VA purchase price, and nearly 6 times the actual acquisition cost to pharmacies. According to our findings, excessive reimbursement for albuterol alone was costing Medicare and its beneficiaries up to $264 million per year.

In another of our reports, *Medicare Reimbursement for Albuterol* (June 2000), we found that Medicare would have saved almost $120 million in 1999 by reimbursing for albuterol at the amount paid by Medicaid.

In addition to the OIG, GAO has also found that Medicare reimbursement for albuterol is excessive. In its September 2001 report, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs* (GAO-01-1118), GAO found that the average widely available price to pharmacies for albuterol was 85 percent below the published AWP of the drug.

METHODOLOGY

We reviewed laws and regulations concerning Medicare drug reimbursement. We accessed CMS's Part B Extract Summary System to determine Medicare's total payments for the unit-dose solution form of albuterol in CY 2002. We obtained Medicare's CY 2003 reimbursement amounts for albuterol from all 4 DMERCs.

To determine Medicaid's 2003 reimbursement amount for albuterol, we obtained pricing information for the drug from the Medicaid Federal Upper Limit list.

To estimate pharmacy acquisition costs for albuterol, we obtained spring 2003 pricing information for albuterol from a

national wholesaler/distributor and from a GPO. As an additional estimate of pharmacy acquisition costs, we also obtained manufacturer-reported WACs from the January 2003 edition of the *Red Book*. The *Red Book* defines WAC as manufacturer-quoted list prices to wholesale distributors. These prices are not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

To determine the VA's 2003 payment amounts for albuterol, we accessed a file on their website that lists prices available to the agency through the Federal Supply Schedule.

To calculate potential Medicare savings based on Medicaid, we compared Medicare's reimbursement amount for 1 mg of albuterol to the Medicaid Federal Upper Limit amount. We determined the percentage difference in price by subtracting Medicaid's price from Medicare's price and then dividing the result by the Medicare price. This percentage indicates how much Medicare would save if the program could base reimbursement on the Medicaid Federal Upper Limit amount. We then multiplied the percentage difference by the total amount Medicare paid for albuterol in 2002 to calculate dollar savings.

The exact savings estimates presented in this report are for 2002. Because the 2004 reimbursement amount for albuterol was lowered to 80 percent of AWP from 95 percent of AWP, the savings that Medicare would achieve by paying the Medicaid Federal Upper Limit amount would now be lower. However, the difference in price between Medicare and Medicaid would still be large, and significant savings would still result if Medicare were able to reimburse albuterol at the Federal Upper Limit amount.

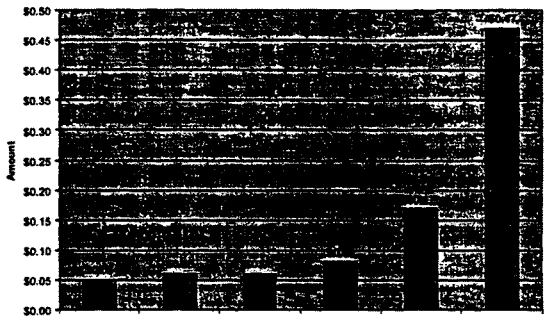
This study was conducted in accordance with the *Quality Standards for Inspections* issued by the Presidents Council on Integrity and Efficiency.

F I N D I N G S

Medicare continues to pay more for albuterol than other payers, costing the program and its beneficiaries millions of dollars a year.

In 2003, Medicare reimbursed $0.47 per mg for albuterol, an amount that was considerably higher than the reimbursement amounts of other Government payers and the prices available to the supplier community. If Medicare were able to base its reimbursement amount for albuterol on prices available to these sources, the program and its beneficiaries could have saved millions of dollars in 2002. Chart 1 below compares the Medicare reimbursement amount to prices available to Medicaid, the supplier community, and VA.

Chart 1: Comparison of Albuterol Prices



Source: VA website, OIG survey of pharmacy prices, 2003 *Red Book*, Medicaid Federal Upper Limit list, and DMERC pricing publications.

Medicare and its beneficiaries would have saved $263 million in 2002 if the program were able to reimburse albuterol at the Medicaid Federal Upper Limit amount.

CMS sets the Medicaid Federal Upper Limit amount for albuterol at $0.17 per mg, compared to $0.47 per mg for Medicare. If Medicare were able to reimburse for albuterol at the Medicaid Federal Upper Limit amount, the program would have saved $263 million in 2002. Approximately $53 million of the savings would have had a direct

impact on Medicare beneficiaries in the form of reduced coinsuran payments.

The Medicare reimbursement amount for albuterol was eight times higher than the median price available to the supplier community.

Data collected from a drug wholesaler and a GPO showed that pharmacies were able to purchase albuterol for substantially less than the Medicare reimbursement amount. In spring 2003, the unit-dose solution form of albuterol was available from these sources at prices ranging from a low of $0.05 per mg to a high of $0.10 per mg. The median price of albuterol at both the wholesaler/distributor and GPO was $0.06 per mg. Medicare's reimbursement amount of $0.47 per mg was nearly eight times more for the same amount of the drug.

Pharmacies were able to acquire albuterol for less than a Medicare beneficiary would pay in coinsurance alone ($0.09 per mg). For example, a beneficiary using a typical monthly supply of albuterol (250 mg) would pay $23.50 in Medicare coinsurance. Through the sources we identified, pharmacies, on average, would pay just $15.00 for the same supply. We did not collect data from pharmacies regarding any additional costs related to providing albuterol to Medicare beneficiaries.

Furthermore, manufacturer-reported WACs published in the *Red Book* also showed that pharmacies were able to purchase albuterol for prices substantially below Medicare. In January 2003, the median WAC reported in the *Red Book* was $0.08 per mg. The *Red Book* defines WAC as manufacturer-quoted list prices to wholesale distributors, not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

Since our last report, the price at which albuterol was available to the supplier community decreased, while the Medicare reimbursement amount remained the same. In 2001, we calculated that the median price of albuterol through wholesaler/distributors and GPOs was $0.08 per mg, 33 percent higher than the 2003 price of $0.06 per mg. In addition, manufacturer-reported WACs also decreased from a median of $0.11 per mg in 2001 to $0.08 in 2003.

If Medicare were able to use prices available to the supplier community as a basis for albuterol reimbursement, the program and its beneficiaries would save millions of dollars a year.

The Medicare reimbursement amount for albuterol was over nine times higher than the median price available to VA.

In 2003, the median Federal Supply Schedule price available to VA for albuterol was $0.05 per mg. In comparison, Medicare reimbursed nine times more ($0.47 per mg) for the same amount of the drug. However, it should be noted that, unlike Medicare, VA purchases drugs for its health care system directly from manufacturers or wholesalers, rather than reimbursing pharmacies for the drug.

Both the VA Federal Supply Schedule price and the Medicare reimbursement amount for albuterol have remained constant since our previous report (*Excessive Medicare Reimbursement for Albuterol)* in 2002 (based on 2001 data). The 2003 VA price, however, was still over 50 percent lower than it was in 1998 ($0.11 per mg), while the Medicare price had not changed during the same 5-year period.

CONCLUSION

Despite numerous attempts by CMS to lower reimbursement amounts for prescription drugs, Medicare still pays a high premium for albuterol. This report is part of a series of reports on albuterol which have consistently found that the published AWPs, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers.

Because of Medicare's reliance on published AWPs, the program's reimbursement remains constant, despite the fact that other purchasers pay significantly less for albuterol than they did several years ago. In addition, Medicare's total reimbursement for albuterol continues to increase substantially each year. Consequently, the Medicare program loses progressively more money every year.

We understand that, unlike most drugs covered by Medicare, albuterol is usually provided by pharmacies rather than administered by physicians. These pharmacies obviously need to make a profit from the products they supply, yet the spread between what Medicare reimburses for albuterol and the price at which suppliers are able to purchase the drug is significant.

Furthermore, we recognize that the VA acts as a purchaser of drugs, while Medicare reimburses pharmacies for the product. However, the fact that one Government agency is able to purchase a drug for one-ninth of Medicare's reimbursement amount is troubling.

Congress has recently passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act). This Act provides for numerous changes in Medicare's reimbursement methodology for drugs covered under Part B, including albuterol. Based on this new Act, Medicare will reimburse albuterol at 80 percent of AWP in 2004. We hope that the data presented in this report is helpful to CMS in determining an appropriate payment amount for the drug beyond 2004.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia Regional Office, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

UPDATE: EXCESSIVE MEDICARE REIMBURSEMENT FOR IPRATROPIUM BROMIDE

Inspector General

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EXECUTIVE SUMMARY

OBJECTIVE

To update data provided in a 2002 report comparing Medicare reimbursement for ipratropium bromide to prices available to Medicaid, the supplier community, and the Department of Veterans Affairs (VA).

BACKGROUND

Ipratropium bromide is an inhalation drug commonly used with a nebulizer to treat patients suffering from chronic bronchitis or emphysema. Prior to 2004, Medicare's reimbursement methodology for ipratropium bromide and other prescription drugs was set forth in section 1842(o) of the Social Security Act, as amended by section 4556 of the Balanced Budget Act of 1997. At the time, reimbursement for a covered drug was set at 95 percent of the drug's average wholesale price (AWP). Recently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 lowered reimbursement for many Part B drugs, including ipratropium bromide. In 2004, Medicare reimbursement for ipratropium bromide will be 80 percent of AWP.

Medicare beneficiaries are responsible for paying a 20 percent coinsurance payment for covered drugs. In calendar year (CY) 2002, Medicare and its beneficiaries paid $594 million for ipratropium bromide, up from $348 million in CY 2000.

Ipratropium bromide is usually provided to Medicare beneficiaries by pharmacies, which then submit claims for reimbursement to Medicare. Medicaid beneficiaries also obtain ipratropium bromide through pharmacies. Pharmacies can purchase drug products through group purchasing organizations (GPOs), wholesalers, and directly from manufacturers. Unlike Medicare and Medicaid, VA provides veterans with drugs purchased directly from manufacturers or wholesalers. There are several purchase options available to VA, including the Federal Supply Schedule, blanket purchase agreements, and VA national contracts.

We obtained Medicare's CY 2003 reimbursement amount for ipratropium bromide. For comparison, we: (1) obtained Medicaid's 2003 reimbursement amount for ipratropium

bromide by reviewing the Federal Upper Limit list. (2) estimated 2003 pharmacy acquisition costs for ipratropium bromide by obtaining pricing information from a national wholesaler/distributor and a GPO, and (3) determined the VA's 2003 payment amount for ipratropium bromide by accessing pricing data available on its website. We also obtained manufacturer-reported wholesale acquisition costs (WACs) from the January 2003 edition of the *Drug Topics Red Book*. We calculated potential savings by multiplying Medicare's 2002 total payments for ipratropium bromide by the percentage difference between the Medicare reimbursement amount and the Medicaid reimbursement amount.

The exact savings estimates presented in this report are for 2002. Because the 2004 reimbursement amount for ipratropium bromide was lowered to 80 percent of AWP from 95 percent of AWP, the savings that Medicare would achieve by paying the Medicaid Federal Upper Limit Amount would now be lower. However, the difference in price between Medicare and Medicaid would still be large, and significant savings would still result if Medicare were able to reimburse ipratropium bromide at the Federal Upper Limit amount.

FINDINGS

Medicare continues to pay more for ipratropium bromide than other payors, costing the program and its beneficiaries millions of dollars a year. In 2003, the Centers for Medicare & Medicaid Services (CMS) set the Medicaid Federal Upper Limit amount for ipratropium bromide at $1.17 per milligram (mg), 65 percent less than the $3.34 that Medicare pays for the same amount of the drug. If Medicare could reimburse for ipratropium bromide at the Medicaid Federal Upper Limit Amount, Medicare and its beneficiaries would have saved $386 million in 2002. Approximately $77 million of the savings would have resulted from reduced coinsurance payments.

Data collected from a drug wholesaler/distributor and a GPO showed that pharmacies were able to purchase ipratropium bromide for substantially less than the Medicare reimbursement amount. In spring 2003, the median price of ipratropium bromide at the wholesaler/distributor was $0.57 per mg, while it was $0.05 higher ($0.62 per mg) at the GPO. Medicare's

reimbursement amount of $3.34 per mg was over five times more for the same amount of the drug. We did not collect data from pharmacies regarding any additional costs related to providing ipratropium bromide to Medicare beneficiaries.

Furthermore, manufacturer-reported WACs published in the *Red Book* also showed that pharmacies were able to purchase ipratropium bromide for prices substantially below the Medicare reimbursement amount. In January 2003, the median WAC reported in the *Red Book* was $1.01 per mg.

If Medicare were able to use prices available to the supplier community as a basis for ipratropium bromide reimbursement, the program and its beneficiaries would save millions of dollars a year.

Since our 2002 report, which was based on 2001 data, the price at which ipratropium bromide was available to the supplier community had decreased, while the Medicare reimbursement amount had remained the same. In 2001, we calculated that the median price of ipratropium bromide through wholesaler/distributors and GPOs was $0.82 per mg, substantially higher than 2003 prices. In addition, manufacturer-reported WACs also decreased, from a median of $1.20 per mg in 2001 to $1.01 in 2003.

The median Federal Supply Schedule price available to VA for ipratropium bromide was $0.39 per mg. In comparison, Medicare reimbursed 8 times more ($0.47 per mg) for the same amount of the drug in 2003. However, it should be noted that, unlike Medicare, VA purchases drugs for its health care system directly from manufacturers or wholesalers, rather than reimbursing pharmacies for the drug.

The VA price for ipratropium bromide has decreased substantially since our previous report, while Medicare's price has remained constant. The VA price has fallen from $0.66 per mg in 2001 to $0.39 per mg in 2003 (in 1998, the VA price was even higher at $1.29 per mg).

CONCLUSION

Despite numerous attempts by CMS to lower reimbursement amounts for prescription drugs, Medicare still pays a high

premium for ipratropium bromide. This report is part of a series of reports on ipratropium bromide that have consistently found that the published average wholesale prices, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers.

Because of Medicare's reliance on published average wholesale prices, the program's reimbursement remains constant, despite the fact that other purchasers pay significantly less for ipratropium bromide than they did several years ago. In addition, Medicare's total reimbursement for ipratropium bromide continues to increase substantially each year. Consequently, the Medicare program loses progressively more money every year.

We understand that, unlike most drugs covered by Medicare, ipratropium bromide is usually provided by pharmacies rather than administered by physicians. These pharmacies obviously need to make a profit from the products they supply, yet the spread between what Medicare reimburses for ipratropium bromide and the price at which suppliers are able to purchase the drug is significant.

Furthermore, we recognize that the VA acts as a purchaser of drugs while Medicare reimburses pharmacies for the product. However, the fact that one Government agency is able to purchase a drug for one-eighth of Medicare's reimbursement amount is disconcerting.

Congress has recently passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act). This Act provides for numerous changes in Medicare's reimbursement methodology for drugs covered under Part B, including ipratropium bromide. Based on the new Act, Medicare will reimburse ipratropium bromide at 80 percent of AWP in 2004. We hope that the data presented in this report is helpful to CMS in determining an appropriate payment amount for the drug beyond 2004.

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INTRODUCTION

OBJECTIVE

To update data provided in a 2002 report comparing Medicare reimbursement for ipratropium bromide to prices available to Medicaid, the supplier community, and the Department of Veterans Affairs (VA).

BACKGROUND

Medicare Coverage of Ipratropium Bromide

Currently, Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, Medicare Part B will cover drugs that are necessary for the effective use of durable medical equipment. One such product, ipratropium bromide, is an inhalation solution commonly used with a nebulizer to treat patients suffering from chronic bronchitis or emphysema. Ipratropium bromide is typically provided to Medicare beneficiaries by pharmacies.

Medicare Reimbursement of Ipratropium Bromide

The Centers for Medicare & Medicaid Services (CMS) contracts with four companies, known as durable medical equipment regional carriers (DMERCs), to process and reimburse medical equipment and supply claims, including ipratropium bromide. Each DMERC is responsible for determining the reimbursement amount for ipratropium bromide in their respective region, based on Medicare's reimbursement methodology.

Prior to 2004, Medicare=s reimbursement methodology for ipratropium bromide and other prescription drugs was set forth in section 1842(o) of the Social Security Act, as amended by section 4556 of the Balanced Budget Act of 1997. At the time, the Social Security Act stated that reimbursement for a covered drug was to be set at 95 percent of the drug's average wholesale price (AWP). CMS directed carriers to obtain average wholesale price data from the *Drug Topics Red Book* or similar pricing publications used by the pharmaceutical industry. In 2003, each DMERC reimbursed $3.34 per milligram (mg) for ipratropium bromide.

Recently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act) lowered payments for many

Part B drugs in 2004 and beyond by revising Section 1842(o) of the Social Security Act. According to the new Act, the payment for a drug contained in the table, "Medicare Part B Drugs in Most Recent GAO and OIG Studies" published in the Federal Register (68 FR 50445) will be the percentage of the AWP indicated in the table. If the percentage in the table is less than 80 percent, then the percentage applied to reimbursement will be 80 percent. Based on the data presented in this table, in 2004, Medicare reimbursement for ipratropium bromide will be 80 percent of AWP.

Medicare paid $594 million for ipratropium bromide in calendar year (CY) 2002, up from $348 million in 2000. This total represents 7 percent of the $8.2 billion Medicare paid for all prescription drugs in 2002. Medicare payments include both the 80 percent that Medicare reimburses, and the 20 percent coinsurance payment for which beneficiaries are responsible.

CMS Use of Office of Inspector General (OIG) Data

In a proposed rule published in the Federal Register on August 20, 2003 CMS states, "If the OIG performs a new market analysis, we expect to incorporate this information into the Medicare payment limits...Initially, we would use the market analyses available to us from GAO and OIG studies to transition widely available market prices into the Medicare payments." Because of the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the proposed rule did not take effect. However, according to the Act, new pricing data may be useful for setting Medicare reimbursement amounts in the future.

Recent Attempts to Lower Medicare Reimbursment

Inherent Reasonableness. Section 4316 of the Balanced Budget Act of 1997 allows CMS to diverge from Medicare=s statutorily-defined payment method if the method results in payment amounts that are not inherently reasonable. In late 1998, CMS attempted to use this authority to lower what it considered excessive reimbursement for several items. One of these items was albuterol, an inhalation drug similar to ipratropium bromide, which was targeted for an 11 percent fee reduction. However, the lower prices were never implemented, as Congress suspended the use of CMS's inherent reasonableness authority through a provision of the Medicare, Medicaid, and SCHIP

Balanced Budget Refinement Act of 1999. This provision required the General Accounting Office (GAO) to complete a study on the potential effects of using inherent reasonableness measures before CMS could invoke the authority. The GAO report, issued in July 2000, found that inherent reasonableness reductions for some items were justified. However, GAO questioned the methodology that the carriers used in their collection of pricing data for albuterol.

On February 11, 2003, a new interim final rule for the application of inherent reasonableness went into effect. According to the regulation, payment amounts may be considered unreasonable based on a number of criteria, including: (1) payment amounts are grossly excessive when compared to other purchasers in the same locality, or (2) payment amounts are grossly excessive when compared to acquisition costs. According to the regulation, a payment amount is considered grossly excessive if a reduction of at least 15 percent is required to produce a realistic and equitable reimbursement amount.

Competitive Bidding. CMS included ipratropium bromide and several other inhalation drugs in a competitive bidding project in the San Antonio, Texas area that sought to use market forces to set accurate prices for durable medical equipment and related supplies. In November 2000, CMS announced the selection of durable medical equipment suppliers who had submitted competitive bids for the included items. New prices for these items went into effect in the bidding area on February 1, 2001. The new reimbursement amount for ipratropium bromide set by the competitive bidding process was $2.55 per mg, approximately 24 percent below the usual Medicare amount. CMS hopes to use the results from these demonstrations more generally in the Medicare program.

Medicaid Reimbursement of Ipratropium Bromide

As with Medicare, Medicaid beneficiaries typically receive ipratropium bromide from pharmacies. Pharmacies are then reimbursed by the Medicaid program.

Federal regulations require that each State Medicaid agency's reimbursement for a drug not exceed the lower of its estimated acquisition cost plus a reasonable dispensing fee, or the provider's usual and customary charge to the public for the

drug. CMS allows States flexibility in defining estimated acquisition cost. Like Medicare, most States base their calculation of estimated acquisition cost on a drug's AWP discounted by a certain percentage. This discount ranged from 5 percent to 15 percent in the year 2001. A few States use published wholesale acquisition costs (WACs) plus a percentage markup rather than average wholesale prices when calculating estimated acquisition cost.

For certain drugs, States also use the Federal Upper Limit and State Maximum Allowable Cost programs in determining reimbursement amounts. **According to CMS, the purpose of Federal Upper Limits is to ensure that the Federal Government acts as a prudent purchaser by taking advantage of current market prices for multiple-source products. CMS has established Federal Upper Limit amounts for over 400 drugs.** In addition, more than half of the States have implemented a Maximum Allowable Cost program in order to reduce reimbursement amounts for certain drugs. Individual States determine the types of drugs that are included in their Maximum Allowable Cost program, and the method by which the Maximum Allowable Cost for a drug is calculated.

Acquisition Sources of Ipratropium Bromide for Pharmacies

Pharmacies can purchase drug products through several sources, including group purchasing organizations (GPOs), wholesalers/distributors, and directly from manufacturers. GPOs provide their members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or from a wholesaler/distributor who accepts GPO's price. Wholesalers/distributors purchase large volumes of drugs from manufacturers and sell them directly to physicians, suppliers, and pharmacies.

VA Payments for Ipratropium Bromide

Unlike Medicare and Medicaid, VA purchases drugs for its health care system directly from manufacturers or wholesalers. There are several options available to VA when purchasing drugs, with the most common being the Federal Supply Schedule. The Federal Supply Schedule provides agencies like VA with a simple process for purchasing commonly-used products in any quantity while still obtaining the discounts

associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide supplies over a given period of time at the Federal Supply Schedule price. However, VA is sometimes able to negotiate prices lower than Federal Supply Schedule amounts through other avenues, such as blanket purchase agreements and VA national contracts.

Related Work on Ipratropium Bromide

OIG has previously found that Medicare's usual reimbursement amount for ipratropium bromide (based on AWP) is excessive. In our report *Excessive Medicare Reimbursement for Ipratropium Bromide* (March 2002), we calculated that the Medicare reimbursement amount for ipratropium bromide in 2000 was more than 5 times higher than the VA purchase price and over 4 times the actual acquisition cost to pharmacies. According to our findings, excessive reimbursement for ipratropium bromide alone was costing Medicare and its beneficiaries up to $279 million per year.

In addition to OIG, GAO has also found that Medicare reimbursement for ipratropium bromide is excessive. In its September 2001 report, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs* (GAO-01-1118), GAO found that the average widely available price to pharmacies for ipratropium bromide was 78 percent below the published average wholesale price of the drug.

METHODOLOGY

We reviewed laws and regulations concerning Medicare drug reimbursement. We accessed CMS's Part B Extract Summary System to determine Medicare's total payments for ipratropium bromide in CY 2002. We obtained Medicare's CY 2003 reimbursement amounts for ipratropium bromide from all 4 DMERCs.

To determine Medicaid's 2003 reimbursement amount for ipratropium bromide, we obtained pricing information for the drug from the Medicaid Federal Upper Limit list.

To estimate pharmacy acquisition costs for ipratropium bromide, we obtained spring 2003 pricing information for the drug from a national wholesaler/distributor and from a GPO. As an additional estimate of pharmacy acquisition costs, we also

obtained manufacturer-reported WACs from the January 2003 edition of the *Red Book*. The *Red Book* defines WACs as manufacturer-quoted list prices to wholesale distributors. These prices are not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

To determine the VA's 2003 payment amounts for ipratropium bromide, we accessed a file on their website that lists prices available to the agency through the Federal Supply Schedule.

To calculate potential Medicare savings based on Medicaid, we compared Medicare's reimbursement amount for 1 mg of ipratropium bromide to the Medicaid Federal Upper Limit amount. We determined the percentage difference in price by subtracting Medicaid's price from Medicare's price and then dividing the result by the Medicare price. This percentage indicates how much Medicare would save if the program could base reimbursement on the Medicaid Federal Upper Limit amount. We then multiplied the percentage difference by the total amount Medicare paid for ipratropium bromide in 2002 to calculate dollar savings.

The exact savings estimates presented in this report are for 2002. Because the 2004 reimbursement amount for ipratropium bromide was lowered to 80 percent of AWP from 95 percent of AWP, the savings that Medicare would achieve by paying the Medicaid Federal Upper Limit amount would now be lower. However, the difference in price between Medicare and Medicaid would still be large, and significant savings would still result if Medicare were able to reimburse ipratropium bromide at the Federal Upper Limit amount.

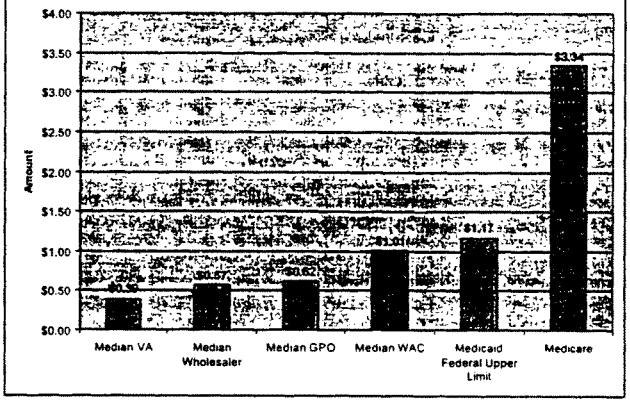
This study was conducted in accordance with the *Quality Standards for Inspections* issued by the Presidents Council on Integrity and Efficiency.

F I N D I N G S

Medicare continues to pay more for ipratropium bromide than other payors, costing the program and its beneficiaries millions of dollars a year.

In 2003, Medicare reimbursed $3.34 per mg for ipratropium bromide, an amount that was considerably higher than the reimbursement amounts of other Government payors and the prices available to the supplier community. If Medicare were able to base its reimbursement amount for ipratropium bromide on prices available to these sources, the program and its beneficiaries could have saved millions of dollars in 2002. Chart 1 below compares the Medicare reimbursement amount to prices available to Medicaid, the supplier community, and VA.

Chart 1: Comparison of Ipratropium Bromide Prices



Source: VA website, OIG survey of pharmacy prices, 2003 *Red Book*, Medicaid Federal Upper Limit list, and DMERC pricing publications.

Medicare and its beneficiaries would have saved $386 million in 2002 if the program were able to reimburse ipratropium bromide at the Medicaid Federal Upper Limit amount.

CMS sets the Medicaid Federal Upper Limit amount for ipratropium bromide at $1.17 per mg, 65 percent less than Medicare ($3.34 per mg) for the same amount of the drug. If Medicare were able to reimburse for ipratropium bromide at the

Medicaid Federal Upper Limit amount, the program would have saved $386 million in 2002. Approximately $77 million of the savings would have had a direct impact on Medicare beneficiaries through reduced coinsurance payments.

The Medicare reimbursement amount for ipratropium bromide was five times higher than the median price available to the supplier community.

Data collected from a drug wholesaler/distributor and a GPO showed that pharmacies were able to purchase ipratropium bromide for substantially less than the Medicare reimbursement amount. In spring 2003, generic versions of ipratropium bromide were available from these sources at prices ranging from a low of $0.40 per mg to a high of $0.79 per mg. **The median price of ipratropium bromide at the wholesaler/distributor was $0.57 per mg**, while it was $0.05 higher ($0.62 per mg) at GPO. **Medicare's reimbursement amount of $3.34 per mg was over five times more for the same amount of the drug.**

Pharmacies were able to acquire ipratropium bromide for less than a Medicare beneficiary would pay in coinsurance alone ($0.67 per mg). For example, a beneficiary, using a typical monthly supply of ipratropium bromide (50 mg), would pay $33.40 in Medicare coinsurance. Through the sources we identified, pharmacies, on average, would pay between $28.50 and $31.00 for the same supply. We did not collect data from pharmacies regarding any additional costs related to providing ipratropium bromide to Medicare beneficiaries.

Furthermore, manufacturer-reported WACs published in the *Red Book* also showed that pharmacies were able to purchase ipratropium bromide for prices substantially below the Medicare reimbursement amount. In January 2003, the median WAC reported in the *Red Book* was $1.01 per mg. The *Red Book* defines WAC as manufacturer-quoted list prices to wholesale distributors, not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

Since our last report, the price at which ipratropium bromide was available to the supplier community decreased, while the Medicare reimbursement amount remained the same. In 2001, we calculated that the median price of ipratropium bromide through wholesaler/distributors and GPOs was $0.82 per mg,

substantially higher than 2003 prices. In addition, manufacturer-reported WACs had also decreased from a median of $1.20 per mg in 2001 to $1.01 in 2003.

If Medicare were able to use prices available to the supplier community as a basis for ipratropium bromide reimbursement, the program and its beneficiaries would save millions of dollars a year.

The Medicare reimbursement amount for ipratropium bromide was eight times higher than the median price available to the VA. In 2003, the median Federal Supply Schedule price available to VA for ipratropium bromide was $0.39 per mg. In comparison, Medicare reimbursed eight times more ($3.34 per mg) for the same amount of the drug. However, it should be noted that, unlike Medicare, VA purchases drugs for its health care system directly from manufacturers or wholesalers, rather than reimbursing pharmacies for the drug.

The VA price for ipratropium bromide decreased substantially since our previous report, while Medicare's price has remained constant. The VA price has fallen from $0.66 per mg in 2001 to the 2003 price of $0.39 per mg (in 1998, the VA price was even higher at $1.29 per mg).

CONCLUSION

Despite numerous attempts by CMS to lower reimbursement amounts for prescription drugs, Medicare still pays a high premium for ipratropium bromide. This report is part of a series of reports on ipratropium bromide that have consistently found **that the published AWPs, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers.**

Because of Medicare's reliance on published AWPs, the program's reimbursement remains constant, despite the fact that other purchasers pay significantly less for ipratropium bromide than they did several years ago. In addition, Medicare's total reimbursement for ipratropium bromide continues to increase substantially each year. Consequently, the Medicare program loses progressively more money every year.

We understand that, unlike most drugs covered by Medicare, ipratropium bromide is provided by pharmacies rather than administered by physicians. **These pharmacies obviously need to make a profit from the products they supply, yet the spread between what Medicare reimburses for ipratropium bromide and the price that suppliers pay for the drug is significant.**

Furthermore, we recognize that the VA acts as a purchaser of drugs while Medicare reimburses pharmacies for the product. However, the fact that one Government agency is able to purchase a drug for one-eighth of Medicare's reimbursement amount is disconcerting.

Congress has recently passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act). This Act provides for numerous changes in Medicare's reimbursement methodology for drugs covered under Part B, including ipratropium bromide. Based on the new Act, Medicare will reimburse ipratropium bromide at 80 percent of AWP in 2004. We hope that the data presented in this report is helpful to CMS in determining an appropriate payment amount for the drug beyond 2004.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A Vito. Regional Inspector General for Evaluation and Inspections in the Philadelphia Regional Office, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

DEC 7 2004

TO: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

FROM: Daniel R. Levinson Daniel R. Levinson
Acting Inspector General

SUBJECT: OIG Final Report: "Addition of Qualified Drugs to the Medicaid Federal Upper Limit List," OEI-03-04-00320

Attached for your review is our final inspection report that (1) determined the length of time it took the Centers for Medicare & Medicaid Services (CMS) to include drugs on the Federal upper limit list once the drugs met the statutory and regulatory criteria, and (2) calculated the losses that may have resulted due to drugs not being added to the Federal upper limit list in a timely manner. This inspection was requested by the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations.

Statutory and regulatory criteria require CMS to include a drug on the Federal upper limit list if: (1) at least three versions of the drug are rated as therapeutically equivalent by the Food and Drug Administration, and (2) the drug has at least three suppliers listed in current editions of national compendia. We found that CMS does not consistently add qualified drugs to the Federal upper limit list in a timely manner. Of the 252 first-time generic drugs approved between January 2001 and December 2003, 109 products met the statutory and regulatory criteria for inclusion on the Federal upper limit list; however, only 25 were actually added. For the 25 drugs that were added, CMS took an average of 36 weeks to place the products on the Federal upper limit list once the drugs were qualified for inclusion. As of July 15, 2004, the 84 drugs that were not added had been qualified for an average of 55 weeks. Qualified drugs not being added to the list in a timely manner cost the Medicaid program an estimated $167 million between 2001 and 2003. We recommended that CMS establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits. The CMS concurred with intent of our recommendation and stated that it had taken steps to support this objective. However, CMS did not concur with the OIG's methodology and the subsequent savings estimates.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions about this report, please do not hesitate to call me or one of your staff may contact Tricia Davis, Director, Medicare and Medicaid Branch, at (410) 786-3143 or through email [Tricia.Davis@oig.hhs.gov]. To facilitate identification, please refer to report number OEI-03-04-00320 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ADDITION OF QUALIFIED DRUGS TO THE MEDICAID FEDERAL UPPER LIMIT LIST

Inspector General

December 2004
OEI-03-04-00320

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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ABSTRACT

The objectives of this study were to (1) determine the length of time it took the Centers for Medicare & Medicaid Services (CMS) to include drugs on the Federal upper limit list once the drugs met the statutory and regulatory criteria, and (2) calculate the losses that may have resulted due to drugs not being added to the list in a timely manner. We found that CMS does not consistently add qualified drugs to the Federal upper limit list in a timely manner. Of the 252 first-time generic drugs approved between January 2001 and December 2003, 109 products met the statutory and regulatory criteria for inclusion; however, only 25 were actually added. For the 25 drugs that were added, CMS took an average of 36 weeks to place the products on the list once the drugs were qualified for inclusion. As of July 15, 2004, the 84 drugs that were not added had been qualified for an average of 55 weeks. Qualified drugs not being added to the list in a timely manner cost the Medicaid program an estimated $167 million between 2001 and 2003. We recommend that CMS establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits.

EXECUTIVE SUMMARY

OBJECTIVE

The objectives of this study were to: (1) determine the length of time it took the Centers for Medicare & Medicaid Services (CMS) to include drugs on the Federal upper limit list once the drugs met the statutory and regulatory criteria, and (2) calculate the losses that may have resulted due to drugs not being added to the list in a timely manner.

BACKGROUND

Statutory and regulatory criteria require CMS to include a drug on the Federal upper limit list if: (1) at least three versions of the drug are rated as therapeutically equivalent by the Food and Drug Administration, and (2) the drug has at least three suppliers listed in current editions of national compendia. However, according to CMS staff, the agency will only establish a Federal upper limit if it would lead to cost savings. Neither the regulation nor the statute set timeliness guidelines for adding qualified drugs to the Federal upper limit list.

The Federal upper limit amount for a drug is set at 150 percent of the published price for the least costly therapeutically equivalent product plus a reasonable dispensing fee. The CMS publishes the list of drug products with Federal upper limits in the *State Medicaid Manual* and on its Web site.

In February 2004, the Office of Inspector General (OIG) issued a report entitled *Omission of Drugs from the Federal Upper Limit List in 2001* (OEI-03-02-00670). We found that 90 drug products were not included on the Federal upper limit list in 2001 despite meeting the criteria established by Federal laws and regulations. Medicaid could have saved $123 million in 2001 by adding 55 of the 90 drug products to the Federal upper limit list. In June 2004, the OIG received a letter from the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations requesting that we provide further analysis of CMS's oversight of the Federal upper limit list.

We developed a list of first-time generic drug products approved by the Food and Drug Administration between January 2001 and December 2003. We then determined if and when each of these drug products qualified for inclusion on the Federal upper limit list according to statutory and regulatory criteria. For each calendar quarter that a

qualified drug was not included on the Federal upper limit list, we calculated potential Medicaid losses by: (1) subtracting the potential Federal upper limit amount from the average Medicaid price, and (2) multiplying the price difference by Medicaid utilization. We then aggregated the losses for each quarter to determine the overall potential losses to Medicaid caused by qualified drugs not being added to the Federal upper limit list in a timely manner.

FINDINGS

The CMS does not consistently add qualified drugs to the Federal upper limit list in a timely manner. The CMS did not consistently add qualified drugs to the Federal upper limit list in a timely manner during the period under review. Of the 252 first-time generic drugs approved between 2001 and 2003, 109 products met the statutory and regulatory criteria for inclusion on the Federal upper limit list. While 25 of the 109 drugs had been added to the list by July 15, 2004, very few were included in a timely manner. As of that date, 84 of the 109 drugs we reviewed had not been added by CMS.

For the 25 drugs that were added, CMS took an average of 36 weeks to place the products on the Federal upper limit list once they met all requirements for inclusion. Only 3 of the 25 drugs were included on the list at the time they qualified. Three of the drugs were added more than 1 year after they first became eligible for inclusion.

Eighty-four drugs approved between 2001 and 2003 are currently qualified for the Federal upper limit list but have not been added by CMS. As of July 15, 2004, these 84 drugs had been qualified for an average of 55 weeks yet were still not included on the Federal upper limit list. Twenty-nine of these drugs had been qualified for at least 80 weeks (approximately 1 year and 7 months).

Medicaid lost an estimated $167 million between 2001 and 2003 because qualified drugs were not added to the Federal upper limit list in a timely manner. Failure to add qualified drugs in a timely manner cost the Medicaid program an estimated $167 million (both Federal and State shares) between 2001 and 2003. Eighty-five percent ($143 million) of the estimated losses were attributable to lags in adding just 8 drugs.

The product with the highest loss figure, Fluoxetine 20 mg capsules (brand name Prozac), illustrates the effect of not adding drugs to the Federal upper limit list in a timely manner. The two-quarter lag in

adding the 20 mg dosage size of Fluoxetine capsules cost Medicaid an estimated $57 million.

In the next several months, new generic versions of several other major brand name drugs may become qualified for the Federal upper limit list. For example, Gabapentin (brand-name Neurontin), Oxycodone Hydrochloride (brand-name Oxycontin), and Paroxetine Hydrochloride (brand-name Paxil) have recently come off patent and, therefore, now have available generic versions. These 3 drugs accounted for a total of $5.3 billion in retail sales in 2003. As was the case with Fluoxetine, not adding these three drugs in a timely matter could cause substantial losses to Medicaid.

RECOMMENDATION

The CMS should establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits.

We believe that all qualified drugs should be included on the Federal upper limit list in a timely manner. The findings of both this report and our February 2004 report show that lags in adding qualified drugs are costing the Medicaid program substantial amounts. However, we are aware of the difficulties CMS faces in managing the Federal upper limit list. As CMS noted in their comments to the previous report, "pharmaceutical pricing and product information changes almost daily." While we continue to believe that all qualified drugs should be added to the Federal upper limit list in a timely manner, another option would be for CMS to consider focusing its resources on high-volume brand name drugs that are coming off patent. As our findings show, a large portion of the estimated losses can be attributed to lags in adding a small number of major drugs. If CMS makes a concerted effort to keep track of FDA ratings, number of suppliers, and published prices for these high-volume products, significant lags in placing qualified drugs on the Federal upper limit list could be avoided, thereby saving Medicaid millions of dollars per year.

Agency Comments

The CMS concurred with intent of our recommendation and stated that it had taken steps to support this objective. However, CMS did not concur with the OIG's methodology and the subsequent savings estimates.

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INTRODUCTION

OBJECTIVE

The objectives of this study were to: (1) determine the length of time it took the Centers for Medicare & Medicaid Services (CMS) to include drugs on the Federal upper limit list once the drugs met the statutory and regulatory criteria, and (2) calculate the losses that may have resulted due to drugs not being added to the list in a timely manner.

BACKGROUND

Medicaid Program

Medicaid is a jointly funded, Federal and State health insurance program for certain low income and medically needy people. Individual States establish eligibility requirements, benefits packages, and payment rates for their Medicaid programs under broad Federal standards administered by CMS. Federal regulations mandate that States provide basic services to beneficiaries in order to receive Federal matching funds. States may also receive Federal funding if they provide other optional services as well. One of the most commonly covered optional services that States provide is prescription drug coverage. All 50 States and the District of Columbia currently offer prescription drug coverage under the Medicaid program. In calendar year (CY) 2003, CMS estimates that Medicaid payments for prescription drugs totaled over $31 billion.[1]

Medicaid Drug Reimbursement Methodology

Each State is required to submit a Medicaid State plan to CMS describing its payment methodology for covered drugs. Federal regulations require, with certain exceptions, that each State's reimbursement for a drug not exceed the lower of its estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drug. States have implemented dispensing fees that range from $1.89 to $11.46 per prescription.

The CMS allows States flexibility to define estimated acquisition cost. Most States base their calculation of estimated acquisition cost on a drug's average wholesale price (AWP) discounted by a certain percentage. In CY 2003, this discount ranged from 5 percent to

[1] This amount includes both the Federal and State shares of payments. It does not include rebates collected under the Medicaid Drug Rebate program.

50 percent of AWP, sometimes depending on whether the drug was brand name or generic or on the type of pharmacy from which the drug was purchased. A small number of States use wholesale acquisition costs plus a percentage markup rather than or in addition to discounted AWPs when determining estimated acquisition cost.

For certain drugs, States also use the Federal upper limit and/or State maximum allowable cost programs in determining reimbursement amounts. The CMS has established Federal upper limit amounts for over 400 drugs. In addition, numerous States have implemented a maximum allowable cost program to limit reimbursement amounts for certain drugs. Individual States determine the types of drugs that are included in their maximum allowable cost program and the method by which the maximum allowable cost for a drug is calculated.

In summary, States use a variety of different pricing mechanisms when setting reimbursement amounts. In most cases, States reimburse for a drug at the lower of its estimated acquisition cost, the Federal upper limit amount, the State maximum allowable cost, or the provider's usual and customary charge, plus a reasonable dispensing fee.

Federal Upper Limit List

Pursuant to 42 CFR § 447.332, CMS is to establish Federal upper limits in order to reduce the amount that Medicaid reimburses for multiple-source drugs. According to CMS, Federal upper limits were put in place to ensure that the Federal Government acts as a prudent payer by taking advantage of current market prices for multiple-source drugs. Federal regulation (42 CFR § 447.301) defines a multiple-source drug as "... a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name." In other words, a multiple-source drug is a drug that has more than one brand or generic version.

Originally, under 42 CFR § 447.332, CMS was to establish a Federal upper limit amount for a drug when: (1) all versions of a drug had been rated as therapeutically equivalent by the Food and Drug Administration (FDA), and (2) at least three suppliers of the drug were listed in current editions (or updates) of published compendia of cost information for drugs available for sale nationally. The Omnibus Budget Reconciliation Act of 1990 changed the criteria originally established by the regulation by requiring a Federal upper limit when three or more versions of a drug had been rated therapeutically and pharmaceutically equivalent by FDA, regardless of the ratings of other

versions. The FDA identifies equivalent drugs in its publication *Approved Drug Products with Therapeutic Equivalence Evaluations.* According to FDA, drugs that are therapeutically equivalent are designated as "A-rated." Neither the regulation nor the statute set timeliness guidelines for adding qualified drugs to the Federal upper limit list.

Federal regulation (42 CFR § 447.332) sets the Federal upper limit amount at 150 percent of the published price for the least costly therapeutically equivalent product that can be purchased in quantities of 100 tablets or capsules plus a reasonable dispensing fee. If the drug is not typically available in quantities of 100 or if the drug is a liquid, the Federal upper limit amount is based on a commonly listed size.

The CMS applies an additional standard in determining which drugs should be included on the Federal upper limit list. According to CMS staff, only drugs that could potentially lead to savings should be subject to Federal upper limits. Therefore, if a drug does not have a published price that when multiplied by 150 percent is lower than the AWP (upon which reimbursement is typically based), CMS does not include the product on the Federal upper limit list.[2]

In summary, statutory and regulatory criteria require that CMS include a drug on the Federal upper limit list if: (1) at least three versions of the drug are rated as therapeutically equivalent by FDA, and (2) the drug has at least three suppliers listed in national compendia. The CMS uses an additional standard that requires that the Federal upper limit amount would potentially lead to cost savings.

The CMS publishes a list of drugs for which Federal upper limits are established in the *State Medicaid Manual* and on its Web site.[3] Any revisions to the Federal upper limit list are typically noted in Medicaid program memoranda and on the CMS Web site. The CMS establishes an upper limit for specific forms and strengths for each multiple-source drug on the list. The Federal upper limit list also provides the source of the pricing information used to calculate the upper limit amount for each drug.

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[2] In our previous report, we disagreed with CMS about the usage of this additional standard. States reimburse for a drug at the lower of its estimated acquisition cost, the Federal upper limit amount, the State maximum allowable cost, or the provider's usual and customary charge. Therefore, States would only pay the Federal upper limit amount for a drug if it were the lowest of these options.

[3] Federal upper limit information is located at www.cms.gov/medicaid/drugs/drug10.asp.

Related Work by the Office of Inspector General

In February 2004, the Office of Inspector General (OIG) issued a report entitled *Omission of Drugs from the Federal Upper Limit List in 2001* (OEI-03-02-00670). The OIG found that 90 drug products were not included on the Federal upper limit list in 2001 despite meeting the criteria established by Federal laws and regulations. Medicaid could have saved $123 million in 2001 by adding 55 of the 90 drug products to the Federal upper limit list. The remaining 35 drug products met the criteria for inclusion on the Federal upper limit list, but did not have any associated savings. The OIG recommended that CMS take steps to ensure that all drugs meeting the criteria set forth in Federal laws and regulations are included on the Federal upper limit list.

Inspection Requested by Congressional Subcommittee

On June 29, 2004, the OIG received a letter from the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. The letter expressed concern with the amount of time CMS takes to add new generic products to the Federal upper limit list, and requested that the OIG provide an analysis of the issue. Among other things, we were asked to determine the amount of time it takes for qualified drugs to be included on the Federal upper limit list, and the subsequent cost to the program of drugs not being added in a timely manner.

METHODOLOGY

Determining Generic Drugs Approved From 2001 to 2003

We developed a list of all first-time generic drugs approved by FDA between January 2001 and December 2003. According to FDA, a first-time generic is a drug that has never been approved as a generic before and is, therefore, a new generic to the marketplace. After deducting certain over-the-counter and physician-administered products, we created a list of 252 first-time generic drugs approved between 2001 and 2003.

Determining If Approved Drugs Meet Federal Upper Limit Criteria

The CMS is required to include on the Federal upper limit list all prescription drugs that have three versions rated therapeutically equivalent by FDA and three suppliers listed in national compendia. For each of the 252 first-time generic drugs approved between 2001 and 2003, we determined if three therapeutically equivalent versions were listed by FDA, and, if so, the date that the third therapeutically equivalent version was approved. To determine if these drugs also met

the three-supplier criterion, we obtained data from the *Red Book™ for Windows®* CD-ROM (a national compendium). For each of the drugs with three A-rated versions, we determined the first subsequent quarter (i.e., the first quarter after a third A-rated version was approved) that three suppliers were listed in the *Red Book*. In total, 109 of the first-time generics approved in 2001, 2002, or 2003 met both criteria for inclusion on the Federal upper limit list. For the remainder of this report, the phrase "reviewed drugs" will refer to these 109 products.

Determining If Drugs were on the Federal Upper Limit List

We obtained the most recent Federal upper limit list from the CMS Web site. We also obtained from the Web site all changes to the list between November 22, 2000, and July 15, 2004, and the date that the Federal upper limit prices for a drug were to go into effect. We determined if any of the 109 reviewed drugs were on the Federal upper limit list, and, if so, the date they were added. For any drugs that were included on the list, we determined the amount of time between when they became qualified for the Federal upper limit list and the date they were actually added.[4]

Estimating Potential Losses

For each quarter that a drug was qualified for but not included on the Federal upper limit list, we compared the potential Federal upper limit amount (150 percent of the lowest published price) to the average Medicaid reimbursement amount for the drug that quarter.[5] If the result was a positive number (i.e., the Federal upper limit amount was less than the average Medicaid amount), we multiplied it by the total number of units reimbursed by Medicaid that quarter. The product of this multiplication shows the estimated losses Medicaid had that quarter due to the drug(s) not being included on the Federal upper limit list. We aggregated the quarterly totals to determine the total estimated losses to the program between 2001 and 2003.

A more complete discussion of our methodology is presented in Appendix C.

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[4] For the purposes of this report, the term "qualified" refers to the date that a drug met the statutory and regulatory criteria for inclusion on the Federal upper limit list.

[5] Because the Federal upper limit amount is calculated by multiplying the lowest published price for a drug by 150 percent, there are instances when this amount would be higher than the reimbursement amount based on discounted AWP. In order to limit the time required to do this analysis, we only calculated estimated losses for drugs that may have actually led to losses (e.g., had at least one published price that when multiplied by 150 percent was below AWP).

FINDINGS

The CMS does not consistently add qualified drugs to the Federal upper limit list in a timely manner

The CMS did not consistently add qualified drugs to the Federal upper limit list in a timely manner during the period under review. Of the 252 first-time generic drugs approved between 2001 and 2003, 109 met the statutory and regulatory criteria for inclusion on the list. While 25 of the 109 drugs had been added to the Federal upper limit list by July 15, 2004, very few of the 25 were included in a timely manner. As of that date, an additional 84 of the 109 reviewed drugs had not been added by CMS. A list of the 109 drugs is presented in Appendix A.

The 25 drugs that were included on the Federal upper limit list had been qualified for an average of 36 weeks before being added by CMS. For the 25 drugs that were added, CMS took an average of 36 weeks to place the products on the Federal upper limit list once the drugs met the statutory and regulatory criteria for inclusion. Only 3 of the 25 drugs were included on the list at the time they first became qualified. Table 1 below presents a summary of the time CMS took to include the 25 drugs.

The longest period between when a drug initially qualified and when it was actually added to the Federal upper limit list was for two versions of Metformin Hydrochloride, a drug used to treat Type II diabetes. The third A-rated versions of Metformin Hydrochloride were approved in January of 2002, and the 500 mg and 850 mg dosage sizes had three suppliers as of April 1, 2002. However, CMS did not add the drugs until March 18, 2004, or 102 weeks after the drugs first became qualified.

Table 1: Amount of Time Between When a Drug Qualified and When a Drug Was Added

Number of Weeks Qualified	Number of Drugs
0 weeks	3
20 weeks	2
23 weeks	5
35 weeks	8
36 weeks	1
48 weeks	3
More than 52 weeks	3
Average 36 Weeks	**25 Drugs**

Sources: FDA Web site, *Red Book*, Federal upper limit list

In addition to the statutory and regulatory criteria, CMS applies an additional standard requiring that a Federal upper limit amount would potentially lead to cost savings before a drug is included on the list. Using CMS's additional standard, these 25 drugs were still not added to the Federal upper limit list in a timely manner. On average, the 25 drugs were included on the Federal upper limit list 32 weeks after they may have first led to cost savings (i.e., met CMS's additional standard).

Eighty-four drugs that were not added to the Federal Upper Limit list had been qualified for an average of 55 weeks.

Eighty-four of the 109 drugs we reviewed had not been added by CMS as of July 15, 2004. At that date, these 84 drugs had been qualified for an average of 55 weeks. Twenty-nine of these drugs had been qualified for at least 80 weeks (approximately 1 year and 7 months). A summary of these 84 drugs is presented in Table 2 below.

Table 2: Drugs Not Included on the Federal Upper Limit List as of 7/15/2004

[illegible]	[illegible]
15 weeks or less	16
28 weeks	14
41 weeks	11
54 weeks	9
67 weeks	5
80 weeks	15
93 weeks	5
More than 104 weeks	9
Average 55 Weeks	**84 Drugs**

Sources: FDA website, *Red Book*, Federal upper limit list

Twenty-three of these eighty-four met CMS's additional cost-savings standard as well. Each of these 23 drugs had sufficiently low published prices that may have led to savings, yet were still not included on the Federal upper limit list by CMS.

Medicaid lost an estimated $167 million between 2001 and 2003 because qualified drugs were not added to the Federal upper limit list in a timely manner

Between 2001 and 2003, only 27 of the 109 reviewed drugs were associated with potential losses caused by products not being added to the Federal upper limit list when they first qualified.[6] However, the failure to add these 27 drugs in a timely manner cost the Medicaid program (both Federal and State shares) an estimated $167 million over the 3-year period. A majority of the losses were attributable to just eight drugs. These 8 drugs, listed in Table 3 below, were each associated with more than $5 million in estimated losses, accounting for 85 percent ($143 million) of the total. A complete list of the drugs and their potential losses is provided in Appendix B.

Table 3: Largest Losses Associated with Qualified Drugs

[illegible]	[illegible]	[illegible]
Fluoxetine HCL 20 mg capsule	2	$56,697,780
Buspirone HCL 15 mg tablet	2	$23,261,047
Metformin HCl 1 gm tablet	7	$16,011,279
Famotidine 20 mg tablet	1	$11,487,628
Buspirone HCL 10 mg tablet	2	$10,536,672
Tramadol HCl 50 mg tablet	2	$9,632,958
Metformin HCl 850 mg tablet	7	$8,893,822
Fluoxetine HCl 10 mg capsule	2	$6,404,089

Sources: FDA Web site, *Red Book*, Federal upper limit list, CMS State Medicaid Data

The product with the highest estimated loss figure, Fluoxetine Hydrochloride 20 mg capsules (brand name Prozac), illustrates the potential effect of not adding drugs to the Federal upper limit list in a timely manner. As Table 3 shows, the two-quarter lag in adding the

[6] Because Medicaid payment data were unavailable for 2004, we could only calculate potential losses for the period between 2001 and 2003. Thirty-three of the reviewed drugs did not meet the statutory and regulatory criteria until 2004, and were therefore not included in any savings estimates. In addition, failure to add some drugs with sufficiently low published prices in a timely manner did not actually lead to any losses.

[7] Medicaid expenditure data were only available by quarter. Therefore, for the purposes of calculating potential losses, if a drug was added to the Federal upper limit list at any point during a quarter, we considered it included for the entire quarter.

20 mg dosage size of Fluoxetine Hydrochloride capsules cost Medicaid an estimated $57 million.[8] The first generic version of Fluoxetine Hydrochloride 20 mg capsules was approved in August 2001. According to FDA, the product had three therapeutically equivalent versions as of January 2002. The April 2002 *Red Book* listed more than three suppliers for the drug. Based on the lowest published price, a Federal upper limit for Fluoxetine Hydrochloride 20 mg capsules should have been set at $0.60 (150 percent of $0.40) by April 1, 2002. However, CMS did not place Fluoxetine Hydrochloride 20 mg capsules on the Federal upper limit list until December 1, 2002 (at $0.60 per capsule). During this period, four other versions of Fluoxetine Hydrochloride also qualified for the Federal upper limit list. In total, not adding these four versions when they first qualified cost Medicaid an additional $15 million.

In the next several months, new generic versions of several other major brand name drugs may become qualified for the Federal upper limit list. For example, Gabapentin (brand-name Neurontin), Oxycodone Hydrochloride (brand-name Oxycontin), and Paroxetine Hydrochloride (brand-name Paxil) have recently come off patent. These three drugs accounted for a total of $5.3 billion in retail sales in 2003. As was the case with Fluoxetine, not adding these three drugs to the Federal upper limit list in a timely matter could cause substantial losses to Medicaid.

[8] The estimated $57 million in losses only includes the period between April 1 and September 30, 2002. It does not include the partial quarter between October 1 and December 1, 2002. Nor does it account for the fact the drug may have been qualified for inclusion as early as January 29, 2002.

RECOMMENDATION

The CMS should establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits.

We believe that all qualified drugs should be included on the Federal upper limit list in a timely manner. The findings of both this report and our February 2004 report show that lags in adding qualified drugs are costing the Medicaid program substantial amounts. However, we are aware of the difficulties CMS faces in managing the Federal upper limit list. As CMS noted in their comments to the previous report, "pharmaceutical pricing and product information changes almost daily." While we continue to believe that all qualified drugs should be added to the Federal upper limit list in a timely manner, another option would be for CMS to consider focusing its resources on high-volume brand name drugs that are coming off patent. As our findings show, a large portion of the estimated losses can be attributed to lags in adding a small number of major drugs. If CMS makes a concerted effort to keep track of FDA ratings, number of suppliers, and published prices for these high-volume products, significant lags in placing qualified drugs on the Federal upper limit list could be avoided, thereby saving Medicaid millions of dollars per year.

Agency Comments

The CMS concurred with intent of our recommendation and stated that it had taken steps to support this objective. However, CMS did not concur with the OIG's methodology and subsequent savings estimates.

Specifically, CMS stated that the OIG incorrectly describes the therapeutic equivalency criterion used to determine if drugs should be placed on the Federal upper limit list. According to CMS, for a drug to meet the criterion, the FDA must "list two therapeutically equivalent formulations of the drug when all formulations of that drug product are 'A' rated. Where there are also 'B' rated drugs included with the 'A' drugs, there must be at least three 'A' drugs listed as therapeutically and pharmaceutically equivalent." The CMS believes this criterion is more rigorous.

The CMS then lists additional actions they take above those performed by the OIG, including (1) consulting additional compendia beyond the *Red Book*, and (2) verifying that the drug is actually available in the market by contacting manufacturers and suppliers.

The full text of CMS's comments is presented in Appendix D.

OIG Response

In their comments, CMS stated that they have taken steps to address our recommendation. However, CMS did not provide any details on these steps. Therefore, we cannot determine if CMS's efforts will alleviate the problems identified in this report.

In response to CMS's comments concerning therapeutic equivalency requirements, we point out that the Omnibus Budget Reconciliation Act of 1990 explicitly states, "[CMS] shall establish a Federal Upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such..." We understand that before this statute was enacted, regulations may have allowed for a Federal upper limit to be established if only two versions of a drug were available and both were therapeutically equivalent. However, as we read the statutory provisions, a product must have three A-rated versions to be included on the Federal upper limit list.

In any case, CMS's interpretation would potentially allow for more instances where a product would be placed on the Federal upper limit list. The OIG's interpretation requires three versions of a drug to be A-rated while CMS takes the position that two may be sufficient. If the OIG followed CMS's interpretation, it is possible that we would have identified additional drugs that should have been added.

Finally, we recognize that CMS takes additional steps in determining product availability, and understand their reasons for doing so. However, CMS has not explained why the additional steps account for the delays identified by the OIG.

APPENDIX ~ A

Complete List of 109 Reviewed Drugs

Drug	[illegible]	Strength	[illegible]	[illegible]	[illegible]
Acetaminophen; Butalbital; Caffeine; Codeine	Capsule; Oral	325MG;50MG;40MG;30MG	22-Aug-01	01-Oct-01	
Amcinonide	Cream; Topical	0.10%	31-May-02	1-Jul-02	
Ammonium Lactate	Cream; Topical	12%	10-Apr-03	1-Jul-03	
Amoxicillin	Suspension; Oral	400MG/5ML	4-Dec-02	1-Jan-03	
Amoxicillin	Suspension; Oral	200MG/5ML	4-Dec-02	1-Apr-03	
Amoxicillin; Clavulanate Potassium	Tablet; Oral	875MG;125MG	17-Sep-02	1-Oct-02	
Amoxicillin; Clavulanate Potassium	Tablet; Oral	500MG;125MG	30-Oct-02	1-Jan-03	
Amoxicillin; Clavulanate Potassium	Suspension; Oral	200MG/5ML;28.5MG/5ML	16-Dec-02	1-Jan-03	
Amoxicillin; Clavulanate Potassium	Suspension; Oral	400MG/5ML;57MG/5ML	16-Dec-02	1-Jan-03	
Amoxicillin; Clavulanate Potassium	Chewable Tablet; Oral	200MG;28.5MG	3-Dec-03	1-Jan-04	
Amoxicillin; Clavulanate Potassium	Chewable Tablet; Oral	400MG;57MG	3-Dec-03	1-Jan-04	
Betamethasone Diproprionate	Augmented Gel; Topical	0.05%	2-Dec-03	1-Jan-04	
Betamethasone Diproprionate	Augmented Cream; Topical	0.05%	9-Dec-03	1-Jan-04	
Betamethasone Diproprionate; Clotrimazole	Cream; Topical	0.05%	5-Jun-01	01-Jul-01	
Bupropion Hydrochloride	ER Tablet; Oral	150MG	22-Mar-04	1-Apr-04	
Buspirone Hydrochloride	Tablet; Oral	5MG	27-Feb-02	01-Apr-02	01-Dec-02
Buspirone Hydrochloride	Tablet; Oral	10MG	27-Feb-02	01-Apr-02	01-Dec-02
Buspirone Hydrochloride	Tablet; Oral	15MG	27-Feb-02	01-Apr-02	01-Dec-02
Buspirone Hydrochloride	Tablet; Oral	30MG	25-Mar-04	01-Apr-04	
Butorphanol Tartrate	Nasal Spray	1MG/SPRAY	12-Mar-02	01-Apr-02	
Cefaclor	ER Tablet; Oral	500MG	4-Sep-02	1-Oct-02	
Cefuroxime Axetil	Tablet; Oral	250MG	2-Oct-02	1-Jan-03	
Cefuroxime Axetil	Tablet; Oral	500MG	2-Oct-02	1-Jan-03	
Clindamycin Hydrochloride	Capsule; Oral	300MG	18-Mar-03	01-Apr-03	
Econazole Nitrate	Cream; Topical	1%	26-Nov-02	1-Jan-03	
Ethinyl Estradiol; Norethindrone Acetate	Tablet; Oral	0.03MG;1.5MG	18-Sep-03	1-Oct-03	
Ethinyl Estradiol; Norethindrone Acetate	Tablet; Oral	0.02MG;1MG	18-Sep-03	1-Jan-04	
Ethinyl Estradiol; Norgestimate	Tablet; Oral	0.035MG;0.25MG	9-Jan-04	1-Apr-04	
Ethinyl Estradiol; Norgestimate	Tablet; Oral	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.025MG	26-Mar-04	1-Apr-04	
Famotidine	Tablet; Oral	20MG	16-Apr-01	01-Jul-01	20-Nov-01
Famotidine	Tablet; Oral	40MG	16-Apr-01	01-Jul-01	20-Nov-01
Flecainide Acetate	Tablet; Oral	100MG	28-Oct-02	01-Jan-03	
Flecainide Acetate	Tablet; Oral	150MG	28-Oct-02	01-Jan-03	
Flecainide Acetate	Tablet; Oral	50MG	28-Oct-02	01-Jan-03	
Fludrocortisone Acetate	Tablet; Oral	0.1MG	21-Jan-03	1-Apr-03	
Fluoxetine Hydrochloride	Capsule; Oral	10MG	29-Jan-02	01-Apr-02	01-Dec-02
Fluoxetine Hydrochloride	Capsule; Oral	20MG	29-Jan-02	01-Apr-02	01-Dec-02
Fluoxetine Hydrochloride	Capsule; Oral	40MG	29-Jan-02	01-Apr-02	01-Dec-02

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Fluoxetine Hydrochloride	Solution, Oral	20MG/5ML	29-Jan-02	01-Apr-02	01-Dec-02
Fluoxetine Hydrochloride	Tablet; Oral	10MG	29-Jan-02	01-Apr-02	01-Dec-02
Fosinopril Sodium	Tablet; Oral	10MG	23-Apr-04	1-Jul-04	
Fosinopril Sodium	Tablet; Oral	20MG	23-Apr-04	1-Jul-04	
Fosinopril Sodium	Tablet; Oral	40MG	23-Apr-04	1-Jul-04	
Hydrocodone Bitartrate; Ibuprofen	Tablet; Oral	7.5MG;200MG	31-Dec-03	1-Jan-04	
Ipratropium Bromide	Nasal Spray	0.021MG/SPRAY	31-Mar-03	1-Jul-03	
Ipratroplum Bromide	Nasal Spray	0.042MG/SPRAY	31-Mar-03	1-Jul-03	
Isotretinoin	Capsule; Oral	10MG	24-Dec-02	1-Jan-03	
Isotretinoin	Capsule; Oral	20MG	24-Dec-02	1-Jan-03	
Isotretinoin	Capsule; Oral	40MG	24-Dec-02	1-Jan-03	
Lidocaine; Prilocaine	Cream; Topical	2.5%;2.5%	27-Aug-03	1-Oct-03	
Lisinopril	Tablet; Oral	30MG	1-Jul-02	1-Oct-02	11-Mar-03
Lithium Carbonate	ER Tablet; Oral	300MG	21-Apr-03	1-Jul-03	
Lithium Carbonate	ER Tablet; Oral	450MG	21-Aug-03	1-Oct-03	
Lovastatin	Tablet; Oral	10MG	17-Dec-01	01-Jan-02	01-Dec-02
Lovastatin	Tablet; Oral	20MG	17-Dec-01	01-Jan-02	01-Dec-02
Lovastatin	Tablet; Oral	40MG	17-Dec-01	01-Jan-02	01-Dec-02
Mefloquine Hydrochloride	Tablet; Oral	250MG	29-Dec-03	1-Jan-04	
Megestrol Acetate	Suspension; Oral	40MG/ML	15-Feb-02	01-Apr-02	
Metformin Hydrochloride	Tablet; Oral	500MG	24-Jan-02	1-Apr-02	18-Mar-04
Metformin Hydrochloride	Tablet; Oral	850MG	24-Jan-02	1-Apr-02	18-Mar-04
Metformin Hydrochloride	Tablet; Oral	1GM	24-Jan-02	1-Apr-02	
Metolazone	Tablet; Oral	2.5MG	23-Dec-03	1-Jan-04	
Metolazone	Tablet; Oral	10MG	24-Dec-03	1-Apr-04	
Metolazone	Tablet; Oral	5MG	1-Mar-04	1-Apr-04	
Midodrine Hydrochloride	Tablet; Oral	5MG	11-Sep-03	1-Jan-04	
Mirtazapine	Tablet; Oral	15MG	19-Jun-03	1-Oct-03	
Mirtazapine	Tablet; Oral	30MG	19-Jun-03	1-Oct-03	
Mirtazapine	Tablet; Oral	45MG	19-Jun-03	1-Oct-03	
Mixed Salts (Amphetamine)	Tablet; Oral	2.5MG	14-Jun-02	1-Jul-02	
Mixed Salts (Amphetamine)	Tablet; Oral	1.25MG	19-Jun-02	1-Jul-02	
Mixed Salts (Amphetamine)	Tablet; Oral	5MG	14-Jun-02	1-Oct-02	
Mixed Salts (Amphetamine)	Tablet; Oral	7.5MG	14-Jun-02	1-Oct-02	
Mixed Salts (Amphetamine)	Tablet; Oral	1.875MG	9-Sep-03	1-Apr-04	
Mixed Salts (Amphetamine)	Tablet; Oral	3.125MG	9-Sep-03	1-Apr-04	
Mixed Salts (Amphetamine)	Tablet; Oral	3.75MG	9-Sep-03	1-Apr-04	
Mometasone Furoate	Ointment; Topical	0.10%	14-Nov-03	1-Jan-04	
Mupirocin	Ointment; Topical	2%	7-Nov-03	1-Jan-04	
Nizatidine	Capsule; Oral	150MG	5-Jul-02	1-Oct-02	11-Mar-03

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Nizatidine	Capsule; Oral	300MG	5-Jul-02	1-Oct-02	11-Mar-03
Ofloxacin	Tablet; Oral	200MG	2-Sep-03	1-Oct-03	
Ofloxacin	Tablet; Oral	300MG	2-Sep-03	1-Oct-03	
Ofloxacin	Tablet; Oral	400MG	2-Sep-03	1-Oct-03	
Omeprazole	DR Capsule; Oral	20MG	1-Nov-02	1-Jan-03	
Omeprazole	DR Capsule; Oral	10MG	1-Nov-02	1-Oct-03	
Oxaprozin	Tablet; Oral	600MG	31-Jan-01	01-Apr-01	01-Dec-02
Paroxetine Hydrochloride	Tablet; Oral	10MG	8-Mar-04	1-Apr-04	
Paroxetine Hydrochloride	Tablet; Oral	20MG	8-Mar-04	1-Apr-04	
Paroxetine Hydrochloride	Tablet; Oral	30MG	8-Mar-04	1-Apr-04	
Paroxetine Hydrochloride	Tablet; Oral	40MG	8-Mar-04	1-Apr-04	
Pergolide Mesylate	Tablet; Oral	.05 MG	4-Sep-03	1-Jan-04	
Pergolide Mesylate	Tablet; Oral	.25MG	4-Sep-03	1-Jan-04	
Pergolide Mesylate	Tablet; Oral	1MG	4-Sep-03	1-Jan-04	
Prednisolone Sodium Phosphate	Solution; Oral	5MG/5ML	23-Dec-02	1-Jan-03	
Promethazine Hydrochloride	Suppository; Rectal	12.5MG	11-Apr-03	1-Jul-03	
Propafenone Hydrochloride	Tablet; Oral	300MG	7-Feb-02	01-Apr-02	
Rimantidine Hydrochloride	Tablet; Oral	100MG	30-Aug-02	01-Oct-02	
Sotatol Hydrochloride	Tablet; Oral	120MG	8-Apr-04	1-Jul-04	27-Jun-04
Sotatol Hydrochloride	Tablet; Oral	160MG	8-Apr-04	1-Jul-04	27-Jun-04
Sotatol Hydrochloride	Tablet; Oral	80MG	8-Apr-04	1-Jul-04	27-Jun-04
Tamoxifen Citrate	Tablet; Oral	10MG	20-Feb-03	1-Apr-03	
Tamoxifen Citrate	Tablet; Oral	20MG	20-Feb-03	1-Apr-03	
Tizanidine Hydrochloride	Tablet; Oral	2MG	3-Jul-02	1-Oct-02	11-Mar-03
Tizanidine Hydrochloride	Tablet; Oral	4MG	3-Jul-02	1-Oct-02	11-Mar-03
Torsemide	Tablet; Oral	100MG	27-May-03	1-Jul-03	
Torsemide	Tablet; Oral	10MG	27-May-03	1-Jul-03	
Torsemide	Tablet; Oral	20MG	27-May-03	1-Jul-03	
Torsemide	Tablet; Oral	5MG	27-May-03	1-Jul-03	
Tramadol Hydrochloride	Tablet; Oral	50MG	19-Jun-02	1-Jul-02	11-Mar-03
Trimethobenzamide Hydrochloride	Capsule; Oral	300MG	28-Aug-03	1-Oct-03	

Sources: FDA Web site, *Red Book*, Federal upper limit list

APPENDIX - B

Estimated Losses to Medicaid

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Fluoxetine HCL	20 MG	Capsule	2	$56,697,780
Buspirone HCL	15 MG	Tablet	2	$23,261,047
Metformin HCl	1 GM	Tablet	7	$16,011,279
Famotidine	20 MG	Tablet	1	$11,487,628
Buspirone HCL	10 MG	Tablet	2	$10,536,672
Tramadol HCl	50 MG	Tablet	2	$9,632,958
Metformin HCl	850 MG	Tablet	7	$8,893,822
Fluoxetine HCL	10 MG	Capsule	2	$6,404,089
Metformin HCl	500 MG	Tablet	7	$4,922,364
Fluoxetine HCL	40 MG	Capsule	2	$4,015,053
Fluoxetine HCL	10 MG	Tablet	2	$3,276,601
Tamoxifen Citrate	10 MG	Tablet	3	$2,285,933
Oxaprozin	600 MG	Tablet	6	$2,184,381
Buspirone HCL	5 MG	Tablet	2	$2,163,399
Famotidine	40 MG	Tablet	1	$1,601,892
Fluoxetine HCL	20 MG/5 ML	Solution	2	$1,299,147
Mirtazapine	30 MG	Tablet	1	$572,887
Nizatidine	150 MG	Capsule	1	$448,501
Tamoxifen Citrate	20 MG	Tablet	3	$444,140
Mirtazapine	45 MG	Tablet	1	$413,550
Flecainide Acetate	50 MG	Tablet	3	$339,654
Mirtazapine	15 MG	Tablet	1	$254,751
Flecainide Acetate	100 MG	Tablet	3	$148,689
Flecainide Acetate	150 MG	Tablet	3	$115,875
Lisinopril	30 MG	Tablet	1	$32,077
Nizatidine	300 MG	Capsule	1	$20,014
Rimantidine HCL	100 MG	Tablet	1	$829
[illegible]				[illegible]

Sources: FDA Web site, *Red Book*, Federal upper limit list

APPENDIX - C

METHODOLOGY

Determining Generic Drugs Approved From 2001 to 2003

We developed a list of all first-time generic drugs approved by FDA between January 2001 and December 2003. According to FDA, a first-time generic is a drug that has never been approved as a generic before and is, therefore, a new generic to the marketplace. Prior to approval of a first-time generic, only brand versions were available for sale. Using information obtained from the FDA Web site, we determined that 331 first-time generic drugs were approved during this time period.[9]

To focus on prescription drugs that are typically available at pharmacies, we removed from the list 50 injectable drugs and 17 over-the-counter products. We also removed 12 drugs that had additional branded versions (i.e., non-generics) available before 2001, and therefore may have been eligible for inclusion on the Federal upper limit list prior to the review period. After these deductions, 252 drugs remained on our list of first-time generics approved between January 2001 and December 2003.

Determining if Approved Drugs Meet Federal Upper Limit Criteria

The CMS is required to include on the Federal upper limit list all prescription drugs that have three versions rated therapeutically equivalent by FDA and three suppliers listed in national compendia. On June 1, 2004, we downloaded a file containing therapeutic equivalence data from the FDA Web site. For each of the 252 first-time generic drugs approved between 2001 and 2003, we determined if three therapeutically equivalent versions were listed on the FDA file, and, if so, the date that the third therapeutically equivalent version was approved. Of the 252 drugs, 113 had at least 3 versions rated therapeutically equivalent by FDA.

To determine if these drugs also met the three-supplier criterion, we obtained data from the *Red Book™ for Windows®* CD-ROM, a national drug compendium published quarterly by Micromedex (hereinafter, referred to as *Red Book*). For each of the 113 drugs with three A-rated versions, we determined the first subsequent quarter (i.e., the first quarter after a third A-rated version was approved) that three suppliers were listed in *Red Book*. All but 4 drugs had the required number of suppliers listed in a subsequent quarter, leaving 109 of the first-time generics approved in 2001, 2002, or 2003 that met the criteria for inclusion on the Federal upper limit list.

[9] The 331 drugs represent various forms and dosage sizes of approved products. For example, a product with dosage sizes of 20 mg, 40 mg, and 80 mg counted as three drugs.

A P P E N D I X ~ C

Determining if Drugs were on the Federal Upper Limit List

We obtained the current Federal upper limit list from the CMS Web site. We also obtained from the Web site all changes to the list between November 22, 2000, and July 15, 2004. We determined if any of the 109 reviewed drugs were on the Federal upper limit list, and, if so, the date they were added. For any drugs that were included on the list, we determined the amount of time between when they became qualified for the Federal upper limit list and the date they were actually added.

For example, Oxaprozin had its third A-rated version approved in January 2001. We checked subsequent quarters of *Red Book* and determined that the drug had three suppliers as of April 1, 2001. Oxaprozin was added to the Federal upper limit list on December 1, 2002. Therefore, the amount of time between when Oxaprozin first qualified for the Federal upper limit list and when it was actually added equaled 87 weeks.

Estimating Potential Losses

For each quarter that a drug was qualified for but not included on the Federal upper limit list, we compared the potential Federal upper limit amount to the average Medicaid reimbursement amount for the drug that quarter. Because the Federal upper limit amount is calculated by multiplying the lowest published price for a drug by 150 percent, there are instances when this amount would be higher than the reimbursement amount based on discounted AWP. In order to limit the time required to do this analysis, we only calculated estimated losses for drugs that may have been associated with actual losses if not added in a timely manner (e.g., had at least one published price significantly below AWP).

Calculating Potential Federal Upper Limit Amounts

To calculate a potential Federal upper limit amount, we used pricing information from the *Red Book*. Federal regulations set the upper limit amount at 150 percent of the least costly therapeutically equivalent product that can be purchased in package sizes of 100 (with certain exceptions). Therefore, for every calendar quarter that a drug was not included on the Federal upper limit list, we determined which of the A-rated versions available in a package size of 100 had the lowest price listed in the *Red Book*. If a drug was not typically available in a package size of 100, we determined the lowest price for the most common package size listed in the *Red Book*. We then multiplied this price by 150 percent to determine the Federal upper limit amount for the drug each quarter. We did not verify that the prices published in the *Red Book* were actually available in the marketplace.[10]

[10] According to staff, CMS often verifies that the lowest published price is actually available in the marketplace by contacting manufacturers and/or distributors.

A P P E N D I X ~ C

Calculating Medicaid Reimbursement Amounts

To determine the amount Medicaid reimbursed for the drugs, we downloaded 50 Medicaid payment and utilization files for CY 2001 through CY 2003 from CMS's Web site. State reimbursement data was only available by quarter. We did not obtain data from the first 2 quarters of CY 2004 because the files were not yet available; therefore, potential losses could only be calculated through the end of CY 2003. We also did not include data from Arizona because its drug reimbursement and utilization files were not available. Each file contained variables representing total State reimbursement, number of units reimbursed, and number of prescriptions written for every drug by calendar quarter.

The total State reimbursement amount listed in the files included both the payments for the drug and the dispensing fees paid to the pharmacy. To determine a State's reimbursement for the drug only, we:

(1) calculated the total amount paid in dispensing fees for the drug by multiplying the State's dispensing fee by the number of prescriptions written for the drug in each State each quarter;

(2) subtracted total dispensing fees from the total reimbursement for the drug in each State each quarter; and

(3) aggregated reimbursement for the drug only, number of units reimbursed, and number of prescriptions written for the drug each quarter.

We then calculated the average Medicaid reimbursement amount per quarter for each of the drugs by dividing the total of all States' reimbursement for the product (without the dispensing fee) by the total number of units reimbursed.

Calculating Potential Losses

For each drug for which the untimely addition may have led to losses, we subtracted the potential Federal upper limit amount from the average Medicaid reimbursement amount. If the result was a positive number (i.e., the Federal upper limit amount was less than the average Medicaid amount), we multiplied it by the total number of units reimbursed that quarter. The product of this multiplication shows the estimated losses Medicaid had that quarter due to the drug(s) not being included on the Federal upper limit list. We aggregated the quarterly totals to determine the total estimated losses to the program between 2001 and 2003.

Our methodology assumes that each of the reviewed drugs became qualified for the Federal upper limit list on the first day of a calendar quarter. However, drugs could be added to the Federal upper limit list at any time. To allow for this when calculating losses, we considered a drug that was added at any point in the quarter to be included for the entire quarter, and therefore it was not accounted for in our estimates. For example, Oxaprozin first became qualified for the Federal upper limit list on April 1, 2001, but the

A P P E N D I X - C

drug was not added to the Federal upper limit list until December 1, 2002. Therefore, we calculated potential losses for the last 3 quarters of 2001 and the first 3 quarters of 2002 (April 1, 2001, through September 30, 2002), but did not calculate losses for the period between October 1, 2002, and December 1, 2002 (the date Oxaprozin was added). Because of this, our estimates of program losses may be below the true amount. Furthermore, because State reimbursement data was not available for CY 2004, we were unable to calculate losses for any drugs approved between 2001 and 2003 that did not meet all criteria for inclusion until 2004.

APPENDIX - D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

RECEIVED
2004 DEC -2 AM 11:19
OFFICE OF INSPECTOR GENERAL

Administrator
Washington, DC 20201

DATE: DEC -1 2004

TO: Daniel R. Levinson
Acting Inspector General

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

IG
EAIG
PDIG
DIG-AS
DIG-EI ✓
DIG-OI
DIG-MP
OCIG
ExecSec ✓
Date Sent 12-2

SUBJECT: Office of Inspector General (OIG) Draft Report: "*Addition of Qualified Drugs to the Medicaid Federal Upper Limit List,*" (OEI-03-04-00320)

Thank you for the opportunity to review and comment on the subject draft report. The OIG report addresses the time frame that it took the Centers for Medicare & Medicaid Services (CMS) to include drugs on the Federal upper limit (FUL) list after statutory and regulatory criteria were met. This report also addresses the potential losses to the Medicaid program due to the untimely addition of these drugs. Our response to the audit recommendation follows.

OIG Recommendation

The CMS should establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits.

CMS Response

While we concur with the intent of the recommendation made by the OIG and note that CMS has taken steps to support this objective, we cannot concur with the OIG methodology in performing this review and the subsequent savings estimates for the reasons that follow.

The OIG report incorrectly describes the therapeutic equivalency criteria used to establish drugs to be placed on the FUL list. Specifically, the report states that a FUL is established on a product if three or more versions of the product have been classified as therapeutically equivalent by the Food and Drug Administration (FDA). The actual criteria are more rigorous. Instead, the FDA's Orange Book must list two therapeutically equivalent formulations of the drug when all formulations of that drug product are "A" rated. Where there are also "B" rated drugs included with the "A" drugs, there must be at least three "A" drugs listed as therapeutically and pharmaceutically equivalent.

Once a product has met the FDA criteria, CMS must also verify that the drug meets the necessary compendium criteria. OIG said that they obtained data from the *Red Book* compendium. CMS consults the three national drug-pricing compendia which includes *Red Book, First Data Bank* and *Medi-Span* to identify current market data. If there are three suppliers of the drug, the FUL system selects the lowest price (Average Wholesale Price,

Page 2 – Daniel R. Levinson

Wholesale Acquisition Cost, or Direct Price) that can be purchased by pharmacists and multiplies it by 150 percent as required by 42 CFR 447.332, to arrive at the FUL price.

While this verification gives us the universe of drugs that may be included in the FULs, it does not determine our final list. Before a drug is placed on the FUL list, it is important to be certain that the products listed are actually available in the marketplace. New drugs may be in limited supply or unavailable nationwide. To meet this list, we then manually verify that the FUL drug continues to be available from manufacturers or suppliers to assure current market availability. Both of these steps must be completed before CMS can add a drug to the FUL list.

For these reasons, we can support neither the number of drugs the OIG estimates should have been added to the FUL nor the resultant savings.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

David Tawes, *Project Leader*

Tricia Davis, *Director, Medicare and Medicaid Branch*

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

SEP 15 2004

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, DC 20515-6115

Dear Mr. Chairman:

Thank you for your letter regarding the Medicaid Federal Upper Limit (FUL) list. The Centers for Medicare & Medicaid Services (CMS) is committed to helping states reduce Medicaid drug costs. One way to accomplish this is through wider use of generic alternatives in place of brand name products. Because the FUL prices encourage the dispensing of generic drugs and those generics are generally significantly less expensive than the brand-names, the upper limits also help ensure that the states act as prudent buyers of drugs. As a result, CMS' FUL program has proven to be a significant factor in reducing overall state Medicaid pharmacy expenditures.

In your letter, you express concern over the amount of time it takes CMS to add new generic drug products to the FUL list. You also request the statutory and regulatory history of the FUL list, the current criteria for adding a drug to the FUL list, the process used to add drugs to the FUL list, the number of CMS employees involved in evaluating whether drugs satisfy the FUL criteria or in adding drugs to the FUL list, and the amount of money that CMS has allocated to the FUL program over the past 5 fiscal years.

In 1976, the Department of Health and Human Services (the Department) implemented drug reimbursement rules in Federal regulations at 45 CFR Part 19 under the authority of statutes pertaining to upper payment limits (UPLs) for Medicaid and other programs. Following a 1983 Departmental Task Force review of the Department's drug reimbursement regulations, a notice of proposed rulemaking was published on August 19, 1986 (51 FR 29560), announcing proposed revisions to procedures for establishing upper limits for drug payments. A final rule revising Medicaid rules concerning the methodology for determining UPLs was published and became effective October 29, 1987 (52 FR 28648 (July 31, 1987)). In accordance with the final rule, and as authorized by sections 1902(a)(30)(A) and 1927(f)(2) of the Social Security Act, CMS will establish a specific upper limit for multiple source drugs if the following requirements are met:

- All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent (category A) in the current edition of the publication, Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or successor publications); *OR*

- At least three of the formulations of the drug approved by the FDA have been evaluated as therapeutically and pharmaceutically equivalent (category A) in the most current edition of the publication, Approved Drug Products with Therapeutic Equivalence Evaluations (including supplements or in successor publications), regardless of whether all additional formulations are rated as such; *AND*

- At least three suppliers list the drug in the current editions (or updates) of published compendia of cost information for drugs (e.g., Red Book, Blue Book, Medi-Span).

The CMS last published a complete revision of the FUL list in November 2001. Since that time, CMS has issued 13 program issuances concerning changes to the list, including product additions and deletions and FUL price increases and decreases. These changes are made several times a year in response to feedback that is received from pharmacies, manufacturers, and state Medicaid agencies regarding pharmaceutical marketplace pricing and availability changes. In particular, there have been 62 product additions, 93 product deletions, and 198 product price changes to the FUL list since 2001. When information is received regarding a possible addition to the FUL list, CMS staff performs a thorough review of the product to confirm whether the criteria established in the regulations have been met. If so, the product is added to the FUL list. In addition, CMS staff has also reviewed the 93 items that have been deleted from the FUL list since 2001 to determine whether any of those products should be added back to the list. In the 10 instances where the FUL criteria were met, the products were put back on the list.

Currently, CMS has available less than one full time equivalent (FTE) for evaluating whether drugs satisfy the FUL criteria and whether drugs can be added to the FUL list. In addition, there are various regional office, administrative, and supervisory staff who work on the FUL program in varying capacities; however, those numbers cannot be quantified.

The estimated expenditures for administration of the FUL program over the past 5 fiscal years are as follows:

- Federal Fiscal Year 1999 – $45,600
- Federal Fiscal Year 2000 – $47,800
- Federal Fiscal Year 2001 – $48,700
- Federal Fiscal Year 2002 – $49,335
- Federal Fiscal Year 2003 – $50,000

These estimates only include the cost of the compendia data that are purchased each year to assist in the establishment of the FUL prices. Beyond the cost of the compendia data, there are associated personnel and overhead costs that cannot be quantified.

I hope this information adequately addresses your concerns regarding the Medicaid FUL program. I will also provide this response to the cosigner of your letter.

Sincerely,

Mark B. McClellan, M.D., Ph.D.

Medicaid Prescription Reimbursement Information by State

STATE	INGREDIENT COST	DISPENSING FEE	CO-PAY	STATE MAC
Alabama	WAC +9.2% then AWP -10%	$5.40	$.50 - 3.00	Yes
Alaska	AWP -5%	$3.45 - 11.46 (based on pharmacy/Medicaid volume)	$2.00	No
Arizona	AWP -15%	$2.00 (FSS only)	none	No
Arkansas	AWP -20%(generic); AWP -14%(brand)	$5.51	$.50 - 3.00	Yes
California	AWP -10%	$4.05	$1.00	Yes
Colorado	AWP -35%(gen.); AWP -13.5%(br.)	$4.00 (retail pharmacy)	$.75(gen.); $3.00(br.)	Yes
Connect.	AWP -40%(gen.); AWP -12%(br.)	$3.60	$1.00	Yes
Delaware	AWP -14%	$3.65	none	Yes
DC	AWP -10%	$4.50	$1.00	No
Florida	Lower of AWP -13.25% or WAC +7%	$4.23; $4.73 (NH-long term)	2.5% of payment up to $300	Yes
Georgia	AWP -10%	$4.63 (br. for profit pharm); $4.33 (br. not for profit); $5.13 (gen. for profit pharm); $4.63 (gen. not for profit)	$.50(gen.); $.50-3.00(br.); $.50 (preferred br.)	Yes
Hawaii	AWP -10.5%	$4.67	none	Yes
Idaho	AWP -12%	$4.94 ($5.54 for unit dose)	none	Yes
Illinois	AWP -25%(gen.); AWP -12%(br.)	$4.60 (gen.); $3.40 (br.)	$0(gen.); $3.00(br.)	Yes
Indiana	AWP -20%(gen.); AWP -13.5%(br.)	$4.90	$3.00	Yes
Iowa	AWP -12%	$4.26	$1.00	Yes
Kansas	AWP -27%(gen.); AWP -13%(single source)	$3.40	$3.00	Yes
Kentucky	AWP -12%	$4.51	$1.00	Yes
Louisiana	AWP -13.5% (AWP -15% for chains)	$5.77	$.50 - 3.00	Yes
Maine	AWP -15%	$3.35, $4.35, $5.35 (compounding)	$2.50(gen. and br.) (not to exceed $25/mo.)	Yes
Maryland	Lower of AWP -12% or WAC +8%	$4.69 (gen.); $3.69 (br.)	$2.00	Yes
Mass.	WAC +6%	$3.50(single source); $5 (multi.source)	$1(multi-source & non-legend OTC); $3(non-exempt)	Yes
Michigan	AWP -15.1% (chain (+5 stores))	$3.77	$1.00	Yes
Minnesota	AWP -11%	$3.65	none	Yes
Miss.	AWP -12%	$3.91	$1(gen.); $2(prefer. br.); $3(br.)	No
Missouri	Lower of AWP -10.43% or WAC +10%	$4.09	$.50-$2.00	Yes
Montana	AWP -15%	$4.70	$1.00	No
Nebraska	AWP -11%	$3.27-5.00 (based on service delivery, unit dosage, 3rd party payors)	$2.00 $1(gen.); $2(br.)	Yes
Nevada	AWP -15%	$4.76	$1(gen.); $2(br.)	No
New Hamp.	AWP -16%	$1.75	$1(gen.); $2(br. & compound)	Yes
New Jer.	AWP -12.5%	$3.73; $4.07 (addt'l services)	none	No
New Mex.	AWP -14%	$3.65	none	Yes
New York	AWP -12%	$4.50 (gen.); $3.50 (br.)	$.50(gen.); $2(br.)	No
North Car.	AWP -10%	$5.60 (gen.); $4.00 (br.)	$1(gen.); $3(br.)	Yes
North Dak.	AWP -10%	$5.60 (gen.); $4.60 (br.)	$3(br.)	No
Ohio	Lower of WAC +9% or AWP -12.8%	$3.70	$3(if not on PDL)	Yes
Oklahoma	AWP -12%	$4.15	$1.00-2.00	Yes
Oregon	AWP -15% (noninstitutional)	$3.50 (retail); $3.91 (institutional)	$2(gen.); $3(br.)	Yes
Penn.	AWP -10%	$4.00	$1.00	No
Rhode Is.	WAC +5%	$3.40	none	No
South Car.	AWP -10%	$4.05 (independ. pharm.)	$3.00	Yes
South Dak.	AWP -10.5%	$4.75 ($5.55 for unit dose)	$2.00	Yes
Tennessee	AWP -13%	$2.50 (long term dual eligib.); $5.00 (NH only if 28+ days)	N/A	Yes
Texas	Lower of AWP -15% or WAC +12%	$5.14	none	Yes
Utah	AWP -15%	$3.90 (urban); $4.40 (rural)	$3.00	Yes
Vermont	AWP -11.9%	$4.25	$1.00-3.00	Yes
Virginia	AWP -10.25%	$3.75; $5.00 (unit dose drugs)	$1.00	Yes
Wash.	AWP - 14%(single & multiple source (w/2-4 manufact.)); AWP -50% (multi. source from 5+)	$4.20-5.20 (based on 3-tier pharm. volume); $3.25 (mail order)	none	Yes
West Vir.	AWP -12%	$3.90 (+$1 for compounding)	$.50 - 3.00	No
Wisconsin	AWP -11.25%	$4.88	$.50(OTC); $1(gen.); $3(br.)	Yes
Wyoming	AWP -11%	$5.00	$2.00	No

: www.cms.hhs.gov/medicaid/drugs/prescriptions.asp

Quarter ending September 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-21-17
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

SMDL #04-006

SEP - 9 2004

Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) recently approved State Plan Amendments (SPAs) for five states in order to allow them to pool their purchasing power to acquire prescription drugs for their Medicaid populations. The purpose of this letter is to clarify issues related to multi-state pooling arrangements in the event that other states decide to implement similar "purchasing pools." In addition, this letter provides some points of consideration for states that have implemented Preferred Drug Lists (PDLs) and prior authorization requirements as part of their Medicaid supplemental rebate programs, including both state-specific supplemental rebate programs and multi-state supplemental rebate programs. In particular, to the extent that states wish to take any of these steps, we believe that it is important for CMS to provide guidance on how states can implement these programs to achieve cost savings while at the same time protecting the interests of Medicaid beneficiaries and promoting competition.

Under Sections 1927(a)(1) and 1927(a)(4) of the Social Security Act (the Act) and as previously specified in the September 18, 2002, State Medicaid Director letter, the Secretary may authorize a state to enter directly into separate or supplemental rebate agreements with manufacturers. Any drug rebate agreement between a state and a drug manufacturer may constitute a rebate agreement in compliance with the statute if CMS determines that the agreement provides for rebates that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers, which is published at 56 Fed. Reg. 7049 (Feb. 21, 1991). In an effort to gain additional rebates, a state can submit to CMS for its approval a SPA to allow the state to implement a prior authorization program to negotiate drug discounts for Medicaid populations or, consistent with previous guidance, to use a Medicaid prior authorization program to secure drug benefits, rebates, or discounts for non-Medicaid beneficiaries.

Under Section 1927(d)(5), States may also submit a SPA to CMS for approval in order to implement prior authorization programs to require authorization prior to dispensing covered outpatient drugs to Medicaid beneficiaries. States may establish a PDL of covered outpatient drugs that will not be subject to prior authorization and may, with CMS authorization, require manufacturers to enter into supplemental rebate agreements as a condition of including the manufacturer's covered outpatient drugs on the state's PDL. Many states have implemented these measures to address concerns with escalating Medicaid budgets.

Before a state decides whether to implement a PDL and pursue supplemental rebates, either on its own or as part of a multi-state pool, it must consider, and demonstrate to us that it has considered, numerous factors. These factors will ensure that any such program complies with section 1902(a)(19) of the Act, which requires that care and services under a Medicaid state plan be provided in a manner consistent with simplicity of administration and the best interests of beneficiaries. To that end, we would expect that any program will continue to ensure that appropriate medically necessary drugs will be available to Medicaid-eligible individuals. We intend to evaluate any SPA seeking to implement a prior authorization program and PDL, establish a state-specific supplemental rebate program, or join a multi-state pooling arrangement, to ensure that the state's program furthers Medicaid goals and objectives. In particular, before approving any SPA seeking to implement these initiatives, we will seek assurance from the state that its PDL is designed in a manner that balances the interests of beneficiaries in receiving medically necessary drugs with the state's interest in ensuring that Medicaid pays for prescription drugs in an efficient and economical manner. For example, we would expect a state's PDL to be based on several factors, including the needs of the state's Medicaid beneficiaries. We further would expect a state's PDL to address the needs of beneficiaries with special and complex medical conditions. We especially urge states to consider including in their PDLs drugs that are needed by some of Medicaid's most vulnerable populations, such as individuals with HIV/AIDS, mental health conditions, cancer, and other conditions for which clinical effectiveness or individual tolerance and responsiveness to drugs frequently vary.

We also believe that the level of supplemental rebates received by states will benefit from a competitive environment. For this reason, we believe that states should not limit their choice of vendors to develop and operate a supplemental rebate program to those vendors that have current contracts with other states solely on the basis that those vendors' programs have already received CMS approval through a SPA approval. In fact, we believe that states should consider other vendors, and not necessarily seek approval to join other state purchasing pools merely because those pools already exist. There are a number of contractors in the marketplace that have the knowledge and experience to provide these services. Some of these vendors have more experience in the broader market of health insurers and payers than in Medicaid, but may provide the best value to Medicaid programs. Therefore, you should not limit your choice to vendors that have current contracts with other states, nor should you limit your attempt to join a multi-state pooling arrangement to those arrangements already approved by CMS through the SPA process. In fact, in considering any SPA request to implement a prior authorization program and PDL, establish a state-specific supplemental rebate program, or join a multi-state pooling arrangement, CMS will consider the extent to which the state considered these competitive factors and will look favorably upon a state that uses other vendors or develops multi-state pooling arrangements other than those already approved. Through these competitive efforts, states can ensure that they and the Federal Government receive high quality services at the most competitive price.

The document enclosed provides additional technical guidance for states. We look forward to working with you on additional pharmacy cost savings measures in the Medicaid program. If you have questions or need additional information, you may contact Larry Reed at (410) 786-3325 or Deirdre Duzor at (410) 786-4626.

Sincerely,

Dennis G. Smith
Director

Enclosures

cc:
CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Kathryn Kotula
Director, Health Policy Unit
American Public Human Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors Association

Brent Ewig
Senior Director, Access Policy
Association of State and Territorial Health Officials

Jim Frogue
Director, Health and Human Services Task Force
American Legislative Exchange Council

Trudi Matthews
Senior Health Policy Analyst
Council of State Governments

Enclosure

Guidelines for Multi-State Pooling Agreements

As discussed below, states may use vendors, such as pharmacy benefit administrators (PBAs), to negotiate supplemental or multi-state pooling rebate agreements with manufacturers. Participation in any multi-state pool requires that the services of the vendor, if any, be procured by each participating state in a manner consistent with Federal and state procurement standards. While the five states participating in the new multi-state pool have contracts with the same vendor, we do not expect that all 50 states will participate in this arrangement. In fact, we believe that states should not limit their choice of vendors to develop and operate a supplemental rebate program to those vendors that have current contracts with other states solely on the basis that those vendors' programs have already received CMS approval. Moreover, we believe that states should consider other vendors, and not necessarily seek approval to join other state purchasing pools merely because those pools already exist.

We will review any SPA involving multi-state pools for compliance with section 1902(a)(19) of the Act. In accordance with these provisions, we will monitor the impact of one vendor on beneficiary access. States may form pools that use a different vendor or join together to negotiate supplemental rebates without using a vendor. Any Request for Proposal (RFP) for vendor contracts, whether issued jointly by all the states or separately by each participating state, should identify the populations for which the supplemental rebates would apply and should specify all of the states involved to clearly indicate from the outset which states are participating in the new pool.

In addition to the procurement requirements described above, each state participating in a new pool should submit a SPA package that includes the following elements:

1. **Standard multi-state pooling language incorporated into the supplemental rebate agreement portion of the state plan.** Specifically, this language should read as follows:

   "CMS has authorized the state of [insert state name] to enter into the [insert the name of the multi-state pooling agreement]. This Supplemental Drug Rebate Agreement was submitted to CMS on [insert submittal date] and has been authorized by CMS."

2. **A supplemental rebate agreement template.** Consistent with section 1902(a)(19) of the Act, we expect that the SPA would include a standard template, to ensure uniformity of the pool's supplemental rebate agreements for ease of administration. The template should be the same for each participating state and should not include an effective date that is earlier than the first day of the quarter in which the SPA was submitted. In addition, as a template, the model agreement should not contain any manufacturer-specific information.

3. **A document referenced in the supplemental rebate agreement template that indicates the state's participation in the purchasing pool.** This document will serve as the mechanism by which other states will be added to the multi-state pooling agreement and should be filled in with any necessary state-specific information. This document will also serve as a template; therefore, it should be the same for each participating state and should not contain any manufacturer-specific information.

4. **A document that indicates if a state joining the pool intends to include its non-Medicaid program in the supplemental rebate program that has been approved by CMS, if applicable.** States that intend to include non-Medicaid programs must receive approval from CMS prior to joining the pool under the procedures outlined in the letter from Dennis Smith, Director, Center for Medicaid and State Operations, to all State Medicaid Directors (Sept. 18, 2002). In addition, each state should provide specific evidence to demonstrate that its prior authorization requirement furthers Medicaid goals and objectives and is designed to increase the efficiency and economy of the Medicaid program.

Guidance for States on Preferred Drug Lists (PDLs) and Prior Authorization

A state that seeks for the first time to use its prior authorization authority to create a PDL and to negotiate supplemental rebates (regardless of whether it seeks to join or create a multi-state pooling arrangement) must amend its state plan to refer to the supplemental rebate agreement and submit its proposed rebate agreement for CMS' authorization. Along with the implementation of a supplemental rebate program, most states have also implemented a PDL in conjunction with their prior authorization program. Because non-preferred drugs remain available to beneficiaries through prior authorization, a PDL allows states to ensure appropriate patient access to needed medications and maintain continuity of patient therapy.

1. **Patient Access to Needed Medications** - Upon implementation of a PDL, states should ensure that patients continue to have appropriate access to needed medications. A prior authorization program is intended to balance the interests of beneficiaries in receiving medically necessary drugs and the interests of states in ensuring that Medicaid pays for prescription drugs in an efficient and economical manner. Therefore, we will seek assurance from states that all covered outpatient drugs that are not included on a PDL remain available pursuant to prior authorization, consistent with section 1927(d)(5) of the Act.

2. **Autonomy of the State PDL** - Because we are concerned about beneficiary access to medications, we would expect states to ensure that a PDL is consistent with Medicaid goals and objectives and section 1902(a)(19) of the Act.

3. **Continuity of Care** - When implementing PDLs, we urge states to be mindful of patients who are stabilized on previously prescribed, non-preferred medications. Consistent with our concerns for balancing the needs of patients with the efficiency and economy of the

Medicaid program, we further urge states to consider the impact on beneficiaries of sudden changes in therapy as a result of a state's implementation of a PDL. Such a sudden change could, in some instances, result in higher costs due to a patient's failure of therapy on PDL drugs.

4. **Vendor Contracting** – In contracting with a pharmacy benefit manager or other vendor for purposes of negotiating state-specific or multi-state supplemental rebates, states should make sure that the selected contractor discloses all types of remuneration and the methodology for calculating any such remuneration, all rebate offers being made by manufacturers, and any other pertinent information including vendor administrative costs and incentives related to vendor supplemental rebate negotiation and PDL development. We suggest that such information include descriptions of any and all payment from manufacturers or other entities involved in the manufacture, distribution, sale, or payment of pharmaceuticals.

5. **State-Specific Supplemental Rebate Agreements** – In order to realize additional cost savings, states are encouraged to continue negotiating state-specific supplemental rebate agreements, either in addition to, or in lieu of, multi-state pooling agreements.

6. **Annual Evaluations** – If states choose to participate in a multi-state pooling agreement, we recommend that those states annually evaluate and issue a public report on the aggregate cost savings associated with their participation to determine whether expenditures in other Medicaid areas, such as hospitalizations or physician services, have increased as a result of the implementation of the multi-state pooling agreement. Even if a state chooses not to participate in a pool, we encourage such an evaluation in connection with the state's PDL, prior authorization program, and state-specific supplemental rebate agreement, if applicable.

7. **Non-Medicaid Programs** - As we stated in our September 18, 2002, SMD, in submitting a SPA to link a Medicaid prior authorization program to rebates or discounts for non-Medicaid drug purchases, states should be prepared to demonstrate through appropriate evidence that the prior authorization program will further the goals and objectives of the Medicaid program.

COPY

TAB 19

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

RECEIVED JUL 25 2002

Don A. Gilbert, M.B.A.
COMMISSIONER

July 25, 2002

Medicaid Rate Analysis

JUL 26 2002

Texas Health & Human Services Commission

Linda Wertz
Deputy Commissioner for Medicaid and CHIP
Texas Health and Human Services Commission
4900 North Lamar, Fourth Floor
Austin, Texas 78751

Dear Ms. Wertz:

We have completed a drug acquisition cost audit of contracted providers in the Texas Medicaid Vendor Drug Program of the Texas Department of Health (TDH) as designated by the Texas Health and Human Services Commission (HHSC). This audit is a follow-up to the drug acquisition cost surveys that we completed in August 2000 and April 2001.

BACKGROUND

TDH/HHSC administers the Texas Medicaid Vendor Drug Program. Federal regulation requires the use of "estimated acquisition cost" (EAC) in calculating payment for drugs (42 CFR, Reg. 447.301 and Reg. 447.331). The Vendor Drug Program uses cost information gathered from drug manufacturers based on the lower of average wholesale price (AWP) minus 15% or wholesale acquisition cost (WAC) plus 12% to establish EAC.

The Vendor Drug Program has received information that indicates some drug manufacturers may have overstated the drug cost used to establish EAC. Our previous drug acquisition surveys' did find overstated estimated acquisition costs for specific drug products.

SCOPE OF AUDIT

We conducted our audit in accordance with Government Auditing Standards. The objective of our audit was limited to determining the accuracy of the Vendor Drug Program's cost basis (AWP-15% or WAC+12%) as listed in the Program's product cost reimbursement formulary and whether the program's EAC reasonably reflects drug cost paid by contracted providers.

TX-D & W - 16284

We utilized a statistically valid random sample of contracted providers for the following categories: (a) Urban-Independent (219), (b) Rural-Independent (170), (c) Urban-Chain Retailer (130), (d) Rural-Chain Retailer (48), and (e) Urban-Specialty Retailer (96) pharmacies. A 100% review of the Rural-Specialty Retailer (11) pharmacies and seven of eleven Chain Warehouse pharmacies was conducted. At each pharmacy, we compared AWP, WAC and EAC with "invoice cost", i.e., the cost to the pharmacy according to the invoices from the wholesaler. For each covered legend drug for which invoice data was obtained, we divided AWP, WAC and EAC by the invoice cost to compute the "AWP vs. Invoice", "WAC vs. Invoice" and "EAC vs. Invoice" percentages.

In addition, a separate sample for validation purposes utilizing three randomly selected invoices from 100 independent pharmacies was conducted to verify the results of our original sample by pharmacy category.

AUDIT FINDINGS

Tables A, B, C, D and E (see below) list the number of pharmacies sampled, average "AWP vs. Invoice", average "WAC vs. Invoice" and average "EAC vs. Invoice" for each type of pharmacy audited. Our audit did not include examining amounts actually paid to contracted providers for prescriptions. However, our analysis of "AWP vs. Invoice" and "WAC vs. Invoice" indicates that overpayments to providers have occurred, since EAC historically has been based on the lower of AWP-15% or WAC+12%, in calculating the payments made to the contracted providers.

The tables below summarize the results of our audit:

TABLE A: INDEPENDENT PHARMACIES

NUMBER OF PHARMACIES	AVERAGE AWP vs. INVOICE %	AVERAGE WAC vs. INVOICE %	AVERAGE EAC vs. INVOICE %
170 RURAL	-34.27%	-08.35%	146.02%
219 URBAN	-34.05%	-08.60%	148.68%

TABLE B: CHAIN RETAILER PHARMACIES

NUMBER OF PHARMACIES	AVERAGE AWP vs. INVOICE %	AVERAGE WAC vs. INVOICE %	AVERAGE EAC vs. INVOICE %
48 RURAL	-43.66%	-15.13%	172.74%
130 URBAN	-34.27%	-08.30%	146.52%

TABLE C: SPECIALTY RETAILER PHARMACIES

NUMBER OF PHARMACIES	AVERAGE AWP vs. INVOICE %	AVERAGE WAC vs. INVOICE %	AVERAGE EAC vs. INVOICE %
11 RURAL	-38.45%	-11.88%	151.75%
96 URBAN	-39.22%	-14.18%	167.76%

TABLE D: INDEPENDENT PHARMACIES (VALIDATION SAMPLE)

NUMBER OF PHARMACIES	AVERAGE AWP vs. INVOICE %	AVERAGE WAC vs. INVOICE %	AVERAGE EAC vs. INVOICE %
100 TOTAL	-35.48%	-09.87%	152.68%

Data was collected from seven of eleven chain warehouse pharmacies, however is excluded from this report due to warehouse pricing having been historically determined to be 98% of WEAC (wholesale estimated acquisition cost) or 100% of DEAC (direct estimated acquisition cost) in the case of direct purchases from drug manufacturers. This data is summarized in the table below for informational purposes and is currently under further review.

TABLE E: CHAIN WAREHOUSE PHARMACIES

NUMBER OF PHARMACIES	AVERAGE AWP vs. INVOICE %	AVERAGE WAC vs. INVOICE %	AVERAGE EAC* vs. INVOICE %
7 TOTAL	-24.92%	-04.06%	113.50%

* (Warehouse price)

RECOMMENDATIONS

We recommend that EAC be recalculated as necessary for all covered legend drugs in the Texas Medicaid Vendor Drug Program formulary. Detail of the audit results for each drug by pharmacy type has been provided to the Vendor Drug Program.

We also recommend that the Department continue to work with the Attorney General's Office for possible recoupment of any overpayments caused by the drug manufacturers' overstatement of drug costs.

We recommend that the Vendor Drug Program utilize this data to adjust EAC for drugs as needed.

MANAGEMENT COMMENTS

The Medicaid Vendor Drug Program appreciates the Audit Division's prompt response to its request for a large-scale drug invoice audit. This information was needed by the program to evaluate the relationships between Average Wholesale Price (AWP), wholesale acquisition cost (WAC) and the pharmacy provider's invoice acquisition costs and apply these relationships to an overall pricing formula.

The information provided in the audit findings is currently being analyzed to determine the different pricing structures used for Brand Name products, generic products, pharmacy type and pharmacy location. Once this analysis is complete, the program will recommend a new pricing formula be implemented that will provide a more accurate estimated acquisition cost. Cost savings from these changes are estimated to save approximately $20.3 million in general revenue for FY 03.

The program will also share these audit finds with HHSC Office of Investigation and Enforcement for any possible recoupement of overpayments caused by the drug manufacturer's overstatement of drug costs.

Please contact me if you have any questions or concerns about these findings, recommendations or management comments.

Sincerely,

Larry Havel
Auditor V
Audit Division

cc: Patsy Napier, Director
Vendor Drug Program, HHSC

Rodger Love, Director
Customer Service, HHSC

TAB 20

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

Don A.Gilbert, M.B.A.
COMMISSIONER

May 10, 2002

Dear Manufacturer:

Thank you for your continued participation in Texas Medicaid's Vendor Drug Program (VDP). The purpose of this letter is to inform you of statutory and regulatory changes to the program and its requirements for participation.

On April 21, 2002, the VDP implemented a regulation found at Title 1 of the Texas Administrative Code, section 354.3092. For each of your company's products to be placed on the Texas Drug Code Index, this regulation, which is attached, requires you to provide the VDP with the "average manufacturer price" (AMP). In the context of the new regulation, AMP has the meaning assigned to it by Title 42 of the United States Code, section 1396r-8(k).

In addition to the copy of the new regulation, you will also find enclosed the required data format and a new form of the questionnaire to include new products on the Texas Drug Code Index, as well as NDC numbers of products whose prices have not been updated in approximately two years. The old version of the form will no longer be accepted. Please maintain this new form for use in the future.

As you are aware, Texas is required by federal regulation to reimburse pharmacies based on our best estimate of their acquisition cost. That estimate is based in large part on information provided by manufacturers and, to that end, you are currently required to provide the VDP with updated pricing information as that information becomes available. The AMP is now considered a part of the information that should be reported to the VDP. The AMP reported to federal Centers for Medicare and Medicaid Services for the first quarter of 2002 should be provided to VDP by May 31, 2002.

Finally, nondiscounted figures do not provide the VDP with reliable information from which to estimate pharmacies' acquisition costs. If the pricing information previously reported by your company for any product does not accurately reflect the cost to or price paid by wholesalers, distributors, pharmacies, chain pharmacies, or other buyers net of chargebacks and typical rebates or discounts as defined in the questionnaire, you must amend your report immediately. Please ensure that all future applications and updates also reflect accurate pricing after application of discounts and chargebacks. The system set up by the laws and regulations of the State of Texas fails if a manufacturer does not accurately report its pricing.

If you have any questions regarding your obligations to the VDP, please do not hesitate to contact me.

Very truly yours,

Martha McNeill

Martha McNeill, R.Ph.

Texas Administrative Code

TITLE 1	ADMINISTRATION
PART 15	TEXAS HEALTH AND HUMAN SERVICES COMMISSION
CHAPTER 355	MEDICAID REIMBURSEMENT RATES
SUBCHAPTER J	PURCHASED HEALTH SERVICES
DIVISION 28	PHARMACY SERVICES: REIMBURSEMENT
RULE §355.8541	Legend and Nonlegend Medications

For all medication, legend and non-legend, covered by the Vendor Drug Program and appearing in the Texas Drug Code Index (TDCI) and updates, the following requirements must be met.

(1) Reimbursement. A pharmaceutical provider is reimbursed based on the lesser of:

(A) the HHSC's best estimate of acquisition cost (EAC) plus the HHSC's currently established dispensing fee per prescription; or

(B) the usual and customary price charged the general public.

(2) Estimated acquisition cost (EAC).

(A) EAC is defined as:

(i) wholesale estimated acquisition cost (WEAC)

(ii) direct estimated acquisition cost (DEAC), according to the pharmacist's usual purchasing source and the pharmacist's usual purchasing quantity; or

(iii) maximum allowable cost (MAC) for multi-source drugs.

(B) EAC is verifiable by invoice audit conducted by the HHSC to include necessary supporting documentation that will verify the final cost to the provider.

(C) All drug purchases through a central purchasing agreement or from a central purchasing entity must be billed to the HHSC as warehouse purchases.

(D) The WEAC is established by the HHSC using market sources, which include, but are not limited to:

(i) the current Redbook;

(ii) Redbook Update;

(iii) First Databank;

(iv) First Alert; or

(v) Reported manufacturer pricing.

(E) The WEAC may not exceed wholesaler cost, as supplied by the drug manufacturer plus an amount representing wholesaler operating costs and profits under current market conditions. Market conditions will be examined at least every two years. Market conditions will be determined from information supplied to the department by reliable sources, which include, but are not limited to the manufacturer, the wholesaler, and contracted providers. Exceptions to general pricing determinations may be made on certain drugs and/or drug categories based on information from these same market sources.

(F) The DEAC is established by the HHSC using direct price information supplied by drug manufacturers. Providers are reimbursed only at the DEAC on all drug products that are available from select manufacturers/distributors who actively seek and encourage direct purchasing. The TDCI is used as the reference for drugs included in the scope of benefits and for allowable package sizes. No acquisition cost is billed to the HHSC for samples dispensed.

(3) Nonlegend drugs.

(A) Reimbursement for nonlegend drugs is based on the lesser of:

(i) the usual and customary price charged to the general public; or

(ii) EAC, plus 50% of the EAC.

(B) No dispensing fee is added to the price of nonlegend drugs, and 50% of the EAC may not exceed the assigned dispensing fee.

(4) Public Hearing. Notice of a public hearing to receive comments on proposed changes to general pricing determinations derived under these rules shall be published in the Texas Register.

(5) Definitions. As used in the previous section, these terms shall be defined as follows:

(A) Reported Manufacturer Price-Information on pricing submitted to VDP by the manufacturer, including Average Wholesale Price, Average Manufacturer Price, wholesaler costs, direct prices and institutional or contract prices.

(B) Reliable Sources--Sources including other state/federal agencies and pricing services, as well as verifiable reports by contracted pharmacists and VDP field staff.

(C) Market Conditions--Conditions within the overall retail and wholesale pharmacy drug market place.

(D) Wholesaler Costs--The net cost of a product to a drug wholesaler or distributor.

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TEXAS 915
QUARTERLY PRICING DATA

DATA REPORTING

Data is to be submitted within 30 days of the end of the calendar quarter. Please submit current quarter data only (correction flag = 0). There are 2 files required: Drug Product file containing basic information about the products, and the Drug Price file containing AMP Data. Pricing data can be submitted in one of two ways.

1. Electronic

   Submit a 3 1/2" disc or CD ROM ASCII text file using the attached record formats.

2. Paper

   For small companies, paper submission can be sent/faxed on the required form TX-915. **This method is reserved for companies having 5 or fewer NDC's.**

Please submit to:

Texas Department of Health, Y-915
Martha McNeill, R.Ph.
1100 West 49th Street
Austin, TX 78756

Questions on this information may be referred to:

Martha McNeill, R.Ph.	512-338-6965
Heather A. Murphy	512-338-6963

TEXAS 915
QUARTERLY PRICING DATA

FILE 1: DRUG PRODUCT FILE
ASCII FORMAT FOR EXPORT TO TEXAS

Field	Size	Position	Remarks
Labeler Name	39	1 - 39	Company associated with NDC #1
Labeler Code	5	40 - 44	NDC #1
Product Code	4	45 - 48	NDC #2
Package Size Code	2	49 - 50	NDC #3
Drug Category	1	51 - 51	See Quarterly Pricing Data Definitions
DESI Indicator	1	52 - 52	See Quarterly Pricing Data Definitions
Drug Type Indicator	1	53 - 53	See Quarterly Pricing Data Definitions
Drug Termination Date	8	54 - 61	MMDDYYYY
Unit Type	3	62 - 64	See Quarterly Pricing Data Definitions
Units Per Pkg Size	10	65 - 74	999999V999
FDA Approval Date	8	75 - 82	MMDDYYYY
Date Entered Market	8	83 - 90	MMDDYYYY New item Only
Ther. Equiv. Code	2	91 - 92	See Orange Book Definitions
Filler	1	93	
Product Registration Name	63	94 - 156	FDA Registration Name
Filler	4	157 - 160	

FILE 2: DRUG PRICE FILE
ASCII FORMAT FOR EXPORT TO TEXAS

Field	Size	Position	Remarks
Record ID	1	1 - 1	Constant of "4"
Labeler Code	5	2 - 6	NDC #1
Product Code	4	7 - 10	NDC #2
Package Size Code	2	11 - 12	NDC #3
Period Covered	5	13 - 17	QYYYY (Qu/Yr)
AMP	11	18 - 28	99999V999999
Best Price	11	29 - 39	00000V000000
Filler OR	24	40 - 63	
Accretion Date	*8*	*40 - 47*	*YYYYMMDD*
Correction Date	*8*	*48 - 55*	*YYYYMMDD*
Submission Date	*8*	*56 - 63*	*YYYYMMDD*
Correction Flag	1	64 - 64	See Quarterly Pricing Data Definitions
Drug Category	1	65 - 65	See Quarterly Pricing Data Definitions
Line Feed	1	66 - 66	

TEXAS 915
QUARTERLY PRICING DATA DEFINITIONS

AMP (Average Manufacturer's Price)	The AMP per unit per product code only for the period covered, based on sales. If a drug is distributed in multiple package sizes, there will be one "weighted" AMP for the product, which will be the same for all package sizes. Numeric values, 11 digit field: 5 whole numbers and 6 decimal places. Compute to 7 decimal places, and round to 6 decimal places.
Best Price	Numeric values, 11 digit field; 5 whole numbers and 6 decimal places. ZERO FILL.
Correction Record Flag	Indicator that this record corrects and replaces a record already submitted for the initial submission. Numeric value, 1 digit field. Only send 0 records. Valid values: 0 = Original record 1 = Correction record
Date Entered Market	If marketed prior to 10-01-90, first day of the first month that the drug was marketed for the entire month; otherwise, actual date the product is marketed. Numeric values, 8 digit field (MMDDYYYY).

TEXAS 915
QUARTERLY PRICING DATA DEFINITIONS

DESI Drug Indicator	A DESI drug is any drug that lacks substantial evidence of effectiveness (less than effective (LTE)) and is subject by the FDA to a Notice of Opportunity for Hearing (NOOH). This includes drugs which are identical, related or similar (IRS) to DESI drugs. Numeric value, 1 digit. Valid values: 2 = Safe and effective or non-DESI drug 3 = Drug under review (no NOOH issued) 4 = LTE/IRS drug for SOME indications 5 = LTE/IRS drug for ALL indications 6 = LTE/IRS drug withdrawn from market
Drug Category	Classification of drug for purposes of rebate calculations. Alpha-numeric values, 1 character. Valid values: N = Non-innovator multiple source S = Single source I = Innovator multiple source
Drug Termination Date	Date drug was withdrawn from market or shelf life of last lot sold if no longer distributed by labeler. Numeric values, 8 digit field. (MMDDYYYY).
Drug Type Indicator	Indicator to show whether this drug product can be acquired only by prescription or can be acquired OTC. Numeric value, 1 digit field. Valid values: 1 = Rx 2 = OTC

TEXAS 915
QUARTERLY PRICING DATA DEFINITIONS

FDA Approval Date	Date of FDA approval of the NDA, without regard to whether the drug has been sold or transferred to any entity, including a subsidiary or division of the original manufacturer. For OTC drugs, use Monograph date. Numeric values, 8 digit field, (MMDDYYYY).
Labeler Code	First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug. Numeric values only, 5 digit field, right justified and 0-filled with 4 digit labeler codes.
Labeler Name	Company associated with labeler code. Alpha-numeric values, 39 characters, left justified.
Package Size Code	Third segment of National Drug Code. Two digit field, right justified, 0-filled.
Period Covered	Calendar quarter and year covered by data submission. Numeric 5 digit field, QYYYY. Valid values for Q: 1 = January 1 - March 31 2 = April 1 - June 30 3 = July 1 - September 30 4. = October 1 - December 31 Valid values for YYYY: Four digit calendar year covered.
Product Code	Second segment of National Drug code. Numeric values only, 4 digit field, right justified, 0-filled.

TEXAS HB 915
QUARTERLY PRICING DATA DEFINITIONS

Product Registration Name	Product name as it appears on FDA registration form. Alpha-numeric values, 63 characters, left justified.
Therapeutic Equivalence Code	The classification as contained in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the FDA Orange Book) for the last day of the calendar quarter for which the rebate payment is being made. Alpha-numeric values, 2 character field. Valid Values: AA BC BS AB BD BT AN BE BX AO BN NR - Not rated AP BP A1 thru A9 = AB value AT BR
Unit Type	Basic measurement that represents the smallest unit by which the drug is normally measured. The rebate amount will be calculated per unit. Alpha-numeric values, 3 character field, left justified. Valid values: AHF = refers only to injectable Anti-Hemophilic Factor (AHF) units CAP = Capsule SUP = Suppository GM = Gram ML = Milliliter TAB = Tablet TDP = Transdermal Patch EA = EACH (Refers to drugs not identifiable by any other drug type as given in program instructions.)

TEXAS 915
QUARTERLY PRICING DATA DEFINITIONS

Units Per Package Size Code	Total number of units, as defined in the Unit Type field, in the smallest dispensable container or entity for the product defined by the full NDC. Numeric values, 10 digit field: 7 whole numbers and 3 decimal places.

DATE:__/__/_____ PAGE ___ OF ___
MM/DD/YYYY

LABELER QUARTERLY PRICING DATA
PAPER REPORTING FORMAT

QUARTERLY REPORT FOR __/____ LABELER CODE _____
Q YYYY

PRODUCT CODE: _____ PACKAGE SIZE CODE: ___

DRUG CATEGORY: _
THERAPEUTIC EQUIV. CODE: ___
DESI INDICATOR: _
AMP: _____.__
BEST PRICE: 000000.000000
DATE ENTERED MARKET: _____
BASELINE AMP: _____.__
TERMINATION DATE: _____
CORRECTION FLAG: _ (Activate for Baseline Data and/or Pricing Data Corrections.)
UNIT TYPE: ____
UNITS PER PACKAGE SIZE: _____.____
FDA APPROVAL DATE: _____
DRUG TYPE: _
PRODUCT NAME: _____
_____
_____

****

PRODUCT CODE: _____ PACKAGE SIZE CODE: ___

DRUG CATEGORY: _
THERAPEUTIC EQUIV. CODE: ___
DESI INDICATOR: _
AMP: _____.__
BEST PRICE: 000000.000000
DATE ENTERED MARKET: _____
BASELINE AMP: _____.__
TERMINATION DATE: _____
CORRECTION FLAG: _ (Activate for Baseline Data and/or Pricing Data Corrections.)
UNIT TYPE: ____
UNITS PER PACKAGE SIZE: _____.____
FDA APPROVAL DATE: _____
DRUG TYPE: _
PRODUCT NAME: _____
_____
_____

HEALTH AND HUMAN SERVICES COMMISSION
Chapter 35. Pharmacy Services
Subchapter H. Texas Drug Code Index-
Addition, Retention, and Deletion of Drugs

§35.801 Application for Addition of Drugs to the Texas Drug Code Index

(A) Any drug company that has a valid rebate agreement under section 1927 of Social Security Act may submit an application to the Health and Human Services Commission for addition of a drug not currently listed in the Texas Drug Code Index (TDCI). Drug companies include any manufacturer, own label distributor or relabeler.

(B) The drug company must complete the application form provided by the department. All questions on the form must be answered and all statements must be complete. For a multi-source drug, the drug company may reference the actual manufacturer's data, if the manufacturer's drug is listed in the Texas Drug Code Index.

(C) Sources other than drug companies may request the addition of a drug not currently listed in the TDCI. If the request is not from a drug company, the department requests the manufacturer to submit an application as described in subsection (B) of the section.

(D) The drug company and other sources, if applicable, are entitled to receive notification of approved or denied applications. If the application has been denied, the department states the reasons for the denial.

§354.3092 Review and Evaluation

(a) The department reviews each application to determine the need for a drug to be added to the Texas Drug Code Index and to determine the need for restrictions, when appropriate. In determining need, the department considers the following:

(1) expansion of the prescriber's armamentarium by a new drug or an additional multisource drug;

(2) predominant use of the drug in an outpatient setting;

(3) the cost of the drug to pharmacies compared to:

(A) wholesale estimated acquisition cost (WEAC) or direct estimated acquisition costs (DEAC) listed in the Redbook (Annual Pharmacists' Reference);

(B) the Average Manufacturer's Price (AMP) as defined by 42 U.S.C. §1396r-8(k), as amended; and

(C) other generically equivalent drug products..

(b) The department returns an application for any of the following reasons:

(1) discovery of false, erroneous, or incomplete information or documentation on the application form;

(2) failure of the drug company to provide the department with documentation of the :

(A) approved new drug application (NDA) or abbreviated new drug application (ANDA), if applicable; or

(B) Food and Drug Administration (FDA) approval for marketing;

(3) failure of the drug company to provide the department with the national drug code (NDC), as defined by and filed with FDA, for the drug product as shown on the drug product container sold to the pharmacy;

(4) failure of the drug company to provide the department with the current DEAC to a pharmacy, cost to a wholesaler, estimated wholesale cost to a pharmacy, or AMP. The allowable WEAC and DEAC are the costs to a pharmacy, as determined by review of published or non-published prices resulting from routine marketing practices. The drug company shall update the AMP each quarter at the same time the information is reported to the Secretary of Health and Human Services.

(c) The department may deny an application if it determines that the drug is included in one or more of the following classes:

(1) amphetamines, when used for weight loss, and obesity control drugs;

(2) appliances;

(3) cosmetics;

(4) DESI-ineffective products;

(5) diagnostic aids;

(6) durable medical equipment (rental or purchase);

(7) elastic stockings;

(8) experimental drugs;

(9) fertility drugs;

(10) first aid supplies;

(11) immunizing agents;

(12) irrigating sets;

(13) IV sets;

(14) medical devices;

(15) medical supplies;

(16) oxygen;

(17) products unsuitable for use outside of physician offices or health care facilities;

(18) shampoos, unless medicated for parasite control;

(19) skin lotions and creams (nonlegend cosmetic types);

(20) soaps and soap substitutes;

(21) supports and suspensories;

(22) syringes and needles;

(23) unit-dose or convenience packaging; and

(24) vitamin and antianemia combinations.

§35.803 Resubmittal of a Denied Questionnaire

(A) If a questionnaire for an addition is denied, the drug company may request reconsideration of the decision. The request is presented to the Vendor Drug Advisory Subcommittee for reconsideration and recommendation.

The department, however retains the right to make the final decision.

(B) If a questionnaire and/or a request for reconsideration of a questionnaire for an addition is denied, the drug company may not resubmit the questionnaire for six months. The department, however, may reconsider a denied questionnaire during the six month period.

§35.804 Retention and Deletion of Drugs

(A) The department reviews the TDCI to evaluate the need for retaining or deleting drugs according to the following criteria:

(1) If the drug company fails to remove from pharmacies any drug recalled by the FDA or fails to meet other federal requirements, the department may request that HHS allow deletion of the drug. If the drug company repeatedly fails to meet FDA or other federal requirements, the department may request permission to delete all drugs manufactured by the company.

(2) If the drug company fails to provide the department the current drug cost including the direct estimated acquisition cost (DEAC) to the pharmacy, the cost to a wholesaler, and the estimated wholesale cost to a pharmacy the department may request that HHS allow deletion of the drug. If the department retains a drug for which the cost was not reported, the department establishes the cost. The allowable WEAC and DEAC are the cost to a pharmacy, as determined by review of published or non-published prices resulting from routine marketing practices.

(3) The department deletes a legend drug if the same drug becomes available as an over-the-counter drug.

(4) Effective upon notification, the department deletes discontinued or permanently recalled drugs. This provision applies to:
(a) drugs permanently recalled by the manufacturer.
(b) Drugs permanently recalled by the FDA
(c) Drugs no longer manufactured.

(5) The department deletes drugs for which federal matching funds are no longer available. Federal matching funds are not available for:
(a) drugs for which a rebate is not available under public law 101-508; and
(b) drugs for which notice of opportunity for hearing has been published in the Federal Register.

(B) If a drug is deleted, the drug company is entitled to be notified and given the opportunity to request reconsideration of the decision unless the deletion is based on criteria in subsection (A)(3)-(5) of this section. The department presents the request to the Vendor Drug Advisory Subcommittee for reconsideration and recommendation. The department, however retains the right to make the final decision.

MAY 20 2004 11:01 FR OFFICE OF ATT.GENERAL512 499 0712 TO 12022262447 P.18/23

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

Don A.Gilbert, M.B.A.
COMMISSIONER

Since Federal and State regulations require the Texas Vendor Drug Program to pay contracted pharmacies our best estimate of the cost of a pharmaceutical product to the pharmacies, the State relies upon information provided by manufacturers in setting price reimbursement. To ensure Texas' ability to continue to price products accurately, it is critically important that you report information which accurately reflects the market prices paid within the classes of trade for which pricing information is requested. A form is included so that all necessary information from the manufacturer will be available for pricing and dosing recommendations. Questionnaires should be limited to no more than 20 per submittal request for any one month period. A separate questionnaire is to be submitted for each drug and strength. Please supply a cover sheet listing all products, strengths and package sizes for which you are submitting applications. Questions must be answered in full. If you leave a pricing category blank, you are representing to the State of Texas that you DO NOT sell this product to entities in that category. This form may be reproduced.

All inquiries regarding this questionnaire and revisions are to be directed to:

Texas Department of Health
Vendor Drug Program
1100 West 49th Street.
Austin, Texas 78756-3174

Drugs are listed using the NDC number of the manufacturer or distributor who is holding the drug forth as it's own and has the company's name on the label of the container that is sold to the pharmacy. If your company has a product to which the "New Drug Coverage" applies, please add the FDA approval date of the New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA), or Antibiotic Drug Approval (ADA) to the questionnaire.

Martha McNeill, R.Ph.
Director of Product Management
Vendor Drug Program
(512)338-6965
(512)338-6462-Fax
(512)338-6932-Secretary

MAY 20 2004 11:02 FR OFFICE OF ATT.GENERAL512 499 8712 TO 12022262447 P.19/23

REQUEST FOR INFORMATION FOR NEW DRUG PRODUCT OR FOR
ADDITIONAL INFORMATION OF PRODUCTS CURRENTLY
INCLUDED IN TEXAS MEDICAID

Please fill out the following information for consideration in Texas Medicaid
An altered form will not be accepted

1. DRUG DESCRIPTION

NDC. NO: (multiple package size of same strength	PACKAGE QTY: products may be included)	
PRODUCT BRAND NAME:_____ GENERIC NAME:_____ THERAPEUTICALLY SIMILAR DRUGS:_____		
COLOR:	FLAVOR:	
DOSAGE FORM:	IS THIS DRUG LEGEND OR OTC?	DEA SCHEDULE OF THE DRUG:
DRUG STRENGTH:		
MAXIMUM DAILY DOSE:		
RECOMMENDED DAILY DOSE:		
INGREDIENTS/DESCRIPTION:		
LIST SHELF LIFE:		
ESTIMATED AVG. DURATION OF THERAPY:		
MAXIMUM DURATION OF TREATMENT:		

ORANGE BOOK RATING:

A - Drug products that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products.

B - Drug products that FDA at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products.

C - Not listed in Orange Book

Revised - May 1, 2002

FOR PURPOSES OF PROVIDING THE PRICE INFORMATION BELOW, THE FOLLOWING DEFINITIONS SHALL APPLY:

a) Except as otherwise defined in law (e.g. Average Manufacturer Price), price is the net price after all chargebacks, discounts and rebates to wholesalers/distributors or pharmacies are applied, other than commercially reasonable prompt pay discounts.

b) "Pharmacy" includes all entities with an approved Class A or Class C pharmacy license issued by the State Board of Pharmacy.

2. PRICE INFORMATION

AVERAGE OF SUGGESTED WHOLESALE PRICE TO PHARMACY (AWP)	$
AVERAGE MANUFACTURER PRICE (AMP)	$
PRICE TO WHOLESALER AND/OR DISTRIBUTOR	$
DIRECT PRICE TO PHARMACY	$
CENTRAL PURCHASE PRICE TO CHAIN (SUCH AS WAREHOUSE PRICE)	$
INSTITUTIONAL OR OTHER CONTRACT PRICE (Nursing Home, Home Health Care)	$
OTHER PRICE	$

IF YOU DO NOT SELL AT A SINGLE PRICE, YOU MAY PROVIDE US WITH A RANGE OF PRICES

INCLUDE A COPY OF FILE CARD, PACKAGE INSERT AND OR MATERIAL FOR PHYSICIANS

3. Please circle the companies to whom you report pricing information.

FIRST DATA BANK PRICE ALERT RED BOOK

MEDI-SPAN BLUE BOOK

OTHER:_____

4. Do you sell to distributors, repackagers, or relabelers, other than full-service drug wholesalers, who in turn sell your product to the retail trade bearing your NDC number?

If yes, attach a listing.

P. O. Box 13247 • Austin, Texas 78711 • 4900 North Lamar, Fourth Floor, Austin, Texas 78751

5. Attach a copy of your Vendor Liability Insurance:

   a. Included or

   b. Previously submitted or unchanged. (Do not need to resubmit)

6. Available date through WHOLESALERS_____

7.

Name of firm:		
Address:		
City:	State:	Zip:
Name and address of Manufacturer of drug:		
City:	State:	Zip:
Name and Address of representatives/government affairs persons covering the Texas area; if applicable:		
City:	State:	Zip:
Phone:		

8. Is this product now marketed under an approved NDA or ANDA?

   Submit a copy of the FDA letter of approval of the NDA or ANDA, or, if not applicable, a copy of the FDA letter of approval for marketing.

9. Please circle DESI classification of this product.

   2 Non-DESI/IRS: safe and effective

   3 DESI/IRS under review

   4 LTE DESI/IRS for some indications

   5 Non-Covered - LTE DESI/IRS for all indications

   6 Non-Covered - LTE DESI/IRS withdrawn form the market

A product added to the Texas Vendor Drug Program must bear the labeler code, as defined by the FDA, of the party, with the exception of a licensed full-service drug wholesaler, marketing the final sale to the provider.

Manufacturers or distributors having one or more of their pharmaceuticals included in the program are responsible for submitting notification of any changes pertaining to any of the above information not later than such revisions are scheduled to occur to:

Health & Human Services Commission
Vendor Drug Program
Attn: Martha McNeill, R.Ph.
Director of Product Management
1100 West 49th Street
Austin, Texas 78756-3174

The Vendor Drug Program adheres to the confidentiality requirements of 42 USC § 1396r-8(b)(3)(D) concerning drug pricing information.

I certify that the information submitted is correct to the best of my knowledge and that this product is not now in violation of either Federal or State Law. I also agree to inform the Health & Human Services Commission, in writing, of any changes in formulation, product status, price or availability as herein describe, within fifteen (15) days of such change.

Responsible Person (Type or Print) _____ Signature _____

Title _____ Date _____

Address _____ City _____ State _____ Zip _____

Company Name _____ ( ) Telephone _____

TDCI CAN BE FOUND AT: WWW.HHSC.STATE.TX.US/HCF/VDP/PRODUCTENROLL.HTML

MAY 20 2004 11:03 FR OFFICE OF ATT.GENERAL512 499 0712 TO 12022262447 P.23/23

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

Don A.Gilbert, M.B.A.
COMMISSIONER

May 10, 2002

Dear Manufacturer:

In reviewing the Texas Drug Code Index the following products and/or package sizes do not have current prices. We have not received pricing information from your company on these products for at least two years:

SEE ATTACHMENT

The above listed products will be deleted if no communication is received from your company within the next two weeks. Please inform me if these products are still available or if they have been discontinued or replaced by another NDC number. If they have been deleted from your product line, please provide an expiration date of the last lot manufactured. For the products that are still available please provide the current prices (the AMP, price to wholesalers and/or distributors, the direct price to pharmacies, warehouse price, and any other applicable pricing) and the effective date of those prices.

Thank you in advance for your assistance and cooperation.

Send information to the following address:
Texas Department of Health
Attn: Jerry Rodriguez
1100 West 49th ST
Austin, TX 78756-3174

Enclosures

*** TOTAL PAGE.23 ***

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

MAY 3 2004

RECEIVED
MAY 10 2004
Office of the Attorney General
Antitrust Division

Patrick J. O'Connell
Assistant Attorney General
Chief, Civil Medicaid Fraud Section
Office of the Attorney General
P.O. Box 12548
Austin, TX 78711-2548

Dear Mr. O'Connell:

This is in response to your letter in which you request guidance from the Centers for Medicare & Medicaid Services (CMS) with regard to issues involving the reporting of prices to the Vendor Drug Program of the Health and Human Services Commission of Texas pursuant to Texas law. I regret the delay in this response.

First, you ask for confirmation that State Medicaid programs may not use the rebate information, including the Unit Rebate Amount (URA) and Reconciliation of State Invoice (ROSI) reports, to calculate an estimated acquisition cost (EAC) for reimbursement. You are correct. In light of the confidentiality provisions of section 1927(b)(3)(D) of the Social Security Act (the Act), drug pricing information disclosed by manufacturers pursuant to the drug rebate provisions is confidential and shall not be disclosed by either the Secretary or the State.

In addition, you seek confirmation that the Texas Medicaid State program does not have the authority to remove a manufacturer from its formulary even if the manufacturer is violating Texas law so long as the manufacturer properly complies with its obligations under the rebate agreement. This is also correct. The statute generally requires State Medicaid programs to cover the drugs of manufacturers that have signed a Medicaid drug rebate agreement with CMS. Under section 1927(b)(4)(B) of the Act, the Secretary and the manufacturers are given the authority to terminate a rebate agreement. The Act does not provide such authority to the states. We will follow up with the state of Texas regarding next steps.

I trust that this response has adequately addressed your questions. If you have additional questions, please contact Larry Reed at (410) 786-3325.

Sincerely,

Dennis G. Smith
Director

Determination of the Cost of Dispensing Pharmaceutical Prescriptions For the Texas Vendor Drug Program

Prepared for the
Texas Health and Human Services Commission
Austin, Texas

August 2002

Myers and Stauffer LC
Certified Public Accountants

Table of Contents

Chapter
1

Executive Summary

Introduction

Under contract to the Texas Health and Human Services Commission, Myers and Stauffer LC performed a study of the cost of dispensing prescription medications to Medicaid recipients. This report includes a narrative of the methodologies and findings relevant to the survey of dispensing costs.

The dispensing cost study followed the methodology and used a survey instrument similar to those used by Myers and Stauffer in Medicaid pharmacy engagements in 18 other states. A stratified random sample of Texas pharmacy providers enrolled in the Medicaid program were surveyed; 703 pharmacies filed dispensing cost surveys that could be included in the study. All data received including the dispensing cost surveys were subject to extensive desk review procedures. Additionally, 31 pharmacies were selected for on-site field examinations to validate reported costs.

Summary of Findings

The significant findings of the study are as follows:

- **The statewide median cost of dispensing, weighted by Medicaid volume, was $5.95.**

Table 1.1 Dispensing Cost[A] for Texas Pharmacies

Pharmacies Included in Analysis [B]	650
Weighted Median [C]	**$5.95**
Weighted Mean [C]	$6.16
Unweighted Mean	$6.96

[A] Inflated to June 30, 2002.
[B] Excludes pharmacies that dispensed intravenous, home infusion or compounded prescriptions.
[C] Weighted by Medicaid volume.

- Average dispensing cost at certain pharmacy specialties was observed to be higher than dispensing cost at "typical" retail pharmacies. In particular we noted higher dispensing cost associated with pharmacies that provided services related to the dispensing of intravenous, home infusion and

compounded prescriptions.

- There was some association between dispensing cost and the urban or rural location of a pharmacy. Pharmacies in urban areas tended to have higher dispensing costs. This was noted to be particularly the case for labor related costs.

- No association was found between dispensing cost and unit-dose packaging or other measures of long term care dispensing activity; i.e., ambulatory and long term care pharmacies had similar mean costs of dispensing.

- No systematically higher costs associated with pharmacies that have a higher percentage of Medicaid prescription volume were found.

Conclusions and Recommendations

The Commission's current pharmacy dispensing fee results in average payments that are slightly higher than the median cost of dispensing prescriptions[1]. Any overall evaluation of the adequacy of current pharmacy reimbursement rates should consider findings related to dispensing cost in tandem with an analysis of ingredient reimbursement rates and the cost pharmacies incur acquiring prescription medications. Similarly, possible modifications to reimbursement policies should consider both dispensing and acquisition cost aspects of reimbursement. Should the Commission desire to modify its current dispensing fee, several options are available:

1) Continued Use of a Variable Dispensing Fee:
The Commission currently utilizes a dispensing fee that is variable based upon the ingredient cost of the medication being dispensed (i.e. the inventory management factor). A distinct disadvantage to the variable dispensing fee is that there is little correlation between the actual cost to dispense and the cost of the medication being dispensed provided that similar medication forms are being compared (e.g. dispensing a prescription of 30 pills of a low-cost generic medication requires essentially the same commitment of resources as dispensing a prescription of 30 pills of an expensive brand-name product). Furthermore, increases in drug cost (whether due to manufacturer price increases or the introduction of new and more expensive products) causes increases in the dispensing fee at a rate that is typically higher than the rate of inflation for overhead and labor dispensing costs.

One advantage of the variable dispensing fee methodology is that dispensing fees paid for certain specialty products that require special preparation (e.g. intravenous and home infusion products) are higher on average due to the high

[1] While the Commission's base dispensing fee is $5.27, the actual average dispensing fee is approximately $6.10 to $6.40 with the inventory management factor add-on to the dispensing fee.

cost of the drug ingredients typically used in these prescriptions. However, the current overall cap on the dispensing fee of $200 does appear to be out of proportion to actual dispensing costs observed.

2) Flat Rate Dispensing Fee:
Most states and private insurers use a single, flat rate dispensing fee. These fees are administratively simple to use and are readily understood by all providers. Should the Commission decide to set such a fee, it would be appropriate to set the fee considering the actual dispensing costs incurred in an efficient pharmacy operation.

The dispensing cost study considered several pharmacy attributes to determine if dispensing costs were significantly different based on variables of pharmacy affiliation, location, and specialty. For many tested attributes, we did not observe statistically significant differentials in dispensing cost. We did, however, observe systemically higher dispensing cost associated with pharmacies that specialize in dispensing intravenous and compounded prescriptions. Several significant issues related to these pharmacy specialties are addressed in the study, and one possibility for the Commission to consider is to set multiple flat rate pharmacy dispensing fees specific to certain specialties. We note, however, that many Medicaid pharmacy programs have successfully operated using a single dispensing fee for all pharmacy types. A single dispensing fee must be considered in conjunction with ingredient reimbursement such that overall levels of reimbursement are sufficient to guarantee sufficient participation of various pharmacy specialties.

3) Combination of a Variable Dispensing Fee and a Flat Rate Dispensing Fee
Alternatively, the Commission could evaluate implementing a flat rate dispensing fee to be used in "traditional" pharmacy settings, while maintaining the variable dispensing fee for use among certain pharmacy specialty types. Such a combination would maintain the most advantageous aspects of the variable dispensing fee, yet set the reimbursement for the vast majority of "traditional" prescriptions in a manner consistent with the most widely utilized dispensing fee methodology (i.e., a flat rate).

Chapter
2

Program Overview

Texas Medicaid Pharmacy Program Overview

The Texas Medicaid program includes a benefit for prescription drugs. This program allows recipients access to many commonly prescribed drugs through its formulary.

The current pharmacy dispensing fee is based on the following formula:

$$\text{Dispensing Fee} = \frac{(\text{Est. Drug Ing. Cost}) + (\text{Est. Disp. Exp.})}{(1 - (\text{Inventory Mgmt. Factor}))} - (\text{Est. Drug Ing. Cost}) + (\text{Delivery Fee})$$

The "estimated dispensing expense" currently in use is $5.27, the "inventory management factor" is 2.0% and the "delivery fee[2]" is $0.15. The calculation of the "estimated drug ingredient cost" is subsequently described. The total dispensing fee is limited to $200 per prescription.

An analysis of the Texas dispensing fee formula in conjunction with recent Medicaid utilization leads to the conclusion that the average dispensing fee paid for Texas Medicaid pharmacy claims is approximately $6.10 to $6.40 (based on prescriptions of "average" drug ingredient cost).

Texas Medicaid ingredient reimbursement is based on the following provisions:

- Wholesale estimated acquisition cost (WEAC) or direct estimated acquisition cost (DEAC) based on the pharmacist's usual source of purchasing. WEAC and DEAC are established by the Health and Human Services Commission using market sources including published drug prices and pricing reported directly from drug manufacturers. In practice, WEAC and DEAC are typically derived from benchmark pricing such as "Average Wholesale Price" (AWP) and "Wholesale Acquisition Cost" (WAC) which is reported by drug manufacturers to the Commission.

[2] The delivery fee is paid on all prescriptions filled for pharmacies offering no-charge delivery service.

- Texas Maximum Allowable Ingredient Cost (TMAC) or Federal Upper Limit (FUL), as applicable for multi-source products[3]. A physician may override the FUL or TMAC limits by indicating "brand medically necessary" on a prescription for multi-source drugs with an upper limit price.

Regardless of ingredient cost basis, the overall dispensing fee and ingredient reimbursement formula amount is limited to a maximum of the provider's usual and customary charge to the general public.

Reimbursement policies vary slightly for certain special classes of medications. For example, over-the-counter (OTC) products are reimbursed at 150% of the estimated acquisition costs (based on WEAC or DEAC) with no additional dispensing fee.

Approximately 3,700 pharmacy providers participate in the Texas Medicaid drug program. Approximately 60% of the stores are chain-affiliated, and 40% are independently-owned stores. However, independent pharmacies fill approximately 55% of Texas Medicaid prescriptions. Among Texas Medicaid providers, the mean annual Medicaid prescription volume is approximately 6,500 prescriptions. This mean is impacted by a small number of pharmacies filling over 50,000 Medicaid prescriptions per year. The median annual Medicaid prescription volume is much less, roughly 3,000 prescriptions.[4]

Drug Utilization Profile

Myers and Stauffer obtained a claims summary file from the Texas Health and Human Services Commission. This file summarized pharmacy claims processed for calendar year 2001. Information from this file indicates that the Medicaid program reimbursed approximately:

- 21,000 drug products.
- 28.2 million prescriptions.
- $1.4 billion for prescription drug products.

Although approximately 84% of the 21,000 drug products and 61% of the 28.2 million prescriptions were multi-source drug products, these products account for only 28% ($384 million) of the expenditures. The majority of the program's expenditures, $997 million, were for single source drug products. The proportion of drug expenditures that is for single source drugs has increased in recent years

[3] Reimbursement for many multi-source drug products is limited by FUL prices. For drugs on the FUL list, CMS semiannually reviews and updates the FUL drug list. Each FUL equates to 150% of the lowest wholesale price listed in any of the various published compendia of cost information of drugs. Reimbursement for a limited number of multi-source products is limited by the TMAC prices that are set internally by the Health and Human Services Commission.

[4] Statistics regarding pharmacies that participate in the Vendor Drug Program were derived from a pharmacy provider file obtained from the Health and Human Services Commission. Further descriptions of these data are provided in Chapter 3 under the heading "Pharmacy Sample Selection."

as new and more expensive pharmaceutical products continue to become available.

The following table summarizes the makeup of the program's expenditures by single source and multi-source categories. The table also subdivides drug products based on whether the product has a Federal Upper Limit or a Texas Maximum Allowable Cost.

Table 2.1 Summary of Texas Medicaid Pharmacy Program Utilization

	Product Type	Number of Drug Products [1]	Percent of Total Number of Drug Products	Number of Rxs [2]	Percent of Total Number of Rxs	Amount Reimbursed [2]	Percent of Program Expenditures
	Single Source Products	3,391	16%	11.0	39%	$997.0	72%
Multi-Source Products	Products with an FUL/TMAC [3] Price	9,773	46%	10.0	36%	$195.6	14%
	Products without an FUL/TMAC Price	7,897	38%	7.1	25%	$188.4	14%
	Subtotal: Multi-Source Products	17,715	84%	17.1	61%	$384.0	28%
	Total: All Products	21,061	100%	28.2	100%	$1,381.0	100%

[1] Based on unique NDC.
[2] In millions
[3] Existence of a FUL/TMAC price is based upon August 2002 formulary file from the Health and Human Services Commission.
Note: Utilization figures were obtained from the Health and Human Services Commission and are for Calendar Year 2001.

Chapter
3

Dispensing Cost Survey

The two primary components for reimbursement of pharmaceuticals are drug ingredient cost and the dispensing fee. The dispensing, or professional, fee is paid to pharmacies to cover their overhead and labor costs. Federal regulations at 42 CFR 447.331-333 require states to establish a reasonable dispensing fee for their Medicaid pharmacy programs and to document their pharmacy reimbursement methodology in their state plan.

Dispensing fees for Medicaid programs nationally have typically been based on an analysis of costs incurred by pharmacies within the state and tend to vary somewhat from state to state. In order to determine costs incurred to dispense pharmaceuticals to Medicaid recipients in Texas, Myers and Stauffer utilized a survey method consistent with the methodology of the previous surveys conducted by Myers and Stauffer in 18 states.

Methodology of the Survey

Development of Methodology

Survey methodologies used by the firm have been developed and refined since our first dispensing cost study engagements in the 1970's. The cost accounting principles used in the study are, however, standard to the health care industry and are similar to methods other experts have used to study pharmacy dispensing cost. Please refer to Appendix A for references to other pharmacy studies and the accounting principles that provide background to the methodologies used in this study.

Pharmacy Sample Selection

Myers and Stauffer received a pharmacy provider file from the Health and Human Services Commission that included the following information:

- Medicaid provider numbers
- Provider names
- Provider address and phone number information

- Pharmacy location by county
- Pharmacy location: urban versus rural status
- Pharmacy "provider type description"
- Prescription claim count for calendar year 2001
- Prescription claim dollar amount for calendar year 2001

Based on an analysis of predicted statistical variation, expected participation rates and other considerations, Myers and Stauffer developed a survey plan that involved soliciting participation in the dispensing cost survey from approximately 900 pharmacies. The selection criterion for the sample was primarily random. However, certain stratification protocols were implemented to promote adequate representation of various pharmacy specialties and geographic locations. Myers and Stauffer determined that certain pharmacy traits were broadly distributed, and were therefore appropriately captured in adequate numbers in a random sample. There were also some attributes for which better representation was obtained via a stratification process.

After importing the pharmacy provider data into internal database formats, Myers and Stauffer performed a process of making preliminary identifications of pharmacy specialties. Various "flags" were created for the purpose of performing appropriate sample stratification. Pharmacy attributes that were flagged are as follows:

- **Chain versus Independent Affiliation**
  Myers and Stauffer made a preliminary determination of chain versus independent based on a preliminary visual inspection of the provider file. As applicable, Myers and Stauffer staff also utilized their experience with and exposure to various national chain organizations. For the purposes of this project, a chain was considered an entity with five or more stores nationally.

- **Urban versus Rural Location**
  Myers and Stauffer used the urban versus rural status designated in the provider file by the Commission. For informational purposes, Myers and Stauffer used zip code data from the U.S. Census Bureau to crosswalk the pharmacy location to individual Texas counties. A county was deemed to be "urban" based on its location in a "Metropolitan Statistical Area" (MSA) as used by the Census. Other counties were considered "rural." Pharmacies not physically located in the state of Texas were not classified as to urban or rural status and are merely referred to as "out of state." This process determined that the urban versus rural status assigned by Commission were reasonably consistent with Census Bureau designations.

- **Long-Term Care Pharmacy Provider Status**
  The pharmacy provider data included a pharmacy description field as designated by the Commission. One code is used to identify pharmacies dispensing to nursing facility residents. Such pharmacies were identified with

the long-term care flag. A few additional providers were so classified based on name recognition of the provider.

- **Provision of Intravenous Prescription Services**
  Myers and Stauffer used the pharmacy description field to identify pharmacies that appear to specialize in home infusion services or otherwise provide intravenous prescription dispensing services. A few additional providers were so classified based on name recognition of the provider.

- **Hospital Based Pharmacies**
  Based on prior discussions with the Commission staff, it was determined that the dispensing cost survey would not include pharmacies that are hospital-based. Based on previous experience, Myers and Stauffer has learned that it is extremely difficult to get meaningful data from these types of pharmacies due to the types of accounting records maintained in hospital environments. Myers and Stauffer visually examined pharmacies that had names or designations in the description field indicating that they were hospital based.: Pharmacies so identified were not included in subsequent sample selection procedures. There were approximately 60 pharmacies excluded based on this criteria. Collectively, these pharmacies account for approximately 1.5% of prescriptions dispensed for the Texas Medicaid Vendor Drug Program.

Low Volume Exclusion from Pharmacy Sample
Prior to selecting any pharmacies into the random sample, Myers and Stauffer excluded all pharmacies that dispensed fewer than 250 prescriptions and received payments of less than $10,000 during calendar year 2001. It has been our experience that these pharmacies with low volume of Medicaid prescriptions often are out-of-state, newly opened, or recently closed pharmacies. As such, these pharmacies do not represent the norm of Medicaid participating providers. Additionally, our experience has shown that due to their low Medicaid volume, many of these pharmacies would be reluctant to spend the time and effort required to participate in the survey. These pharmacies also have little impact on the overall cost structure of pharmacies in the Medicaid pharmacy program (and conversely are often only minimally impacted by the Medicaid program). Approximately 290 pharmacies were excluded based on this criteria. Collectively, all of these low Medicaid volume pharmacies dispensed less than one-tenth of one percent of Medicaid prescriptions in calendar year 2001.

Stratification Protocols based on Pharmacy Specialty
Based on our preliminary analysis, there were certain specialties that were not broadly distributed among the pharmacy population (exclusive of the low Medicaid volume pharmacies previously described). In particular we noted that there were 56 pharmacies that met the criteria for the long-term care pharmacy provider designation. Also, there were only 43 pharmacies identified that dispensed intravenous prescriptions as a significant portion of their volume. Myers and Stauffer believed that in order to ensure adequate representation of

specialties represented by these flags, 100% of the pharmacies so identified should be included in the sample.

Stratification Protocols Based on Pharmacy Location
It was noted that there were 642 pharmacies located in counties designated as "rural" in the provider population eligible for inclusion in the survey. The attribute of being located in a rural location appeared to be somewhat broadly distributed and suitable for random selection without stratification. However, Myers and Stauffer determined that a random sampling of rural pharmacies could cause certain regions of the state to have a low representation in the sample. Therefore, we developed a computer algorithm to ensure that each Texas county was represented by at least one pharmacy (assuming that there was at least one Medicaid pharmacy in the county that did not meet the low volume or hospital-based exclusion criteria).

Random Selection
After including the stratification groups identified previously, a computer algorithm randomly selected pharmacies for inclusion in the survey sample.

Mailing Procedures

Survey forms were mailed on April 23, 2002 to 890 pharmacy providers currently enrolled in the Texas Medicaid program that were selected from the sampling methodology. Each pharmacy received a copy of the cost survey (Exhibit 1), a list of instructions (Exhibit 2), a letter of introduction from the Commission (Exhibit 3), a letter of explanation from Myers and Stauffer (Exhibits 4 and 5) and a business reply envelope.

Survey Participation

Of the 890 surveyed pharmacies, 34 pharmacies were determined to be ineligible to participate. Providers were deemed ineligible if they had closed their pharmacy, had a change of ownership, or had less than six months of cost data available.

Concerted efforts to encourage maximum participation were made by various parties concerned with the success of the survey. An official letter explaining the purpose of the study was sent to the sampled pharmacy providers by the Commission. The cost survey forms and instructions and a letter of explanation from Myers and Stauffer offered pharmacy owners the option of having Myers and Stauffer complete certain sections of the survey form if copies of financial statements and/or tax returns were supplied. A toll-free telephone number was listed on the survey form, and pharmacists were urged to call to resolve any questions they had concerning completion of the survey form.

By the original filing deadline of May 10, 2002, 63 cost surveys had been received. In an effort to increase the response rate, surveys were accepted after the due date and Myers and Stauffer sent letters to non-responding pharmacies encouraging them to participate in the survey (Exhibits 6 and 7). Additionally, key staff at various chain pharmacy headquarters were contacted by telephone.

As is typical with these projects, many of the submitted cost surveys contained errors or were incomplete. For cost surveys with such errors or omissions, the pharmacy was contacted for clarification. There were some cases in which issues on the cost survey were not resolved in time for inclusion in the final analysis. Ultimately, 703 surveys were entered into a database and used in our analysis of dispensing costs.

The following table, 3.1, summarizes the cost survey response rate.

Table 3.1 Dispensing Cost Survey Response Rate

Type of Pharmacy / Pharmacy Attribute	Total Medicaid Participating Pharmacies	Pharmacies Receiving Cost Surveys	Pharmacies Exempt from Filing	Eligible Pharmacies	Usable Cost Surveys Received	Response Rate
Chain	2,240	472	21	451	396	88%
Independent	1,457	418	18	400	307	77%
Urban[1]	2,951	655	32	623	505	81%
Rural[1]	654	228	7	221	195	88%
Institutional[2]	62	56	3	53	46	87%
Intravenous[3]	59	43	3	40	19	48%
All Pharmacies[4]	**3,697**	**890**	**39**	**856**	**703**	**82%**

[1] Urban versus rural status determined for in-state pharmacies only.

[2] Initial determination of institutional pharmacy status was based on a review of the Texas Medicaid provider file sent by the Health and Human Services Commission. Review of submitted cost reports later indicated that some pharmacies originally considered to be "institutional" did not meet the criteria that is typically implied with the term. Analyses subsequent to the collection of cost report data modified classification criteria based on self-reported statistics.

[3] Initial determination of intravenous dispensing status was based on a review of a sample of the Texas Medicaid provider file sent by the Health and Human Services Commission. Analyses subsequent to the collection of cost report data determined intravenous dispensing status based on self-reported sales statistics.

[4] The pharmacy types in the table include some overlap, therefore the total for all pharmacies is not a sum of the above categories.

Reporting Bias

For the traits listed in Table 3.1, the sample of 703 pharmacies was tested to determine if it was representative of the population of Medicaid provider pharmacies. Since the response rate of the sample pharmacies was less than 100 percent, the possibility of bias in the responding sample should be considered. To measure the likelihood of this possible bias, chi square (χ^2) tests were performed. Among other attributes, a chi square test was used to determine whether the final sample was independent with respect to traits that were assumed to be broadly distributed.

Of the 703 cost surveys, 307 were from independent pharmacies and 396, or 56%, were from chain pharmacies. We observed slight differences in the response rates for chain and independent pharmacies. There are several factors that appear to have caused this phenomenon. First, the decision of a chain organization to file typically meant filing for all, or at least the majority, of its pharmacies included in the pharmacy sample. There were eleven large pharmacy chains in Texas that filed usable cost surveys for five or more stores, and these eleven chain organizations collectively supplied approximately 379 usable surveys. The decision for an independent pharmacy to file, however, typically only affected one, or on some occasions, two stores. Chain organizations typically have corporate accounting offices or third party program managers in place to handle tasks such as completing cost surveys. Owners of independent pharmacies, however, are often involved in many facets of their business operation, and consequently are in some cases less likely to have the time or resources available to complete a cost survey. An additional reason for a greater number of chain pharmacy surveys being available was an increased difficulty of contacting independent pharmacists to resolve any issues involved with their cost report. Chain pharmacies, alternatively, could be contacted through their corporate offices where again, mechanisms were in place to deal with our inquiries.

Other characteristics (e.g. specialty pharmacy straits) of the final sample are represented in slightly different proportions than exist in the population of Texas Medicaid provider pharmacies due to the stratification techniques used in the sample selection process.

Due to the use of these stratification protocols and the possibility of reporting bias, further analysis is indicated to determine whether there is a significant difference in dispensing costs of the various pharmacy characteristics. This issue is further addressed in the "Analysis and Findings" section of this chapter.

Receipt and Review Procedures

For confidentiality purposes, each pharmacy was randomly assigned a four-digit identification number and each cost survey was carefully examined. This review identified cost surveys considered incomplete, and pharmacies submitting these cost surveys were sent a "Request for Additional Information" letter specifying the information necessary for completion (Exhibit 8) or were contacted by telephone.

Field Examination Procedures

A total of 31 pharmacies were selected for a field examination. The selection was primarily random, but geographic location was taken into consideration. A letter was sent to each selected pharmacy explaining the selection process, the time period during which the field examination would take place, and the necessary data to have available. Each pharmacy was then contacted by telephone for

further explanation of the field examination and confirmation of the time and date. An examination file was prepared for each of the pharmacies containing a uniform field examination program, a copy of the completed reviewed cost survey, and other necessary work papers.

Following the actual visit to the pharmacy, work papers were completed by making a second examination of each file to ensure that all necessary information had been obtained. Follow-up letters were sent to pharmacies visited, expressing appreciation for the time and cooperation of pharmacy personnel. Each work paper file was reviewed for quality assurance. Results of the field examinations showed no significant bias in overstating or understating costs reported on the cost survey (Exhibit 9).

Cost Finding Procedures

Cost finding is the process of recasting cost data using rules or formulas in order to accomplish an objective. In this study, the objective is to estimate the cost of dispensing prescriptions to Medicaid recipients. To accomplish this objective, some pharmacy costs must be allocated between the prescription dispensing function and other business activities. This process identified the reasonable and allowable costs necessary for prescription dispensing to Medicaid recipients.

Most pharmacies are also engaged in lines of business other than the dispensing of prescription drugs. For example, many pharmacies have a retail business with sales of over-the-counter (OTC) drugs and other non-medical items. Some pharmacies are involved in the sale of durable medical equipment. The existence of these other lines of business necessitate that procedures be taken to isolate the costs involved in the prescription dispensing function of the pharmacy.

Dispensing cost consists of two components: overhead and labor. The cost finding rules employed to determine each of these components are described in the following sections.

Overhead Costs

Overhead cost per prescription was calculated by summing the allocated overhead of each pharmacy and dividing this sum by the number of prescriptions dispensed. Overhead expenses originally reported for the entire pharmacy were allocated to the prescription department based on either:

- Sales ratio (prescription sales divided by total sales)
- Area ratio (prescription department floor space (in square feet) divided by total floor space)
- All (100%)
- None

Overhead costs that were considered *entirely prescription-related* include:

- Prescription department fees
- Prescription delivery expense
- Prescription computer expense
- Prescription containers and labels (For many pharmacies the costs associated with prescription containers is captured in their cost of goods. Subsequently, it was often the case that a pharmacy was unable to report expenses for prescription containers. In order to maintain consistency, a standardized allowance for prescription containers was determined after consultation with several pharmacists. See Exhibit 10.)
- Certain other expenses that were separately identified on lines 27-29[5] (see the cost survey in Exhibit 1)

Overhead costs that were *not allocated as a prescription expense* include:

- Income taxes[6]
- Bad debts[7]
- Advertising
- Contributions[8]

Certain costs reported on Lines 27, 28, and 29 were occasionally excluded. An example is freight expense, which usually relates only to nonprescription purchases or cost of goods sold.

The remainder of the costs was assumed to be related to *both prescription and nonprescription sales*. Joint cost allocation is necessary to avoid understating or overstating the cost of filling a prescription.

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[5] Expenses that were considered entirely prescription-related were transferred to Line 28. One example is continuing professional education for a pharmacist.

[6] Income taxes are not considered an operational cost because they are based upon the profit of the pharmacy operation. Although a separate line was provided for the state income taxes of corporate filers, it was not allowed as a prescription cost in order to afford equal treatment to each pharmacy, regardless of the type of ownership.

[7] Bad debts were not considered a prescription-related expense since they are revenue offsets arising through an accrual recognition of revenues which are later found to be not collectible. Disallowing this expense also afforded equal treatment to providers, irrespective of their method of accounting.

[8] Individual proprietors and partners are not allowed to deduct contributions as a business expense for federal income tax purposes. Any contributions made by their business are deducted along with personal contributions as itemized deductions. However, corporations are allowed to deduct contributions as a business expense for federal income tax purposes. Thus, while Line 19 on the cost report recorded the business contributions of a corporation, none of these costs were allocated as a prescription expense. This, again, afforded equal treatment for each type of ownership.

Those overhead costs allocated on the ratio of the *floor space* (as previously defined) include:

- Depreciation
- Real estate taxes
- Rent
- Repairs
- Utilities

The costs in these categories were considered a function of floor space. For example, the larger the facility, the higher the rent, if other factors are considered equal. The floor space ratio was increased by 50 percent from that reported on the original cost survey to allow for waiting area for patients and prescription department office area. The resulting ratio was adjusted downward, when necessary, not to exceed the sales ratio (in order to avoid allocating 100% of these costs in the rare instance where the prescription department occupies the majority of the area of the store).

Overhead costs allocated using the *sales ratio* include:

- Personal property taxes
- Other taxes
- Insurance
- Interest
- Accounting and legal fees
- Telephone and supplies
- Dues and publications

Labor Costs

Labor costs are calculated by allocating total salaries, payroll taxes, and benefits based on the percent of time spent in the prescription department. The allocations for each labor category were summed and then divided by the number of prescriptions dispensed to calculate labor cost per prescription. There are various classifications of salaries and wages requested on the cost survey (Lines 31-44) due to the different cost treatment given to each labor classification.

An Example:

An employee pharmacist spends 90 percent of their time in the prescription department. The 90 percent factor would be modified to 95 percent:

$$\frac{(2)(.9)}{(1+.9)}$$

Thus, 95 percent of the reported salaries, payroll taxes, and benefits would be allocated to the prescription department. It should be noted that most employee pharmacists spent 100 percent of their time in the prescription department.

The total salaries, payroll taxes, and benefits of employee pharmacists (Lines 34-38) were multiplied by a factor based upon the percent of prescription time. Although some employee pharmacists spent a portion of their time performing nonprescription duties, it was assumed that their economic productivity when performing nonprescription functions was less than their productivity when performing prescription duties. Therefore, a higher percentage of salaries, payroll taxes, and benefits was allocated to prescription labor costs than would have been allocated if a simple percent of time allocation was utilized. Specifically, the percent of prescription time indicated was multiplied by two and divided by the percent of prescription time plus one.

The allocation of salaries, payroll taxes, and benefits for all other prescription employees (Lines 39-43) was based directly upon the percentage of time spent in the prescription department as indicated on the individual cost survey. For example, if the reported percentage of prescription time was 75 percent and total salaries were $10,000, then the allocated prescription cost would be $7,500.

Owner Compensation Issues

The allocation of salaries, payroll taxes, and benefits of the owner pharmacists (Lines 31-33) was based upon the same modified percentage as that used for employee pharmacists. However, limitations were placed upon the allocated salaries, payroll taxes, and benefits of owner pharmacists. Since amounts shown for owner pharmacists are not historical costs that have arisen from arm's length negotiations, they are not similar to other costs. A pharmacy owner has a different attitude toward other expenses than toward his/her own salary. In fact, owners often pay themselves above the market costs of securing the services of an employee pharmacist. This excess effectively represents a withdrawal of business profits, not a cost of dispensing. Some owners may underpay themselves for business reasons, which would also misrepresent the true dispensing cost.

A factor considered in determining the allocation of owner's salaries was the variability in productivity. For example, one owner pharmacist may dispense 5,000 prescriptions per year while another may dispense 30,000. Those owner pharmacists who dispensed a greater number of prescriptions were allowed a higher salary than were owner pharmacists who dispensed a smaller number of prescriptions. Since variance is not nearly as great with respect to employee pharmacists, the owner pharmacist's salary was subjected to limits based upon employee pharmacists' salaries per prescription.

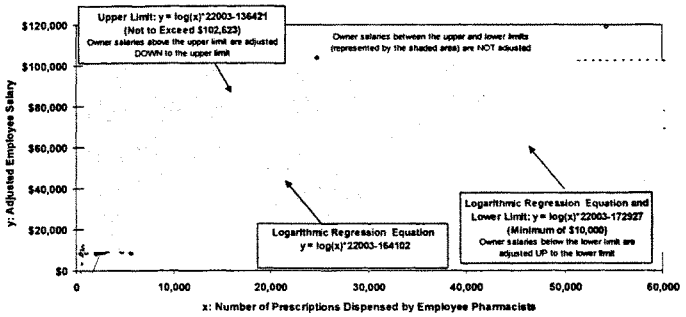
Determining Owner Compensation Allowances

To estimate the cost that would have been incurred had an employee been hired to perform the prescription-related functions actually performed by the owner, a

statistical regression technique was used. A bivariate plot shows the correlation between an independent (predictor) variable and a dependent (predicted) variable. The upper and lower limits on owner pharmacist salary were determined from a bivariate regression (Chart 3.1)[9]. In order to accurately reflect the trend of decreasing marginal costs with increasing volume, a regression technique that fit the bivariate data to a logarithmic curve was used. The resulting regression equation to predict pharmacist labor cost at varying amounts of work performed is:

***Labor cost* = 22,003 *X ln (number of prescriptions dispensed*[10]*)* – 164,102**
(where ***ln*** represents the natural logarithm function)

Chart 3.1 Owner Pharmacist Limits Based on Employee Pharmacist Salaries



This equation was used to establish limits for allocating owner pharmacist costs. There was variation in actual employee salaries both above and below this regression line. This variation is measured by the equation's *standard error of the estimate*, $16,828. The standard error of the estimate was used to construct upper and lower limits of owner pharmacist labor cost:

***Upper Limit* = 22,003 *X ln (number of prescriptions dispensed)* – 136,421**
***Lower Limit* = 22,003 *X ln (number of prescriptions dispensed)* – 172,927**

These two constraints effectively set upper and lower thresholds at approximately the 30th and 95th percentiles of volume adjusted employee salaries. An additional constraint is a $102,623 maximum annual salary and a $10,000 minimum salary.

[9] Employee pharmacist salary per prescription was used to set limitations on owner pharmacist salary estimates due to the "arm's length" nature and lack of variance in employee productivity compared with owner productivity.

[10] The number of prescriptions filled by the owner pharmacist was determined by multiplying the percent of owner-filled prescriptions (Lines 31-33 of the cost report) by the total number of prescriptions dispensed (Line a).

These amounts are based on the 30th and 95th percentile of volume adjusted employee salaries.

There is no reason to believe that managerial or clerical duties performed by the nonpharmacist owners were more valuable to the prescription dispensing function than for other functions. As with other owners, the amount shown for salaries, payroll taxes, and benefits was not a result of arm's length negotiations. Therefore, an upper limit of $35,000 and a lower limit of $17,000 were placed upon these prescription costs. These limits were chosen based on experience from this survey and prior surveys. No adjustment was made to the percentage of prescription time factor for owner nonpharmacists (Lines 31-33).

Overall Labor Cost Constraints

An overall constraint was placed on the proportion of total reported labor that could be allocated as prescription labor. The constraint assumes that a functional relationship exists between the proportion of allocated prescription labor to total labor **and** the proportion of prescription sales to total sales. It is also assumed that a higher input of labor costs is necessary to generate prescription sales than nonprescription sales, within limits.

The parameters of the applied labor constraint are based upon an examination of data submitted by all pharmacies. These parameters are set in such a way that any resulting adjustment affects only those pharmacies with a percentage of prescription labor deemed unreasonable. For instance, the constraint would come into play for an operation that reported 75 percent pharmacy sales and 100 percent pharmacy labor (obviously, some labor must be devoted to generating the 25 percent nonprescription sales).

To determine the maximum percentage of total labor allowed, the following calculation was made:

$$\frac{0.3(\text{Sales Ratio})}{0.1+(0.2)(\text{Sales Ratio})}$$

Inflation Factors

Pharmacies were requested to supply financial and statistical data from their "most recent fiscal year ending on or before December 31, 2001" (see survey instructions, Exhibit 2). There was some variation in the financial reporting cycles for which pharmacy data was submitted (see Exhibit 11). However, the vast majority of pharmacies reported information for fiscal years ending in 2001 or early 2002.

Due to the variation in fiscal reporting cycles, all allocated costs for overhead and labor were totaled and multiplied by an inflation factor. Inflation factors are

intended to reflect cost changes from the middle of the reporting period of a particular pharmacy to a common fiscal period ending December 31, 2002 (specifically from the *midpoint* of the pharmacy's fiscal year to the *midpoint* of the common fiscal period, June 30, 2002). The midpoint and terminal month indices used were taken from the U. S. Government Consumer Price Index (CPI), Urban Consumer (see Exhibit 11). The use of inflation factors is preferable in order for pharmacy cost data from various fiscal years to be compared uniformly.

Recent experience with pharmacy cost studies has indicated that the CPI may tend to overstate increases in dispensing cost over an extended time. This appears to be the result of increased cost containment pressures exerted on retail pharmacies by reduced reimbursement from managed care entities. The impact of these cost containment pressures may have been mitigated during the period of the dispensing cost survey by apparent escalations in pharmacists salaries driven, in part, by a perceived pharmacist shortage.

Analysis and Findings

The dispensing costs for all pharmacies in the sample are summarized in the tables and paragraphs following. Findings for all pharmacies in the sample are presented collectively, and additionally are presented for subsets of the sample based on pharmacy characteristics. There are several statistical measurements that may be used to express the central tendency of a distribution, the most common of which are the mean and the median (see sidebar). Findings are presented in the forms of means and medians, both raw and weighted.

In many real world settings such as this dispensing cost survey, statistical "outliers" are a common occurrence. These outlier pharmacies have dispensing costs that are not typical of the majority of pharmacies.

Different Measures of Central Tendency:

Unweighted mean: the arithmetic mean cost for all pharmacies.

Weighted mean: the mean cost of all prescriptions dispensed by pharmacies included in the sample, weighted by prescription volume. The resulting number is the mean cost for all prescriptions, rather than the mean for all pharmacies as in the unweighted mean. This implies that low volume pharmacies have a smaller impact on the weighted mean than high volume pharmacies. This approach, in effect, sums all costs in the sample and divides that sum by the total of all prescriptions in the sample. The weighting factor can be either total prescription volume or Medicaid prescription volume.

Median: the value that divides a set of observations (such as dispensing cost) in half. In the case of this survey, the median is the dispensing cost such that the cost of one half of the pharmacies in the set are less than or equal to the median and the dispensing costs of the other half are greater than or equal to the median.

Weighted Median: This is determined by finding the pharmacy observation that encompasses the middle value prescription. The implication is that one half of the prescriptions were dispensed at a cost of the weighted median or less, and one half were dispensed at the cost of the weighted median or more.

Suppose, for example, that there were 1,000,000 Medicaid prescriptions dispensed by the pharmacies in the sample. If the pharmacies were arrayed in order of dispensing cost, the median weighted by Medicaid volume, is the dispensing cost of the pharmacy that dispensed the middle, or 500,000th prescription.

Medians are often preferred to arithmetic means in situations where the magnitude of outlier values results in a mean that does not represent what is thought of as "average" or normal in the common sense. The measurement that is the most ideally suited for determining the typical cost of dispensing prescriptions to Medicaid recipients is the **median weighted by Medicaid volume**.

For all pharmacies in the sample, dispensing cost findings are presented in Table 3.2.

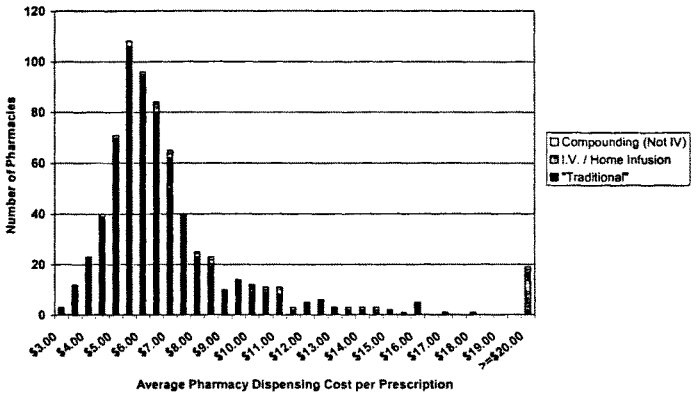
Table 3.2 Cost Per Prescription – All Pharmacies

	Dispensing Cost[1]
Unweighted Mean	$9.12
Mean Weighted by Medicaid Volume	$6.58
Unweighted Median	$6.48
Median Weighted by Medicaid Volume	$6.11

[1] Dispensing Costs have been inflated to the common point of June 30, 2002.

Chart 3.2 is a histogram of the dispensing cost for all pharmacies in the sample. There was a large range between the highest and lowest dispensing cost observed for pharmacies in the sample. The majority of pharmacies (75%), however, had dispensing costs between $4 and $8.

Chart 3.2 Dispensing Cost by Pharmacy



The two most significant characteristics that affected pharmacy dispensing cost were the provision of intravenous or home infusion solutions and the provision of pharmaceutical compounding services. Our analysis revealed significantly higher cost of dispensing associated with the 53 pharmacies in the sample that provided these services.

In every pharmacy dispensing study where information on intravenous solution and home infusion dispensing activity has been collected by Myers and Stauffer,

such activity has been found to be associated with higher dispensing costs. Discussions with pharmacists providing intravenous solutions indicate that the activities and costs involved in filling intravenous prescriptions are significantly different from the costs incurred by the typical retail (or long term care) pharmacy. The reasons for this difference include:

- Costs of special equipment for mixing and storage of intravenous solutions.
- Higher direct labor costs because most intravenous prescriptions must be mixed in the pharmacy, whereas the manual activities to fill a non- intravenous prescription are mainly limited to counting pills (or vials, etc.) and printing and affixing the label.
- A pharmacy may mix and deliver many "dispensings" of a daily intravenous solution from a single prescription, thus incurring additional costs spread over a smaller number of prescriptions.

This latter factor, in particular, can have a dramatic impact on increasing a pharmacy's apparent cost per prescription.

Similar to the dispensing of intravenous prescriptions, the provision of complex pharmaceutical compounding services was also observed to be associated with significantly higher cost.

The differences in dispensing costs which were observed for providers of intravenous or compounding services compared to those pharmacies that did not offer these services are summarized in Table 3.3.

Table 3.3 Cost Per Prescription - Intravenous / Compounding Pharmacies Versus other Pharmacies

Type of Pharmacy	Number of Pharmacies	Unweighted Mean Cost[1]	Standard Deviation
Pharmacies Dispensing Intravenous / Home Infusion Prescriptions	43	$41.75	$72.59
Pharmacies Dispensing Compounded Prescriptions (but not intravenous Rxs)	10	$9.13	$5.48
Pharmacies Not Dispensing Intravenous or Compounded Prescriptions	650	$6.96	$2.46

[1] Dispensing Costs have been inflated to the common point of June 30, 2002.

Based on this analysis and analyses performed in other studies, pharmacies that dispense intravenous or compounded prescriptions as a significant part of their business can have dispensing costs far in excess of those found in a traditional pharmacy. Based on our cost findings, it must be concluded that the costs incurred to dispense intravenous or compounded prescriptions are not representative of the costs incurred by a general pharmacy. If the costs of intravenous and compounding services were to be included in the computation of an mean or median dispensing cost that was then used to establish a reimbursement rate, the effect would be to pay approximately 95% of pharmacies an additional allowance for a service they never provided. And, for those pharmacies providing intravenous services, the marginal increase in the fee would be immaterial in relation to the cost of actually dispensing an intravenous or compounded prescription.[11]

Consequently, many of the analyses that follow exclude providers that had dispensed a significant volume of intravenous or compounded prescriptions. Table 3.4 restates the measurements noted in Table 3.2 excluding pharmacies that dispensed significant volumes of intravenous or compounded prescriptions.

Additional comments regarding pharmacies that dispense intravenous or compounded prescriptions is included in Appendix D.

Table 3.4 Cost Per Prescription – Excluding Intravenous and Compounding Pharmacies

	Dispensing Cost
Unweighted Mean	$6.96
Mean Weighted by Medicaid Volume	$6.16
Unweighted Median	$6.42
Median Weighted by Medicaid Volume	**$5.95**[1]

[1] Dispensing Costs have been inflated to the common point of June 30, 2002.

Analysis of Pharmacy Characteristics

Responding pharmacies were categorized into various groups of interest and their dispensing costs analyzed to determine statistical significance. These characteristics include:

- Total prescription volume
- Chain versus independent pharmacy affiliation
- Urban versus rural pharmacy location

[11] Although typical dispensing fees reimburse less than the dispensing costs of intravenous pharmacies, they are generally able to break even based on the margin allowed on ingredient cost reimbursement. Compounding pharmacies predominantly market their services to self-pay customers and do not solicit Medicaid reimbursement for most compounding services.

- Total Medicaid volume
- Medicaid volume as a percent of total volume
- Provision of unit dose dispensing services
- Provision of prescription drugs to residents of long-term care facilities

One way to determine the statistical significance of differences in dispensing cost between the pharmacies classified by the above referenced characteristics is through the use of a *t*-test. The sample data may show that a certain group of pharmacies has a sample mean lower or higher than another group. Recognizing that the data only represents a sample, a *t*-test is a statistical technique that seeks to determine if the findings are strong enough that a similar relationship can be expected to exist for the entire population. The *t*-test takes into consideration the sample's size, mean, and underlying variance. Although the preference of using a weighted median as a measurement of central tendency was previously explained, a *t*-test requires the comparison of the *unweighted mean* costs.

Exhibit 12 provides additional statistical measures including the standard error of the mean and confidence intervals. Confidence intervals given in Exhibit 12 were calculated using appropriate statistics from the *t* distribution at the 90% and 95% confidence levels. These intervals are a range estimate for the population mean, and are based upon the sample mean, standard deviation, and sample size. A 95% confidence interval identifies the range which one would expect the mean from *any* sample to fall 95% of the time. It can be inferred that there is approximately a 95% probability that the population mean lies within the range of the confidence interval.

All costs referred to in these analyses have been inflation adjusted to the common point of June 30, 2002.

1) Total Prescription Volume

Pharmacies were classified into meaningful groups based upon their differences in total prescription volume. Dispensing costs were then analyzed based upon these volume classifications.

Table 3.5 Pharmacy Total Annual Prescription Volume

Total Annual Prescription Volume of Pharmacy	Number of Stores	Unweighted Mean Cost	Standard Deviation of Cost
0 to 29,999	158	$8.94	$3.74
30,000 to 59,999	220	$6.67	$1.70
60,000 and Higher	272	$6.05	$0.96

There is a significant correlation between a pharmacy's total prescription volume and the dispensing cost per prescription. For all categories noted above differences in the mean dispensing cost were statistically significant (at the 5% level of significance). This result is not surprising because many of the costs associated with any business, including the dispensing of prescriptions, are fixed in nature, and do not vary significantly with increased volume. For stores with a higher total prescription volume, these fixed costs are spread over a greater number of prescriptions resulting in lower costs per prescription. (A more detailed analysis of cost variations attributable to total prescription volume using statistical regression techniques is presented later in the report.)

2) Chain Versus Independent Pharmacy Affiliation

Of the 650 pharmacies that did not dispense a significant volume of intravenous or compounded prescriptions, 265 were independent pharmacies and 385 were chain pharmacies.

Table 3.6 Chain Versus Independent Pharmacies

Type of Pharmacy	Number of Stores	Unweighted Mean Cost	Standard Deviation of Cost	Mean Annual Total Prescription Volume
Independent	265	$6.82	$2.83	39,214
Chain	385	$7.07	$2.17	75,850

The use of a *t*-test indicates that the difference in the unweighted means is not statistically significant (at the 5% level of significance).

Also noted in Table 3.6 is the mean prescription volume for independent and chain pharmacies. It is noteworthy that the mean volume of chain pharmacies in the sample is approximately 93% greater than the mean volume observed for independent pharmacies.

3) Urban Versus Rural Pharmacy Location

Myers and Stauffer used the urban versus rural status designated in the provider file by the Commission. Table 3.7 shows calculated dispensing cost and standard deviation for pharmacies categorized by their urban versus rural location.

Table 3.7 Urban Versus Rural Pharmacy Location

Location of Pharmacy	Number of Stores	Unweighted Mean Cost	Standard Deviation of Cost	Mean Annual Total Prescription Volume
Urban	460	$7.10	$2.55	67,890
Rural	189	$6.64	$2.21	43,520

Note: Excludes out of state pharmacies that participate in the Texas Vendor Drug Program.

The use of a *t*-test indicates that the difference in the unweighted means **is** statistically significant (at the 5% level of significance).

Previously it was noted that the process of selecting pharmacies into the sample to be surveyed included some stratification protocols to ensure adequate representation of pharmacies in rural Texas counties. Because of the observed differential in dispensing cost between urban and rural pharmacies, measurements of dispensing cost that combine urban and rural pharmacies should be considered in light of possible skewing in favor of rural pharmacies.

As an additional analysis of pharmacy dispensing cost by location, pharmacies were grouped into regional classifications (see Table 3.8 and Chart 3.3).

Table 3.8 Dispensing Costs by Medicaid Subregion [1]

Location of Pharmacy (Region)	Number of Stores	Unweighted Mean Cost	Standard Deviation of Cost	Mean Annual Total Rx Volume	Mean Medicaid Rx Volume as % of Total Rx Volume
1. Houston – West	37	$7.66	$4.62	72,421	13%
2. Tyler	48	$6.46	$2.12	59,403	22%
3. Austin	56	$6.60	$1.72	72,770	11%
4. San Antonio – West	33	$7.04	$1.89	70,452	17%
5. Fort Worth	43	$7.22	$2.30	74,809	5%
6. El Paso	43	$7.21	$2.70	56,135	23%
7. Dallas	53	$8.33	$2.79	57,224	7%
8. Brownsville / Corpus Christi	50	$6.57	$1.68	56,399	42%
9. Abilene / Wichita Falls	40	$7.22	$3.01	46,837	14%
10. San Antonio – East	45	$6.65	$2.26	55,921	10%
11. Amarillo / Lubbock	53	$6.82	$2.18	42,740	14%
12. Arlington	52	$7.50	$2.44	65,697	10%
13. Beaumont / Galveston	45	$6.03	$1.39	58,585	10%
14. Houston – North	51	$6.36	$1.78	65,348	12%

1. Pharmacy subregion codes were defined in the pharmacy address file provided by the Texas Health and Human Services Commission. Subregion descriptions use city names to indicate an approximate geographical location of the subregion. Out of state pharmacies not included in regional breakdown.

Several of the differences observed in the regional breakdown of dispensing cost were statistically significant (at the 5% level of significance). It is also noted that there is some variation in the mean total prescription volume between the various

regions. Furthermore, the distribution of Medicaid volume was highly skewed towards certain regions. For example, the mean Medicaid utilization ratio of Region 8 (Brownsville / Corpus Christi) pharmacies in the sample was 42% compared to an overall mean Medicaid utilization ratio of 15%. In other regions, the mean Medicaid utilization ratio for pharmacies in the sample was as low as 5% to 10%.

4) Medicaid Prescription Volume

Pharmacies were also classified based upon their Medicaid prescription volume. Medicaid volume was supplied to Myers and Stauffer by the Health and Human Services Commission.

Table 3.9 Pharmacy Annual Medicaid Prescription Volume

Annual Medicaid Prescription Volume of Pharmacy	Number of Stores	Unweighted Mean Cost	Standard Deviation of Cost
0 to 1,999	159	$8.40	$3.34
2,000 to 10,000	344	$6.70	$2.03
10,000 and Higher	147	$6.02	$1.39

For the classifications shown, some differences in the mean dispensing cost were found to be statistically significant (at the 5% level of significance). It should be noted, however, that there is a correlation between Medicaid volume and total prescription volume. The relationship noted with regard to Medicaid volume, is a function of total prescription volume rather than Medicaid volume alone.

5) Medicaid Prescription Volume as a Percent of Total Prescription Volume

A better measure of the effect of a provider's Medicaid volume was to use Medicaid volume as a percent of total volume. To facilitate this analysis, pharmacies were arrayed into meaningful classifications of Medicaid utilization.

Table 3.10 Pharmacy Medicaid Utilization Ratio

Medicaid Prescription Volume as a Percent of Total Volume	Number of Stores	Unweighted Mean Cost	Standard Deviation of Cost
0.0% to 9.9%	338	$7.11	$2.20
10.0% to 24.9%	194	$6.66	$2.16
25.0% and Higher	118	$7.06	$3.44

The differences in the sample means shown in Table 3.10 were not statistically significant (at the 5% level of significance) such that it can be inferred that a relationship between the Medicaid utilization ratio dispensing cost exists.

Anecdotally, pharmacists have reported that high labor input is required to meet the requirements of dispensing Medicaid prescriptions. For example, the process of securing prior authorization approval was commonly mentioned as being time intensive. Although there are obviously costs associated with this type of activity, the survey data does not show any systemically higher costs associated with pharmacies that dispense higher percentages of Medicaid prescriptions.

6) Provision of Unit Dose Dispensing Services

Pharmacies were classified by whether or not they provided prescription drugs in unit dose packaging.

Table 3.11 Provision of Unit Dose Prescription Services

Type of Pharmacy	Number of Stores	Unweighted Mean Cost	Standard Deviation of Cost
Provides Unit Dose Services	206	$6.76	$2.30
Does Not Provide Unit Dose Services	444	$7.06	$2.53

The differences in the unweighted sample means observed here were **not** statistically significant (at the 5% level of significance).

7) Retail Versus Institutional Pharmacies

Pharmacies were classified by whether or not they provided a significant number of prescriptions to residents of long-term care facilities (based on analysis of Texas Medicaid provider file designations and other indications of nursing facility dispensing).

Table 3.12 Retail Versus Institutional Pharmacies

Type of Pharmacy	Number of Stores	Unweighted Mean Cost	Standard Deviation of Cost
Retail	622	$6.93	$2.39
Institutional	28	$7.68	$3.70

Despite the apparent differences in mean dispensing cost, the differences in the unweighted sample means observed here were **not** statistically significant (at the 5% level of significance). Additional comments regarding institutional pharmacies are included in Appendix D.

Multivariate Analysis

The analyses described above tested for significant differences in cost by analyzing one pharmacy attribute at a time. A more sophisticated method to analyze the impact of pharmacy characteristics upon dispensing cost is to use a multivariate regression analysis. In such an analysis, it is possible to control for factors known to affect dispensing cost, such as total prescription volume, and determine if other factors have a significant impact on dispensing cost. It is possible for an attribute to not be statistically significant in a *t*-test, but still be shown to have some effect on dispensing cost in a multivariate analysis (or vice versa).

Several analyses were conducted to identify potential correlation between pharmacy dispensing cost and certain pharmacy traits. These analyses used a multivariate stepwise linear regression technique. Using this approach, it is possible to control for factors known to affect dispensing cost, and at the same time test for the significance of any effect on dispensing cost caused by other traits. This approach allows for a more robust analysis of the potential influence of pharmacy characteristics on dispensing cost than can be achieved by *t*-tests alone. The traits that were used in the analysis included:

- Prescription sales volume
- Type of location
- Type of affiliation
- Type of ownership
- Unit dose delivery systems
- Delivery service
- Level and percent of Medicaid volume
- Total prescription volume
- Pharmacy building ownership
- Geographic location
- Provision of intravenous prescription dispensing services
- Provision of compounding services
- Hours open
- Length of operation at location
- Percent of prescriptions dispensed paid by third party payers
- Percent of prescriptions dispensed to residents of long-term care facilities

The attributes which proved to be the most significant were:

- Total prescription volume
- Provision of intravenous services
- Provision of compounding services

The relationship between total prescription volume and dispensing cost was especially pronounced. A linear model to predict total prescription dispensing costs based on prescription volume alone was able to explain over 80% of the variation in dispensing costs. Linear regression methods indicate that the regression equation which best describes the relationship of total prescription volume and total dispensing cost is:

Total Costs (inflated)= $ 59,306 + $5.30x (Total Prescription Volume)[12]

Chart 3.3 Relationship Between Total Costs and Total Prescription Volume

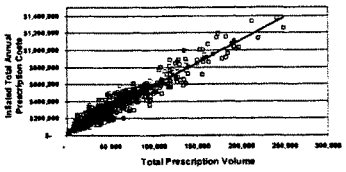
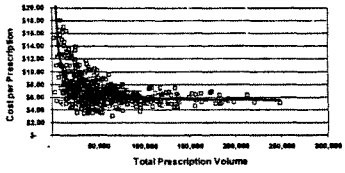


Chart 3.4 Relationship Between Cost per Prescription and Total Prescription Volume



This result implies that there are fixed costs of $59,306 and variable costs of $5.30 per prescription associated with the "typical" pharmacy. The mean total prescription volume for pharmacies was approximately 59,500. For such a pharmacy, total prescription costs predicted by the equation are approximately $375,000, or $6.30 per prescription. Clearly, for pharmacies with a high total prescription volume, fixed costs per prescription decrease. Conversely, low volume pharmacies have greater fixed costs per prescription (see Charts 3.3 and 3.4).

No other attribute contributed more than 2% to the predictive power of the linear regression techniques after controlling for the variation of total prescription volume. After controlling for the efficiency impact of prescription volume, there

[12] Excludes pharmacies which dispense a significant volume of intravenous, home infusion or compounded prescriptions. The regression equation shown above was produced using an iterative regression technique that excluded some statistical outliers that would have had the effect of distorting the regression equation.

was some correlation between the provision of delivery services with higher overhead costs[13]. Additionally, the same methodology found that chain pharmacies and pharmacies in urban areas tended to have higher labor cost inputs after controlling for volume-based efficiencies.

Components of Cost

The dispensing costs of the surveyed pharmacies were broken down into the various components of overhead and labor related costs. More information on this subject is included in Appendix B.

Comparison to Other Dispensing Cost Surveys and Economic Analysis

Myers and Stauffer has conducted several surveys of dispensing cost in other states in recent years. Data from the Texas and other surveys were compared to ascertain the similarities and differences in pharmacy dispensing cost in the state of Texas as compared to other states. Of particular interest was the level of labor related costs that were observed.

There has been some widespread reporting in the profession regarding a pharmacist "shortage" and there is considerable discussion of this trend in industry literature[14]. This shortage has apparently been caused by the recent increase in overall prescription volume nationwide, rapid growth of retail pharmacy outlets, and a decline in pharmacy school graduation rates.

It would appear that the tight pharmacist labor market has had an impact on pharmacist salaries in Texas. Recent experience with pharmacist salary survey data in other states indicates salary and benefit increases in the range of 15% to 20% over the last several years. In contrast, the change in overhead costs in recent years has been less pronounced. In part, this is because increases in overhead costs have been restrained due to cost containment pressures exerted by some commercial insurance and managed care entities. Additionally, modest increases in overhead cost have been somewhat mitigated by recent increases in pharmacy prescription volume and the enhanced efficiency that is typically a by-product of higher prescription volume.

The current survey is based on pharmacy fiscal data primarily from calendar year 2001. Calendar year 2000 and the first part of calendar year 2001 corresponds

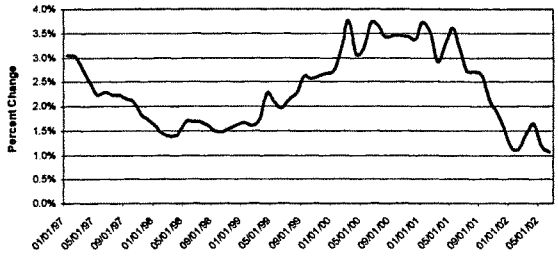
[13] Due to the way pharmacies tended to report delivery related costs on the cost survey, it was not possible to discretely identify the portion of cost associated exclusively with delivery service at all pharmacies. In many cases, delivery related costs (e.g. vehicle related expenses, gasoline, driver labor costs) were inseparable from other non-delivery related dispensing costs. However, average dispensing cost cited in the study is always inclusive of delivery cost.

[14] Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, "Report to Congress. The Pharmacist Workforce: A Study of Supply and Demand for Pharmacists." December 2000.

with the period during which general economic trends were resulting in a tight labor market and subsequent wage inflation. During 2001 and 2002, economic trends have changed significantly with strong indications of a recession in progress. There has been a dramatic softening of the labor market that will very likely lead to a slowdown in the rate of increase for wages. It is therefore possible that the rate of increase in labor cost noted in recent years is a unique phenomenon and that rates of increase for labor cost will return to more normal levels in the years ahead.

It is also noted that the overall rate of inflation, as measured by the CPI, has been considerably lower since mid-2001 as compared to the previous 18 months (see Chart 3.5). In a broad economic scope, this peak of inflationary pressures during 2000 and early 2001 was associated with high energy costs and wage inflation resulting from a tight labor market. Although some of this inflationary period occurred after the time period for which pharmacies reported their costs for the current survey, they do have a significant impact on the inflation factors that were used to trend forward the financial data to calendar year 2002.

Chart 3.5
Consumer Price Index (CPI-U)
Percentage Change from Previous 12 Months
Source: Bureau of Labor Statistics



Summary

To summarize, the significant findings from the dispensing cost survey are as follows:

- **The statewide median cost of dispensing[15], weighted by Medicaid volume, was $5.95.**
- Average dispensing cost at certain pharmacy specialties was observed to be higher than dispensing cost at "typical" retail pharmacies. In particular we noted higher dispensing cost associated with pharmacies that provided services related to the dispensing of intravenous, home infusion and compounded prescriptions.
- There was an association between dispensing cost and the urban or rural location of a pharmacy. Pharmacies in urban areas tended to have higher dispensing costs. This was noted to be particularly the case for labor related costs.
- No association was found between dispensing cost and unit-dose packaging or other measures of long term care dispensing activity; i.e., ambulatory and long term care pharmacies had similar mean costs of dispensing.
- No systematically higher costs associated with pharmacies that have a higher percentage of Medicaid prescription volume were found.

Table 3.13 Inflation Adjusted Mean Dispensing Cost

Period	Midpoint	Inflation Adjusted [A] Median [B] Dispensing Cost[C]
Calendar Year 2002	6/30/2002	**$5.95**
State Fiscal Year 2003 (Ending 8/31/2003)	2/28/2003	$6.04
Calendar Year 2003	6/30/2003	$6.10
State Fiscal Year 2004 (Ending 8/31/2004)	2/28/2004	$6.19

[A] Inflation factors are based on the CPI, All Urban. Future inflation projections are based on the CPI, All Urban, as published in *Health Care Cost Review, Fourth Quarter 2001* by Standard & Poor's DRI.
[B] Weighted by Medicaid prescription volume.
[C] Excludes pharmacies that dispensed intravenous, home infusion or compounded prescriptions.

[15] Dispensing costs have been inflated to the common point of June 30, 2002. Excludes pharmacies that dispensed a significant amount of intravenous, home infusion or compounded prescriptions.

Appendix A. Development of the Dispensing Cost Survey Methodology

The methodology used for conducting the survey of pharmacy dispensing costs is presented in Chapter 3 of the report. The following tables provide background information regarding the development of the methodology and references to other surveys and publications which provide discussion regarding the calculation of pharmacy dispensing cost and related matters.

Table A.1 Academic References to Pharmacy Dispensing Cost Studies

Gagnon, Jean Paul, "Prescription Department Cost Analysis." Pharmacy Management 151 (Sept. – Oct., 1979): 235-40.
Carroll, N.V. "Costs of Dispensing Private-Pay and Third-Party Prescriptions in Independent Pharmacies." Journal of Research in Pharmaceutical Economics 1991;3(2):3-16
Carroll, N.V. "Forecasting the Impact of Participation in Third-Party Prescription Programs on Pharmacy Profits." Journal of Research in Pharmaceutical Economics 1991;3(3):3-23
Huey, Cheryl; Jackson, Richard; Pirl, Margaret, "An Analysis of the Impact of Third-Party Prescription Programs on Community Pharmacy." Journal of Research in Pharmaceutical Economics 1995;6(2):57-72
Schommer, Jon et. al., "1999 Minnesota Pharmacist Compensation and Labor Survey: Part 1, Pharmacists' Hourly Wages and Benefits." University of Minnesota College of Pharmacy, 1999.
Wen, Lonnie k. et. al., "A Survey of Operational Costs Incurred by Home Infusion Pharmacies." Infusion, May 1997 pp. 44-51.

Table A.2 Cost Allocation Methodologies Commonly Used in Health Care Settings

Type of Cost	Statistical Basis Used for Pharmacy Survey	Statistical Basis Used in Medicare Cost Reporting
Capital Related (e.g. depreciation, rent, repairs, real estate taxes)	Square Footage	Square Footage
Utilities	Square Footage	Square Footage
Interest, Insurance, telephone, supplies, accounting and legal fees	Revenue	Revenue, Accumulated Costs
Labor	Hours Worked	Hours Worked

Table A.3 Pharmacy Dispensing Cost Surveys Using Similar Cost Allocation Methodologies

Report Date	Title of Published Report	Organization / Individuals Performing Survey	Survey Sponsor
May 1990	An Assessment of Chain Pharmacies' Cost of Dispensing a Third Party Prescription	Pharmaceutical Economics Research Center; School of Pharmacy and Pharmaceutical Sciences; Purdue University; Kenneth W. Schafermeyer; Stephen W. Schondelmeyer; Joseph Thomas III	National Association of Chain Drug Stores
March 1991	Reimbursement for Pharmaceutical Services in Missouri	University of Missouri – Kansas City School of Pharmacy - Ashok K. Gumbir, Ph. D.; Johnny L. Anderson, Ph. D. (candidate)	Missouri Department of Social Services – Division of Medical Care
June 1994	Pharmacy Reimbursement Rates: Their Adequacy and Impact on Medicaid Beneficiaries	E. Kathleen Adams, Ph. D.; Norma Gavin; SysteMetrics; David H. Kreling, Ph. D.	Health Care Finance Administration

(Additionally, Myers and Stauffer has performed approximately 40 studies of pharmacy dispensing cost in approximately 18 states.)

Appendix B. Components of Pharmacy Dispensing Cost

Information on prescription dispensing cost was collected on the cost survey in individual expense categories. We analyzed the various components of the average dispensing cost for the pharmacies in the sample. Table B.1 and Charts B.1 and B.2 display the various cost components of the mean costs for pharmacies in the sample. Mean costs shown are weighted by Medicaid prescription volume.

Expenses were classified as follows:

- Owner professional labor – owner's labor costs were subject to constraints in recognition of its special circumstances as previously noted.
- Employee professional labor consists of employee pharmacists.
- Other labor includes the cost of delivery persons, interns, technicians, clerks and any other employee with time spent performing the prescription function of the pharmacy.
- Building and equipment expense includes depreciation, rent, ownership costs, repairs, utilities and any other expenses related to building and equipment.
- Prescription-specific expense includes pharmacist-related dues and subscriptions, prescription containers and labels, prescription-specific computer expenses, continuing education, and any other expenses that are unique to the prescription dispensing business.
- Other business expenses consist of all other expenses that were allocated to the prescription dispensing function of the pharmacy including interest, insurance, telephone, and legal and professional fees.

Table B.1 Components of Prescription Dispensing Cost[1]

Type of Expense	Chain Pharmacies	Independent Pharmacies
Owner Professional Labor	$0.00	$1.54
Employee Professional and Other Labor	$4.42	$2.49
Building and Equipment	$0.56	$0.60
Prescription Specific Expenses	$0.49	$0.63
Other Business Expenses	$0.74	$0.87
Total	$6.21	$6.13

[1] Excludes pharmacies which dispensed intravenous, home infusion or compounded prescriptions.

Clearly, the single largest component of cost is labor with both independents and chain pharmacies spending between 70% and 80% of their overall prescription costs on labor related costs. Chain pharmacies tend to have a larger portion of their labor costs devoted to professional labor compared to independents which tended to have higher "other" labor (which is partially explained by labor costs for delivery services). Otherwise, the distributions of costs between chain and independent pharmacies were similar.

Chart B.1 Components of Cost per Prescription for Chain Pharmacies

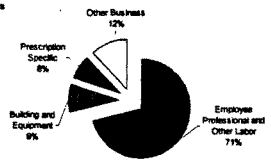
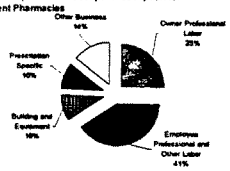


Chart B.2 Components of Cost per Prescription for Independent Pharmacies



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Appendix C. Summary of Pharmacy Attributes

A number of pharmacy attributes were collected on the cost survey. Many of these attributes were used during the review of the cost survey, and also allowed for an analysis of the variations in cost. In the following table, many of these attributes are summarized for informational purposes without any discussion as to their relationship to dispensing cost.

Table C.1 Summary of Pharmacy Attributes

Attribute	Number of Pharmacies Responding Affirmatively	Mean for Pharmacies Responding Affirmatively
Provision of Delivery Services	326	32% of prescriptions
Provision of Delivery Services for Medicaid Recipients	309	37% of Medicaid prescriptions
Provision of Unit Dose Services	234	28% (approximately 93% of unit dose prescriptions were reported to haven been prepared in the pharmacy; 7% were purchased already prepared from a manufacturer)
Provision of Compounding Services	427	5% of prescriptions (27 pharmacies reported compounding for 10% or more of prescriptions dispensed – for these 27 pharmacies, the mean was 43%). Many pharmacies reported a nominal amount of compounding by reported "1%" or "less than 1%".
Provision of Prescriptions to Nursing Homes	260	21% of prescriptions
Provision of intravenous / Home Infusion Services	57	34% of prescription sales (43 pharmacies had IV sales greater than 1% of prescription sales – for these 43 pharmacies, the mean was 45%)
Provision of 24 Hour Emergency Services	273 (39%)	N/A
Hours Open Per Week	701	67 hours
Years Open at Current Location	694	15 years
Allows sales on credit[15]	365 (52%)	N/A
Percent of Prescriptions to Third Party Payers	621	79 %

Appendix D. Dispensing Cost Issues for Institutional, Intravenous, Home Infusion and Compounding Pharmacies

Based on previous experience performing dispensing cost studies, Myers and Stauffer has become aware of specific concerns relating to the dispensing costs of certain pharmacy specialties. Paramount among the concerns expressed are the dispensing costs of pharmacies that dispense prescriptions to residents of long-term care facilities, pharmacies that dispense intravenous or home infusion prescriptions, and pharmacies that provide specialty prescription compounding services. This appendix includes a discussion of issues specific to these pharmacy types.

Institutional Pharmacies

The survey data supported the conclusion that there was not a statistically significant difference in dispensing cost for pharmacies that primarily serviced long-term care facilities versus pharmacies with a more traditional retail structure. It was noteworthy that these institutional pharmacies are operated in a distinctly different manner than a traditional retail pharmacy. One primary consideration is that these pharmacies tended to be very high volume pharmacies. As noted previously in the report, pharmacies with a high prescription volume tend to be more efficient with lower dispensing costs per prescription.

Institutional pharmacies typically provide services not offered in many retail pharmacies. This includes a heavier reliance on delivery services and unit dose dispensing systems. While there may be higher labor and overhead costs associated with the prescription delivery and packaging of unit dose prescriptions, there are also efficiencies associated with the "assembly line" production style of the pharmacy. In contrast, traditional retail pharmacies dispense prescriptions "one at a time" as customers come to the store or as physician office calls are received. The greater control over the queuing of prescription requests in an institutional pharmacy creates a significant advantage in terms of scheduling the optimal amount of labor required to perform prescription dispensing functions.

It is also noteworthy that institutional pharmacies often provide other services to nursing homes beyond the typical prescription dispensing services offered in a retail pharmacy. This includes the services of a consultant pharmacist in the

[16] Myers and Stauffer tried to delineate the issue of allowing prescription sales on credit to imply that a pharmacy maintained its own accounts receivables balance as opposed to merely accepting credit cards as a form of payment. However, there apparently was some confusion on this issue; therefore the results obtained do not appear to represent "sales on credit" in the manner intended.

long-term care facility as well as medication carts, emergency medication kits and various expanded inventory control procedures. It is also significant to note that these additional services are provided as the result of a direct contractual relationship between the institutional pharmacy and the long-term care facility. Remuneration to the pharmacies for these services is subject to the provisions of those contractual relationships. Consequently, any cost for these pharmaceutical consulting services would be reported to Medicaid via the *nursing facility cost report*. It would therefore be inappropriate to include these consulting services in a survey of the cost of *dispensing* prescription medications. To the extent that such costs could be explicitly identified, the costs associated with consultant pharmacists were not included in the analysis of dispensing cost.

Intravenous and Home Infusion Pharmacies

A small number of pharmacies that responded to the dispensing cost survey indicated that a significant portion of their business consisted of filling intravenous or home infusion prescriptions. In every dispensing cost survey performed by Myers and Stauffer in which data on the provision of intravenous services was collected, the provision of this service has been associated with higher dispensing costs.

There is some difficulty, however, in determining an average dispensing cost for this type of activity with any degree of stability. Reasons for this include the following:

- There is a significant inconsistency in the way in which pharmacies count the number of intravenous prescriptions dispensing. A pharmacy may mix and deliver many "dispensings" of a daily intravenous solution from a single prescription, thus incurring additional costs spread over a smaller number of prescriptions. Alternatively, some pharmacies count each daily dispensing individually.
- Many pharmacies that dispense intravenous prescriptions also dispense traditional prescriptions. The task of segregating intravenous and traditional dispensing costs is made difficult by the combined approach to financial and prescription record keeping which make it difficult to isolate costs associated with the dispensing of intravenous prescriptions.
- Based on a review of the literature, there is also considerable variability in the labor and equipment cost inputs into various types of intravenous prescriptions.

Because of these factors, Myers and Stauffer has typically seen extreme variation in the dispensing cost calculated for pharmacies that provide intravenous prescription services. In the current survey, the dispensing cost in the 43 responding pharmacies that dispensed intravenous prescriptions ranged from approximately $6.00 to over $100. The mean dispensing cost was $41.75, but it should be noted that this mean is highly unstable (i.e. there was a very high standard deviation).

One of the reasons it is difficult to determine a stable average dispensing cost for pharmacies that provide intravenous prescriptions is the low number of pharmacies for which data is collected in each survey. Additionally, the proportion of intravenous prescriptions filled at each pharmacy is highly variable.

To better understand dispensing cost in these pharmacies, Myers and Stauffer performed an analysis of the dispensing cost from data collected on over 100 surveys in recent years (inflation adjusted to calendar year 2002). Data for this analysis includes pharmacies in Texas, but was also supplemented by data from other states. Although each of these pharmacies had indicated on the survey forms that they dispensed intravenous prescriptions, most of these pharmacies also dispensed traditional prescriptions as well. After calculating a cost of dispensing for each pharmacy, statistical regression techniques were used in an attempt to isolate the costs associated strictly with the dispensing of intravenous prescriptions.

Although the analysis should not be considered comprehensive, the data suggests that dispensing costs ranging from $20 to $40 per intravenous prescription would be considered typical. In addition to variable states of efficiency in these pharmacies, it should be noted that there are various levels of complexity associated with dispensing intravenous prescriptions. A pharmacy's utilization mix of dispensing various types of intravenous prescriptions can have a significant effect on dispensing cost. It is therefore possible that some pharmacies could very well have dispensing costs in excess of $40 per prescription.

Under current policies, the Health and Human Services Commission reimburses for intravenous prescriptions in a dispensing fee plus ingredient reimbursement formula similar to traditional retail prescriptions. Although dispensing costs at intravenous pharmacies appears to be in excess of the current base dispensing fee ($5.27), this reimbursement methodology has been accepted by these pharmacies likely due to the inventory management add-on to the dispensing fee (which can be significant on the expensive drugs traditionally dispensed in intravenous forms) and the margin on ingredient reimbursement which has allowed pharmacies to offset any shortfall from the base dispensing fee.

In recent years, some states have dealt with the issue of intravenous prescription reimbursement rates *in light of reduced ingredient reimbursement.* For example, the state of Utah recently adopted "revised AWPs" for certain products based on the recommendations of the United States Department of Justice and the National Association of Medicaid Fraud Control Units (NAMFCU).[17] Products with these "revised AWPs" were primarily injectable, infusion, and inhalation drugs. Subsequent to the adoption of these prices, intravenous and home infusion pharmacies alleged that the margins on ingredient reimbursement were no longer sufficient such that they could accept the typical Medicaid dispensing fee. As a result of these allegations, the state of Utah created alternate

[17] "Medicaid's Use of Revised Average Wholesale Price." Department of Health and Human Services, Office of the Inspector General, OEI-03-01-00010, September 2001.

dispensing fees primarily for home infusion pharmacies. The rates were set through a negotiated process and varied based on the perceived level of input costs required to fill the prescription. Table D.1 shows the various dispensing fee categories created by Utah Medicaid.

Table D.1 Utah Medicaid Home Infusion Drug Categories[18]

Dispensing Fee Category	Level of Service	Current Dispensing Fee
Category 'B' or 'C'	Traditional: technician input point-of-sale; pharmacist input; fixed overhead costs	$3.90 or $4.40
Category 'J'	Dispensing fee B or C plus: Labor II factor; clinical monitoring; prefilled syringes/PB; horizontal hood; technician input	$8.90
Category 'K'	Dispensing fee J plus: Clinical monitoring; quality assurance; labor factor	$18.90
Category 'L'	Dispensing fee K plus: Replacement into individual doses such as syringe; recalculations from vial to syringe to bag; large bulk inventory costs; peer review	$22.90
Category 'M'	Dispensing fee L plus: Double gloves; gown; vertical hood; labor factor V; OSHA documentation; special handling; special storage; clean room; hazardous waste	$33.90

The Utah Medicaid home infusion dispensing fee methodology has the advantage that dispensing fee reimbursement is more closely tied to actual dispensing costs. It has the disadvantage that it necessitates increased complexity for the claims adjudication process. It is noteworthy to emphasize that the Utah rates were established based on a negotiated process rather than being based on a survey of actual costs and that the rates were created only because of significant cuts in ingredient reimbursement such that the margin on ingredients for intravenous prescriptions was reduced.

[18] Derived from Utah Medicaid State Plan Amendment documents and discussions with Utah Medicaid officials.

Compounding Pharmacies

A small number of pharmacies that responded to the dispensing cost survey indicated that a significant portion of their business consisted of filling compounded prescriptions. Survey data indicated that this practice was associated with statistically significant higher dispensing costs.

The observation that the practice of compounding prescriptions resulted in higher dispensing cost is not surprising given the special labor and equipment needs that are required in this type of pharmacy practice. Preparation time for individual compounded prescriptions, though highly variable depending upon the specific task, tend to be higher than the time associated with filling "traditional" prescriptions in pre-manufactured tablet, capsule, or liquid (etc.) forms. Additionally, the practice of pharmacy compounding does require some additional expensive equipment such as clean rooms for sterile preparation, sensitive scales, and other equipment for making special pharmaceutical dosage forms.

The practice of pharmaceutical compounding has proven to be somewhat controversial given the perception of a fine line between "compounding" and "manufacturing". The U.S. Food and Drug Administration has imposed some limits relating to the practice and advertising of compounding services.

Despite these restrictions, the practice of compounding is appealing to many pharmacists, not only because the practice is perceived to be a return to a historical form of pharmacy practice, but also because compounding is a niche business, which, if successful, can yield high margins. In part, these high margins are due to the promotion of compounding services primarily to cash customers, often in more affluent areas. In some aspects, pharmacy compounding appeals to those seeking "alternative" forms of medical treatments and provides traditional medications in non-traditional forms or in a form free of dyes or other perceived allergens.

Compounding pharmacies have made only minimal attempts to promote wide acceptance of third-party coverage for compounded pharmaceuticals. Primarily, this appears to be related to a desire to avoid reimbursement limitations that could be imposed by a broad acceptance of third party reimbursement plans and fee schedules based primarily on ingredient cost. Compounding pharmacists seem to prefer to maintain the relatively high margins and billing simplicity associated with cash-paying customers. Additionally, because of the potential for billing complexities associated with compounded prescriptions (which sometimes cannot be captured with ease using typical pharmacy claim forms), pharmacies have experienced difficulty in establishing acceptable standards for transmitting suitable claims data that is compatible with the electronic claims processing standards used by most third party payers.

Due to the apparent variability in the cost associated with dispensing compounded prescriptions, a single dispensing fee for compounded prescriptions may be less ideal for matching reimbursement with actual costs incurred. The primary variable that determines dispensing cost incurred by a pharmacy is the amount of professional time required to prepare a particular compounded prescription. A more limited amount of cost variability can be attributed to the special equipment needs of certain preparations. To determine the precise mix of cost inputs into the various types of compounded prescriptions would require some type of time and motion study, the cost of which may be unjustified given the relatively small volume that would be associated with compounded prescription volume.

Given these limitations, a negotiated fee or set of fees is likely to be a preferable means of setting rates for compounding services. Such a fee could be linked to specific types of prescriptions or could be linked to professional time expended with reasonable upper limits. The inclusion of certain compounding services under prior authorization protocols to determine medical necessity may also be appropriate if modifications to dispensing fees for compounding services are considered.

Table of Exhibits

Study of Medi-Cal Pharmacy Reimbursement

Prepared for the
California Department of Health Services
Sacramento, California

June 2002

Myers and Stauffer LC
Certified Public Accountants

Chapter
1

Executive Summary

Introduction

Under contract to the California Department of Health Services, Myers and Stauffer LC performed a study of the adequacy of Medi-Cal pharmacy reimbursement rates. This study was designed to meet the legislative requirements of Senate Bill No. 393, Section 1, Article 24. 4426:

> *"The State Department of Health Services shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates including the cost of providing prescription drugs and services."*

A major component of the study was a survey of pharmacy dispensing cost. However, as overall pharmacy Medi-Cal payments are significantly influenced by reimbursement for pharmaceutical ingredients, we have incorporated results of a study of pharmacy acquisition cost. Other factors, including payment rates by other payers of pharmaceutical services and an analysis of the accessibility of pharmacy services to Medi-Cal recipients, have also been included in a broad discussion of the adequacy of pharmacy reimbursement rates.

This report includes a narrative of the methodologies and findings relevant to the survey of dispensing costs and a general discussion of the adequacy of Medi-Cal pharmacy reimbursement rates. A separate report issued by Myers and Stauffer LC includes a detailed discussion of the methodology and findings of the study of pharmaceutical acquisition costs.

The dispensing and acquisition cost study followed the methodology and used a survey instrument similar to those used by Myers and Stauffer in Medicaid pharmacy engagements in 17 other states. A stratified random sample of California pharmacy providers enrolled in the Medi-Cal program were surveyed; 847 pharmacies filed dispensing cost surveys and 491 pharmacies provided a sample of pharmaceutical purchase invoices that could be included in the study. All data received including the dispensing cost surveys were subject to extensive desk review procedures. Additionally, 50 pharmacies were selected for on-site field examinations to validate reported costs.

Summary of Findings

The significant findings of the study are as follows:

- **The statewide average (median) cost of dispensing, weighted by Medi-Cal volume, was $6.95.** The average cost of dispensing observed in California pharmacies is higher than has been observed in similar studies in other states. This higher dispensing cost is mainly due to higher pharmacist salaries in California than were observed in other state surveys.

Table 1.1 Dispensing Cost[A] for California Pharmacies

Pharmacies Included in Analysis[B]	798
Weighted Average (Median)[C]	**$6.95**
Weighted Average (Mean)[C]	$7.21
Unweighted Average (Mean)	$7.87

[A] Inflated to June 30, 2002.
[B] Excludes pharmacies that dispensed a significant amount of intravenous, home infusion or compounded prescriptions.
[C] Weighted by Medi-Cal volume.

- Average dispensing cost at certain pharmacy specialties was observed to be higher than dispensing cost at "typical" retail pharmacies. In particular we noted higher dispensing cost associated with pharmacies that provided services related to the dispensing of intravenous, home infusion and compounded prescriptions.

- A significant portion of pharmacy reimbursement is associated with payments for drug ingredient cost. A report of the findings and methodology of a pharmaceutical acquisition cost study was published separately. This study indicates that for a "typical" prescription, a pharmacy's margin on ingredient reimbursement is approximately $10.

- Considering both the dispensing and acquisition portions of cost and reimbursement, current levels of Medi-Cal pharmacy reimbursement provide margins, or profits, to pharmacies of approximately 11%. Study results indicate that this amount is significantly higher than margins associated with other third party payers of prescription drugs.

- Myers and Stauffer's examination of Medi-Cal pharmacy participation rates and other analyses related to the proximity of pharmaceutical services to Medi-Cal recipients did not indicate any significant impediments to access.

Conclusions and Recommendations

Myers and Stauffer considered many factors to evaluate the overall adequacy of Medi-Cal pharmacy reimbursement rates. This included an analysis of pharmacy dispensing and acquisition cost compared to the current Medi-Cal pharmacy reimbursement rate formula. Additionally, Myers and Stauffer evaluated market rates for prescriptions filled for other third party payers and examined issues related to the accessibility of pharmaceutical services to Medi-Cal recipients.

We concluded that the current Medi-Cal pharmacy reimbursement rates are, in the aggregate, sufficient to cover the dispensing and acquisition costs of the vast majority of pharmacies. Medi-Cal pharmacy reimbursement rates are typically higher than those of other third party payers (such as commercial insurance plans) and we did not identify any systemic problems related to the accessibility of pharmaceutical services to Medi-Cal recipients. Participation in the Medi-Cal pharmacy program is almost universal among California pharmacies, and pharmacies are geographically located such that accessibility for Medi-Cal recipients is not curtailed.

We offer the following recommendations to the California Department of Health Services as suggestions for improving the Medi-Cal pharmacy reimbursement program.

Ingredient Reimbursement Recommendations
There was sufficient evidence in the study of pharmacy acquisition cost to suggest that the Department's current ingredient cost allowance of the Average Wholesale Price (AWP) minus 5% provides for ingredient reimbursement in excess of a pharmacy's actual acquisition cost. Ten to fifteen years ago, when many states set their Medicaid ingredient reimbursement rates and the average brand name Medicaid prescription cost $12 - $15, the margin between the pharmacy's true acquisition cost and the cost assumed by an AWP less 5% formula was equivalent to $1 added to the dispensing fee. Now, with the average brand name Medicaid prescription in California costing more than $120, the margin on drug ingredient cost for a brand name prescription can be *more than $15 per prescription.*

In light of these findings, we recommend that the Department should consider increasing the discount from the Average Wholesale Price (AWP) for both single source and multi-source drugs. The acquisition cost study indicates that the Department could justify setting ingredient reimbursement for brand name drugs at a level between AWP minus 12% and AWP minus 15%. The study would also support a differential reimbursement rate for generic drugs such as one between AWP minus 20% and AWP minus 25%.

For drugs from a limited number of labelers, the Medi-Cal pharmacy program currently bases ingredient reimbursement on the Direct Price. The acquisition

cost study indicates that the relationship between pharmacy actual acquisition cost and the Direct Price is less predictable than the relationship between acquisition cost and discounted AWP. Additionally, the Direct Price system results in reimbursement for several products below pharmacy cost. Based on these observations, we recommend that the Department consider eliminating the use of Direct Prices and standardize ingredient reimbursement under an AWP system (for drugs without federal or state upper limits).

Some multi-source drugs are currently paid under one of two upper limit price systems: Federal Upper Limits (FUL) and California Maximum Allowable Ingredient Costs (MAIC). The use of FUL pricing is almost universal among state Medicaid pharmacy programs in order to assure compliance with aggregate upper limit policies required by federal regulations. Additionally, most Medicaid programs also use Maximum Allowable Cost (MAC) prices to set reimbursement limits on drugs not covered by the FUL system, or to set a rate lower than an existing FUL. FUL and MAC systems are appropriate for certain multi-source drugs where the relationship of acquisition cost to the AWP can be highly skewed (e.g. acquisition cost of AWP minus 90% or greater is not uncommon) and incentives to promote generic utilization are appropriate.

As compared to MAC systems observed in other states, Medi-Cal's MAIC prices have not been set for a broad range of multi-source drugs. An expansion of MAIC pricing to cover a more comprehensive set of multi-source drugs might be desirable. If an expansion of MAIC pricing expansion is considered, we would recommend that rates be based upon observations of pharmacies' actual acquisition cost incorporating appropriate margins to assure cost coverage.

Dispensing Fee Recommendations

The Department's current pharmacy dispensing fee is below the average cost of dispensing prescriptions. This finding alone does not indicate that the current pharmacy reimbursement rates are inadequate since both dispensing and ingredient reimbursement rates should be considered in tandem. Should the Department desire to more closely match the pharmacy dispensing fee with observed pharmacy dispensing cost, then an increase in the dispensing fee would be appropriate. Such an increase would be most appropriately considered in conjunction with an adjustment the Department may make in pharmaceutical ingredient reimbursement.

The dispensing cost study considered several pharmacy attributes to determine if dispensing costs were significantly different based on variables of pharmacy affiliation, location, and specialty. For many tested attributes, we did not observe statistically significant differentials in dispensing cost. We did, however, observe systemically higher dispensing cost associated with pharmacies that specialize in dispensing intravenous and compounded prescriptions. Several significant issues related to these pharmacy specialties are addressed in the study, and one possibility for the Department to consider is to set pharmacy dispensing fees

specific to certain specialties. We note, however, that many pharmacy programs have successfully operated without a dispensing fee set specifically for these pharmacy types and to continue a single dispensing fee for all pharmacy types is also a valid option.

TAB 24

North American Leadership Team
Bridgewater, NJ

Aventis Pharmaceuticals Policy Decision Memorandum
"AWP"
November 12, 2002

This Memorandum was prepared by US Public Policy without a cross-functional development team. Review comments were provided by: Liz Cirri, Joseph Haggerty, Glenn Forrester, Chris Panarites, Loreen Brown, and John McNamara

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Executive Summary

This Memorandum provides for the North American Leadership Team's consideration a proposed public policy stance on the use of Average Wholesale Price (AWP) as a reimbursement standard within public programs, such as Medicare Part A (Hospital Insurance) and B (Supplemental Medical Insurance) and Medicaid.

The Memorandum sets forth the following positions concerning AWP reform:

- **A stated preference for well established alternatives to AWP that more accurately reflect actual acquisition cost of drugs in private market transactions;**
- **Support for separate but full reimbursement of drug-related medical services, such as physician services in the administration of oncology drugs and hospital pharmacy labor and overhead costs.**
- **Opposition to a Bush Administration proposal to continue to rely upon AWP as a standard for reimbursement, albeit with changes to make AWP more reflective of actual acquisition cost;**
- **Opposition to the use of competitive bidding as an alternative to AWP; and**
- **Support for incremental transparency of pricing transactions as a way of determining reimbursement for drug costs together with new statutory protections for the data.**

The adoption of a formal position on this issue is necessary because recent administrative, legislative and judicial developments seek, on the one hand, to use AWP to increase manufacturer rebates and government revenues and, on the other, to replace AWP with alternative pricing systems that will reduce reimbursement to drug manufacturers. Currently in the mix of alternatives to AWP are: a) other statistical standards that reflect actual market pricing such as Average Manufacturer's Price and Average Sales Price; and b) competitive bidding. Given the growing interest in reform, USPP believes that Aventis should choose between a reportable figure other than AWP and the collective bidding program (advocated by CMS and at least one House Committee) and encourage a more favorable policy decision.

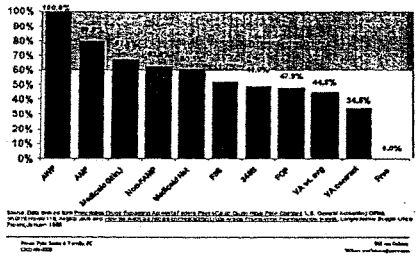
Overview and Background

Average Wholesale Price or AWP was intended to represent the average price at which wholesalers sold drugs to physicians, pharmacies, and other customers. In practice, however, it has become a price of a prescription drug reported by companies that compile prescription drug price data, such as First DataBank and Thomson Medical Economics, which publishes the *Red Book*. The *Red Book* indicates that the pricing information is based on data obtained from manufacturers, distributors, and other suppliers.

The AWPs reported by commercial publishers of pricing data are widely understood to bear no relationship to the actual acquisition cost of a particular drug. Indeed, there are no requirements that AWP reflect the price of any actual sale of drugs by a manufacturer. AWP is not defined in law or regulation, and it does not account for the deep discounts available to various payers, including federal agencies, providers, and large purchasers.

The wide variation between AWP and other price reference points in the US market are illustrated in the following chart –

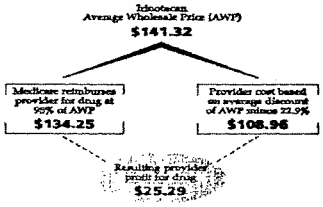
Background on U.S. Pharmaceutical Market:
Comparison of Prices



Repeated attempts by authorities to find a market-based pricing reference point for government reimbursement have largely failed, and AWP remains the starting point for determining prescription drug reimbursement under Medicare and Medicaid. Payments are typically based on a formula using AWP minus some percentage.

However, the weak financial condition of these programs has strengthened the motivation to reform the AWP standard and to eliminate provider overpayment. In particular, federal and state authorities are concerned about the significant difference between published AWP and the providers' actual acquisition costs in the marketplace. As a result of this disparity, some providers have been able to benefit financially from these transactions because reimbursement payments from Medicaid and Medicare have been more closely aligned with AWP than actual acquisition costs as illustrated here –

Medicare Payment vs. Provider Cost for Part B Outpatient Prescription Drugs: An Example



Source: Based on information from U.S. General Accounting Office, Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, September 2001 (GAO-01-1118), Washington, D.C.

Recent government investigations underscore the financial importance of the "spread" between AWP and actual acquisition costs –

- In 1999 Medicare spent almost $4 billion on outpatient drugs, with 82 percent of that cost attributable to 35 drugs, primarily cancer, inhalation therapy, and oral immunosuppressive medications. An audit by the HHS Office of the Inspector General (OIG) in 1989 found that the AWP overstated what pharmacies paid for drugs by 10% to 20%.

- An OIG August, 2001 audit report likewise stated that Medicaid programs overpaid for brand-name prescription drugs by $1billion in 1999. States failed, it said, to accurately assess pharmacies' actual costs and demand sufficient discounts to ensure "reasonable" drug prices. The OIG report indicated that Medicaid programs typically pay pharmacists a percentage of the average wholesale price (AWP) for brand-name drugs. In 1999, Medicaid programs averaged a 10.3% discount off the AWP, the audit said.[1]

- For the 2001 OIG report, HHS auditors reviewed more than 16,000 invoice prices for brand-name prescriptions at 216 pharmacies in eight states. The actual acquisition cost for the 200 most often prescribed brand-name drugs was 21.6% below the AWP, according to the report. The OIG urged the Centers for Medicare and Medicaid Services to bring brand-name drug reimbursement more in line with purchase costs.

- In September 2001, the General Accounting Office (GAO) issued a report to Congress entitled "*Payments for Covered Outpatient Drugs Exceed Providers' Costs.*" It found that for most physician-administered drugs, the average discount from AWP ranged from 13% to 34%. GAO recommended Congress take steps to establish Medicare payment levels for Part-B prescription drugs that are more closely related to their costs.

The 2001 OIG report mentioned above also said that some state Medicaid programs are achieving short-term savings by using more accurate "average wholesale prices" to determine reimbursement for prescription drugs. In response to the 2001 OIG investigation, the US

[1] Attached End Chart contrasts and compares the changes in ingredient costs between 1991 and 2001. Over that time period, 28 states lowered their reimbursement to pharmacies.

Department of Justice and the National Association of Medicaid Fraud Control Units collected actual AWP data for medications including roughly 400 of the more than 50,000 national drug codes presently in use. However, most states using the revised AWP calculations expressed concern that they would not result in long-term savings. States said savings would be limited because the drugs chosen amount to a small percentage of Medicaid costs and the revisions were based on specific national drug costs rather than entire classes of drugs. Many of them fear that providers and manufacturers might circumvent the new prices. Therefore, the OIG said, "we continue to believe that the current system's reliance on reported AWPs as a basis for drug reimbursement is fundamentally flawed."

In the past six months, two Congressional Committees have developed proposals to reform Medicare Part-B reimbursement for drugs. The House **Energy & Commerce Committee's** proposal is based on average manufacturers' sales price, based on a 12-month rolling average. The **House Ways & Means Committee** proposes to base drug price on an average of competitive bids submitted by "contract entities." Both committees collaborated over the summer (2002) and will likely propose a bill in the new 108th Congress. Under a compromise approach developed by the committees, AWP reform would begin with an average sales price then transition to a competitive bidding system. A competitive bidding system would rely upon contact entities such as PBMs to submit to CMS bids to supply drugs, and prescribing physicians would purchase drugs through these entities. CMS' payment would be based on the average of all bids by contract entities for a particular drug.

Encouraged by Congressional hearings, the Justice Department investigation and an $875 million settlement in the TAP case, class-action lawyers have begun filing suits on behalf of health insurance funds and others, to recover money they say they lost to inflated drug prices allegedly engineered by the pharmaceutical industry. A recently filed case by United Food Commercial Workers Unions, Employers Midwest Health Benefits Fund and others alleges that Johnson & Johnson inflated the AWP for its arthritis drug Remicade® and charged doctors substantially less – encouraging them to profit from the difference (or "spread") between Medicare reimbursement and the actual cost. This and other cases have been consolidated in a class action suit in US District Court in Massachusetts. In general, these lawsuits maintain that the AWP has become a tool to allow pharmaceutical companies to build market share and provide a financial carrot to doctors who buy and prescribe their drugs, at the expense of taxpayers and employee medical plans. At least two state Attorneys General have filed similar suits, and others may follow.

In approaching the AWP reform issue, two other considerations must be taken into account by pharmaceutical manufacturers: first, transparency; and second, the use of prescription drug AWP to reimburse for other medical services.

First, transparency. Any option involving reportable figures for prices will run head on into this issue. Drug manufacturers operate with multi-tiered pricing strategies, the results of which are not generally known by the public. One option available to policymakers is a replacement figure, such as average sales price or average manufacturer price. This new reportable figure would require manufacturers to submit precise pricing data to federal and state authorities.

Various state open public records statutes (called Freedom of Information Acts or FOIAs) provide for the public disclosure of information submitted to the state by regulated parties and contracting vendors when a request for specific information is made by a member of the public. Generally, there is a presumption in these statutes that the state will provide any information held by a state agency whenever there is a public request for it, unless there is a specific statutory exclusion of a particular type of information from the disclosure requirement. Contracts with a state agency or an operating assumption of confidentiality held by the party submitting information are insufficient to override the effect of the public record statute. Furthermore, many state agencies are collecting information including pharmaceutical pricing information apart from federal law and programs (under state pharmaceutical assistance programs, for example), which may limit the applicability of federal limits on public disclosure of information.

State statutes containing provisions that exclude from public disclosure "trade secrets" and "proprietary information" may prevent some state authorities from sharing information about Average Manufacturing Price, Average Sales Price, or Best Price if an individual pharmaceutical manufacturer establishes a prima facie case for exception and no state agency submits a rebuttal to the claim as a matter of law. In these situations, however, the manufacturer's burden is heavy. It must show that substantial competitive injury – based upon factual or evidentiary material, not conclusory or generalized allegations – would result from disclosure. Other specific exceptions include matters of litigation involving the state, or "confidential" information that is designated as such pursuant to law.

Many state FOIAs also have strict timelines for public disclosure following receipt of a FOIA request. Generally, these timelines range from 30 to 90 days, with opportunities for immediate redress granted to a requestor whose information the state fails to disclose. In general, a third party using the FOIA system can expect to get information within one to two calendar quarters. *Therefore, pricing information including any updates could be made public every quarter if FOIA was employed by a member of the public on a revolving basis.*

The second consideration is AWP-based reimbursement for medical services. Because of the links that have been established between AWP and payment systems for medical goods and services in public programs, any proposed change to the AWP-based method for determining drug reimbursement faces enormous complications. For example, when providers or pharmacies believe they are inadequately compensated for administering or dispensing prescription drugs, the AWP-based reimbursement formula is relied upon to make up the difference. *From a policy perspective, therefore, the AWP must be viewed as part of a larger pricing infrastructure, and these related issues ought to be considered in the company's policy position on AWP. Drug manufacturers would be prudent to explicitly underscore the need for separate reimbursement of services related to the delivery of their products to patients.*

The Impact of AWP Reform on Aventis and Other Stakeholders

Commercial Issues –

- *Price Transparency on Reportable Figures* – Some pharmaceutical companies are voluntarily submitting average manufacturers price (AMP) at the request of state authorities (Aventis Behring included), and Bayer is required to report average sale price (ASP) as a provision of a lawsuit settlement with state Attorneys General. Pressure to disclose price will make "best price" become the starting point of contract negotiations and will put downward pressure on prices overall. Some customers are also disclosing their pricing information and impacting these negotiations. It is expected that once prices are disclosed, after about one negotiating cycle, prices will equalize based on the price set by the class innovator or first to market – assuming of course that the prices reflect private market transactions rather than competitive bids. Among the possible reportable figures, AMP is of particular concern because the term is so general that it is not uniformly calculated by manufacturers.

- *Products Covered by Medicare Part B* – Taxotere is likely to be the Aventis product most directly affected by a move away from AWP. The impact is likely to be favorable for sales growth because it would eliminate the large spread currently favoring Taxol and the generic substitutes for Taxol. Without the skewed economics, oncologists will likely increase use of Taxotere because it is a superior product. Price transparency is also not an issue of concern for Taxotere because it does not rely to any significant degree on discounts.

  Two other Medicare Part B products, Anzemet and Lovenox will be impacted, but will not be affected. Anzemet and Lovenox will not be advantaged by elimination of the spread.

- *Other Products* – Most product teams have not yet analyzed the impact of changes to AWP pricing or the specific impact on Medicaid volume.

Impact on other Stakeholders –

Pharmacists - Retail pharmacists charge that the August 2001 Inspector General report was not accurate, and should not be used by states to determine Medicaid reimbursement rates. The National Association of Chain Drugstores (NACDS) and the National Community Pharmacists Association (NCPA) hired the University of Texas Center for Pharmacoeconomic Studies to evaluate the OIG report. The Center's report entitled "A Review of the HHS Office of the Inspector General Report" found that the Federal government's estimates of what pharmacies pay for the drugs they dispense were seriously flawed. The report cited serious limitations with the approach used by the OIG, e.g., the OIG did not accurately sample Medicaid pharmacy providers and many not have included a representative Medicaid drug sample. They also noted, the government inconsistently categorized brand versus generic products, failed to correct its estimate for pharmacies that didn't respond to its survey and overestimated Medicaid savings. In addition, they did not take into consideration costs of inventory storage, returned goods, shrinkage and other factors.

NACDS opposes a switch away from AWP toward average sales price contending the following: a) AWP has been widely used and is well understood; b) ASP is not appropriate for pharmacy reimbursement because it does not reflect actual costs to pharmacies of drug acquisition, it cannot be calculated across purchasers, it will be outdated by the time it is used, it does not incentivize prudent purchasing, it will disrupt thousands of existing contracts, and it does not reflect the cost of dispensing and providing professional services to patients.

At its annual meeting in 2001, the NCPA called for the use of a reimbursement formula that would include five key elements of pharmacy practice: product costs, overhead, a base dispensing fee, a professional services fee and a return on investment. NCPA initiated a study to determine what it really costs to put a prescription drug on a pharmacy shelf, not just its acquisition costs.

One development on the Medicaid front, according to NACDS, is an indication that the Department of Health and Human Services' Office of the Inspector General is eyeing a revision of its calculation of what retail pharmacies pay for drugs provided to Medicaid recipients. NACDS noted in a report to its members, "We were encouraged to see that agency officials might consider a new calculation that would separate 'single source' drugs from innovator multiple source and 'branded generics'."

They reported that originally, the OIG concluded from last year's survey that retail pharmacies pay an average of nearly 22 percent below average wholesale prices for the drugs they obtain. State Medicaid administrators jumped on those findings in their efforts to reduce the costs of drug reimbursements to pharmacies. But distinguishing between the average costs pharmacies pay for branded vs. generic drugs could lead to a somewhat more liberal reimbursement policy for the Medicaid program.

NCPA, the American Society of Consultant Pharmacists (ASCP), NACDS and the American Pharmaceutical Association (APhA) want to move to a system that is different than AWP. However, they haven't seen anything they like. They dislike average sales price (ASP) because costs are determined retrospectively, i.e., prices for June, July and August are based on the previous quarter price survey.

State Government – States are already getting the benefit of best price for product through the rebate mechanism, however a move away from traditional AWP as a basis for reimbursing physicians and pharmacists for Medicaid patient drugs may reduce their up-front costs. Elected

officials may be reluctant, however, to reduce reimbursement to physicians and pharmacists because they are vocal constituent groups and it may cause providers to drop out of the Medicaid program if they are forced to operate at a loss.

Consumers – Medicare patients pay a 20% co-insurance on Part B drugs. These patients will benefit if the pharmacy or physician bill them 20% of the actual acquisition price, rather that 20% of the AWP.

Consideration of Policy Options

A decision by the NALT on AWP must address three points –
- Acceptance of an alternative to AWP. (This is a mere re-confirmation given that Aventis no longer reports AWP for its products. It reports wholesale acquisition cost. WAC is the manufacturer's charge to a wholesaler to purchase a drug. WAC is published and does not generally reflect any rebates or discounts. Presumably, federal and state authorities would apply a percentage discount to this figure as they have with AWP.)
- Choice between a reportable figure, such as ASP or AMP, and competitive bidding. The use of a reportable figure contains risks of transparency and disclosure. Competitive bidding processes administered by monopolistic or oligopolistic buyers contains risks as well, especially for innovative medicines with premium pricing. This is, however, the stated preference of HHS and at least one congressional committee.
- Acceptance of potential transparency with a reportable figure. Existing state laws require disclosure of publicly held information in response to a citizen's request. While these laws have not led to the rampant disclosure of pricing data thus far, they could in the future particularly if more sensitive information is provided on a a regular basis.

Statement of Non-Concurrence
At least one of the reviewers of the draft PDM noted that a reportable figure approach would require guarantees of confidentiality. These guarantees cannot be granted under state and federal law, nor could pricing data gathered in the competitive bidding process absent new statutory protections for the data. This Memorandum has attempted to address this concern by recommending that Aventis seek in conjunction with an alternative reportable figure additional statutory changes to protect pricing data from disclosure.

Statement of Policy

1. Aventis supports reimbursement policies and policy changes that lead to drug reimbursement standards within public programs that reflect the actual acquisition price of medicinal products established in private market transactions. Our view of the current AWP reimbursement scheme, as used under federal and state law, is that AWP does not reflect actual acquisition prices nearly as well as several alternatives to AWP, such as Wholesale Acquisition Cost, Average Manufacturer's Price and Average Sales Price. **We therefore support governmental efforts to adopt alternative standards that more accurately reflect private market transactions.** In fact, Aventis has chosen to express its own price communications in terms of the Wholesale Acquisition Cost standard except where compliance dictates the use of the AWP standard, and recommend adoption of WAC as a standard.

2. Aventis recognizes that the AWP standard has over time become a reimbursement vehicle for non-drug expenses in public programs. Whenever AWP reimbursement standards are being revised, replaced or withdrawn, **Aventis supports proposals that ensure physicians and hospitals are fully reimbursed** for their services and costs related to the acquisition, handling, and administration of a covered drug. Aventis opposes, however, drug reimbursement policies and standards that have the intention or effect of using drug reimbursement to subsidize various elements of the distribution chain for services not directly related to the drug product or its administration by a physician or physician's practice (including physician assistant and nurse practitioners) and that these costs should be addressed by government payers through a

separate reimbursement system that clearly differentiates these costs from the acquisition costs of drugs and clearly identifies the services to be supported by these indirect costs.

3. Aventis also notes, with respect to the Inspector General reports of 12 March 2002 and 16 September 2002 ultimately recommending a four-tier AWP-based reimbursement scheme for Medicaid, that this proposal will more deeply embed the AWP concept in practice and law at a time when the concept is under growing suspicion as a legitimate reimbursement model. The Inspector General Report of 16 September supports CMS's proposed change in the FFY03 budget that would substitute AWP in place of AMP and connect the manufacturers' rebate amount to AWP to "more closely reflect the actual acquisition cost of a given drug." We believe **that efforts by other federal and state authorities to drive reimbursement toward alternatives to AWP will be hampered by the four-tiered AWP-based system, and urge CMS and the states to forego this option.** Reforms should move beyond AWP to benchmarks that reflect private market determinations of value.

4. The consideration of various reimbursement alternatives to the AWP model has led some policymakers to consider the use of "competitive bidding" under government procurement programs as way of identifying market prices for pharmaceuticals. **Aventis opposes the competitive bidding approach** given: a) the availability of market data on pharmaceuticals under OBRA 90 and OBRA 93 upon which government agencies can determine best price; b) the constraints of the competitive bidding process in terms of best value purchasing versus lowest cost purchasing; c) the costs associated with the government's creation of an infrastructure to replicate the market or engaging third parties in direct negotiation, given the availability of the OBRA best price formula; and d) there are roughly 65,000 different drug products available in the US, including different dosage forms of the same product.

5. **Aventis would provide periodic updates on its pricing transactions** where the confidentiality of this proprietary information can be guaranteed and the request involves information related to the lowest price available to commercial customers in the US. Such a guarantee will likely require modifications in current law in some jurisdictions.

Pharmacy Payment and Patient Cost Sharing (1991 vs. 2001)

State	1991 Ingredient Reimbursement Basis & Dispensing Fees	2001 Ingredient Reimbursement Basis & Dispensing Fees
Alabama	WAC+ 9.2% + $5.40	AWP- 10%; WAC+9.2% + $5.40
Alaska	+$3.45-$11.46	AWP-5% + $3.45
Arizona	All plans capitated under AHCCCS	*
Arkansas	AWP-10.5% + $4.51+0.103	AWP-10.5% + $5.51
California	AWP-5% + $4.05	AWP-5% + $4.05
Colorado	Lesser of WAC+18 OR AWP - 10% + $4.08	AWP-11% or WAC+18%, whichever is lowest + $4.00
Connecticut	AWP-8% + $4.10	AWP-12% + $4.10
Delaware	AAC (if not over AWP –6%) + 3.65	AWP-12.9% + $3.65
DC	AWP-10% + $4.50	AWP-10% + $3.75
Florida	WAC+7% + $4.23	AWP-13.25%; WAC+7% + $4.23-$4.73
Georgia	AWP-10% + $4.41	AWP-10% + $4.63 + $0.50 for G or P
Hawaii	AWP-10.5% + $4.67	AWP-10.5% + $4.67
Idaho	Full AWP + $4.30	AWP-12% + $4.94 ($5.54 for unit dose)
Illinois	AWP-10% + $3.58	AWP-11% + G: $5.10, B: $4.00
Indiana	AWP-10% + $4.00	AWP-10% + $4.00
Iowa	AWP-10% + $4.02-$6.25	AWP-10% + $5.17
Kansas	AWP-10% + $3.45-$6.10	AWP-10%, IV AWP-50%, blood AWP-30% + $4.50
Kentucky	AWP-10% + $4.75	AWP-10% + $4.50
Louisiana	AWP-10.5% + $4.68	AWP-13.5% (AWP-15% for chains) + $5.77
Maine	AWP-5% + $3.35	AWP-10% + $3.35 (+extra fees for compounding)
Maryland	AWP-10% + $4.69-$5.92	Lowest of :WAC+10%, direct+10%, AWP-10% + $4.21
Massachusetts	WAC+10% + $4.06	WAC+10% + $3.00
Michigan	AAC (if not over AWP-10%) + $3.72	AWP-13.5% (1-4 stores), AWP-15.1% (5+stores) + $3.72
Minnesota	AWP-10% + $4.10	AWP-9% + $3.65
Mississippi	AWP-10% + $4.91	AWP-10% + $4.91
Missouri	Full AWP + $4.09	AWP-10.43%, WAC+10% + $4.09
Montana	AWP-10% + $4.08	AWP-10%, direct price for some labelers + $2.00 - $4.20
Nebraska	Lesser of WAC+12.52 or AWP-8.71% + $2.84-5.05	AWP-10% + $3.84 - $5.05
Nevada	AWP-10% + $3.95	AWP-10% + $4.76
New Hampshire	AWP-10% + $3.25-$3.65	AWP-12% + $2.50
New Jersey	AWP-6% + $3.73-$4.07	AWP-10%, WAC+30%, AAC for injectables + $3.73 - $4.07
New Mexico	AWP-10.5% + $4.00	AWP-12.5% + $4.00
New York	Full AWP + $2.60	AWP-10% + B: $3.50 G: $4.50
North Carolina	AWP-10% + $5.60	AWP-10% + $5.60
North Dakota	AWP-10% + $3.56	AWP-10% + $4.60
Ohio	AWP-7% + $3.23	AWP-11% + $3.70
Oklahoma	AWP-10.5% + $5.10	AWP-12.0% + $4.15
Oregon	AWP-11% + $3.67-$4.02	AWP-13% + Retail: $3.50 Inst./NF: $3.80
Pennsylvania	Full AWP +$ 2.75	AWP-10% + $4.00
Rhode Island	Full AWP + $3.40	WAC+5% + OP: $3.40, LTC: $2.85
South Carolina	AWP-9.5% + 4.05	AWP-10% + $4.05
South Dakota	AWP-10.5 % + $4 25	AWP-10.5% + $4.75 ($5.55 for unit dose)
Tennessee	AWP-8% + $3.91	*
Texas	Lesser of WAC+12 or AWP-10.49% (EAC+$3.26)x0.945 4.88 (Avg)	AWP-15% or WAC+12%, whichever is lowest + (EAC+$5.27)/0.98 & delivery fee
Utah	AWP-12% + $3.65	AWP-12% + $3.90-$4.40 (based on area)
Vermont	AWP-10% + $4.25	AWP-11.9% + $4.25
Virginia	AWP-9% + $4.40	AWP-9% + $4.25
Washington	AWP-11% + $3.24-$4.33	AWP-11% + $4.14-$5.12 (based on annual # of Rx)
West Virginia	Full AWP + $2.75	AWP-12% + $3.90 (+ extra $1.00 for compounding)
Wisconsin	AWP-10% + $3.83	AWP-11.25% + $4.88 (to a maximum $40.11)
Wyoming	AWP-11% + $4.16	AWP-11% + $5.00

WAC = WHOLESALERS ACQUISITION COST; AWP = AVERAGE WHOLESALE PRICE; EAC = ESTIMATED ACQUISITION COST;
AAC= ACTUAL ACQUISITION COST;
G = GENERIC; B = BRAND NAME; OP = OUTPATIENT; LTC = LONG TERM CARE; P = PREFERRED; NP = NON-PREFERRED.
*WITHIN FEDERAL AND STATE GUIDELINES, INDIVIDUAL MANAGED CARE AND PHARMACY BENEFIT MANAGEMENT ORGANIZATIONS MAKE FORMULARY/DRUG DECISIONS.
SOURCE: AS REPORTED BY STATE DRUG PROGRAM ADMINISTRATORS IN THE 2001 NPC SURVEY.

TAB 25

DEY LABORATORIES, INC.

MEMORANDUM

TO: Pam Marrs
Charles Rice
Jean-Pierre Termier

FROM: Robert F. Mozak

DATE: February 24, 1992

RE: ALBUTEROL PRICING STRATEGIES

Although the pricing strategy will be reviewed at the March 6 meeting, I thought you would be interested in reviewing it sooner in light of the earlier approval of Albuterol.

Essentially this pricing strategy will be followed by Dey sales people through the initial introduction and until competition emerges. If there are any questions, let me know.

Bob

RFM:ms

PRICING

OBJECTIVES:

* TO SEEK THE HIGHEST PRICES POSSIBLE IN RETAIL, HOMECARE AND HOSPITAL SEGMENTS. TO MAXIMIZE DEY PROFITABILITY.

* TO SEEK LONG – TERM (3 YEARS) AGREEMENTS WITH MAJOR PURCHASING GROUPS FOR ALL DEY PRODUCTS THROUGH LEVERAGING OF ALBUTEROL UD.

* TO PROVIDE INCENTIVE TO RETAIL / CHAIN PROVIDERS TO USE DEY'S ALBUTEROL UD BY INCREASING THE SPREAD ON MEDICARE / MEDICAID REIMBURSEMENTS.

COMPETITIVE PRICES:

	AWP	WHOLESALE	DIRECT PHCY.	
SCHERING:	35.50*	29.50*	31.86	NEW 2/1/92
DEY:	32.30	24.95	26.50	
DIFF:	- 8.0%	- 15%	- 17%	

* SOURCES: REDBOOK, BLUEBOOK, (2/92)
FIRST DATA BANK, MEDISPAN

PRICING STRATEGIES

1) INCREASE THE SPREAD TO RETAIL / HOMECARE ACCOUNTS BY LOWERING ACQUISITION COST MORE THAN AWP.

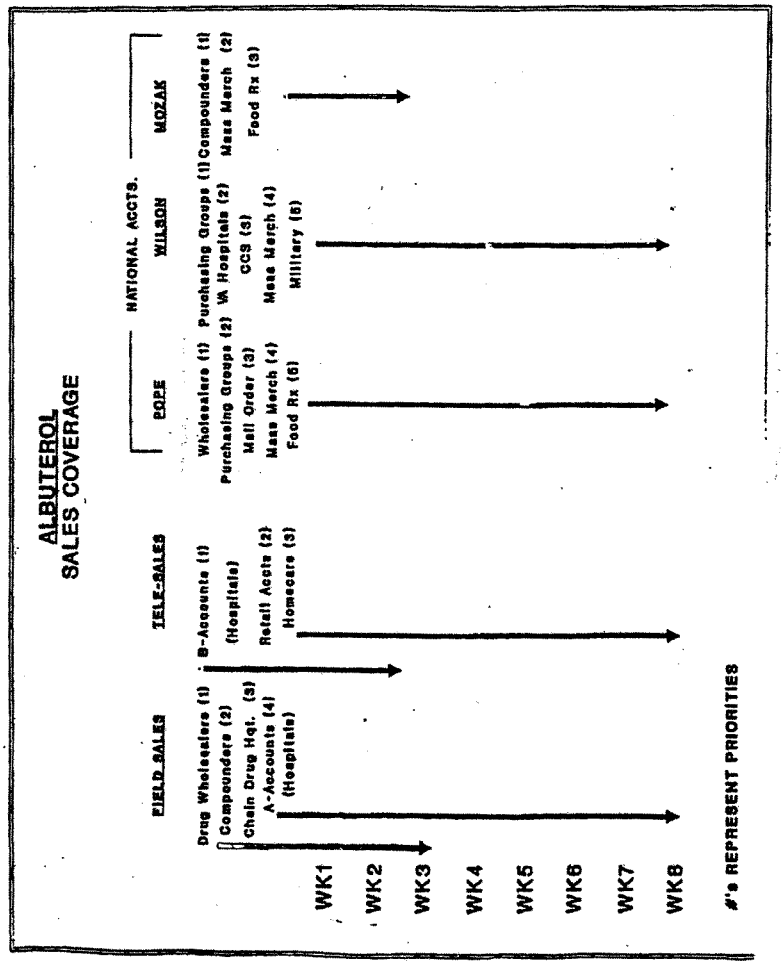
2) PHARMACY / CHAIN BID RANGE:
$23.95 – $26.50 (AVG. $25.95)
WILL INCREASE SPREAD FOR RETAIL AND PROVIDE DEY WITH HIGHEST PROFIT.

3) INDIVIDUAL DIRECT HOSPITAL BID RANGE:
$19.00 – $24.95 (AVG. $22.50)
WILL PROVIDE INDIVIDUAL HOSPITALS INCENTIVE TO USE DEY WHILE MAXIMIZING DEY PROFIT.

4) LARGE GROUPS PRICES:
$11.00 – $18.00 RANGE (AVG. $12.50).
DEY TO BID IN THIS RANGE FOR LONGER TERM CONTRACTS (3 YEARS) FOR FULL AWARDS.

5) COMPOUNDERS:
MAKING OWN PRODUCT FOR .25 – .30 PER DOSE
DEY TO SELL FOR .45 – .60 PER DOSE
($11.25 – $15.00 PER CARTON)
DEPENDING ON CONTRACT LENGTH AND VOLUMES.

NOTE: PRICING ASSUMES NO INITIAL GENERIC COMPETITION.



RAAP #: 01-002
Revision #: 2
Effective Date: JAN 3 1 1995

ISSUED BY
DOCUMENTATION
CONTROL

DEY LABORATORIES
ADVERTISING APPROVAL RECORD

PART NO.: 09-338-00	PRODUCT CODE: 647-03	DATE: 4-5-95

PIECE: REIMBURSEMENT COMPARISON WORKSHEET

PRODUCT: ALBUTEROL SULFATE INHALATION SOLUTION 0.083%

DESCRIPTION OF CHANGES:
NEW

DRAFT COPY APPROVAL

MARKETING REVIEW AND COMMENTS:
OK to route. 4/5/95

MARKETING APPROVAL 4/5/95 DATE 4/21/95

QA REVIEW AND COMMENTS:

QA APPROVAL DATE 4-19-95

REGULATORY AFFAIRS REVIEW AND COMMENTS:

REGULATORY AFFAIRS APPROVAL DATE 4/18/95

CHIEF EXECUTIVE OFFICER REVIEW AND COMMENTS:

CEO APPROVAL DATE 4/22/9

FINAL COPY APPROVAL

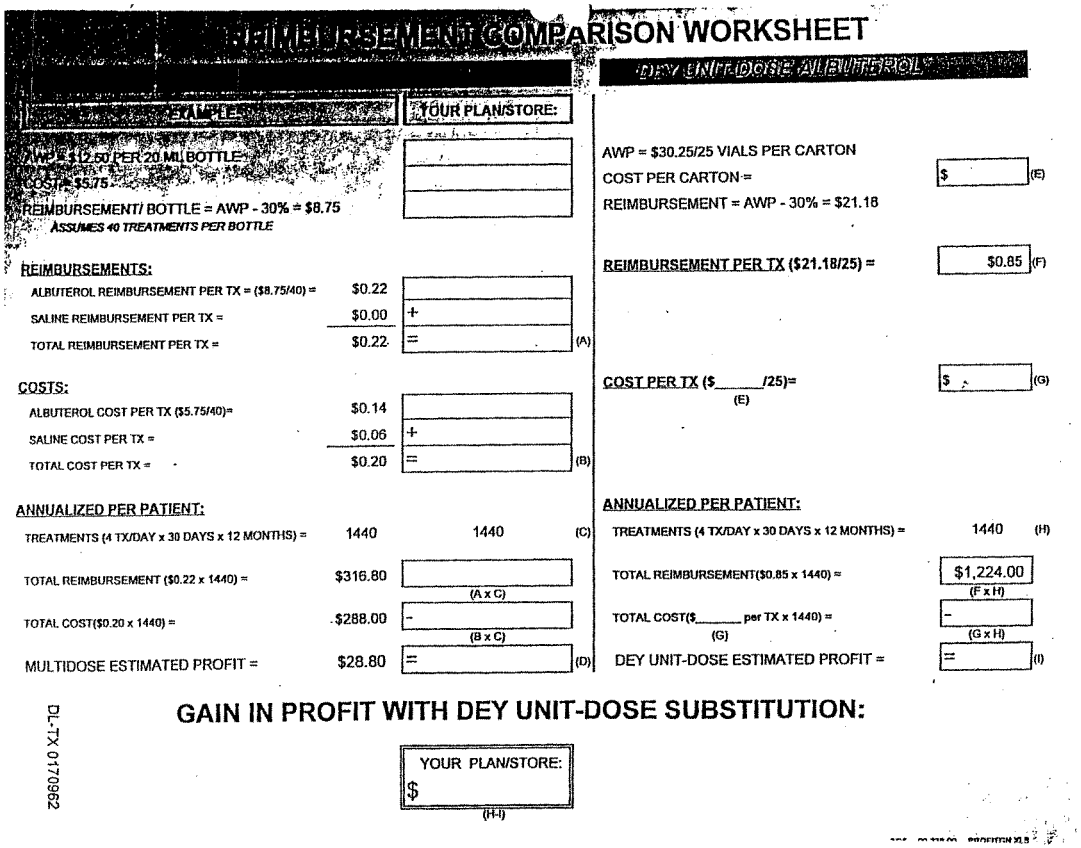
Marketing: 4/24/95 DATE

Regulatory Affairs: 5/5/95 DATE

Comments:

TAB 26

DL-TX 0170961



REIMBURSEMENT COMPARISON WORKSHEET

DEY UNIT-DOSE ALBUTEROL

EXAMPLE	YOUR PLAN/STORE:
AWP = $12.50 PER 20 ML BOTTLE=	
COST = $5.75	
REIMBURSEMENT/ BOTTLE = AWP - 30% = $8.75	
ASSUMES 40 TREATMENTS PER BOTTLE	

REIMBURSEMENTS:

ALBUTEROL REIMBURSEMENT PER TX = ($8.75/40) =	$0.22		
SALINE REIMBURSEMENT PER TX =	$0.00	+	
TOTAL REIMBURSEMENT PER TX =	$0.22	=	(A)

COSTS:

ALBUTEROL COST PER TX ($5.75/40)=	$0.14		
SALINE COST PER TX =	$0.06	+	
TOTAL COST PER TX =	$0.20	=	(B)

ANNUALIZED PER PATIENT:

TREATMENTS (4 TX/DAY x 30 DAYS x 12 MONTHS) =	1440	1440	(C)
TOTAL REIMBURSEMENT ($0.22 x 1440) =	$316.80	(A x C)	
TOTAL COST($0.20 x 1440) =	$288.00	- (B x C)	
MULTIDOSE ESTIMATED PROFIT =	$28.80	=	(D)

AWP = $30.25/25 VIALS PER CARTON
COST PER CARTON = $ (E)
REIMBURSEMENT = AWP - 30% = $21.18

REIMBURSEMENT PER TX ($21.18/25) = $0.85 (F)

COST PER TX ($_____/25)= $ (G)
(E)

ANNUALIZED PER PATIENT:

TREATMENTS (4 TX/DAY x 30 DAYS x 12 MONTHS) =	1440	(H)
TOTAL REIMBURSEMENT($0.85 x 1440) =	$1,224.00 (F x H)	
TOTAL COST($_____ per TX x 1440) = (G)	- (G x H)	
DEY UNIT-DOSE ESTIMATED PROFIT =	=	(I)

GAIN IN PROFIT WITH DEY UNIT-DOSE SUBSTITUTION:

YOUR PLAN/STORE:
$
(H-I)

DL-TX 0170962

DEY LABORATORIES

MEMORANDUM

TO: Debi Codute

FROM: Todd Galles

DATE: May 30, 1995

RE: **Copy Clearance: Managed Care Inservice**

Here is the approved Managed Care Inservice piece you put into copy clearance. Some changes were made to the piece. Please review the piece and let me know if you are satisfied and plan to use it.

Normal review should not take anywhere as long as this piece did. I believe the piece was misplaced and filed with other material, but I can not prove it. In the future, I'll track any pieces you submit and try to facilitate a more prompt turn around.

attachment

cc: Helen Burnham
Bruce Tipton

~~ADF #~~: 01-002
Revision #: 2
Effective Date: JAN 3 1 1995

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DOCUMENTATION
CONTROL

DEY LABORATORIES
ADVERTISING APPROVAL RECORD

PART NO.: 09-337-00	PRODUCT CODE: N/A	DATE: 3-13-95

PIECE: Managed Care Inservice Presentation
PRODUCT: not product specific
DESCRIPTION OF CHANGES: new

DRAFT COPY APPROVAL

MARKETING REVIEW AND COMMENTS: To be used by managed care specialists during inservice programs. OK with changes. 3-13-95

MARKETING APPROVAL: 3/13/95 DATE 5/1/95

QA REVIEW AND COMMENTS:

QA APPROVAL: DATE 3-30-95

REGULATORY AFFAIRS REVIEW AND COMMENTS:

REGULATORY AFFAIRS APPROVAL: DATE 4/18/95

CHIEF EXECUTIVE OFFICER REVIEW AND COMMENTS:

Approved with corrections noted on copy.

CEO APPROVAL: DATE 4/28/95

FINAL COPY APPROVAL

Marketing: 5-15-95 DATE

Regulatory Affairs: 5/15/95 DATE

Comments:

DL-TX 0170964

JUSTIFICATION FOR THE CONVERSION
"MULTIDOSE" TO "UNIT-DOSE" PRODUCTS

Advantages to Pharmacy & PBM:

-Gain in Profit Margin. $$
-No "Glass" Shipping.
-DEY packaging is "Unit of Use."
(Automation Friendly)
-No Saline products required.
-More control on refills, dosing can be calculated.
-Monthly shipments vs. weekly shipments.
-No wastage and need for re-shipment.

Advantages to Insured Group:

Unit Dose Reduces Overall Treatment Cost*

Fixed Cost per dose
Fixed Cost per day
Fixed Cost per treatment

-More control on refill costs, dosing can be calculated.
-Unit-Dose Presentation ensures accurate dosing.
-Premixed Meds: No cross contamination.
-Easy to monitor patient drug compliance, "Better Patient Outcomes."
-Vials do not require refrigeration, easy for travel.
-Easy to open for the geriatric or handicapped patient.
-Waste (spillage) controlled.

*Data on file

DL-TX 0170965

09-337-00 3/95

PACF #: 21-002
Revision #:
Effective Date: MAR 2 8 1995 CHANGE →

ISSUED BY
DOCUMENTATION
CONTROL

DEY LABORATORIES, INC.
ADVERTISING APPROVAL RECORD

PART NO.: 07-337-00	PRODUCT CODE: N/A	DATE: 3-1-95

PIECE: Managed Care Service Presentation

PRODUCT:
not product specific

DESCRIPTION OF CHANGES:
new

MARKETING REVIEW AND COMMENTS: To be used with in-house presentation by Dey Reps for managed care organizations.

MARKETING APPROVAL	DATE
[signature] 3-1-95	

QA REVIEW AND COMMENTS:

QA APPROVAL	DATE

REGULATORY AFFAIRS REVIEW AND COMMENTS:
[illegible] 3/6/95 Needs corrections noted on 4 pg. This form has been updated. No revised/correct version [illegible] 3/6/95

REGULATORY AFFAIRS APPROVAL	DATE

CHIEF EXECUTIVE OFFICER REVIEW AND COMMENTS:

DL-TX 0170966

CEO APPROVAL	DATE

JUSTIFICATION FOR THE CONVERSION
"MULTI-DOSE" TO "UNIT-DOSE" PRODUCTS

Advantages to Pharmacy & PBM:

-Gain in Profit Margin $$
-No "Glass" Shipping
-Dey's packaging is "Unit of Use"
(Automation Friendly)

-No Saline products required.
-More control on refills, dosing can be calculated.
-Monthly shipments vs. weekly shipments.
-No wastage and need for re-shipment.

Advantages to Insured Group:

Unit Dose Reduces Overall Treatment Cost*
~~—And Enhances Patient Lifestyle.~~

Fixed Cost per dose
Fixed Cost per day
Fixed Cost per treatment
-More control on refill costs, dosing can be calculated.
-Unit-Dose Presentation ensures accurate dosing.
-Premixed Meds: No cross contamination.
-Easier to monitored patient drug compliance, "Better Patient Outcomes"
-Vials do not require refrigeration*, easy for travel
-Easy to open for the geriatric or handicapped patient.
-Waste (spillage) controlled.
~~* Products must be stored @ controlled room temperature as low as 77 degrees.~~ not exceeding

* Data on file

DL-TX 0170967

09-337-00 3/95

JUSTIFICATION FOR THE CONVERSION
"MULTIDOSE" TO "UNIT-DOSE" PRODUCTS

Advantages to Pharmacy & PBM:

-Gain in Profit Margin. $$
-No "Glass" Shipping.
-DEY packaging is "Unit of Use."
(Automation Friendly)
-No Saline products required.
-More control on refills, dosing can be calculated.
-Monthly shipments vs. weekly shipments.
-No wastage and need for re-shipment.

Advantages to Insured Group:

Unit Dose Reduces Overall Treatment Cost*

Fixed Cost per dose
Fixed Cost per day
Fixed Cost per treatment

-More control on refill costs, dosing can be calculated.
-Unit-Dose Presentation ensures accurate dosing.
-Premixed Meds: No cross contamination.
-Easy to monitor patient drug compliance, "Better Patient Outcomes."
-Vials do not require refrigeration, easy for travel.
-Easy to open for the geriatric or handicapped
-Waste (spillage) controlled.

*Data on file

DL-TX 0170968

09-337-00 3/95

JUSTIFICATION FOR THE CONVERSION
"MULTIDOSE" TO "UNIT-DOSE" PRODUCTS

Advantages to Pharmacy & PBM:

-Gain in Profit Margin. $$
-No "Glass" Shipping.
-DEY packaging is "Unit of Use."
(Automation Friendly)
-No Saline products required.
-More control on refills, dosing can be calculated.
-Monthly shipments vs. weekly shipments.
-No wastage and need for re-shipment.

Advantages to Insured Group:

Unit Dose Reduces Overall Treatment Cost*

Fixed Cost per dose
Fixed Cost per day
Fixed Cost per treatment

-More control on refill costs, dosing can be calculated.
-Unit-Dose Presentation ensures accurate dosing.
-Premixed Meds: No cross contamination.
-Easy to monitor patient drug compliance, "Better Patient Outcomes."
-Vials do not require refrigeration, easy for travel.
-Easy to open for the geriatric or handicapped patient
-Waste (spillage) controlled.

*Data on file

RETAIL REIMBURSEMENT COMPARISON WORKSHEET

ALBUTEROL MULTIDOSE 0.5% 20 ML	DEY UNIT-DOSE ALBUTEROL
Current Situation Analysis:	**DEY:**
REIMBURSEMENT:	**REIMBURSEMENT:**
AWP = $_____PER 20 ML BOTTLE	AWP = $_____ OF 25 VIALS PER CARTON: $30.25
REIMBURSEMENT/ BOTTLE = **AWP-30%** = ____	REIMBURSEMENT/CARTON = **AWP-30%**= $21.18
ALBUTEROL PER TX = ($_____/40) =	ALBUTEROL PER TX = ($21.18/25) = $0.85
ASSUMES 40 TREATMENTS PER BOTTLE	*25 UNIT-DOSE TREATMENTS*
SALINE PER TX = +	SALINE PER TX = NA
TOTAL REIMBURSEMENT PER TX = = (A)	**TOTAL REIMBURSEMENT PER TX =** $0.85 (F)
COST:	**COST:**
ALBUTEROL COST PER 20 ML BOTTLE =	ALBUTEROL COST PER CARTON = $ (E)
ALBUTEROL COST PER TX ($5.75/40)=	ALBUTEROL COST PER TX ($_____ (E) /25)= $ (G)
SALINE COST PER TX = +	SALINE COST PER TX = NA
TOTAL COST PER TX = = (B)	**TOTAL COST PER TX =** =
ANNUALIZED PER PATIENT:	**ANNUALIZED PER PATIENT:**
TREATMENTS:	TREATMENTS:
(4 TX/DAY x 30 DAYS x 12 MONTHS) = 1440 (C)	(4 TX/DAY x 30 DAYS x 12 MONTHS) = 1440 (H)
TOTAL REIMBURSEMENT ($_____ x 1440) = (A x C)	TOTAL REIMBURSEMENT($0.85 x 1440) = $1,224.00 (F x H)
TOTAL COST($____ x 1440) = - (B x C)	TOTAL COST($_____ per TX x 1440) = - (G x H)
MULTIDOSE ESTIMATED PROFIT = = (D)	**DEY UNIT-DOSE ESTIMATED PROFIT =** = (I)

GAIN IN PROFIT PER PATIENT WITH DEY UNIT-DOSE SUBSTITUTION:

YOUR STORE/PLAN: $ (I-D)

DL-TX 0170970

*Sterile Sulfate Inhalation Solution 0.083% (potency expressed as albuterol)

7/98 09-339-01 Proflgn

DEY, L.P.
ADVERTISING/PROMOTIONAL LABELING APPROVAL RECORD

ART NO: 09-338-02	PRODUCT CODE: 196, 697	DATE: 3/29/99

PIECE: Retail Reimbursement Comparison Worksheet

PRODUCT: Albuterol Sulfate Inhalation Solution 0.083%, Albuterol Sulfate Inhalation Solution 0.5%

DESCRIPTION OF CHANGES: Form revised to include customized logo and updated formulas to reflect 50% reimbursement rate.

DRAFT COPY APPROVAL		FINAL COPY APPROVAL	
MARKETING REVIEW AND COMMENTS:		MARKETING REVIEW AND COMMENTS: 3/29/99 RFM	
MARKETING APPROVAL	DATE 3-29-99	MARKETING APPROVAL	DATE
REGULATORY AFFAIRS REVIEW AND COMMENTS:			
REGULATORY AFFAIRS APPROVAL	DATE	REGULATORY AFFAIRS APPROVAL	DATE
QA REVIEW AND COMMENTS:			
QA APPROVAL	DATE		DATE
OTHER REVIEW AND COMMENTS:			
OTHER APPROVAL (please identify)	DATE	OTHER APPROVAL (please identify)	DATE

Cannot be used per RFM

CANNOT be used please destroy RFM

MECHANICAL COPY APPROVAL

Marketing: _____ Date

Regulatory Affairs: _____ Date

Comments:

DL-TX 0170971

RAOP #: 01-002
Version #: 0
Page 5 of 5

[name/logo] RETAIL REIMB_ _EMENT COMPARISON WORKSHEET

ALBUTEROL MULTIDOSE FOR NEB 0.5% 20 ML		DEY UNIT-DOSE ALBUTEROL	
Current Situation Analysis:			DEY:
REIMBURSEMENT:		**REIMBURSEMENT:**	
AWP = $_____PER 20 ML BOTTLE		AWP = $_____ OF 25 VIALS PER CARTON	$30.25
REIMBURSEMENT/ BOTTLE = **AWP-50%** =____		REIMBURSEMENT/CARTON = **AWP-50%**=	$15.13
ALBUTEROL PER TX = ($_____/40) = *ASSUMES 40 TREATMENTS PER BOTTLE*		ALBUTEROL PER TX = ($15.13/25) = *25 UNIT-DOSE TREATMENTS*	$0.61
SALINE PER TX =	+	SALINE PER TX =	NA
TOTAL REIMBURSEMENT PER TX =	= (A)	**TOTAL REIMBURSEMENT PER TX =**	**$0.61** (F)
COST:		**COST:**	
ALBUTEROL COST PER 20 ML BOTTLE =		ALBUTEROL COST PER CARTON =	$ (E)
ALBUTEROL COST PER TX ($5.75/40)=		ALBUTEROL COST PER TX ($_____ (E) /25)=	$ (G)
SALINE COST PER TX =	+	SALINE COST PER TX =	NA
TOTAL COST PER TX =	= (B)	**TOTAL COST PER TX =**	=
ANNUALIZED PER PATIENT:		**ANNUALIZED PER PATIENT:**	
TREATMENTS: (4 TX/DAY x 30 DAYS x 12 MONTHS) =	1440 (C)	TREATMENTS: (4 TX/DAY x 30 DAYS x 12 MONTHS) =	1440 (H)
TOTAL REIMBURSEMENT ($_____ x 1440) =	(A x C)	TOTAL REIMBURSEMENT($0.61 x 1440) =	$878.40 (F x H)
TOTAL COST($____ x 1440) =	- (B x C)	TOTAL COST($_____ per TX x 1440) = (G)	- (G x H)
MULTIDOSE ESTIMATED PROFIT =	= (D)	**DEY UNIT-DOSE ESTIMATED PROFIT =**	= (I)

GAIN IN PROFIT PER PATIENT WITH DEY UNIT-DOSE SUBSTITUTION:

YOUR STORE/PLAN:
$
(I-D)

DL-TX 0170972

*** Albuterol Sulfate Inhalation Solution 0.083% (potency expressed as albuterol)

3/99 09-338-02 Prof/399

TAB 27

DEY LABORATORIES

MEMORANDUM

TO: Bruce Tipton

CC: Pam Marrs
Bob Mozak

FROM: Robert Covay

DATE: May 8, 1995

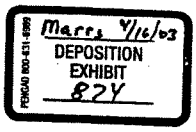
RE: ACHIEVEMENT OF OBJECTIVES FOR 1995 COMMISSIONS

Each Managed Care employee must meet certain objectives in order to receive 30% of their commission each quarter. These objectives were summarized in your memo to the Managed Care Team dated April 5, 1995.

I would appreciate a memo from you no later than the 10th day of the month following each quarter end indicating who has and has not met their objectives for the quarter. I would like the memo related to first quarter commissions as soon as possible.

If you have any questions, please call me at extension 243.

RAC:njk



1995 Compensation Criteria
(PART B)

As you recall, 70% of your incentive package (Part A) is predicated on Dey Laboratories ittaining their targeted national sales figures. The remaining 30% (part B) is based upon your joal attainment of the following:

		Weight
(1)	Implementation of at least one AWP reimbursement proposal to convert multi dose albuterol to Dey unit dose albuterol per qtr.	10%
(2)	Implementation of at least one Cromolyn conversion program to a qualified major retail chain drug customer./qtr.	10%
(3)	Open at least one new account per qtr that represents annualized sales of $50,000 or more	10%

National factory sales information is easily quantifiable and internal accounting will be the basis for the data to measure (Part A). Documentation of 1,2 and 3 above, including competitive utilization information, simulated savings, agreed upon goals, etc. is mandatory to qualify for the part B portion.

SUPER BONUS

Extra 10% bonus if Dey Albuterol U.D. is reintroduced to customer warehouse. (Intent is to regain lost business) Emphasis is with retail drug chains

(PART A)

94 Actual Sales Total	$109,199,668.61
95 Forecast (annual)	$123,286,177.49 (+ 12.9%)

95 Forecast by Quarters

1st. qtr (000)	2nd qrt	3rd qrt	4th qrt
$33,040	$29,445	$29,835	$30,994

Keep in Mind that:

- Provision for a full year's Cromolyn sales
- Erosion of Albuterol price
- Impact of our group

etc., etc.

Have all been factored in to these forecast numbersF

Bruce W. Clayton 5/23/95

Marcs 4/16/03
DEPOSITION
EXHIBIT
873

RFMorgan 5/31/95

TAB 28

DEY LABORATORIES

MEMORANDUM

TO: Sales and Marketing cc: R. F. Mozak

FROM: Helen Burnham

DATE: May 30, 1995

Re: ALBUTEROL WAC PRICING

Attached is a copy of a fax sent to all database managers to update their records with our wholesale acquisition cost (WAC) for albuterol.

As you know, the following states are now using WAC instead of AWP to calculate Medicaid reimbursement:

- Alabama
- Colorado
- Florida
- Maryland
- Massachusetts

WAC is not representative of our published wholesale list prices, but like AWP, is used for calculation of reimbursement. Our updated WAC values are in line with the Warrick WAC values provided by First Data Bank and should level the playing field for Medicaid reimbursement.

Please give me a call if you have any questions.

HB:mf

DEY LABORATORIES
2751 NAPA VALLEY CORPORATE DRIVE
NAPA, CA 94558
TELEPHONE: (707) 257-9740
FAX: (707) 224-8918

DATE: May 30, 1995

TO: Beth Raider

FAX#: (415) 588-6867

FIRM: Price Alert and Pharmacy Blue Book Update

FROM: DEY Laboratories

NUMBER OF PAGES, INCLUDING THIS ONE 1

Re: PRICING UPDATE

For your records, we are updating our pricing on the following products:

NDC NUMBER	PRODUCT DESCRIPTION	SIZE	UNITS PER CARTON	AWP	WAC
49502-697-03	Albuterol Sulfate Inhalation Solution 0.083%	3 mL	25	$30.25	$24.75
49502-697-33	Albuterol Sulfate Inhalation Solution 0.083%	3 mL	30	$36.30	$29.70
49502-697-60	Albuterol Sulfate Inhalation Solution 0.083%	3 mL	60	$72.60	$59.40

WAC: 25 @ 99¢ ea = 24.75
50 @ 99¢ ea = 49.50
30 @ 99¢ ea = 29.70

Medispan
Also send AWP "for your records"

MEDICAID Rx REIMBURSEMENT REPORT

State	Fiscal 1994 Dispensing fees	Co-pay	Ingredient reimbursement basis	Fiscal 1993 Total prescription reimbursements	Total dosg. recipients	Average prescription update
Alabama	$3.40	50 cents–$3	WAC+9.82%	$146,877,201	395,458	$23.28
Alaska	3.45–11.46		AWP–5%	14,225,812	38,307	34.23
Arizona	AHCCCS-Arizona Health Care Cost Containment			827,249	22,289	0.71
Arkansas	4.51 + .003 EAC	50 cents–$3	AWP–10.5%	78,183,072	257,281	22.88
California	4.05	$1*	AWP–5%	991,564,256	3,598,435	n/a
Colorado	4.08	$2/50 cents*	AWP–10/WAC+18%*	63,646,706	205,153	n/a
Connecticut	4.10*		AWP–8%	100,434,809	239,681	n/a
Delaware	3.85	—	AAC	15,067,081	49,086	22.89
District of Columbia	4.50	50 cents	AWP–10%	23,690,315	86,812	n/a
Florida	4.25	$1	WAC+12%	424,291,258	1,252,458	23.60
Georgia	4.11–6.00	50 cents	AWP–10%	221,384,507	756,130	20.13
Hawaii	4.67*		AWP–10.5%	28,351,062	85,978	n/a
Idaho	4.50**		AWP	23,768,958	72,837	19.43
Illinois	3.59*		AWP–10%	330,956,798	1,060,236	31.47
Indiana	4.00*	50 cents/$1	AWP–10%	214,534,028	448,450	22.03
Iowa	4.02–6.25	$1	AWP–10%	80,357,979	220,157	21.46
Kansas	3.85–6.97	$1	AWP–10%	60,328,511	176,507	22.50
Kentucky	4.75		AWP–10%	194,148,552	482,752	22.27
Louisiana	5.77		AWP–10.5%	234,322,114	577,942	23.53
Maine	3.35–5.35	50 cents–$2	EAC/AWP–5%	56,296,968	128,151	25.59
Maryland	4.64/6.17	—/$1	WAC+10%	110,500,576	312,816	24.92
Massachusetts	3.95	50 cents	WAC+10%	216,541,834	517,313	n/a
Michigan	3.22*	$1*	AWP–10%/AAD	259,324,929	855,328	20.09
Minnesota	4.10		AWP–7.6%	111,005,588	292,217	18.50
Mississippi	4.91*	$1*	AWP–10%	130,918,361	409,252	22.82
Missouri	4.09	50 cents–$2	AWP–10.43%	188,313,966	484,468	22.94
Montana	2.00–4.08	$1/$2	AWP–10%	21,255,810	63,451	22.82
Nebraska	2.84–5.05	$2	AWP–5.71%/WAC+12.52%	49,721,877	126,239	20.44
Nevada	4.42	—	AWP–10%	15,879,829	54,232	39.55
New Hampshire	3.25–4.15*	50 cents/$1*	AWP–10%	24,570,855	69,867	19.97
New Jersey	3.73–4.07		AWP–0/6%*	273,596,577	606,718	26.91
New Mexico	4.00		AWP–10.5%	38,211,864	156,939	n/a
New York	2.80**		AWP	636,257,592	1,877,378	25.91
North Carolina	5.80	$1	AWP–10%	189,861,296	622,062	22.84
North Dakota	4.25*		AWP–10%	15,708,915	42,090	22.35
Ohio	3.23		AWP–7%	368,993,132	1,030,405	n/a
Oklahoma	5.10	$1/$2	AWP–10.5%	89,523,200	288,004	28.78
Oregon	3.67–4.02		AWP–11%	72,282,487	213,383	n/a
Pennsylvania	3.50	$1	AWP	389,167,236	947,430	22.78
Rhode Island	3.90		AWP	36,906,809	130,489	22.83
South Carolina	4.85*	$1.50	AWP–9.5%	94,030,373	341,554	28.07
South Dakota	4.75*	$1	AWP–10.5%	16,965,819	44,697	24.48
Tennessee	—	Temicare	—	240,079,482	701,196	22.31
Texas	—	—	AWP–10.48%/WAC+12%	444,718,089	1,843,546	23.71
Utah	3.90–4.40*		AWP–12%	32,297,582	111,536	n/a
Vermont	4.25*	$1/$2	AWP–10%	23,937,810	63,287	n/a
Virginia	4.40	$1	AWP–9%	161,448,803	429,746	n/a
Washington	3.85–4.50	—	AWP–11%	155,125,823	484,653	22.98
West Virginia	2.75*	50 cents–$1	AWP	57,516,490	261,235	n/a
Wisconsin	4.89	$1	AWP–10%	162,741,531	341,097	36.20
Wyoming	4.20*	$1	AWP–9%	8,444,108	35,508	28.15

*Connecticut and New Hampshire: Incentive fee added to pharmacy reimbursement for dispensing a lower-cost product.
*California: Collection by pharmacy is optional.
*Illinois: 3.58 or 10% x cost > $35.80.
*Texas: Amount paid pharmacy equals (EAC+$4.55) divided by 0.970.
*New Hampshire: $1.00 – branded or compound products; $.50 – generics.
*Michigan: AAC with AWP minus 10% screens.
*New Jersey: AWP minus up to 6% based on Medicaid percentage of Rx sales.
*Colorado: $2.00 trade name; $.50 generic (MAC) products.
*Michigan: $1.63 effective 10/1/93.
*Oklahoma: $1.00 for prescriptions up to $29.99; $2.00 for prescriptions costing more than $30.00.
*Vermont: $1.00 copayment; $2.00 copayment when ingredient costs exceed $29.99.
*Utah: $3.90 urban; $4.40 rural.

NOTE: The dispensing fees, copayments, and ingredient reimbursement are current to July 1993. The average Rx price and prescriptions processed data are approximations based upon 1993 fiscal year data.

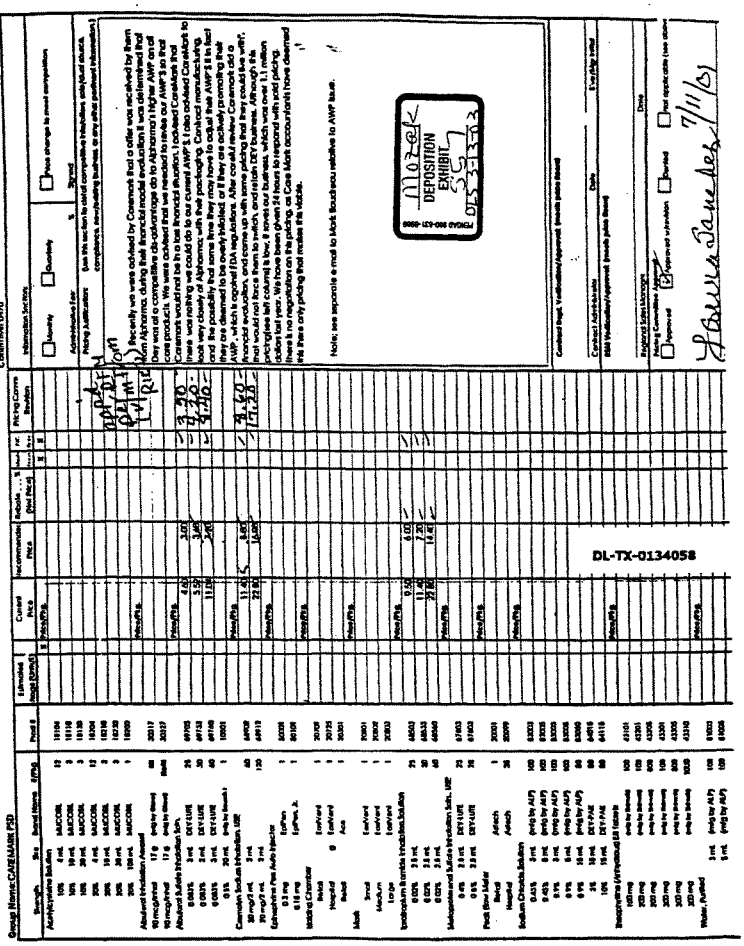
Source: National Pharmaceutical Council Inc.

TAB 29

6/28/00

Voice mail from Dan Maloney to Mike Wilson (707) 224-3200 ext. 8100.

Mike this is Dan Maloney from Omnicare. How are you doing? I am calling on your voice mail to give you a chance to think about this but you need to think about it really fast. I am having a really big problem with ipratropium. Alpharma has come out with product that has an AWP that is dramatically higher than yours. For example, your 25's cartons that we use most of is $44.10/carton and Alpharma's is $56.50/carton. On a P&L, if you notice on our Web Site we are not going to make our second quarter earnings. I am striving to get some of our earnings back. I would lose $3.0 million this year by continuing to use your product with all these MACs going on. I don't know what to tell you but the same thing happen with albuterol. Your AWP is out of wack with your competitors. Unless you raise your AWP, I will be forced to switch to the other product. We need to talk seriously about this. I want to stay loyal to you but I can't be forced to give up $3.0 million extra earnings to me. Give me a call and we will talk about it today (606)393-3364.



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TAB 30

DEY-CO-0004565

Mike Wilson
07/10/2001 11:36 AM

To: Laura Sanchez
cc: Mark Boudreau
Subject: Caremark,

Laura, attached is CareMark bpw, i will advise if Mark gets pricing approved,you can verify with him or

Mozak. RIDWRKS\Hcaremark 7-10-01 fi

Mike Wilson
07/10/2001 03:50 PM

To: jmiller@caremark.com
cc: Mark Boudreau/Dey_Labs/Merck-Gen/Merck, Laura Sanchez/Dey_Labs/Merck-Gen/Merck
Subject: Pricing

Janet, tommorrow you will receive via fax, and hard copy to follow the following price revisions;

Albuterol u. d. 25's $3.50 per carton

Cromolyn u. d. 60's $ 8.60 per carton

Ipratropium u. d. 25's $ 6.00 per carton

In addition we welcome the opportunity to partner on an intervention program for DuoNeb, pending approval to your formulary.

Mike Wilson
07/10/2001 11:33 AM

To: Laura Sanchez
cc:
Subject: CareMark

---------- Forwarded by Mike Wilson/Dey_Labs/Merck-Gen/Merck on 07/10/2001 01:32 PM ----------

Mike Wilson
06/19/2001 08:23 PM

To: Mark Boudreau
cc:
Subject: CareMark

As you know we are facing a very serious challenge to our business with CareMark. Again the "favorable AWP'S " that Alpharma has estalblished are "haunting " us. Although similar to the Omnicare situation where they are reimbursed AWP - 10%, the higher the AWP, the better the spread. CareMark has a different formula, spread over cost. Again the higher AWP is more favorable to the customer due to reimbursement. We have an opportunity to save this business, which last year totaled $1.2 million on all products. This year through May we are at $619,000. I have spoken both with Steve Basiago, V. P. of trade Relations, and Janet Miller, Director, Generic purchasing of some options we may have to offset the favorable AWP. Option One, and probably the most favorable to CareMark would be to take the difference in cost between the AWP'S, and reimburse CareMark the difference in free goods [see calculations below]. Option Two, would be to provide a credit memo for the same dollar amount of the difference, and provide a quarterly credit . I have also Addressed with Janet and Steve the issue of Alpharma's source of manufacturing, as well as their packaging. Janet told me she has requested this information, and will advise their clinical staff to review. CareMark knows the concerns involving switching vendors and the confusion it can cause at the patient level, especiall y dealing with mail service. Th issue however is simple, they can not continue to dispense our products with our current AWP'S on Albuterol, Cromolyn, and Ipratropium, when there are are more favorable AWP'S from Alpharma. It is not a price issue. Before you pass this on lets discuss via phone to determine a path forward or specific recommendation:

DEY AWP ALBUTEROL 25's $30.25 CROMOLYN 120's $84.00
IPRATROPIUM 25's $ 44.10

ALPHARMA AWP ALBUTEROL 25's $30.90 CROMOLYN 120's$ 92.86
IPRATROPIUM 25's $ 56.50

CAREMARK VOLUME YTD. THROUGH MAY;

ALB. 52,135 CROM. 1,502
I. B. 30,961

CONFIDENTIAL

DL-TX-0134061

00581

DEY-CO-0004568

TAB 31

Laura Sanchez
08/01/02 10:05 AM

To: "'Strout, Michael A." <MZS4211@pharmerica.com>
cc: "'Chris.Gurchiek@deyinc.com'" <Chris.Gurchiek@deyinc.com>, "'laura.sanchez@deyinc.com'" <laura.sanchez@deyinc.com>
Subject: RE: DuoNeb Proposal

Michael,

Since our Executive VP of Finance, Pam Marrs, oversees customer indemnification requests, I have routed your request to her. I will follow up on the status and get back to you.

Laura
"Strout, Michael A." <MZS4211@pharmerica.com>

"Strout, Michael A." <MZS4211@pharmerica.com>
08/01/02 08:21 AM

To: "'Chris.Gurchiek@deyinc.com'" <Chris.Gurchiek@deyinc.com>, "'laura.sanchez@deyinc.com'" <laura.sanchez@deyinc.com>
cc:
Subject: RE: DuoNeb Proposal

Chris/Laura,

Just wanted to follow up to see where things stand with the Agreement. I'd like to get this loaded at the AmerisourceBergen ASAP.

Thanks for your help,

Mike

-----Original Message-----
From: Strout, Michael A.
Sent: Friday, July 12, 2002 11:45 AM
To: 'Chris.Gurchiek@deyinc.com'; 'laura.sanchez@deyinc.com'
Subject: DuoNeb Proposal

<< File: Notes on Purchase Agreement Dey.doc >>

Chris/Laura

Attached please find an MS Word document with my requested changes to the DuoNeb proposal. Once we reach agreement, I will provide a copy to our Legal departmnt for their final review.

Chris, if there are any ways in which Dey can offer greater discounts (perhaps vai rebate) on this product, I'd like to explore them.

The differences in both cost and spread between this product and albuterol + ipratropium are dramatic. We firmly believe that this is a safer product for our patient population, but the hit to our bottom line is a tough one to take.

Thanks,

CONFIDENTIAL

DL-TX-0145847

DL-TX-0145847

DEY-CO-0004608

TAB 32

Pam Marra
03/12/2001 06:33 PM

To: Klaus Rueth/EMD/Merck@Merck
cc:
Subject: Re: Antwort: Cash flow projections 2001

Dear Klaus

Regarding the change in receivables.....this is always a very hard number for us to predict due to the way we do business with our customers.....which is far too complicated to explain in an e mail message. Suffice it to say that as of 12/31/00 we were actually in a net payable position with our customers due to the large amounts due to customers for rebates and chargebacks. The customers usually pay us for their receivables before we pay them for their rebates and chargebacks. Unusual at best.....but that is the way it works. This is especially true when wholesalers make the large buy-in orders they have made during this past year. (i.e. when the wholesalers buy several months of inventory at one time)

The situation is expected to turnaround in 2001 for two main reasons. (1) The large chargeback accruals are driven by the large spread between our actual net selling price and the invoice price. Over time, this difference grows as price erosion increases and we therefore periodically lower the invoice price to reduce the spread and the related accruals. We reduced the invoice list price in February 2001 for most products, therefore, the accruals should be less ..... assuming price erosion does not catch up with us again by the end of 2001. (2) The main thing that will cause receivables to increase in 2001 is the launch of DuoNeb. This product should not be heavily discounted and therefore not subject to the same large chargeback and rebate accruals our existing products are currently experiencing. I am a bit concerned that receivables will increase even more than we have included in our projections if the Sales Department decides they must offer 60 day terms instead of our current 30 day terms. For now we have assumed 30 day terms.

Regarding the change in income taxes.....by way of background keep in mind that a significant portion of the taxes payable account is normally a reserve for tax exposures on prior year returns and remains relatively stagnant. The decrease in taxes payable in 2001 is attributable to refundable income taxes that will be generated from the carry back of the estimated 2001 losses of Lexigen and EMD.....i.e. in 2001 Lexigen and EMD's losses will exceed Dey's taxable income, therefore Dey will carryback the excess loss to reduce its prior year taxable income and will receive a tax refund.....this estimated receivable is netted with the payable. This transaction is a bit unusual, but in order to record Dey's intercompany payable to Lexigen and EMD at their full book value this entry is necessary. In 2002, when the refund from the IRS is received by Dey, the intercompany account will be paid and Dey's tax payable will likewise increase.

I hope I have not totally confused you. Please don't hesitate to ask for any additional information you may need. If you have an urgent need for further explanation,, you can always call me at home.....(707) 429-4991.

Best regards.

Pam

Klaus Rueth@MERCK

Klaus Rueth@MERCK
03/12/2001 01:22 PM

To: Pam Marra/Dey_Labs/Merck-Gen/Merck@DEY_LABS
cc:
Subject: Antwort: Cash flow projections 2001

Dear Pam,

DL-TX-0164080

CONFIDENTIAL

thanks for your mail. You met exactly what I was asking for (2nd column).

A major part of the cash consumption is related to "change in A/R and prepaids, mio (18,3) $ and change in intercompany payable, mio 15,2 $. Can you give me some explanations to this items?
Income tax payables mio (9,4) $, Tax payments 2000?

Thanks again for your appreciated assistance.

Kind regards,
Klaus.

TAB 33

DEY L.P. facsimile transmittal

To:	Russ Johnston – Contract Dept.	Fax:	(707)224-0988
From:	Joe Ruhmel – DEY L.P.	Date:	05/12/00
	Tel: (800)786-5775 ext. 8130		
	Fax: (315)768-8371		
Re:	CVS Agreement	Pages:	4 (including cover)
CC:			

☑ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

Russ,

Please find the attached signed CVS agreements.

1. Addendum to CVS Agreement
   A. Change name to CVS Meridian Inc. as noted
   B. Were noted include clause that data supplied will exclude Medicaid & federally sponsored programs (will only decrease the number of units claimed – our benefit)

2. Preferred Vendor Rebate Agreement
   A. Change name to CVS Meridian Inc. as noted.
   B. Revise rebate to 7.5% from 6%. The reason for doing this is that we only will account the accrual for direct purchases under this agreement. To reach an equivalent dollar amount quoted to CVS in our initial proposal we need to increase the percentage because indirect sales are not taken into consideration in this calculation. Bottom line here is that we still are offering the same dollar value to CVS as originally quoted.
   C. Add clause "based upon an AWP/net price spread that is acceptable to CVS" at the end of the two sentences marked with *. CVS is requiring this clause based on a lack of pricing information on Duoneb at this time. If AWP price spread is not favorable to the chains, they will not support this product and where DAW is not specified, will continue to dispense the more profitable generics.
   D. Based on verbal negotiated agreement, remove "Preferred Vendor Credits are not valid for application against DEY's Ace Holding Chamber, Astech, Easivent, and Epipen products."

Please issue a clean hardcopy to Matt Leonard with these noted revisions and a copy to me for my files.

Thank you!

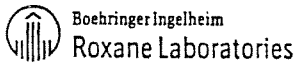
CONFIDENTIAL
DL-TX-0153225

CONFIDENTIAL

CONFIDENTIAL
DL-BO-077292

DL-TX-015322!

DEY-CO-0004617



Roxane Laboratories, Inc.

Ms. Terri Factora
First Data Bank
1111 Bayhill Drive
Suite 350
San Bruno, CA 94066

October 20,1999

Lesli Paoletti
Telephone (614) 276-4000 x2079
Telefax (614) 276-3876
E-Mail lpaoletti@col. boehringer-ingelheim.com

P.O. Box 16532
Columbus, Ohio 43216-6532
Telephone (614) 276-4000

Product Listing for Roxane Laboratories, Inc.

Dear Ms. Factora:

Thank you for the opportunity to provide First Data Bank with the most up-to-date product listing. Please note the corrections to pricing and discontinuations and remove inaccurate WAC pricing, where indicated. Accurate WAC pricing will not be furnished, as it is company policy not publish this information.

If you require any further information, I may be contacted at (614) 276-4000, extension 2079.

Sincerely,

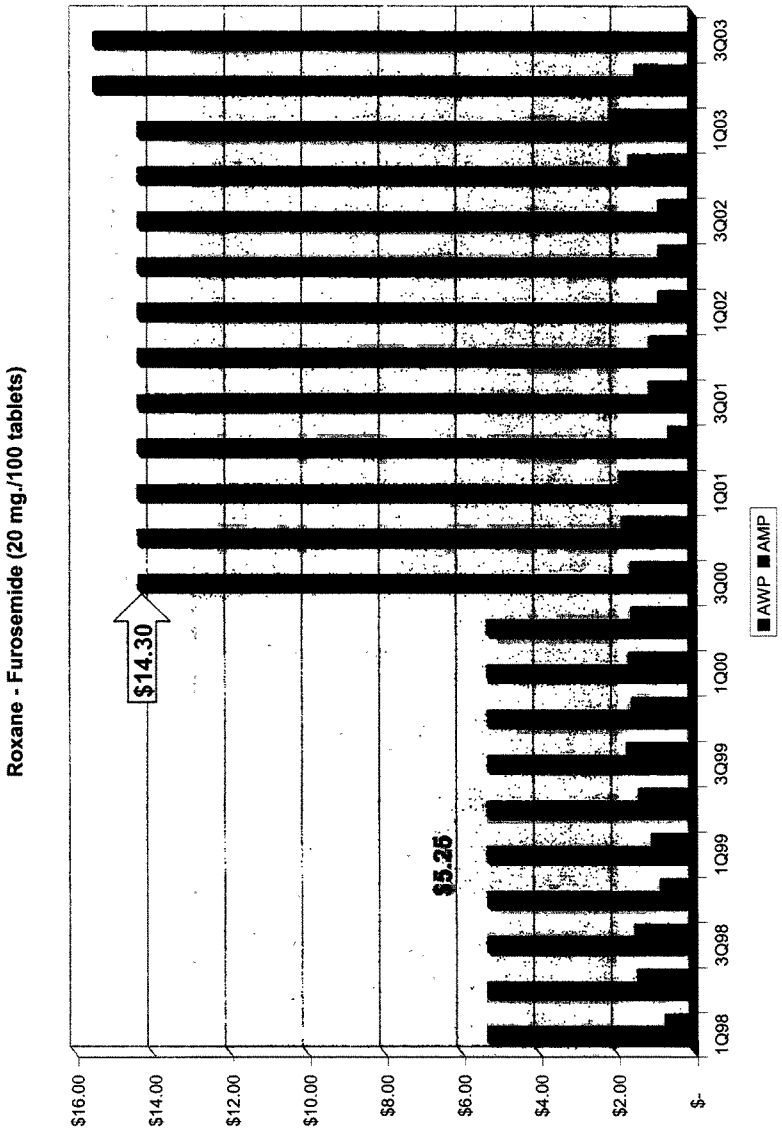
Lesli Paoletti
Assistant Manager, Multi-Source Products

/ms

Enclosure

cc: J. Waterer

TAB 35


Roxane - Furosemide (20 mg./100 tablets)
$14.30
$5.25
$16.00
$14.00
$12.00
$10.00
$8.00
$6.00
$4.00
$2.00
$-
1Q98
3Q98
1Q99
3Q99
1Q00
3Q00
1Q01
3Q01
1Q02
3Q02
1Q03
3Q03
AWP
AMP

From: SYKORA, ROBERT ROXUS
Sent: Friday, April 14, 2000 1:18 PM
To: WATERER, JUDY ROXUS; POWERS, JOHN ROXUS
Cc: FELDMAN, RICHARD ROXUS; PAOLETTI, LESLI ROXUS
Subject: furosemide awp

Hello,
Anthony approached Caremark about furosemide when he heard that they were dissatisfied with their current supplier. Janet Miller of Caremark said she would like to give us the business except our AWP was far too low for it to be profitable for them. Anthony did some rsearch and found out the following.

Lasix 40mg 1000	AWP
Hoescht	241.62
Furosemide 40mg 1000	
Mylan	151.90
Watson	141.90
ZenithGoldline	151.90
Geneva	140.30
Roxane	45.25

This is certainly a hindrance to retail customers wanting to use our product. It would appear that an adjustment to the mid-140's is justified. If we can do this quickly, we can get the Caremark business.Thanks.

TAB 37

From: WATERER, JUDY ROXUS
Sent: Wednesday, July 26, 2000 7:43 AM
To: PAOLETTI, LESLI ROXUS
Subject: FW: Furosemide Tablet AWP adjustment

-----Original Message-----
From: SYKORA, ROBERT ROXUS
Sent: Tuesday, July 25, 2000 6:58 PM
To: WATERER, JUDY ROXUS
Cc: FELDMAN, RICHARD ROXUS; Russillo, Tom BICLE; CIARELLI,GREGG MK BIPUS; POWERS, JOHN ROXUS
Subject: Furosemide Tablet AWP adjustment

Per your request, attached is the sales justification for an upward adjustment in the AWP of Furosemide tablets based upon the competitive environment.

Please note that Mylan's latest (within the last few days) WAC & AWP changes are not reflected. I expect to have this in hand by Wednesday, however, I'm leaving on customer calls and I wanted to get the ball rolling in case it didn't arrive before I left. Regardless, since Mylan changes are increases, it only serves to make our current AWPs more deleterious in our customers' view.

If anyone has any questions, I'll be in the office Wednesday until 1pm and back on Friday afternoon. Thanks.


FuroAWP.doc


FuroAWP.xls

FUROSEMIDE
AWP

1. Market Situation

Furosemide tablets are a product marketed as a multisource generic by RLI for many years. Due to the recent raising of wholesale acquisition cost (WAC), average wholesale price (AWP), and most probably contract pricing by Mylan Labs, a number of customers have proactively contacted us about contracting for their award on the product. After providing information on the product including AWP and contract prices, these customers have rejected our bids even though our contract prices have been competitive. This is due to the RLI Furosemide having the lowest AWP of all the generic Furosemide so when they are reimbursed on an AWP less fixed percentage by third party insurance (85% of their business), our low AWP ensures them the worse profitability.

The RLI Furosemide has not been adjusted since April 11, 1994 while Mylan's has been raised seven times since then (1995, 3x in 1996, 1998, 1999, & 2000) and the brand has had at least annual AWP & WAC increases.

By raising our AWP to reflect that of the other generic Furosemide, RLI can remove the barrier to securing additional Furosemide business from the customer's perspective. Additional Furosemide unit volume would not only increase revenues but also lower overhead costs on all products due to the large tablet volume of the product.

2. Competition

See FuroAWP.xls (tab #1) for a comparison of AWPs of all currently available generics and brand Furosemide.

3. Reimbursement Analysis

See FuroAWP.xls (tab #2) for analysis of our customer's profitability dispensing RLI Furosemide versus Mylan's on third party reimbursed insurance plans.

This shows that the customer loses money ($70-80) on every 1000 tablets of Roxane Furosemide dispensed if used instead of Mylan. Based upon CVS volume, this represents $934,500 of profit margin loss to CVS annually.

4. Customer Analysis

The following three customers requested contract pricing, received a contract bid, and rejected a RLI award since April 2000.

Caremark:

Furo 20mg	5.6 million tablets
Furo 40mg	13.35 million tablets
Furo 80mg	2.38 million tablets

E-mail from Anthony Tavolaro (RLI) per vm left by Janet Miller of Caremark (April 2000)

JM- "Your AWP's are 78% below the rest of the industry. I am not aware of any competitor with AWP's below $100.00 for bottles of 40mg 1000s. Mylan and Zenith are approximately $120.00, yours is $29.00"

AT- Caremark's commented they could not possibly award the product to us unless we increased our AWP's. Janet Miller also added that Roxane has a history of having AWP's out of sync with the rest of the industry.

AT- I don't know why we have to wait until our customers complain before we adjust an AWP. Major customers (Walgreen, Wal-Mart, CVS, Medco, Caremark) expect their leading suppliers to maintain their AWP's. Not executing this core competency reflects negatively on Roxane, and promotes a perception of Roxane not understanding industry dynamics.

CVS:

Furo 20mg	36 million tablets
Furo 40mg	68 million tablets
Furo 80mg	11.5 million tablets

E-mail from Steve Snyder (RLI) per vm left by Matt Leonard of CVS (June 2000)

SS- CVS is looking for a Furosemide vendor. Apparently, the HCFA Macs are changing at shortly, and they are not happy with the margins from their current supplier. They did not have the new MACs available to share with me, but being public record, I am certain we should have them somewhere. In fact, I think Bob has them on his desk. In the past,

CVS has asked for AWP less 55% to be competitive on generics. I am not sure how the MAC impacts this. I would like to discuss this with Bob and/or Anthony before we bid. For now I have listed the requested bid price at AWP less 50%.

ML- "CVS would award Roxane the product if we would adjust our AWPs to reflect where the other generic companies are. Otherwise, CVS would award to ZenithGoldline"

Can I request that we (Judy, John, Bob) discuss this Thursday or Friday AM? They asked that I get them a quote by the end of the day Friday. I think it would put us in a good light if we could respond by then. However, I made no promises except that I would notify them if we could not meet that timeframe. If a Friday PM response is out of the question, I just want to let CVS know when they will receive our reply.

Safeway-Vons

Furo 20mg 4.3 million tablets
Furo 40mg 9 million tablets
Furo 80mg 1.95 million tablets

Voicemail from Colin Carr-Hall (RLI) from live conversation with Rita Bonowski of Safeway-Vons (July 2000)

RB- "Watson notified us that they will no longer supply be able to supply us with Furosemide. I'd love to give the business to Roxane but there's an AWP problem with that product?"

5. Opportunity

Roxane Furosemide Volume in 1999

Furo 20mg 29.9 million tablets
Furo 40mg 64.5 million tablets
Furo 80mg 5.8 million tablets

By securing at least one of the three awards above, RLI could have increased its Furosemide unit volume by 10% to 100% depending on the account. This would account for $610,000 to $6.1 million in increased revenue.

With Watson exiting the Furosemide business and Mylan having isolated customers by increasing the WAC (July 2000) and most probably their contract pricing in September 2000, there exists an opportunity for Roxane to significantly increase it unit volume sales of Furosemide tablets.

We have an immediate opportunity with Bergen to gain the prime award for their autosubstitution volume which should be comparable to the CVS unit volume listed above.

		AWP		AWP		AWP			AWP	
Furosemide	20mg	100	Ranking	500	Ranking	1000	Ranking	Label	Change Date	WAC
		11.86	7	26.64	4			ESI-Lederle		
		13.58	5	na	na	122.78	5	Geneva		2.82/17.74
		13.45	6	na	na	121.55	6	Major		3.73/27.49
		14.30	2	na	na	139.90	2	Mylan	1/19/2000	
		9.05	8	na	na	81.83	7	Qualitest		
		5.25	9	na	na	36.05	8	*Roxane*		
		na	na	na	na	na	na	URL		
		13.58	4	64.51	2	133.25	3	Watson		
		13.60	3	42.70	3	133.25	4	Zenith Goldline		
Lasix	20mg	19.92	1	94.02	1	178.44	1	Aventis		16.60/17.45/78.35

		AWP		AWP		AWP			AWP	
Furosemide	40mg	100	Ranking	500	Ranking	1000	Ranking	Label	Change Date	WAC
		13.56	7	na	na	59.46	9	ESI-Lederle		
		15.50	3	na	na	140.30	4	Geneva		3.25/22.18
		15.35	6	na	na	138.90	6	Major		4.95/32.99
		16.30	2	na	na	159.50	2	Mylan	1/19/2000	
		na	na	na	na	93.53	8	Qualitest		
		5.98	8	na	na	45.25	10	Roxane		
		na	na	na	na	140.28	5	URL		18.33
		15.50	4	na	na	141.90	3	Watson		
		15.50	5	48.69	2	133.25	7	Zenith Goldline		
Lasix	40mg	27.90	1	132.30	1	251.28	1	Aventis		

		AWP		AWP		AWP			AWP	
Furosemide	80mg	100	Ranking	500	Ranking	1000	Ranking	Label	Change Date	WAC
		20.69	7	65.13	7	na		ESI-Lederle		
		41.60	4	198.00	4	na		Geneva		6.64/29.99

Lasix											
80mg											
	41.19	5	196.05	5	na	Major					
	43.70	1	213.90	1	na	Mylan					
	27.74	6	na	6	na	Qualitest		1/19/2000			
	13.49	8	67.47	8	na	Roxane					
	41.60	2	na	na	na	URL			5.49		
	41.60	3	203.75	3	na	Watson					
	na	na	na	na	na	Zenith Goldline					
na	na	na	213.84	2	na	Aventis					

Roxane Furosemide

Furosemide	Actual WAC	Actual AWP	Av. Contract Price	% Off AWP	% WAC Mark-Up
20mg 1000	$ 23.11	$ 36.05	$ 10.00	35.89%	56%
40mg 1000	$ 29.01	$ 45.25	$ 12.00	35.89%	56%
80mg 500	$ 43.25	$ 67.47	$ 12.00	35.90%	56%

Mylan Furo

Furosemide	Actual WAC	Actual AWP
20mg 1000	$ 89.69	$ 139.90
40mg 1000	$ 102.26	$ 159.50
80mg 500	$ 137.13	$ 213.90

Customer Profit

SUMMARY COMPARISON	
Spread after Rebate calculated at	30%
Roxane AWP less	
Mylan AWP less	

	Rox AWP	Rox Contract	Reimbursement on Roxane	Customer Profit Roxane at AWP less 30%	Competitor AWP
20mg 1000	$ 36.05	$ 10.00	$ 25.24	$ 15.24	$ 139.90
40mg 1000	$ 45.25	$ 12.00	$ 31.68	$ 19.68	$ 159.50
80mg 500	$ 67.47	$ 12.00	$ 66.77	$ 54.77	$ 213.90

	0% AWP Adj.	Roxane vs. Mylan		280% AWP Adj. To	Roxane vs. Mylan
20mg 1000	$ -	$ (72.70)	Loss	$ 136.99	$ (2.04)
40mg 1000	$ -	$ (79.98)	Loss	$ 171.95	$ 8.71
80mg 500	$ -	$ (82.96)	Loss	$ 256.39	$ 29.74

semide

Av. Contract PRICE	% Off AWP	% WAC Mark-Up
$ 10.00	35.89%	55.98%
$ 12.00	35.89%	55.98%
$ 12.00	35.89%	55.98%

Competitor Contract	Customer Reimbursement on Mylan	Profit Competitor at AWP less 30%
$ 10.00	$ 97.93	$ 87.93
$/ 12.00	$ 111.65	$ 99.65
$ 12.00	$ 149.73	$ 137.73

National Account Manager - Eastern Midwest
Ph - 614-898-9607
voicemail - 800-848-0120 ext. 2529
fax - 614-898-9647

TAB 38

-----Original Message-----
From: WATERER, JUDY ROXUS
Sent: Wednesday, June 28, 2000 8:40 PM
To: SNYDER,STEVE SLS BIPUS; POWERS, JOHN ROXUS; STORCK, KIM ROXUS
Cc: LEARK, CARRIE ROXUS; FELDMAN, RICHARD ROXUS; SYKORA, ROBERT ROXUS; PAOLETTI, LESLI ROXUS; Russillo, Tom BICLE; Pera, Tony BICLE
Subject: RE: CVS Furosemide opportunity - (RFQ)

Steve - I'm in budget and Annual Discussion "Hell" through next week. I will be in Cleveland tomorrow, and in shortly on Friday AM. If it can wait, please beg for extension. If not - try to get Lesli to find me in Cleveland - she'll have information I'll need.

Because our AWP is out of line with rest of market, it's a bigger issue then a straight price. I've asked Bob to prepare a concise summary of customer comments, requests, and documentation regarding Furosemide AWP, and will pursue raising it to be in line with our competitors once I have it in hand. Tom R. is aware of the issue, and is willing to champion it - provided we have an extremely solid and well documented background. In today's environment, AWP changes are being scrutinized, and if we are to risk consumer backlash, we need to pretty much guarantee we'll generate immediate and substantial results. I know this is necessary to level the playing field with our competitors, but it can be difficult to explain it when questioned - even when we're being held at a competitive disadvantage in our customers' eyes, and excluded from consideration at the same or lower bid prices they'd willingly buy another's product.

Bob and I have discussed this at length, and he knows all the relevant issues and concerns. We'd like the business. Let's all work together to facilitate the required changes.

-----Original Message-----
From: SNYDER,STEVE SLS BIPUS
Sent: Wednesday, June 28, 2000 3:42 PM
To: WATERER, JUDY ROXUS; POWERS, JOHN ROXUS; STORCK, KIM ROXUS
Cc: LEARK, CARRIE ROXUS; FELDMAN, RICHARD ROXUS
Subject: CVS Furosemide opportunity - (RFQ)

Gang, CVS is looking for a Furosemide vendor. Apparently, the HCFA Macs are changing at shortly, and they are not happy with the margins from their current supplier. They did not have the new MACs available to share with me, but being public record, I am certain we should have them somewhere. In fact, I think Bob has them on his desk. In the past, CVS has asked for AWP less 55% to be competitive on generics. I am not sure how the MAC impacts this. I would like to discuss this with Bob and/or Anthony before we bid. For now I have listed the requested bid price at AWP less 50%.

Can I request that we (Judy, John, Bob) discuss this Thursday or Friday AM? They asked that I get them a quote by the end of the day Friday. I think it would put us in a good light if we could respond by then. However, I made no promises except that I would notify them if we could not meet that timeframe. If a Friday PM response is out of the question, I just want to let CVS know when they will receive our reply.

Workbook - not all complete yet, but I think everything needed for this request is filled in.

<< File: Trade Program Workbook-CVS.xls >>

Thanks all.

Steve Snyder
National Account Manager - Eastern Midwest
Ph - 614-898-9607
voicemail - 800-848-0120 ext. 2529
fax - 614-898-9647

TAB 39

WATERER, JUDY ROXUS

From: TAVOLARO,ANTHONY SLS BIPUS
Sent: Monday, July 24, 2000 9:08 PM
To: WATERER, JUDY ROXUS
Cc: zzCOL ROXANE NATIONAL ACCOUNTS; SYKORA, ROBERT ROXUS; FELDMAN, RICHARD ROXUS
Subject: RE: Furosemide

Judy, as you know Caremark had shown interest with our Furosemide back in April. After a review of our AWP's on the product, the opportunity was DEAD.

Our AWP's are 78% below the rest of the industry. I am not aware of any competitor with AWP's below $100.00 for bottles of 40mg 1000s. Mylan and Zenith are approximately $120.00, ours is $29.00 Caremark's commented they could not possibly award the product to us unless we increased our AWP's. Janet Miller also added that Roxane has a history of having AWP's out of sync with the rest of the industry.

I don't know why we have to wait until our customers complain before we adjust an AWP. Major customers (Walgreen, Wal-Mart, CVS, Medco, Caremark) expect their leading suppliers to maintain their AWP's. Not executing this core competency reflects negatively on Roxane, and promotes a perception of Roxane not understanding industry dynamics.

I hope this helps.

-----Original Message-----
From: WATERER, JUDY ROXUS
Sent: Monday, July 24, 2000 9:32 AM
To: TAVOLARO,ANTHONY SLS BIPUS
Cc: zzCOL ROXANE NATIONAL ACCOUNTS
Subject: RE: Furosemide

Marketing's hands are tied until we receive a summary from Bob of customer comments/complaints. Hopefully he'll get this put together shortly. Any assistance you can provide him, such as customer verbatims will be helpful.

-----Original Message-----
From: TAVOLARO,ANTHONY SLS BIPUS
Sent: Monday, July 24, 2000 9:25 AM
To: DOAN,MIKE SLS BIPUS; FELDMAN, RICHARD ROXUS; SYKORA, ROBERT ROXUS; WATERER, JUDY ROXUS; POWERS, JOHN ROXUS; zzCOL ROXANE NATIONAL ACCOUNTS
Subject: RE: Furosemide

Hi Gang: My sources tell me that Mylan has doubled their price.

Mike : I had requested an AWP increase back in April. Mylan's and Zenith's AWP are significantly higher than ours. Our current AWP will be an insurmountable obstacle in securing new retail business.

-----Original Message-----
From: DOAN,MIKE SLS BIPUS
Sent: Friday, July 21, 2000 5:00 PM
To: FELDMAN, RICHARD ROXUS; SYKORA, ROBERT ROXUS; WATERER, JUDY ROXUS; POWERS, JOHN ROXUS; zzCOL ROXANE NATIONAL ACCOUNTS
Subject: Furosemide

Thanks to Colin's ear to the ground, this news just came in. Mylan raised the WAC price of Furosemide. This means that a contract price will probably follow in the future. One reason that Watson may have dropped Furosemide is that Schein has the item. If we can get our AWP's in line it will be Roxane and Zenith fighting for the business. At this time, Zenith has the AWP advantage.
Thanks
Mike

From: Ater, Steve BVL-US-B
Sent: Friday, July 13, 2001 10:10 AM
To: Waterer, Judy ROXUS; Paoletti, Lesli ROXUS
Cc: Strelau, Karen BVL-US-B
Subject: RE: Albuterol and Ipratroprium Update

Ooops. That's what I meant. Our AWP is too low.....

-----Original Message-----
From: **Waterer, Judy ROXUS**
Sent: Friday, July 13, 2001 5:44 AM
To: Ater, Steve BVL-US-B; Paoletti, Lesli ROXUS
Cc: Strelau, Karen BVL-US-B
Subject: RE: Albuterol and Ipratroprium Update

AWP too high? Thought you said earlier it was too low???

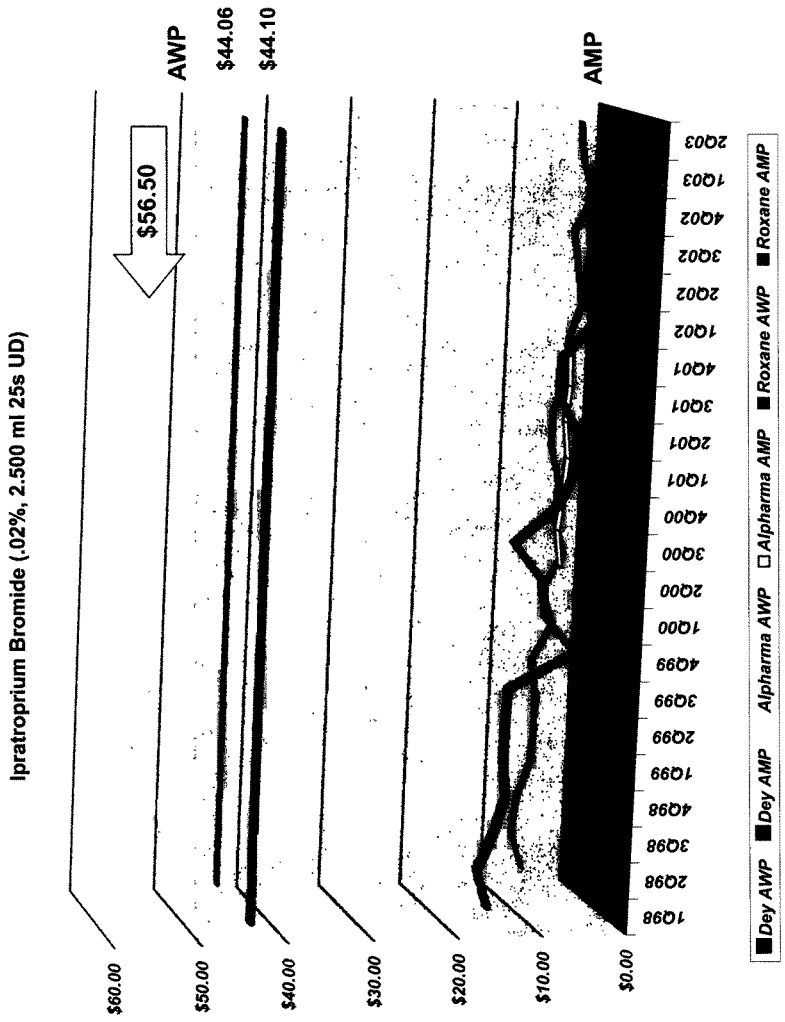
-----Original Message-----
From: Ater, Steve BVL-US-B
Sent: Thursday, July 12, 2001 9:14 PM
To: Paoletti, Lesli ROXUS; Waterer, Judy ROXUS
Cc: Strelau, Karen BVL-US-B
Subject: Albuterol and Ipratroprium Update

Unfortunately, we did not receive the Ipratroprium from Caremark. It was awarded to Alpharma. They stated that our price quoted was too high. They also suggested that our AWP was also too high and therefore our contract price would have to be substantially lower to make it worth it to use our product.

Karen and I were at MP Total care today. Still looking great. They have committed verbally to giving us at least 50% of their business during a ramp up period. All that is left is finishing the specifics of the deal with them. If all goes according to plan, they should be ready to start ordering product within the next 30 days. They will also be visiting the plant within the next few months. I will keep you updated.

See you.
Steve

TAB 41


Ipratroprium Bromide (.02%, 2.500 ml 25s UD)
AWP
AMP
$56.50
$44.06
$44.10
$60.00
$50.00
$40.00
$30.00
$20.00
$10.00
$0.00
1Q98
2Q98
3Q98
4Q98
1Q99
2Q99
3Q99
4Q99
1Q00
2Q00
3Q00
4Q00
1Q01
2Q01
3Q01
4Q01
1Q02
2Q02
3Q02
4Q02
1Q03
2Q03
Dey AWP
Dey AMP
Alpharma AWP
Alpharma AMP
Roxane AWP
Roxane AMP

TAB 42

From: SNYDER,STEVE SLS BIPUS
Sent: Thursday, April 20, 2000 9:50 AM
To: WATERER, JUDY ROXUS
Cc: SYKORA, ROBERT ROXUS; FELDMAN, RICHARD ROXUS
Subject: CVS Cyclophosphamide

CVS can bring an estimated 60% market share if we are willing to give them a 50% - 60% spread on the price up front. This is not as good to us as if we could sell them on the market share program, but they can not get the spread they need (want) via the market share program. I heard that some other chains were making similar noise, and wanted to make sure CVS's request was at least considered.

CVS annual Cytoxin volume is:

25mg - 1,000 bottles
50mg - 5,000 bottles

We would also get an initial load in on the 50mg somewhere between 500 and 1000 bottles in the CVS warehouse.

For your consideration

Steve Snyder
National Account Manager - Eastern Midwest
Ph - 614-898-9607
voicemail - 800-848-0120 ext. 2529
fax - 614-898-9547

----Original Message----
From: Leonard, Matthew J. [SMTP:MJLeonard@cvs.com]
Sent: Tuesday, April 18, 2000 2:43 PM
To: 'ssnyder@rdg.boehringer-ingelheim.com'
Subject: RE: Roxane Cyclophosphamide inquiry

Steve,
Cytoxan 25mg- We dispense approximately 1000 bottles a year (100 count) on this brand.
Cytoxan 50mg- We dispense approximately 5100 bottles (100 count) a year on this brand.

If I warehouse the product (50mg) I will drive substitution through a variety of programs including DTC messaging to patients and store systems messaging to pharmacists.

Matt

From: ssnyder@rdg.boehringer-ingelheim.com [SMTP:ssnyder@rdg.boehringer-ingelheim.com]
Sent: Tuesday, April 18, 2000 1:00 PM
To: Leonard, Matthew J.
Subject: Roxane Cyclophosphamide inquiry

Matt, Thought an email might be a little quicker and easier than trying to exchange voicemails on this.....

We spoke about Cyclophosphamide (comparable to Cytoxan) a week or so ago.

You indicated that our spread was not significant enough to peak your

interest. I would like to approach my company about what it might take to
get CVS on board. Can you provide me with CVS' annual volume of the 25mg
and 50mg brand product? Also, pass me the volume that you believe CVS could
sway to the generic if I can bring you a 50%-60% spread via a contract
price.

Thanks

Steve Snyder
National Account Manager - Eastern Midwest
Ph - 614-898-9607
voicemail - 800-848-0120 ext. 2529
fax - 614-898-9647

From: GORDON,DAWN SLS BIPUS
Sent: Wednesday, May 03, 2000 3:17 PM
To: WATERER, JUDY ROXUS
Cc: SYKORA, ROBERT ROXUS; DOAN,MIKE SLS BIPUS
Subject: CCP issues

Judy,

Both Eckerd and WalMart have an issue with the CCP spread. Both require a MINIMUM of a 40% spread before generic promotion is considered. They claim that the contract price should offer a 40-50% spread between it and AWP, and any market share rebate is profit earned for market share shift.

Eckerd has brought the product into the warehouse and is willing to participate in the market share program (with modifications of course). Lynn King expects the rebate to include all sales starting now, even though the agreement hasn't been signed yet. Lynn King is confident Eckerd will shift market share, especially on the 50mg since it is warehoused. Lynn wouldn't agree to promote unless CCP offered a profit over the brand.

As for Walmart, Bill Spradlin wants to warehouse, but will not warehouse or promote unless the contract price is adjusted. I have a meeting with him on Wed morning. Hopefully he will agree to accept the contract price and rebate offer as it is, but I wouldn't count on it. Verbally he has advised me he wants the rebate NOW...that he doesn't believe WalMart should have to wait for something that should be given during launch. Once again he is claiming Roxane doesn't know what it is doing. He thinks some of our spreads are way off (ie) furosemide. He thinks this is one more example of Roxane not knowing how the generic world works. Until an acceptable contract price or offer is agreed upon, Wal Mart will continue to promote the brand. Current brand movement is:

25mg 75 bottles/month
50mg 300/month

Any suggestions prior to Wed is appreciated.

Thanks,
Dawn

533

TAB 43

TAB 44

Barr Laboratories, Inc.

2 Quaker Road • P.O. Box 2900 • Pomona, NY 10970-0519 • 845/362-1100

Barr Laboratories/Wal-Mart
Fluoxetine 20mg Capsules Agreement

Scenario A

Pricing

	Suggested AWP	WAC/Invoice	Rebate %	Dead Net Price	Third Party Spread
Prozac 20mgx100	$296.46	$247.05	0%	$247.05	16.7%
Fluoxetine 20mgx100	$266.52	$170.35	3%	$165.24	38.0%

Scenario B

Pricing

	Suggested AWP	WAC/Invoice	Rebate %	Dead Net Price	Third Party Spread
Fluoxetine 20mgx100	$266.52	$170.35	10%	$153.32	42.5%

Assumptions

1. Wal-Mart will achieve an average generic substitution level of 70% of the units/Rx's during Barr's 180 day exclusivity period.
2. Wal-Mart's current Prozac 20mg annualized purchases based on March 2001 actual is 39,000,000 capsules.
3. Wal-Mart will purchase/dispense 13,650,000 20mg capsules from Barr during the 180 day exclusivity period.
4. Wal-Mart will experience an average third party reimbursement percentage of AWP less 30%. Note: The following analysis assumes 100% of the Fluoxetine business is third party.

Profitability Analysis

	Suggested AWP	AWP Less 30%	Dead Net Cost	Profit Per 100 Caps	Total Profit for 180 Days
Scenario A	$266.52	$186.56	$165.24	$21.32	$2,910,080
Scenario B	$266.52	$186.56	$153.32	$33.24	$4,537,260
Incremental Profit					$ 1,627,180

Barr Laboratories, Inc.

2 Quaker Road • P.O. Box 2900 • Pomona, NY 10970-0519 • 845 362-1100

Terms and Conditions:

1. Wal-Mart agrees to award Barr the primary formulary position for a mutually agreed multi-source generic product (i.e. Fluvoxamine Maleate tablets, Amiodarone tablets, or Nortrel tablets) prior to the launch of Barr's Fluoxetine 20mg capsules.

This newly added product will be included in the Barr Preferred Product Program outlined in our agreement dated February 6, 2001.

2. Wal-Mart agrees to award Barr the primary formulary position for Fluoxetine 20mg capsules for a period of 12 months following market introduction. Once again, Fluoxetine will be included in the Preferred Product Agreement outlined above.

3. Barr will offer Wal-Mart the product pricing outlined in Scenario B above for all Fluoxetine 20mg capsules purchased from Barr during the 180-day exclusivity period.

Barr Laboratories

Wal-Mart

July 29, 2002

NOTE: THE PRICE WAS CHANGED TO $82.62, BUT CAME FROM BARR HOME OFFICE - NOT FROM ME

[Redacted]

Dear [Redacted]

Effective July 29, 2002, [Redacted] price for Barr's Fluoxetine Capsules, 20mg, is as follows:

NDC#	Product	Pkg. Size	*SWP Price	Direct Price
(0555-)				
0877-07	**Fluoxetine Capsules, 20mg**	2000	$5,336.20	$88.06

***SWP – suggested AWP**

Should you have any questions or require any additional information, please do not hesitate to contact me directly.

Sincerely,

BARR LABORATORIES, INC.

Richard L. Fleming, R.Ph.
National Account Manager
Phone # (219) 465-7270
Fax # (219) 477-4950

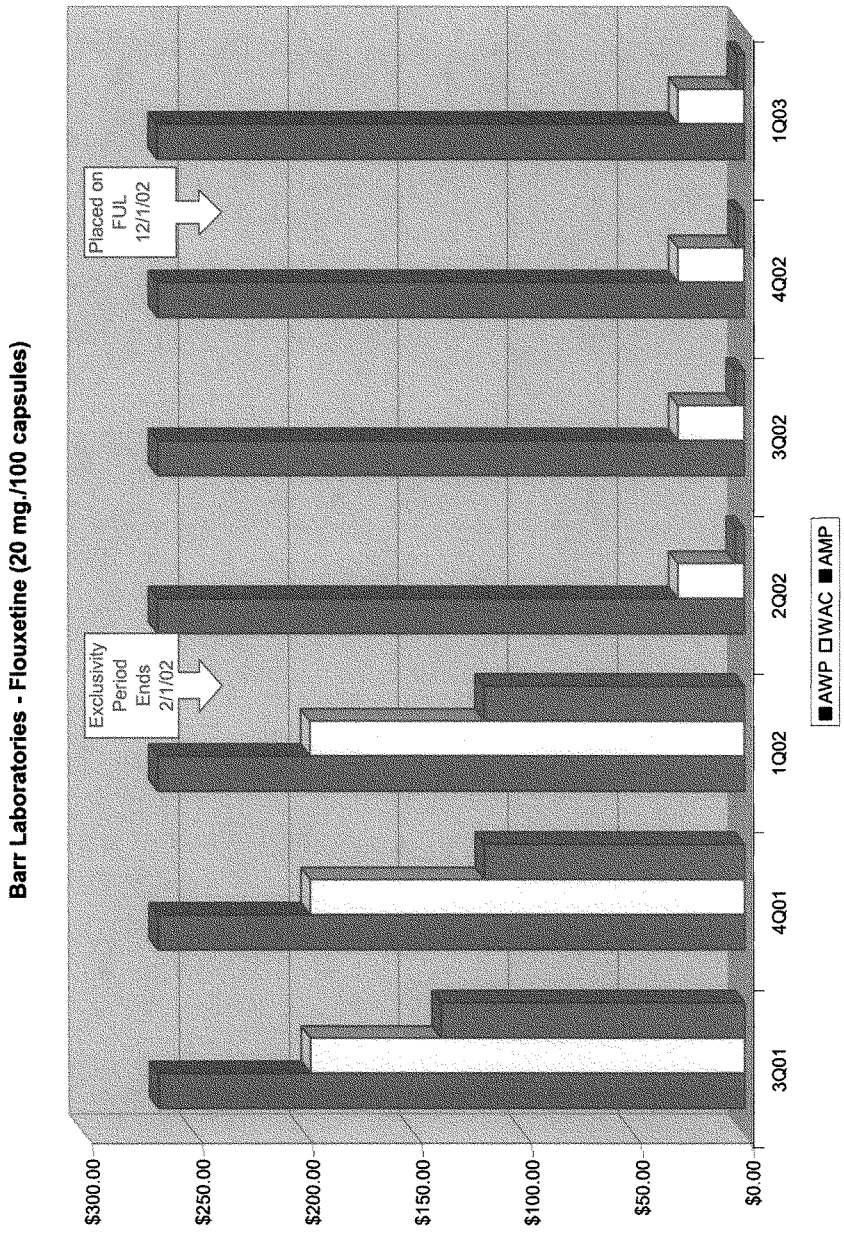
cc: [Redacted]
T. Catlett
T.Sawyer
M. Canada
M. Altamuro

Product Information

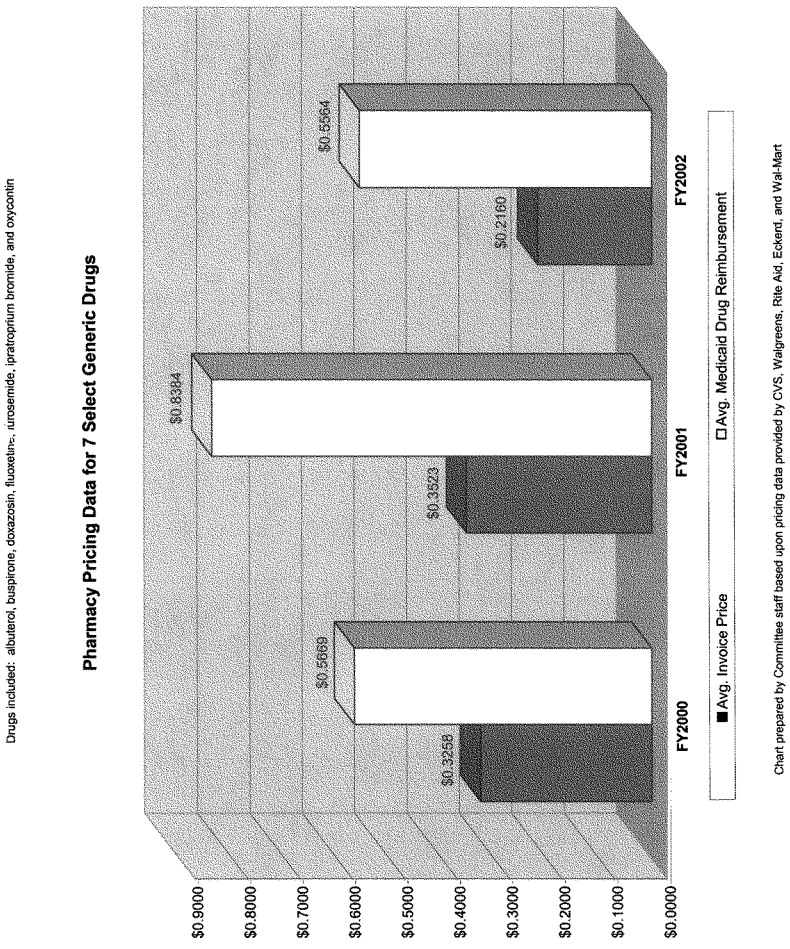
Product	Manuf/Dist	Identifier	Form	Strength	Size	UD	AWP	WAC
FLUOXETINE HCL	Barr	00555-0877-07	CAP	20 MG	2000s ea		5336.20	400.00

Post-it® Fax Note 7671 | Date 5/3/04 | # of pages ▶ 1
To Andrew Snavely | From Robert Vella
Co./Dept. | Co.
Phone # 202.226.2432 | Phone # 215.861.4558
Fax # 202.226.2447 | Fax # 215.861.4557

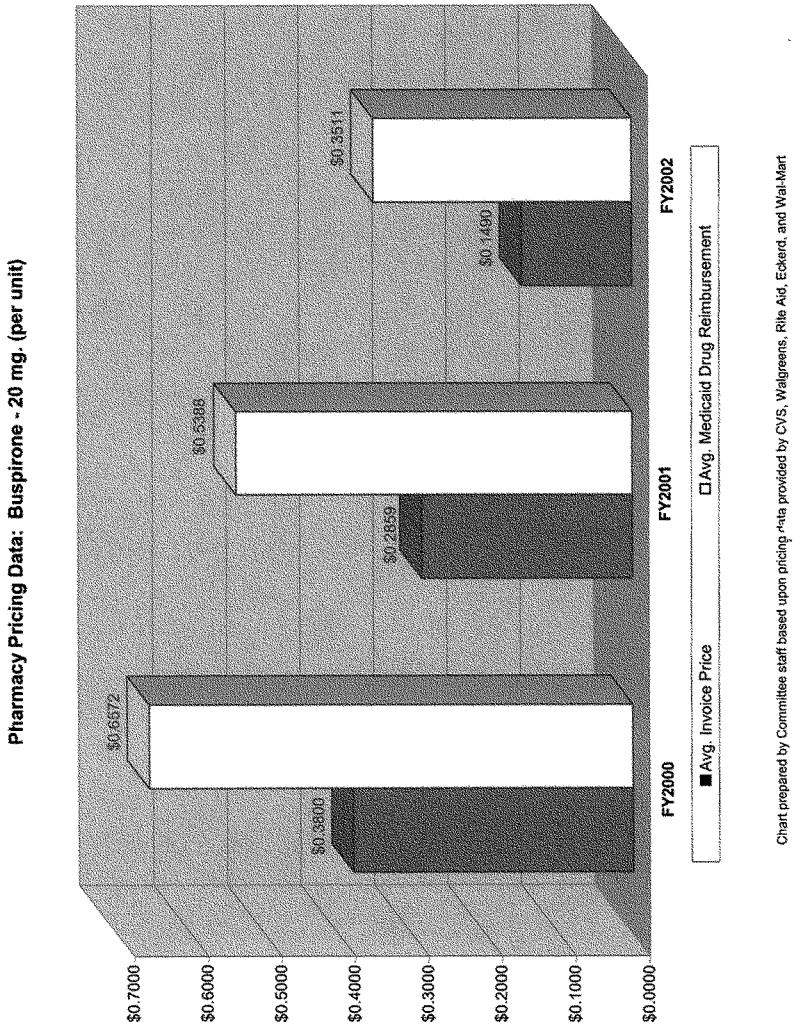
TAB 47


Barr Laboratories - Flouxetine (20 mg./100 capsules)
Exclusivity Period Ends 2/1/02
Placed on FUL 12/1/02
$300.00
$250.00
$200.00
$150.00
$100.00
$50.00
$0.00
3Q01
4Q01
1Q02
2Q02
3Q02
4Q02
1Q03
AWP WAC AMP

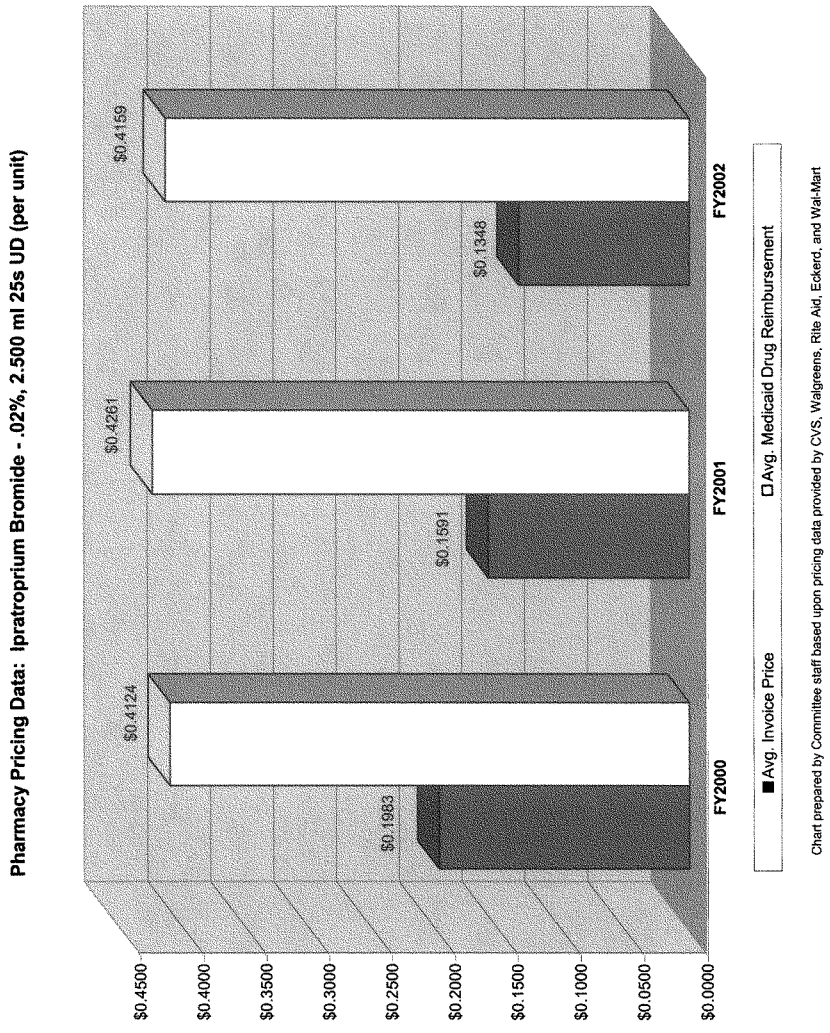
TAB 48


Pharmacy Pricing Data for 7 Select Generic Drugs
Drugs included: albuterol, buspirone, doxazosin, fluoxetine, furosemide, ipratropium bromide, and oxycontin
$0.9000
$0.8000
$0.7000
$0.6000
$0.5000
$0.4000
$0.3000
$0.2000
$0.1000
$0.0000
$0.3258
$0.5669
$0.8384
$0.3523
$0.2160
$0.5564
FY2000
FY2001
FY2002
Avg. Invoice Price
Avg. Medicaid Drug Reimbursement
Chart prepared by Committee staff based upon pricing data provided by CVS, Walgreens, Rite Aid, Eckerd, and Wal-Mart

TAB 49


Pharmacy Pricing Data: Buspirone - 20 mg. (per unit)
$0.6572
$0.5386
$0.3511
$0.3600
$0.2859
$0.1490
$0.7000
$0.6000
$0.5000
$0.4000
$0.3000
$0.2000
$0.1000
$0.0000
FY2000
FY2001
FY2002
Avg. Invoice Price
Avg. Medicaid Drug Reimbursement
Chart prepared by Committee staff based upon pricing data provided by CVS, Walgreens, Rite Aid, Eckerd, and Wal-Mart

TAB 50


Pharmacy Pricing Data: Ipratroprium Bromide - .02%, 2.500 ml 25s UD (per unit)
$0.4500
$0.4000
$0.3500
$0.3000
$0.2500
$0.2000
$0.1500
$0.1000
$0.0500
$0.0000
$0.4124
$0.4261
$0.4159
$0.1983
$0.1591
$0.1348
FY2000
FY2001
FY2002
Avg. Invoice Price
Avg. Medicaid Drug Reimbursement
Chart prepared by Committee staff based upon pricing data provided by CVS, Walgreens, Rite Aid, Eckerd, and Wal-Mart

TAB 51

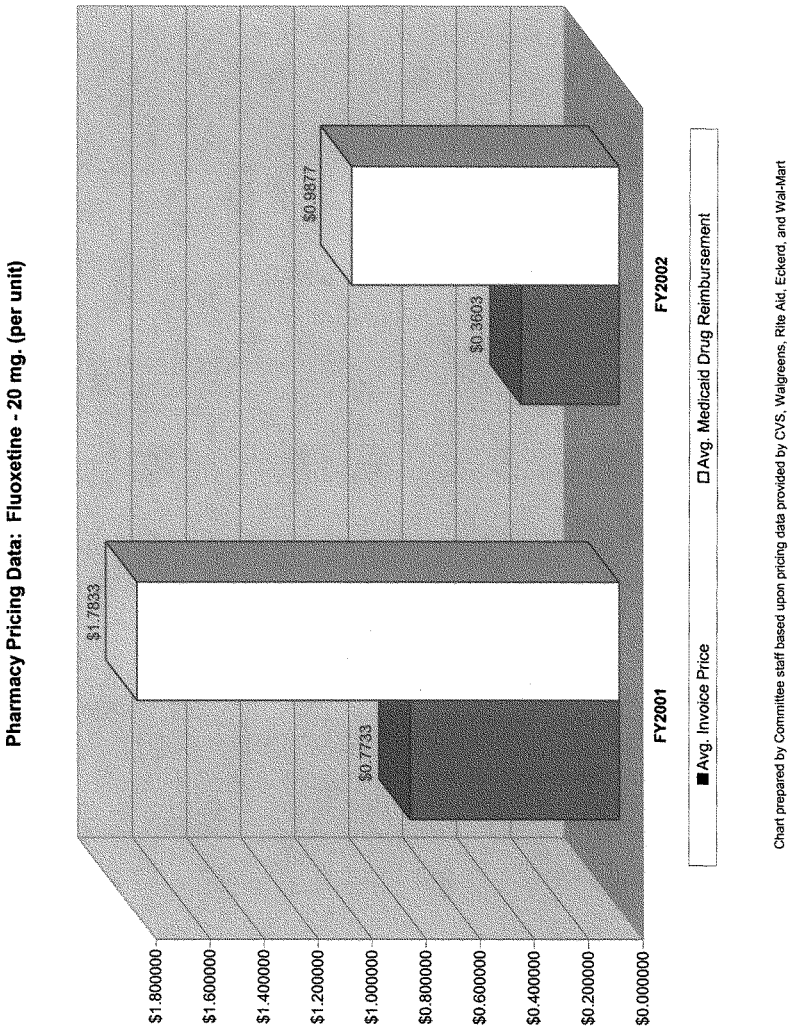


Chart prepared by Committee staff based upon pricing data provided by CVS, Walgreens, Rite Aid, Eckerd, and Wal-Mart

TAB 52

Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003

Prepared by:

Jeffrey S. Crowley and Deb Ashner
Health Policy Institute, Georgetown University

and

Linda Elam, Kaiser Commission on Medicaid and the Uninsured

December 2003

ACKNOWLEDGMENTS

The authors would like to thank the state Medicaid officials who were instrumental to completing this survey. We are especially appreciative of the commitment they have shown in helping us ensure that the results presented are as accurate as possible by responding to a relatively comprehensive survey and reviewing multiple sets of draft data tables. We are also grateful to Barbara Lyons for her invaluable assistance in structuring the document and presenting the data, and Molly O'Malley for her review of the data tables.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Today, Medicaid is fundamental to the provision of outpatient drugs to the low-income population and is particularly important for low-income people with disabilities and elderly beneficiaries who depend on prescription drugs to maintain or improve their health and functioning. The prescription drug benefit is one of the fastest growing components of Medicaid spending and one of the program's most widely utilized services. Medicaid is estimated to spend $27.5 billion in 2003 on outpatient prescription drugs and outpatient prescription drug spending accounts for 12% of Medicaid spending on benefits. This spending is largely directed toward people with disabilities and elderly beneficiaries who, in 2000, constituted approximately 27% of Medicaid beneficiaries, but who accounted for roughly 85% of Medicaid drug spending.

Pharmaceutical spending growth has been an important contributor to increased health care costs in all sectors, including Medicaid. Outpatient prescription drugs are an optional service under Medicaid, the federal/state partnership that provides health coverage to low-income people, but all states provide this important benefit. Despite mounting drug costs, state Medicaid programs have remained committed to maintaining prescription drug coverage in recognition of the importance of this benefit to the populations they serve. The drug benefit has been particularly important to dual eligibles in the absence of a Medicare drug benefit.[1] However, primarily as a consequence of decreased state tax revenues, state budgets are tight and Medicaid programs are being squeezed—every state has implemented or is planning Medicaid pharmaceutical cost containment activities in FY 2004.[2]

In early 2003 (February-May), the Kaiser Commission on Medicaid and the Uninsured, working with the Health Policy Institute at Georgetown University, conducted a survey of state Medicaid pharmacy programs. Forty-two states plus the District of Columbia responded to the survey.[3] The 2003 survey updates a survey conducted in 2000,[4] and, where possible, changes and trends between the surveys are reported in this report. The findings of the current survey reflect Medicaid prescription drug policies in effect in early 2003, and provide important background information to assess the coming changes as dual eligibles move to Medicare Part D. This survey covers utilization management policies, payment and purchasing policies, utilization review policies, and policies for managed care enrollees and persons residing in institutions. For ease of reference, throughout this report, references to "states" should be inferred to include the District of Columbia.

In general, when states elect to cover outpatient prescription drugs through Medicaid, they must cover all Food and Drug Administration (FDA)-approved pharmaceuticals of every manufacturer that has signed a federal drug rebate agreement with the Secretary of Health and Human Services (HHS).[5] Within this general framework, states have considerable discretion in designing and managing the prescription drug benefit. However, because people on Medicaid have low-incomes and tend to have higher health care needs, federal law provides a number of safeguards to the benefit. As a result, Medicaid beneficiaries have access to a wide array of drugs and have a number of protections such as limits on

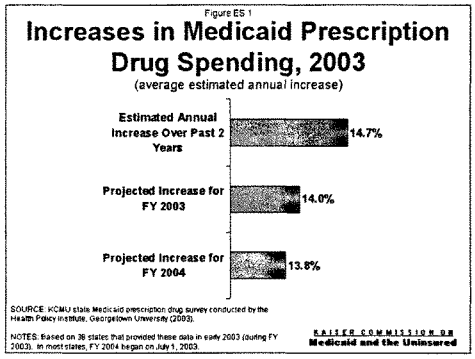
co-payments that may be charged to certain populations, timely review of prior authorization requests, the provision of emergency supplies of drugs while awaiting state approval, and the right to appeal if approval is not granted.

Key Findings

State officials anticipate that prescription drug spending growth will continue at a rapid pace, however there is wide variation in the amount of growth states project. Based on 38 responses, states anticipate that Medicaid prescription drug spending will increase roughly 14% over the current year, slightly lower growth than over the last three years. (Figure ES1).

- ESTIMATED INCREASE OVER LAST TWO YEARS: The average estimated annual increase in prescription drug costs over the last two years (FY 2001 and FY 2002) was 14.7% (based on 38 states reporting in 2003), and ranged from roughly 4% to 25% per year.
- PROJECTED INCREASE FOR FY 2003: The average projected cost growth in FY 2003 (which ended on June 30, 2003 in most states), was 14.0%, ranging from a decline of roughly 1% from the previous year to a 27% increase.
- PROJECTED INCREASE FOR FY 2004: Projected average cost growth in FY 2004 (the current fiscal year, with projections being made in early 2003) was 13.8%, ranging from a decline of about 5% from the previous year to a 23% increase.

Figure ES 1

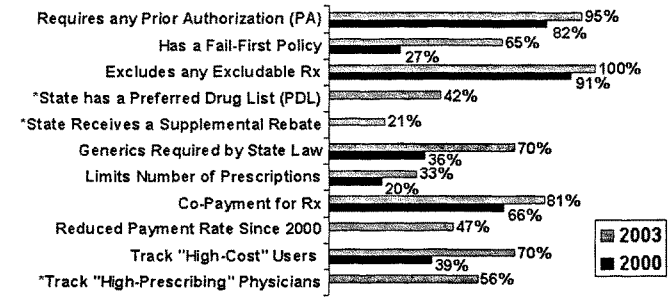


States have been hit hard by prescription drug spending growth and have been challenged to take advantage of the tools available to them to manage the Medicaid outpatient drug benefit while maintaining beneficiary access **(Figure ES 2)**.

Figure ES 2

Medicaid Pharmacy Management Policies: Selected Indicators

(percentage of states reporting)



SOURCE: KCMU state Medicaid prescription drug surveys conducted by the Health Policy Institute, Georgetown University (2003) and Health Systems Research (2000).

NOTE: Based on survey responses from 43 states in 2003 and 44 states in 2000.
* indicates baseline data for 2000 are not available.

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By nearly every measure, states are more aggressively managing the Medicaid prescription drug benefit in 2003 than in 2000.

- PRIOR AUTHORIZATION (PA): Ninety-five percent of states in 2003 (41 of 43 states) require prior approval or authorization for at least some prescription drugs, an increase from the 82% of states reporting the use of PA in 2000 (36 of 44 states). Many states do not impose PA on certain drug categories, such as antiretrovirals for HIV/AIDS or mental health drugs in order to assure that patient access to these critical products is not unduly impeded. For all drug classes surveyed, states reported a greater use of PA in 2003 than in 2000. In many cases, the percentage of states requiring PA for a specific class of drug increased dramatically.

- FAIL-FIRST/STEP THERAPY REQUIREMENTS: In fail first or step therapy, a particular product may not be dispensed unless it is documented that a designated product has been tried and is inappropriate for the patient. Roughly two-thirds of states in the 2003 survey reported fail-first policies (28 of 43 states), more than a doubling since 2000 when only 27% of states had fail first policies (12 of 44 states).

- EXCLUDED DRUGS: Although Medicaid covers most drugs, states are allowed to exclude certain drugs or drug categories that are specified in Medicaid law, for example, drugs with a high potential of abuse or drugs used for cosmetic purposes.

Every state (43 of 43 states reporting in 2003) excludes at least some of the prescription drugs that are excludable by the Medicaid law.

- PREFERRED DRUG LISTS (PDLs): Nearly half of the states (18 of 43 states reporting in 2003) operate PDLs. A PDL must be established by a committee appointed by the Governor (or the state drug use review board) and must include physicians, pharmacists, and other appropriate individuals. These lists are typically mediated through prior authorization, and even when a drug is not on a state's PDL, Medicaid law requires that it be made available through prior approval from the state. In addition, nine states are pursuing supplemental rebates from manufacturers in return for placing their drugs on the PDL.

- SUPPLEMENTAL REBATES: States are permitted to negotiate additional rebates with pharmaceutical manufacturers, in addition to the federal rebate, although a relatively small number of states do so (9 of 43 reporting in 2003). The leverage for these rebates typically comes from the institution of a state Medicaid PDL.

- GENERICS: Seventy percent of states require the prescribing of generics or generic substitution when available (30 of 43 states reporting in 2003), roughly twice as many states that required the dispensing of generics in 2000 (16 of 44 states). Even when generics are required, 93% of states allow for an override if the prescriber deems it medically necessary.

- QUANTITY LIMITS: States may limit quantities of drugs dispensed in a number ways, whether through the number of prescriptions a beneficiary may have in a period of time or the number of refills permitted per prescription. In 2003, 14 states (or about a third of responding states) reported limiting prescriptions allowed per month, up from a fifth of states in 2000. Ninety-eight percent of states (42 of 43 states reporting in 2003) limit the quantity of a drug that can be dispensed at one time.

- COST-SHARING: Thirty-five of 43 states in 2003 reported cost sharing for prescription drugs, when permitted. Medicaid cost sharing is limited to nominal payments ($0.50 - $3.00) and drugs are not supposed to be withheld if patients do not pay co-payments, although seven of the 35 states charging co-payments reported that drugs can be withheld for lack of payment. In most cases, when states charge cost-sharing they apply this policy to all populations eligible for cost-sharing, including the elderly, people with disabilities, and parents. Children under age 18, pregnant women with respect to services relating to pregnancy or any other medical condition that may complicate the pregnancy, terminally ill individuals receiving hospice care, and inpatients in hospitals, nursing facilities, or intermediate care facilities for persons with mental retardation (ICF/MRs) who are required to contribute all, but a minimal amount of their income for their medical care are exempted from cost-sharing.[6] States may impose higher cost sharing for waiver populations.

- OVER-THE-COUNTER (OTC): Thirty-nine of 43 states reporting in 2003 cover some OTCs. The extent of OTC coverage varies dramatically from state to state. A

smaller number of states (12 of 43 states reporting in 2003) cover drugs that were previously available by prescription and that are newly available as OTCs.

- PAYMENT RATES: Nearly half of the states (18 of 38 states reporting in both 2000 and 2003) reduced their pharmacy reimbursement by increasing the discount taken off of estimated acquisition cost.

- MONITORING: States are required by law to review Medicaid drug utilization. Seventy percent of states (30 of 43 states reporting in 2003) track "high-cost" users of prescription drugs, a 30% increase since 2000 (17 of 44 states). Fifty-six percent of states also track "high-prescribing" physicians (24 of 43 states reporting in 2003).

- INSTITUTIONAL SPENDING: The Medicaid law expressly states that provisions described in this report do not apply to institutionalized persons, however, as institutional spending is a significant proportion of overall state prescription drug spending, they are examined here. The average state estimate of the percentage of total Medicaid prescription drug spending for persons residing in institutions was 21% (based on 20 states reporting in 2003) and ranged from 6% to 33% of total drug spending. Half of the states (23 of 43 states reporting in 2003) indicated that they carve out institutional drug spending—meaning they separate payment for drugs from an institutional payment rate and purchase drugs on a fee-for-service basis

Policy Implications

In order to protect the sick and poor population it serves, Medicaid law limits the types of management tools that are permitted and extent to which states can use them. Given these safeguards, states are constantly working to balance cost control with appropriate patient access to prescription drugs.

Most states have taken advantage of most of the tools available to them to manage prescription drug utilization and constrain cost growth. For every year that state budgets are tight, and states are forced to identify ways to reduce spending, they have a diminishing range of tools available to them to reduce pharmaceutical costs.

Greater federal and state efforts are needed to examine the impact of cost control activities on beneficiary access to medically necessary prescription drugs. As states employ more and more cost-constraining strategies and as they become more aggressive in using tools such as prior authorization or drug limits, more attention needs to be placed on examining and protecting beneficiary access to prescription drugs.

Future progress in constraining drug costs may be difficult for states to achieve on their own. If states are approaching the limit of what they can achieve in constraining pharmaceutical cost growth through tight management of the outpatient prescription drug benefit, future progress in limiting drug costs may depend on policy changes at the federal level. One approach is to increase the size of the federal Medicaid drug rebate. Many

states are exploring or implementing supplemental rebates, raising the possibility that the federal rebate formula should be revisited. Outside of Medicaid, some advocates and policy makers have proposed more far reaching reforms of drug pricing and promotion in the United States, often using practices in other developed nations as models.

Conclusion

The importance of prescription drugs in the clinical management of many health conditions continues to grow with the discovery of new medications and with improvements to existing therapies. The promise of new therapeutics is exciting both for its potential to bring new treatments to previously untreatable or poorly treated conditions and for its potential to play a role in improving the quality of life of many individuals—while reducing other costs in the health system.

For state Medicaid programs, the prospect of a future with new and improved drugs must also be balanced with the daunting challenge of financing the provision of these medications. Medicaid plays a unique role in providing access to prescription drugs to the neediest and costliest cohorts of Americans (low-income people with severe disabilities and low-income elderly individuals). Financing new medications that often demand top dollar in comparison to older drugs is especially challenging at the same time that Medicaid programs adapt to changing demographics that will undoubtedly lead to more people with disabilities and elderly beneficiaries who need many services, including pharmaceuticals. Because of the clear benefits to be gained by individual Medicaid beneficiaries and the health of the general public by ensuring that Medicaid beneficiaries can access the full compliment of pharmaceuticals, it will be worth the effort for policy makers to ensure that these challenges are overcome.

Finally, the enactment of a Medicare drug benefit will have a major impact on Medicaid and many of the people it serves. Among those who will be most affected by the new Medicare law are the dual eligibles. As of January 1, 2006 dual eligibles will be covered by Medicare Part D and not Medicaid for prescription drugs. The full implications of this change for duals – including many nursing home residents and Medicaid waiver participants – and for states are yet to be determined. [7]

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[1] The recently enacted Medicare drug benefit, once implemented, will significantly impact Medicaid's prescription drug utilization profile. Dual eligibles (those Medicare beneficiaries currently receiving Medicaid coverage for services including prescription drugs) will no longer receive prescription drugs through Medicaid as of January 1, 2006.

[2] Smith, V., Ramesh, R., Gifford, K., Ellis, E., and Wachino, V., *States Respond to Fiscal Pressure: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2003 and 2004: Results from a 50-State Survey*, Kaiser Commission on Medicaid and the Uninsured, September 2003.

[3] The eight states that did not respond to the 2003 survey were AL, IN, NV, OH, OR, RI, TN, and WY. In 2000, 43 states and DC responded; the seven states that did not respond were AZ, CO, OH, OK, TN, TX, and WI.

[4] Schwalberg R, Bellamy H, Giffin M, Miller C, Williams SS, Elam L., *Medicaid Outpatient Prescription Drug Benefits: Findings From a National Survey and Selected Case Study Highlights.* Kaiser Commission on Medicaid and the Uninsured, Washington D.C. October 2001.

[5] §1902(a)(54) of the Social Security Act.
[6] §1916(a)(2) of the Social Security Act.
[7] For more information on the Medicare drug benefit and its likely impact on beneficiaries and states, please see the following documents, which can be accessed at www.kff.org:

- Guyer J. *Implications of the New Medicare Law for Dual Eligibles: 10 Key Questions and Answers*, and *The New Medicare Prescription Drug Benefit Law: Implications for State Medicaid Programs.* Kaiser Commission on Medicaid and the Uninsured. December 2003;
- Guyer J. Smith V, Kramer S, Guyer J. *Coordinating Medicaid and Medicare Prescription Drug Coverage: Findings From a Focus Group Discussion with Medicaid Directors,* Kaiser Commission on Medicaid and the Uninsured, November 2003;
- Bruen B, Holahan J. *Shifting the Cost of Dual Eligibles: Implications For States and the Federal Government.* Kaiser Commission on Medicaid and the Uninsured, November 2003;
- Schnieder A. "Dual Eligibles in Nursing Facilities and Medicare Drug Coverage," a Nov. 13, 2003 briefing note.

INTRODUCTION

Today, Medicaid is fundamental to the provision of outpatient drugs to the low-income population and is particularly important for low-income people with disabilities and elderly beneficiaries who depend on prescription drugs to maintain or improve their health and functioning. The prescription drug benefit is one of the fastest growing components of Medicaid spending and one of the program's most widely utilized services. Medicaid is estimated to spend $27.5 billion in 2003 on outpatient prescription drugs and outpatient prescription drug spending accounts for 12% of Medicaid spending on benefits. This spending is largely directed toward people with disabilities and elderly beneficiaries who, in 2000, constituted approximately 27% of Medicaid beneficiaries, but who accounted for roughly 85% of Medicaid drug spending.

Pharmaceutical spending growth has been an important contributor to increased health care costs in all sectors, including Medicaid. Outpatient prescription drugs are an optional service under Medicaid, the federal/state partnership that provides health coverage to low-income people, but all states provide this important benefit. (Table 1 outlines prescription drug coverage options by state.) Despite mounting drug costs, state Medicaid programs have remained committed to maintaining prescription drug coverage in recognition of the importance of this benefit to the populations they serve.[1] The drug benefit has been particularly important to dual eligibles in the absence of a Medicare drug benefit.[1] However, primarily as a consequence of decreased state tax revenues, state budgets are tight and Medicaid programs are being squeezed—every state has implemented or is planning Medicaid pharmaceutical cost containment activities in FY 2004.[2]

Tighter management of the pharmacy benefit can be important not just in controlling costs, but in improving the quality of care. In many instances, state policies that are part of an overall strategy to limit cost growth also are critical to ensuring that beneficiaries receive appropriate drug therapies consistent with current clinical practice standards, and that do not interact with other medications. At the same time, state efforts to constrain pharmacy spending have the potential to create significant barriers to appropriate drug access for some beneficiaries. The challenge for policy makers at both the federal and state levels is to recognize the need for a balanced approach to cost-containment as they make changes to this essential benefit.

States have a fixed array of tools available to them to constrain spending on Medicaid prescription drugs and to ensure that pharmaceuticals are only provided when they are medically necessary. In early 2003 (February-May), the Kaiser Commission on Medicaid and the Uninsured, with the Health Policy Institute at Georgetown University, conducted a survey of state Medicaid pharmacy programs. Forty-two states plus the District of Columbia responded to the survey.[3, 4] This survey updates an earlier survey conducted in 2000.[5] Where possible, changes and trends between the surveys are

reported in this brief. The findings of this survey reflect policies in effect in early 2003, and some states may have implemented new policies since that time.

UTILIZATION MANAGEMENT

In general, when states elect to cover outpatient prescription drugs through Medicaid, they must cover all Food and Drug Administration (FDA)-approved pharmaceuticals made by every manufacturer that has signed a federal drug rebate agreement with the Secretary of Health and Human Services (HHS).[6] Within this general framework, states have considerable discretion in designing and managing the prescription drug benefit.

The survey examined state utilization management policies in eight areas:

1. Dispensing Limits;
2. Excluded Drugs;
3. Preferred Drug Lists (PDLs) and Formularies;
4. Prior Authorization (PA);
5. Fail-First and Step Therapy;
6. Generic Drugs;
7. Cost-Sharing; and,
8. Coverage of Over-the-Counter (OTC) Medications

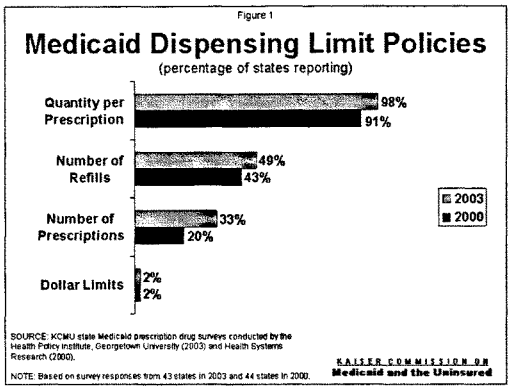
Dispensing Limits
Table 2

Federal Medicaid law requires states to ensure that benefits they provide are "sufficient in amount, duration, and scope to reasonably achieve (their) purpose".[7] Nonetheless, this does not prevent states from placing limits on the amount, duration and scope of benefits. Under federal regulations, states may place "appropriate" limits on a service based on "medical necessity or on utilization control procedures".[8] The Medicaid law also permits states, "to impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills if such limitations are necessary to discourage waste". [9]

Dispensing Limits: State policies that restrict the quantity of prescription drugs that Medicaid will purchase for a Medicaid beneficiary.

Most Medicaid programs (42 of 43 states reporting in 2003) have limits on the quantity of medication that can be dispensed per prescription, and a growing number have limits on number of refills per prescription and the number of prescriptions a beneficiary can have at one time before the state requires prior authorization **(Figure 1)**. Every state

reporting any dispensing limits reported imposing a limit on the quantity dispensed per prescription. Only the District of Columbia reported imposing a dollar limit on prescription drugs ($1,500 per 30-day supply of a drug).



Excluded Drugs

Table 3

Excluded Drugs:
Prescription drugs for which a state Medicaid program does not provide coverage.

The Medicaid law provides four circumstances when states can exclude coverage for prescription drugs:[10]

1) States can exclude drugs if the prescribed use is not for a medically accepted condition.[11] The law further defines medically accepted condition in a way that allows states to exclude drugs not approved by the FDA or listed in recognized compendia.[12, 13] This permits states to exclude drug coverage for drugs that are in clinical trials or that have not yet received FDA approval (based on safety and efficacy) and drugs that have been determined to be ineffective.

2) The following drugs or classes of drugs (or their medical uses) may be restricted from coverage or otherwise restricted: 1) Drugs when used for anorexia, weight loss, or weight gain; 2) drugs when used to promote fertility; 3) drugs when used for cosmetic purposes or hair growth; 4) drugs when used for the symptomatic relief of coughs and colds; 5) drugs when used to promote smoking cessation; 6) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; 7) nonprescription drugs; 8) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or

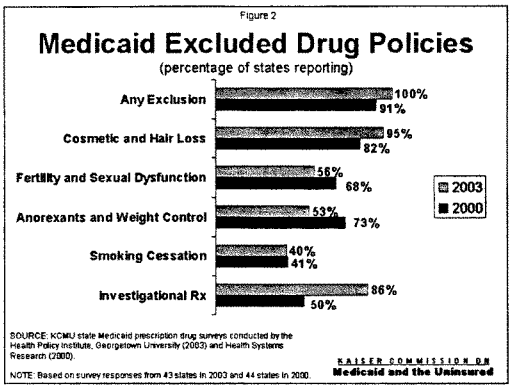
monitoring services be purchased exclusively from the manufacturer or its designee; 9) barbiturates; and, 10) benzodiazepines.[14] (Note: These listed exclusions were enacted into law in the Omnibus Budget Reconciliation Act of 1990 and are sometimes referred to as "OBRA exclusions" or "OBRA-90" exclusions.)

3) Drugs can be excluded if this restriction is part of a drug rebate agreement between a manufacturer and HHS; and,

4) The state has established a formulary meeting specific requirements, subject to prior authorization.

Every state (43 of 43 states reporting in 2003) restricts coverage for at least some prescription drugs **(Figure 2)**. The most commonly applied exclusions are for cosmetic and hair loss drugs (41 of 43 states reporting in 2003) and investigational drugs (37 of 43 states reporting in 2003). Investigational drugs are the category of excludable drugs that experienced the greatest change in state policies since 2000. The number of states excluding investigational drugs rose from 22 of 44 states in 2000 to 37 of 43 states in 2003.

A smaller number of states exclude coverage for both fertility and sexual dysfunction drugs (24 of 43 states reporting in 2003), although the number rises (26 of 43 states reporting in 2003) for exclusions that apply only to fertility drugs. Anorexant and weight control drugs and smoking cessation drugs are the least likely of the excludable drugs to be excluded (23 and 17 of 43 states reporting in 2003, respectively).



Preferred Drug Lists (PDLs) and Formularies
Table 4

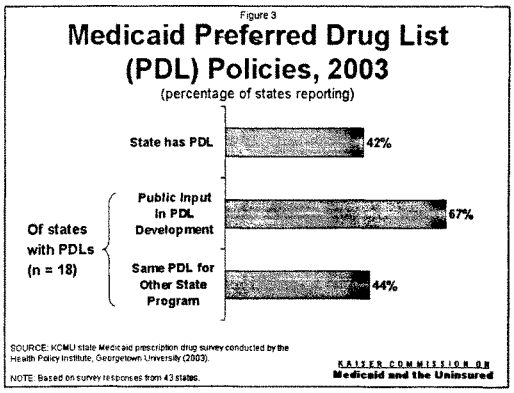
Preferred drug lists (PDLs) are equivalent to formularies. The Medicaid law permits states to establish formularies subject to certain requirements.[15] The formulary must be established by a committee appointed by the Governor (or the state drug use review board) and must include physicians, pharmacists, and other appropriate individuals. The formulary must include all drugs made by manufacturers with rebate agreements in effect with HHS (except for excludable drugs) unless the drug excluded from the formulary, "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion".[16] The Secretary is also permitted to impose additional requirements to "achieve program savings consistent with protecting the health of program beneficiaries".[17]

The development and implementation of PDLs in some state Medicaid programs has met with controversy. Some states that have implemented PDLs have faced lawsuits from the pharmaceutical industry claiming that the PDL was in violation of the formulary requirements of the Medicaid law. Additionally, some beneficiary groups have opposed the institution of PDLS citing potential drug access problems. Nonetheless, ongoing cost pressure is likely to cause states to consider the establishment of PDL programs.

Preferred Drug List (PDL):
A list of covered prescription drugs that a state Medicaid program agrees to provide without prior authorization.

All other medically necessary pharmaceuticals require prior authorization.

Nearly half of the states have PDLs (18 of 43 states reporting in 2003) **(Figure 3)**. Of states with PDLs, the majority provide for public input in determining which drugs are included on the list (12 of 18 states reporting in 2003). Forty-four percent of the states with PDLs apply the PDL to other state programs, such as drug coverage for state employees or the State Children's Health Insurance (SCHIP) program (8 of 18 states reporting in 2003).

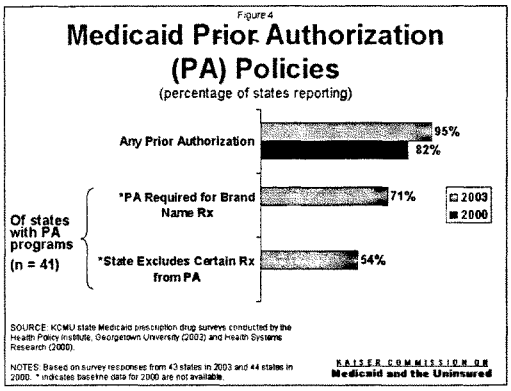


Prior Authorization (PA)
Tables 5-9

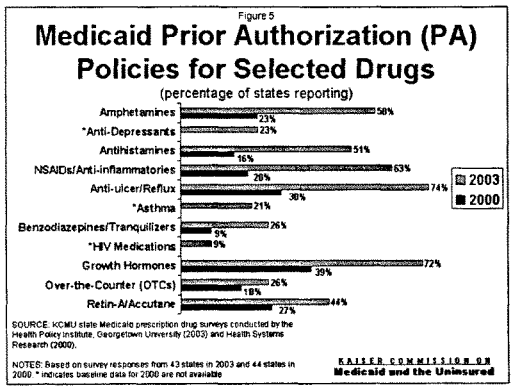
The Medicaid law permits states to subject any covered outpatient prescription drug to prior authorization (PA).[18] States that require prior authorization must have a system for providing approval that ensures that a response will be provided within 24 hours (by telephone or otherwise) and, except for excludable drugs, they must dispense at least a 72-hour supply of a requested drug in cases of an emergency (as defined by the Secretary).[19]

Prior Authorization (PA): Policy of a state Medicaid program that requires a pharmacist to obtain approval from the state (or a subcontractor) before dispensing a drug.

Most states use PA as part of their utilization management activities (41 of 43 states reporting in 2003) **(Figure 4)**. More than two-thirds of states with PA programs (29 of 41 states reporting in 2003) require PA before dispensing brand name drugs. More than half of the states with PA programs, however, identify specific types or classes of drugs that they exclude from PA (22 of 41 states reporting in 2003). Some states reported that they exclude most drugs from PA, whereas other states exclude drugs for specific conditions (such as HIV/AIDS), and still other states reported that they exclude specific individual drugs from PA.

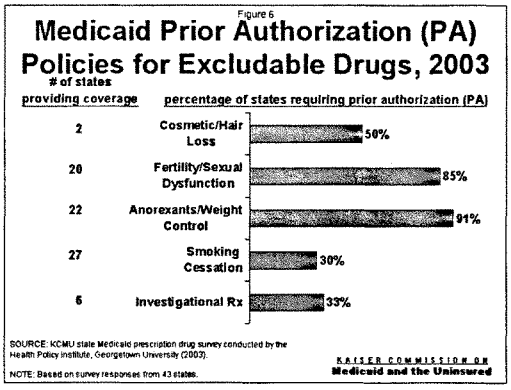


The use of PA by states is growing **(Figure 5)**. For all drug classes surveyed, states reported a greater use of PA in 2003 than in 2000. In many cases, the percentage of states requiring PA for a specific class of drug increased dramatically. For several drug classes, the percentage of states requiring PA more than doubled, including amphetamines (25 of 43 states in 2003 vs. 10 of 44 states in 2000), non-steroidal anti-inflammatory drugs (NSAIDs) (27 of 43 states in 2003 vs. 9 of 44 states in 2000), anti-ulcer/reflux medications (32 of 43 states in 2003 vs. 13 of 44 states in 2000), and benzodiazepines and other tranquilizers (11 of 43 states in 2003 vs. 4 of 44 states in 2000).



When states decide to cover excludable drugs, they frequently require PA before the drugs can be dispensed **(Figure 6)**. In 2003, 1 of only 2 states providing coverage for cosmetic/hair growth drugs, 17 of 20 states providing coverage for fertility and sexual dysfunction drugs, and 20 of 22 states providing coverage for anorexants/weight control drugs require PA (out of 43 states responding in 2003). States are less likely to require PA for smoking cessation and investigational drugs. Roughly one-third of states providing coverage for smoking cessation (8 of 27 states) and investigational drugs (2 of 6 states) require PA (out of 43 states reporting in 2003).

Figure 6

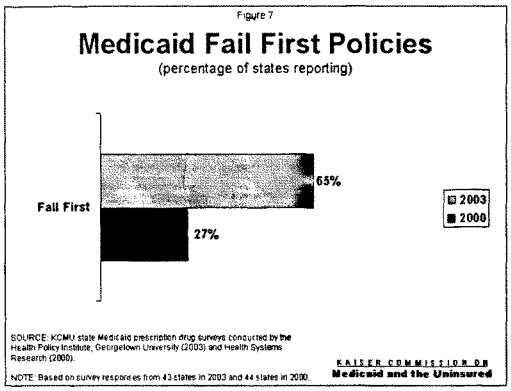


Fail First and Step Therapy Policies
Table 10

Fail-first or step therapy policies are a variation of prior authorization. Under these policies, a physician must generally demonstrate that an alternative therapy is ineffective or otherwise inappropriate for the individual before the requested drug can be dispensed.

Fail First/Step Therapy Requirement: Policy that requires an individual to use and fail on a particular drug (generally a low cost alternative) before a state Medicaid program will pay for another drug.

As with PA policies more generally, states have increased their reliance on fail-first policies **(Figure 7)**. Roughly two-thirds of states use fail-first policies: 28 of 43 states reporting in 2003 vs. 12 of 44 states in 2000. In general, when states adopt fail-first policies, they apply them to commonly-prescribed medications, such as NSAIDs, the anti-ulcer proton-pump inhibitors (PPIs) and COX-II inhibitors for arthritis. Some states also require beneficiaries to fail on generics before dispensing brand-name alternatives.



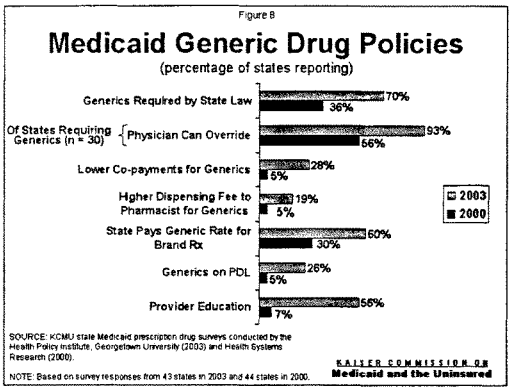
Generic Drug Policies
Tables 11 and 12

As discussed previously, Medicaid law generally requires states to provide coverage for all FDA-approved medications by manufacturers with rebate agreements in effect with the federal government. Medicaid law does not, however, prevent states from requiring or encouraging the use of generic medications.

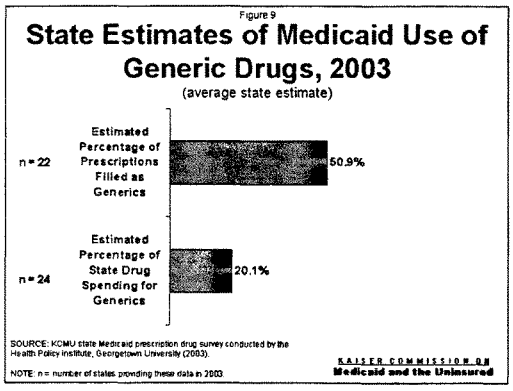
Seventy percent of states require the dispensing of generics (30 of 43 states in 2003 vs. 16 of 44 states in 2000) **(Figure 8)**. All, but two states that require generics, however, report that physicians can override this policy by writing "brand medically necessary" when writing the prescription (28 of 30 states that require generics in 2003). States also employ numerous approaches to encouraging the use of generics. By every measure, states have become more aggressive in encouraging the use of generics since 2000. The percentage of states that pay the generic rate for brand name drugs has doubled since 2000 (26 of 43 states in 2003 vs. 13 of 44 states in 2000). States also rely heavily on provider education as a strategy for encouraging the use of generics (24 of 43 states in 2003 vs. 3 of 44 states in 2000). Smaller numbers of

Generic Drug: A generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.

states also charge lower co-payments for generic drugs (12 of 43 states in 2003 vs. 2 of 44 states in 2000), pay higher dispensing fees to pharmacists for generics (8 of 43 states in 2003 vs. 2 of 44 states in 2000), and automatically place generics on the PDL (11 of 43 states in 2003 vs. 2 of 44 states in 2000).



States were asked to estimate the percentage of prescriptions filled that were generic. The average response was 51% and ranged from 34% to 72% **(Figure 9)**. States were also asked to estimate the percentage of state outpatient drug spending that is for generics. The average response was 20% and ranged from 10% to 44%.



Cost-Sharing
Table 13

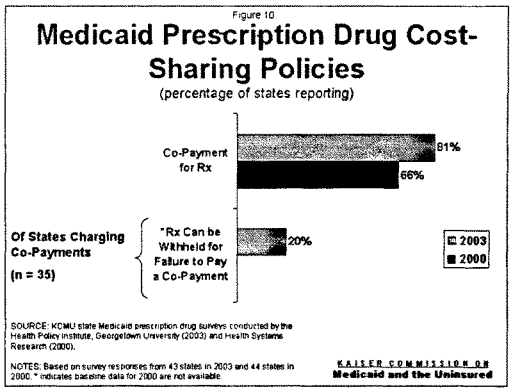
Medicaid permits states to charge "nominal" cost-sharing to certain groups of beneficiaries for certain services. Medicaid law prohibits cost-sharing for the following groups: children under age 18; pregnant women with respect to services relating to pregnancy or any other medical condition that may complicate the pregnancy; terminally ill individuals receiving hospice care; and inpatients in hospitals, nursing facilities, or intermediate care facilities for persons with mental retardation (ICF/MRs) who are required to contribute all, but a minimal amount of their income for their medical care.[20]

Cost-Sharing: Medicaid policy that requires a beneficiary to pay a portion of the cost of a service. In the case of prescription drugs, states have the option of requiring certain beneficiaries to pay a "nominal" co-payment, although a state cannot deny a beneficiary a drug based on the failure to pay the co-payment.

When cost-sharing is permitted, states are required to prohibit providers from denying care or services to an eligible individual on account of an individual's inability to pay a co-payment.[21]

The vast majority of states charge eligible beneficiaries co-payments for outpatient prescription drugs (35 of 43 states reporting in 2003 vs. 29 of 44 states in 2000) **(Figure 10)**. When states charge co-payments, they generally apply them to all eligible beneficiary groups, including the elderly, people with disabilities, and parents. A small number of states (Florida, Missouri, and New Mexico) apply prescription drug co-payments to only a small proportion of their overall Medicaid population.

Although the Medicaid law prohibits denial of prescription drugs based on failure to pay the co-payment, a small number of states (7 of 35 states reporting that they require cost-sharing) reported restrictions on prescription drugs for failure to pay copayments, especially for repeat violations.



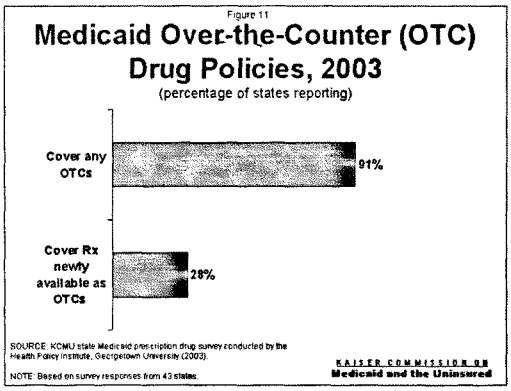
Over-the-Counter Medications (OTCs)

Table 14

Medicaid permits states to cover over-the-counter medications (OTCs), but the Medicaid law does not extend the same policies to OTCs that apply to prescription medications. The Medicaid law's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) requirement that requires states to cover all medically necessary covered Medicaid services for children applies to OTCs (states may require a prescription written by a physician as evidence of medical necessity). For adult beneficiaries in all eligibility groups, states have broad flexibility in deciding whether and how to cover OTCs.

Over-the-Counter Medications (OTCs): Drugs that are available without a prescription.

Thirty-nine of 43 states reporting in 2003 cover some OTCs **(Figure 11)**. The extent of OTC coverage varies dramatically from state to state. A smaller number of states (12 of 43 states reporting in 2003) cover OTCs that were previously available by prescription and that are newly available as OTCs.



PAYMENT AND PURCHASING POLICIES
Tables 15-17

States have considerable discretion in setting payment rates for Medicaid outpatient prescription drugs. The overall price for Medicaid drugs consists of three components: 1) the amount the state pays the pharmacist for the drug itself; 2) the amount of the dispensing fee that that state pays the pharmacist for filling the prescription; and, 3) the size of the rebate that the state receives from the drug manufacturer for purchasing the drug.

Payment for the drug itself: The Medicaid law does not set any minimum payment standards, but it does establish maximum payments for which states can receive a federal match.

For brand name drugs (i.e. drugs still under patent), and multi-source drugs with fewer than 3 therapeutically equivalent generics, the maximum payment cannot exceed the lesser of the drug's estimated acquisition cost (EAC) plus a dispensing fee or the provider's usual and customary charges to the general public. Each state determines its own EAC, and in most states is based on the average wholesale price (AWP). AWP is a price determined by the drug manufacturer and is the suggested price that wholesalers charge retail pharmacists for the drug. Most states set their EAC as AWP minus some percentage discount. The actual cost paid for drugs by pharmacies is generally believed to be well below AWP, providing a justification for the discount. A study in 1999 by the HHS Office of the Inspector General estimated that the actual acquisition cost for pharmacies was AWP – 21.84%.[22] A smaller number of states set their EAC based on the wholesale acquisition cost (WAC), an estimate of the wholesaler's cost for the drug plus a percentage add-on.[23]

For generic drugs (i.e., multi-source drugs with at least 3 therapeutic equivalents), federal matching payments are limited by the Federal Upper Limit (FUL). The FUL is set at 150% of the published price for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules.[24] Medicaid regulations stipulate, however, that the FUL payment ceiling does not apply if a prescribing physician (in his or her own handwriting) specifies that a specific brand is medically necessary.[25]

Virtually all states (42 of 43 reporting in 2003) set their EAC on the basis of AWP. Florida, Maryland, and Missouri use both AWP and WAC. Massachusetts is the only state that indicated that it determined its EAC based on WAC.

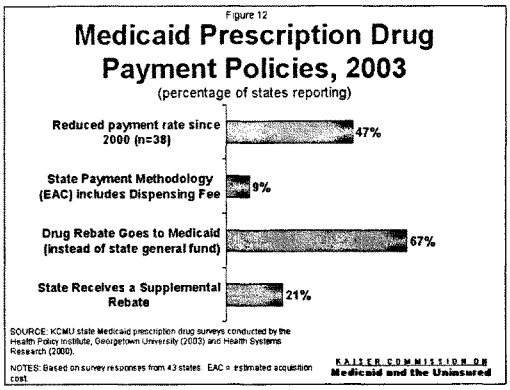
Nearly half of the states (18 of 38 states reporting in both 2000 and 2003) have reduced their payment rate since 2000—through increasing the discount taken off of AWP **(Figure 12)**. Relatively few states (4 of 43 reporting in 2003) include their dispensing fee when calculating the EAC. When states receive drug rebate payments, it is at their discretion to return these funds to Medicaid or return them to the state's general fund. Two-thirds of the states (29 of 43 reporting in 2003) return drug rebate payments to Medicaid.

Dispensing fee: The Medicaid law and the payment ceilings described above permit states to pay a "reasonable" dispensing fee to the pharmacist. Federal regulations do not define what is reasonable, and there is significant variation in the fees paid by states.

Drug rebates: The actual cost to Medicaid for prescription drugs is reduced by the rebates that manufacturers pay to states. The federal rebate is based on agreements between the manufacturer and the Secretary of HHS and is uniform across the states. Some states, however, have negotiated supplemental rebates directly with manufacturers. The federal rebate extends only to drugs purchased by states on a fee-for-service basis. When states purchase drugs through capitated managed care programs, the managed care organizations are permitted to negotiate their own discounts.

A relatively small number of states (9 of 43 reporting in 2003) reported that they receive supplemental rebates from drug manufacturers. The leverage for these rebates typically comes from the institution of a state Medicaid PDL.

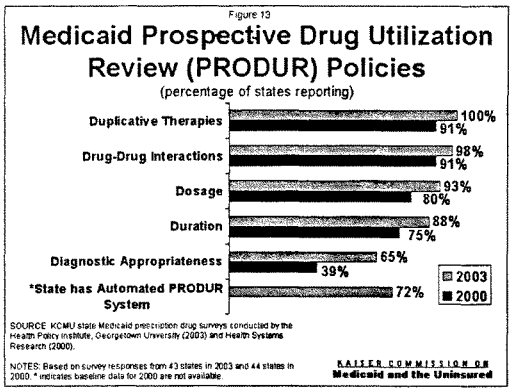
States were asked to list the five most commonly dispensed prescription drugs and the five most costly drugs (in terms of total state expenditures). The five most commonly dispensed drugs, according to states rankings are albuterol (for asthma), furosemide (a diuretic used to control hypertension) hydrocodone (pain medication), Celebrex (an anti-inflammatory used for arthritis) and the antibiotic amoxicillin. The five most costly drugs, according to states' rankings are Zyprexa and Risperdal (both antipsychotics), Prevacid, and Prilosec (both anti ulcer medications) and Celebrex (an anti-inflammatory). To view these data for individual states, see Tables 16 and 17.



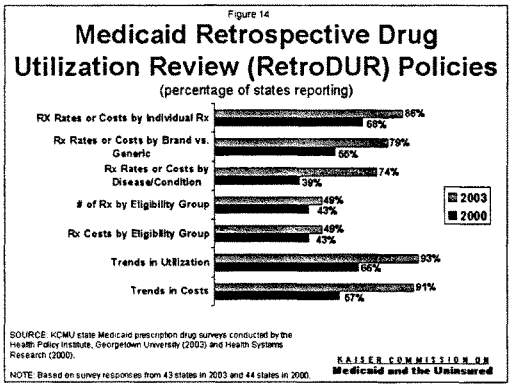
UTILIZATION REVIEW AND MONITORING
Tables 18-22

Medicaid law requires states to operate drug utilization review (DUR) programs. These include prospective drug utilization review (PRODUR), which takes place before a drug is dispensed and retrospective drug utilization review (RetroDUR), which takes place after the drug is dispensed.[26] The emphasis of PRODUR is on protecting the health and safety of beneficiaries receiving prescription drugs and the emphasis of RetroDUR is on identifying fraud, abuse, and gross overuse of prescription medications. States have frequently identified PRODUR and RetroDUR as among the easiest to implement and most effective utilization management and cost control strategies.

The vast majority of states, although not all states, conduct PRODUR activities using the criteria established in the Medicaid law **(Figure 13)**. In 2003, all states reported reviewing for duplicative therapies, and most states review for drug-to-drug interactions (42 of 43 states), incorrect dosage (40 of 43 states), inappropriate duration (38 of 43 states), and diagnostic appropriateness (28 of 43 states). Although not a requirement, more than two-thirds (31 of 43 states) reported that their PRODUR systems are automated.

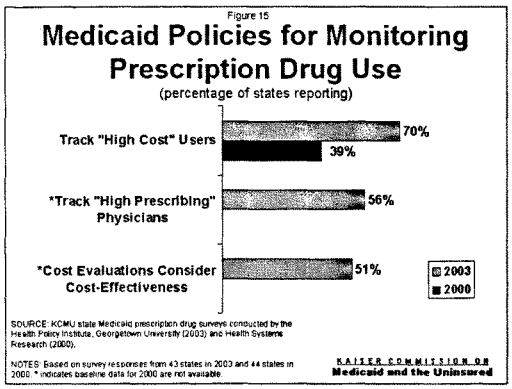


Medicaid requires states to conduct RetroDUR, although the law is not as specific regarding the criteria for the review as it is for PRODUR. In 2003, nearly all states (40 of 43) monitor trends in utilization, trends in costs (39 of 43 states), and drug costs for each individual drug (37 of 43 states) **(Figure 14)**. A large majority of states also review drug costs on the basis of brand name versus generic status (34 of 43 states) and drug costs by condition (32 of 43 states). Nearly half of the states also monitor the number of drugs by eligibility group (21 of 43 states reporting in 2003), and drug costs by eligibility group (21 of 43 states reporting in 2003).



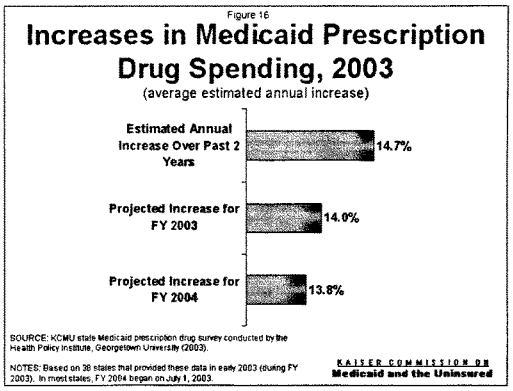
States also monitor prescription drug use by tracking both "high-cost users" and "high prescribing physicians" **(Figure 15)**. Seventy percent of states (30 of 43 states

reporting in 2003) reported that they track high-cost users. Several states indicated that these users are identified by selecting the top 100 or 200 beneficiaries on the basis of their monthly drug costs. At least one state reported tracking high users of certain "abusable" drugs. Many states (24 of 43 states reporting in 2003) reported that they track high-prescribing physicians. Similarly, several states reported that they identify high prescribers on the basis of total cost to the state in a given month. Educational letters and personal visits were commonly cited by states as interventions used to address high-prescribing physicians. Half of the states (22 of 43 reporting in 2003) indicated that they consider cost-effectiveness when conducting cost evaluations. Of these respondents, many indicated that cost-effectiveness is considered through the use of disease management programs.



States were asked to give estimates of their recent cost experience in purchasing prescription drugs and their projections for the next two years **(Figure 16)**. The average estimated annual increase in prescription drug costs over the last two years was 15% (based on 37 states reporting) and ranged from 4% to 25% per year. The average projected cost growth in FY 2003 (which ended on June 30, 2003 in most states), was 14%, and ranged from a decline of 1% from the previous year to an increase of 27%. Projected average cost growth in FY 2004 (the current fiscal year, with projections being made in early 2003 was 14%, and ranged from a decline of 5% from the previous year to a 23.1% increase.

Figure 16



PRESCRIPTION DRUG POLICIES FOR MANAGED CARE ENROLLEES
Tables 23-25

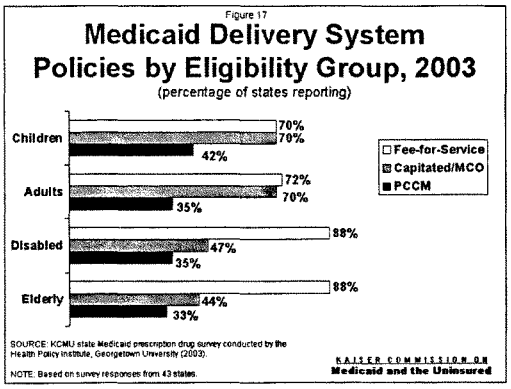
State Medicaid programs deliver health care and long-term services to beneficiaries through more than one type of delivery system. Fee-for-service was previously the only type of delivery system in Medicaid. Medicaid law also gives beneficiaries a right to freedom-of-choice of health care providers. Over time, through state initiatives in which managed care enrollment was voluntary and through the use of Medicaid waivers wherein federal approval was required to waive the freedom-of-choice provision in order to mandate managed care enrollment, the use of managed care has grown. The Balanced Budget Act of 1997 (BBA) also gave states new authority to mandate managed care enrollment through amending their Medicaid plans without seeking waivers, thereby creating even more opportunities for states to employ managed care models.

While managed care exists on a continuum and in many forms, there are two dominant types of managed delivery systems: capitated managed care and primary care case management (PCCM) programs. Capitated managed care programs are operated through contracts by the state Medicaid program with managed care organizations (MCOs), purchasing a package of health care and other services for Medicaid beneficiaries by paying a negotiated per person rate. In this type of arrangement, much of the state's risk for the costs of health care and provision of covered services is shifted onto the MCO. States with capitated managed care programs can include some or all covered Medicaid benefits in the contract with the MCO, therefore, states may purchase prescription drug benefits on a capitated or fee-for-service basis. In PCCM programs, the state contracts with a PCCM agency to perform certain health care administrative functions. This usually involves the primary care case manager serving as a gatekeeper for services, and conducting utilization review before approving access to

specialty care. In PCCM arrangements, the state continues to pay for services approved by the PCCM on a fee-for-service basis.

Most states employ more than one type of delivery system for their Medicaid beneficiaries. States also may employ more than one type of delivery system for each eligibility group. For example, through a waiver, a state may operate a capitated managed care program in the urban areas of the state for some beneficiaries, while operating a fee-for-service system in rural areas. Some states serve all eligibility groups through all 3 of the major types of delivery systems. Most states operate fee-for-service and capitated managed care programs for at least some Medicaid beneficiaries **(Figure 17)**. A sizable minority of states also operate PCCM programs. More states serve people with disabilities and the elderly in fee-for-service systems than non-disabled children and adults (38 of 43 states reporting in 2003 for people with disabilities and the elderly, respectively vs. 30 and 31 states, for non-disabled children and adults, respectively). Conversely, more states serve non-disabled children and adults in capitated managed care programs than people with disabilities and the elderly in capitated managed care programs (30 of 43 states reporting in 2003 for non-disabled children and adults vs. 20 and 19 for people with disabilities and the elderly, respectively). A third or more of the states serve all eligibility groups through PCCM programs. Eighteen states use PCCM programs to serve non-disabled children, 15 states use PCCM programs to serve non-disabled adults and people with disabilities, and 14 states use PCCM programs to service the elderly (out of 43 states reporting in 2003).

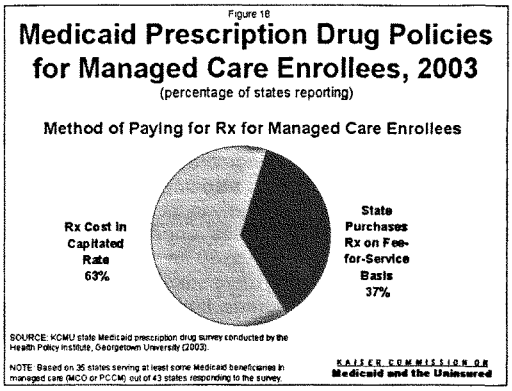
Figure 17



Of states that serve at least some beneficiaries through capitated managed care programs, the majority purchase prescription drugs by including drug costs in the capitated rate paid to MCOs (22 of 35 states with capitated managed care programs in 2003, out of a total response from 43 states) **(Figure 18)**. One-third of states with

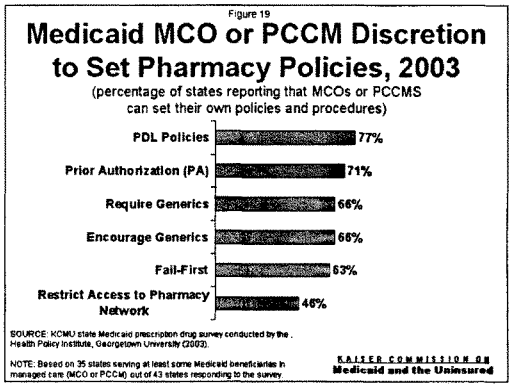
capitated managed care programs (13 of 35 states, out of a total response from 43 states) indicate that they purchase prescription drugs on a fee-for-service basis.

Figure 18



The level of discretion that states give MCOs in managing the prescription drug benefit has significant implications for beneficiary access and cost containment. Roughly two-thirds of states with capitated managed care programs give MCOs discretion to set their own policies in a broad range of areas, including PDL policies, PA policies, requiring or encouraging generics, and establishing fail-first policies **(Figure 19)**. Less than half of the states (16 of 35 states with capitated managed care programs, out of a response from 43 states in 2003) permit MCOs to restrict access to only certain pharmacies within an MCO network.

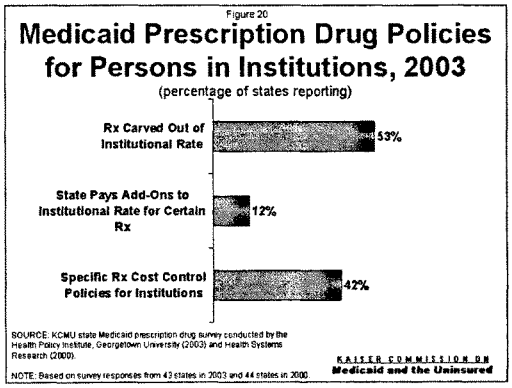
Figure 19



PRESCRIPTION DRUG POLICIES FOR PERSONS RESIDING IN INSTITUTIONS
Table 26

The Medicaid law provisions described in this report apply only to Medicaid beneficiaries receiving prescription drugs on an outpatient basis. The law expressly states that they do not apply to persons in inpatient settings including hospitals, nursing homes, and ICF/MRs.[27] Medicaid spending on prescription drugs for persons residing in institutions [including hospitals, nursing homes, ICF/MRs, and institutions for mental diseases (IMDs)], comprise a significant proportion of overall state prescription drug spending, thereby meriting an examination of state purchasing and management practices in institutional settings.

States were asked to estimate the percentage of total Medicaid prescription drug spending for persons residing in institutions. The average response was 21% (based on 20 states reporting in 2003) and ranged from 6% to 33% of total drug spending. States were asked how they administer the institutional prescription drug benefit **(Figure 20)**. Half of the states (23 of 43 states reporting in 2003) indicated that they carve out institutional drug spending—meaning they separate payment for drugs from an institutional payment rate and purchase drugs on a fee-for-service basis. The remaining half of the states presumably include prescription drug costs in a bundled institutional payment rate. A small number of states (5 of 43 states reporting in 2003) pay an add-on to the institutional rate for certain drug costs, such as OTCs and vitamins. Forty-two percent of states (18 of 43 states reporting in 2003) have pharmacy cost control policies that are unique to the institutional setting.



POLICY IMPLICATIONS

This survey has shown that states are taking advantage of the tools available to them to manage the Medicaid outpatient prescription drug benefit. By design, however, states are limited in terms of how aggressively they can constrain the Medicaid drug benefit because of the vulnerability of the populations served. To plan for the future, policy makers should consider the following:

- **Most states have taken advantage of the full range of tools available to them for managing prescription drug utilization and to constrain cost growth.**

On virtually every measure, between 2000 and 2003, more states have taken advantage of the flexibility in the Medicaid law to manage prescription drug use and to monitor prescribing practices. For every year that state budgets are tight, and states are forced to identify ways to reduce spending, they have a diminishing range of tools available to them to reduce pharmaceutical costs. Additionally, states have probably considered many pharmacy utilization tools that they are not currently using. Whether states rejected various utilization management approaches out of concerns for beneficiary access, feasibility, or administrative burden, the remaining tools are increasingly less attractive to states, having been considered and rejected in the past.

As has been shown, states have broad flexibility within Medicaid to manage the pharmacy benefit. New flexibility, such as greater latitude to tailor benefits to specific populations, is unlikely to lead to meaningful cost savings. Nonetheless, new flexibility could come at a potentially great cost to the subset of Medicaid beneficiaries who rely extensively on prescriptions and who are disproportionately responsible for a major portion of pharmacy spending. Tailoring benefits packages to deny benefits to certain beneficiaries is unlikely to yield results. If the groups denied the benefit were lower utilizers of prescription drugs there would not be much cost savings to gain, and if the groups with the greatest needs were denied the benefit, undue hardship and increases in other health care costs would likely ensue. Moreover, since Medicaid programs would continue to be responsible for other health care costs, achieving marginal cost-savings in prescription drugs may come at the expense of poorer health outcomes and higher overall Medicaid spending.

- **Greater federal and state efforts are needed to examine the impact of cost control activities on beneficiary access to medically necessary prescription drugs.**

This survey did not assess beneficiary access to pharmaceuticals or variations in quality of the Medicaid prescription drug benefit. Federal and state governments are facing a large and increasing burden in providing a comprehensive drug benefit to a needy population. As states employ more and more cost-constraining strategies and as they become more aggressive in using tools such as prior authorization or drug limits, more

attention needs to be placed on examining and protecting beneficiary access to prescription drugs.

- **Future progress in constraining drug costs may depend on policy change at the federal level.**

If states are approaching the limit of what they can achieve in constraining pharmaceutical cost growth through tight management of the outpatient prescription drug benefit, future progress in limiting drug costs may depend on policy changes at the federal level.

One federal approach is to increase the size of the Medicaid drug rebate. While this survey indicates that nine states receive supplemental rebates, negotiating them is challenging for many states. Small states are at a great disadvantage in negotiating rebates with manufacturers because they may not generate high enough volumes of business for the drug manufacturers to have meaningful bargaining power. Additionally, political pressure in many states would make it impossible to seek supplemental rebates. A change in the Medicaid law would have the advantage of leveraging all outpatient prescription drugs purchased by every Medicaid program. While pharmaceutical manufacturers would likely strenuously oppose such a move, it is unlikely that they would no longer be willing to participate in Medicaid.

Outside of Medicaid, some advocates and policy makers have proposed more far reaching reforms of how drugs are priced in the United States. Some have advocated models used by many other developed nations to place certain limits on pharmaceutical prices. While such reform seems remote at the present time, it holds the greatest potential to give states the most significant and long-term relief in financing their Medicaid pharmacy programs. Additionally, one factor that is believed to have contributed to increasing prescription drug costs is direct-to-consumer marketing of pharmaceuticals. Since federal regulations related to direct marketing to consumers was changed in the late 1990's, there has been an explosion of pharmaceutical manufacturer spending on television and print advertisements of drug products for consumers. Some health policy analysts have asserted that increases in Medicaid drug costs can be directly tied to this new ability to market to consumers. Policy makers may wish to consider new prohibitions or restrictions on marketing of pharmaceuticals to consumers.

CONCLUSION

The importance of prescription drugs in the clinical management of many health conditions continues to grow with the discovery of new medications and with improvements to existing therapies. The promise of new therapeutics is exciting both for its potential to bring new treatments to previously untreatable or poorly treated conditions and for its potential to play a role in improving the quality of life of many individuals—while reducing other costs in the health system.

For state Medicaid programs, the prospect of a future with new and improved drugs must also be balanced with the daunting challenge of financing the provision of these medications. Medicaid plays a unique role in providing access to prescription drugs to the neediest and costliest cohorts of Americans (low-income people with severe disabilities and low-income elderly individuals). Financing new medications that often demand top dollar in comparison to older drugs is especially challenging at the same time that Medicaid programs adapt to changing demographics that will undoubtedly lead to more people with disabilities and elderly beneficiaries who need many services, as well as many pharmaceuticals. Because of the clear benefits to be gained by individual Medicaid beneficiaries and the health of the general public by ensuring that Medicaid beneficiaries can access the full compliment of pharmaceuticals, it will be worth the effort for policy makers to ensure that these challenges are overcome.

Finally, the enactment of a Medicare drug benefit will have a major impact on Medicaid and many of the people it serves. Among those who will be most affected by the new Medicare law are the dual eligibles. As of January 1, 2006, dual eligibles will no longer have Medicaid drug coverage but will receive prescription drugs through Medicare Part D. All of the implications of this change for duals – including many nursing home residents and Medicaid waiver participants – are yet to be determined. In addition, state Medicaid programs will experience major change as payments for this large drug consuming population shift to Medicare. As all stakeholders begin to grasp the details of how Medicare Part D will operate, understanding the dynamics and complexities of serving the dual eligibles under Medicaid can help to identify ways that a Medicare drug benefit can best serve these poorest and sickest beneficiaries.

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[1] The recently enacted Medicare drug benefit, once implemented, will significantly impact Medicaid's prescription drug utilization profile. Dual eligibles (those Medicare beneficiaries currently receiving Medicaid coverage for services including prescription drugs) will no longer receive prescription drugs through Medicaid as of January 1, 2006.

[2] Smith, V., Ramesh, R., Gifford, K., Ellis, E., and Wachino, V., *States Respond to Fiscal Pressure: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2003 and 2004: Results from a 50-State Survey*, Kaiser Commission on Medicaid and the Uninsured, September 2003.

[3] The eight states that did not respond to the 2003 survey were AL, IN, NV, OH, OR, RI, TN, and WY. In 2000, 43 states and DC responded; the seven states that did not respond were AZ, CO, OH, OK, TN, TX, and WI.

[4] For ease of reference, throughout this report, references to "states" should be inferred to include the District of Columbia.

[5] Schwalberg R, Bellamy H, Giffin M, Miller C, Williams SS, Elam L., *Medicaid Outpatient Prescription Drug Benefits: Findings From a National Survey and Selected Case Study Highlights*. Kaiser Commission on Medicaid and the Uninsured, Washington D.C. October 2001.

[6] §1902(a)(54) of the Social Security Act.

[7] §1903(i) of the Social Security Act. See first sentence after (20).

[8] 42 CFR 440.230 (d).

[9] §1927(d)(6) of the Social Security Act.

[10] §1927(d)(1)(B) of the Social Security Act.

[11] §1927(d)(1)(B)(i) of the Social Security Act.

[12] §§1927 (k)(6) and (g)(1)(B)(i) of the Social Security Act.

[13] The Medicaid law recognizes the following compendia: the American Hospital Formulary Service Drug Information; the United States Pharmacopoeia Drug Information; the DRUGDEX Information System; and the American Medical Association Drug Evaluations.

[14] §1927(d)(2) of the Social Security Act.
[15] §1927(d)(4) of the Social Security Act.
[16] §1927(d)(4)(C) of the Social Security Act.
[17] §1927(d)(4)(E) of the Social Security Act.
[18] §1927(d)(1)(A) of the Social Security Act.
[19] §1927(d)(5) of the Social Security Act.
[20] §1916(a)(2) of the Social Security Act.
[21] §1916(e) of the Social Security Act.
[22] Office of the Inspector General, *Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products* (August 10, 2001) (A-06-00-00023) http://oig.hhs.gov/oas/reports/region6/60000023.htm.
[23] Schneider A and Elam L. *Medicaid: Purchasing Prescription Drugs*. Kaiser Commission on Medicaid and the Uninsured, January 2002.
[24] 42 CFR 447.332(b).
[25] 42 CFR 447.331(c).
[26] §1927(g) of the Social Security Act.
[27] §1927(k)(3) of the Social Security Act.

Table 1: Medicaid Prescription Drug Coverage Options, by State.

STATE	Medicaid Rx Coverage: Categorically Needy	Medicaid Rx Coverage: Medically Needy*	Specific State Policies to Cover QMBs/SLMBs	Pharmacy Plus Waiver	Eligible Populations
Alabama					
Alaska	•				
Arkansas	•	•			
Arizona**	•				
California	•	•			
Colorado	•				
Connecticut	•	•			
Delaware	•				
District of Columbia	•	•			
Florida	•	•	•	•	Medicare beneficiaries ≥ 65
Georgia	•	•			
Hawaii	•	•			
Idaho	•				
Illinois	•	•		•	≥ 65, below 200% FPL
Indiana					
Iowa	•	•			
Kansas	•	•			
Kentucky	•	•			
Louisiana	•	•			
Maine	•	•			
Maryland	•	•	•		
Massachusetts	•	•			
Michigan	•	•			
Minnesota	•	•			
Mississippi	•				
Missouri	•				
Montana	•	•			
Nebraska	•	•			
Nevada					
New Hampshire	•	•			
New Jersey	•	•			
New Mexico	•				
New York	•	•	•		
North Carolina	•	•	•		
North Dakota	•	•			
Ohio					
Oklahoma	•	•			
Oregon					
Pennsylvania	•	•			
Rhode Island					
South Carolina	•		•	•	≥ 65 w/o insurance
South Dakota	•				
Tennessee					
Texas	•	•	•		
Utah	•	•			
Vermont	•	•			
Virginia	•	•			
Washington	•	•			
West Virginia	•	•			
Wisconsin	•	•	•	•	≥ 65
Wyoming					
TOTAL	**43**	**33**	**7**	**4**	

Shaded text signifies states that did not respond to the survey. *Medically needy notes: New Jersey limits Rx coverage to pregnant women, children under 21, and long-term care recipients; Pennsylvania limits Rx coverage to children under 21, and long-term care recipients; Texas' medically needy program does not cover people with disabilities or the elderly, except in long term care facilities; and Utah has different co-payment requirements and benefit limitations. **Survey does not reflect Arizona's policies for a small number of beneficiaries whose services are reimbursed on a fee-for-service basis.

Table 2: Medicaid Prescription Drug Dispensing Limits, by State.

STATE	*Any Limits*	*Amount of Rx*	*# of refills*	*# of Rx*
Alabama				
Alaska	•	30 days		
Arkansas*	•	31 days	5/6 months	6/month w/ PA request
Arizona	•	30 days/100 units		
California	•	100 days		6/month
Colorado	•	30 days		
Connecticut	•	30 days/240 units	5/6 months for non-controlled Rx	
Delaware	•	34 days/100 units		
District of Columbia**	•	30 days	3/4 months for maintenance	
Florida	•	34 days	6/month for specific Rx	4 brand/month, unlimited generics
Georgia	•	31 days		Adults: 5/month, kids: 6/month
Hawaii	•	30 days/100 units		
Idaho	•	34 days/100 units		
Illinois	•	30 days		
Indiana				
Iowa	•	30 days		
Kansas	•	31 days	1 year supply	5/month for single source
Kentucky	•	32 days	5/6 months	
Louisiana	•	30 days	5/6 months	8/month
Maine	•	30 days for brand	11/year	
Maryland	•	34 days	11/year for non-controlled	
Massachusetts	•	30-90 days	12/year	
Michigan	•	34 days	12/year	
Minnesota	•	3 months		
Mississippi	•	34 days	5/6 months	5/month; 7/month w/PA, no limit for LTC and <21
Missouri***	•	31 days		5/month
Montana	•	34 days		
Nebraska	•	90 days		
Nevada				
New Hampshire	•	30 days	1 year supply	
New Jersey	•	34 days/100 units	5/6 months	
New Mexico	•	34 days		
New York	•	Varies by drug	5/6 months	43/year
North Carolina^	•	34 days		6/month
North Dakota	•	34 days		
Ohio				
Oklahoma	•	34 days/100 units		3/month
Oregon				
Pennsylvania	•	34 days/100 units	5/6 months	
Rhode Island				
South Carolina	•	34 days		4/month
South Dakota	•	34 days		
Tennessee				
Texas****	•	180 days	5/180 days	3/month
Utah	•	1 month		
Vermont				
Virginia	•	34 days/100 units	5 controlled, 2 others	
Washington	•	34 days	2/30 days	>4 brand needs review
West Virginia	•	34 days	5/6 months	
Wisconsin	•	34 days/100 units	12/year	
Wyoming				
TOTAL	**42**	**42**	**21**	**14**

Shaded text signifies states that did not respond to the survey. Many states reported exceptions to above policies, such as with prior approval. Many states also have higher dispensing limits for maintenance Rx. *Arkansas long-term care patients have no refill limits. **The District of Columbia also has an expenditure limit of $1,500/30 day supply per Rx. ***Missouri allows exceptions for individuals with long-term chronic conditions. ****Since survey, Texas now limits individuals with unlimited prescriptions to 34 day supply. Persons limited to 3 Rx/month can still receive a 180 day supply. N/A = information not available. ^North Carolina has a 3 month supply of birth control tablets and HRT dialpaks. No state reported limits based on total Rx costs per person.

Table 3: Prescription Drugs Excluded from Medicaid Coverage, by State.

STATE	*Any Exclusion*	*Cosmetic and Hair Loss*	*Fertility/Sexual Dysfunction*	*Anorexants/ Weight Control*	*Smoking Cessation*	*Investigational Rx*
Alabama						
Alaska	•	•	•	•	•	•
Arkansas	•	•	•	•	•	•
Arizona*	•					
California	•	•				
Colorado	•	•		•		•
Connecticut**	•	•	•	•	•	•
Delaware	•	•	•			•
District of Columbia	•					•
Florida	•	•	•			•
Georgia***	•	•		•	•	•
Hawaii	•	•	•		•	•
Idaho****	•	•	•		•	•
Illinois^	•	•	•	•		•
Indiana						
Iowa	•	•			•	•
Kansas^^	•	•				
Kentucky	•	•	•		•	
Louisiana	•	•		•		•
Maine^^^	•	•				•
Maryland^^^	•	•	•	•		•
Massachusetts	•	•	•	•	•	
Michigan	•	•		•		•
Minnesota	•	•	•	•		•
Mississippi	•	•		•		•
Missouri	•	•		•	•	•
Montana	•	•				•
Nebraska	•	•	•	•	•	•
Nevada						
New Hampshire	•	•	•			•
New Jersey	•	•	•		•	•
New Mexico	•	•	•			•
New York	•	•		•		•
North Carolina	•	•				•
North Dakota	•	•	•			
Ohio						
Oklahoma	•	•	•	•		•
Oregon						
Pennsylvania	•	•	•	•		•
Rhode Island						
South Carolina	•	•	•	•	•	•
South Dakota	•	•	•	•	•	•
Tennessee						
Texas^^^^	•	•		•		•
Utah	•	•	•	•	•	•
Vermont	•	•				•
Virginia	•	•	•		•	•
Washington	•	•	•	•	•	•
West Virginia	•	•		•		•
Wisconsin	•	•				•
Wyoming						
TOTAL	**43**	**41**	**24**	**23**	**17**	**37**

Shaded text signifies states that did not respond to the survey. *Arizona permits each of its 14 MCOs to establish their own policies for excluding Rx, as permissible by federal law. **Connecticut excludes anorexants/weight control Rx, except for certain diagnosis codes. ***Georgia excludes fertility Rx, but covers sexual dysfunction Rx with restrictions. ****Idaho excludes coverage for anorexants/weight control Rx, but does cover Xenical for hypertriglyceridemia. ^Illinois excludes anorexants/weight control and fertility/sexual dysfunction, except for certain diagnosis codes. ^^Kansas limits Viagra coverag to 4 pills/month. ^^^Maine and Maryland exclude sexual dysfunction, but cover fertility Rx. ^^^^Texas excludes coverage for fertility Rx, but covers sexual dysfunction.

Table 4: Medicaid Preferred Drug List (PDL)* Policies, by State.

STATE	*State has PDL*	*Body that sets PDL Policies*	*Criteria for Inclusion of Rx on PDL*	*Public Input in PDL*	*PDL Used for Other State Programs*
Alabama					
Alaska					
Arkansas					
Arizona	•	MCO's set their own formularies	P&T review, evidence-based therapeutic value, rebateable		
California	•	Agency and Medi-Cal Contract Drug Advisory Committee (MDAC)	Efficacy, essential need, safety, misuse potential, and cost	•	
Colorado					
Connecticut					
Delaware					
District of Columbia					
Florida	•	Agency and P&T	P&T review, rebateable	•	
Georgia	•	Agency sets PDL w/ recommendations from DUR Board	P&T review, recommended by DUR reviews	•	SCHIP, State employees, and Board of Regents
Hawaii					
Idaho					
Illinois	•	Agency with outside input	Clinical efficacy, cost		SCHIP, Pharmacy Plus
Indiana					
Iowa					
Kansas	•	PDL Committee	Clinical equivalency and then cost	•	
Kentucky	•	Agency	Medically necessary, FDA approved	•	
Louisiana	•	Agency	P&T review	•	
Maine	•	Private contractor			Applies to other non-specified programs
Maryland					
Massachusetts	•	Agency clinical staff	Efficacy and safety		
Michigan	•	Agency and P&T	Clinical efficacy, cost	•	Applies to other non-specified programs
Minnesota	•	Agency pharmacists and committee of physicians and pharmacists	Therapeutic equivalents, proton pump inhibitors, ACE inhibitors & non-sedating antihistamines	•	General Assistance Medical Care, state prescription Rx program, and other state funded programs
Mississippi	•	P&T Committee	Evidence based		
Missouri					
Montana					
Nebraska					
Nevada					
New Hampshire					
New Jersey					
New Mexico					
New York					
North Carolina					
North Dakota					
Ohio					

STATE	State has PDL	Body that sets PDL Policies	Criteria for Inclusion of Rx on PDL	Public Input in PDL	PDL Used for Other State Programs
Oklahoma**	•	DUR Board		•	
Oregon					
Pennsylvania					
Rhode Island					
South Carolina					
South Dakota					
Tennessee					
Texas***	•	Agency	Rebateable, FDA approved		SCHIP, Children with special health care needs, and adults with kidney disease
Utah					
Vermont	•	DUR Board	Rebateable, not excluded by §1927	•	State prescription Rx programs
Virginia					
Washington	•	DUR Board	Safety, efficacy, outcomes, and cost	•	State employees and labor and industries (workers comp)
West Virginia	•	Agency and P&T	Safety, efficacy, and cost	•	
Wisconsin					
Wyoming					
TOTAL	**18**			**12**	**8**

Shaded text signifies states that did not respond to the survey. *Some states refer to their preferred drug list as a "formulary". P&T refers to a pharmaceutical and therapeutics committee. Nearly all states with PDLs subject all Medicaid beneficiaries to their PDL: In Kentucky, long-term care recipients are occasionally exempted from the PDL. In Mississippi, the PDL is voluntary, although cost-sharing for non-PDL Rx is higher. In Washington, the PDL applies only to fee-for-service beneficiaries. **Oklahoma's PDL is limited to H2 blockers/proton pump inhibitors, NSAIDs, ACE inhibitors, Calcium channel blockers, and ADHD Rx. ***Texas plans to implement a PDL by 03/01/04.

Table 5: Medicaid Prescription Drug Prior Authorization (PA) Policies, by State.

STATE	*Any PA*	*PA for Brand Name Rx*	*Specified PA Exclusions*
Alabama			
Alaska	•		
Arkansas	•	•	
Arizona*			
California**	•		HIV, cancer
Colorado	•	•	PPI, Oxycontin/Oxycodone ER, Epoetin, ED Rx, Growth Hormones
Connecticut			
Delaware	•	•	Long acting narcotics, emetics of the 5HT3 category, Epoetin, Renigel, Narcoleptic drugs, Alzheimer's Rx, Synagist, Regranex
District of Columbia	•	•	Rx with fewer than 3 generics
Florida	•	•	Birth control, HIV, insulin, mental health
Georgia***	•	•	
Hawaii	•		
Idaho****	•	•	Coumadin, Lanoxin, Dilantin, Sinemet CR, Rx with low therapeutic index
Illinois**	•	•	HIV/AIDS, Cancer, Birth Control
Indiana			
Iowa^	•	•	
Kansas^^	•	•	All mental health
Kentucky	•	•	
Louisiana	•	•	≈ 60 therapeutic classes
Maine	•	•	N/A
Maryland^^	•	•	
Massachusetts	•	•	
Michigan^^^	•	•	
Minnesota	•		Antipsychotics, blood clotting factors
Mississippi	•	•	Drugs on PDL; only 12 Rx classes require PA
Missouri^^^^	•	•	See website, www.dss.state.mo.us/dms
Montana	•	•	
Nebraska	•	•	Most Rx excluded
Nevada			
New Hampshire	•	•	Most are excluded
New Jersey	•		Based on state DUR standards
New Mexico	•	•	Most Rx excluded
New York	•	•	
North Carolina	•		Only 12 classes included
North Dakota	•		
Ohio			
Oklahoma	•		
Oregon			
Pennsylvania	•	•	
Rhode Island			
South Carolina	•	•	
South Dakota	•		N/A
Tennessee			
Texas	•		
Utah	•	•	N/A
Vermont	•	•	See website, www.path.state.vt.us/OVHA/PDL_menu/PDL_menu.htm
Virginia	•		
Washington	•		PA is required for brand name reimbursement for Rx paid at MAC or FUL rates
West Virginia	•	•	
Wisconsin	•	•	
Wyoming			
TOTAL	**41**	**29**	**22**

Shaded text signifies states that did not respond to the survey. *Arizona policies established by each of 14 MCOs. **California and Illinois PA policies based on drug evaluation, not brand/generic status. ***Georgia requires PA for brand name on MAC. All other PA Rx are based on clinical evaluations and not brand status. ****Idaho requires PA when less costly therapeutic alternative available. ^Iowa requires PA for Rx on Federal Upper Limit (FUL) and maximum allowable cost (MAC) lists. ^^Kansas and Maryland require PA for brand name, unless indicated "dispense as written". ^^^Michigan requires PA for brand name reimbursement for generic classes paid at MAC and for PDL non-preferred Rx. ^^^^Missouri requires PA for brand name reimbursement for generic classes paid at MAC or FUL rates. N/A = Exclusions provided, specific information not available.

Table 6: Medicaid Prior Authorization (PA) Requests and Appeals, by State.

STATE	*PA Requests (2002)*	*PA Denials (2002)*	*Special Appeal Mechanism*	*# of Appeals**
Alabama				
Alaska	1,200	Minimal	Medical justification can be submitted	
Arkansas	≈ 156,000	≈ 39%	Medical justification can be submitted	
Arizona			Second level appeal to Medicaid agency	
California	2,048,056	187,522	Providers have a two-tier appeals process	
Colorado	≈ 10,000	≈ 900	Appeals go to Administrative Law Judge	
Connecticut				
Delaware	8,000	5%	Request Medical Director review	
District of Columbia	N/A	N/A	1st level reconsideration and 2nd level QIO review	
Florida	≈ 37,500	≈ 21%	Agency/fiscal agent pharmacist available by phone or fax	
Georgia	N/A	N/A	Written appeal to PBM or agency	
Hawaii	13,922	N/A	Medical Standards Branch review before formal hearing	
Idaho	≈ 30,000	25		
Illinois	542,000	71,375	Medical justification can be submitted, written appeal to agency	
Indiana				
Iowa	56,000	≈ 5%	Exception to policy or written appeal to state	
Kansas	N/A	N/A	Can appeal to fiscal agent prior to fair hearing	100
Kentucky	329,969	30,629	Recipient can appeal denial	
Louisiana	> 75,000	N/A		
Maine	34,989	9		
Maryland	≈ 2,000	≤ 5%	Medical justification can be submitted	
Massachusetts	28,586	17,020		476
Michigan	≈ 160,000	≈ 3%	All denials reviewed by agency staff physicians	≈ 5,000
Minnesota	15,872	495		
Mississippi	178,000	15,482		
Missouri	≈ 70,000	≈ 23,600	Written appeal to Medicaid agency	≈ 400
Montana	25,000	≈ 21.3%	Written appeal to PA board, to be presented at DUR meeting	25
Nebraska	24,000	14,400	Written appeal to Medicaid agency	1,000
Nevada				
New Hampshire	7,475	1,839		
New Jersey**	600,298	22,767		
New Mexico	≈ 400-500	< 15%		
New York	≈ 10,300	0		
North Carolina	N/A	1%	Physician appeal can override decision	
North Dakota	N/A	N/A		
Ohio				
Oklahoma	95,210	28,085		
Oregon				
Pennsylvania	N/A	N/A		
Rhode Island				
South Carolina	N/A	N/A		
South Dakota	27	0		
Tennessee				
Texas	1,177	161		
Utah	2,361		Physicians can petition the DUR board.	
Vermont	19,859	120	Physician appeal can override decision	
Virginia				
Washington	1,618,370	20%	Medical Director review	
West Virginia	159,280	35,042	Medical Director review	
Wisconsin	77,349	243		9
Wyoming				
TOTAL			**24**	

Shaded text signifies states that did not respond to the survey. N/A = information not available. *Only a small number of state provided a number of appeals—their responses are listed. **New Jersey denials exclude sentinel effect resulting from pharmacy intervention. All states must provide for a fair hearing. Special appeal mechanisms are voluntary state programs that complement the fair hearing process.

Table 7: Selected Medicaid Drugs that Require Prior Authorization, by State (1 of 2 Tables).

STATE	Amphetamines	Anti-Depressants	Antihistamines	Anti-inflammatories/ NSAIDs	Anti-ulcer/reflux	Asthma	Benzodiazepine/ Tranquilizers	HIV medications	Growth Hormones	Over-the-Counter (OTC)	Retin-A/ Accutane	Vasodilators	Vitamins
Alabama													
Alaska									•	•			
Arkansas			•	•	•								
Arizona*													
California	•	•	•	•	•	•	•		•	•	•	•	•
Colorado	•				•				•	•	•		•
Connecticut													
Delaware									•		•		
District of Columbia	•	•	•	•	•	•	•	•	•		•	•	•
Florida**			•	•	•	•			•				•
Georgia***	•		•		•				•		•		
Hawaii	•		•	•	•				•	•			•
Idaho	•		•	•	•				•		•		
Illinois	•	•	•	•	•	•	•		•	•	•	•	•
Indiana													
Iowa****	•		•	•	•		•		•		•		•
Kansas	•				•		•		•				
Kentucky	•		•	•	•		•		•	•	•		•
Louisiana	•	•	•	•	•	•			•				
Maine	•		•	•	•				•	•	•		•
Maryland^									•				
Massachusetts		•	•	•	•			•	•				
Michigan^^	•		•	•	•	•			•	•	•		•
Minnesota		•	•	•	•								
Mississippi			•	•	•								
Missouri	•		•	•	•				•		•		
Montana				•	•						•		
Nebraska		•	•	•	•				•	•			
Nevada													
New Hampshire	•			•	•		•						
New Jersey	•	•		•	•	•	•	•	•		•		
New Mexico	•									•			
New York									•				
North Carolina	•			•					•				
North Dakota													
Ohio													
Oklahoma	•		•	•	•		•		•	•			•
Oregon													
Pennsylvania					•								
Rhode Island													
South Carolina	•			•	•						•		
South Dakota									•				
Tennessee													
Texas	•				•				•				
Utah^^^	•				•				•		•		
Vermont	•	•	•	•	•	•	•	•	•		•	•	
Virginia													
Washington	•		•	•	•				•		•		•
West Virginia	•	•	•	•	•	•	•		•		•		
Wisconsin				•	•				•				
Wyoming													
TOTAL	**25**	**10**	**22**	**27**	**32**	**9**	**11**	**4**	**31**	**11**	**19**	**4**	**12**

Shaded text signifies states that did not respond to the survey. *Arizona permits each of its 14 MCOs to establish their own prior authorization policies. **Florida requires PA for several classes only when prescribing brand name Rx. ***Georgia permits 1 antihistamine script per year w/o PA. ****Iowa requires PA for several classes of Rx only for single source Rx. ^Maryland requires a written diagnosis stating that amphetamines are not for weight control. ^^Michigan does not necessarily require PA for each Rx in a class. ^^^Utah requires PA for COX-II's.

Table 8: Selected Medicaid Drugs that Require Prior Authorization, by State (2 of 2 Tables).

STATE	Cosmetic/ Hair Loss	Fertility/ Sexual Dysfunction	Anorexants/ Weight Control	Smoking Cessation	Investigational Rx
Alabama					
Alaska	--	--	--	--	--
Arkansas	--	--	--	--	--
Arizona*					
California	--	•	•	•	•
Colorado	--	•	--	•	--
Connecticut	--	--	--	--	--
Delaware	--	--	•		--
District of Columbia	•	•	•		--
Florida	--	--	•		--
Georgia	--	•	--	--	--
Hawaii	--	--	•	--	--
Idaho	--	--	•	--	--
Illinois	--	--	--		--
Indiana					
Iowa	--	•	•		--
Kansas	--	•	•		
Kentucky	--	--	•	--	
Louisiana	--		--		--
Maine	--	•	•		--
Maryland	--	--	--		
Massachusetts	--	•	•	--	•
Michigan	--	--	--		--
Minnesota	--	--	--		--
Mississippi	--	•	--		--
Missouri	--	•	--	--	--
Montana	--	•	•	•	--
Nebraska	--	--	--	--	--
Nevada					
New Hampshire	--	--	•		--
New Jersey	--	--	•	--	--
New Mexico	--	•	•		--
New York	--	•	--	•	--
North Carolina	--	•		•	--
North Dakota	--	--	•		--
Ohio					
Oklahoma	--	--	•	•	--
Oregon					
Pennsylvania	--	--	--		--
Rhode Island					
South Carolina	--	--	--	--	--
South Dakota	--	--	--	--	--
Tennessee					
Texas	--		--		--
Utah	--	--	--	--	--
Vermont	--	•	•		--
Virginia	--	--	•	--	--
Washington**	--	--	--	--	--
West Virginia	--	•	--	•	--
Wisconsin	--	•	•	•	--
Wyoming					
TOTAL	**1**	**17**	**20**	**8**	**2**

Shaded text signifies states that did not respond to the survey. -- indicates Rx that are not covered/excluded. *Arizona permits each MCO to set its own policy. **Washington does not cover smoking cessation, except for pregnant women enrolled in a smoking cessation program.

Table 9: Medicaid Criteria for Imposing Prior Authorization (PA), by State.

STATE	*Criteria for Requiring Prior Authorization (PA)*
Alabama	
Alaska	State regulation. Additional information is available at http://www.medicaid.state.ar.us
Arkansas	DUR Board Review
Arizona	
California	Efficacy, essential need, safety, misuse potential, and cost
Colorado	OBRA 90 and abuse
Connecticut	
Delaware	FDA guidelines
District of Columbia	
Florida	
Georgia	Criteria based on FDA approved-indications and generally accepted care standards
Hawaii	
Idaho	When an effective generic equivalent or other less expensive equally effective therapeutic alternatives are available
Illinois	Medical necessity, FDA Guidelines, PDL
Indiana	
Iowa	DUR Review Board
Kansas	DUR review board and state regulations
Kentucky	Criteria are developed for each drug class on PA
Louisiana	Treatment failure, condition that prevents use of preferred drug, potential drug interaction between another medication and preferred product, intolerable side effects
Maine	Potential misuse or abuse, therapeutic step therapy, less expensive alternatives
Maryland	Ensure use is medically documented and used for appropriate diagnosis
Massachusetts	Medical necessity
Michigan	Clinical Review
Minnesota	Clinical and cost effectiveness, medical necessity, Rx that need monitoring, less costly drug available, newly developed or modified, or considered to be cosmetic.
Mississippi	High risk, problem-prone Rx
Missouri	FDA medically accepted use, DUR Board recommendations
Montana	
Nebraska	Expensive, diagnosis, and medical necessity
Nevada	
New Hampshire	Abuse, cost and high utilization
New Jersey	DUR standards by the State
New Mexico	Medical necessity
New York	If the drug has a high cost or impact on the health of the Medicaid population; requires monitoring of prescribing protocols to protect the efficacy of the drug and the public health; has a history of misuse or abuse; or appears to be used in the Medicaid population in amounts inconsistent with non-Medicaid usage patterns
North Carolina	
North Dakota	DUR Board provides recommendations to the Department
Ohio	
Oklahoma	
Oregon	
Pennsylvania	Depends on drug or drug class
Rhode Island	
South Carolina	
South Dakota	Clinical and cost factors, fail first on antipsychotic prior to using Clozapine
Tennessee	
Texas	PA conducted in house by DUR staff
Utah	Clinical criteria established by the DUR Board
Vermont	Clinical criteria established by the DUR Board
Virginia	
Washington	Narrow therapeutic indication, safety or high risk/benefit ratio, potential for abuse or misuse and high cost
West Virginia	FDA approved use, medically accepted use, or step therapy
Wisconsin	Specific to class by DHFS recommendation
Wyoming	

Shaded text signifies states that did not respond to the survey.

Table 10: Medicaid Use of Fail-First Prescription Drug Policies, by State.

STATE	*Uses Fail-First Requirement*	*Rx or Class of Rx*
Alabama		
Alaska	•	COX-II inhibitors
Arkansas	•	Enbrel, Humira, Kineret, Non-sedating antihistamines, NSAIDs, PPIs
Arizona*		
California	•	PA requests require info on products tried/considered. State will exempt individuals if prescriber shows reasons not to try first-line Rx (e.g. allergy to a drug class)
Colorado		
Connecticut		
Delaware	•	Fail on Phos-lo, then use Renogel. Fail on amphetamines, then use Provigil
District of Columbia	•	Must fail generic before brand approved
Florida		
Georgia		
Hawaii	•	
Idaho	•	COX-II inhibitors, PPIs, Non-sedating antihistamines. Must fail generic before brand approved
Illinois	•	COX-II inhibitors for people under 65 years of age and PDL products
Indiana		
Iowa	•	Anti-Acne, Benzodiazpines
Kansas		
Kentucky	•	Based on criteria requirements for specific drug classes
Louisiana		
Maine	•	
Maryland		
Massachusetts	•	NSAIDs
Michigan	•	For PDL non-preferred Rx, may apply in certain clinical PA situations
Minnesota	•	PPI's not on PDL must first try H2 blocker. COX-II inhibitors must first try NSAIDs
Mississippi	•	Non-sedating antihistamines, Embrol, NSAIDs, PPIs
Missouri	•	HMG CoA , Second generation antihistamines, ACE inhibitors. See website for updates
Montana	•	Benzodiazepines and NSAIDs
Nebraska	•	Low-sedating antihistamines, COX-II inhibitors, PPIs
Nevada		
New Hampshire	•	
New Jersey	•	Many drugs subject to DUR standards
New Mexico		
New York		
North Carolina		
North Dakota		
Ohio		
Oklahoma	•	Antiulcer, ACE inhibitors, ACE/CCB combinations & ACE/HCTZ combinations, calcium channel blockers, NSAIDs
Oregon		
Pennsylvania	•	COX-II inhibitors
Rhode Island		
South Carolina	•	Must fail generic before brand approved
South Dakota		
Tennessee		
Texas		
Utah	•	Anti-inflammatory TNF inhibitors, anti-inflammatory Interlukin-1 receptor antagonists, growth hormones, PPIs, and Xenical
Vermont	•	See website for clinical criteria, www.path.state.vt.us
Virginia	•	Anti-ulcer drugs
Washington	•	Non-first line agents. Must fail generic before brand approved
West Virginia	•	NSAIDs
Wisconsin		
Wyoming		
TOTAL	**28**	

Shaded text signifies states that did not respond to the survey. *Arizona's 14 MCOs set individual policies.

Table 11: Medicaid Policies for Generic Prescription Drugs, by State.

STATE	Generics Required		Generics Encouraged				
	Generics Required	*Physician Can Override*	*Lower Co-Pays for Generics*	*Higher Dispensing Fee to Pharmacist*	*State Pays Generic Rate for Brand Rx*	*Generics on PDL/ Formulary*	*State Educates Physicians on Use of Generics*
Alabama							
Alaska	•	•					•
Arkansas	•	•		•	•		•
Arizona				•			
California*		•			•		
Colorado	•	•	•				
Connecticut	•	•			•		
Delaware	•				•		•
District of Columbia	•	•					•
Florida	•	•	•		•		•
Georgia	•	•	•	•	•	•	•
Hawaii	•	•			•		•
Idaho**	•	•					
Illinois			•	•	•	•	
Indiana							
Iowa*					•		
Kansas					•		•
Kentucky	•	•				•	•
Louisiana						•	
Maine			•				•
Maryland	•	•	•	•	•	•	
Massachusetts	•			•	•	•	•
Michigan						•	
Minnesota	•	•					•
Mississippi	•	•	•		•		•
Missouri	•	•			•		
Montana	•	•					
Nebraska	•	•			•		•
Nevada							
New Hampshire	•	•	•		•		
New Jersey	•	•					
New Mexico					•		•
New York	•	•	•	•		•	•
North Carolina	•	•	•	•	•		•
North Dakota			•		•		•
Ohio							
Oklahoma	•	•				•	
Oregon							
Pennsylvania	•	•					
Rhode Island							
South Carolina	•	•			•		
South Dakota					•		
Tennessee							
Texas***	•	•			•		•
Utah	•						•
Vermont	•	•					•
Virginia			•		•		
Washington	•	•			•	•	•
West Virginia	•	•			•	•	•
Wisconsin					•		•
Wyoming							
TOTAL	**30**	**28**	**12**	**8**	**26**	**11**	**24**

Shaded text signifies states that did not respond to the survey. *California and Iowa require least costly, appropriate Rx. **Idaho includes brand name Rx in FUL and MAC lists. ***Texas does not require generics, but its MAC program functions in a similar manner.

Table 12: Estimated Medicaid Use of Generics (When Available), by State.

STATE	*Estimated % of Rx Filled as Generics*	*Estimated % of Total Rx Spending for Generics*
Alabama		
Alaska		
Arkansas	49.0%	
Arizona	72.0%	35.0%
California		
Colorado	50.6%	17.7%
Connecticut		
Delaware		
District of Columbia		
Florida	46.0%	21.0%
Georgia	49.0%	17.0%
Hawaii		
Idaho		
Illinois	62.0%	30.0%
Indiana		
Iowa	51.0%	20.0%
Kansas	59.0%	24.0%
Kentucky	57.0%	
Louisiana	49.0%	22.0%
Maine	49.8%	15.7%
Maryland	50.0%	18.0%
Massachusetts	52.0%	17.5%
Michigan	50.0%	14.2%
Minnesota	49.4%	14.6%
Mississippi	44.0%	44.0%
Missouri		
Montana		
Nebraska	50.0%	10.0%
Nevada		
New Hampshire		
New Jersey	33.7%	14.2%
New Mexico		
New York		
North Carolina	48.1%	14.5%
North Dakota	50.0%	17.6%
Ohio		
Oklahoma	50.0%	23.0%
Oregon		
Pennsylvania		
Rhode Island		
South Carolina		
South Dakota		
Tennessee*		
Texas	48.0%	15.0%
Utah		
Vermont		
Virginia		
Washington	53.5%	17.4%
West Virginia	49.5%	20.6%
Wisconsin		
Wyoming		
AVERAGE	**50.9%**	**20.1%**

Shaded text signifies states that did not respond to the survey. Most estimates based on "educated guess" of State Medicaid Pharmacy officials and not on quantitative data analysis.

Table 13: Medicaid Prescription Drug Cost-Sharing Policies, by State.

STATE	*Populations Subject to Cost-Sharing*	*Co-Pay Amount*	*Rx Withheld for Failure to Pay Co-Pay***
Alabama			
Alaska	E, D, P	$2.00/Rx. P exempt if children <18	
Arkansas	E, D, P	$0-$10 Rx, co-pay $0.50; $10.01- $25 Rx, co-pay $1; $25.01-$50 Rx, co-pay $2; > $50 Rx, co-pay $3	
Arizona*			
California	E, D, P	$1/Rx, voluntary for E and D, foster P excluded from cost-sharing	
Colorado	E, D, P	$3/Rx, excludes individuals exceeding maximum annual co-pay of $150	
Connecticut	E, D, P	$1/Rx, excludes Rx for family planning drugs or supplies	
Delaware			
District of Columbia	E, D, P	$1/Rx	
Florida	Pharmacy Plus Only	$2/Rx for generics, $5/Rx for PDL, and $15/Rx for non-PDL	
Georgia	E, D, P	$0.50/Rx for PDL, $0.50-$3/Rx for non-PDL, depending on cost	
Hawaii			
Idaho			
Illinois	E, D, P	For regular Medicaid, no co-pay for generics and $3/Rx for brand name. For Pharmacy Plus, no co-pay if income < poverty level; if income > poverty level, $1/Rx for generics and $4/Rx for brand name	•
Indiana			
Iowa**	E, D, P	$1/Rx	
Kansas	E, D, P	Only 35% of enrollees have a $3 co-pay	
Kentucky	E, D, P	$1/Rx	•
Louisiana	E, D, P	$0.50-$3/Rx tied to cost of drug	
Maine	E, D, P	$0.50-$3/Rx tied to cost of drug and generic or brand name	
Maryland	E, D, P	$2/Rx for brand name only	
Massachusetts	E, D, P	$2/Rx	
Michigan	E, D, P	$1/Rx	•
Minnesota			
Mississippi	E, D, P	$1/Rx for generic, $2/Rx for brand preferred, $3/Rx for non-preferred	
Missouri	Uninsured Adults & Waiver Children	0-$10 Rx, co-pay $5.50; $10.01-$25 Rx, co-pay $6; $25.01 and higher Rx, co-pay $7; Waiver children up to 300% of poverty, co-pay $9/Rx	
Montana	E, D	Up to $5/Rx to a maximum of $25/month	
Nebraska	E, D, P	$2/Rx	•
Nevada			
New Hampshire	E, D, P	$0.50/Rx for generics and $1/Rx for brand name	
New Jersey			
New Mexico	Working Disabled and SCHIP	$2/Rx	
New York	E, D, P	$0.50/Rx for generics and OTCs, $2/Rx for brand name, excludes pregnant women and special needs children	
North Carolina	E, D, P	$1/Rx for generics and $3/Rx for brand name	
North Dakota	E, D, P	$3/Rx for brand name	
Ohio			
Oklahoma	E, D, P	<$29.99 Rx, then $1/Rx; ≥ $30, then $2/Rx	
Oregon			
Pennsylvania	E, D, P	$1/Rx	•
Rhode Island			
South Carolina	E, D, P	$2/Rx (Pharmacy Plus co-pays are $10/Rx for	

STATE	*Populations Subject to Cost-Sharing*	*Co-Pay Amount*	*Rx Withheld for Failure to Pay Co-Pay***
		generic, $15/Rx for brand, and $20/Rx for Rx requiring prior authorization)	
South Dakota	E, D, P	$2/Rx	
Tennessee			
Texas			
Utah	E, D, P	$3 to $15/month/person	•
Vermont	E, D, P	$0-$29.99 Rx, co-pay $1; $30.00 - $49.99 Rx, co-pay $2; ≥ $50 Rx, co-pay $3	
Virginia	E, D, P	$1/Rx for generic and $2/Rx for brand name	
Washington			
West Virginia	E, D, P	< $10 Rx, then $0.50/Rx, $10 -$24.99 Rx, then $1/Rx, > $25 Rx, then $2/Rx	•
Wisconsin	E, D, P	$1/Rx for legend Rx and $0.50 OTC	
Wyoming			
TOTAL	**35**		**7**

Shaded text signifies states that did not respond to the survey. E= elderly, D= disabled, P= parents. *Arizona implemented co-payments on 10/01/03 of $4 generic and $10 for brand if generic is available. The state also permits Rx to be withheld for failure to pay the co-payment. **On 07/01/03, Iowa implemented co-payments of $1/Rx for generic and $0.50 - $3.00/Rx for brand based on cost of Rx. ***Rx can be withheld in Illinois only with a waiver; in Kentucky, the pharmacy may not withhold service when the prescription is presented and the recipient must receive prior notice; in Michigan, Rx can be withheld on follow-up visits if beneficiary has reused to pay co-payments on previous visits and has received notice; in Nebraska, Rx may be withheld if patient doesn't pay subject to pharmacy credit policy and pharmacist must notify patient; in Pennsylvania, pharmacy may refuse refill if they can document that the patient is able to pay, but refuses; in West Virginia Rx may be withheld if there is clear evidence that the patient has the ability to pay; and in Wisconsin, Rx may be withheld for regular Medicaid and medically needy groups.

Table 14: Medicaid Over-the-Counter (OTC) Coverage Policies, by State.

STATE	*Covers any OTCs*	*How OTC Coverage Decisions are Made*	*Cover Rx newly available as OTC*
Alabama			
Alaska	•	DUR Committee	
Arkansas	•		•
Arizona	•	Cost effectiveness versus legend medication	
California	•	Decisions to add OTCs to the PDL are handled in same manner as legend Rx	
Colorado	•	Cover aspirin and insulin	
Connecticut	•	The following not covered: antacids, H2 blockers, birth control, diabetic supplements, vitamins, cough, cold, allergy, antihistamines, decongestants, topical and vaginal antifungals, and artificial tears	
Delaware	•	DUR Committee	•
District of Columbia	•		
Florida	•		
Georgia	•		
Hawaii	•		•
Idaho			
Illinois	•	Prescription is required	•
Indiana			
Iowa	•	Historically from DUR committee in coordination with PA suggestions	
Kansas	•	No nutritional supplements are included	•
Kentucky	•	Most new OTCs aren't added to the formulary which is based on CMS excludable guidelines	•
Louisiana	•	Limited coverage for OTCs	
Maine	•	Cost effectiveness versus legend medication	•
Maryland	•		
Massachusetts	•	Cost effectiveness versus legend medication	
Michigan	•	State P&T Committee recommendation	
Minnesota	•	Recommendation by Drug Formulary Committee. State mandates coverage for antacids, aspirin, formulary products and insulin	
Mississippi	•	Must be rebateable and cost-effective	
Missouri		07/01/02 OTC's became non-covered. 02/01/03 covered list of nonaligned OTCs less costly then their equivalent legend Rx	•
Montana	•	DUR Board	
Nebraska	•	Based on medical necessity and rebate availability	
Nevada			
New Hampshire	•	OTC coverage is under review	
New Jersey	•	EPSDT requirements and cover cost effective alternatives to legend Rx	
New Mexico	•		
New York	•	Cost effectiveness and prevention of more expensive interventions	
North Carolina**			
North Dakota	•	DUR Board	
Ohio			
Oklahoma	•	Covers insulin, family planning and OTC antihistamines for children	
Oregon			
Pennsylvania	•	Covers categories defined in regulation	•
Rhode Island			
South Carolina	•		•
South Dakota			
Tennessee			
Texas	•	Does not cover vitamins	•
Utah	•	Drug Program Managers	
Vermont	•		
Virginia	•	OTC list	
Washington	•	Covered if less costly than prescription; family planning is covered	
West Virginia	•	DUR board recommends OTC products to add to the OTC formulary	
Wisconsin	•	State Administrative Code	•
Wyoming			
TOTAL	**39**		**12**

Shaded text signifies states that did not respond to the survey.

Table 15: Medicaid Prescription Drug Payment Practices, by State.

STATE	Estimated Acquisition Cost (EAC)	EAC Includes Dispensing Fee	Dispensing Fee	Rebate Payments go to Medicaid*	State Receives a Supplemental Rebate
Alabama					
Alaska	AWP-5%		$3.45- $11.46	•	
Arkansas	AWP-14% for brand name and AWP-20% for generic		$5.51	•	
Arizona**					
California	AWP-10%		$3.55	•	•
Colorado	AWP-13.5% for brand, AWP - 35% for generic		$4 retail, $1.89 institutional		
Connecticut	AWP-12%		$3.60	•	
Delaware	AWP-14%, AWP-16% for non-traditional pharmacy		$3.65	•	
District of Columbia	AWP-10%	•	$4.50		
Florida***	Lower of WAC+7%, or AWP-13.25%		$4.23 retail and $4.73 institutional	•	•
Georgia^	AWP-10%		For profit $4.63 and non-profit $4.33	•	
Hawaii	AWP-10.5%		$4.67	•	
Idaho	AWP-12%	•	$4.94 regular dose, $5.54 unit dose		
Illinois	Regular Medicaid: AWP-12% for single source and AWP-25% for multi-source Rx. Pharmacy Plus: AWP-14% for single source and AWP-25% for multi-source; MAC/ FUL (if applicable)		Regular Medicaid: $3.40 brand name, $4.60 generic Pharmacy Plus: $2.25 for both brand and generic	•	•
Indiana					
Iowa	AWP-10%		$5.17	•	
Kansas	AWP-13% for single source Rx, and AWP-27% for multi-source Rx		$3.40	•	
Kentucky	AWP-12%		$4.51		
Louisiana	AWP-13.5% for independent pharmacist, AWP-15% for retail chains		$5.77 maximum	•	•
Maine	AWP-13%		$3.35- $5.35, fees depend on whether it is a single ingredient or compound drug	•	
Maryland	AWP-10% or WAC+10%		$4.69 retail generic, $3.69 retail brand, $5.65 LTC generic, and $4.65 LTC brand		
Massachusetts	WAC+6%	•	$3.50 brand name and $5.00 generic	•	
Michigan	AWP-15.1% or 13.5%, depending on the # of pharmacy sites		$3.77, except compound Rx, compound Rx fee is $6-10		•
Minnesota	AWP-11.5%	•	Most Rx's $3.65, IV compounded $8.00/ bag for regular IV Rx, $14/bag for chemotherapy Rx, $30/bag for TPN solutions to 1 liter and $44/bag for TPN > 1 liter	•	•
Mississippi	AWP-12%		$3.91	•	

Missouri	AWP-10.43% or WAC+10%; MAC/FUL (if applicable)		In-state $8.04, $8.19 for LTC. Out-of-state, $4.09, $4.24 for LTC	•	
Montana	AWP-15%		$2- $4.70, and additional $0.75 for dispensing unit dose		
Nebraska	AWP-11%		$3.27-$5.00	•	
Nevada					
New Hampshire	AWP-12%		$2.50		
New Jersey	AWP-10%		$3.73; pharmacy adds $0.15 for impact allowance, $0.08 for pharmaceutical consultation, and $0.11 for 24-hour availability	•	
New Mexico	AWP-12.5%		$3.65		
New York	Lower of AWP-10%; FUL; or usual and customary		$3.50 brand name and $4.50 generic		
North Carolina	AWP-10%		$5.60 brand and $4.00 generic, no dispensing fees for same month refills	•	
North Dakota	AWP-10%		$5.10	•	
Ohio					
Oklahoma	AWP-12%		$4.15 maximum		
Oregon					
Pennsylvania	AWP-10%		$4.00	•	
Rhode Island					
South Carolina	AWP-10%		$4.05	•	
South Dakota	AWP-10.5%		$4.75-$5.55	•	
Tennessee					
Texas^^	Lesser of AWP – 15% or WAC + 12%		$5.27 + (EAC/0.98 - EAC)	•	
Utah	AWP-15%		$3.90 in urban areas, $4.40 in rural areas		
Vermont	AWP-11.9%		$4.25	•	•
Virginia	AWP-10.25%		$4.25	•	•
Washington	AWP-14%, AWP-50% for multisource drugs with 5 or more labelers		$4.20 to $5.20		
West Virginia	AWP-12%		$3.90 for a single ingredient, $4.90 for compound Rx	•	•
Wisconsin	AWP-11.25% or MAC price		$4.88 to $ 40.11	•	
Wyoming					
TOTAL		**4**		**29**	**9**

Shaded text signifies states that did not respond to the survey. *Drug rebate payments that do not go to the state's general fund; Virginia splits rebate payments between Medicaid and the general fund. ** Arizona's 14 MCOs set individual policies. ***Florida's dispensing fee became $.23 for all Rx on July 1, 2003. ^Georgia has a most favored pricing policy: If a provider accepts a lower rate than the state's standard rates, then they must bill Medicaid the lowest rate they accept from any payer. ^^Texas limits reimbursement to the MAC and has lower payment rates for Rx purchased from the manufacturer or central purchasing entity (i.e. chain warehouse).

Table 16: Most Commonly Dispensed Medicaid Prescription Drugs, by State.

STATE	1	Program Cost	Monthly Unit Cost	2	Program Cost	Monthly Unit Cost	3	Program Cost	Monthly Unit Cost	4	Program Cost	Monthly Unit Cost	5	Program Cost	Monthly Unit Cost
Alabama															
Alaska	Antidepressants	$4.7 Million	$57.98	Narcotic Analgesics	$5.3 Million	$71.89	Antipsychotic tranquilizers	$7.1 Million	$77.45	Anticonvulsants	$3 Million	$47.89	Antiulcerants	$3.9 M	$62.94
Arkansas*	Zithromax	$1.3 Million	$38.95	Furosemide	$189,000	$7.44	Hydrocodone /APAP	$297,000	$13.10	Albuterol	$471,000	$24.40	Amoxil	$209,000	$12.41
Arizona**															
California	Celebrex 200mg cap, 00025-1525-31	$74.3 Million	$2.61 T	Prevacid 30mg cap, 00300-3046-13	$76.5 Million	$4.23 T	Lipitor 10mg tab, 00071-0155-23	$35,072.44	$1.65 T	Codeine number 3, w/APAP 00093-0150-10	$4.1 Million	$0.21 T	Vioxx 25 mg tab, 00006-0110-68	$31.7 Million	$2.20 T
Colorado	Hydrocodone w/ APAP 5/500mg		$8.23 average cost	Lansoprazole 30mg		$126.07 average cost	Furosemide 40mg		$6.07 Average cost	Albuterol 90 mg		$18.42	Furosemide 20mg		
Connecticut	Albuterol 90mg, 17gm		$7.47	Prozac, 00777-3105-30		$69.71	Ultram, 00045-0659-60		$68.17	Ibuprofen, 400mg, 100each		$3.38	Glucophage, 00087-6060-5		$58.87
Delaware	Albuterol 90mg, 17gm	$600,000 estimated	$7.47	Prevacid 30	$2.1 Million	$141.00	Percacet	$126,000	$9.00	Zyrtec10mg	$660,000 estimated	$57	Celebrex	$1.2 Million estimated	$113
District of Columbia	Albuterol 90mg, 17gm		$7.47	Codeine Phosphate/APAP, 39778-0579-40		$167.07	Furosemide, 20 mg, 100 each		$2.10	Diphenhydramine HCl Syrup 12.5 mg/5 ml, 450 ml			Ranitidine, 54569-4507-02		$26.74
Florida	Albuterol	$13.3 Million		Furosemide			Prevacid	$61.3 Million		Hydrocodone/APAP	$5 Million		Alaprazolam	$3.6 Million	
Georgia	Celebrex, 0025-1525	$13.5 Million	$92.24	Albuterol, 59930-1560	$2.8 Million	$23.19	Prilosec 00186-0742	$13.9 Million	$118.36	Zithromax, 00069, 3060	$4.3 Million	$38.99	Amoxil, 00029-6049	$1.4 Million	$13.55
Hawaii	Lipitor 10mg			Cimetidine 400mg			Albuterol inhaler 90mcg			Celebrex 200mg			Aspirin 81mg		
Idaho	Hydrocodone/ APAP 500, 7.5mg	$350,038	$0.19 T	Albuterol MDI	$524,417	$0.85 T	Amoxicillin 250 mg	$240,320	$0.04 T	Propoxyphene/APAP100/650	$309,837	$0.23 T	Furosemide 40	$134,710	$0.06 T
Illinois	Furosemide	$4.2 Million	$6.25	Prevacid	$70.4 Million	$129.06	Ibuprofen	$3.6 Million	$8.17	Albuterol	$6.7 Million	$22.11	Lisinopril	$6.4 Million	$23.93
Indiana															
Iowa	Ranitidine 150mg		$17.68	Furosemide 40mg		$6.59	Albuterol 90mcg, 17gm		$22.82	Zoloft 100mg	$3.2 Million	$84.06	Hydrocodone /Acetaminophen		$8.21
Kansas	Prilosec	$4.8 Million		Celebrex A	$3 Million		Furosemide		$183,470	Celexa	$1.7 Million		Prevacid		$2.6 Million
Kentucky	Ranitidine	$7.3 Million	$31.67	Furosemide	$815,048	$6.43	Lipitor	$12 Million	$80.73	Zithromax	$5.8 Million	$40.12	Albuterol	$3.2 Million	$24.65
Louisiana	Celecoxib	$9.9 Million		Loratadine	$7 Million		Omeprazole	$10.5 Million		Celiriizine	$4 Million		Lanasoprazole	$9.3 Million	
Maine	Protonix	$9.3 Million	$2.79 T	Hydrocodone/ APAP 5/500	$406,000	$0.04 T	Albuterol Inhaler	$1.1 Million	$0.81 T	Lipitor 10mg	$3.6 Million	$1.77 T	Metoprolol 50mg	$300,00	$0.09 T
Maryland	Risperdal	$18.8 Million	$152.41	Furosemide	$550,000	$4.45	Zyprexa	$30.4 Million	$275.68	Depakote	$6.4 Million	$68.18	Zoloft	$7.2 Million	$78.23
Massachusetts	Albuterol	$5.6 Million		Lipitor	$25.8 Million		Furosemide	$1.3 Million		Clonazepam	$3 Million		Neurontin	$25.5 Million	
Michigan	Hydrocodone BIT/Acetaminophen	~$4 M	~$10.38	Furosemide	$1.45 M	~$5.01	Alorvastatin Calcium	$22.5 M	~$76.96	Levothyrodne Sodium	~$3.5 M	~$13.06	Paroxetine HCL	~$18.9 M	~$72.57
Minnesota***	Protonix 40mg	$13.8 Million	$107.67	Zoloft 100mg	$3.6 Million	$77.49	Lipitor 10mg	$3 Million	$70.51	Celexa 20mg	$3.1 Million	$82.06	Albuterol Inhaler	$703,361	$21.02
Mississippi	Furosemide	$1.2 Million		Hydrocodone	$2.5 Million		Norvasc	$8.3 Million		Zithromax	$5.2 Million		Proxychene Napsylate w/APAP	$1.7 Million	
Missouri	Hydrocodone/APAP	$3.9 Million	$12.45	Furosemide	$2.4 Million	$8.09	Amoxicillin	$1.7 Million	$6.34	Potassium Supplements	$4.3 Million	$17.96	Levothyrodne	$4.4 Million	$17.96
Montana	Prilosec, 00186-0606-68		$321.37	Prozac 00777-3105-30		$71.30	Hydrocodone/ APAP 500mg-7.5mg, 100 each		$18.37	Zoloft 00049-429120-41		$218.86	Albuterol Inhaler 90mcg, 17gm		$7.47
Nebraska	Propoxyphene napsylate 100mg/APAP	$495,444.78	$0.01 T	Furosemide 40mg	$231,627.06	$0.06 T	Sertraline 100mg	$2.9 Million	$2.36 T	Albuterol Inhaler	$720,797.64	$5.65	Lanesoprazole 30mg	$1.6 Million	$4.12
Nevada															
New Hampshire	Acetaminophen	$240,224	$0.07 T	Furosemide	$225,224	$0.16 T	Levothyroxine Sodium	$365,852	$0.39 T	Zoloft	$2.3 Million	$82.06	Amoxicillin	$183,154	$0.07
New Jersey	Celebrex 200mg	$9.2 Million	AWP- 10%	Prevacid 30mg	$9.4 Million	AWP-10%	Lipitor 10mg	$4.8 Million	AWP- 10%	Norvasc 5mg	$3.4 Million	AWP- 10%	Proventil 8mg Inhaler	$1.5 Million generic, $0.2 Million brand-name	AWP-10
New Mexico****	Prilosec 20mg, 00186-074231	$2.1 Million	$137.48	Ortho Tricyclen 00062-190315	$450,000	$36.50	Albuterol Inhaler 17 gm, 59930156001	$275,000	$19.00	Lipitor 10mg 00071-015523	$720,000	$63.00	Fosamax 70mg, 00006-0031-3144	$675,000	$62.36
New York	Lipitor 10 mg	$35.6 Million	$68.95	Albuterol Aerosol	$12.2 Million	$25.08	Celebrex 200mg caps	$50.3 Million	$107.84	Prevacid 30mg caps	$58.8 Million	$136.34	Prilosec 20mg caps	$53.4 Midlion	$149.13
North Carolina	Hydrocodone/ APAP/J	$4.8 Million	$0.22 T	Furosemide	$2.8 Million	$0.17 T Generic	Albuterol 90 mcg, 17gm inhalers and tablets	$5.7 Million	$0.26 T	Prevacid	$37.7 Million	$3.98 T	Norvasc U	$13.8 Million	$1.62 T
North Dakota	Furosemide	$221,171		Zoloft	$1.4 Million		Synthr**	$254,824		Potassium Chloride	$1.5 Million		Risperdal	$4.2 Million	

STATE	1	Program Cost	Monthly Unit Cost	2	Program Cost	Monthly Unit Cost	3	Program Cost	Monthly Unit Cost	4	Program Cost	Monthly Unit Cost	5	Program Cost	Monthly Unit Cost
Ohio															
Oklahoma	Furosemide	$629, 933		Hydrocodone	$1.5 Million		Ranitidine HCL	$1.7 Million		Risperdal	$10 Million		Potassium Chloride	$823,785	
Oregon															
Pennsylvania	Zithromax Tab 250 mg	$3.1 Million	$6.82	Albuterol Inhaler 17Gm	$2.7 Million	$1.13	Levaquin Tab 500 mg	$4.1 Million	$9.06	Cipro Tab 500mg	$3.2 Million	$4.92	Prevacid Cap 30mg	$21.1 Million	$4.16
Rhode Island															
South Carolina	Albuterol Inhaler 90mcg	$1.6 Million	$30.81	Norvasc 10mg	$3.7 Million	$63.77	Lipitor 10mg	$3.4 Million	$60.53	Zyrtec 10mg	$2.8 Million	$51.14	Prilosec 20mg	$6.8 Million	$134.24
South Dakota	Prevacid 30mg, 00300-3046-13	$1 Million	$4.14	Furosemide 40 mg 100 each, 00378-0216-0	$52,784	$0.09	Celebrex 200 mg, 00025-1525-31	$667,311	$2.58	Zithromax 00069-3060-75	$26,716	$6.78	Prilosec 20mg, 00186-0742-31	$979,694	$4.13
Tennessee															
Texas	Ibuprofen	$6.3 Million		Hydrocodone Acetaminophen	$6.2 Million		Zithromax	$17.1 Million		Albuterol Sulphate	$5.8 Million		Furosemide	$2.7 Million	
Utah	Prevacid 00300304813	$2.5 Million	$113.75	Hydrocodone/APAP7.5/500 52544638505	$243.5 Million	$11.67	Celebrex 00025152531	$1.5 Million	$85.60	Hydrocodone/APAP 5/500, 2544034905	$122,282.65	$61.81	Albuterol Inhaler 59930136001	$122,282.65	$23.90
Vermont	Prilosec, 00186-0606-66		$314.59	Lipitor, 54868-3934-00		$62.80	Albuterol, 90 mcg, 17 gm		$7.47	Prozac, 00777-3105-30		$69.79	Prevacid, 00300-3046-11		$329.02
Virginia^															
Washington	Hydrocodone/ APA, 500mg-7.5 mg 100ea/ch	$3.1 Million	$9.36	Furosemide	$1.3 Million	$6.58	Albuterol	$2.5 Million	$18.36	Ranitidine	$1.7 Million	$12.56	Lipitor	$9.5 Million	$74.12
West Virginia	Ranitidine, GSN 011673	$1.1 Million	$13.91	Propyphene Napsylate, GSN 004273	$1.1 Million	$14.48	Albuterol, 90 mcg, GSN 065057	$1.5 Million	$23.72	Furosemide 40 mg, GSN 006209	$33,596	$5.39	Hydrocodone/acetaminophen 5-500mg, GSN 4204	$414,194	$6.99
Wisconsin	Analgesics Narcotics	$22.8 Milion	$46.47	Antipsychotics Atypicals	$65.4 Million	$178.27	Antidepressants-SSRI's	$26.9 Million	$75.22	Diuretics Loop	$1.9 Million	$8.92	ACE Inhibitors	$6.7 Million	$28.63
Wyoming															

Shaded text signifies states that did not respond to the survey. T= tablet cost, *Arkansas data are from 01/02 - 3/02. **Arizona data are collected by category not by drug, ***Minnesota data do not include gross cost rebates. ****New Mexico data are highly approximated cost figures. ^Virginia data are based on generic codes or by therapeutic class.

Table 17: Most Costly Medicaid Prescription Drugs (Total Expenditures), by State.

STATE	1	Population	Unit Cost	2	Population	Unit Cost	3	Population	Unit Cost	4	Population	Unit Cost	5	Population	Unit Cost
Alabama															
Alaska	Antipsychotic	Medicaid	$104.96	Narcotic Analgesics	Medicaid	$71.89	Antidepressants	Medicaid	$57.08	Unclassified Rx such as Nupogen, hemophiliac blood factors	Medicaid	$188.33	Antiulcerants	Medicaid	$89.28
Arkansas*	Zyprexa		$298.76	Synagis		$16.39	Risperdal		$157.84	Prevacid		$127	Zithromax		$36.85
Arizona**															
California	Zyprexa 10 mg 00002-4117-60		$6.21	Prevacid 30mg cap, 00300-3046-13			Celebrex 200mg cap, 00025-1525-31		$2.61	Prilosec 20mg cap 200188-0742-31		$4.38	Zyprexa 5mg tab, 00002-4115-60		$5.61
Colorado	Clozaril 100mg, 00078-012705		$197.78 Average cost	Clozapine 100mg, 00172-4356060		$93.17 average cost	Albuterol Inhaler, 59930-156001		$14.96 Average cost	Fluoxetine 20mg, 00555-087702		$53.28 Average cost	Humidin 70/30, 000026-715001		
Connecticut															
Delaware	Prevacid 30		$141.00	Antihemophiliac Factor 8		$458	Synogest 100mg		$1,003.40	Nexium 40		$142	Zyprexa10		$275
District of Columbia															
Florida															
Georgia	Prilosec 00186-0742		$118.36	Celebrex 00025-1525		$92.24	Zyprexa 0002-4117		$350.49	Synagis 60574-4111		$1395.62	Vioxx 00006-0110		$73.85
Hawaii	Zyprexa 10mg			Oxycontin 80mg			Lipitor 10mg			Pluvix 75mg			Celebrex 200mg		
Idaho	Zyprexa 10		$8.46	Prevacid 30		$4.07	Zyprexa 5		$5.58	Prilosec 20		$4.06	Seroquel 200		$4.83
Illinois	Prevacid		$120.06	Zyprexa		$271.06	Risperdal		$165.47	Zocor		$108.82	Seroquel		$195.78
Indiana															
Iowa	Zyprexa 10mg		$319.26	Zoloft 100mg		$64.06	Prevacid 30mg		$119.34	Risperdal 1mg		$117.15	Seroquel 200mg		$363.72
Kansas	Zyprexa	D	$210.55	Risperdal	D	$116.53	Seroquel	D	$117.42	Prilosec	E	$102.58	Neurontin	D	$61.90
Kentucky	Zyprexa	Adult	$307.48	Lipitor	Adult	$80.73	Risperdal	Adult	$178.99	Celebrex	Adult	$97.87	Neurontin	Adult	$120.55
Louisiana	Lansoprazole			Palivizumab			Celecoxib			Olanzapine			Clopidogrel		
Maine	Protonix 40mg	40-49	$2.79	Lipitor 10mg	70-79	$1.77	Celebrex 200mg	Over 60	$2.24	Zoloft 100mg	30-50	$2.07	Lipitor 20mg	50-79	$2.66
Maryland	Zyprexa		$275.68	Risperdal		$152.41	Prevacid		$121.06	Seroquel		$167.11	Depakote		$68.18
Massachusetts	Zyprexa	D	$55.8 Million	Risperdal	D	$32 Million	Seroquel	D	$27 Million	Lipitor	D	$25.8 Million	Neurontin	D	$25.5 Million
Michigan	Olanzapine		$309.43	Risperidone		$187.92	Quetiapine Fumarate		$190.73	Atorvastatin Calcium		$78.96	Paroloprazole Sodium Sesquihydrate		$93.52
Minnesota	Protonix 40mg		$107.67	Zyprexa 10mg		$415.59	Seroquel 200mg		$343.81	Zyprexa 15mg		$497.18	Zyprexa 5mg		$230.53
Mississippi	Zyprexa		$309.26	Prevacid		$131.72	Prilosec		$141.85	Risperdal		$161.62	Celebrex		$85
Missouri	Olanzapine	Permanently Totaled Disabled (PTD,) Old Age Assistance (OAA)	$265.53	Risperidone	PTD and OAA	$152.45	Celecoxib	PTD and OAA	$103.60	Quetiapine	PTD	$173.54	Atorvastatin	PTD	$82.22
Montana	Zyprexa			Risperdal			Prilosec			Prevacid			Oxycontin		
Nebraska	Lanasoprazole 30 mg	D	$4.12	Omeprazole 10mg	D	$3.67	Olanzapine 10mg	Mental health	$8.58	Celecoxib 200mg	D	$2.58	Gemtatine 100mg	D	$2.36
Nevada															
New Hampshire	Zyprexa	MN	$7.37	Risperdal	MN	$3.23	Seroquel	MN	$2.18	Zoloft	MN	$2.16	Depakote	MN	$ 97
New Jersey	Zyprexa 10mg		AWP-10%	Prevacid 30mg		AWP-10%	Celebrex 200mg		AWP-10%	Prilosec 20mg,		AWP-10	Combivir		AWP-10%
New Mexico***	Prilosec 20 mg	General/Medicaid	$137.48	Zyprexa 10 mg tab	General/Medicaid	$295	Prevacid 30mg cap	General/Medicaid	$127	Celebrex 200mg	General/Medicaid	$95.00	Zyprexa 5mg	Nursing Home	$170.00
New York	Zyprexa 10mg	Mental Health	$361.35	Combivir	AIDS	$579.93	Prevacid 30mg caps	Ulcer patients	$136.34	Prilosec 20mg caps		$149.13	Celebrex 200 mg caps		$107.84
North Carolina	Zyprexa	D	$7.51	Prevacid	Over 65	$3.98	Risperdal	D	$3.61	Prilosec	D	$4.25	Lipitor	Aged	$2.59
North Dakota	Zyprexa		$2.7 Million	Risperdal		$2.1 Million	Zoloft		$1.4 Million	Seroquel		$1.3 Million	Prevacid		$1 Million
Ohio															
Oklahoma	Zyprexa			Risperdal			Prevacid			Paxil			Zoloft		
Oregon															
Pennsylvania	Prevacid Cap 30mg		$4.16	Zyprexa Tab 10mg		$8.87	Prilosec Cap 20mg		$4.15	Celebrex Cap 200mg		$2.59	Zyprexa Tab 5mg		$5.70
Rhode Island															

STATE	1	Population	Unit Cost	2	Population	Unit Cost	3	Population	Unit Cost	4	Population	Unit Cost	5	Population	Unit Cost
South Carolina	Prilosec 20mg	E, D	$134.24	Zyprexa 10mg	E	$377.88	Prevacid 30mg	E, D	$128.67	Celebrex 200 mg	E	$100.39	Nexavasc 10mg	E, D	$63.77
South Dakota	Zyprexa 10mg	D	$8.63	Prevacid 30mg	D	$4.14	Prilosec	D	$4.13	Celebrex 200mg	D	$2.58	Monarch-M	D	$.83
Tennessee															
Texas	Zyprexa		$69.90	Risperdal		$50.50	Celebrex		$30.60	Prevacid		$26.40	Prilosec		$24.80
Utah	Zyprexa		$694.60	Risperdal		$470.25	Seroquel		$240.46	Prevacid		$334.91	Zoloft		$127.13
Vermont	Zyprexa	D		Zocor	D, E		Protonix	D, E		Seroquel	D		Risperdal	D	
Virginia****															
Washington	Zyprexa		Avg. $292.81	Risperdal		$163.32	Neurontin		Avg. $125.45	Oxycontin		Avg. $190.76	Protonix		Avg. $87.67
West Virginia	Olanzapine 10mg, GSN 027960		$345.40	Fluoxetine 20mg, GSN 046214		$102.21	Paroxetine 20mg, GSN 046223	Unknown	$78.93	Gabapentin 300 mg, GSN 021414		$96.23	Sertraline 100mg, GSN 045229		$81.57
Wisconsin	Antipsychotics Atypicals	MN	$178.27	PPIs	$127.95	MN	SSRIs	MN	$75.22	Analgesics-Narcotics	MN	$48.47	Anticonvulsants w/ secondary conditions	MN	$69.43
Wyoming															

Shaded text signifies states that did not respond to the survey. MN=Medically Needy, D=Disabled, E=Elderly. *Arkansas data are from 01/02 - 03/02. **Arizona data are collected by category, not by Rx. ***New Mexico data are highly approximated cost figures. ****Virginia data are based on generic codes or by therapeutic class. Dollar amounts for unit costs vary greatly: some states have furnished dose costs, other states monthly unit costs and finally yearly costs

Table 18: Medicaid Prospective Drug Utilization Review (PRODUR) Criteria, by State.

STATE	Duplicative Therapies	Drug to Drug Interactions	Dosage	Duration	Diagnostic Appropriateness	Other	State has Automated System
Alabama							
Alaska	•	•	•	•	•		•
Arkansas	•	•	•	•	•		
Arizona	•	•	•	•	•		
California	•	•	•	•	•		•
Colorado	•	•	•	•	•		•
Connecticut	•	•	•	•	•		•
Delaware	•	•	•	•	•	Compliance, Pregnancy	•
District of Columbia	•	•	•	•			•
Florida	•	•	•	•	•		•
Georgia	•	•	•	•			•
Hawaii	•	•	•	•	•		
Idaho	•		•	•			
Illinois	•	•	•		•	Early refill	•
Indiana							
Iowa	•	•	•	•		Early refill; excess supply; duplicate claim; dose and cost effectiveness (optional)	
Kansas	•	•	•	•	•		•
Kentucky	•	•				Early refill; ingredient duplication	
Louisiana	•	•		•	•		•
Maine	•	•	•	•	•		•
Maryland	•	•	•	•	•	Early refill	•
Massachusetts	•	•	•		•	Early refill	
Michigan	•	•	•	•		Early refill	•
Minnesota	•	•	•	•	•		
Mississippi	•	•	•	•	•		
Missouri	•	•	•	•	•		
Montana	•	•	•	•			•
Nebraska	•	•	•	•	•		
Nevada							
New Hampshire	•	•	•	•			•
New Jersey	•	•	•	•	•		
New Mexico	•	•	•	•			•
New York	•	•	•	•	•		•
North Carolina	•	•	•	•		Diagnostic appropriateness as determined by DUR Board	
North Dakota	•	•	•	•			•
Ohio							
Oklahoma	•	•	•	•		Early refills	
Oregon							
Pennsylvania	•	•	•			Early or late refills	•
Rhode Island							
South Carolina	•	•	•	•	•		•
South Dakota	•	•	•	•	•		•
Tennessee							
Texas	•	•	•	•			•
Utah	•	•	•	•	•	Drug-Disease; addictive; toxicity; and early refill	
Vermont	•	•	•	•	•		•
Virginia	•	•	•	•	•		•
Washington	•	•	•	•	•		•
West Virginia	•	•	•	•			•
Wisconsin	•	•	•	•	•		•
Wyoming							
TOTAL	43	42	41	39	28		21

Shaded text signifies states that did not respond to the survey.

Table 19: Medicaid Retrospective Drug Utilization Review (RetroDUR) Criteria, by State.

STATE	Rx Rates or Costs, by Rx	Rx Rates or Costs, by Rx Class	Rx Rates or Costs by Brand vs. Generic	Rx Rates or Costs by Disease/ Condition	# of Rx by Eligibility Group	Rx Costs by Eligibility Group	Trends in Utilization	Trends in Costs
Alabama								
Alaska	•	•	•	•	•	•	•	•
Arkansas	•	•	•	•	•	•	•	•
Arizona*								
California	•	•		•			•	•
Colorado	•	•	•	•			•	•
Connecticut	•	•	•	•			•	•
Delaware	•	•		•			•	•
District of Columbia	•	•	•	•	•	•	•	•
Florida	•	•	•	•	•	•	•	•
Georgia	•	•	•	•	•	•	•	•
Hawaii	•	•	•	•	•	•	•	•
Idaho	•	•	•	•			•	•
Illinois		•	•	•			•	•
Indiana								
Iowa	•	•	•	•	•	•	•	•
Kansas	•	•	•	•	•	•	•	•
Kentucky		•		•			•	•
Louisiana	•	•	•	•			•	•
Maine	•	•	•	•	•	•	•	•
Maryland	•	•	•	•	•	•	•	•
Massachusetts	•	•	•		•	•	•	•
Michigan	•	•	•		•	•	•	•
Minnesota	•	•	•	•			•	•
Mississippi	•	•	•	•	•	•	•	•
Missouri	•	•		•	•	•	•	•
Montana	•	•	•				•	•
Nebraska	•	•	•	•			•	•
Nevada								
New Hampshire	•	•	•	•			•	•
New Jersey							•	•
New Mexico	•	•	•	•	•	•	•	•
New York	•	•	•	•	•	•	•	•
North Carolina	•	•	•	•	•	•	•	•
North Dakota	•	•	•	•	•	•	•	•
Ohio								
Oklahoma	•	•	•	•	•	•	•	•
Oregon								
Pennsylvania	•	•	•	•			•	•
Rhode Island								
South Carolina	•						•	•
South Dakota	•	•	•				•	
Tennessee								
Texas	•	•	•	•			•	•
Utah	•	•	•				•	•
Vermont								
Virginia								
Washington	•	•	•	•	•	•	•	•
West Virginia	•	•	•		•	•	•	•
Wisconsin	•	•	•	•			•	•
Wyoming								
TOTAL	**37**	**38**	**34**	**32**	**21**	**21**	**40**	**39**

Shaded text signifies states that did not respond to the survey.

Table 20: Medicaid Policies for Monitoring High-Cost Drug Users, High Prescribing Physicians and Prescription Drug Cost-Effectiveness, by State.

STATE	*Rx Users*		*Physicians*			*Cost-Effectiveness*	
	Track "High Cost" Users	Definition of "High Cost"	Track "High Prescribing" Physicians	Definition of "High Prescribing"	*Manner of Addressing Prescribing Patterns*	Cost Evaluations Consider Cost-Effectiveness	Method of Considering Cost-Effectiven
Alabama							
Alaska	•	Highest ranked users				•	Look at users of Rx and other services
Arkansas			•		MD and patient letters		
Arizona	•	MCOs define	•	MCOs define	Education, letters	•	Done by MCOs
California	•	Audits and investigations	•	Audits and investigations	Audits and investigations	•	
Colorado	•	# of Rx and total $	•	Ingredient cost, average # of Rx, and brand %	Program Integrity Review	•	Review of PA
Connecticut	•		•				
Delaware	•	Total amount of claims	•	Large number of narcotics	Letters		
District of Columbia	•		•			•	
Florida	•	Rank in program and Prescriber Panel criteria	•		Letters and visits from pharmacy	•	P and T Committee
Georgia							
Hawaii	•		•	# of paid claims	Education, calls by staff, and provider bulletin		
Idaho					Education letters	•	Asthma and diabetes ıe managem
Illinois	•	High users of abusable Rx	•	Outliers	Audit & investigation; suspension; termination		
Indiana							
Iowa	•	Monthly report of users by $ paid and # of Rx	•	Top prescribing report by # of Rx and avg. cost	DUR letters to doctors	•	The evaluations are strictly reports based on POS information
Kansas	•	Outliers	•	Outliers	Education, letters	•	
Kentucky						•	P and T Committee
Louisiana			•	Top prescribers by $ of Rx	Education, letters		
Maine	•		•			•	
Maryland	•	Outliers	•	Quarterly volume of Rx	Letters		
Massachusetts	•	Monthly top 200 by $	•	Total $ prescribed, avg. cost, and brand use	Letters, phone calls		
Michigan	•	Outliers, audits, ad hoc reports	•	Outliers	*SURS investigations	•	MAC, CQI, Disease Management, PDL
Minnesota						•	
Mississippi	•		•	Outliers	Education, letters	•	
Missouri	•	High users by $	•	# of high cost Rx	Educational letters	•	New disease management

STATE	*Rx Users*		*Physicians*			*Cost-Effectiveness*	
	Track "High Cost" Users	Definition of "High Cost"	Track "High Prescribing" Physicians	Definition of "High Prescribing"	*Manner of Addressing Prescribing Patterns*	Cost Evaluations Consider Cost-Effectiveness	Method of Considering Cost-Effectiveness
Montana	•	Top 200 by $	•	Ingredient cost and # of Rx	In development		
Nebraska	•	Exceptional claims (> 250)				•	
Nevada							
New Hampshire	•	Audits, Lock-in Program and *SURS reports					
New Jersey	•	>12 Rx/month					
New Mexico	•	Monthly top 250 clients by # of Rx and $	•	Monthly top 100 doctors by # of Rx, ingredient cost, brand use		•	Varied methodologies
New York	•	Use of 100 mostly costly Rx	•	# of Rx	MDs required to use "Post and Clear" system		
North Carolina							
North Dakota	•	Top 1% of recipients by $, then by Rx volume	•	Based on cost and volume	Educational letters		
Ohio							
Oklahoma							
Oregon							
Pennsylvania	•	Ad hoc reports	•	Select an Rx, then use a high-low report	Integrity review or education intervention	•	Use the disease management approach
Rhode Island							
South Carolina						•	Awareness
South Dakota							
Tennessee							
Texas	•	> 9 Rx/month	•	Looks at specific therapy	Letters, visits, track behavior change		
Utah	•	University of Utah College tracks high cost clients					
Vermont			•			•	
Virginia							
Washington	•	Monthly top 1000	•	Monthly top 120	Personal visits	•	Pharmaco-economic evaluation before and after the intervention
West Virginia	•	Monthly top 100 cases by $	•	Monthly top 100 prescribers by $			
Wisconsin		High utilization, indirect cost analysis	•	Ad hoc	Refer to DHFS	•	Recipient lock-in program looks at all services, target intervention
Wyoming							
TOTAL	**30**		**24**			**22**	

Shaded text signifies states that did not respond to the survey. *SURS = State Utilization Review Services.

Table 21: State Estimates and Projections of Medicaid Pharmacy Cost Increases, by State.

STATE	*% increase in Rx costs over last 2 years (Yr 1/Yr 2)*	*Projected increase in Rx costs for FY 2003**	*Projected increase in Rx costs for FY 2004*
Alabama			
Alaska	(12%/28%)	20%	10%
Arkansas	17%		
Arizona			
California	46%	9.2%	12.7%
Colorado	13.25%	11%	
Connecticut		16-18%	16-18%
Delaware	20%	15%	
District of Columbia	(16%/14%)	11%	11%
Florida	(13%/ 11.25%)		
Georgia	18%	17%	
Hawaii			
Idaho	49%	4.57%	
Illinois	47%	27%	15%
Indiana			
Iowa	(18.1%/18.6%)	16.3%	
Kansas	(12%/13%)	14%	
Kentucky	(25%/6%)	6%	3%
Louisiana	20%	18- 19%	18-19%
Maine			
Maryland	(18%/14%)	12%	12%
Massachusetts	20%	5%	5%
Michigan	(6.1%/18%)		
Minnesota	38.22%	27%	11%
Mississippi	20%	0%	
Missouri	30%	15%	13%
Montana	(15.67%/15.67%)	7.33%	10.3
Nebraska	(20%/20%)	11.9%	18-25%
Nevada			
New Hampshire	(15%/7.5%)	18%	18%
New Jersey	(13.1%/4%)	-1%	-5.3%
New Mexico	22%		
New York	(22.4%/17.1%)	15-20%	15-20%
North Carolina	(23%/14%)	15.94%	23.1%
North Dakota	(16.5%/18.3%)	18%	18%
Ohio			
Oklahoma	(14.2%/24.3%)	17%	20%
Oregon			
Pennsylvania	(13.25%/27.25%)	14%	
Rhode Island			
South Carolina	(0%/20%)	20%	15%
South Dakota	33.5%	13.6%	14%
Tennessee			
Texas	17%	23%	22%
Utah	39.7%	18%	18%
Vermont	8%	12%	11%
Virginia		10%	
Washington	36%	6.8%	14%
West Virginia	30.2%	18.3%	13.3%
Wisconsin	28.2%	16.5%	14.9%
Wyoming			
AVERAGE	**14.70%**	**13.96%**	**13.83%**

Shaded text signifies states that did not respond to the survey. *For states responding to the survey, state fiscal year 2003 ended on June 30, 2003, except for Minnesota and New Mexico whose fiscal year ended on July 31, 2003; New York whose fiscal year ended on March 31, 2003; and Texas whose fiscal year ended on August 31, 2003.

Table 22: State Experience with Ease of Implementation of Various Utilization Management Strategies, by State.

STATE	*Utilization-Management Strategies Ranked by Ease of Implementation*		
	1	*2*	*3*
Alabama			
Alaska	PRODUR	RetroDUR	Generics
Arkansas			
Arizona			
California	PA	PDL	
Colorado	PA	PDL	Cost-sharing
Connecticut	PRODUR	RetroDUR	Dispensing Limit
Delaware	PDL	Cost-sharing	Generics
District of Columbia	PRODUR	PA	Generics
Florida	Generics	PDL	PA
Georgia	PRODUR	RetroDUR	Dispensing Limit
Hawaii	Generic	Dispensing Limit	PA
Idaho	Payment	Generics	PA
Illinois	Cost-sharing	PRODUR	PDL
Indiana			
Iowa	Dispensing Limit	Generics	Cost-sharing
Kansas	PRODUR	Generics	Dispensing Limit
Kentucky	Dispensing Limit	Generics	Payment
Louisiana	Dispensing Limit	PA	PDL
Maine	Generics	PDL	Dispensing Limit
Maryland	Generics	PRODUR	RetroDUR
Massachusetts	Generics	Cost-sharing	PDL
Michigan	PRODUR	Automated edits	MAC Pricing
Minnesota	Generics	PA	PDL
Mississippi	PA	Dispensing Limit	PRODUR
Missouri	Generics	PRODUR	PA
Montana	Generics	PRODUR	PA
Nebraska	Payment	Cost-sharing	Generics
Nevada			
New Hampshire	Generics	PRODUR	RetroDUR
New Jersey	Fail-first	Generics	Dispensing Limit
New Mexico	Generics	Dispensing Limit	PRODUR
New York	Generics	Dispensing Limit	Cost-sharing
North Carolina	PRODUR	RetroDUR	Generics
North Dakota	PRODUR	Cost-sharing	Payment
Ohio			
Oklahoma	Dispensing Limit	Generics	Cost-sharing
Oregon			
Pennsylvania	PRODUR	Cost-sharing	PA
Rhode Island			
South Carolina	Dispensing Limit	PA	Generics
South Dakota	Cost-sharing	Payment	Generics
Tennessee			
Texas	Generics	Dispensing Limit	PRODUR
Utah			
Vermont	PDL (nr)	PA (nr)	Generics (nr)
Virginia	Dispensing Limit	Generics	Cost-sharing
Washington	Generics	PA	Dispensing Limit
West Virginia	Generics	Cost-sharing	PA
Wisconsin	Generics	PRODUR	RetroDUR
Wyoming			
AVERAGE			

Shaded text signifies states that did not respond to the survey. PA = Prior Authorization. Payment = payment policy changes. PDL = Formulary/PDL. nr = not ranked.

Table 23: Type of Delivery System for Medicaid Beneficiary Groups, by State.

STATE	Type of Delivery System*											
	Children			Adults			Disabled			Elderly		
	Fee-for-Service	Capitated/MCO	PCCM	Fee-for-Service	Capitated/MCO	PCCM	Fee-for-Service	Capitated/MCO	PCCM	Fee-for-Service	Capitated/MCO	PCCM
Alabama												
Alaska	•			•			•			•		
Arkansas	•			•			•			•		
Arizona	•	•		•	•		•	•		•	•	
California	•	•	•	•	•	•	•	•	•	•	•	•
Colorado	•	•	•	•	•		•	•	•	•	•	•
Connecticut	•	•		•	•		•	•		•	•	
Delaware		•	•		•		•			•		
District of Columbia		•			•		•			•		
Florida		•	•		•			•	•		•	•
Georgia	•		•	•		•	•			•		
Hawaii		•			•		•			•		
Idaho	•		•	•		•	•		•	•		•
Illinois	•	•		•	•		•			•	•	
Indiana												
Iowa	•			•			•			•		
Kansas	•	•	•	•	•	•	•		•	•		•
Kentucky	•	•	•	•	•	•	•	•	•	•	•	•
Louisiana	•			•			•			•		
Maine	•	•		•	•		•			•		
Maryland		•			•		•	•		•		
Massachusetts	•	•	•	•	•	•	•	•	•	•	•	•
Michigan	•	•		•	•		•	•		•		
Minnesota	•	•		•	•		•	•		•	•	
Mississippi	•			•			•			•		
Missouri		•			•		•			•		
Montana			•			•			•			•
Nebraska		•	•		•	•		•	•		•	•
Nevada												
New Hampshire	•	•		•	•		•	•		•	•	
New Jersey		•		•	•		•	•		•	•	
New Mexico		•			•			•			•	
New York	•	•		•	•		•	•		•	•	
North Carolina			•			•			•			•
North Dakota	•			•			•			•		
Ohio												
Oklahoma	•	•	•	•	•	•	•	•	•	•	•	•
Oregon												
Pennsylvania	•	•		•	•		•	•		•	•	
Rhode Island												
South Carolina	•	•	•	•	•	•	•	•	•	•	•	•
South Dakota	•			•			•			•		
Tennessee												
Texas		•			•		•	•		•	•	
Utah	•			•			•			•		
Vermont	•		•	•		•	•		•	•		•
Virginia	•	•	•	•	•	•	•	•	•	•	•	•
Washington	•	•	•	•	•	•	•			•		
West Virginia	•	•	•	•	•	•	•		•	•		
Wisconsin		•			•		•			•		
Wyoming												
TOTAL	**30**	**30**	**18**	**31**	**30**	**15**	**38**	**20**	**15**	**38**	**19**	**14**

Shaded text signifies states that did not respond to the survey. *Note: States can serve each population group through more than one type of delivery system. Responses provided are not intended to indicate the predominant delivery system for each group.

Table 24: Medicaid Policies for Delivering Prescription Drugs to Managed Care Enrollees, by State.

STATE	For Managed Care Enrollees			
	State Purchases Rx on Fee-For-Service Basis	*State Includes Rx Costs in MCO Capitation Rate*	*MCO Delivers Rx*	*PBM or Other Entity Delivers Rx*
Alabama				
Alaska				
Arkansas				
Arizona			•	
California*		•	•	
Colorado		•		
Connecticut		•		
Delaware	•			
District of Columbia		•	•	
Florida		•	•	
Georgia	•			
Hawaii		•	•	
Idaho	•			
Illinois		•	•	
Indiana				
Iowa				
Kansas		•	•	
Kentucky	•	•	•	
Louisiana				
Maine	•			
Maryland		•	•	
Massachusetts		•	•	
Michigan**		•	•	
Minnesota		•	•	
Mississippi				
Missouri		•	•	
Montana	•			
Nebraska	•			
Nevada				
New Hampshire	•			
New Jersey		•	•	
New Mexico		•	•	•
New York	•			
North Carolina	•			
North Dakota				
Ohio				
Oklahoma		•	•	
Oregon				
Pennsylvania		•	•	
Rhode Island				
South Carolina		•	•	
South Dakota				
Tennessee				
Texas	•			
Utah				
Vermont	•			•
Virginia		•	•	
Washington		•	•	
West Virginia	•			
Wisconsin		•	•	
Wyoming				
TOTAL	**13**	**22**	**21**	**2**

Shaded text signifies states that did not respond to the survey. *California purchases HIV medications and some psychotropic medications on a fee-for-service basis. **Michigan purchases psychotropic medications on a fee-for-service basis.

Table 25: Medicaid Policies Regarding MCO or PCCM Discretion to Set Pharmacy Management Policies, by State.

STATE	State Permits MCO or PCCM to Set Own Policies and Procedures					
	Formulary/ PDL Policy	*Prior Authorization (PA)*	*Require Generics*	*Encourage Generics*	*Fail-First*	*Restrict Access to Pharmacy Network*
Alabama						
Alaska						
Arkansas						
Arizona	•	•	•	•	•	•
California	•	•	•	•	•	
Colorado	•	•	•	•	•	•
Connecticut	•	•	•			
Delaware						
District of Columbia	•	•	•	•	•	•
Florida	•	•	•	•	•	•
Georgia						
Hawaii	•	•	•	•	•	•
Idaho						
Illinois*	•	•		•	•	•
Indiana						
Iowa						
Kansas	•	•	•	•	•	
Kentucky	•	•	•	•	•	
Louisiana						
Maine						
Maryland**	•	•	•	•	•	•
Massachusetts	•	•	•	•	•	•
Michigan***	•	•				
Minnesota	•	•	•	•	•	
Mississippi**	•	•	•	•	•	•
Missouri	•	•	•	•	•	•
Montana						
Nebraska						
Nevada						
New Hampshire						
New Jersey	•	•	•	•	•	•
New Mexico	•	•	•	•	•	•
New York						
North Carolina						
North Dakota						
Ohio						
Oklahoma	•	•	•	•	•	•
Oregon						
Pennsylvania	•	•	•	•	•	
Rhode Island						
South Carolina****	•	•	•	•	•	•
South Dakota						
Tennessee						
Texas						
Utah						
Vermont	•	•	•	•		
Virginia	•	•	•	•	•	•
Washington^	•	•	•	•	•	
West Virginia						
Wisconsin	•	•	•	•	•	•
Wyoming						
TOTAL	**25**	**25**	**23**	**23**	**22**	**16**

Shaded text signifies states that did not respond to the survey. *Illinois' MCO pharmaceutical benefit cannot be more restrictive than the fee-for-service pharmaceutical benefit. **Maryland and Mississippi permit restricted access to a pharmacy network, but do not permit requiring the use of mail-order pharmacies. ***Michigan requires MCOs to cover drugs on the PDL when medically necessary. ****South Carolina's MCO policies cannot be more restrictive than traditional Medicaid. ^Washington: If an MCO places an Rx on PA that is covered by Medicaid, then the MCO must cover an alternative in the same therapeutic class.

Table 26: Medicaid Policies for Delivering Prescription Drugs to Beneficiaries Residing in Institutions (*i.e. Nursing Homes*), by State.

STATE	*Estimated % of Rx Spending on Beneficiaries in Institutions*	*Rx Carved Out of Institutional Rate*	*Add-Ons to Institutional Rate*	*Specific Rx Cost-Control Policies*	*Planned Policy Changes*
Alabama					
Alaska		•		Using maximum limits for selected analgesics	
Arkansas	18%			PA, same for all recipients	
Arizona					
California	10%				
Colorado	30%			Return and reuse policy for selected Rx	
Connecticut			OTCs		
Delaware	33%	•		PA, Limit therapeutic duplications	
District of Columbia					Developing LTC program and increasing payment rates
Florida	15%	•			Strengthen FUL brand cap, establish PDL
Georgia		•		Audit high users (large number of Rx/month)	Possible capitation program for LTC
Hawaii		•		DUR, internal reviews	
Idaho					
Illinois	20%	•			
Indiana					
Iowa					
Kansas					
Kentucky	13%	•		PA requirements same as outpatients	
Louisiana	21%				
Maine					
Maryland*	25%	•	Dispensing Fee		
Massachusetts	15%	•	OTCs	Return and reuse policy for selected Rx and on-site audits	
Michigan**		•	State pays for unit does repackaging: $0.03/tab	Pharmacy audits	
Minnesota	14%	•		Return and reuse policy	
Mississippi		•		Return and reuse policy	
Missouri***	15%	•		Return and reuse policy	Several changes under consideration
Montana					Deny Rx refills
Nebraska	17%	•		Return and reuse policy	
Nevada					
New Hampshire		•		1 dispensing fee/month; post consumption and unit dose credit	
New Jersey	20%	•		Reviews conducted by pharmacy consultants	
New Mexico					
New York****					
North Carolina					
North Dakota	33%	•			
Ohio					

STATE	Estimated % of Rx Spending on Beneficiaries in Institutions	Rx Carved Out of Institutional Rate	Add-Ons to Institutional Rate	Specific Rx Cost-Control Policies	Planned Policy Changes
Oklahoma	32%	•		Early refill edit	Dispense only 3(supply and limit 1 dispensing fee/Rx/month
Oregon					
Pennsylvania	31%	•		Limit dispensing fees for maintenance Rx to 1/30 days	
Rhode Island					
South Carolina	6%	•		Alternate reimbursement methodology, pays pharmacy to provide all Rx's for LTC	
South Dakota			Yes, unspecified		
Tennessee					
Texas	18%				
Utah		•			Implementing LTC return and reuse policy
Vermont				PA added to PDL	
Virginia					
Washington		•		Higher dispensing fee paid for true unit dose systems (return and credit)	
West Virginia		•			
Wisconsin	24%				
Wyoming					
TOTAL	**21% (Avg.)**	**23**	**5**	**20**	**7**

Shaded text signifies states that did not respond to the survey. *Maryland Rx costs are carved out of institutional rate only in fee-for-service. **Michigan carves out most Rx from the institutional rate, but not diabetes supplies, enteral formulas, and some OTCs. ***Missouri Rx costs are carved out of institutional rate, except for stock items. ****New York Rx costs are not carved out of institutional rate, except in limited circumstances.