United States Government Accountability Office

GAO

Report to Congressional Requesters

August 2005

PRESCRIPTION DRUGS

Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004

GAO-05-779

August 2005

PRESCRIPTION DRUGS

Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004

GAO Accountability·Integrity·Reliability

Highlights

Highlights of GAO-05-779, a report to congressional requesters

Why GAO Did This Study

Prescription drug spending has been the fastest growing segment of national health expenditures. As the federal government assumes greater financial responsibility for prescription drug expenditures with the introduction of Medicare part D, federal policymakers are increasingly concerned about prescription drug prices. GAO was asked to examine the change in retail prices and other pricing benchmarks for drugs frequently used by Medicare beneficiaries and other individuals with health insurance from 2000 through 2004.

To examine the change in retail prices from 2000 through 2004, we obtained usual and customary (U&C) prices from two state pharmacy assistance programs for drugs frequently used by Medicare beneficiaries and non-Medicare enrollees in the 2003 Blue Cross and Blue Shield (BCBS) Federal Employee Program (FEP). The U&C price is the price an individual without prescription drug coverage would pay at a retail pharmacy. Additionally, we compared the change in U&C prices for brand drugs from 2000 through 2004 to the change in two pricing benchmarks: average manufacturer price (AMP), which is the average of prices paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade, and average wholesale price (AWP), which represents the average of list prices that a manufacturer suggests wholesalers charge pharmacies.

www.gao.gov/cgi-bin/getrpt?GAO-05-779.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marjorie Kanof at (202) 512-7114 or kanofm@gao.gov.

What GAO Found

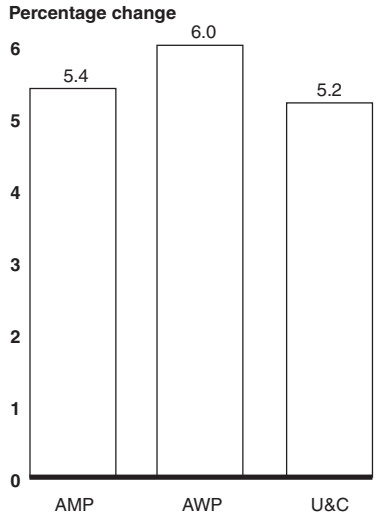
We found the average U&C prices at retail pharmacies reported by two state pharmacy assistance programs for a 30-day supply of 96 drugs frequently used by BCBS FEP Medicare and non-Medicare enrollees increased 24.5 percent from January 2000 through December 2004. Of the 96 drugs:

- Twenty drugs accounted for nearly two-thirds of the increase in the U&C price index.
- The increase in average U&C prices for 75 prescription drugs frequently used by Medicare beneficiaries was similar to the increase for 76 prescription drugs frequently used by non-Medicare enrollees.
- The average U&C prices for 50 frequently used brand prescription drugs increased three times as much as the average for 46 generic frequently used prescription drugs.

AWPs increased at a faster rate than AMPs and U&C prices for the 50 frequently used brand drugs from first quarter 2000 through fourth quarter 2004. Ten drugs in each index accounted for almost 50 percent of the increase for AMP, AWP, and U&C prices. Eight of these 10 drugs were consistent across the three price indexes.

The Centers for Medicare & Medicaid Services (CMS), two state pharmacy assistance programs, and BCBS FEP reviewed a draft of this report. While CMS noted that U&C and AWP do not reflect discounts in a drug's price, this report's focus was to examine price trends rather than price levels. Technical comments were incorporated as appropriate.

Average Annual Percentage Change of AMP, AWP, and U&C Price Indexes for 50 Brand Drugs Frequently Used by Enrollees in BCBS FEP, from First Quarter 2000 through Last Quarter 2004



Source: GAO analysis of data from CMS, First DataBank, New York's Elderly Pharmaceutical Insurance Coverage program, Pennsylvania's Pharmaceutical Assistance Contract for the Elderly program, and BCBS FEP.

Contents

Abbreviations

AMP	average manufacturer price
AWP	average wholesale price
BCBS	Blue Cross and Blue Shield
BLS	Bureau of Labor Statistics
CMS	Centers for Medicare & Medicaid Services
EPIC	Elderly Pharmaceutical Insurance Coverage
FEP	Federal Employee Program
NDC	National Drug Code
PACE	Pharmaceutical Assistance Contract for the Elderly
U&C	usual and customary

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

August 15, 2005

The Honorable Olympia J. Snowe
Chair
Committee on Small Business and Entrepreneurship
United States Senate

The Honorable Ron Wyden
United States Senate

Prescription drug spending as a share of national health expenditures increased from 5.8 percent in 1993 to 10.7 percent in 2003 and was the fastest growing segment of health care expenditures.[1] In addition to increasing utilization and the introduction of newer drugs, rising prescription drug prices are a key component of increasing drug expenditures. Increasing drug prices can affect consumers, employers, and federal and state governments. Policymakers are increasingly concerned about drug prices as the federal government will assume greater financial responsibility for prescription drug expenditures with the introduction of a prescription drug benefit to Medicare beneficiaries in January 2006, known as Medicare part D. Medicare beneficiaries also will continue to be responsible for a large share of drug costs under Medicare part D.

Tracking prescription drug prices can be complicated by the different prices that different purchasers, such as consumers, insurers and other third-party payers, and wholesalers, pay for the same drug. Several price benchmarks represent these differing amounts paid by different purchasers. For example, individuals without prescription drug coverage, including Medicare beneficiaries who do not currently have drug coverage, may pay the full retail price at the pharmacy, known as the usual and customary (U&C) price. Insurers and other third-party payers, including state Medicaid programs, typically pay negotiated prices with retail pharmacies, often receiving discounts from the average wholesale price (AWP), commonly referred to as a list price.[2] Retail pharmacies may obtain

[1]Our calculations are based on data from the national health accounts prepared by the Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

[2]The AWP is the average of the list prices that a manufacturer suggests wholesalers charge pharmacies.

drugs directly from pharmaceutical manufacturers or through wholesalers. The average manufacturer price (AMP) represents the average of prices paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade, and is used by the Centers for Medicare & Medicaid Services (CMS) to determine rebates due by law to Medicaid programs. Prices also substantially vary depending on whether drugs are marketed as brand or generic, with some third-party payers encouraging the use of less expensive generic drugs through lower cost sharing for consumers and other strategies.

To provide a baseline of prescription drug prices before the implementation of the Medicare part D drug benefit, you asked GAO to review drug price changes from 2000 through 2004, including drugs frequently used by seniors. Specifically, we examined the following questions.

1. How have retail prices for prescription drugs frequently used by Medicare beneficiaries and other individuals with health insurance changed from 2000 through 2004?

2. How does the change in retail prices for brand drugs frequently used by Medicare beneficiaries and other individuals compare to other drug pricing benchmarks from 2000 through 2004?

To examine the change in retail prices for prescription drugs frequently used by Medicare beneficiaries and other individuals with health insurance, we selected the 100 most frequently dispensed retail prescriptions in 2003 for Medicare beneficiaries and for non-Medicare enrollees in the Blue Cross and Blue Shield (BCBS) Federal Employee Program (FEP).[3] Combined, these two lists of 100 frequently used drugs represented a total of 133 unique drugs. Of these 133 drugs, we analyzed 96 drugs (50 brand and 46 generic) for which we were able to obtain U&C prices at retail pharmacies for every month from January 2000 through

[3]We used data of frequently dispensed prescriptions from BCBS FEP because they represent a large number of retail prescriptions dispensed and could provide data for drugs used by FEP enrollees who were Medicare beneficiaries and those who were not Medicare eligible. Of the nearly 55 million retail prescriptions dispensed to BCBS FEP enrollees in 2003, 21 million were for FEP enrollees who were also Medicare beneficiaries.

December 2004.[4] These 96 drugs included 75 drugs that were frequently used by BCBS FEP Medicare enrollees and 76 drugs that were frequently used by BCBS FEP non-Medicare enrollees, with 55 of these drugs overlapping the Medicare and non-Medicare frequently used lists. To calculate a price index, we weighted each drug using the number of prescriptions dispensed to BCBS FEP enrollees in 2003. We collected the average monthly U&C prices for a typical 30-day supply from two large state programs that assist low-income Medicare beneficiaries in purchasing prescription drugs: Pennsylvania's Pharmaceutical Assistance Contract for the Elderly (PACE) program from January 2000 through December 2004, and New York's Elderly Pharmaceutical Insurance Coverage (EPIC) program from August 2000 through December 2004.[5]

To compare the change in U&C prices at retail pharmacies with other drug-pricing benchmarks, we examined changes in the AMP and AWP for the 50 brand drugs frequently used by BCBS FEP enrollees. We calculated a quarterly AMP index for a 30-day supply for the 50 brand drugs based on data we collected from CMS from the first quarter of 2000 through the fourth quarter of 2004. We calculated a quarterly AWP index for a 30-day supply for the same 50 brand drugs based on data we collected from First DataBank for the same period. We determined that the data from BCBS FEP, PACE, EPIC, CMS, and First DataBank were sufficiently reliable for our purposes. Our analyses are limited to drugs most frequently used by Medicare beneficiaries and non-Medicare enrollees in the 2003 BCBS FEP, and our analyses using U&C prices are limited to prices reported by retail pharmacies in Pennsylvania to the PACE program and by retail pharmacies in New York to the EPIC program. See appendix I for more information about our selected drugs and detailed information on our

[4]For the purpose of this report, we refer to single-source and multisource drugs that are marketed under a proprietary, trademark-protected name as brand drugs. Single-source drugs include those brand drugs that have no generic equivalent on the market and are generally available from only one manufacturer. Brand multisource drugs include those brand drugs that have generic equivalents available from multiple manufacturers and are marketed under their brand name. Generic drugs include multisource drugs that are chemically identical to their branded counterparts and are generally marketed by multiple manufacturers under a non-proprietary name.

[5]We used data from PACE and EPIC because they were two of the largest state pharmaceutical assistance programs, collected data from pharmacies on U&C prices for drugs, and had historical price data available from 2000.

methodology. We performed our work from April 2004 through July 2005 in accordance with generally accepted government auditing standards.[6]

Results in Brief

From January 2000 through December 2004, based on our analysis of data from PACE and EPIC, the average monthly U&C prices for a 30-day supply of 96 prescription drugs frequently used by BCBS FEP Medicare and non-Medicare enrollees increased 24.5 percent. Twenty of the 96 drugs accounted for nearly two-thirds of the increase in the U&C price index. The average U&C prices for 75 prescription drugs frequently used by BCBS FEP Medicare beneficiaries and the average U&C prices for 76 prescription drugs frequently used by BCBP FEP non-Medicare enrollees increased at similar rates of 24.0 percent and 24.8 percent, respectively. The average U&C prices for 50 brand prescription drugs increased 28.9 percent, three times as much as the average U&C price increase of 9.4 percent for 46 generic prescription drugs.

The AWP index increased by 31.6 percent for the 50 frequently used brand drugs from the first quarter of 2000 through the fourth quarter of 2004—about 3 to 4 percentage points more rapidly than the AMP and U&C price indexes. Ten drugs in each index accounted for nearly 50 percent of the increase for the AMP, AWP, and U&C indexes, with 8 of these top 10 drugs consistent for all three prices. As a result of AWP's faster rate of increase, AWP as a percentage of U&C price increased from an average of about 91 percent in the first quarter of 2000 to about 94 percent in the last quarter of 2004. AMP stayed about 72 percent of the U&C price during this period.

We provided a draft of this report to CMS, PACE, EPIC, and BCBS FEP. CMS noted that U&C and AWP do not reflect discounts in a drug's price. While our analysis does not reflect these discounts, our focus was to examine price trends rather than price levels and U&C and AWP are consistent measures used to examine price trends. CMS also suggested that we examine the effect on prices when generic alternatives are introduced, but such an analysis was beyond the scope of this report.

[6]We also reported on trends in U&C prices for 99 drugs from January 2000 through June 2004 in GAO, *Prescription Drugs: Trends in Usual and Customary Prices for Drugs Frequently Used by Medicare and Non-Medicare Enrollees*, GAO-05-104R (Washington, D.C.: Oct. 6, 2004). This report includes 3 fewer drugs than our earlier analysis because pricing data were not available for these 3 drugs through December 2004.

PACE and BCBS provided technical comments that we incorporated as appropriate; EPIC stated that it did not have any comments.

Background

Several measures of price are commonly used within the health care sector to measure the price of prescription drugs. These varying price measures are due to the different prices that drug manufacturers and retail pharmacies charge different purchasers, and drug prices can vary substantially depending on the purchaser. (See fig. 1.)

- The U&C price, the retail price for a drug, is the price an individual without prescription drug coverage would pay at a retail pharmacy. The U&C price includes the acquisition cost of the drug paid by the retail pharmacy and a markup charged by the pharmacy.
- AWP is the average of the list prices or sticker price that a manufacturer of a drug suggests wholesalers charge pharmacies. AWP is typically less than the U&C price, which includes the pharmacy's own markup. AWP is not the actual price that large purchasers normally pay. Nevertheless, AWP is part of the formula used by many state Medicaid programs and private third-party payers to reimburse retail pharmacies.[7]
- AMP is the average of prices paid to a manufacturer by wholesalers for a drug distributed to the retail pharmacy class of trade, after subtracting any account cash discounts or other price reductions.[8] CMS uses AMP in determining rebates drug manufacturers must provide, as required by the Omnibus Budget Reconciliation Act of 1990, to state Medicaid programs as a condition for the federal contribution to Medicaid spending for the manufacturers' outpatient prescription drugs.[9] For brand drugs, the

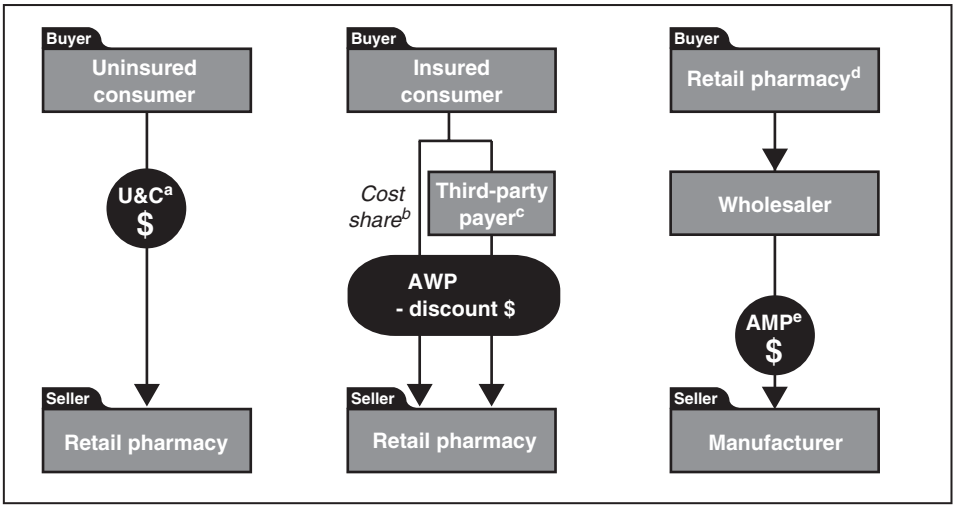
[7]Before 2005, Medicare reimbursement for prescription drugs covered under Medicare part B was based on AWP. The average sales price generally replaced AWP as the basis for outpatient drug reimbursement under Medicare part B beginning in 2005. The average sales price is defined for each drug as a manufacturer's sales to all purchasers in a given quarter, net of discounts and rebates and excluding certain government and other purchasers, divided by the number of units of the drug sold by the manufacturer in that quarter. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 303(c), 117 Stat. 2066, 2239-2245 (to be codified at 42 U.S.C. § 1395w-3a).

[8]AMP does not include prices to government purchasers based on the Federal Supply Schedule, which are prices for prescription drugs negotiated with manufacturers by the Department of Veterans Affairs. AMP also does not include prices from direct sales to health maintenance organizations and hospitals or prices to wholesalers when they relabel drugs they purchase under their own label.

[9]Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-156 (codified as amended at 42 U.S.C. § 1396r-8(k) (2000)).

minimum rebate amount is the number of units of the drug multiplied by 15.1 percent of the AMP.

Figure 1: Drug Prices for Different Buyers and Sellers



Source: GAO.

[a]U&C is the price an individual without prescription drug coverage would pay at a retail pharmacy.

[b]When an insured consumer purchases a drug at a retail pharmacy, the pharmacy collects from the insured consumer the appropriate cost-sharing amount and then submits a claim to the third-party payer for reimbursement.

[c]Third-party payers often negotiate a discount off AWP, the average of the list prices that a manufacturer suggests wholesalers charge pharmacies. However, third-party payers may pay other negotiated rates not based on AWP.

[d]Retail pharmacies can also purchase prescription drugs directly from manufacturers.

[e]AMP represents the average of prices paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade.

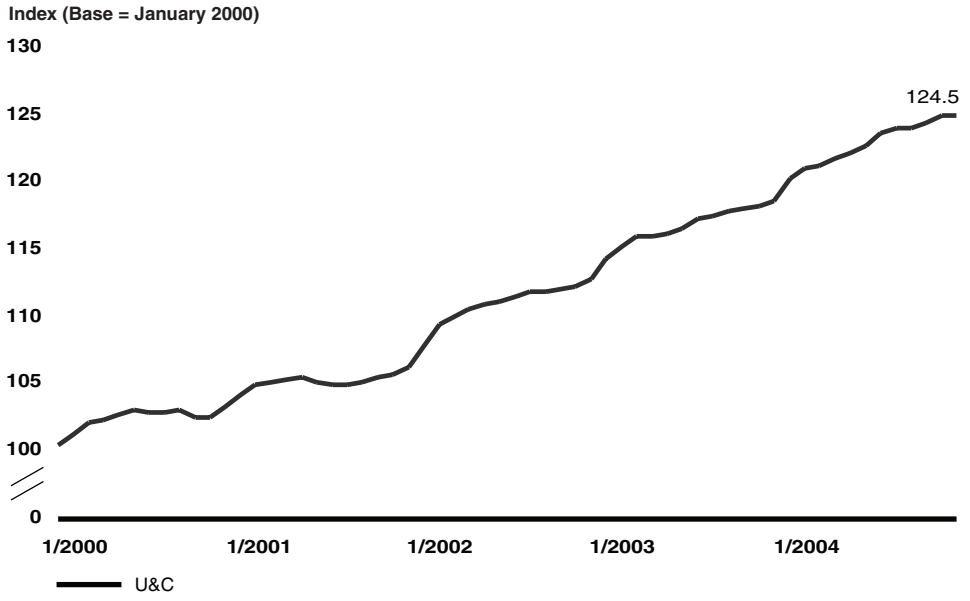
Retail Prices Increased from 2000 through 2004, with Larger Increases for Brand Than Generic Drugs

From January 2000 through December 2004, the average U&C prices for a typical 30-day supply of 96 prescription drugs frequently used by BCBS FEP Medicare and non-Medicare enrollees increased 24.5 percent. The average U&C prices for 75 prescription drugs frequently used by Medicare beneficiaries and for 76 prescription drugs frequently used by non-Medicare enrollees increased at similar rates. The average U&C prices for 50 frequently used brand drugs increased three times faster than the average U&C prices for 46 frequently used generic drugs.

U&C Prices for Frequently Used Drugs Increased 24.5 Percent

From January 2000 through December 2004, the average U&C price collected from retail pharmacies by PACE and EPIC for a 30-day supply for 96 prescription drugs frequently used by BCBS FEP Medicare beneficiaries and non-Medicare enrollees increased 24.5 percent, a 4.6 percent average annual rate of increase. (See fig. 2.) During the same period, using nationwide data from the Bureau of Labor Statistics (BLS), prices for prescription drugs and medical supplies for all urban consumers increased 21.3 percent, a 4.0 percent average annual rate of increase. Additionally, using BLS data, prices for all consumer items for all urban consumers—the Consumer Price Index—increased 12.7 percent, a 2.5 percent average annual rate of increase from January 2000 through December 2004.

Figure 2: Index of Average U&C Prices for 96 Drugs Frequently Used by BCBS FEP Enrollees, by Month, 2000 through 2004

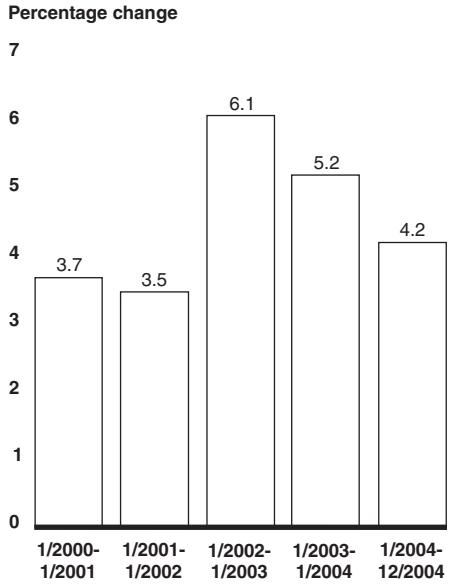


Source: GAO analysis of data from BCBS FEP, EPIC, and PACE.

While U&C prices increased each year from 2000 through 2004, the greatest annual rate of increase—6.1 percent—occurred from January 2002 to January 2003. (See fig. 3.) Since then, annual rates of increase have

been less, increasing 5.2 percent from January 2003 to January 2004 and 4.2 percent from January 2004 to December 2004.[10]

Figure 3: Annual Change in U&C Price Index for 96 Drugs Frequently Used by BCBS FEP Enrollees, 2000 through 2004



Source: GAO analysis of data from BCBS FEP, EPIC, and PACE.

Note: The change in average U&C prices from January 2004 through December 2004 is expressed as an annual percentage change.

Twenty drugs, representing 33 percent of BCBS FEP prescriptions for the 96 drugs we reviewed, accounted for 64 percent of the total increase in the U&C price index from January 2000 through December 2004.[11] The drug with the largest effect on the price index was Lipitor 10mg, which accounted for 6.6 percent of the total increase. Nineteen of the 20 drugs were brand drugs and 1 was a generic drug, Hydrocodone/Acetaminophen 5/500mg. The twenty drugs accounting for the largest changes in the U&C price index are listed below.

[10]The change in average U&C prices from January 2004 through December 2004 is expressed as an annual percentage change.

[11]We measured the share each drug contributed to the overall index by comparing the ratio of (1) each drug's price change from January 2000 through December 2004 multiplied by its weight based on BCBS FEP prescriptions, to (2) the sum of all drugs' price changes multiplied by their associated weights.

- Lipitor 10mg
- Celebrex 200mg
- Plavix 75mg
- Prevacid 30mg
- Lipitor 20mg
- Ambien 10mg
- Zocor 20mg
- Levaquin 500mg
- Hydrocodone/Acetaminophen 5/500mg
- Flonase 0.05mg
- Zithromax 250mg
- Wellbutrin SR 150mg
- Singular 10mg
- Premarin 0.625mg
- Celexa 20mg
- Zoloft 50mg
- Evista 60mg
- Norvasc 5mg
- Neurontin 300mg
- Aciphex 20mg

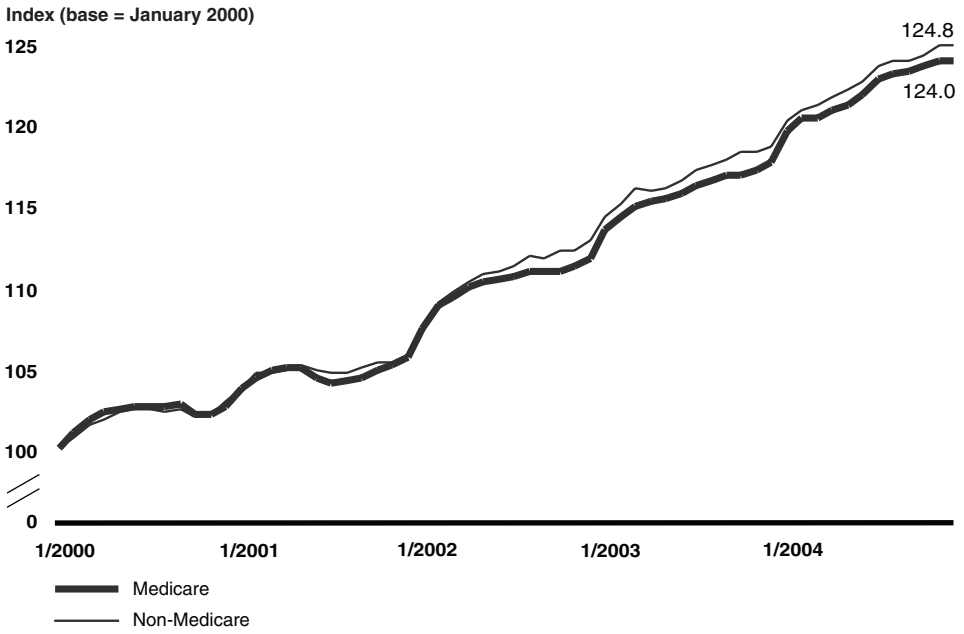
U&C Prices for Drugs Frequently Used by Medicare Beneficiaries and by Non-Medicare Enrollees Increased at Similar Rates

From January 2000 through December 2004, the average U&C prices collected by PACE and EPIC for 75 prescription drugs frequently used by BCBS FEP Medicare beneficiaries increased at a similar rate as the average U&C prices for 76 prescription drugs frequently used by BCBS FEP non-Medicare enrollees.[12] (See fig. 4.) The prices of 75 Medicare drugs increased 24.0 percent, a 4.5 percent average annual rate of increase. The prices of 76 non-Medicare drugs increased 24.8 percent, a 4.6 percent average annual rate of increase.[13]

[12]While 55 drugs were used in calculating both the Medicare and non-Medicare U&C price indexes, each drug had a different weight in each index depending on the frequency of prescriptions dispensed to BCBS FEP Medicare enrollees or BCBS FEP non-Medicare enrollees.

[13]We found the non-Medicare index rose slightly faster than the Medicare index, in part because drugs that treat depression were present to a larger extent in the non-Medicare index. The U&C prices for the eight drugs that treat depression increased at an average rate of 31.1 percent from January 2000 through December 2004. Excluding the eight drugs that treat depression from our analysis resulted in a 24.0 percent rate of increase for both the Medicare and non-Medicare index.

Figure 4: Indexes of Average U&C Prices for Drugs Frequently Used by BCBS FEP Medicare and Non-Medicare Enrollees, by Month, 2000 through 2004

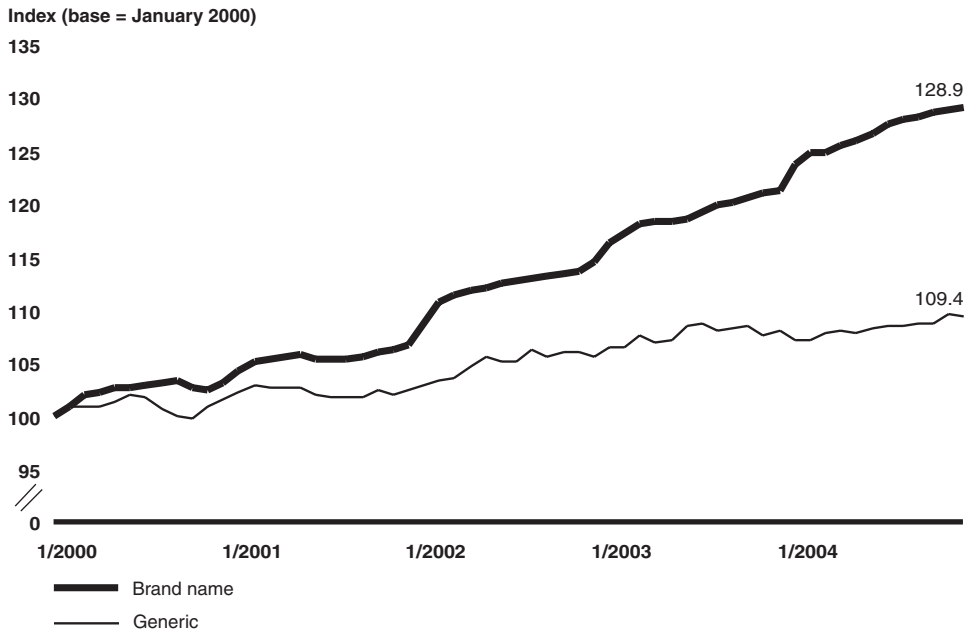


Source: GAO analysis of data from BCBS FEP, EPIC, and PACE.

U&C Prices Increased Three Times Faster for Brand Drugs Than for Generic Drugs

From January 2000 through December 2004, the average U&C price (based on PACE and EPIC data) for 50 frequently used brand drugs rose three times faster than the average U&C price for 46 frequently used generic drugs. (See fig. 5.) Specifically, the average U&C price for brand drugs increased 28.9 percent, a 5.3 percent average annual rate of increase, whereas U&C prices for generic drugs increased 9.4 percent, a 1.8 percent average annual rate of increase.

Figure 5: Indexes of Average U&C Prices for 50 Brand and 46 Generic Drugs Frequently Used by BCBS FEP Enrollees, by Month, 2000 through 2004



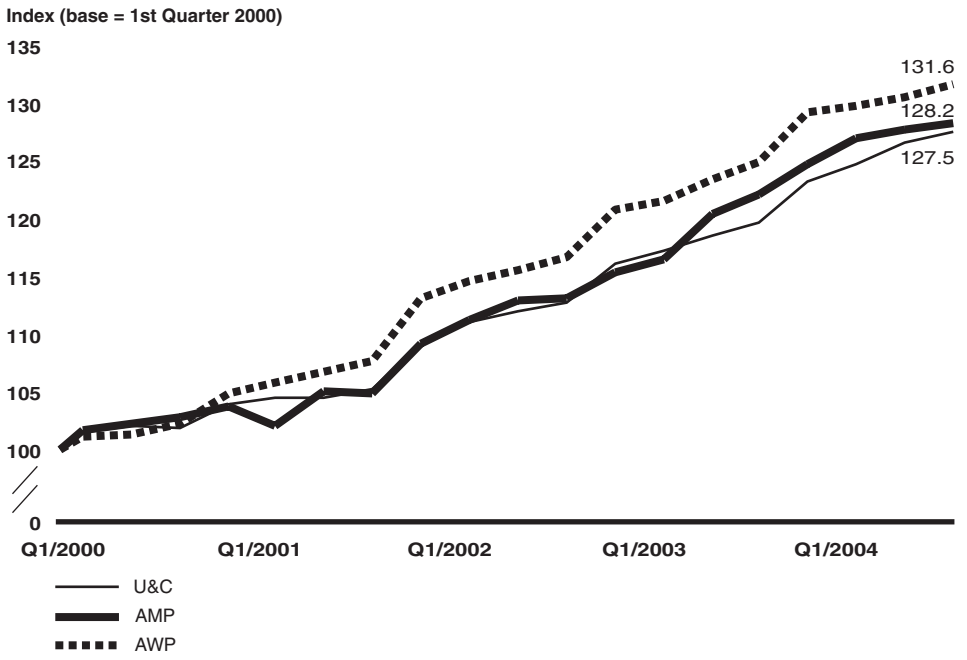
Source: GAO analysis of data from BCBS FEP, EPIC, and PACE.

AWPs Increased at a Faster Rate Than AMPs and U&C Prices for 50 Brand Drugs from 2000 through 2004

From the first quarter of 2000 through the fourth quarter of 2004, AMPs and U&C prices for the 50 brand drugs increased at similar rates, but AWPs increased at a faster rate. The quarterly AWPs for 50 brand prescription drugs increased 31.6 percent, a 6.0 percent average annual rate of increase. For these same 50 drugs, the quarterly AMPs increased 28.2 percent, a 5.4 percent average annual rate of increase, while the average quarterly U&C prices increased 27.5 percent, a 5.2 percent average annual rate of increase.[14] Over the entire period, the AWP index increased about 3 to 4 percentage points more than the AMP or U&C price indexes. (See fig. 6.)

[14]The quarterly U&C price index increased at a slightly lower rate of increase than the monthly U&C price index because the base and end periods differ. Whereas the base period for the monthly U&C index is January 2000, the base period for the quarterly index is January through March 2000. Similarly, the end period for the monthly index is December 2004 and for the quarterly index is October through December 2004.

Figure 6: Indexes of AMPs, AWPs, and Average U&C Prices for 50 Brand Drugs Frequently Used by BCBS FEP Enrollees, by Quarter, 2000 through 2004



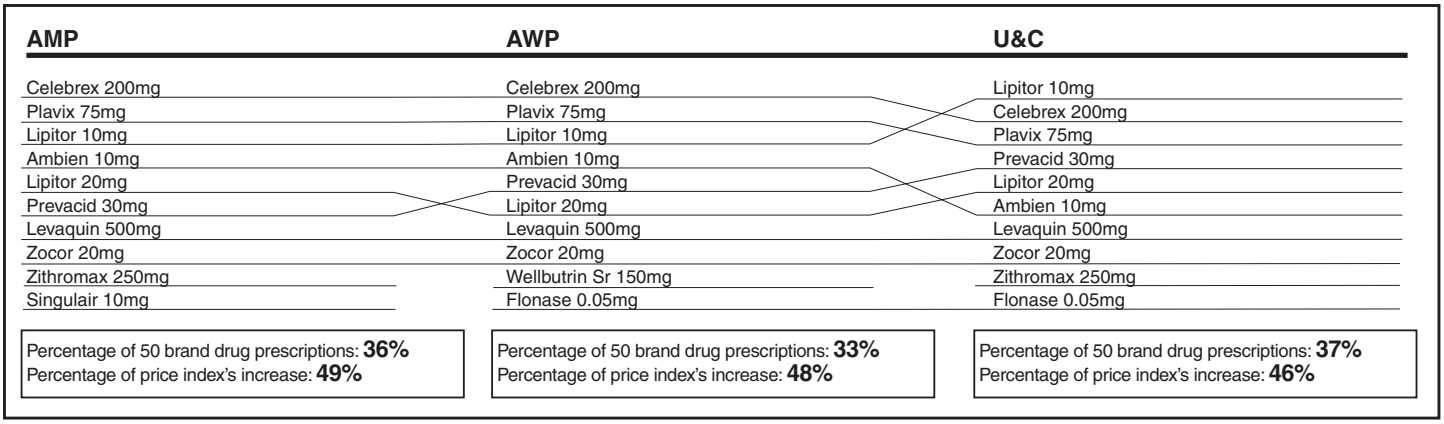
Source: GAO analysis of data from CMS, First DataBank, EPIC, PACE, and BCBS FEP.

The difference between the levels of AWP and U&C prices for brand drugs narrowed slightly during the time period we analyzed. Whereas in the first quarter of 2000 AWP was on average about 91 percent of the U&C price for the same drug, by the fourth quarter of 2004 AWP was on average about 94 percent of the U&C price. In contrast, AMP stayed a similar portion of U&C in first quarter 2000 and fourth quarter 2004, with the AMP on average about 72 percent of the U&C price.

Ten brand drugs in each index, representing one-third or more of the prescriptions for the 50 brand drugs, accounted for almost 50 percent of the increase for the quarterly AMP, AWP, and U&C price indexes. Eight of these 10 drugs were the same across all three price indexes. The drug accounting for the largest portion of the change in the AMP and AWP indexes was Celebrex 200mg, accounting for 8.6 percent of the increase for AMP and 7.5 percent for AWP. Lipitor 10mg was the drug accounting for the largest portion of the change in the quarterly U&C price index and

accounted for 7.2 percent of the increase for the 50 brand drugs. (See fig. 7.)

Figure 7: Comparison of 10 Drugs Accounting for the Largest Portions of Changes in AMP, AWP, and U&C Price Indexes for 50 Brand Drugs Frequently Used by BCBS FEP Enrollees, by Quarter, 2000 through 2004



Source: GAO analysis of data from CMS, First DataBank, EPIC, PACE, and BCBS FEP.

Concluding Observations

From 2000 through 2004, retail prices for drugs frequently used by Medicare beneficiaries increased 24.0 percent—an average rate of 4.5 percent per year. In general, higher drug prices mean higher spending by consumers and health insurance sponsors, including employers and federal and state governments. With brand drug prices increasing three times as fast as generic drug prices, public and private health insurance sponsors will likely continue to focus on strategies to encourage increased use of generic drugs when available. Starting in 2006, with the introduction of the Medicare prescription drug benefit, Medicare will be paying claims for a wider array of drugs and, as a result, the federal government will be affected more than previously by rising drug prices.

We found that from 2000 through 2004, on average the AWPs for 50 frequently used brand drugs rose 0.8 percent per year faster than the retail prices for these same drugs. A continuation of this difference between AWP and retail prices increases could affect many Medicaid programs and private third-party payers that base their reimbursement of drug claims on AWPs.

Agency and Other External Comments

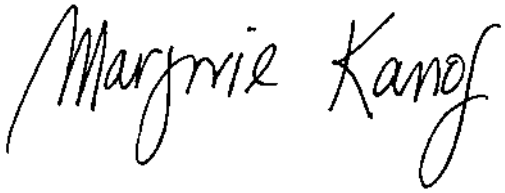
We provided a draft of this report to CMS, PACE, EPIC, and BCBS FEP. In commenting on this report, CMS highlighted the discounts and price information tools that will be available under the Medicare drug benefit. CMS also stated that neither the U&C price nor AWP reflect discounts, such as manufacturers' discount programs, or other price concessions affecting a drug's price. We noted in the report that U&C represents the retail pharmacy price paid by consumers without insurance. The U&C does not reflect prices available from other sources, such as mail order pharmacies. We also noted that AWP is a list price that is not the actual price paid by large purchasers. We agree that consumers may be able to obtain lower prices than reflected by the U&C and AWP. However, the focus of our analysis was to examine price trends rather than price levels, and U&C and AWP are consistent measures used to assess price trends. Further, increases in the published AWP may increase what many public or private third-party purchasers pay for prescription drugs because AWP is often included in the formula to calculate payments to pharmacies.

Additionally, CMS suggested that we examine the effect on prices when generic alternatives are introduced. We agree that the introduction of generic drugs can reduce consumer payments for drugs. Examining changes in consumer spending for drugs, which are also affected by changes in utilization and the introduction of new drug alternatives, would be useful, but was beyond the scope of this report in examining price trends for frequently-used brand and generic drugs.

PACE and BCBS provided technical comments that we incorporated as appropriate; EPIC stated that it did not have any comments.

As agreed with your offices, unless you publicly announce the contents earlier, we plan no further distribution of this report until 30 days after its date. We will then send copies of this report to the Administrator of CMS and other interested parties. We will also provide copies to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please call me at (202) 512-7114 or kanofm@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.



Marjorie Kanof
Managing Director, Health Care

Appendix I: Scope and Methodology

To examine the change in retail prices for prescription drugs frequently used by Medicare beneficiaries and other individuals with health insurance, we used data from the Blue Cross and Blue Shield (BCBS) Federal Employee Program (FEP) to select the 100 prescription drugs most frequently dispensed through retail pharmacies in 2003 for BCBS FEP Medicare enrollees and the 100 most frequently dispensed for BCBS FEP non-Medicare enrollees.[1] Combined, these two lists included 133 unique drugs.[2]

We obtained average monthly usual and customary (U&C) prices reported by retail pharmacies to Pennsylvania's Pharmaceutical Assistance Contract for the Elderly (PACE) program from January 2000 through December 2004 and New York's Elderly Pharmaceutical Insurance Coverage (EPIC) program from August 2000 through December 2004.[3,4] We collected prices based on a specific strength, dosage form, and common number of units (such as pills), typically for a 30-day supply.[5] Based on combined PACE and EPIC data, 96 of the 133 drugs we selected had prices reported for every month from January 2000 through December 2004. We

[1]BCBS FEP covered nearly 55 million prescriptions dispensed to enrolled federal employees, retirees, and their dependents at retail pharmacies in 2003, including 21 million prescriptions for FEP enrollees who were also Medicare beneficiaries. The 96 drugs that we included in our analyses represented about 32 percent of total prescriptions dispensed to BCBS FEP enrollees in 2003. Of these 96 drugs, 50 were brand drugs and represented about 17 percent of total prescriptions dispensed to BCBS FEP enrollees in 2003.

[2]Drugs with the same name but with different forms (such as capsules or tablets) or number of units dispensed were counted separately as unique drugs.

[3]PACE covered more than 9 million prescriptions and EPIC covered nearly 10 million prescriptions dispensed to mostly low-income seniors in 2003. As of June 2005, PACE officials reported that approximately 2,800 retail pharmacies—95 percent of pharmacies in Pennsylvania—participated in PACE, while EPIC officials reported approximately 4,150 retail pharmacies—87 percent of pharmacies in New York—participated in EPIC.

[4]We merged price data from PACE and EPIC for August 2000 through December 2004, but report price data from PACE alone for January 2000 through July 2000. Because the average of the U&C prices reported by PACE and by EPIC were nearly identical, we do not believe that including the EPIC data beginning in August 2000 notably affected the price trend.

[5]The Department of Veterans Affairs Pharmacy Benefits Management Strategic Healthcare Group provided the most common number of units for a retail prescription for a 30-day supply.

analyzed price trends on a monthly basis from January 2000 through December 2004 for these 96 drugs.[6]

Of the 96 drugs, 75 were among those most frequently used by BCBS FEP Medicare enrollees, and 76 were among those most frequently used by BCBS FEP non-Medicare enrollees. Fifty-five of the 96 drugs were frequently used by both BCBS Medicare enrollees and non-Medicare enrollees.[7] We first determined the total number of prescriptions in 2003 for the drugs we selected dispensed to BCBS FEP Medicare enrollees and the total number of prescriptions dispensed to BCBS FEP non-Medicare enrollees. Separately for drugs frequently used by Medicare and by non-Medicare enrollees, we calculated the share of the total number of BCBS FEP prescriptions attributed to each drug. The price of each drug was then weighted by its relative share of total Medicare or total non-Medicare prescriptions in 2003 to calculate the average price for frequently used Medicare drugs and the average price for frequently used non-Medicare drugs for each month from January 2000 through December 2004.[8,9] We standardized these averages to create a Medicare price index and a non-Medicare price index, each with a value of 100 as of January 2000.

We also separately analyzed monthly trends in U&C prices for brand and generic drugs frequently used by BCBS FEP enrollees. Of the 96 drugs, 50 were brand drugs and 46 were generic drugs. Similar to our calculation of

[6]We also analyzed price trends for 117 drugs that had prices reported for every month from January 2002 through December 2004, which had an average annual rate of increase of 5.2 percent. For the 96 drugs that had reported prices for every month from January 2000 through December 2004, the average annual rate of increase from January 2002 through December 2004 was also 5.2 percent.

[7]While these 55 drugs were used in calculating both the Medicare and non-Medicare U&C price indexes, they had different weights in each index depending on the frequency of prescriptions dispensed to BCBS FEP enrollees who were either Medicare beneficiaries or not Medicare eligible.

[8]BCBS FEP retail prescriptions represent various days supply (such as 34- or 90-day supply), while PACE and EPIC price data we obtained are limited only to retail prescriptions for a typical 30-day supply. Over half of BCBS FEP retail prescriptions are for a 30-day supply.

[9]The 2003 BCBS FEP retail prescription drug weights applied to PACE and EPIC retail prices for 96 drugs from January 2000 through December 2004 were held constant throughout the entire period of the analysis. We also obtained 2004 BCBS FEP retail prescription data for 89 of the 96 drugs and found almost no difference in the change in the U&C price index for the 89 drugs using constant 2003 or 2004 BCBS FEP drug weights throughout the period of analysis.

Medicare and non-Medicare price indexes, we calculated indexes for brand drugs and generic drugs based on each drug's share of the total number of brand or generic prescriptions dispensed to BCBS FEP enrollees in 2003.

To examine the change in retail prices for frequently used drugs compared to other drug price benchmarks, we compared an index based on the U&C prices reported by PACE and EPIC for 50 brand drugs to indexes based on the average manufacturer prices (AMP) and average wholesale prices (AWP) for these 50 drugs on a quarterly basis from the first quarter of 2000 through the fourth quarter of 2004.[10] The Centers for Medicare & Medicaid Services (CMS) requires manufacturers to report AMP within 30 days of the end of each calendar quarter. Manufacturers submit AWPs on a periodic basis to publishers of drug-pricing data, such as First DataBank. Using the National Drug Codes (NDC)[11] reported by PACE and EPIC for the U&C prices for the 50 brand drugs, we obtained per unit AMPs from CMS and per unit AWPs from First DataBank associated with each NDC.[12] For each drug, we calculated a quarterly AMP and a quarterly AWP by multiplying the per unit price by the most common number of units for a 30-day supply.[13] We created an AMP and AWP index by weighting the 50 brand drugs by the number of prescriptions in 2003 from BCBS FEP.

[10]These 50 brand drugs were frequently used by Medicare beneficiaries and non-Medicare enrollees in the BCBS FEP in 2003 and had reported U&C prices to PACE and EPIC for every month from January 2000 through December 2004.

[11]NDCs are three segment numbers that are the universal product identifiers for drugs for human use; the U.S. Food and Drug Administration assigns the first segment of the NDC, which identifies the firm that manufacturers, repackages, or distributes a drug. The second segment identifies a specific strength, dosage form, and formulation for a particular firm and the third segment identifies package size. A single drug can have multiple NDCs associated with it. For example, a drug made by one manufacturer, in one form or strength, but in three package sizes would have three NDCs.

[12]We obtained quarterly AMPs from CMS for each two-segment NDC, represented by 9 digits (not accounting for package size), associated with the 50 brand drugs from the first quarter of 2000 through the fourth quarter of 2004. Similarly, we obtained monthly AWPs from First DataBank for each three-segment NDC, represented by 11 digits, associated with the 50 brand drugs from first quarter 2000 through fourth quarter 2004. Specifically, we obtained the AWP effective on the last day of each month for each 11-digit NDC.

[13]For brand drugs with multiple 9-digit NDCs, we calculated an average quarterly AMP for the drug weighted by the number of PACE and EPIC prescriptions for each 9-digit NDC during that quarter. For brand drugs with multiple 11-digit NDCs, we calculated an average monthly AWP for the drug weighted by the number of PACE and EPIC prescriptions during that month. We created a quarterly AWP by taking a simple average of the three monthly prices in each quarter.

Similarly, we recalculated the U&C price for the 50 brand drugs on a quarterly basis to make comparisons to AMP and AWP.

We also determined how much each drug's change in price contributed to the overall change in price for the 50 brand drugs for AMPs, AWPs, and U&C prices. We measured the share each drug contributed to the overall index by comparing the ratio of (1) each drug's price change from January 2000 through December 2004 multiplied by its weight based on BCBS FEP prescriptions, to (2) the sum of all drugs price changes multiplied by their associated weights.

Our analyses are limited to drugs most frequently used by Medicare beneficiaries and by non-Medicare enrollees in the 2003 BCBS FEP. Additionally, our analyses using U&C prices are limited to prices reported by retail pharmacies in Pennsylvania to the PACE program and by retail pharmacies in New York to the EPIC program. We reviewed the reliability of data from BCBS FEP, CMS, First DataBank, EPIC, and PACE, including screening for outlier prices in the PACE and EPIC data and ensuring that the price trends and frequently used drugs were consistent with other data sources. We determined that these data were sufficiently reliable for our purposes. We performed our work from April 2004 through July 2005 in accordance with generally accepted government auditing standards.

Appendix II: Drugs Included in Analyses

Table 1 lists the 96 drugs used in constructing monthly U&C price indexes from January 2000 through December 2004. Fifty of the 96 drugs are brand drugs and were also used in examining price changes in AMP, AWP, and U&C on a quarterly basis from first quarter 2000 through fourth quarter 2004. Of the 96 drugs, 75 were frequently used by Medicare beneficiaries and 76 were frequently used by non-Medicare enrollees, with 55 of these drugs frequently used by both Medicare beneficiaries and non-Medicare enrollees.

Table 1: Ninety-Six Drugs Included in U&C Price Indexes, by Month, January 2000 through December 2004

Drug name and strength	Units dispensed and dosage form for a typical 30-day supply	Brand or generic	Medicare or non-Medicare
Acetaminophen/Codeine 30/300mg	60 tablets	Generic	Both
Aciphex 20mg	30 tablets delayed release	Brand	Both
Albuterol 90mcg	17gm aerosol	Generic	Both
Allegra-D 60-120 mg	60 tablets extended release	Brand	Non-Medicare
Allopurinol 300mg	30 tablets	Generic	Medicare
Alprazolam 0.25mg	60 tablets	Generic	Both
Alprazolam 0.5mg	60 tablets	Generic	Both
Ambien 5mg	30 tablets	Brand	Medicare
Ambien 10mg	30 tablets	Brand	Both
Amoxicillin 500mg	21 capsules	Generic	Both
Aricept 10mg	30 tablets	Brand	Medicare
Atenolol 25mg	30 tablets	Generic	Both
Atenolol 50mg	30 tablets	Generic	Both
Carisoprodol 350mg	90 tablets	Generic	Non-Medicare
Celebrex 200mg	60 capsules	Brand	Both
Celexa 20mg	30 tablets	Brand	Both
Cephalexin 500mg	30 capsules	Generic	Both
Cipro 500mg	20 tablets	Brand	Non-Medicare
Clonazepam 0.5mg	60 tablets	Generic	Non-Medicare
Combivent 103-18mcg	14.7gm aerosol	Brand	Medicare
Cosopt 2-0.5%	5mL solution	Brand	Medicare
Coumadin 5mg	30 tablets	Brand	Medicare
Cozaar 5mg	30 tablets	Brand	Medicare
Cyclobenzaprine HCl 10mg	60 tablets	Generic	Non-Medicare

Drug name and strength	Units dispensed and dosage form for a typical 30-day supply	Brand or generic	Medicare or non-Medicare
Doxycycline Hyclate 100mg	30 capsules	Generic	Non-Medicare
Effexor XR 75mg	30 capsules extended release	Brand	Non-Medicare
Effexor XR 150mg	30 capsules extended release	Brand	Non-Medicare
Evista 60mg	30 tablets	Brand	Both
Flomax 0.4mg	30 capsules	Brand	Both
Flonase 0.05mg	16gm spray	Brand	Both
Folic Acid 1mg	30 tablets	Generic	Both
Furosemide 20mg	60 tablets	Generic	Both
Furosemide 40mg	60 tablets	Generic	Both
Hydrochlorothiazide 25mg	30 tablets	Generic	Both
Hydrocodone/Acetaminophen 5/500mg	90 tablets	Generic	Both
Hydrocodone/Acetaminophen 7.5/500mg	90 tablets	Generic	Both
Hydrocodone/Acetaminophen 7.5/750mg	90 tablets	Generic	Non-Medicare
Ibuprofen 800mg	90 tablets	Generic	Non-Medicare
Isosorbide Mononitrate 30mg	30 tablets extended release	Generic	Medicare
Isosorbide Mononitrate 60mg	30 tablets extended release	Generic	Medicare
Klor-Con 10 10mEq	30 tablets extended release	Generic	Medicare
Lanoxin 125mcg	30 tablets	Brand	Medicare
Lanoxin 250mcg	30 tablets	Brand	Medicare
Levaquin 500mg	10 tablets	Brand	Both
Lipitor 10mg	30 tablets	Brand	Both
Lipitor 20mg	30 tablets	Brand	Both
Lipitor 40mg	30 tablets	Brand	Non-Medicare
Lorazepam 0.5mg	60 tablets	Generic	Both
Lorazepam 1mg	60 tablets	Generic	Both
Meclizine HCl 125mg	90 tablets	Generic	Medicare
Methylprednisolone 4mg	30 tablets	Generic	Non-Medicare
Metoprolol Tartrate 50mg	60 tablets	Generic	Both
Miralax 17gm	255gm powder	Brand	Medicare
Naproxen 500mg	60 tablets	Generic	Non-Medicare
Nasacort AQ 55mcg	16.5gm spray	Brand	Non-Medicare
Nasonex 50mcg	17gm spray	Brand	Non-Medicare

Drug name and strength	Units dispensed and dosage form for a typical 30-day supply	Brand or generic	Medicare or non-Medicare
Neurontin 300mg	90 capsules	Brand	Both
Norvasc 5mg	30 tablets	Brand	Both
Norvasc 10mg	30 tablets	Brand	Both
Oxycodone/Acetaminophen 5/325mg	90 tablets	Generic	Non-Medicare
Paxil 20mg	30 tablets	Brand	Both
Penicillin V Potassium 500mg	30 tablets	Generic	Non-Medicare
Plavix 75mg	30 tablets	Brand	Both
Potassium Chloride 10mEq	60 capsules extended release	Generic	Medicare
Potassium Chloride 10mEq	30 tablets extended release	Generic	Medicare
Pravachol 20mg	30 tablets	Brand	Medicare
Pravachol 40mg	30 tablets	Brand	Both
Prednisone 5mg	30 tablets	Generic	Medicare
Prednisone 10mg	35 tablets	Generic	Both
Prednisone 20mg	30 tablets	Generic	Non-Medicare
Premarin 0.625mg	30 tablets	Brand	Both
Prevacid 30mg	30 capsules delayed release	Brand	Both
Promethazine HCl 25mg	60 tablets	Generic	Non-Medicare
Propoxyphene Napsylate/Acetaminophen 100/650mg	90 tablets	Generic	Both
Ranitidine HCl 150mg	60 tablets	Generic	Both
Singulair 10mg	30 tablets	Brand	Both
Spironolactone 25mg	30 tablets	Generic	Medicare
Sulfamethoxazole/Trimethoprim 800/160mg	20 tablets	Generic	Both
Synthroid 50mcg	30 tablets	Brand	Both
Synthroid 75mcg	30 tablets	Brand	Both
Synthroid 100mcg	30 tablets	Brand	Both
Toprol XL 50mg	30 tablets extended release	Brand	Both
Toprol XL 100mg	30 tablets extended release	Brand	Both
Trazodone HCl 50mg	90 tablets	Generic	Both
Triamterene/Hydrochlorothiazide 37.5/25mg	30 capsules	Generic	Both
Triamterene/Hydrochlorothiazide 37.5/25mg	30 tablets	Generic	Both
Warfarin Sodium 5mg	30 tablets	Generic	Medicare
Wellbutrin SR 150mg	60 tablets extended release	Brand	Non-Medicare

Drug name and strength	Units dispensed and dosage form for a typical 30-day supply	Brand or generic	Medicare or non-Medicare
Xalatan 0.005%	2.5mL solution	Brand	Both
Zithromax 200mg/5mL	30 suspension	Brand	Non-Medicare
Zithromax 250mg	6 tablets	Brand	Both
Zocor 20mg	30 tablets	Brand	Both
Zocor 40mg	30 tablets	Brand	Both
Zoloft 50mg	30 tablets	Brand	Both
Zoloft 100mg	30 tablets	Brand	Both
Zyrtec 10mg	30 tablets	Brand	Both

Source: GAO analysis of data from BCBS FEP, EPIC, and PACE.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Marjorie Kanof (202) 512-7114 or kanofm@gao.gov

Acknowledgments

In addition to the contact named above, John E. Dicken, Director; Rashmi Agarwal; Jessica L. Cobert; Martha Kelly, Matthew L. Puglisi; and Daniel S. Ries made key contributions to this report.

GAO's Mission

The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are $2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, D.C. 20548

Public Affairs

Paul Anderson, Managing Director, AndersonP1@gao.gov (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, D.C. 20548