EXAMINING REFORMS TO IMPROVE THE MEDICARE PART B DRUG PROGRAM FOR SENIORS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

JUNE 28, 2013

Serial No. 113–64

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

86–388 WASHINGTON : 2014

For sale by the Superintendent of Documents, U.S. Government Printing Office
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FRIDAY, JUNE 28, 2013

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

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Present: Representatives Pitts, Burgess, Whitfield, Lance, Cassidy, Griffith, Bilirakis, Ellmers, Engel, Capps, Green, Barrow, Caster, and Waxman (ex officio).

Staff Present: Clay Alspach, Chief Counsel, Health; Gary Andres, Staff Director; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Member; Julie Goon, Health Policy Advisor; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Carly McWilliams, Professional Staff Member, Health; Monica Popp, Professional Staff Member, Health; Andrew Powaleny, Deputy Press Secretary; Heidi Stirrup, Health Policy Coordinator; Brian Cohen, Staff Director, Oversight and Investigations, Minority Senior Policy Advisor; Alli Corr, Minority Policy Analyst; Elizabeth Letter, Minority Assistant Press Secretary; Karen Lightfoot, Minority Professional Staff Member; and Stephen Salisbury, Minority Special Assistant.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. The time of 10:00 o'clock having arrived, the subcommittee will come to order. The chair will recognize himself for an opening statement.

Today's hearing is an opportunity for us to examine Medicare's part B drug benefit and to assess how well it is working for both seniors and providers. While most prescription drugs are covered under Medicare part D, certain outpatient prescription drugs and biologics are covered under part B. Covered part B drugs are usually those administered in a physician's office or hospital outpatient setting, including injectable and infused drugs, drugs used in conjunction with durable medical equipment, oral drugs for cancer or end stage renal disease, and some self-administered drugs in the hospital outpatient setting. As a result of the 2003 Medicare Mod-

ernization Act, MMA, Medicare reimburses providers for the cost of part B drugs and their administration at what is known as the average sales price, ASP, plus 6 percent, with Medicare paying 80 percent of that amount and beneficiaries paying the remaining 20 percent. I would like to commend members on both sides of the aisle for their work on the part B drug benefit. And I will highlight a few pieces of legislation.

H.R. 800 by Congressmen Whitfield and Green, which seeks to exclude prompt pay discounts from manufacturers to wholesalers from the calculation of ASP; H.R. 1416 by Congresswoman Ellmers, which would terminate application of sequestration to certain physician-administered part B drugs; and H.R. 1428 by Dr. Burgess and Representative Kind which seeks to provide coverage for immunosuppressive drugs for kidney transplant recipients.

And there are other issues as well. For example, reimbursement rates have caused a shift of some patient populations, such as those with primary immune deficiency diseases and other rare diseases, from treatment in the physician's office, treatment in the hospital outpatient department, arguably the worst setting for someone with a compromised immune system. We should also examine the variation in reimbursement rates for the same drugs and services across various settings to ensure that patients are being treated at the most clinically appropriate and cost effective site. While some drugs and biologics must be administered in the hospital outpatient setting, it is also the most expensive site of care for the Medicare program itself and for the beneficiary, who pays a 20 percent copayment.

I would like to welcome our witnesses today. They represent perspectives from the Federal Government, providers, and patients. And I look forward to their testimony. Thank you.

I yield the remainder of my time to Dr. Burgess.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today's hearing is an opportunity for us to examine Medicare's Part B drug benefit and to assess how well it is working for both seniors and providers.

While most prescription drugs are covered under Medicare Part D, certain outpatient prescription drugs and biologics are covered under Part B.

Covered Part B drugs are usually those administered in a physician's office or hospital outpatient setting, including injectable and infused drugs, drugs used in conjunction with durable medical equipment, oral drugs for cancer or End-Stage Renal Disease, and some self-administered drugs in the hospital outpatient setting.

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I'd like to commend Members on both sides of the aisle for their work on the Part B drug benefit, and I'll highlight a few pieces of legislation:

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We should also examine the variation in reimbursement rates for the same drugs and services across various settings, to ensure that patients are being treated at the most clinically appropriate and cost-effective site.

While some drugs and biologics must be administered in the hospital outpatient setting, it is also the most expensive site of care for the Medicare program itself, and for the beneficiary, who pays a 20% copayment.

I'd like to welcome our witnesses today. They represent perspectives from the federal government, providers, and patients, and I look forward to their testimony.

Thank you, and I yield the remainder of my time to Rep. _____.

Mr. BURGESS. I thank the chairman for the recognition.

So there is no question the part B drug coverage has improved the lives of patients. But Federal regulations can really stand in the way of compassionate patient care and common sense. After the Medicare Modernization Act, now nearly 10 years ago, we saw dramatic consolidations in the oncology space such that now the purchase and storage of drugs is regarded as physician service for the purposes of sequestration. Well, this ruling does not serve patients well. In fact, it is contrary to the statute itself, I believe. It is contrary certainly to any flexibility the agencies are supposed to have. And it is contrary to basic math.

Mr. Chairman, thank you for working with myself and others on both sides of the dais here to pursue answers from the Centers for Medicare & Medicaid Services on this important issue.

The math is also problematic and doesn't add up in how we pay for patient care after kidney transplantation. Medicare pays for 50,000 kidney transplants each year at a cost per patient of well over $125,000. So do the math on that, and it is over $60 billion a year. Kidney transplantation offered end stage renal disease patients an alternative to a lifetime of costly, time consuming, and sometimes painfully dialysis treatment. However, the government's protection of its investment arbitrarily ceases after 36 months, when Medicare suddenly refuses to pay for the life-sustaining immunosuppressant drug coverage needed to keep a transplanted kidney alive and functioning. So oddly, it is Federal policy—not the disease itself—that is the greatest threat to these patients. So instead of ensuring the investment, the government would rather lose patients or rather patients lose their graft, lose their kidney, return to dialysis, and get back in line for another transplant, taking another organ out of circulation for someone else. Instead of protecting the transplant, we further limited supply of donors' organs, and we burden the Federal budget while jeopardizing patient lives.

I challenge every member on this committee to support the bipartisan H.R. 1428 to correct this irrational and arbitrary policy. Our patients are waiting. I think they have waited long enough. It is time for us to put common sense in front of arcane policy.

Thank you, Mr. Chairman. I yield back.

Mr. PITTS. The chair thanks the gentleman.

Now filling in for the ranking member of the subcommittee Mr. Pallone, we have Mr. Green from Texas, who is recognized for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Chairman Pitts, for holding this important hearing. And thank you to the witnesses for taking the time to be with us, particularly Dr. Brooks and Dr. Melton. And we have so many Texans on here, you will hear we are from the great State of Texas many times, although sometimes that is redundant.

The part B drug program, which helps pay for chemotherapy and other services, is an important piece of Medicare. I have had a long interest in preserving seniors' access to quality care by ensuring Medicare pay at a rate that will retain a robust network of providers. This is what we are trying to do with the SGR reform. And I think part B rates are part of this larger discussion.

Today we are discussing at least three bills. The first, a bipartisan bill offered by my colleague from Texas Dr. Burgess, will provide Medicare coverage for immunosuppressive drugs for kidney transplant recipients. This bill has earned support from both sides of this committee. And it is my hope we can act on it and move to the full House for a vote.

The next bill offered by Mrs. Ellmers has earned support from both sides of this committee. Also it is imperative that we examine the impact of sequestration on cancer patients. And I am pleased this bill has been introduced because it highlights the shortcomings of using sequestration as a tool to accomplish our much needed goal of balancing the Federal budget. I am proud to lead the letter to CMS with my colleague from Texas, Congressman Pete Sessions, that was signed by 124 Members of Congress expressing concerns that cuts resulting from sequestration to critical cancer medications are forcing oncologists to turn cancer patients away. We asked CMS to do something about this problem with their existing authority but haven't gotten the answer we wanted. I should point out that I do not believe Mrs. Ellmers' bill goes far enough as part of the discussion around restoring the reimbursement rates. It must also be restoring funding for after-school lunches, medical research, education funding, Corps of Engineers, and other critical funding.

Finally, H.R. 800 is also known as the prompt pay bill that is being discussed today. I am proud to have introduced this bill in past sessions of Congress. I am pleased my colleague and friend Chairman Whitfield decided to introduce it most recently. We have worked together over the years to move this issue forward. The bill simply excludes the prompt pay discounts offered by manufacturers to wholesalers for the average sales price for drugs and biologics covered under Medicare part B. This became an issue when the Medicare Modernization Act was enacted. It reduces the amount doctors are reimbursed, sometimes below the amount they actually pay for administering cancer treatment and the result is fewer doctors participating in Medicare. Reducing the number of options for cancer patients reduces access, and that is just bad policy.

While some of my colleagues have pointed out that sequestration has also done this—and they are right—this is a separate issue. The prompt pay discount has negatively affected cancer patients for many years before sequestration. Whether we adopt legislation, repealing it, replacing it or otherwise altering sequestration, without adopting H.R. 800, the underlying issue will still exist. H.R. 800 is noncontroversial and has been supported by virtually every member of this committee. In fact it was adopted by this committee during the consideration of the Affordable Care Act by a voice vote, only to be unfortunately left out in the bicameral negotiations. The prompt pay bill deserves this committee's support. And I ask that Chairman Pitts move forward by marking up this legislation in the near future. Moving this bill or including it in a larger package makes sense.

And now, Mr. Chairman, I would like to yield my remaining time to my colleague, Congressman Engel.

Mr. ENGEL. Thank you. Thank you very much. I appreciate it.

As Wednesday's hearing highlighted, the current Medicare benefit structure is very complicated. It is particularly true with the drug benefit, where some drugs are covered if infused by an infusion pump under the part B benefit while others are covered under the part D benefit. Unfortunately, the part D benefit does not cover the supplies, equipment, and professional services necessary to deliver infusion drugs safely in the house. The nursing component for infusion therapy can only be performed under part A through a certified home health agency if the patient meets the definition of "homebound." As a result of this fractured benefit, many beneficiaries that could safely receive treatment at home are relegated to being served in a skilled nursing facility or hospital which adds unnecessary costs to the health care system and exposes patients to hospital-acquired infections. Unfortunately, Medicare stands virtually alone in denying coverage for home infusion even though the private sector has proven for decades that infusion in the home can be cost effective as well as done in a setting that best meets the patient's wishes. While Medicaid covers the drugs used in home infusion therapy and while that payment is important, we cannot continue to look only at the silo of drug payment without also looking at the need for full coverage of the associated equipment, supplies, and services for infusion therapy provided in the home or other alternate site settings. In the past, I have included legislation to make sure that the least costly clinically appropriate environment for infusion services is covered rather than forcing individuals to obtain these services in the hospital or nursing homes. And it is my hope that the committee and Congress work with me in that effort.

Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

We are voting on the floor. We have 11 minutes left. We will try to finish the opening statements of members at this time.

The chair yields to Mr. Whitfield for 5 minutes.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Well, Chairman Pitts, thanks very much. And I really appreciate the witnesses being with us today as we discuss these important topics. I certainly want to thank Gene Green and others who have been involved in our efforts to resolve the so-called prompt pay issue. As many of you know, manufacturers give discounts to distributors that help offset costs of shipping, handling, and reflects the time value of money and risk incurred in the distribution process. But when Medicare calculates how much a physician will be reimbursed for drugs under the part B program, it includes them in the sales price. And doing this artificially reduces the reimbursement to the physician, the oncologist, which places even more stress on these practices. In cancer, for instance, we know that four out of five patients that are treated are treated outside of a hospital, within a physician's practice. And over the past few years, there has been a trend of closings and consolidation of these practices. And any time I meet with an oncologist today—it makes no difference where they are from—they all cite reimbursement as one of the primary reasons for this consolidation and closing. But it is ultimately the patient that suffers the consequence of this problem, as clinics close or consolidate, access to care for the treatment of cancer is diminished, and patients are shifted into the hospital which we all know is the most expensive type of treatment. So I hope that as we work on this physician payment reform that we also take a serious look and solve the so-called prompt pay issue.

So I look forward to working with you, Mr. Chairman, and others as we try to resolve this very serious problem. And at this time, I would like to yield whatever time she may consume to Mrs. Ellmers of North Carolina.

Mrs. ELLMERS. Thank you to my colleague and thank you, Mr. Chairman, for holding this subcommittee hearing on these very important pieces of legislation. I have sponsored H.R. 1416, which is the Cancer Patient Protection Act. This benefit to our seniors, our Medicare recipients, is essential. We all know sequester went into effect. We needed those funding cuts at the Federal level. However, I believe wholeheartedly that as an unintended consequence of this, we have now harmed one of our most vulnerable populations, Medicare patients who have now received the diagnosis of cancer. You know we have wonderful cancer treatment centers in our communities. And I would like to point out also that it isn't just about cancer patients. It is also about patients with rheumatoid arthritis, osteoporosis, lupus, any autoimmune disease that medication has to be given under the direction of a physician.

We have to restore this sequester cut because it is the drugs that have been cut. And these drugs are very, very expensive. The physicians have received their 2 percent cut in reimbursement. But we have to restore that drug cut because we will not be able to continue to provide that benefit to them within their communities.

I can't imagine a family in crisis finding out about cancer to their loved one and then knowing that they are going to have to travel 20 miles outside of their community to go to a hospital. Many of

these individuals are on fixed incomes. They are low income. They will not have the ability to be transported to those facilities where the cost actually increases which, as we all know, defeats the purpose of the sequester to begin with.

So I feel very strongly we need to pass this piece of legislation. We have a bipartisan list of cosponsors. I am very proud of that. And we will continue in this effort, again, to protect those seniors in this way. It is very important.

And I yield back the remainder of my time.

Mr. PITTS. The chair thanks the gentlelady.

We have a little over 6 minutes left. At this time, the chair recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman. I want to thank our witnesses for coming here today. And I want to thank you for holding this hearing. It is our first time in quite a while that we have looked at the Medicare part B drugs. And this is a worthwhile focus because we spend, according to the GAO, almost $20 billion for these drugs each year, including some of the most expensive drugs on the market. We should be looking carefully at where the money goes.

We will be hearing about several pieces of legislation. We have already heard about them. And I know for several years oncologists and other providers have raised concerns about whether payments under the part B program are adequate. Their focus has been on legislation that would increase the Medicare average sales price and part B reimbursements by excluding prompt pay discounts. The Obama administration has a different view. Its budget proposes cuts in reimbursement rates. And I hope our witnesses can give us some insight on both the adequacy of part B drug reimbursement rates and whether there are opportunities to save money for taxpayers by modifying these rates.

We have already heard a little bit about Congresswoman Ellmers' bill. It would exempt part B drug reimbursement from the effects of the sequester. As part of the broad sequestered Medicare payments, part B drug reimbursement rates were reduced by 2 percent. We are going to hear from other witnesses today that will say that this cut will have a disproportionate impact on administrative reimbursements. Cancer clinics have reported that due to these payment cuts, they will have to turn patients away. Well, that would be a terrible outcome. These drugs are essential to cancer patients, and the arbitrary payment cuts undermine patient health and the entire Medicare program. This illustrates once again why an arbitrary and automatic sequester is such a bad policy.

My concern with Mrs. Ellmers' bill is that it only addresses one problem. We need a comprehensive and balanced sequester fix, not a piecemeal fix that increases payments for cancer drugs and ignores cuts to Head Start or Pell Grants or physician reimbursements or vaccines for children or vital defense programs. Sequestration was supposed to never happen. It was supposed to be so ri-

diculous that we were to avoid it. And now it is in place, and we ought to correct it.

Mr. Chairman, we shouldn't pretend the consequences of the part B payment cuts are an isolated example. They highlight the broader reality. When you take the hatchet to the Federal budget, there are going to be serious consequences. This is not an unintended, unforeseeable consequence. I also hope we can learn about other ways to cut part B drug spending. As I said earlier, part B drugs pay for $20 billion worth of drugs annually, including many expensive biological and specialty drugs. In some cases, these drugs can cost tens and even hundreds of thousands of dollars per patient per year. The Medicare program is the primary purchaser of these expensive drugs. Drugs save lives. We need these drugs, and we need to keep developing new ones. But we should also make sure that Medicare is getting a good deal.

I supported legislation in the past that ends the pay for delay abuses and brings generic biologics to market faster. My legislation, requiring part D drug manufacturing rebates, would save over $140 billion in the next decade, and we should be looking to see if there are other ways, like negotiations or rebates, that would help make sure taxpayers are getting their money's worth on part B drugs.

Let me give an example: For those people who are on Medicare and Medicaid, the dual eligibles, we used to pay for their drugs under Medicaid and we got a rebate. When the prescription drug part D bill was adopted, they said, let's take them out of Medicaid and put them under Medicare. Suddenly we are paying a higher rate for the same drugs, often for the same people. The drug companies love it. But why should we be spending that extra money when we can be using that for worthwhile purposes by making sure that the cancer drugs and the physicians who deal with those cancer drugs get adequately reimbursed. It is very frustrating to see people wanting to protect the drug companies' profits, wanting to protect every special interest group until they find one that they are sympathetic to. And we all are sympathetic to this issue because it deals with the most vulnerable people who have cancer.

I look forward to the hearing and am looking for some solutions.

Mr. PITTS. The chairman thanks members. That concludes the members' opening statements.

For information of the members, I am looking at the screen here, we have 1½ minutes left in the first vote but still 314 Members haven't voted. So we will have time to get over. We have a series of votes. We will reconvene after the last vote, which should be around 11:00. So at this point, the subcommittee stands in recess.

[Recess.]

Mr. PITTS. The recess having expired, we will reconvene.

On our panel today, we have five witnesses. Mr. Cliff Binder, Health Care Financing Analyst, Congressional Research Service; Dr. Barry Brooks, Partner at Texas Oncology on behalf of the U.S. Oncology Network; Ms. Nancy Davenport-Ennis, President and CEO of the National Patient Advocate Foundation; Dr. Larry Melton, Medical Director of Kidney/Pancreas Transplantation from Baylor Medical Center; James Cosgrove, Director of the Government Accountability Office.

Thank you for coming. Thank you for your patience as we were interrupted by votes on the floor.

Your written testimony will be entered into the record. You will each be given 5 minutes to summarize your testimony. And so at this time the chair recognizes Mr. Binder for 5 minutes for his opening statement.

STATEMENTS OF CLIFF BINDER, HEALTH CARE FINANCING ANALYST, CONGRESSIONAL RESEARCH SERVICE; BARRY BROOKS, M.D., PARTNER, TEXAS ONCOLOGY, ON BEHALF OF THE U.S. ONCOLOGY NETWORK; LARRY B. MELTON, M.D., PH.D., FACP, MEDICAL DIRECTOR, KIDNEY/PANCREAS TRANSPLANTATION, BAYLOR MEDICAL CENTER; NANCY DAVENPORT–ENNIS, CEO AND PRESIDENT, NATIONAL PATIENT ADVOCATE FOUNDATION; AND JAMES COSGROVE, DIRECTOR, GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF CLIFF BINDER

Mr. BINDER. Chairman Pitts, Congressman Green, and distinguished subcommittee members, I appreciate the opportunity to be here today. My name is Cliff Binder. I am a Health Care Financing Analyst at the Congressional Research Service. I was asked to provide an overview——

Mr. PITTS. Pull the mic a little closer, if you could.

Mr. BINDER. I was asked to provide an overview of Medicare part B prescription drug payments. In 2010, Medicare spent about $81 billion on most prescription drugs; and about a quarter of these expenditures, $19 billion, were for part B drugs. There are two broad principles that determine if a drug is covered under part B. The drug is furnished incident to physician services, and it is usually not self-administered. Most part B drugs are administered to patients by injection or infusion, but there are exceptions. Cancer drugs account for a large portion of part B drug expenditures. Providers—mostly physicians—but also hospital outpatient departments, clinics, and durable medical clinic suppliers buy part B drugs, then bill Medicare when they administer the drugs to patients. Physicians and other providers receive two payments from Medicare for part B drugs, one payment for administering the drug and the second payment for purchasing and supplying the drug. The Balanced Budget Act of 1997, BBA, set the payment rate for Medicare part B drugs at 95 percent of the average wholesale price, AWP. In spite of BBA changes, however, Medicare drug payments increased rapidly between 1999 and 2003, rising nearly 25 percent a year. In response to the part B drug price escalation, Congress modified the payment methodology in the Medicare Prescription Drug Modernization Act, MMA. MMA changed part B reimbursement in two ways. It increased the amount physicians received for part B drug administration and it decreased the amount physicians were paid for supplying part B drugs. Beginning in 2005, Medicare began paying for the majority of part B drugs based on a formula of 106 percent of the drug's average sales price, ASP. ASP includes most price concessions, such as volume and prompt pay discounts and rebates. When manufacturers factor price concessions into ASP data, the effect is to lower a drug's ASP. Drug manufacturers are

required to submit data to CMS on ASP and the companion price used mostly for Medicaid rebates average manufacturer price, AMP. CMS sets the part B drug prices for each quarter based on sales data submitted by drug manufacturers from two previous quarters. If drug manufacturers raised prices in the two quarters after they submitted their ASP data, providers might be unable to purchase drugs below what Medicare pays. When prices decline after manufacturers submitted their ASP data, such as when generic products are introduced, providers often are able to purchase these drugs for prices significantly below Medicare's payment rate. Medicare part B drug payments have increased at a slower pace since 2004, posting average increases of less than 5 percent a year. MMA also required the Inspector General to conduct drug price monitoring to determine if ASP is more than 5 percent higher than AMP. If Medicare part B drug payments exceed ASP by 5 percent or more, the Secretary has authority to substitute a different payment methodology that would reduce Medicare drug reimbursement. OIG has reported that there was at least a 5 percent difference between ASP and AMP for some part B drugs. There has been concern that part B drug reimbursement may be inadequate for some providers. Provider groups contend that discounts manufacturers give drug wholesalers have the effect of reducing ASP, making it difficult for these providers to cover the cost of purchasing some drugs. In addition, some in Congress and other groups have questioned whether drug shortages have been complicated by the part B drug pricing methodology and whether these, along with manufacturers' production problems, speculation, industry consolidation, and other factors have contributed to drug shortages, particularly for sterile injectable drugs, a part B drug category. Moreover, questions have been raised whether the two-quarter lag between the time when manufacturers report ASP and the time when CMS releases Medicare part B drug prices make it difficult for some providers to purchase drugs at competitive prices. Most recently, some providers have raised concerns that the effect of applying the mandatory Budget Control Act of 2011, BCA, reductions to Medicare part B drug reimbursement will further reduce payments to providers, potentially reducing Medicare beneficiaries' access to services.

In general, sequestration is the permanent cancelation of budgetary resources by a uniform percentage, but certain programs and activities are exempt from sequestration, and special rules may be applied to programs such as Medicare.

Even though there are special Medicare rules that would limit a reduction in program benefit spending to 4 percent, BCA limits the Medicare program benefits reduction to 2 percent; thus beginning April 1, 2013, Medicare payments for covered services, including physician services and part B drug payments, are subject to 2 percent reductions. According to CMS, the 2 percent reduction applicable to Medicare only applies to Medicare's provider payments. Beneficiary cost sharing amounts and amounts paid by other health insurance are not reduced.

This concludes my statement. I would be happy to answer questions.

Mr. PITTS. The chair thanks the gentleman.

[The prepared statement of Binder follows:]

Examining Reforms to Improve the Medicare Part B Drug Program for Seniors
Cliff Binder, Health Care Financing Analyst
Congressional Research Service
June 28, 2013

Chairman Pitts, Ranking Member Pallone, and distinguished Subcommittee Members, I am Cliff Binder, Health Financing Analyst with the Congressional Research Service. I appreciate the opportunity to be here today to provide an overview on Medicare Part B prescription drugs – what they are and how Medicare reimburses providers for these products. I also will provide context by discussing recently introduced legislation and the potential effect of sequestration on Medicare Part B drug payments. Part B drug reimbursement is complex, I am presenting the major points that I hope will be most useful in facilitating today's discussion.

BACKGROUND

Medicare is a federal program that pays for covered health care services of qualified beneficiaries. It was established in 1965 under Title XVIII of the Social Security Act to provide health insurance to individuals 65 and older, and has been expanded over the years to include permanently disabled individuals under 65.[1] The program is administered by the Centers for Medicare & Medicaid Services (CMS), within the Department of Health and Human Services (DHHS). Medicare consists of four distinct parts:

- Part A covers inpatient hospital services, skilled nursing care, hospice care, and some home health services.
- Part B covers physician services, outpatient services, and some home health and preventive services.
- Part C (Medicare Advantage, or MA) is a private health plan option that covers all Parts A and B services, except hospice. Individuals who choose to enroll in Part C must also enroll in Part B.
- Part D covers outpatient prescription drug benefits.

The majority of beneficiaries, nearly 73%, receive benefits through Medicare's fee-for-service (FFS) program, known as "original" or "traditional" Medicare. The remaining beneficiaries, approximately 27%, chose to enroll in private health care plans under Medicare Part C, the Medicare Advantage (MA) program. Approximately 73% of Medicare beneficiaries chose to enroll in Part D.[2]

Medicare covers drugs and biologics under Part B when they are furnished "incident to physician services," but only if they usually are not self-administered – the drugs are not *usually* taken by the patient without professional assistance.[3] Generally, Part B drugs are infused or injected. Most drugs administered as pills are not covered under Part B because they are self-administered.[4] To be covered by Part B, drugs must meet the following incident to physician services requirements (some drugs furnished by other health care practitioners may meet these requirements):

- furnished by a physician and administered by the physician or by auxiliary personnel under the physician's personal supervision;

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[1] For more information, see CRS Report R40425, *Medicare Primer*, coordinated by Patricia A. Davis and Scott Talaga.
[2] Ibid.
[3] *2013 Medicare Explained*, Sec. 351, Commerce Clearing House, Inc., WoltersKluwer.
[4] Medicare contractors determine whether or not a drug is considered *usually* self-administered. Usually, in this sense, means more than 50% of the time for all Medicare beneficiaries. If a drug was self-administered by more than 50% of Medicare beneficiaries, it would not be covered by Medicare Part B.

- the charge for the drug must be included in the physician's bill and the cost must represent an expense to the physician;
- are reasonable and necessary to diagnose or treat an existing illness or condition; and
- are not considered less than effective by the Food and Drug Administration (FDA).

There are a number of exceptions to these requirements. Preventive vaccinations and inoculations are not covered under Medicare Part B because they are considered "immunizations," unless they are directly related to treatment of a disease.[5] Other exceptions that are covered under Part B include antigens, blood clotting factors, erythropoietin (EPO) for treating anemia in dialysis and cancer patients, immunosuppressive drugs, injected osteoporosis drugs, and oral anti-cancer and anti-nausea drugs.[6,7] Most other outpatient drugs are covered under Medicare's Part D outpatient prescription drug benefit.

Providers, mostly physicians, but also hospital outpatient departments, clinics, and durable medical equipment suppliers, buy Part B drugs, then bill Medicare when they administer the drugs to patients. Physicians and other providers receive two payments from Medicare for Part B drugs (1) for administering the drug and (2) for purchasing and supplying the drug.[8]

In 2010, Medicare expenditures for most prescription drugs were approximately $81 billion.[9] Part B drug expenditures were about one-quarter of this spending, or about $19 billion, including the portion paid by beneficiaries.[10] Medicare beneficiaries generally pay 20% of Part B payments, although about 65% of Medicare beneficiaries have some form of supplemental health insurance coverage that pays most Part B coinsurance costs.[11] Even though a high percentage of Medicare beneficiaries have supplemental insurance, those without this coverage can face large Part B drug cost-sharing expenses, because many cancer and related drugs are expensive.

Medicare Part B covered about 600 outpatient drugs in 2010, although spending on these drugs was concentrated, with the top ten drugs accounting for nearly half of Part B drug expenditures.[12] Cancer

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[5] Medicare Part B covers influenza, pneumococcal, and hepatitis B vaccines regardless of setting, but physician supervision for the administration may not be necessary. Other vaccines, such as the shingles vaccine, are covered under Part D.

[6] Medicare began paying dialysis facilities a bundled rate January 1, 2011. EPO is included in the dialysis bundle although it also is covered under Part B when used in other situations.

[7] Oral dose drugs are covered by Part B when they have the same active ingredients and are used for the same indications as the drugs that are not self-administered and would have been administered incident to physician services. Oral anti-nausea drugs are covered under Part B when used as part of an anti-cancer chemotherapeutic regimen.

[8] Department of Health and Human Services, Office of Inspector General, *Medicare Part B Chemotherapy Administration Payment and Policy* (OEI-09-08-00109), June 2009.

[9] The Medicare Payment Advisory Commission (MedPAC), *Health Care Spending and the Medicare Program, A Data Book*, Section 10, Prescription Drugs, June 2012. This estimate includes Medicare payment, beneficiary cost sharing, and state expenditures for Parts B and D, including drugs supplied in physician offices, renal dialysis facilities, and hospital outpatient departments. These estimates exclude physician and other provider Part B drug administration payments.

[10] Ibid. Supplemental insurance coverage data is for non-institutionalized Medicare beneficiaries in 2009. In addition to the 65% of beneficiaries with supplemental coverage, another 27% of Medicare beneficiaries were enrolled in Medicare Advantage (MA) plans. MA plan beneficiaries might have coinsurance, but it would be lower than the 20% paid by fee-for-service beneficiaries.

[11] Ibid.

[12] MedPAC, *Health Care Spending and the Medicare Program, A Data Book*, Section 10, Prescription Drugs, June 2012.

treatment is the largest category of Part B drug expenditures – in 2010, seven of the top 10 drugs were for fighting cancer or relieving symptoms associated with chemotherapy.[13] The 2010 seven top-selling Part B drugs were biologic products.[14]

Medicare Part B Drug Reimbursement Methodology

The Balanced Budget Act of 1997 (BBA97, P.L. 105-33), set the payment amount for Medicare Part B drugs at 95% of the average wholesale price (AWP).[15] The BBA Part B drug changes were intended to help control Medicare's rising drug payments (Medicare did not cover outpatient drugs then, so the concern was with Part B drugs), but these drug payments continued to escalate rising nearly 25% per year from 1999-2003. AWP is a published list price, similar to the price sticker displayed on a new car's window. AWP and other list prices might be considered the price at which manufacturers would like to sell their product rather than a market price or acquisition cost. Since most buyers do not pay list price, AWP was limited as a benchmark. After BBA97, Medicare was paying substantially in excess of the physician/provider supplier drug acquisition cost, and Medicare's payments were higher than those paid by most other large payers. Providers argued that the reimbursement for Part B drugs was justified, because payments were too low to cover the cost of administering the drugs to beneficiaries.

The Medicare Prescription Drug Improvement and Modernization Act of 2003

In response to the Part B price escalation and with supporting analysis from the Medicare Payment Advisory Commission (MedPAC), Congress made changes to the Part B payment methodology in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA, P.L. 108-173).[16] MMA made the following two changes to Part B drug reimbursement: (1) adjusted (increased) the physician fee schedule amount physicians would receive for administering Part B drugs; and (2) established a new payment methodology for Part B drugs, effectively decreasing physician payments for supplying these drugs. The policy changes embodied in MMA moved drug reimbursement closer to what physicians and other providers and suppliers actually paid for these products and increased the amount they were paid for administering the drugs.

Since passage of MMA, annual Medicare Part B drug expenditures have grown at a slower rate. **Table 1** displays Medicare Part B drug spending and the growth rate percentage from 1997 to 2010.

Table 1. Medicare Part B Drug Expenditures 1997-2010 (in $billions)

Calendar Year	Estimated Part B Drug Expenditures	% Annual Expenditure Change
1997	$2.8	
1998	$3.2	14.3%
1999	$4.1	28.1%

[13] Ibid
[14] Ibid. Drugs refer to both biologic and synthesized products. Biologics are manufactured from living sources, including humans, animals, and micro-organisms. Synthesized products are manufactured from chemicals.
[15] Balanced Budget Act of 1997 (BBA97, P.L. 105-33), Sec. 4556, Reimbursement for Drugs and Biologicals.
[16] Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA, P.L. 108-173), Sec. 303, Payment Reform for Covered Outpatient Drugs and Biologicals.

2000	$5.0	24.4%
2001	$6.4	25.5%
2002	$8.5	32.8%
2003	$10.3	21.2%
2004	$10.9	5.8%
2005	$10.1	-7.3%
2006	$10.6	5.0%
2007	$11.0	3.8%
2008	$10.7	-2.7%
2009	$11.1	3.7%
2010	$11.5	3.6%

Source: Medicare Payment Advisory Commission (MedPAC), A Data Book: Health Care Spending and the Medicare Program, Section 10, June 2012.

Notes: Data include Part B covered drugs administered in physician offices or furnished by suppliers (e.g., durable medical equipment). Data do not include Part B drugs furnished in hospital outpatient departments or dialysis facilities.

MMA passed on December 8, 2003. The Part B drug payment changes were phased-in, so 2004 was a transition year during which time providers were paid for most Part B drugs based on 85% of the product's AWP.[17] Beginning in 2005, Medicare began paying for the majority of Part B drugs based on 106% of a drug's Average Sales Price (ASP).[18] ASP is defined as a manufacturer's quarterly sales of a drug to all U.S. purchasers; divided by the drug's total units sold for the same quarter.

However, MMA allowed for exceptions to this methodology depending on the site where a drug was administered. For example, vaccines, infusion drugs furnished through Durable Medical Equipment (DME), and blood products are paid at 95% of AWP.[19] Since sales data might not be available, new drug reimbursement may be based on the product's list price or invoice price. In addition, even though Medicare reimbursement for Part B drugs administered in hospital outpatient departments is based on ASP, there can be year to year variation. In 2013, hospitals receive 106% of ASP, but in some situations when the cost of the drugs exceed a certain threshold, Medicare makes additional (pass through) payments under the outpatient prospective payment system for certain drugs (some cancer drugs, new drugs, and orphan drugs).[20]

Drug manufacturers are required to report certain types of price information to the DHHS Secretary (the Secretary), including ASP and Average Manufacturer Price (AMP). CMS collects and maintains these confidential data. Drug manufacturers submit ASP and AMP data to CMS quarterly using National Drug Codes (NDCs), a standard 11-digit code that identifies the manufacturer, dosage form, and the product package size. Using a CMS-supplied template, manufacturers submit the number of units sold and the

[17] AWP has some limitations as a drug price benchmark including that is not necessarily based on actual sales transactions; it is not defined in law or regulation so it varies across manufacturers; and it fails to account for prompt pay or other discounts, rebates, and price concessions.
[18] Social Security Act Sec. 1847A(b)(1).
[19] CMS sets payment rates for blood products and vaccines based on current AWPs, but infusion drugs used with DME reimbursement is based on AWPs in effect October 1, 2003.
[20] In FY2012 the threshold was $75. Orphan drugs are those approved by the Food and Drug Administration to treat rare diseases. Drug manufacturers generally are given a seven-year market exclusivity period and other financial incentives for these drugs.

ASP for those units. CMS aggregates all drug manufacturers' ASP data and groups it by Medicare billing codes, so that ASP is the weighted average of all manufacturers' sales prices for each product classified under a Medicare billing code.[21] CMS calculates Part B ASPs for each billing code using an equation that includes the following variables: the ASP for the 11-digit NDC as reported by the manufacturer, the volume of sales for the NDC as reported by the manufacturer, and the number of billing units in the NDC as determined by CMS.[22]

Generally, there is one billing code for sole source products, but there can be many multiple-source products under a single billing code. Each billing code has a volume-weighted ASP.

ASP includes most price concessions – volume, prompt-pay, and cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates except Medicaid rebates.[23] Price concessions have the effect of lowering a drug's ASP.[24] Manufacturers' ASP data exclude nominal price sales and "best price" sales. To calculate ASP a manufacturer uses the amount that a buyer paid for a product, after deducting the amount or value of price concessions. The following examples help illustrate how price concessions affect ASPs.

- If a hospital bought 400 units of a drug for $2.50 per unit and was offered a 3% prompt pay discount, the manufacturer would consider the ASP for this transaction to be $2.425 per unit.
- If a drug wholesaler bought 400,000 units of the same drug and received a 3% prompt pay discount as well as a 5% rebate for a higher volume purchase, the ASP would be $2.304 for this product.
- If a manufacturer sold a state Medicaid program 1,000 units of the same drug for 2.50 per unit, then paid the state and the federal Medicaid program a combined 23.1% rebate, this entire transaction would be excluded from the manufacturer's ASP reporting for the quarter.

CMS sets the Part B drug ASPs for each quarter based on sales data submitted by drug manufacturers from two previous quarters. For example, ASP data submitted for sales from January-March (Quarter 1) is used to set Part B drug payment rates for the third quarter (October-December). If drug manufacturers raise prices in the two quarters after they submit their ASP data, it may be more difficult for providers to purchase products below the Medicare payment rate. However, when prices decline after manufacturers submit their ASP data, providers often are able to purchase these drugs for prices significantly below Medicare's payment rate. Part B drug prices decline when generic, multiple-source products are introduced that compete with sole source products or when other therapeutic equivalent sole-source products are introduced.

MMA also required the DHHS Office of Inspector General (OIG) to conduct drug price monitoring studies to determine if widely available market prices (WAMP) for Part B drugs varied by a specified percentage above AMP. MMA set the threshold at 5% for 2005, but the Secretary was to determine the

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[21] Manufacturers report ASP data by NDC code, but Part B drug prices are set by billing codes (called J-codes), so CMS "crosswalks" NDC codes to J-codes. J-codes are Level II Healthcare Common Procedure Coding System Codes.

[22] Social Security Act Sec. 1847A(b)(6).

[23] Manufacturers negotiate discounted prices with some purchasers who buy through wholesalers. Wholesalers can deliver the drugs at discounted prices, inform the manufacturers, and then request reimbursement from the manufacturers. These discounts, handled through wholesalers, are generally known as charge-backs.

[24] Social Security Act Sec. 1847A(c)(3), Net of Discounts, identifies the price concessions that manufacturers are to subtract from ASP.

threshold after 2005. The Secretary set the threshold at 5% in 2006, and it has remained at that level.[25] If the Medicare Part B drug payment rate for specific drugs exceeds WAMP or ASP by 5% or more, the Secretary has authority to substitute the lesser of either WAMP or 103% of a drug's AMP for ASP in setting Part B drug reimbursement. Generally, AMP is lower than ASP, so that Medicare would reduce provider reimbursement for most Part B drugs, under AMP. The OIG has consistently found that there was at least a 5% difference between WAMP or AMP and ASP for some portion of Part B drugs.[26] In November 2012, CMS published a final rule that will implement a Part B drug price substitution policy beginning on January 1, 2014.[27]

Selected Issues

A number of Medicare Part B drug payment issues have been discussed for some time. In spite of considerable analysis, there is concern that Part B drug reimbursement may be inadequate for some providers in some situations. Some providers are concerned that discounts provided by manufacturers to drug wholesalers have the effect of reducing ASP, making it difficult for these providers to cover their costs when purchasing some Medicare Part B drugs.[28] In addition, some in Congress and some stakeholders have questioned whether drug shortages have been complicated by the Part B drug pricing methodology changes in MMA and whether these, along with manufacturers' production problems, speculation, industry consolidation, and other factors, have contributed to drug shortages, particularly for sterile injectable drugs, a Part B drug category.[29] [30]
Moreover, concerns have been raised that the two-quarter lag between the time when manufacturers report ASP and AMP and the time when CMS releases Medicare Part B drug prices make it difficult for some providers to purchase drugs at competitive prices.[31] The OIG also has reported that the two-quarter lag between ASP reporting and setting new prices causes the federal government to overpay for Part B drugs, particularly when new generic drugs are released.[32] Most recently, some providers have raised concerns that the effect of applying the mandatory Budget Control Act of 2011 (BCA, P.L. 112-25)

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[25] See 77 *Federal Register* 68891, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013," November 16, 2012.
[26] Department of Health and Human Services Office of Inspector General, Memorandum Report: *Comparison of First-Quarter 2012 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for the Third Quarter 2012*, OEI-03-12-00730, December 2012. This report was the 26th report on Medicare ASPs prepared by OIG.
[27] See 77 *Federal Register* 68891, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013," November 16, 2012.
[28] See letter to U.S. House of Representatives from the American Society of Clinical Oncology and other cancer organizations, April 1, 2013 at https://media.gractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/40a929e3-7abc-4ab8-ba26-8f1127438934.pdf.
[29] House Committee on Oversight and Government Reform, *FDA's Contribution to the Drug Shortage Crisis*, Staff Report, June 15, 2012 at http://oversight.house.gov/wp-content/uploads/2012/06/6-15-2012-Report-FDAs-Contribution-to-the-Drug-Shortage-Crisis.pdf.
[30] *Shining Light on the "Gray Market," An Examination of Why Hospitals Are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages*, Staff Report, July 25, 2013. at http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=afa98935-2ff5-4004-88dc-be70d1c22b5d.
[31] Department of Health and Human Services, Office of Inspector General, *Average Sales Prices: Manufacturer Reporting and CMS Oversight* (OEI-03-08-00480), February 2010.
[32] Department of Health and Human Services, Office of Inspector General, *Medicare Payments for Newly Available Generic Drugs* (OEI-03-09-00510), January 2011.

reductions to Medicare Part B drug reimbursement will further reduce payments to providers, potentially reducing beneficiaries' access to services.[33]

The Effect of Sequestration on Medicare Part B Drug Reimbursement

"Sequestration" is a process of automatic, largely across-the-board spending reductions to meet or enforce certain budget policy goals.[34] It was first established by the Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA, Title II of P.L. 99-177, 2 U.S.C. 900-922) to enforce deficit reduction targets.

Most recently under BCA, sequestration was tied to enforcement of new statutory limits on discretionary spending and achievement of the budget goal established for the Joint Select Committee on Deficit Reduction. A sequestration was triggered by the Joint Committee's failure to achieve its goal and was originally scheduled to occur on January 2, 2013, to affect spending for FY2013. Congress enacted legislation that delayed the effective date of this sequester until March 1, 2013 (American Taxpayer Relief Act of 2012, P.L. 112-240).[35]

In general, sequestration entails permanent cancellation of budgetary resources by a uniform percentage.[36] The uniform percentage reduction is applied to all "programs, projects, and activities" (PPAs) within a budget account, but certain programs and activities are exempt from sequestration, and special rules may be applied to other programs, such as Medicare.[37]

Specifically, Section 256(d) of BBEDCA contains special rules for the Medicare program in case of a sequestration. However, while BBEDCA ordinarily limits reduction of Medicare spending on program benefits to 4% under a sequestration order (which would apply in the case of a Statutory PAYGO sequestration), BCA limits the size of this reduction to 2%. Thus, beginning April 1, 2013, Medicare payments for covered services, including physician services and Part B drug payments, are subject to 2% reductions.

According to CMS guidance, provider payment adjustments are to be made to claims after determining coinsurance, any applicable deductible, and Medicare Secondary Payer adjustments.[38] In other words, the 2% reduction applicable to Medicare only applies to Medicare's provider payments; the beneficiary cost-sharing amounts and amounts paid by other health insurance are not reduced.

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[33] Healthcare Distribution Management Association, Medicare Average Sales Price Policy, at http://www.hdma.net/gov_affairs/pdf_positions/MedicareAverageSalesPrice.pdf.

[34] For more information on sequestration and its historical application, see (1) CRS Report RL31137, *Sequestration Procedures Under the 1985 Balanced Budget Act*, by Robert Keith; (2) CRS Report RS20398, *Budget Sequesters: A Brief Review*, by Robert Keith; and (3) CRS Report R41901, *Statutory Budget Controls in Effect Between 1985 and 2002*, by Megan S. Lynch.

[35] President Obama issued the sequestration order on March 1, 2013. See http://www.whitehouse.gov/sites/default/files/omb/memoranda/2013/m-13-06.pdf.

[36] "Budgetary resources" include new budget authority, unobligated balances, direct spending authority, and obligation limitations, as defined in Section 250(c)(6) of BBEDCA, as amended.

[37] For accounts included in appropriations acts, "programs, projects, and activities" (PPAs) within each budget account are delineated in those acts or accompanying reports; for accounts not included in appropriations acts, they are delineated in the most recently submitted President's budget. See Section 256(k) of BBEDCA, as amended.

[38] CMS, Medicare FFS Provider e-News, March 8, 2013, *Monthly Payment Reductions in the Medicare Fee-for-Service (FFS) Program – "Sequestration,"* http://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf.

Table 2 illustrates how budget cuts might affect Medicare Part B drug payments for physicians and patients.[39] As shown in line #2 in **Table 2**, for a Part B drug with an ASP of $943.40, the Part B drug

Table 2. Example Sequestration Effects on Medicare Part B Drug Payments

Line #	Medicare Part B Drug Payment Calculation	Medicare Payment Amount
1	ASP	$943.40
2	106% ASP	$1,000.00
3	Beneficiary Coinsurance	$200.00
4	Pre-sequestration Medicare Payment Portion	$800.00
5	Medicare Payment Portion after 2% Sequester	$784.00
	Physician Payment Before Sequester	
6	Medicare	$800.00
7	Beneficiary	$200.00
8	Total	$1,000.00
	Physician Payment After Sequester	
9	Medicare	$784.00
10	Beneficiary	$200.00
11	Total	$984.00

Source: Centers for Medicare & Medicaid Services (CMS).

Notes: This example assumes that the beneficiary has met the deductible. This example also assumes that the provider participates in Medicare and accepts assignment, so the beneficiary may not be billed for higher copayments to make up for reduced provider reimbursement.

reimbursement would be $1,000 based on the normal Medicare payment methodology. Line 3 displays the beneficiary's coinsurance, which is 20% of what Medicare pays – in this case $200. Line 4 displays what the physician would have received in payment from Medicare for the Part B drug, prior to sequestration (106% of ASP [$1000] – beneficiary coinsurance $200, i.e. $200. Line 5 shows the reduced payment the physician receives under sequestration, where the 2% reduction was applied only to the portion of the reimbursement paid by Medicare [($800* 2% = $16) and ($800-$16 = $784)]. As shown in lines 9-11, under sequestration physicians would receive a total payment of $984 for this Part B drug, which represents approximately a 1.6% payment reduction from the $1,000 that they would have been paid before sequestration. The sequestration cuts would reduce Medicare Part B drug payments in this example to approximately 104.3% of ASP.

Some providers and other stakeholders assert that the BCA budget cuts potentially could force providers to stop seeing Medicare patients who need particular drugs that these providers cannot purchase at competitive prices.[40]

[39] Letter to Representative Sessions (R-TX) from Marilyn Tavenner, Administrator, Centers for Medicare & Medicaid Services, June 3, 2013.

[40] See April 1, 2013 letter to United States House of Representatives from American Society of Clinical Oncology, Community Oncology Alliance, International Oncology Network/AmerisourceBergin, and the US Oncology

Proposed Legislation

H.R. 800, introduced by Representative Whitfield on February 15, 2013, would amend the Social Security Act to exclude customary prompt pay discounts extended by manufacturers to wholesalers from the Medicare Part B ASP calculation.[41] This exclusion would increase manufacturers' ASPs.[42] Supporters of the legislation assert that higher ASPs would increase reimbursement for physicians who are administering Medicare Part B drugs. This higher reimbursement might be more important and more beneficial for smaller, community-based oncology practices that are unable to purchase drugs in sufficient volume to get the most competitive market prices.

Excluding customary wholesale prompt pay discounts from ASP calculations would not change other price concessions that are subtracted from ASP. Pharmaceutical pricing can be very dynamic, so that price concession currently provided to wholesalers as prompt payment discounts might re-emerge in another form or be passed on through other existing mechanisms such as chargebacks, rebates, or in bundled prices. In addition, H.R. 800 also might increase coinsurance payments for Medicare beneficiaries, since they pay 20% of Medicare Part B drug costs.

H.R. 1428, the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2013, was introduced by Representative Burgess on April 9, 2013. Under current law, individuals with End Stage Renal Disease (ESRD), who meet certain requirements, are eligible for Medicare. If an ESRD patient receives a kidney transplant, Medicare eligibility expires three years after the successful kidney transplant. Generally, kidney transplant recipients must take immunosuppressive drugs the rest of their lives to suppress their body's immune system reaction to the transplanted organ. Medicare covers immunosuppressive drugs under Part B for an unlimited period of time, but kidney transplant patients lose their Medicare eligibility three years after they received their successful transplant. H.R. 1428 would, among other things, amend the Social Security Act to provide Medicare coverage of immunosuppressive drugs beyond the three-year period.

H.R. 1416, the Cancer Patient Protection Act of 2013, was introduced by Representative Ellmers (R-NC) on April 12, 2013. H.R. 1416 would exempt Medicare Part B drug payments from the BCA mandatory budget cuts. H.R. 1416 would be effective for payments made beginning April 1, 2013, and would not be applicable to any other Medicare program or law.

Network at https://media.gractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/40a929e3-7abc-4ab8-ba26-8f1127438934.pdf.

[41] Senator Roberts introduced S. 806, a parallel bill, April 24, 2013.

[42] Similar legislation was introduced in the 111th and 112th Congresses.

Mr. PITTS. I now recognize Dr. Brooks for 5 minutes for an opening statement.

STATEMENT OF BARRY BROOKS, M.D.

Dr. BROOKS. Chairman Pitts, Congressman Green, members of the committee, thank you for the opportunity to testify on behalf of the U.S. Oncology Network and community oncology in general on the Medicare part B drug program.

I am Barry Brooks. For 31 years, I have been taking care of cancer patients. Being an oncologist is intellectually and emotionally challenging, but I think it is the best job in the world, and I love it. As a community oncologist, I feel I am part of a dying breed. Our way of life and practice is being squeezed out of existence. We are struggling to make ends meet and continue to care for our beloved cancer patients in the private practice setting. But the way red ink is spreading over our ledgers, there won't be many of us left in a few years. Instead, we will all be employed in arrangements we don't like in institutions where doing the right thing requires executive approval. But I am not here to complain about my job prospects. I am here to talk about demographics and math.

Medicare covers over 60 percent of cancer patients and the Medicare population is growing every day. And worse, the expensive care these patients need are shifting from my low cost realm into higher cost arenas. You all know the problem, cancer care costs more in the hospital outpatient department. And hospital-based care is growing by leaps and bounds. The root of the problem has two parts. One, Medicare doesn't adequately cover the cost of community oncology practice care; and, two, Medicare payments and rules are tilted in favor of the hospital. Since 2005, community oncologists have been slowly bleeding to death. After MMA, Medicare pays us for cancer patients an average sales price plus a 6 percent service payment for the costs and risks associated with purchasing, storing, mixing, administering, disposing these drugs. The 6 percent is the only Medicare payment for the significant work to prepare chemotherapy for administration. And even if the drugs are ready for infusion on arrival to our practice, paying acquisition costs would not reflect the cost of inventory and the systems needed to manage it.

Even prior to sequestration, Medicare drug reimbursement did not cover our costs. Due to technical flaws in the ASP formula plus six in theory does not equal plus six in reality. Wholesaler prompt pay discounts reduce ASP values that are not extended to our clinics. ASP values always take 6 to 8 months to be reflected in our price. We cannot collect the entire copay allowable and Medicare does not reimburse us for uncollectible beneficiary coinsurance.

These issues are not new. As far back as 2007, MedPAC reported the reimbursement for some drugs was below market price. This means that we have to give away our services for free or, worse, we have to pay for seniors' cancer drugs out of our own pockets. Since April 1, we are living under ASP plus 4.3 percent. While controlling deficit spending is important, the Administration's decision to apply the sequester both to our 6 percent payment services part and to the entire drug costs has effectively cut our services pay-

ment by 28 percent. It forces us to subsidize Medicare patients or send them elsewhere for care.

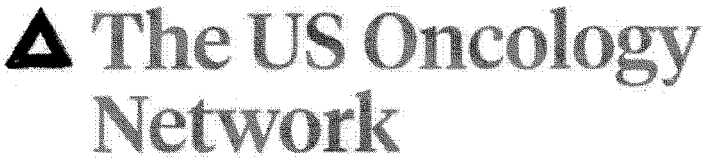
Oncologists around the country are making these difficult decisions, and I respect each practice's choice. But one thing is certain, operating at a loss on more than half your patients is not a sustainable model. While tweaks to the Medicare reimbursement rates would go a long way towards shoring up community cancer care, variations in reimbursement for the same services in different outpatient services tilt the competitive landscape in favor of the hospital and encourage inefficiency. One-third of U.S. hospitals purchase chemotherapy drugs through the 340(b) program and enjoy margins of over 30 percent on their Medicare cancer drugs. It is no wonder drug spending in hospitals is increasing so rapidly and patients and oncologists alike are migrating to these settings. Pushing patients with expensive to treat conditions into more expensive settings to get the same care and the same result makes as much sense as adding a trap door to a canoe. The patients get lost in this setting. The hospitals get lower drug costs. They get higher reimbursements. The patients have to travel further. They have to wait longer. They have to pay more out of pocket. This is just not right, and it is not necessary.

I know I am preaching to the choir here. Members of this committee have introduced and supported legislation like that from Congressmen Green and Whitfield to help with prompt pay; Congresswoman Ellmers' H.R. 1416; 30 members of the committee have signed a letter questioning how the Administration handles sequester cuts on Medicare part B for oncology; and others have just signed a recent leadership letter to the so-called Lance-Pascrell. We also want to thank Congressman Rogers and others working with him to implement site-neutral payment, as recommended recently by MedPAC. The world's best cancer care delivery system is struggling to take care of our patients. We and they need your help.

Thank you for letting me talk today.

Mr. PITTS. The chair thanks the gentleman.

[The prepared statement of Dr. Brooks follows:]



Submitted Testimony of Dr. Barry Brooks on the
Benefits and Challenges of Medicare Part B Drugs
Energy and Commerce Health Subcommittee Hearing
Examining Reforms to Improve the Medicare Part B Drug Program for Seniors
June 28, 2013

Chairman Pitts and Ranking Member Pallone, thank you for the opportunity to testify today on behalf of The US Oncology Network[1] before the Energy and Commerce Subcommittee on Health on the role and importance of Medicare Part B drugs in community oncology. The Energy and Commerce Committee has always been especially committed to cancer patients and providers over the years and many of the Members on this Committee have been relentless champions for cancer patient access. We appreciate your dedication and support for Americans fighting cancer and for those of us who try to help them live longer, happier lives.

My name is Barry Brooks, and for the last 31 years I have spent the majority of my time taking care of cancer patients. On an average day I work more than 12 hours. Though a lot of my time is spent on administrative tasks, still I see 14-20 patients a day. Slightly over 40 percent of my patients rely on Medicare and another 5-10 percent are either covered by Medicaid or are uninsured. I am proud to be a cog in the world's most

[1] The US Oncology Network is one of the nation's largest networks of community-based oncology physicians dedicated to advancing cancer care in America. Like-minded physicians are united through The Network around a common vision of expanding patient access to high-quality, integrated cancer care in communities throughout the nation. Leveraging healthcare information technology, shared best practices, refined evidence-based medicine guidelines, and quality measurements, physicians affiliated with The US Oncology Network are committed to advancing the quality, safety, and science of cancer care to improve patient outcomes. The US Oncology Network is supported by McKesson Specialty Health, a division of McKesson Corporation focused on empowering a vibrant and sustainable community patient care delivery system to advance the science, technology and quality of care. For more information, visit www.usoncology.com.

effective and successful cancer care delivery system because after nearly 100 years of increasing cancer death rates in the United States, we have started to turn the corner in this fight. Cancer mortality has fallen by 20 percent from a 1991 peak and now cancer patients from around the world seek care here because Americans enjoy the best cancer survival rates in the world.

Yet, there remains much work to do to realize our potential of eradicating cancer. The American Cancer Society estimates 1.6 million Americans will be diagnosed with cancer and more than 580,000 will die of cancer in 2013. As has been the case for decades, only cardiovascular disease will kill more Americans. To step up and win this important fight, we need a stable and sustainable cancer care delivery system. That's where community cancer care and Medicare Part B coverage for physician-administered drugs comes in. Community based cancer care provides patients with convenient, comprehensive, state-of-the-art cancer treatment close to home. And more than 60 percent of US cancer patients rely on Medicare to pay their medical bills. That makes Medicare policy for chemotherapy and other intravenous drugs a huge issue for a lot of Americans.

Medicare Part B Drugs Generally

The Medicare program is the primary source of health coverage for most senior citizens. Part A of the program covers inpatient services, while Part B focuses on the services of physicians and other treatments received in the outpatient setting. Most coverage of prescription drugs is provided separately under Medicare Part D while drugs that require

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physician administration are covered under Part B. Part B coverage is particularly important for cancer patients: chemotherapy drugs and anti-cancer therapies account for 7 of the top 10 therapies covered by Part B.[2]

Medicare Reimbursement for Part B Drugs

In the Medicare Modernization Act of 2003 (MMA), Congress enacted the Average Sales Price (ASP) reimbursement methodology for Part B drugs. ASP reflects the average price of a drug's sales to all purchasers in the United States. Based on data received directly from manufacturers, the Centers for Medicare and Medicaid Services (CMS) calculates the ASP for each Healthcare Common Procedure Coding System (HCPCS) code covered under Medicare Part B. A HCPCS code may include drugs from more than one manufacturer in the case of multiple source drugs, or in the case of single source drugs that shared the same HCPCS code prior to enactment of the MMA.

Pursuant to the MMA statute, Medicare reimburses physicians for cancer drugs at average sales price (ASP) plus a 6 percent services payment to compensate community cancer clinics for the operational complexity and financial risks associated with purchasing, storing, mixing, administering and disposing of these highly potent and effective therapies. Community oncology practices buy the drugs on behalf of CMS and CMS pays an additional six percent above acquisition cost to manage the product and prepare it for administration to patients. This six percent is incredibly important because

[2] Moran Company analysts tabulated the top ten drugs based on Part B spending in 2009. Six of the top ten drugs were chemotherapy agents. Two were drugs designed to treat chemotherapy related anemia.

none of the work that must occur to prepare chemotherapy for administration to a patient is otherwise reimbursed by Medicare. For the most part, state laws require very specific infrastructure and personnel for the storage and preparation of these drugs. The drugs must be stored at controlled temperatures, mixed to the proper dose and bagged for administration by trained pharmacists and admixture technicians within approved clean rooms that often cost tens of thousands of dollars in investments in pharmacy hoods and double negative pressure areas to prevent the toxic materials from harming staff and other patients. Even in small clinics with one or two medical oncologists, the ancillary staff to do all the above can be 4-5 highly trained professionals and in larger clinics, the staffing is accordingly much bigger. Even if every drug were ready to be administered to a patient at the moment it arrived on the doorstep of the practice, paying exactly only acquisition cost for the drug would still be problematic and would not properly reflect the financial costs of inventory as well as the significant infrastructure investment to manage and control this unique inventory.

The current Medicare reimbursement structure for Part B drugs is not perfect, but it has achieved many of the goals of those who designed it back in 2003. It has clearly created a more accurate reimbursement approach than the prior system and it has attenuated the prior significant growth rate of Part B drug units and spending, creating stability in the costs to Medicare and the patients who rely on it. A recent study of Medicare data indicates that "[o]ver the past several years, total payments and units have remained stable, while changes in the weighted average ASP show that pricing in the aggregate for

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drugs and biologics in Medicare Part B…has remained flat."[3] The current ASP system has also diminished overall IV drug prices and price increases, notwithstanding the typical media coverage of new high-priced therapies. The same analysis of Medicare data demonstrates "while CPI-M has gradually been increasing from 2006 to the present, the volume-weighted ASP has maintained a much flatter line."[4] ASPs have been steady, or decreasing, for the last two quarters according to CMS.[5] In other words, price decreases associated with generic transitions have offset price increases and the introduction of new, high-priced drugs over the past decade, just as one should expect from a mature and healthy system that balances innovation with access.

Recent Shifts in Site of Service for Part B Drugs

There are also challenges that impede access to life-saving and life-lengthening therapies that we offer. Recent weeks have raised the national consciousness about the tremendous strain imperiling our nation's cancer care delivery system. Just 8 years ago, 87 percent of cancer care occurred successfully in cost-effective community oncology practices.[6] In recent years, this percentage has dropped significantly as Medicare policies have created an environment where doctors break even or operate at a loss when helping seniors fight cancer.

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[3] Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2012, The Moran Company, December 2012. Online at: https://media.gractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/cef337d0-5331-4659-8cb5-cfa3ca2e8f62.pdf

[4] ibid

[5] CMS ASP Drug Pricing Files, July and April 2013. Online at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2013ASPFiles.html

[6] Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries; The Moran Company, May 2013. Online at: https://media.gractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/01655fe9-7f3d-4d9a-80d0-d2f9581673a1.pdf

The data are clear: our world-class community cancer care delivery system is struggling to survive. Since 2008, 1,338 community cancer care centers have closed, consolidated, or reported financial problems. Over the past several years, the country has experienced a shift of outpatient cancer care delivery from the physician office to the hospital outpatient department; 288 oncology office locations have closed, 407 practices merged or were acquired by a corporate entity other than a hospital, and 469 oncology groups have entered into an employment or professional services agreement with a hospital.[7] By 2011, nearly a third of Medicare's outpatient chemotherapy and anti-cancer drugs had moved to the hospital setting, a more than 150 percent increase for HOPDs. Medicare payments for chemotherapy administration services in hospital outpatient settings have more than tripled since 2005, while payments to community cancer clinics have actually decreased by 14.5 percent.[8] And sadly the flight from community oncology did not end in 2011. Since early 2012, there has been a 20 percent increase in clinic closings and hospital acquisitions, which means increasingly more patients are facing reduced access and more expensive care.[9]

When clinics close their doors, access to care is compromised for all cancer patients, but especially vulnerable seniors. This shift to hospital–based care doesn't just reduce access to care for cancer patients, it also increases costs to Medicare, taxpayers and patients. Recent studies show hospital-based cancer care costs Medicare $6,500 more per

[7] Community Oncology Alliance Practice Impact Report, June 25, 2013. Online at: http://www.communityoncology.org/UserFiles/Community_Oncology_Practice_Impact_Report_6-25-13F.pdf
[8] Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries; The Moran Company, May 2013.
[9] Community Oncology Alliance Practice Impact Report, June 25, 2013.

beneficiary and seniors $650 more out of pocket per patient annually.[10] These differences are even greater for care covered by private insurers. The fact of the matter is that there is no clinical justification for migration of outpatient cancer care to the hospital setting. Patients don't want to be in a hospital and there is simply no advantage to driving care into a more expensive setting.

Issues with the ASP Formula

Even prior to the sequestration policy currently in effect, Medicare's drug payment rate at ASP plus 6 percent has failed to reimburse adequately for the total costs incurred by community cancer clinics in acquiring essential cancer-fighting therapies. Due to technical flaws in the ASP formula, plus 6 in theory is not plus 6 in reality. The ASP formula produces ASP values below the prices clinics can obtain. CMS has interpreted the ASP formula to require the ASP value to be reduced by any wholesaler prompt pay discounts – which typically fall in the range of 1-2 percent of wholesale acquisition cost, but these discounts pharmaceutical manufacturers extend to distributors of chemotherapy drugs for timely payment are not extended to clinics. This artificially lowers Medicare payment for life-saving anti-cancer drugs and results in reimbursement below cost for many critical cancer drugs. Changing the ASP methodology as proposed by Rep. Ed Whitfield (R-KY) through HR 800 would make ASP values and Medicare Part B reimbursement more accurate.

[10] K. Fitch and B. Pyenson, Milliman Client Report, Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy (Oct. 19, 2011), available at http://publications.milliman.com/publications/health-published/pdfs/site-of-service-cost-differences.pdf

Additionally, Medicare reimbursement rates for Part B drugs are set using reported average sales prices from two quarters prior to the reimbursement quarter. The result is that at any given time Medicare is paying for Part B drugs on the basis of prices that are 4-8 months old. As prices for pharmaceuticals increase, providers are essentially covering the difference for the government until the ASP formula catches up. This lag in the ASP values also creates a significant incentive at the end of a product's exclusivity period where Medicare pays brand-based prices for several months after a product has gone generic. Reducing the amount of time between the collection of the data and its use to set reimbursement rates would make ASP values and Medicare Part B more accurate.

These issues with the ASP formula are not new. As early as 2007, MedPAC found that with reimbursement set at ASP plus 6 percent, the difference between acquisition costs and payment was "slim" and some products could not be purchased below the payment rate.[11] When this difference is "slim" or negative, it means there is either no payment for the substantial services provided to store and prepare the drug for administration, or worse that the practice is paying to provide those services and also paying for a portion of the patient's needed therapy instead of Medicare. After the sequester cuts, the payments are well below break-even.

Issues with Beneficiary Coinsurance

[11] MedPAC Report to Congress January 2007: Impact of Changes in Medicare Payments for Part B Drugs. Online at: http://www.medpac.gov/documents/jan07_partb_mandated_report.pdf

While the prompt pay discount problem and two-quarter lag problem makes it difficult for community oncology clinics to break even at ASP plus 6 percent, it is quite rare for practices to be able to collect the entire Medicare allowable rate for Part B drugs. This is principally due to the 20 percent coinsurance responsibility facing beneficiaries, often on very expensive therapies. It has been the experience of practices in The US Oncology Network that approximately 25 percent of the beneficiary coinsurance (approximately 5 percent of the Medicare allowable) is uncollectible and ends up as bad debt. While this is meaningful even in the context of services that involve a physician's time, a nurse or therapist's time and fixed assets that constitute capital expenditures, it is even more meaningful in the context of Part B drugs where the practice buys the drug on behalf of CMS and is then reimbursed for it by Medicare (80 percent) and the beneficiary (20 percent). Unlike hospitals, Medicare does not reimburse physician offices or community cancer clinics for uncollectible beneficiary coinsurance.

Ironically, with the introduction of federally-mandated out-of-pocket caps on all private insurance coverage through the ACA starting January 1, Medicare coverage may actually leave a cancer patient most exposed to the threat of bankruptcy. The US Oncology Network would strongly support efforts to cap Medicare beneficiary out-of-pocket responsibility at a reasonable amount.

Issues with Medicare Payment and Policy Advantages Based on Site of Service

Another key driver of the shift from community clinics to hospital outpatient departments is the steady erosion of revenues in the physician office setting due to significant changes in Medicare payment policies for outpatient services. Additionally, the wide variation of reimbursement for the same services in different outpatient settings compounds the problem. For example, the 2013 Medicare Physician Fee Schedule rate for 1 hr of chemo infusion by iv is $143.24 but the payment rate for the same service under the 2013 Hospital Outpatient Prospective Payment Schedule (HOPPS) fee schedule is 61 percent higher at $230.50. These types of discrepancies in reimbursement throughout oncology and other specialties greatly advantage hospital outpatient departments and in effect subsidize and encourage inefficiency. We know the committee is familiar with this facet of the problem and has supported policies to equalize E&M payments across care settings. The US Oncology Network applauds the Medicare Payment Advisory Commission's recent recommendation to level the playing field for outpatient services, including oncology services. We also strongly support current efforts of committee members to take an urgent approach to site-neutral payment in the oncology space and look forward to working with you to achieve that policy goal.

In addition to these code and service specific payment differentials outlined by MedPAC, hospitals enjoy other advantages relative to government policies around Part B drugs that push more patients and physicians into that setting. Approximately, one third of US hospitals purchase chemotherapy drugs through the 340B program at discount up to 50 percent, typically more than 30 percent below the Medicare reimbursement rate of ASP +

6 percent.[12] For 340B hospitals, the margin on Medicare drugs is over 30 percent, where for community clinics the margin is zero to negative 2 percent. It is no wonder that drug spending is increasing so rapidly in the hospital outpatient setting and that care is moving in that direction.

Issues with the Federal Budget Sequester

The most recent challenge to access to Part B drugs and the viability of community cancer care comes of course through the federal government budget sequestration policy, and in particular, the administration's decision to apply this cut to both the 6 percent services payment and also the acquisition cost of the underlying Part B drugs purchased on behalf of CMS. We support thoughtful deficit reduction and we are not here to request a repeal of or exemption from the sequester. However, the administration's implementation of this policy is effectively forcing cancer clinics to subsidize Medicare — that is, to make up the difference between what Medicare pays and the actual cost of cancer drugs.

Health care providers are never comfortable talking about their work in purely economic terms, but the fact remains that community cancer clinics are small businesses held to the economic reality that operating at a loss cannot be sustained. It is hard to imagine any business—small or otherwise—accepting a policy that requires operating at a loss. *Oncologists should not be put in the untenable position of continuing to treat patients at*

[12] OIG Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System OEI-03-09-00420, October 22, 2010. Online at: http://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf

a loss, which will result in clinic closings, or sending seniors fighting cancer to the hospital for treatment in order to keep the clinic doors open.

It would be one thing for community oncologists to absorb the 2 percent Medicare sequester applied to physician and provider services, but it is entirely another for the sequester cut to apply to the underlying drug acquisition costs paid by practices on behalf of CMS. This is unlike any other payment reduction to Medicare and has had an inordinate impact beyond 2 percent. Medicare reimbursement for cancer drugs is specifically fixed by law at ASP plus 6 percent, as opposed to services or budgets cut by sequestration. The reduction of the 6 percent add-on to effectively 4.3 percent (after sequestration is applied) is a 28 percent cut to the clinic's payment for managing the drugs, not a 2 percent cut. This has put many drugs underwater on acquisition cost alone and has resulted in zero payment for the costs associated with storing and preparing the drugs for administration to patients. We look forward to working with the committee to pass legislation that changes the way the administration implements the sequester so that it properly applies to the 6 percent services payment but not the acquisition costs of the underlying Part B drugs.

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The National Cancer Institute estimated that there were approximately 13.7 million Americans living with cancer in the U.S. last year. About 8 million of those are over the age of 65 and approximately half of all cancer spending is associated with Medicare

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beneficiaries.[13] As the baby boomers continue to reach 65 those numbers will only increase. So, now is the time for Congress to act to ensure the future of community based care and stop the site of service shift into more costly hospital outpatient departments.

Several Members of this Committee have written legislation and signed onto letters that assist in preserving community cancer care. Specifically, H.R. 800, sponsored by Congressman Whitfield, Green and DeGette and 54 additional co-sponsors, would result in a more accurately aligned Part B drug reimbursement by removing any discount between the manufacturer and distributor that is included in the ASP formula but not passed on to the provider. Over 30 Members of this Committee signed a letter to CMS questioning how the Administration handled the sequestration cuts on Medicare Part B drugs, while Congresswoman Ellmers introduced H.R. 1416 and garnered 91 co-sponsors which would remove the 28 percent service cut community oncologists are dealing with under sequestration. Lastly, at a time when access and cost issues are intertwined, we appreciate the support from several on the committee that believe it is important that payment amounts be commensurate with actual services provided, not the site of care. Preferentially paying higher amounts in certain settings will predictably lead to the expansion of higher cost centers. The result will be further increases in the cost of cancer care for those who pay for it – patients, private and government payers.

The primary purpose of a doctor is to relieve suffering. My 10,000 oncology colleagues across the country and I are doing our best. In order to continue to give cancer care to

[13] Mariotto AB, et al. Projections of the Cost of Cancer Care in the United States: 2010–2020, J Natl Cancer Inst 2011;103:1–12. Online at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3107566/

America's elderly and under-served, we need your help. Thank you again for the opportunity to address the committee, when it is appropriate I am happy to answer any questions the committee has regarding my testimony or community oncology.

Mr. PITTS. I now recognize Ms. Davenport-Ennis for 5 minutes for an opening statement.

STATEMENT OF NANCY DAVENPORT-ENNIS

Ms. DAVENPORT-ENNIS. Thank you, Chairman Pitts, and thank you, Congressman Green, and thank you also, members of the committee. I have submitted previously written testimony to the committee. And so what I would like to do now is to simply have a conversation with you and share with you what we see happening to the Medicare patients in the United States that we have been taking care of for the past 17 years.

To date, we have closed over 750,000 cases dealing with Medicare and Medicaid patients in the United States. And what we see is that since the passage of MMA, when we stripped away the reimbursement between the drug margin and the services with the commitment that there would be additional codes put in place in 2004 to bring the reimbursement for physicians up to where they had been so they can maintain their practices, we have seen a waterfall of changes and reductions to reimbursement to physicians. And why do our patients care? Why is that our battle? It is our battle because the number one asset we have in winning our individual war on cancer or any other chronic disease is a physician who is there to treat us. What I can say to you is that we look at the destabilization of the workforce today as a result of things like a prompt pay discount which loses a 2 percent or the imposition of sequestration which is a 2 percent cost cut across both the drug and the service. We look at the continued threat of ASP reduction. So there is no stability when a practice is trying to plan for the future. And the result to the patients that we serve is really simple. They are now facing a reduction in actual practices available in their community to see them. And when we lose a practice in the community, not only does the senior or the disabled lose it, so does every man, woman, and child living in that community. We are seeing patients being shifted to hospitals for site of care. It may mean longer distances for them to travel. It may mean longer wait times for them. We have had it documented that it means an additional cost of $6,000 to the system for each patient that is shifted to the hospital outpatient setting for care. And because the patient is responsible for a 10 percent copayment, it means $600 to $650 for the patient.

We have seen the formularies change within Medicare part B and we have seen many of our newer drugs that our patients need are now being put out on a specialty tier. And at that level when we did an analysis of 996 of our Medicare patients, what we found is that they were paying on average out of pocket for specialty tier drugs through Medicare $684 per prescription that represented 50.2 percent of the cost of the drug.

Let me describe to you the Medicare patients that we handle. Traditionally, their household incomes are under $23,000. They are very proud people, many of whom have worked their entire lives to save and to live independently throughout the final years of their lives. The seniors that we treat come to their diagnosis and seek support through copay even though for them to do that it is such a transgression against their independent living. We had

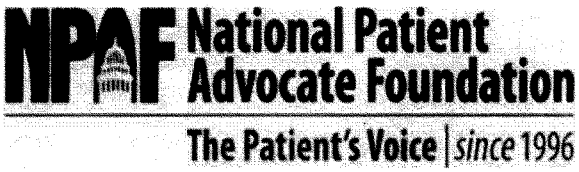
$447.6 million donated to nine copay programs in the United States of America over the past year, and it was not sufficient to meet the demands. As your committee has looked at remedies for the prompt pay issue and you are looking at remedies to solve many of the Medicare part B reimbursement issues, I want to thank you on behalf of the Medicare patients that we represent. And I want to also commit to you that our foundations are here to work by your side to see that these bills that have been introduced through your committee are passed.

I am pleased to answer in great detail what is happening with our patients going through shifts in site of care. But as my closing remark, I would like you to note that since April 1, we have started tracking the number of patients being shifted from a community practice to a hospital outpatient setting. In 90 days, we have had 10 States that have reported shifting patients from the community practice setting into the hospital setting. So I would urge the committee to do what you do best, and that is to look at how do we minimize financial devastation for Medicare part B beneficiaries?

I thank you for the opportunity to answer questions.

Mr. PITTS. The chair thanks the gentlelady.

[The prepared statement of Ms. Davenport-Ennis follows:]



Statement of

Nancy Davenport-Ennis
Founder and CEO
National Patient Advocate Foundation

on

Examining Reforms to Improve the Medicare Part B Drug Program for Seniors

before the

United States House of Representatives Committee on Energy & Commerce
Health Subcommittee

on

June 28, 2013

Chairman Pitts, Ranking Member Pallone and members of the subcommittee, thank you for the opportunity to testify today on ways to improve Medicare Part B, with particular emphasis on the Part B Drug program. My name is Nancy Davenport-Ennis, and I am the Founder and CEO of the National Patient Advocate Foundation (NPAF) and the Patient Advocate Foundation (PAF). I would like to thank the subcommittee for working to protect patients and hope you will continue to support the millions of Americans who endure chronic, debilitating and life-threatening illnesses and who struggle to obtain access to the health care services and medicines they need.

I am here to speak about the long overdue need to improve Medicare Part B. Each of us has heard from patients and constituents who have heart-rending stories of denied access to care. Burdensome out-of-pocket costs make health care inaccessible for Medicare beneficiaries. After 17 years of resolving health care access issues in 750,000 patient cases, I can attest with certainty that patients who struggle to manage chronic, debilitating and life-threatening diseases require access to a physician who knows the patient, who knows the disease, and who understands the particular struggles the patient is trying to manage.

What I would like to stress this morning is that Medicare patients who reach out to PAF for help come from all 50 states and report difficulties with Medicare Parts A and D, as well as B. These difficulties include medical debt crises and cost-of-living issues, reported by 29.5 percent of patients, the most frequently reported issue in 2012. Debt crisis and cost of living issues include the inability to afford transportation, make rent or mortgage payments, meet basic food and nutritional needs, and pay utility bills. These patients represent the most vulnerable among us.

Of the 109,147 patients PAF served in 2012, 23.1 percent are Medicare beneficiaries. In 2011, PAF served 103,000 patients, of whom 28.5 percent were Medicare beneficiaries. As reported in PAF's 2012 Patient Data Analysis Report[1], the vast majority of Medicare patients – 72.6 percent – who reached out to our organization in 2012 for assistance in paying for care had some form of cancer. The second most frequently reported category of disease, affecting 11.9 percent of PAF patients in 2012, includes chronic conditions such as diabetes, osteoporosis, chronic obstructive pulmonary disease (COPD), fibromyalgia, hepatitis and degenerative disc disease, among others.

Coverage issues were reported by 24.4 percent of PAF Medicare patients. Difficulty meeting pharmaceutical co-payment requirements was reported by 21.2 percent of PAF Medicare patients. An analysis completed by PAF of nine national copay programs in the country found that $447.7 million of annual support was made available to patients. Even at this level of support, countless beneficiaries may not qualify for assistance, or their disease silo is not funded. While copay programs provide an invaluable service to Medicare beneficiaries, fundamental changes to out-of-pocket requirements must be made for Medicare benefits to align more closely with those available in insurance products in the commercial market.

Unfortunately, Medicare beneficiaries are having an increasingly difficult time finding and retaining access to providers who have an intimate knowledge of the patients and their conditions. Reductions in Medicare reimbursement to physicians over the past several years have made it difficult to maintain their practices within the community or to continue to accept Medicare beneficiaries as patients. The difficulties include the following:

[1] Patient Advocate Foundation. Patient Data Analysis Report. 2012. 16th Edition.

- The vagaries of the sustained growth rate (SGR) adjustments have made planning uncertain and unpredictable for physician practices.
- Medication reimbursement based on Average Sales Price (ASP) has significantly increased the cost of inventory and reduced compensation for administration of Part B drugs.
- The factoring of prompt pay discounts – which is a matter between manufacturers and wholesale distributors – into the ASP calculation has further cut physician reimbursement for Part B drugs artificially by about 2 percent.
- The President's 2014 Budget Proposal would cut Part B drug reimbursements from ASP + 6 percent down to ASP + 3 percent.
- The sequester effectively has cut Part B drug reimbursements to physicians by 2 percent for medications and for administrative services since April 1.

The following cases reported to PAF case managers illustrate shifts in sites of care for Medicare Part B patients from practice settings to hospital outpatient settings:

1. GA – Georgia Cancer Specialists is a national leader in advanced cancer treatment and research with 46 physicians and 27 locations. On April 1, 2013, Georgia Cancer Specialists joined the network of Northside Hospital due to budget cuts. They have twenty free-standing physician practices located within a 35-mile radius of Northside Hospital that utilize the hospital's billing system. The seven remaining free standing offices (Blue Ridge, Atley, Hawkville, Zononi) are rural offices located outside the 35-mile radius range and routinely send Medicare and Medicare Advantage patients to the hospital setting when the Georgia Cancer Specialists are unable to locate financial support through co-pay assistance, drug card discounts or hardship programs.

2. GA – Northeast Georgia Diagnostic Clinic serves patients in the Gainesville and the surrounding communities of the Northeast Georgia region. They have three offices serving 200-250 patients a day through their seven providers. Their practice has four oncologists and 3 Rheumatoid Arthritis specialists. For anyone needing infusions with Medicare only (and unable to secure supplemental support such as Co-Pay) the patients are shifted to the hospital setting at Northeast Georgia Medical Center.

   In one example, the average out-of-pocket cost for a colon cancer patient is around $500-600 a treatment. One patient was transferred to the hospital setting from the clinic, where his costs tripled for the infusion charge. Despite the increased cost, the patient no longer has access to a trained oncologist.

   A second example involves Rheumatoid Arthritis patients who need Remicade or Rituxan. This facility now sends patients to the hospital because the cost to infuse is too costly for the clinic to absorb. Many patients in Part B are often redirected to Part D drugs that are on specialty tiers requiring a co-insurance from 25 percent to 66 percent. Many of these patients abandon their prescription due to their inability to pay the out-of-pocket cost. If patients in Part B, who are also being prescribed Part D drugs, had a process available to cap out-of-pocket expenses in Part

D to 25 percent, the abandonment rate could drop precipitously. At $200 out-of–pocket cost, the abandonment rate is 25 percent and increases appreciably with each increase in co-insurance.

3. OH - Zangmeister Center serves 70-90 patients daily with chemotherapy through their 11 oncology/hematology physicians. The reductions in Medicare payments are particularly devastating to clinics like Zangmeister Center in Columbus, Ohio, where 50 percent of patients are Medicare beneficiaries. Like many of their peers, physicians at Zangmeister Center are offering critical cancer drugs at break-even or negative reimbursement levels. In fact, they currently provide at least 32 life-saving drugs for which they do not receive full reimbursement. In other words, doctors are forced to pay out of their own pocket if they wish to provide these life-savings drugs to their patients. This is simply unsustainable for the facility and thousands of other community cancer clinics across the country. As a result, the sequester cuts have forced Zangmeister Center and many similar community centers to advise their Medicare patients to seek care elsewhere.

4. NM – New Mexico Cancer Center is an independent physician owned practice with three other satellite offices. They began sending patients in need of chemotherapy infusion to the hospital setting as of April 1, 2013 due to budget constraints.

5. KS – The McKesson Specialty Health /US Oncology Network has expressed its need to move patients into a hospital setting due to budget cuts.

6. IN-- Dr. Koneru of Cancer Care of South Indiana merged with Premier Healthcare Group due to budget cuts.

7. PA – A 70 year-old breast cancer patient was transferred from the Allegheny Cancer Center to the West Penn Hospital after the local clinic was unable to continue to accept her Medicare Advantage Plan, Freedom Health, for her chemotherapy treatment.

8. CO- A 75 year-old ovarian cancer patient was unable to locate a local physician in and so was forced to travel to Denver, 30-45 minutes each way.

9. TX – A provider office could no longer o treat a patient due to unpaid medical co-insurance. The patient was sent to the Medical City Dallas Hospital for administration of her chemotherapy.

10. TX – A 77 year-old ovarian cancer patient, who came to PAF for help, was receiving chemotherapy treatment at the Medical City Hospital in Dallas. Her treating doctor could no longer treat her in his office due to budget cuts. She was already on a $5-a-month payment plan to pay back outstanding medical debt and will be in chemo the rest of her life.

As a matter of fairness, Medicare Part B beneficiaries have a right to receive the same benefits and access to quality care that other health insurance enrollees receive. For example, health benefit plans available in the commercial market include a stop-loss provision that limits out-of-pocket costs after a

threshold has been reached. Part B includes no such provision; beneficiaries continue to pay 20 percent out-of-pocket for every single Part B service provided in perpetuity, with no cap.[2]

This limitless payment requirement presents a significant burden for beneficiaries with multiple, chronic conditions. This is particularly true for those who reach out to PAF: two-thirds of PAF Medicare beneficiaries had annual household incomes of $23,000 or less. Under a traditional insurance plan, at some point the 20 percent liability would end, and the insurance benefit would assume the cost.

Formulary restrictions under Medicare Part B and D further impede beneficiaries' access to optimal care. Medicare patients deserve the proper medication at the right time at a reasonable level of cost-sharing.

Making matters worse for patients, displacement from care in community centers will increase reliance on urban hospital care, where the annual cost of receiving chemotherapy in a hospital outpatient setting is $6,500 higher than receiving care in a physician's office. Additionally, patient co-pay amounts are approximately 10 percent higher for hospital outpatient care, which totaled more than $650 per patient per year.[3]

Furthermore, the perception that radiology is a huge driver of health care costs is the primary reason for the seemingly never-ending string of imaging-related cuts. Radiology has experienced $6 billion in Medicare cuts for imaging services since 2006.[4]

Let me close with two recent examples to illustrate our concerns about patient access. Recently, PAF received a call from a Medicare beneficiary who had been diagnosed with a rare form of Non-Hodgkin's Lymphoma that caused severe hemolytic anemia, which requires almost daily lab tests and possible platelet infusions. The closest hospital that could provide these services was 40 miles away, and the patient's family was struggling to afford the transportation costs. Traveling 80 miles a day to receive necessary care adds severe strain to a patient's quality of life, as they are managing a devastating diagnosis.

In 2012, PAF was contacted by a 65 year-old Medicare beneficiary who had been diagnosed with throat cancer. The patient was in severe pain and was having difficulty affording his medication. After speaking with a PAF case manager, the reason for his difficulties became clear: the patient lived 300 miles from his cancer treatment center, and his transportation costs were leading to medical debt crisis. With an annual income of $40,000 per year, the patient had an extremely difficult time affording his medication, transportation and cost of living.

These Medicare patients need Congress' help to ensure that the health care they require is as conveniently located as possible. Congress must correct the way the sequester is applied to Medicare Part B drug reimbursements and eliminate these cuts that cruelly punish cancer patients. Further, Congress should enact H.R. 800, which removes prompt pay discounts from the calculation of Medicare reimbursement rates to make the ASP formula more closely resemble average costs. Additionally,

[2] Medicare.gov. http://www.medicare.gov/your-medicare-costs/costs-at-a-glance/costs-at-glance.html#collapse-4809
[3] Milliman, Inc., NY. "Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy." October 19, 2011.
[4] Radiology Leaders Criticize Congressional Imaging Cuts. March 01, 2013. http://rsna.org/NewsDetail.aspx?id=8565

Congress stop incentivizing the shift to the hospital outpatient department setting. ASP can only work if it is fair and accurate, and it is up to Congress to ensure that this is the case.

The following recommendations are from PAF professional case management staff, who routinely serve Medicare beneficiaries:

- Launch a national education campaign to enhance enrollment in Medicare Part B and highlight the penalty that is assessed to those beneficiaries who do not have credible coverage and delay enrollment past their initial eligibility date.
- Cap out-of-pocket expenses for those Medicare beneficiaries who simultaneously rely upon Part B and D benefits to enhance adherence to treatment protocols and improve outcomes in disease management. The 20 percent co-payment for Medicare Part B services and products, in combination with the demands of co-insurance for drugs purchased through Part D, with payment required in full at time prescriptions are filled, result in excessive abandonment rates and destabilization of household resources and individual budgets.
- Establish an annual out-of-pocket maximum for Medicare beneficiaries that is consistent with the commercially insured market from which these beneficiaries have had insurance throughout their working lives. Out-of-pocket caps allow planning for utilization of resources to manage illness across their later years.
- Improve Medicare reimbursement to providers so that research hospitals accept Medicare patients with Medicare Advantage plans. . Currently, many of our leading research hospitals will not accept Medicare Advantage plans due to insufficient reimbursement for services and medical supplies.
- Modify Specified Low-Income Medicare Beneficiary (SLIMB) support to more closely align with services that can be paid for through Qualified Medicare Beneficiary. Currently, SLIMB is limited to payment of premium only however, these beneficiaries need support in multiple areas of health care.

The overarching message for Congress to consider is that Medicare Part B should minimize beneficiaries' financial risk over time. This principle will be an increasingly important element of the program as the baby boom population continues to reach Medicare eligibility. I urge you to give careful consideration to the impacts of the sequester, and work to protect the most vulnerable in this country and prevent any further cuts to community cancer care.

Thank you again for the opportunity to testify this morning. I would be happy to address any questions you might have.

Mr. PITTS. And now recognizes Dr. Melton for 5 minutes for an opening statement.

STATEMENT OF LARRY B. MELTON, M.D., PH.D., FACP

Dr. MELTON. Thank you, Chairman Pitts, Congressman Green, and Congressman Burgess, for this opportunity to briefly address the Energy and Commerce Committee as it examines reforms to improve the Medicare part B drug program. I applaud this committee for its leadership and ongoing commitment to strengthening our Nation's health care system. I am Dr. Larry Melton, Medical Director of Kidney and Pancreas Transplantation at Baylor University Medical Center. In my many years of practice and work at Dallas, Texas, I have become familiar with a variety of Medicare program challenges and policy imperfections that could be improved to save both lives and Federal resources. Within my field of organ transplantation, the most obvious and flawed Medicare policy is the program's arbitrary 36-month coverage restriction for patients' immunosuppressive drugs post-transplantation. As you may know, organ transplant recipients must take immunosuppressive medications for the lifetime of the transplanted organ. If immunosuppressive medications are discontinued, rejection and loss of the transplanted organ are almost certain to occur.

Since 1972, Medicare has covered people with end stage renal disease without regard to age or SSDI status. There is no Medicare coverage limit for a dialysis patient. By contrast, kidney transplant recipients lose Medicare coverage at an arbitrary 36 months after transplant. In 1972, it was estimated that the ESRD program would cost $250 million. Today the program costs in excess of $250 billion. These figures are staggering, and there is no question that a functioning transplant with immunosuppressive drug coverage is vastly less expensive than the cost of dialysis. When renal transplants fail, patients again require dialysis, and may even be candidates for retransplantation, both of which would be covered by Medicare. Extending immunosuppressive coverage beyond the 36-month limit would decrease the risk of organ failure due to patients not taking their immunosuppression.

The New England Journal of Medicine highlighted a survey conducted by the American Society of Transplantation that found 70 percent of U.S. kidney transplantation programs reported that their patients had an extremely serious or very serious problem paying for immunosuppressive medications and 68 percent reported deaths and graft losses attributable to cost-related nonadherence. The study further found that since patients with kidney failure need either long-term dialysis or a functioning renal transplant to survive, failing to pay for ongoing immunosuppression ensures that Medicare's initial investment in kidney transplantation is squandered, that patients die prematurely, and the U.S. Taxpayers pay for more expensive but inferior therapy after some transplants fail unnecessarily. At present, Medicare spends approximately $70,000 to $80,000 per year on a dialysis patient, which Medicare covers indefinitely. However, Medicare on average spends less than a quarter of that amount for a kidney transplant recipient after a year of the transplant. For more than a decade now, members of this committee have introduced and supported legislation, the Com-

prehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act, to address Medicare's deficiencies in this area. Most recently, Congressman Michael Burgess and Ron Kind have led the bipartisan and bicameral effort to secure passage of this reform.

I strongly encourage everyone on this committee to cosponsor, support, and pass H.R. 1428 during the 113th Congress. The legislation saves lives, preserves life-saving donor kidneys, and reduces the cost burden to the Federal Government, a win-win for patients and the U.S. Treasury. The bill would allow individuals who are eligible for immunosuppressive drugs whose insurance benefits under part B have ended due to their 36 months running out to remain in the program only for the purpose of receiving immunosuppressive drugs. If they have group health insurance, they would not qualify for coverage beyond the 36 months. The legislation is intended to be a coverage backstop only for those who otherwise have no coverage. The legislation ensures that Medicare would remain the payer of last resort and would not usurp coverage offered by private insurers. It is not sound public policy or cost effective for Medicare to cover the initial costs of a kidney transplant and then stop immunosuppressive drug coverage after 36 months. It is unfair to living donors and to those families who have donated organs of the deceased loved one for the Federal Government not to do everything possible to maintain the transplanted kidney and the gift of life that they have provided.

On behalf of kidney patients, families, physicians, surgeons and all involved in the transplant process, I ask that this committee make the 113th session of Congress the last Congress in which many patients will lose Medicare coverage after only 36 months. The Burgess-Kind legislation simply corrects a costly policy inequity. It covers transplant anti-rejection medicines only.

I thank you for the opportunity to focus a few minutes on what we in the organ transplant community view as the necessary reform to the Medicare drug program. Thank you.

Mr. PITTS. The chair thanks the gentleman and now recognizes Mr. Cosgrove for 5 minutes for his opening statements.

[The prepared statement of Dr. Melton follows:]

Examining Reforms to Improve the Medicare Part B Drug Program for Seniors

Committee on Energy & Commerce

U.S. House of Representatives

Friday, June 28, 2013

Testimony of Dr. Larry Melton, MD, PhD, FACP

Medical Director, Kidney Pancreas Transplant

Baylor Medical Center - Dallas, Texas

Board of Directors, American Society of Transplantation (AST)

Thank you Chairman Upton (R-MI), Ranking Member Waxman (D-CA), and Congressman Burgess (R-TX) for the opportunity to briefly address the Energy & Commerce Committee as it examines reforms to improve the Medicare Part B Drug Program. I applaud this Committee for its leadership and ongoing commitment to strengthening our nation's healthcare system.

I am Dr. Larry Melton, Medical Director Kidney/Pancreas Transplantation at Baylor University Medical Center. In my many years of practice and work in Dallas, Texas, I've become familiar with a variety of Medicare Program challenges and policy imperfections that could be improved to save both lives and federal resources. Within my field of organ transplantation, the most obvious and flawed Medicare policy is the program's arbitrary 36 month coverage restriction for patient's immunosuppressive drugs post transplantation.

As you may know, organ transplant recipients must take immunosuppressive medications for the lifetime of their transplanted organ. If immunosuppressive medications are discontinued, rejection and loss of the transplanted organ are almost certain to occur. Under its current policy, Medicare continues to waste the federal government's investment in kidney transplantation while at the same time paying indefinitely for more costly therapies. It is the equivalent of the Federal Government buying a new car, providing enough gas to drive around the block, and then abandoning the vehicle.

When kidney's fail, patients only have two treatment options: dialysis or transplantation. Since 1972, Medicare has covered people with End Stage Renal Disease (ESRD) – permanent kidney failure requiring dialysis or a kidney transplant – without regard to age or SSDI status. There is no Medicare coverage limit for a dialysis patient. By contrast, kidney transplant recipients lose Medicare coverage at an arbitrary 36 months after transplant. In 1972, it was estimated that the ESRD program would cost $250 million. Today, the program costs in excess of $250 billion.

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These figures are staggering and there is no question that a functioning transplant with immunosuppressive drug coverage is vastly less expensive than the cost of dialysis. When renal allografts fail, patients again require dialysis and may even be candidates for re-transplantation, both of which would be covered by Medicare. Extending immunosuppressive coverage beyond the 36 month limit would decrease the risk of allograft failure due to patients not taking their immunosuppression.

A conservative estimate is that 20 individuals will die today awaiting a life-saving donor organ. Donor organs are a precious resource that fall far short of meeting the actual demand. As we have seen again from recent high profile media coverage organ demand far exceeds supply, as a result, the transplant community works diligently to ensure that every donor organ is given the best opportunity to save and extend life for as long as possible. Current Medicare policy inhibits our ability to that.

A variety of national and international medical journals have focused attention on the U.S. policy of limited immunosuppressive drug coverage and the kidney failure that follows. In particular the New England Journal of Medicine (NEJM) highlighted a survey conducted by the American Society of Transplantation (AST) that found that 70 percent of U.S. kidney-transplantation programs reported that their patients had an "extremely serious" or "very serious" problem paying for immunosuppressive medications, and 68 percent reported deaths and graft losses attributable to cost related non-adherence." The study further found, "Since patients with kidney failure need either long-term dialysis or a functioning renal allograft to survive, failing to pay for ongoing immunosuppression ensures that Medicare's initial investment in kidney transplantation is squandered, that patients die prematurely, and the U.S. taxpayers pay for a more expensive but inferior therapy after some transplants fail unnecessarily." At present, Medicare spends approximately $70,000-80,000 per year on a dialysis patient, which Medicare covers indefinitely. However, Medicare on average spends less than a quarter of that cost for a kidney transplant recipient after a year of the transplant.

For more than a decade, members of this Committee have introduced and supported legislation, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act", to address Medicare's deficiencies in this area. Most recently, Congressmen Michael Burgess, MD (R-TX), and Ron Kind (D-WI) have led the bipartisan effort to secure passage of this reform. Although the legislation consistently enjoys significant bipartisan and bicameral support...this basic correction to better protect patients and federal resources routinely runs out of time and falls short of passage at the conclusion of each session of Congress. I strongly encourage everyone on this Committee to co-sponsor, support and pass H.R. 1428 during the 113th Congress. The legislation saves lives, preserves life-saving donor kidneys, and reduces the cost burden to the federal government -- a win-win for patients and the U.S. Treasury.

The bill would allow individuals who are eligible for immunosuppressive drugs whose insurance benefits under Part B have ended due to their 36 months running out to remain in the program ONLY FOR THE PURPOSE of receiving immunosuppressive drugs. If they have group health insurance, they would not qualify for coverage beyond the 36 months. This legislation is intended to be a coverage backstop only for those who otherwise have no coverage. This legislation ensures that Medicare would remain the payer of last resort and would not usurp coverage offered by private insurers.

It is not sound public policy, or cost effective for Medicare, to cover the initial costs of a kidney transplant and then stop immunosuppressive drug coverage after 36 months. That can, and all too often does, lead to someone rejecting the transplanted kidney because they cannot afford their medicine. It is unfair to living donors and to those families who have donated the organs of a deceased

loved one, for the federal government not to do everything possible to maintain the transplanted kidney and gift-of-life that they have provided. Ironically, when patients lose their transplants, they resume Medicare eligibility for all medical needs, including dialysis or even another transplant.

On behalf of kidney patients, families, physicians, surgeons and all involved in the transplant process, I ask that this Committee make the 113th Session of Congress the last Congress in which many patients will lose Medicare coverage and jeopardize their kidney transplant after only 36 months. The Burgess-Kind legislation, H.R. 1428, simply corrects a costly policy inequity. It covers transplant anti-rejection medications only. Beneficiaries would pay the Part B premium. All other Medicare coverage would cease 3 years after the transplant, as under current law. It is a specific fix and improvement that benefits all involved. This is common sense.

Chairman Upton, Ranking Member Waxman and Congressman Burgess...I thank you for the opportunity to focus a few minutes on what we in the organ transplant community view as a very necessary reform to the Medicare Drug Program.

THANK YOU.

STATEMENT OF JAMES COSGROVE

Mr. COSGROVE. Chairman Pitts, Congressman Green, and members——

Mr. PITTS. Did you push the button? Is the light on?

Mr. COSGROVE. It is on.

I am pleased to be here today as you discussed Medicare's payment for part B drugs and potential reforms. As you have heard, part B drugs are often an important part of treatment for cancer, autoimmune disorders, chronic kidney disease, and other serious conditions. In 2010, Medicare spent nearly $20 billion for part B drugs in all settings, including physician offices and hospital outpatient departments. That was about 9 percent of all part B expenditures that year. Last October, we issued a report that examined spending and utilization data for high expenditure part B drugs. Specifically, we analyzed the 55 drugs with the highest Medicare expenditures in 2010. We also examined spending and utilization trends from 2008 to 2010 for the same drugs. And then finally we estimated national spending for the total U.S. insured population for these drugs and calculated the share attributed to Medicare. So in my statement today, I would like to highlight several findings from our October report.

First, we found that Medicare expenditures were highly concentrated among relatively few drugs. In 2010, the 55 highest expenditure drugs represented about 85 percent of all Medicare spending on part B drugs, or about $16.9 billion. Ten of those drugs accounted for approximately 45 percent of all part B drug spending. Most of the 55 drugs are under patent and can be purchased from only one manufacturer. At the time of our report, none of the 10 highest expenditure drugs and only nine of the 55 drugs we analyzed had a generic drug alternative. Of the 55 drugs in our analysis, 23 were used to treat cancer and its side effects. Others were used to treat various conditions, such as immune system disorders, cardiovascular disease, chronic kidney disease, and asthma or, as you have just heard, to prevent organ transplant rejection.

Second, the number of Medicare beneficiaries who used each drug as well as the average cost per beneficiary varied widely. Some of the drugs were associated with high Medicare expenditures either because many beneficiaries used the drug or because the drug had a very high price. For example, Medicare spent about $193 million on influenza vaccines in 2010. The cost per beneficiary was only about $13. But more than 15 million beneficiaries were vaccinated. Medicare spent about $143 million on Factor VIII recombinant used to treat hemophilia A. In contrast to the influenza vaccines, Factor VIII recombinant was only used by 660 beneficiaries but it cost nearly $217,000 per beneficiary. Among the 10 drugs with the highest cost per beneficiary, four cost more than $50,000 and five more than $20,000.

Third, spending, utilization, and prices generally increased in the 2 years. Medicare expenditures increased for 42 of the 55 drugs. The drugs with the greatest increases in expenditures also had the greatest increases in utilization. In particular, the four drugs with the largest in increases were new drugs that had been recently approved by the FDA. Expenditures for one of these drugs Lexiscan, a stress agent for beneficiaries who cannot take a stress test, grew

by approximately 10,000 percent over the 2-year period because the utilization grew by 11,000 percent. Prices for most drugs increased between 2008 and 2010, although the price changes were not as dramatic as utilization changes. The price of Ventavis, a drug used to treat pulmonary arterial hypertension, increased by 52 percent, which was the largest price increase we observed. Because utilization of Ventavis also increased, expenditures for the drug rose by nearly 94 percent over the period. The price of the vaccine used to prevent pneumonia increased by 36 percent. Some drugs did decrease in price. The largest decline was 38 percent, and yet still remained among the highest expenditure part B drugs.

Finally, our findings show that Medicare is an important part of the national market for many of these high expenditure drugs. Specifically, we found that Medicare spending accounted for the majority of estimated total national spending on 35 of the 55 highest expenditure part B drugs. Almost $17 billion Medicare spent for the highest expenditure part B drugs, $11 billion, or 65 percent, was spent on drugs for which Medicare beneficiaries accounted for the majority of total U.S. spending. For 17 of the drugs, Medicare spending represented two-thirds or more of total spending. And for six part B drugs, Medicare's share of national spending exceeded 85 percent.

This concludes my prepared remarks. I am certainly happy to respond to any questions.

Mr. PITTS. The chair thanks the gentleman.

[The prepared statement of Mr. Cosgrove follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
Expected at 10:00 a.m. EDT
Friday, June 28, 2013

MEDICARE

Information on Highest-Expenditure Part B Drugs

Statement of James Cosgrove
Director, Health Care

GAO Highlights

Highlights of GAO-13-739T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

June 28, 2013

MEDICARE

Information on Highest-Expenditure Part B Drugs

Why GAO Did This Study

In an October 2012 report, GAO examined the levels and trends in expenditures, utilization, and average annual per beneficiary costs for the most expensive Medicare Part B drugs (GAO-13-46R). Unlike Medicare Part D, Part B covers drugs that are commonly administered by a physician or under a physician's close supervision, such as chemotherapy drugs. Many Part B drugs may be expensive for the Medicare program either because their prices are high or because they are used by a large number of beneficiaries. In 2010, the Medicare program and its beneficiaries spent about $19.5 billion on Part B drugs, about 9 percent of total Part B expenditures.

In this statement, GAO highlights the findings from the 2012 report on (1) the Part B drugs for which Medicare expenditures were highest in 2010 and the utilization and expenditure trends for these drugs from 2008 to 2010, and (2) nationwide spending levels for the total U.S. insured population for these high-expenditure Part B drugs in 2010 and Medicare's percentage of total U.S. spending.

GAO calculated the total expenditures for each drug using the Centers for Medicare & Medicaid Services' national claims files for physicians, hospital outpatient, and durable medical equipment and ranked the drugs, selecting the top 55 for analysis of utilization and average annual per beneficiary cost. In addition, GAO obtained estimates of total U.S. expenditures for each of the drugs from IMS Health, a company that collects and analyzes health care data, to estimate Medicare's share of total U.S. spending for these drugs.

View GAO-13-739T. For more information, contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

Medicare expenditures for Part B drugs in 2010 were concentrated among relatively few drugs. The 55 highest-expenditure Part B drugs represented $16.9 billion in spending, or about 85 percent of all Medicare spending on Part B drugs, and the 10 highest-expenditure drugs accounted for about 45 percent of all Part B drug spending in 2010. Most of these drugs were under patent and could be purchased only from a single manufacturer. The number of Medicare beneficiaries who used the 55 drugs ranged from over 15 million beneficiaries who received the influenza vaccine to 660 beneficiaries who used a drug that treats hemophilia. The annual per beneficiary cost of the Part B drugs GAO examined also varied widely in 2010, from $13 for influenza vaccine to over $200,000 for factor vii recombinant to treat hemophilia. Spending, utilization, and prices increased for most of the 55 drugs between 2008 and 2010, with the drugs that showed the greatest increases in expenditures also showing the greatest increases in utilization.

Five Highest-Expenditure Medicare Part B Drugs, 2010

2010 rank by total Medicare expenditures	Brand name(s)	Condition(s) treated	Total 2010 expenditures for Medicare beneficiaries (millions)
1	Epogen/Procrit (end-stage renal disease (ESRD) use)[a]	Anemia in ESRD patients	$2,000
2	Rituxan	Cancer; rheumatoid arthritis	1,302
3	Lucentis	Wet age-related macular degeneration (AMD)	1,180
4	Avastin	Cancer; wet AMD	1,130
5	Remicade	Various autoimmune disorders	900

Source: GAO analysis of data from the Centers for Medicare & Medicaid Services, the Food and Drug Administration, the National Institutes of Health, and drug manufacturers.

[a]ESRD is a condition of permanent kidney failure.

Spending on Medicare beneficiaries accounted for the majority of estimated total U.S. spending for 35 of the 55 highest-expenditure drugs in 2010. For 17 of these drugs, Medicare spending accounted for more than two-thirds of total U.S. spending. Of the $16.9 billion Medicare spent for the 55 highest-expenditure Part B drugs, $11 billion, or 65 percent, was spent on drugs for which Medicare was the largest U.S. payer.

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Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee:

I am pleased to be here today as you discuss reforms to improve the Medicare Part B drug program. Unlike Medicare Part D,[1] Part B covers drugs that are commonly administered by a physician or under a physician's close supervision, such as chemotherapy drugs.[2] Many of these drugs are particularly expensive for the Medicare program, either because they are used by a large number of beneficiaries or because their prices are high. Furthermore, both the utilization and cost of these drugs are increasing. In 2010, the Medicare program and its beneficiaries spent about $19.5 billion on Part B drugs, about 9 percent of total Part B expenditures.

My statement will highlight findings from our October 2012 report on high-expenditure Part B drugs.[3] In that report we examined (1) the Part B drugs for which Medicare expenditures were highest in 2010 and the utilization and expenditure trends for these drugs from 2008 to 2010, and (2) nationwide spending levels for the total U.S. insured population for these high-expenditure Part B drugs in 2010 and Medicare's percentage of total U.S. spending.[4] These findings provide a look at the highest-expenditure Part B drugs in 2010. During or after 2010, several extremely expensive products entered the market—Provenge and Jevtana used to treat prostate cancer, and Benlysta used to treat lupus, among others. Given that costly new drugs entered the market and generic versions of other drugs became available, a snapshot taken today would likely show a somewhat different set of drugs.

[1]Medicare Part D is a voluntary program through which Medicare covers outpatient drugs.

[2]Medicare Part B covers certain physician, outpatient hospital, laboratory and other services, and medical equipment and supplies. Part B drugs are commonly administered in physicians' offices and hospital outpatient departments. In this testimony the term "drugs" refers to chemically synthesized drugs and biologicals unless otherwise specified. Biologicals are products derived from living sources, including humans, animals, and microorganisms.

[3]GAO, *Medicare: High-Expenditure Part B Drugs*, GAO-13-46R (Washington, D.C.: Oct.12, 2012).

[4]For this testimony, we use the term Medicare spending to refer to spending by the Medicare program and spending by or on behalf of Medicare beneficiaries.

To identify the highest-expenditure Part B drugs, we used the Centers for Medicare & Medicaid Services' (CMS) national claims files for physicians, hospital outpatient, and durable medical equipment. We calculated the total expenditures for each drug and ranked the drugs, selecting the top 55 for further analysis. We also obtained utilization and average annual per beneficiary cost from the claims files. We obtained information on the purpose and other characteristics of these drugs from the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and manufacturers. We obtained estimates of total U.S. expenditures for each of the drugs from IMS Health, a company that collects and analyzes health care data, thereby enabling us to estimate Medicare's share of spending for these drugs.

We conducted the work for our October 2012 report that forms the basis for our findings from August 2011 through August 2012 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations to our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions.

Background

Medicare bases its payments for most Part B drugs on the average sales price (ASP), which is calculated from price and volume data that manufacturers report quarterly to CMS, the agency within the Department of Health and Human Services (HHS) that administers Medicare. ASP is the average price, after rebates and discounts, of all sales of a specified drug in the United States; consequently, Medicare's payment rates for Part B drugs are based on prices set in the private market. Payment to physicians for most drugs is set by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) at 106 percent of ASP.[5] Until recently, CMS set payment for separately payable Part B drugs administered in hospital outpatient departments at a rate that has varied between 104 and 105 percent of ASP, but in 2013, CMS set the payment rate at 106 percent of ASP.

[5]Pub. L. No. 108-173, § 303(c)(1),117 Stat. 2066, 2239 (adding Social Security Act (SSA) § 1847A(b)).

The MMA directed the HHS Office of Inspector General (OIG) to compare ASP to the average manufacturer price (AMP), and authorized CMS to lower reimbursement for drugs with ASPs that exceed AMPs by 5 percent or more.[6] OIG's most recent annual report found that there were 58 drug codes in 2011 for which ASP exceeded AMP by at least 5 percent. Beginning in 2013, as authorized by the MMA, CMS is implementing a policy to substitute AMP-based prices in such cases. Specifically, CMS will substitute 103 percent of the AMP for the ASP-based reimbursement amount when OIG identifies a drug code that exceeds the 5 percent threshold in two consecutive quarters or three of four quarters.[7]

In a 2005 report, we analyzed the use of ASP to set payment rates for Part B drugs, and we determined that it was a practical approach compared with methods based on alternative data sources.[8] Nonetheless, we had concerns about CMS's lack of certain information on ASP, and characterized it as "a black box." Specifically, we stated that CMS did not have sufficient information on how manufacturers allocate rebates to individual drugs sold in combination with other drugs and had no data that would allow it to validate the underlying reasonableness of prices. CMS did not obtain price and volume data by purchaser type—for example, physicians, hospitals, and other health care providers. Furthermore, a sufficient empirical foundation did not exist for setting the payment rate for Part B drugs at 6 percent above ASP. The addition of 6 percent to the price is relatively small for a $10 drug, but it is substantial for a $100,000 drug.

Although payment for most Part B drugs is based on ASP, some are paid on a different basis. Vaccines, infusion drugs furnished with durable medical equipment, and blood products are paid at 95 percent of average wholesale price (AWP), which is the manufacturer's average price to wholesalers, but AWP is not defined in law and does not account for

[6]AMP represents the average of actual transaction prices paid to manufacturers for a given drug and is typically less than any of a drug's published compendium prices, which are list prices suggested by drug manufacturers.

[7]42 C.F.R. § 414.904 (2012).

[8]GAO, *Medicare: Comments on CMS Proposed 2006 Rates for Specified Covered Outpatient Drugs and Radiopharmaceuticals Used in Hospitals*, GAO-06-17R (Washington, D.C.: Oct. 31, 2005).

prompt pay or other discounts, rebates, and reductions.[9] In cases where the ASP of a new drug during the first quarter of sales is unavailable, payment may be set at 106 percent of the wholesale acquisition cost (WAC), which the Social Security Act defines as the manufacturer's list price for the drug to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates, or reductions, for the most recent month for which information is available.[10]

For some drugs such as drugs used to treat cancer, certain new drugs, and orphan drugs (drugs used to treat rare diseases), Medicare makes additional payments, known as transitional pass-through payments, for 2 to 3 years when these drugs are administered in the hospital outpatient setting. For new drugs, pass-through status is intended to make the drugs accessible to beneficiaries while a pricing history is developed and the price is established.

New drugs generally are patented and, while under patent, can be manufactured only by the patent holder. Patents generally last for 20 years from the date of application. After the patent expires and generic forms of the drug are marketed at significantly lower prices, the price of the original drug usually falls.

Total Expenditures, Utilization, Average Costs per Beneficiary, and Trends for Part B Drugs from 2008 through 2010

Medicare expenditures for Part B drugs in 2010 were concentrated among relatively few drugs. In 2010, the 55 highest-expenditure Part B drugs represented $16.9 billion in spending, or about 85 percent of all Medicare spending on Part B drugs. Generic alternatives were not available for most of the 55 drugs. Most remained under patent and could be purchased only from a single manufacturer.

The 10 highest-expenditure drugs, shown in table 1, accounted for about 45 percent of all Part B drug spending in 2010. Of these 10 drugs, 8 were biological products and 4 had orphan drug marketing exclusivity in

[9]Prompt pay discounts may be provided when the purchaser pays in advance or within a prescribed time period.

[10]SSA § 1847A(c)(6)(B). The list price is to be determined as reported in wholesale price guides or other publications of drug pricing data.

2010.[11] None of the 10 highest-expenditure drugs had a generic version approved by FDA in 2010.

Table 1: Ten Highest-Expenditure Medicare Part B Drugs, 2010

2010 rank by total Medicare expenditures	Brand name(s)	Drug description	Classification	Condition(s) treated	Total 2010 expenditures for Medicare beneficiaries (dollars in millions)
1	Epogen/Procrit (end-stage renal disease (ESRD) use)	Epoetin alfa, ESRD[a]	Biological	Anemia in ESRD patients	$2,000
2	Rituxan[b]	Rituximab injection	Biological	Cancer; rheumatoid arthritis	1,302
3	Lucentis	Ranibizumab injection	Biological	Wet age-related macular degeneration (AMD)	1,180
4	Avastin[b]	Bevacizumab injection	Biological	Cancer; wet AMD	1,130
5	Remicade[b]	Infliximab injection	Biological	Various autoimmune disorders	900
6	Neulasta	Injection, pegfilgrastim 6mg	Biological	Prevent infection in chemotherapy patients	888
7	Aranesp (non-ESRD use)	Darbepoetin alfa, non-ESRD	Biological	Anemia in chemotherapy patients	504
8	Epogen/Procrit (non-ESRD use)	Epoetin alfa, non-ESRD	Biological	Anemia in chemotherapy and HIV patients; prevent blood loss in surgical patients	443
9	Alimta[b]	Pemetrexed injection	Drug	Cancer	394
10	Taxotere	Docetaxel injection	Drug	Cancer	387
	Total				**$9,128**

Source: GAO analysis of CMS, FDA, NIH, and drug manufacturer data.

[a]ESRD, a condition of permanent kidney failure, is also known as stage 5 chronic kidney disease.

[b]These products had orphan drug marketing exclusivity for specific FDA-approved indications in 2010.

Many of the high-expenditure Part B drugs are used in cancer treatment. Of the 55 highest-expenditure drugs, cancer and its side effects were treated by more drugs (23) than any other set of conditions in 2010. Other conditions treated by several drugs included immune system disorders

[11]Rtiuxan, Avastin, Remicade, and Almita had orphan drug marketing exclusivity.

(13), cardiovascular disease and testing (5), chronic kidney disease (5), asthma and lung diseases (3), and prevention of organ transplant rejection (3).[12]

The number of Medicare beneficiaries in 2010 who used the 55 drugs we reviewed varied widely. Utilization of the 55 highest-expenditure Part B drugs ranged from over 15 million beneficiaries who received the influenza vaccine to 660 beneficiaries who used factor viii recombinant to treat hemophilia A. Although Epogen to treat beneficiaries with end-stage renal disease (ESRD) was Medicare's most expensive Part B drug in 2010,[13] table 2 shows that other drugs among the top 55 were used by more beneficiaries, including two vaccines (to prevent influenza and pneumonia). Apart from the vaccines, the greatest number of beneficiaries (891,000) used Lexiscan, a chemical stress agent used to test heart function in patients who cannot take a stress test on a treadmill.

[12]Some drugs were used to treat more than one type of condition.

[13]Regardless of age, most individuals with ESRD, a condition of permanent kidney failure, are eligible for health care coverage under Medicare. Beginning in 2011, CMS implemented bundled payments for drugs and services to Medicare dialysis facilities, which treat ESRD, in part to discourage excessive use of separately billable drugs such as Epogen. Since then, Medicare has not paid separately for 5 of the 55 drugs in our analysis when they are used to treat chronic kidney disease: Epogen/Procrit, Aranesp, Zemplar, Venofer, and Hectorol.

Table 2: Ten Most Utilized High-Expenditure Medicare Part B Drugs, 2010

Brand name(s)	Condition(s) treated	Utilization (number of unique Medicare beneficiaries)
Influenza vaccine (various)	Prevent influenza	15,229,920
Pnuemovax 23, Pnu-Imune	Prevent meningitis and pneumonia	1,692,940
Lexiscan	Stress agent for myocardial perfusion imaging	890,920
Venofer	Anemia in chronic kidney disease patients	329,260
Epogen/Procrit (End-stage renal disease (ESRD) use)	Anemia in ESRD patients[a]	323,920
Zemplar	Hyperthyroidism in chronic kidney disease patients	230,700
Reclast	Osteoporosis prevention and treatment; treat Paget's disease of bone	218,060
Avastin	Cancer; wet age-related macular degeneration	171,560
Synvisc/Synvisc-One	Osteoarthritis of the knee	168,560
Aloxi	Prevent nausea and vomiting in chemotherapy and surgical patients	164,000

Source: GAO analysis of CMS, FDA, NIH, and drug manufacturer data.

[a]ESRD, a condition of permanent kidney failure, is also known as stage 5 chronic kidney disease.

The annual per beneficiary cost of the Part B drugs we examined also varied widely in 2010. The influenza vaccines had the lowest average per beneficiary cost ($13). Table 3 shows that factor viii recombinant, although used by the smallest number of Medicare beneficiaries, had the highest average per beneficiary cost—$217,000.

Table 3: Ten High-Expenditure Medicare Part B Drugs with Highest Average Annual per Beneficiary Cost, 2010

Brand name(s)	Condition(s) treated	Classification	Average annual cost per beneficiary
Factor viii recombinant (various)	Hemophilia A	Biological	$216,833
Remodulin	Pulmonary arterial hypertension	Drug	130,772
Ventavis	Pulmonary arterial hypertension	Drug	84,205
Primacor, Primacor in Dextrose	Acute decompensated heart failure	Drug	62,790
Erbitux	Cancer	Biological	25,898
Dacogen	Myelodysplastic syndrome	Drug	25,858
Herceptin	Cancer	Biological	25,797
Vidaza	Myelodysplastic syndrome	Drug	22,957
Sandostatin Lar Depot	Acromegaly, diarrhea, and flushing caused by cancerous tumors and vasoactive intestinal peptide secreting adenomas	Drug	22,748
Velcade	Cancer	Drug	19,667

Source: GAO analysis of CMS, FDA, NIH, and drug manufacturer data.

Spending, utilization, and prices increased for most of the 55 most expensive Part B drugs between 2008 and 2010. Expenditures for 42 of these 55 drugs increased during those years, with the drugs that showed the greatest increases in expenditures also showing the greatest increases in utilization. The four drugs for which spending and utilization increased most were Lexiscan, Treanda, Privigen, and Reclast (see table 4). These drugs were approved by FDA in 2007 or early 2008, and it took some months for their use to spread.

Table 4: Ten High-Expenditure Part B Drugs with Largest Changes in Expenditures, Utilization, and Average Price from 2008 to 2010

Change in expenditures, 2008-2010[a]		Change in utilization, 2008-2010		Change in average price, 2008-2010[b]	
Brand name(s)	Percent change	Brand name(s)	Percent change	Brand name(s)	Percent change
Lexiscan	9,550.4	Lexiscan	11,008.7	Ventavis	51.5
Treanda	7,440.2	Treanda	3,271.4	Pneumovax 23, Pnu-Imune	36.0
Privigen	836.3	Privigen	381.1	Myfortic	22.0
Reclast	140.7	Reclast	136.8	Hycamtin	17.5
Myfortic	106.9	Myfortic	73.4	Gammagard Liquid	15.4
Primacor, Primacor in Dextrose	94.0	Hectorol	71.1	Doxil	14.1
Ventavis	93.6	Flebogamma, Flebogamma DIF	46.7	Tysabri	12.3
Vidaza	81.9	Orencia	45.4	Vidaza	11.6
Gammagard Liquid	69.2	Vidaza	41.7	Gamunex	11.3
Orencia	66.9	Gamunex	36.7	Xolair	11.2

Source: GAO analysis of CMS and FDA data.

Notes: Our analysis excludes expenditures and utilization in 2008 that were reported using a not otherwise classified code, which may have artificially increased the changes shown for new drugs, including Lexiscan and Treanda.

[a]We removed factor viii recombinant biological from our analysis of change in expenditures from 2008-2010 because Medicare claims expenditures for 2008 were lower than values in CMS's Part B National Summary Files and we were not confident that the reported expenditures for 2008 were valid.

[b]The change in price analysis was based on the unweighted average ASP across four quarters in each year, and does not include prices for drugs when supplied through infusion equipment.

Most price changes from 2008 to 2010 were also increases but the range was smaller—from an increase of 52 percent to a decrease of 38 percent. Four of the 10 drugs that increased most in expenditures were among the 10 that increased most in price.

Medicare's Proportion of Total U.S. Spending on Highest-Expenditure Part B Drugs

Spending on Medicare beneficiaries accounted for the majority of estimated total U.S. spending for 35 of the 55 highest-expenditure Part B drugs in 2010. For 17 of these drugs, Medicare spending accounted for more than two-thirds of total U.S. spending. Of the $16.9 billion Medicare spent for the 55 highest-expenditure Part B drugs, $11 billion, or 65 percent, was spent on drugs for which Medicare was the largest U.S. payer. Treatment of cancer and its side effects, autoimmune disorders and immunodeficiency, and chronic kidney disease were the most common uses of the 35 drugs for which Medicare spending was the majority of U.S. spending.

Mr. Chairman, this concludes my statement. I would be pleased to respond to any questions you or other members of the subcommittee have.

For questions about this testimony, please contact James Cosgrove at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Individuals who made key contributions to the testimony include Phyllis Thorburn, Assistant Director; George Bogart; Linda Galib; Andrew Johnson; and Elizabeth T. Morrison.

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Mr. PITTS. That concludes the opening statements. We will now go to questioning. I will begin the questioning and recognize myself for 5 minutes for that purpose.

Dr. Brooks, explain a little bit more what impact would removing the prompt pay discount from the Medicare formula have on patients and our overall health care system, if you would.

Dr. BROOKS. Well, sir, obviously the weight of the sequester would not be removed just by removing prompt way but it would help us a great deal. Prompt pay diminishes ASP for our offices by approximately 1 to 2 percent. It is a floating number. It is not consistent. But it decreases our reimbursement by about 1 to 2 percent. As I like to tell my colleagues, my income in 2012 was 102 percent from commercial insurance. And what that means is that we lost 2 percent on our Medicare patients in our office. So if we were to get rid of the prompt pay discount, that would restore us to baseline if the weight of sequester were also treated more uniformly in our space.

Mr. PITTS. Now the President has proposed a 3 percent cut to the SP formula. What would happen to your practice if that were to go into effect?

Dr. BROOKS. Well, sir, I don't know whether to answer you seriously or with some humor. But we did not include in any of my remarks anything about disruption or drama or threats or anything of that sort. But I can assure you that if ASP plus 3 percent were to ever be enacted, that disruption and drama would occur. We would not be able to take care of our Medicare patients at that rate. We would immediately have to discontinue that because the losses would be enormous. The hospital outpatient departments that are currently taking our patients do not have the capacity to overnight take those patients in. And there would be an enormous access problem.

Mr. PITTS. All right. Mr. Cosgrove, page 2 of your testimony states that "Medicare expenditures for part B drugs in 2010 were concentrated among relatively few drugs."

Is it fair to conclude then that the majority of drug expenditures under part B should not be considered high expenditure drugs?

Mr. COSGROVE. Under part B, Medicare covers hundreds of drugs. So yes. I think the problem is just complex and it may not be a one-size-fits-all because you have some drugs that either because a lot of people use them or few people use them and they are very expensive or some combination are very expensive. And that is probably where the attention should be focused.

Mr. PITTS. Ms. Davenport-Ennis, in reviewing the GAO testimony, I noticed that a number of the high expenditure drugs on the list under part B are drugs used to treat cancer and various autoimmune diseases. And I am reminded of the new lupus drug that was recently released, representing the first new treatment for patients with this disease in over 50 years. How important is it for patients with diseases like cancer to have access to new and ground-breaking treatments in your opinion?

Ms. DAVENPORT-ENNIS. Thank you for the question.

So from a patient's point of view, often the traditional drugs that are in the marketplace are not going to continue to work for cancer patients that have been in therapies for years and years. If there

is a cancer patient that has a very advanced cancer, often you have to move them to the newer drugs in the marketplace that will stop that disease where it is. And whether it is cancer or whether it is another chronic debilitating or life-threatening condition, the new drugs hold the promise of independent living. They hold the promise that people can stay at work. They hold the promise that they can maintain their role as a parent, as a spouse, and as a member of society. So each time we create a regulatory hurdle that puts that new drug further away from the patient, the more likely we are to see earlier debilitation due to disease and less independent living and, therefore, additional cost to the system and other places.

Mr. PITTS. Dr. Brooks, please describe for us some of the differences patients experience between being treated in a community-based oncology practice and receiving cancer treatment in a hospital outpatient department.

Dr. BROOKS. Well, I briefly described the differences in convenience and financial commitments in my testimony. But just to review, patients often have to travel a bit further to get to a hospital outpatient department. They often have to wait a bit longer. And CMS' costs in a hospital outpatient department are higher by at least 50 percent. Those are the superficial aspects of the problem. But, in fact, they are greater. I told my colleagues about a husband and wife pair that I used to take care of years ago and I ran into recently. And they told me about their follow-up care in another State. The husband goes to a private practice for his follow-up and he goes in for his appointment at 10:00 o'clock in the morning. He gets to the laboratory, sees his physician, and he is home by 11:00 o'clock. His wife chooses to go to a nearby tertiary hospital outpatient department. And it is a very well run and well respected institution. She has an appointment for a laboratory at 10:00 o'clock and an appointment for an x-ray at 11:00 o'clock, an appointment for a physician at 1:00 o'clock and outpatient counseling at 3:00 o'clock. And she is home by 4:00 o'clock. And she gets basically the same services as her husband does in a local community oncology office.

Those are just—that is just an anecdote for you to understand that while they give good care in hospital outpatient departments, and we never say otherwise, it is just different.

Mr. PITTS. Did you want to add anything, Ms. Davenport-Ennis?

Ms. DAVENPORT-ENNIS. I would. I would like to add the human element to that. So when we have a Medicare patient that contacts us and says, I am now being moved from the community setting with my doctor, and I am going to need to travel 28 miles to get to the hospital, I am going to be in an infusion chair, and I may be there for an hour, I may be there for 6 or 8 hours, the journey when you leave that chair to return to home is indescribable. So if I may be personal with this body, I would like to.

My husband is a stage 4 cancer survivor. We had to move him from a local oncologist, and we had him in a hospital setting. The simple 28-mile journey resulted in such acute emesis that we had to be rescued by an ambulance roadside. We are not a rare exception. The side effects for cancer treatment are serious, and they are not simply managed, and so when we move you to a community

hospital setting, you may indeed be able to handle that transfer no problem whatsoever, but we have many cases that document otherwise.

We think that the hospital cost is something that is important to us. We have worked for 17 years to try to work with patients to handle the cost of care in a financially sound manner, and to exert the full limits of their insurance benefits, and to encourage them to get Medigap policies so that, indeed, they are protected as they move forward, and even though they play by the rules, the system is failing them.

Mr. PITTS. The chair thanks the gentlelady.

I now recognize the gentleman from Texas Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

Ms. Davenport-Ennis, can you expand on Dr. Brooks' testimony and share the patient's point of view how the prompt pay discount would affect access to Medicare beneficiaries?

Ms. DAVENPORT-ENNIS. So as we have talked to many of the patients who have had their sites of care shifted, and as we have worked with the doctors that are handling them, what we know is that many of the practices started operating on reduced margins in 2004 because we never got the codes back up to where they needed to be, and ASP has been unstable at best. So if we could, indeed, restore a 2 percent prompt pay discount to many of these practices, it would be the difference between adding back another oncology nurse case manager or not having one. It would be the difference between being able to have after-hours support for the patient and sending them to the hospital phone line for after-hours support.

So there are many services that we think could be restored, and you could maintain practices. And for the record, I would like to report that to this point we have had 1,200 practices in the United States that have either closed completely or compressed their services into hospital settings in which we lost capacity because the number of chairs available for chemo at the hospital were not commensurate with what they had before the compression and equal to the practice as well.

Mr. GREEN. OK. Dr. Brooks, can you walk through the importance of that 6 percent additional service fee and what has it accounted for? And I know cancer-treating drugs can be very expensive. For example, if it was a $100,000 treatment, that would be $6,000 that would be part of the service fee. Can you walk us through that?

Dr. BROOKS. I would be delighted to, Congressman.

Obviously, the sequester has definitely removed any incentive we have for prescribing expensive drugs, because a small percent on a large number cuts both ways. But the prompt pay discount takes that 6 percent of ASP and attenuates it by 1 to 2 percent, in our opinion. We have to have working capital for inventory, administration, storage, inventory management, systems for transport, pharmacy costs, clean room, equipment, waste disposal. We have to deal with the problem of inadequate copay collection from Medicare beneficiaries—that runs about 5 percent in most of our practices—drug denials. And then there is the problem of price increases which are not reflected in ASP for about 6 months.

This results in pretty much taking away our 6 percent service margin that we previously had, but with sequester we have attenuated that ASP by an additional 1.7 percent, or 28 percent of our services payment that we have gotten before. So now we are, as we say, breathing through a straw because we are under water.

Mr. GREEN. OK. With prompt pay, now sequestration, what is the effective percentage? It is lower than the 6 percent?

Dr. BROOKS. I am not sure I understand your question, but, yes, sir, if we were to restore both of those, we would be back to very close to break even on our cancer—Medicare cancer part B drugs, and we would be able to go back to life as we had it in 2012. Not great, it was a lot of migration into the hospitals, but it would be much better than we currently have.

Mr. GREEN. And I know Ms. Davenport-Ennis talked about the impact on patients. In your practice have you seen the same situation that she talked about?

Dr. BROOKS. Yes, sir. I thought that she was very eloquent describing the patient problems of the frail cancer patient having to travel great distances to a site of care. We see that a lot in our State of Texas, where people have to travel. When community practices close, my Texas oncology, if we were to lose our ability to take care of Medicare patients in rural, small-town, and in medium-sized Texas, cancer patients, Medicare beneficiaries would be traveling, 100, 200 miles each day for site of care that would take——

Mr. GREEN. I only have about 20 seconds.

Mr. Binder, obviously Congressman Whitfield and I have introduced legislation on the prompt pay discount and the calculation. Isn't it true that this was fixed within the Medicaid program, the prompt pay issue?

Mr. BINDER. I am sorry, could you repeat that?

Mr. GREEN. Was the prompt pay issue fixed within the Medicaid program?

Mr. BINDER. The prompt pay——

Mr. GREEN. Is your mike on?

Mr. BINDER. It doesn't—to my knowledge, the prompt pay discount that is proposed in the legislation wouldn't impact the Medicaid program directly. Medicaid prices, the Medicaid rebate is determined off of average manufacturer price, and that price excludes all discounts already.

Mr. GREEN. OK. OK. Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the vice chairman of the subcommittee Dr. Burgess, 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman. Before I get to questions, I would like to submit for the record a few things. The article from the New England Journal of Medicine from, I think, February of last year that Dr. Melton referenced on the impact of coverage limits on immunosuppression. I also have statements from the National Kidney Foundation, the American Society of Nephrology, and the American Society of Transplant Surgeons, and I would like to make those all part of our proceedings today.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. BURGESS. Dr. Melton, frequently here on this committee we hear people talk about, you know, we only want sound science; we want to make our decisions based on sound science. So tell me, is there a good scientific rationale for the 36-month interval for covering immunosuppression after a renal transplant and then stopping that activity?

Dr. MELTON. There is no rationale that that is based on at all that I am aware of. The patients that we transplant are required to take immunosuppressant medications for the life of the transplant. And it is true that many times they require more medications early on in their transplant course, and those can be reduced later on, but the need to take those medications continues to exist forever.

Mr. BURGESS. So there is not some point at which a patient's immune system just kind of accepts life as it is with this new graft that is sitting in the body, and the immune system just kind of turns off its recognition of this as a foreign object? That doesn't happen, does it?

Dr. MELTON. No, sir, that doesn't happen.

Mr. BURGESS. So since it doesn't happen, then what happens to the graft when you run out of the immunosuppressive activity?

Dr. MELTON. The body begins reacting against the graft, the immune system begins to reject that graft, and over a period of time the patient will lose the kidney transplant and will return to dialysis therapy.

Mr. BURGESS. So you as a physician would see what, that the ability—the filtration rate of that grafted kidney would begin to diminish, so tests that you do or blood work that you do would begin to reflect a lower functionality of that transplanted kidney?

Dr. MELTON. Yes, sir, that is correct.

Mr. BURGESS. So what is the patient going to experience during that time?

Dr. MELTON. The patient begins to develop symptoms of kidney failure: tiredness, loss of appetite, inability to concentrate. They will begin to have some pain over and around the kidney transplant itself, indicating that there is an inflammatory rejection process going on there, and many times that results in us having to remove that kidney transplant because of the discomfort and pain that the patient is developing.

Mr. BURGESS. So it is not a silent activity as far as the patient is concerned; they are aware that there is a problem?

Dr. MELTON. Yes, sir, they are.

Mr. BURGESS. Well, let me ask you this: OK, 36 months go by, we stop immunosuppressive drugs because we think that is good Federal policy. The patient begins to reject their kidney. You do the right thing, which is bring that patient back in to the dialysis clinic or refer them back to the dialysis clinic. Does that take care of the problem?

Dr. MELTON. Well, that keeps them alive. It doesn't keep them healthy as they were, and it certainly doesn't correct the problem of losing the drug coverage after 36 months.

Mr. BURGESS. So what about the quality of life for that individual, does it get affected at that point?

Dr. MELTON. Oh, absolutely. Quality of life on dialysis is nothing compared to transplantation. Transplantation essentially makes someone a normal individual, if you will; they are able to work, they are able to travel, they are able to participate in sports activities, they can have families. Many patients who are on dialysis are, frankly, beat up by the procedure and are unable to hold a job, and they suffer a lot of complications from kidney failure and dialysis therapy that shortens their life span.

Mr. BURGESS. Well, as I seem to recall, this is back in the 1970s, so it is probably much more frequent now that a patient could even successfully carry a pregnancy who has gone through a transplant.

Dr. MELTON. Oh, absolutely. We have—at our institution we have about 40 patients now, 40 women, who have successfully had pregnancies with their transplants, most recent—well, not most recently, but recently a young woman with a combined kidney and pancreas transplant that delivered twins successfully.

Mr. BURGESS. That is a remarkable story.

So what about the—immunosuppressive drugs have been around for a while, cyclosporine, I guess. Is that still the main one?

Dr. MELTON. Cyclosporine has been around since the mid-1980s. There are several others that have come into play since that time.

Mr. BURGESS. So do we have generic—the availability of generics for those?

Dr. MELTON. We do have generics for some of the drugs, not for all of them.

Mr. BURGESS. Does the ability of generics reduce the overall price tag for providing immunosuppressant drugs?

Dr. MELTON. Some of the generic drugs are less expensive, particularly if they are covered through some insurance plans. I had our social workers actually run a pro forma on that for me about a year ago, and surprisingly—cyclosporine was one of the drugs that you mentioned, and surprisingly the generic forms of cyclosporine came in only about a third less than the brand-name drug. So there was not a substantial—well, a third is a substantial reduction, but it was still a pricey drug for the patients.

Mr. BURGESS. I guess the point would be the last time—you know, we have got to do stuff that the Congressional Budget Office tells us we can afford to do, so the last time the Congressional Budget Office scored this particular piece of legislation, they gave it a dollar score. Would it be fair to say that rescoring this with this information about the use of generic medications might result in a lower score?

Dr. MELTON. I don't know how they go about their scoring process.

Mr. BURGESS. I don't, either.

Dr. MELTON. It is a mystery to me. The only comment I can make about that is it is—certainly relooking at these drug costs would be of benefit, I think, to our patients.

Mr. BURGESS. It would also be a benefit if we could look longer than a 10-year window, because if you add the cost of dialysis in perpetuity to a patient who lost their graft after 3 or 4 years, clearly it is going to come down on the right side of the cost curve.

Thank you, Mr. Chairman. I am going to yield back my time. If we have time for a second round, I will be willing to participate.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the gentlelady from Florida Ms. Castor, 5 minutes for questions.

Ms. CASTOR. Well, Mr. Chairman, I appreciate you holding today's hearing and all of the very insightful testimony from our witnesses. Thank you very much for being here.

I want to talk about one fixable issue, the two-quarter price lag on the part B price calculations.

Mr. Binder, one issue you discuss in your testimony is that two-quarter lag in part B price calculations for provider reimbursement. Can you elaborate on the issue? How does this come into play?

Mr. BINDER. Well, manufacturers report their data, their ASP prices, to CMS, and then CMS has a period of time to process the information and apply it to the prices they are going to pay for those drugs. And it is done on a billing-code basis, so there is—for some billing codes there is a number of drugs included, and for some there is just one drug when it is a sole-source drug. But that process takes some time, and there is analysis involved, and so it is 6 months before the prices——

Ms. CASTOR. Six months?

Mr. BINDER [continuing]. Are applied.

Ms. CASTOR. What are some of the impacts of that 6-month lag?

Mr. BINDER. Well, it varies. You know, if the drug price goes up, and, you know, certain buyers, say, for instance, buyers who don't buy in very large volume, are more likely to be affected by this than large-volume buyers or purchasers, they could, you know, have to pay more for the drug than they can get from Medicare in payment. If the price goes down, purchasers, providers are more likely to have it—to buy it at a lower price than they are getting.

Ms. CASTOR. Dr. Brooks, you discussed this in your testimony. Give us the real—what is happening in the real world with a 6-month lag?

Dr. BROOKS. Well, the 6-month lag is a problem. There are a lot of the pharmaceutical and biologic firms that have a business model whereby they raise prices about once a year, and they put us under water for 6 months. And then before we quit prescribing their drugs, they allow 6 months where we can more or less hold when ASP comes back to respectability, and then they have another price increase again the next year.

This is what we see, this up-and-down price sequences where we have 6 months under water, then 6 months to try to catch up, and then 6 months down again. It is a relentless process, and a more rapid reconciliation of those price increases that we have to pay with what we are actually reimbursed would be most helpful to our ability to deliver cancer care to our Medicare patients.

Ms. CASTOR. That is consistent with what I am hearing from doctors back in Florida. And I know it seems like an arcane detail, but I think it is having big impacts. And sometimes in Congress we hear about problems that are difficult to solve, and sometimes we hear about problems that are easier to solve, and it seems like one that, Mr. Chairman, would fall into the easier category. In this day and age, when you can communicate with anybody anywhere in the world in seconds, and we can pull up any piece of data on our iPads

that we have here or our iPhones, it certainly seems to me like we should be able to determine accurate Medicare drug prices without a 6-month lag in time.

The two-quarter lag is written into Medicare law, so this is a problem for Congress to solve. And, Mr. Chairman, I hope we can work together to find a solution on this.

I would also like to talk about the impact of the sequester. It has been in place for several months now, but it is no longer front-page news, but that doesn't mean that it is not causing real harm. One area where it has hit hard is in reimbursements for Medicare providers, including the part B drug providers.

The sequester required a 2 percent cut in reimbursements. Earlier this year The Washington Post had quite an article on it identifying one cancer clinic that said that due to the sequester, they would have to stop treating as many as one-third of their 16,000 patients. And this is consistent with the testimony here this morning.

Dr. Brooks, can you tell us what—put us in the real world here. What is this 2 percent cut having—what impact is it having on patients that you see?

Dr. BROOKS. Well, Congresswoman, thank you for the question. I only alluded to it briefly, but it is not a 2 percent cut for Medicare part B drugs in oncology. CMS has interpreted the rule perversely, in our view. They have cut not only our 6 percent services payment, but also the entire 100 percent drug acquisition costs that we do for CMS. So they cut us on all of Medicare's expenditure so that it results in a 28 percent reduction in our services payment, and this has put us under water and has cost those of us——

Ms. CASTOR. It is so irrational. I mean, it really highlights the irrationality of the sequester, just across-the-board cuts that are not based on the real needs of the American people. And it is not just Medicare part B, it is cuts to NIH, and medical research funding, Head Start, Meals on Wheels. And I think the solution—I know that legislation has been filed particularly on this point, but the real solution are both sides of the aisle coming together to replace the sequester.

Now, yesterday the—my side of the aisle, the Democrats, we appointed budget conferees. We are ready to go negotiate, and I would ask my friends on the other side of the aisle to please do not be afraid to come together and negotiate. We are seeing a real-world impact of the sequester.

Thank you, Mr. Chairman.

Mr. PITTS. The gentlelady's time has expired.

The chair recognizes the gentleman from Louisiana Dr. Cassidy, 5 minutes for questions.

Mr. CASSIDY. Dr. Brooks, Ms. Davenport-Ennis, I am struck, it seems like we have a trifecta of bad things driven by government policy. One, 340B program or something else is, among other things, driving community oncologists to go into a hospital outpatient network, that that hospital outpatient network charges Medicare more, that the patient pays more, and that they are less convenient.

For folks who don't know what emesis is, Ms. Davenport, vomiting. Your husband was so sick, he was vomiting on the way back

that he dehydrated in a half-hour drive and had to get an ambulance. This is like a quadrifecta of bad things. Did I hear that right, or am I misstating what the two of you said?

Ms. DAVENPORT-ENNIS. So from my point of view, you have heard it exactly right. And I would like to comment, if I may, on 340B.

Mr. CASSIDY. OK. You may want to elaborate what the program is for those who may not be familiar.

Ms. DAVENPORT-ENNIS. So when we look at 340B, the intention of the program was well intended. We were phasing out Hill-Burton hospitals that were supplying support to the at-risk populations. We introduced 340B concept so that hospitals serving at-risk populations could buy drugs at a reduced price, could bill them at a standard price; the margin could therefore be used for that hospital to make certain they could continue to serve the at-risk populations.

Initially the intent was to have 600 to 900 hospitals in the country as part of 340B. Today we have over 6,000 hospitals in the 340B program, and the margins are not necessarily consistently offering support to the at-risk population. The margins are being used to recruit community oncologists to come into that hospital setting.

Mr. CASSIDY. Now, is that allegedly, or do you have evidence of that?

Ms. DAVENPORT-ENNIS. No, we have evidence of that, in talking with a number of the practices. We work with oncologists in 50 States in the United States who work with us in case management services and in our copay relief services, and so it is not alleged, it is documented, and we—I would like to ask——

Mr. CASSIDY. So just to be sure, I am sorry to interrupt, but the program that supposedly is the subsidized care for the uninsured and for the Medicaid and Medicare patient to bring a set of services that otherwise they would not be able to have, you are saying that there is evidence that it is not being used for that, but rather to subsidize the purchase of community practices, bringing them into the hospital outpatient department, and in the meantime increasing costs to Medicare, to the patient, and decreasing convenience. Is that what you are saying?

Ms. DAVENPORT-ENNIS. Yes. What I am saying is that indeed the 340B hospital structure now allows it to offer very attractive packages to oncologists for them to leave their practices and associate or to bring their entire practices to the hospital setting, yes, sir.

Mr. CASSIDY. Now, I will say that I work and I still see patients in the Louisiana public hospital system, and that there are some hospitals I will declare that are still doing the correct mission with the 340B program.

Ms. DAVENPORT-ENNIS. You are exactly right.

Mr. CASSIDY. Yes. A lot of my patients would not have drugs otherwise.

Mr. Cosgrove, I have been struck anecdotally there is evidence that the drug shortages, for whatever the etiology of the drug shortage is, is leading to the need to substitute more expensive drugs for much less expensive generic drugs; that the shortage of sterile injectables in the oncologic space, for example, is requiring the use of more expensive drugs. Now, that is anecdotes. I read it

in the paper. Did you find evidence for that influencing utilization and cost?

Mr. COSGROVE. We did not. We did not look at that specific——

Mr. CASSIDY. Did you look at that? Microphone, please. Did you specifically look at that, or you just—you looked at it and didn't find it?

Mr. COSGROVE. We did not look at that. GAO has a report it issued in November of 2011, I believe, looking at shortages and their causes. There is follow-up work going on right now. It is a mandated study to try to get behind what is exactly causing those shortages and what the trends are.

Mr. CASSIDY. OK. Dr. Brooks, anecdotally are you seeing evidence for that or—because, again, I read about it in the paper, so that is why I am——

Dr. BROOKS. Well, sir, it is not anecdotal. We in US Oncology are—and with the help of our corporate partner, McKesson, we monitor the space extremely tightly, and I am actually involved in that monitoring. And your comment about steroids is spot on. We sent out an alert recently that methylprednisolone is in short supply. It costs pennies, but it is in very short supply because of the pressure of manufacturers.

ASP plus 6, I believe—and I don't know that the office of MMA—but I believe it was designed to curtail expenditures around expensive products. They never understood that they were going to create a race to the bottom in generic market so that our generic oncology drugs get lower and lower and lower prices, and then eventually it becomes not worthwhile to make these drugs. It costs only 2 or $3. They are expensive, they are hard to store and all this other stuff. It just—the economic incentive vanishes.

Mr. CASSIDY. We are out of time, but if I may say, so Mr. Waxman at the outset saying that we are saving money by price controls, it may be that we are saving money in the short run, but long term penny wise, pound foolish, because we are having to substitute far more expensive drugs.

I yield back. Thank you for your indulgence.

Mr. PITTS. The chair thanks the gentleman.

Now recognize the gentlelady from California Mrs. Capps, 5 minutes for questions.

Mrs. CAPPS. Thank you, Mr. Chairman. I am very pleased we can come together for another bipartisan hearing to address some commonsense improvements to Medicare, including two important provisions that I have cosponsored.

Medicare beneficiaries are a medically vulnerable population, and we have a responsibility to ensure that they have access to high-quality, community-based care and are not facing unreasonable financial burden. Unfortunately this isn't always the case, but I am pleased to see we have a lot of good bills from this committee to help address some of these shortcomings.

I have heard a lot from my constituents about challenges with continuity of care, access to providers, and the prohibitive costs of treatments for cancer and other chronic conditions. Cuts as a result of sequestration are taking a real toll on providers and have serious implications for access. For one oncologist in my district who sees a patient base that is over 90 percent Medicare beneficiaries,

this has meant letting staff go, the sequestration, making serious pay cuts, and taking out a home equity loan just to keep the doors open, because if she doesn't do this, patients will have to travel more than 30 miles to the next closest provider.

While I do have serious concerns about piecemeal approach of easing the impact of only one part of sequestration, that doesn't mean that this issue isn't an incredibly important one and does deserve our attention. I hope we can find a solution that minimizes the harm to patients and providers, especially in the context of an overall sequestration fix. I know it is not going to be easy, but I believe we can do this if the House majority will let us.

I also wanted to highlight that there are other improvements to Medicare part B that do not involve drug benefit, but are also critical to address gaps in care that many patients face. Navigating complicated treatment options for yourself or a loved one, especially with a cancer diagnosis, this can be a full-time job and more, and without a plan it can be really overwhelming. And that is why this week my colleague from the Ways and Means Committee Mr. Boustany and I introduced H.R. 2477, the Planning Actively for Cancer Treatment Act, or the PACT Act. This bill would improve the health of Medicare beneficiaries with a cancer diagnosis while reducing inefficiencies in the Medicare system.

The Medicare program spends over $55 billion each year to treat patients diagnosed with cancer, and too many of those patients do not receive a written care plan that explains the diagnosis, the prognosis, the treatment, and the expected symptoms. This leads to poor coordination among providers, reduced adherence rates, and increased stress or pain for the patient and their family.

However, a strong body of research shows that care planning coordinates care between numerous providers, and it also encourages shared decisionmaking between doctors and patients about how to best move forward based on both medical evidence and patient wishes. It addresses both the cancer treatment, but also the side effects from treatment, while addressing the patient's needs, and this can be done in a holistic way. Research has confirmed that this kind of coordinated care really does improve patient outcomes, increases patient satisfaction, reduces unnecessary utilization of healthcare resources.

Ms. Davenport-Ennis, as someone who is very familiar with the challenges patients face—I know all of you are, but there is not much time—would you share how this bill could help patients as they navigate cancer care, something I have been advocating for for a very long time?

Ms. DAVENPORT-ENNIS. You have, and on behalf of the cancer patients in the country, thank you for the work that you continue to do.

What this would do is provide a road map to survival, and it would show them what the stops are going to be along the way, and it would identify to them what to do when you have reversals. It would also allow them to manage their resources and to plan accordingly. It would also allow us to have an opportunity for end-of-life discussions when we need to have end-of-life discussions as part of planning for the full continuum.

It is, indeed, the beacon for the future, and it is something we have lobbied for in this city for more than 10 years, and we are very hopeful that you are going to make it happen this time.

Mrs. CAPPS. Well, I am going to need a lot of help, as you know, and maybe—Mr. Chairman, this is a request. I have another whole topic to bring up on restraining excessive cost sharing, the Patients' Access to Treatments Act, another bill that I have introduced with Mr. McKinley. I will just submit it for the record, and perhaps some of you may wish to comment on it.

[The information appears at the conclusion of the hearing.]

Mrs. CAPPS. But I kind of wanted to get just a nod from the rest of you about this kind of coordinated care plan that we are advocating to see if it fits your needs, yes or no, quickly. Thumbs up? Is that the verdict?

I mean, it is kind of one of those no-brainers, isn't it, that we should just set ourselves around to doing, and I appreciate very much this opportunity to discuss it.

I yield back.

Mr. PITTS. Without objection that will be entered into the record, and I would also like to ask unanimous consent that the following documents be submitted for the record: a letter from the California Health Institute, a letter from the American Society of Clinical Oncology. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mrs. CAPPS. Mr. Chairman, I was just informed by staff that I should ask, because we had a lot of nods, and I don't think the recorder can——

Mr. PITTS. All right. The witnesses will please respond verbally to——

Mrs. CAPPS. Just really quickly yes or no.

Dr. BROOKS. It would be a great asset, and as long as it wasn't sort of an unfunded mandate, we would cherish it.

Mrs. CAPPS. The question is whether there is agreement about the need for a coordinated care plan, a plan, a written plan.

I guess one strong affirmative. We will note that.

Dr. MELTON. In support of my oncology colleagues, absolutely.

Ms. DAVENPORT-ENNIS. And in support of the patients that we serve in the United States, absolutely.

Mrs. CAPPS. Thank you.

Ms. DAVENPORT-ENNIS. Yes.

Mrs. CAPPS. Thank you.

Mr. PITTS. All right. That concludes the first round. We will have one follow-up. We will go on each side. Dr. Burgess for follow-up.

Mr. BURGESS. Thank you, Mr. Chairman.

You know, I know people watching these hearings sometimes get confused. We have got a representative from the Congressional Research Service here. We appreciate him being here. We also talk about the Congressional Budget Office, which does the scoring of legislation that is introduced in Congress. There is another budgetary body down at the White House called Office of Management and Budget. Certainly Center for Medicare and Medicaid Services makes its own determinations to some degree.

But one of the main things, one of the main foci of today, has been the inclusion in the category of physician services the acquisi-

tion and storage of very expensive drugs. And I think, Mr. Binder—I don't want to put you on the spot, but I think even CRS would agree that you have a family practitioner who diagnoses pneumonia, writes a scrip, tears it off, hands it to the patient, says go down to the pharmacy and buy these penicillin tablets and take them, and you will get better. If you were—it would be wrong to say we are going to include that cost in the physician's service and then subtract 2 percent from that total bill and get that money back to the government. It just wouldn't make good sense.

So the acquisition—and this was part of my opening statement, that the math function doesn't compute here. This is my beef with the Centers for Medicaid and Medicare Services. We sent them a letter signed by a lot of members of this committee; we got a nonresponsive response. Sorry, not good enough. We sent a follow-up letter to them that you really have to delineate to us how in the world that acquisition and storage requires a medical degree and a State license in order to do that, because otherwise it just opens the door for all other sorts of mischief. So I hope that we are able—Dr. Brooks, I hope that we are going to be able to get some sensibility surrounding that.

More difficult aspect to undo the sequester. I mean, the sequester, after all, was bipartisan legislation, much more bipartisan than the Affordable Care Act; was signed by the President. Same President who signed the Affordable Care Act signed the sequester. So we are often told on this committee when we complain about the Affordable Care Act, hey, it is the law of the land, get over it. Well, the same statement could be made about the sequester: It is the law of the land.

But we do need to be certain that it is administered properly, and in this case, I think Dr. Brooks is exactly on target, it is not being administered properly. And you may even want to address—you get some—I mean, your practice margin is pretty narrow, and there is lots of things that put pressure on your business model, but everyone on this dais would say it is a good business model. We want you to be focusing on what you do best, which is taking care of the cancer patient. A patient gets cancer, they want to go to a clinic where that is all they take care of. They don't want to go to a clinic where they are also delivering babies and treating kids with runny noses. They want a cancer specialist, and I don't blame them, and that is what you provide.

But you are also, if I recall correctly, under State law and under our Texas law, with the franchise tax. This is something you also have to deal with with the acquisition and storage costs that also erodes your ability to take care of patients.

But the big thing you brought up, and what I really want to perhaps ask you to comment on, you said 102 percent of your business is required to pay for all of your business, because the government doesn't carry its fair share. Did I understand you correctly when you made that statement?

Dr. BROOKS. Yes, sir. Those were numbers for 2012. That is our calculation. Our professional medical oncology payment for my salary is 102 percent from commercial payers, meaning that the Medicare and Medicaid are minus 2 percent. So we actually paid for the privilege of taking care of those patients, and that sounds like hor-

rible or something, but we were oK with that. I mean, I hate to say it. Our mission is to take care of patients, and we are oK with a small loss to continue doing what we believe we should do.

Now under sequester our incomes are falling like a stone, and I don't—I can't give you a number for how bad it is, but there is a multiplier effect going on here, and it is much worse than we—our accountants projected for us, the actual dollars coming in. And we are anticipating that the—everybody says, oh, there is no drama, nobody is losing access. We anticipate that there will be a two-stage approach here. The smaller practices that are not taking adjustments will begin to have to turn out their lights for the last time in August or September, in our calculations, and our complicated larger practices are working quietly behind the scenes to arrange for transfer of these patients to other venues because we will not be able to continue to subsidize our Medicare beneficiaries.

Mr. BURGESS. But I would just project that the entire—we also heard some discussion about consolidation of practices. Certainly cardiologists saw that with the consolidation of their practices moving to the hospital. The Affordable Care Act is going to put some pressure on practices of all sorts to consolidate. I mean, in fact, Zeke Emanuel, one of the principal architects of the Affordable Care Act over at the White House, said that he wanted doctors to work for a hospital or a health plan or the government; that was a better way, in fact, to practice; that you and I are dinosaurs in private practice.

I do—we do need to keep a focus on this, because your comment that part of your practice pays for the other part, it is the government part that is not carrying its weight. As that level is expanded, and it will be, make no mistake about it, January 1st of this next year, by a year from now we will be seeing that in a big way, we won't be crying about just the sequester, we will be crying about what a significant negative impact that has had on your practice.

I want you to know we are prepared—we are trying to prepare for that, we are trying to make sure we are on top of that, but it is, indeed, a difficult question. But both sides need to be involved in this discussion.

I will yield back, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

Now recognizes the gentlelady Mrs. Capps, 5 minutes for follow-up.

Mrs. CAPPS. Mr. Cosgrove, your testimony provides us a broad overview of key part B drug spending facts. If I could briefly go over some of these facts with you?

First, about how much does Medicare part B pay for drugs each year?

Mr. COSGROVE. In 2010, it was almost $20 billion, $19.5 billion.

Mrs. CAPPS. Your testimony indicates that many of these part B drugs can be particularly expensive, costing tens of thousands of dollars or more. Why is this? I know patients want to know.

Mr. COSGROVE. Well, the price—I mean, Medicare is—working through physicians is accepting market prices, which are set by manufacturers.

Mrs. CAPPS. OK. Am I correct, Mr. Cosgrove, that for many of these drugs, Medicare part B is the largest single—single largest purchaser?

Mr. COSGROVE. Yes, that is absolutely true. For 35 of the 55 drugs that we looked at, Medicare was the majority purchaser, and there were a handful of drugs for which Medicare paid more than 90 percent of the share of the total market.

Mrs. CAPPS. And just to be clear here, we need to do all we can to keep the drug pipeline flowing. These new drugs are expensive, but they do save lives. And a thriving drug industry is important for Medicare and for patients, that goes without saying, but we also need to make sure that we are spending taxpayer dollars wisely, and we are spending so much on these part B drugs that I wonder if we are able to get the best deals possible.

Do you have any thoughts here, Mr. Cosgrove? Does Medicare part B program have all the necessary tools that it needs to help reduce drug costs for taxpayers and beneficiaries?

Mr. COSGROVE. Well, I think this is a lot of money when you are talking about $20 billion.

Mrs. CAPPS. Yes.

Mr. COSGROVE. And you are also talking about drugs that can be incredibly valuable on a wide variety of things, but that can be true for lots of parts of Medicare as well. And so I think that it is the responsibility of this committee and the rest of Congress to make sure that we are always getting the best deal, to make sure that providers are paid appropriately, and that beneficiaries have access to quality care, but that Medicare is not overpaying, and that would include making sure that we pay the right price and we set the right incentives for providers to do the right thing.

Mrs. CAPPS. Mr. Binder, do you have any thoughts on this?

Mr. BINDER. Well, I agree with what Mr. Cosgrove said. The drug-pricing methodologies are complicated, and in this case you are talking about overlaying a methodology on the market mechanism as well, the manufacturers price their drugs. So you are overlaying this methodology, this payment methodology, and that becomes complicated, and you add sequester on that, it becomes even more complicated.

But there have been a number of proposals, including in the President's budget and other places, for other fixes or adjustments to either the ASP plus 6 or other approaches that could potentially help alleviate some of these issues.

Mrs. CAPPS. Thank you.

I will just bring up again the second bill, H.R. 460, the Patients' Access to Treatments Act, that I have introduced with Mr. McKinley, because it does address restraining the excessive cost sharing for specialty drugs, bringing medically necessary treatment within reach for average Americans.

While this bill only addresses the private insurance, the problem isn't unique to the commercial market. Under part B patients who face a serious diagnosis or are living with a chronic health condition are subject to significant financial burdens. Unlike the protection that many of us have with private plans, seniors who can't afford supplemental coverage and have traditional Medicare part B plans have no out-of-pocket max. That means that they continue to

pay 20 percent out of pocket for every part B service, as you know. And for patients undergoing cancer treatments or requiring ongoing doctor-administered therapies, this cost can be prohibitive, especially when you realize that half of Medicare beneficiaries have incomes below $22,000 a year.

I mean, this is a set-up for failure. Health expenses constitute almost 15 percent of household budgets for individuals who are on Medicare, nearly three times the spending of non-Medicare households. I sound like I am on a soapbox, but maybe I will ask just in conclusion, 15 seconds, Ms. Davenport-Ennis to comment.

Ms. DAVENPORT-ENNIS. Certainly the Medicare beneficiary is not in a position to pay what is required in a 20 percent copayment into perpetuity in part B Medicare.

Mrs. CAPPS. Thank you.

Yield back.

Mr. PITTS. The chair thanks the gentlelady.

We are going to go to one more round on each side, one more follow-up on each side. So the chair recognizes Mrs. Ellmers from North Carolina, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman, and I apologize for coming in so late to this so important subcommittee hearing.

I do have a couple of questions, and I would like to ask Ms. Davenport-Ennis and Dr. Barry Brooks this question. Earlier I made an opening statement regarding the Medicare part D and the effect that sequester has on those cancer drugs or chemotherapy agents. Given my discussion with the community oncologists and the numerous media reports that are going on now over the past few months, you know, we are now entering into about the third month of this affecting chemotherapy drugs. Basically patients are being forced out of their local community clinics to the more expensive hospital setting. What impact do you believe my bill would have in stopping this harmful trend?

Ms. DAVENPORT-ENNIS. I believe that it will at least stop some of the hemorrhaging of what is happening now. I think ultimately the committee is going to need to look at a comprehensive approach to what can be done to stabilize reimbursement to the practices, but your bill is certainly going to take a significant step forward in resolving this.

Mrs. ELLMERS. Thank you.

Dr. Brooks?

Dr. BROOKS. I agree that your bill would slow our hemorrhage and allow us to return to some semblance of stability. One-third of the market of community oncology has migrated to the hospital in the last 7 years, and that has been accelerated in the last 3 months under the weight of the sequester burden, and were we to relieve that, hopefully access could be maintained, and community oncology could continue to be practiced the way it has for the last two decades.

Mrs. ELLMERS. Thank you.

I would also like to pose another question to the entire panel. Basically, as you know, the whole point of sequester is to reduce the spending at the Federal level; however, treating people in the hospital is actually more expensive than providing the same service in a physician's office or clinic setting. In fact, studies show that pro-

viding chemotherapy costs Medicare and the taxpayers $6,500 more per patient per year in the hospital setting and $650 out of the patient's own pocket.

Basically also, and I will just add this, just last night I saw attacks from doctor—a doctor from Tulsa, Oklahoma, that read, quote, We have sent 50 percent of our chemo to hospitals in the past week, even patients with good insurance, because drugs are unaffordable for us at this point.

Given that the application of sequester by CMS is actually costing taxpayers money instead of saving it, shouldn't Congress be doing everything in our power to reverse this and make a change where we see a need? And I will just ask a basically yes or no answer from the entire panel.

Mr. BINDER. I am sorry, could you repeat that?

Mrs. ELLMERS. Basically—I caught you off guard. Basically my point is as a result of more patients going to the hospitals and being treated in the hospital setting, it actually costs Medicare and the hard-working taxpayers of America $6,500 more per patient per year, but then also, and this is the truly, you know, shameful part, another $650 out of pocket for that patient. In your opinion, shouldn't we be doing everything we can to fix that?

Mr. BINDER. Yes.

Mrs. ELLMERS. OK. Perfect.

Dr. Brooks?

Dr. BROOKS. Absolutely.

Ms. DAVENPORT-ENNIS. Completely.

Dr. MELTON. I would agree.

Mr. COSGROVE. Medicare needs to save money.

Mrs. ELLMERS. Thank you. I appreciate that from all of you.

And, Mr. Chairman, I would like to submit for the record a statement from the American College of Rheumatology. It is actually a publication examining reforms to improve the Medicare part D drug program for seniors.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mrs. ELLMERS. Thank you, Mr. Chairman, and I yield back the remainder of my time.

Mr. PITTS. The chair thanks the gentlelady.

That concludes the questioning from the Members. The Members may have additional questions that we will submit to you in writing. We ask the witnesses to please respond promptly to the questions that we send you. I remind Members that they have 10 business days to submit questions for the record, and Members should submit those questions by the close of business on Tuesday, July 16th.

Very informative hearing. Thank you very much for your patience as we had to delay due to floor votes. Without objection, the subcommittee is adjourned.

[Whereupon, at 12:50 p.m., the subcommittee was adjourned.

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Today our work continues in the ongoing effort to enhance the quality of health care for our nation's seniors. We will examine the Medicare Part B drug program and reform proposals aimed at improving the important program.

We owe it to our seniors to evaluate the effectiveness of Medicare and suggest improvements to the program. Earlier this week, this subcommittee examined Medicare's traditional benefit design and sought input from experts on how to modernize it.

The Medicare Part B drug program is essential to our nation's seniors, especially those who are battling cancer. The invaluable role that these drugs play in the treatment of chronic illness cannot be overstated. As we look to examine the program, we must ensure that the program, and seniors' access to these essential drugs, only continues to get better.

When Congress changed the Part B drug reimbursements to track their average sales price in 2003, there were questions as to whether that average sales prices was an appropriate pricing mechanism. Since then, MedPAC has weighed in on the issue by noting that Congressional movement to the ASP system has resulted in substantial price savings for Medicare on nearly all drugs covered by these reimbursements, and was contributing to decreased Part B spending.

Recently, members of Congress and the administration have proposed changes to the Part B drug program. Some of the changes seek to improve the program; others, like the president's call to cut physician reimbursements for these drugs, may not have such positive effects.

As we examine reform proposals to improve the Medicare Part B drug program, I want to commend all of my colleagues who have offered such proposals, including Representatives Whitfield, Green, Rogers, Capps, Lance, Ellmers, and Burgess. I look forward to hearing testimony on their proposals today.

With that Mr. Chairman, I yield the balance of my time to———————————————————.

PREPARED STATEMENT OF HON. MIKE ROGERS

Thank you Mr. Chairman for holding this important hearing.

The United States is home to the most effective and successful cancer care in the world, creating an environment that has resulted in the best cancer survival rates across the globe.

According to the National Cancer Institute (NCI), overall cancer death rates have continued to decline in the United States among both men and women -as well as among all major racial and ethnic groups -for all of the most common cancers, including lung, colon and rectum, female breast, and prostate.

However in the last five years, a troubling change in the delivery of cancer care has begun to emerge - a change that has been directly affecting not just the continuing rise in the cost of Medicare, but also the ability for cancer patients to access treatment.

Since 2008, community oncology clinics have seen the steady shift from the physician office setting to the hospital outpatient department (HOPD) as a result of flawed Medicare payment policies that reimburse hospitals at higher rates than oncology clinics for the exact same service.

Due to the significant changes in Medicare payment policies and the eroding revenues to community oncology clinics, physician practices are suffering from serious financial difficulties and struggling to keep their doors open.

The most recent Practice Impact Report from the Community Oncology Alliance (COA) reports that oncology clinics have closed or consolidated at a 20 percent faster in the past year than they did a year before - a statistic that should give us all pause.

In the past year 288 clinic sites closed, 407 practices were financially struggling and 469 practices had entered into a contractual relationship or had been acquired by a hospital.

The consolidation of cancer treatment services to the hospital outpatient setting has serious implications for patient access especially in rural areas where radiation therapy is not always available through local hospitals. Patients may be forced to travel long distances to receive care, posing a considerable barrier to care for beneficiaries who require radiation treatment therapy daily for months at a time.

Moreover, this shift in setting for cancer treatment poses a threat to the solvency of Medicare as the current disparities in payment have created incentives for hos-

pitals to buy physician practices, driving up costs for the Medicare program and for cancer patients.

Reimbursement should be equal for the same service provided to a cancer patient regardless of whether the service is delivered in the hospital outpatient department or a physician office.

I look forward to working with my colleagues to ensure the future of community cancer care.

Thank you Mr. Chairman, I yield back.

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you Chairman Pitts, and thank you for holding this hearing today. Medicare reimburses for prescription drugs in two settings. Outpatient prescription drugs are covered by Medicare Part D, while prescription drugs administered in a physician's office are paid for by Medicare Part B. This is a critical benefit that allows seniors to have access to physician-administered drugs which are most commonly cancer drugs used for chemotherapy and its related side effects or drugs to treat other serious illnesses.

Congress has debated for years on whether Medicare can save more money on the drugs it pays for through the Part B program. Under the Medicare Modernization Act of 2003, to address widespread spending growth, we changed paying physicians based off of the manufacturer's Average Wholesale Price (AWP), which was often inflated, to a payment based on a manufacturer's Average Sales Price, or ASP. Today, a doctor is reimbursed ASP + 6%-an amount much more reflective of the actual price manufactures receive for their products.

The new system has been working. But according to stakeholders and industry leaders, challenges with the ASP+6% reimbursement policy still exist. In addition, some believe that there is a growing shift from receiving this care in a community physician setting to a hospital outpatient setting-a trend which, if based on fact, would have implications to the overall spending of the Medicare program.

Now, I know there are a number of members of our Committee who have taken an interest in this area, some who would like the current system to be amended further. In addition, many stakeholders, some of who are here today, have outlined additional challenges with the reimbursement structure of Part B.

For example, Oncologists are concerned about prompt pay discounts provided to wholesalers by manufacturers for paying within a specified time window. These discounts are not necessarily passed on to physicians when they purchase drugs from the wholesalers, but do have the effect of lowering the ASP reimbursement rate. Accordingly, Oncologists would like to see prompt pay discounts excluded from the ASP calculation. Of course, when it comes to seriously ill cancer patients, we want to ensure they have access to the best care and the best drug for their individual circumstances. So we should certainly tread with caution if there is credible evidence that lowering reimbursement could create market disruptions and result in Oncologist practices closing, thereby limiting Medicare access for seriously ill cancer patients.

Now, as we all know, sequestration has resulted in a two percent across the board cut to Medicare. This includes a cut to Part B drugs. While I believe it is extremely important for seniors to have access to these lifesaving drugs, I do not agree with the approach that we should lift sequestration piecemeal like based on individual member bills. That approach is simply disingenuous.

I opposed sequestration since it was first conceived. The idea that across the board, blind cuts could be used as a vehicle to reduce spending is foolhardy and dangerous. The case of Part B drugs shows just that. I recognized that sequestration would have real world effects, which is why I voted against the set of indiscriminate federal budget cuts. It is hypocritical that the same Members who voted in favor of the Budget Control Act of 2011 are now turning around and introducing legislation to reverse cuts on specific portions of the system. By pursuing a piecemeal approach to fix sequestration, we are being asked to place a higher value on some services than others. These cuts seriously hurt our economy, debilitate programs Americans rely on, and put our public safety at risk. Access to Part B drugs by our nation's seniors is just one example of the negative impact of sequestration on the daily lives of constituents in every one of our districts. We need a long term fix that truly addresses the budget in its entirety.

Thank you.

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Penny Wise, Pound Foolish? Coverage Limits on Immunosuppression after Kidney Transplantation

John S. Gill, M.D., and Marcello Tonelli, M.D.

As a treatment for end-stage renal disease (ESRD), kidney transplantation is superior to dialysis for improving patient survival rates and quality of life. Its long-term success, however, requires ongoing treatment with immunosuppressive drugs. Ironically, although many of the pivotal discoveries related to immunosuppression have been made in the United States, U.S. kidney-transplant recipients do not benefit from a coherent funding policy for these drugs, and thousands of such patients are therefore at risk for allograft failure and premature death. Ensuring lifetime access to these medications for all Americans with kidney transplants would save lives as well as reduce the total cost of treating patients with ESRD.

Under current Medicare rules, coverage for immunosuppressive drugs abruptly ceases 3 years after kidney transplantation for all Medicare patients, except those who are 65 years of age or older or have work-related disabilities. This policy differs from those of other industrialized countries, including Australia, the United Kingdom, and Canada, where lifetime, state-funded coverage of immunosuppressive drugs is provided to all kidney-transplant recipients — and where long-term survival rates are substantially higher than those in the United States (see table), notwithstanding differences in patient case mix, sociodemographic characteristics, and other factors. These observations suggest that it is time to reexamine the funding practices for immunosuppressive medications in the United States.

The lack of funding for essential immunosuppressants for many Medicare patients also contrasts sharply with Medicare's provision of funding for lifelong dialysis. Although it is a lifesaving treatment for kidney failure, dialysis produces poorer outcomes than transplantation and is far more expensive on a yearly basis than immunosuppressant regimens. Yet patients must revert to this more costly and less effective treatment when their renal allografts fail. Although the decision not to provide lifetime coverage for immunosuppressive drugs might once have been justified by the hope that transplantation would improve the health and earning power of patients with kidney

Kidney-Transplant Survival and Immunosuppressive Coverage Policies for Selected Countries (for Recipients of a First Kidney-Only Transplant from a Deceased Donor).*

Country	5-Yr Survival	10-Yr Survival	Government-Funded Immunosuppressive Coverage
	percent		
Australia	81	59	Lifetime for all recipients
Canada	80	58	Lifetime for all recipients
United Kingdom	78	56	Lifetime for all recipients
United States	69	43	Lifetime for recipients >65 yr of age or with work-related disability; 3 yr for all other recipients

* Data include patients whose kidney transplants failed because they died. These data were obtained from the ANZDATA Registry Report, 2010 (Australia and New Zealand Dialysis and Transplant Registry), the Canadian Organ Replacement Register Report, 2011 (Canadian Institute for Health Information), the National Health Services Blood and Transplant Annual Report, 2010–2011 (National Health Services), and the USRDS 2011 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States (United States Renal Data System).

failure, allowing them to obtain private insurance, this optimism is not borne out by the current reality.

Premature transplant failure is the fifth leading cause of initiation of dialysis in the United States. Unfortunately, approximately 25% of patients whose transplants fail die within 2 years after returning to dialysis. This outcome is worse than the 2-year mortality among patients with a functioning transplant from a deceased donor (6%) and still worse than that among age-matched dialysis patients who have never received a transplant (20%).

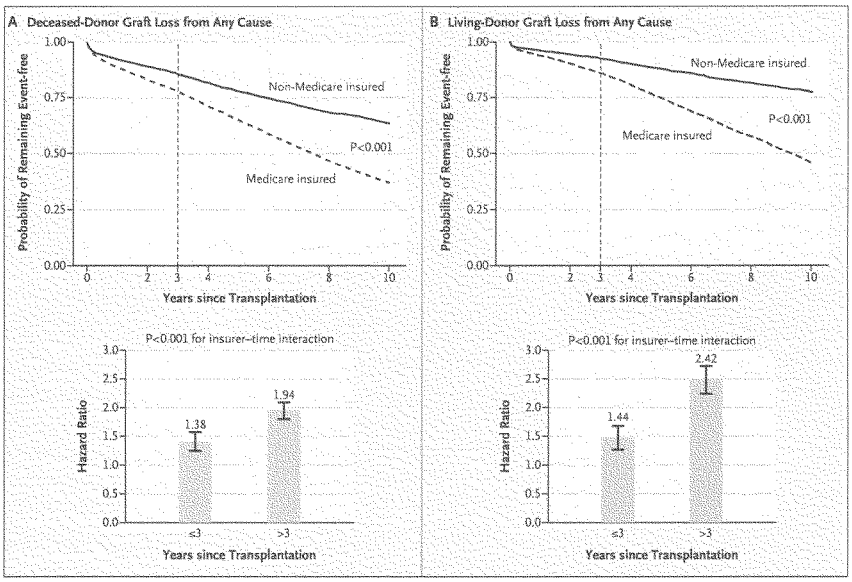
A second transplant is the best treatment option for a patient whose transplant has failed, but the opportunities for repeat transplantation are much more limited than those for initial transplantation. Candidates for repeat transplantation account for about 20% of patients on the waiting list but (because of sensitization from their failed allograft) receive only 12% of the deceased-donor kidneys transplanted annually in the United States.

Transplant failure can result directly from nonadherence to immunosuppressive regimens, which in turn may be due to inability to pay. Although clinically obvious, the link between allograft failure and nonadherence is difficult to confirm on the basis of prospective research, because transplant recipients are unlikely to admit to poor adherence, fearing that it will reduce their chances of repeat transplantation.[1] However, qualitative surveys of kidney-transplant recipients do confirm the high economic burden of paying for immunosuppressive regimens, especially among the socioeconomically disadvantaged.[2] In a 2010 survey, more than 70% of U.S kidney-transplantation programs reported that their patients had an "extremely serious" or "very serious" problem paying for immunosuppressive medications, and 68% reported deaths and graft losses attributable to cost-related nonadherence.

Medicare-insured patients have a greater risk of kidney-transplant failure than privately insured patients who have lifelong coverage for immunosuppressant regimens, and the gap increases significantly when Medicare patients' drug coverage expires after 3 years (see graphs). This finding supports the hypothesis that cost-related nonadherence to immunosuppressive regimens is an important cause of kidney-transplant loss. Mandating lifetime drug coverage could improve adherence and thus lessen the need for more costly dialysis treatment or a second transplant.

The financial benefit of lifelong immunosuppressive therapy is apparent when one examines the costs of ESRD treatment options. An initial kidney transplantation is expensive, costing Medicare an average of approximately $110,000; immunosuppressive medications cost about $15,000 to $20,000 annually (perhaps substantially less if generic alternatives are available). Although the cost of maintaining an allograft is considerable, it should be compared with the approximate annual cost of $75,000 for establishing and maintaining dialysis treatment in the case of allograft failure, as well as with the cost of repeat transplantation in suitable candidates. Since patients with kidney failure need either long-term dialysis or a functioning renal allograft to survive, failing to pay for ongoing immunosuppression ensures that Medicare's initial investment in kidney transplantation is squandered, that patients die prematurely, and that U.S. taxpayers pay for a more expensive but inferior therapy after some transplants fail unnecessarily.

The potential for cost savings through lifetime drug coverage is supported by empirical data. Between 1993 and 1995, Medicare



Renal Allograft Survival as a Function of Insurer Status in the United States.

The line graphs show the adjusted risk of loss of renal allografts from deceased donors (Panel A) and living donors (Panel B) over time as a function of insurer status. Data confirm previous reports indicating that the adjusted likelihood of graft loss is increased among patients solely insured by Medicare. The bar graphs show that this disparity is significantly greater once the 3-year period of Medicare coverage of immunosuppressive medications ends. Non-Medicare–insured patients have private lifelong coverage of immunosuppressive drugs. Data are based on 65,474 Medicare-insured patients and 17,927 non-Medicare–insured patients. Methods can be found in the Supplementary Appendix, available with the full text of this article at NEJM.org.

extended its funding of immunosuppressive medications after kidney transplantation from 1 year to 3 years. This modest extension, albeit suboptimal, reduced costs and income-related disparities in outcomes among kidney-allograft recipients. The subsequent lifetime provision made in 2000 for Medicare patients who are 65 years of age or older or have work-related disabilities has been associated with additional reductions in such disparities.[3] Unsurprisingly, economic analyses also confirm that providing lifetime funding for immunosuppressive medications would lower overall costs — saving an estimated $200 million annually — with the greatest impact seen among patients least able to pay.[4]

Perhaps a more compelling argument in favor of lifelong immunosuppressant drug coverage is that transplantable kidneys are lifesaving gifts made possible by living donors or by families of deceased persons and are of immeasurable benefit to society. Current U.S. policy devalues this gift, potentially jeopardizing the U.S. organ-donation system by discouraging volunteers. Providing lifelong immunosuppressive drug coverage could help preserve this altruistic tradition.

The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2011 (H.R. 2969), currently before Congress, is a proposed amendment to the Social Security Act that would grant lifelong coverage for immunosuppressive medications to all kidney-transplant recipients in the United States. A similar legislative effort made

in 2009 failed after Congress indicated that funds allocated to lifetime immunosuppressive coverage would reduce the resources available for funding oral medications for dialysis patients.[5] But it is not rational to treat lifetime immunosuppressive coverage as a new expense that would cut into other programs, given that this simple policy change would actually reduce net expenditures for ESRD care.

H.R. 2969 represents a key opportunity to correct an irrational, needlessly wasteful policy that has harmed many U.S. patients. Its passage would achieve three important objectives: protect Medicare's investment in each renal allograft, help bring U.S. kidney-transplant outcomes up to par with those in other developed countries, and most important, save the lives of people with kidney failure.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Division of Nephrology, University of British Columbia, Vancouver (J.S.G.); the Division of Nephrology, University of Alberta, Edmonton (M.T.); and the Interdisciplinary Chronic Disease Collaboration, Calgary, AB (J.S.G., M.T.) — all in Canada.

This article (10.1056/NEJMp1114394) was published on February 1, 2012, at NEJM.org.

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Statement of National Kidney Foundation
Support for H.R. 1428, "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2013"

Submitted to the Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives

June 28, 2013

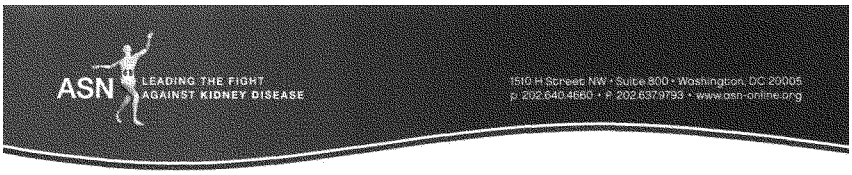
The National Kidney Foundation (NKF) is pleased that the Committee is holding a hearing today on legislation to help kidney transplant recipients obtain access to medications that are required to help maintain the viability of the transplanted kidney. NKF is America's largest and oldest health organization dedicated to the awareness, prevention and treatment of kidney disease for millions of patients and their families and for tens of millions of people at risk. H.R. 1428, introduced by Representative Burgess (R-TX) and Representative Kind (D-WI), would extend Medicare Part B coverage of immunosuppressive drugs for kidney recipients who are non-aged and non-disabled. It is identical to legislation from the 112th Congress that garnered nearly 130 cosponsors.

Individuals with end-stage renal disease (ESRD), who require dialysis or a transplant to survive, are eligible for Medicare regardless of age or other disability as a result of legislation enacted by Congress in 1972. If these ESRD beneficiaries remain on dialysis, there is no time limit on their Medicare eligibility. However, despite quality of life benefits and the cost-effectiveness associated with transplantation compared to kidney dialysis, recipients who are not aged or disabled retain Medicare eligibility only for 36 months following their transplant. After their Medicare ends, they often face the challenge of obtaining group health insurance or finding other coverage, greatly increasing the risk of organ rejection if they cannot afford their required medications. If the transplanted kidney fails, the patient returns to dialysis or receives another transplant, either of which is covered by Medicare. According to the U.S. Renal Data System 2012 Annual Report, Medicare spends about $86,300 annually on a dialysis patient, compared to $24,600 per year for a kidney transplant recipient after the year of transplant.

While the Affordable Care Act will improve the likelihood that kidney transplant recipients will gain health insurance, there are a number of individuals who are expected to remain uninsured after 2014 because they are unable to afford coverage in the Marketplaces. Furthermore, while States' benchmark plans cover the most common immunosuppressive drugs (which mean the plans in the Marketplaces must also cover all of those drugs) the plans participating in the Marketplaces have flexibility in how patient cost-sharing for different drugs is designed. Some plans may place non-preferred drugs on higher tiers with higher patient cost sharing creating barriers for patients to access the medications that work best for them.

H.R. 1428 serves as a safety net for those who could not otherwise afford access to immunosuppressive medications needed to preserve their transplanted kidney. Medicare coverage would continue only for immunosuppressive medications; all other Medicare coverage would end 36 months after the transplant. It also requires group health plans to continue to pay for immunosuppressive drugs if they presently include such a benefit in their coverage, to prevent insurers from passing the obligation to Medicare. This bill will help improve transplant outcomes and enable more kidney patients who lack adequate drug coverage to consider transplantation. H.R. 1428 is the right thing to do for kidney patients, for living donors, organ donor families, and for the American taxpayer. Congress has acted previously in this regard, when it eliminated a similar 36 month immunosuppressive coverage limit for aged and disabled beneficiaries in 2000.

We thank you for your consideration of this legislation and urge its passage in the 113th Congress.



Statement for the Record

American Society of Nephrology

Hearing before the House Energy and Commerce Subcommittee on Health

"Examining Reforms to Improve the Medicare Part B Drug Program for Seniors"

June 28, 2013

The American Society of Nephrology (ASN) applauds Chairman Pitts and Ranking Member Frank Pallone, Jr. for holding the hearing on the Medicare Part B drug program and appreciates the opportunity to submit testimony for the record on this important topic. ASN is grateful to the Subcommittee for including a focus on H.R. 1428, the Comprehensive Lifetime Immunosuppressive Drug Coverage Bill, in the hearing. The society also commends Larry B. Melton, MD, PhD, for sharing his expertise on this issue and thanks the American Society of Transplantation (AST) for its leadership with regard to H.R. 1428.

Representing more than 14,000 members dedicated to leading the fight against kidney disease, ASN is largest organization of kidney health professionals in the world. Foremost among the society's goals is continuous improvement in the quality, efficiency, and accessibility of care available to patients with kidney disease. ASN, together with AST and other national kidney and transplant organizations, strongly supports H.R. 1428, introduced by the Honorable Michael Burgess, MD, and the Honorable Ron Kind.

For most patients with kidney failure, transplantation is superior to dialysis for patient survival and quality of life. However, patients who receive a kidney transplant must take immunosuppressive drugs to keep the kidney healthy daily for their lifetimes. By extending Medicare coverage of immunosuppressive drugs beyond the current 36-month limit, this legislation would protect Medicare's investment in the transplanted kidney and the health of the recipient. Patients without private insurance coverage are often unable to pay for these costly drugs after the 36-month Medicare coverage period ends. Evidence shows that there is an increased rate of transplant failure corresponding with loss of coverage for these necessary drugs, and premature transplant failure is the fifth leading cause of initiation of dialysis in the United States.

Patients whose kidney transplants fail must return to dialysis—which Medicare covers for all patients with kidney failure regardless of age or disability—at a significantly larger cost to Medicare than the immunosuppressive drugs would have been. H.R. 1428

would guarantee that all patients who receive a transplant maintain the lifetime coverage necessary to preserve the donated kidney, keeping the recipients healthy and off dialysis.

A recent study in the New England Journal of Medicine concluded that "failing to pay for ongoing immunosuppression ensures that Medicare's initial investment in the kidney transplantation is squandered, that patients die prematurely, and that U.S. taxpayers pay for a more expensive but inferior therapy after some transplants fail unnecessarily." Moreover, with the recent introduction of generic versions of two of the most commonly used immunosuppressive drugs in the typical regimen, the average sales price of the drugs has declined more than 55 percent. The cost of immunosuppressive drugs is a mere fraction of the cost of dialysis, and the economic case for Medicare providing lifetime immunosuppressive drugs has never been stronger.

H.R. 1428 is a crucial opportunity to correct a senseless policy, protecting Medicare's investment in kidney transplants and making it possible for transplant recipients to contribute to society as healthy citizens. As the Subcommittee examines opportunities to improve the Medicare Part B drug program, ASN encourages the Subcommittee to consider H.R. 1428.

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March 25, 2013

Congressman Michael Burgess, M.D.
2336 Rayburn House Office Building
Washington, D.C. 20515

Congressman Ron Kind
1502 Longworth House Office Building
Washington, D.C. 20515

Dear Congressmen Burgess and Kind:

Thank you for your introducing H.R. 1325, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act" on March 21, 2013. We greatly appreciate your championing this very important legislation for the patients we serve.

Established in 1974, the American Society of Transplant Surgeons (ASTS) serves more than 2,000 surgeons, physicians, scientists, pharmacists, coordinators, and advanced transplant providers. ASTS is committed to fostering the practice and science of transplantation and guiding those who make the policy decisions by advocating for comprehensive and innovative solutions to the needs of ASTS members and their patients.

As you know, this important legislation will eliminate Medicare's arbitrary 36-month limit on immunosuppressive drug coverage that is imposed on end stage renal disease (ESRD) beneficiaries.

The 36 month limit is unfair and harmful to patients, living donors, donor families, and taxpayers. To pay for a kidney transplant and then stop immunosuppressive coverage after 36 months most often will result in the beneficiary rejecting the transplanted kidney. After coverage ends and many of these patients cannot afford their medications, they will often either reduce their use of the medication or stop taking them altogether. As a result, these beneficiaries will inevitably face completely unnecessary failure of the transplanted kidney and placement back on the kidney wait list. Because of this policy, other Medicare patients with ESRD will incur a longer wait for life-sustaining kidney transplants. With nearly 100,000 Americans on the kidney wait list, we must ensure that recipients have access to the drugs that prevent their immune system from rejecting the new organ.

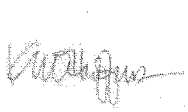
Medicare's current payment policy for ESRD beneficiaries is also fiscally poor policy as it takes a short-sighted view of Medicare costs. While Medicare spends more than $86,000 per year on each dialysis patient, the average annual Medicare expenditure for a kidney transplant recipient is far less expensive - $24,000 (U.S. Renal Data System 2012 Annual Report). Removing the arbitrary time limit on immunosuppressive drug coverage is therefore very likely to result in savings to the federal government.

We appreciate that your legislation is tightly crafted to only remove the time limitation for these beneficiaries for the immunosuppressive benefit and to apply to only those without other coverage. As your approach is a "coverage backstop," these beneficiaries will only use this option as a last resort.

Correcting Medicare's irrational immunosuppressive coverage policy will save lives, allow others on the transplant list a better chance to receive scarce organs, and save Medicare program the unnecessary costs of returning patients to dialysis or re-transplantation surgery.

With your leadership and nearly 150 Members of Congress cosponsoring this legislation last session, we are hopeful that we will finally see passage of this critical legislation. We commend you for your continuing efforts and will work with you toward swift passage of this legislation.

Sincerely,



Kim M. Olthoff, M.D.
President

David J. Reich, M.D
Chair, Legislative Committee

I

113TH CONGRESS
1ST SESSION

H. R. 460

To amend title XXVII of the Public Health Service Act to limit co-payment, coinsurance, or other cost-sharing requirements applicable to prescription drugs in a specialty drug tier to the dollar amount (or its equivalent) of such requirements applicable to prescription drugs in a non-preferred brand drug tier, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 4, 2013

Mr. MCKINLEY (for himself, Mrs. CAPPS, Mrs. CAPITO, Mr. YOUNG of Florida, Mr. MORAN, Mr. WOLF, Mr. TONKO, Mr. RUNYAN, Mr. CONYERS, Ms. BONAMICI, Mr. CICILLINE, Mr. DEFAZIO, Mr. MICHAUD, Mr. FARR, Ms. PINGREE of Maine, Mr. RANGEL, and Mr. CRENSHAW) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title XXVII of the Public Health Service Act to limit co-payment, coinsurance, or other cost-sharing requirements applicable to prescription drugs in a specialty drug tier to the dollar amount (or its equivalent) of such requirements applicable to prescription drugs in a non-preferred brand drug tier, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Patients' Access to Treatments Act of 2013".

SEC. 2. COST-SHARING REQUIREMENTS APPLICABLE TO PRESCRIPTION DRUGS IN A SPECIALTY DRUG TIER.

(a) IN GENERAL.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended by adding at the end the following:

"SEC. 2719B. COST-SHARING REQUIREMENTS APPLICABLE TO PRESCRIPTION DRUGS IN A SPECIALTY DRUG TIER.

"(a) REQUIREMENT.—A group health plan, or a health insurance issuer offering group or individual health insurance, that provides coverage for prescription drugs and uses a formulary or other tiered cost-sharing structure shall not impose cost-sharing requirements applicable to prescription drugs in a specialty drug tier that exceed the dollar amount (or its equivalent) of cost-sharing requirements applicable to prescription drugs in a non-preferred brand drug tier (or prescription drugs in a brand drug tier if there is no non-preferred brand drug tier).

"(b) SPECIAL RULE.—If a formulary used by a group health plan or a health insurance issuer offering group or individual health insurance contains more than one non-preferred brand drug tier, then the requirements of sub-

section (a) shall be applied with respect to the non-preferred brand drug tier for which beneficiary cost-sharing is lowest.

"(c) DEFINITIONS.—In this section:

"(1) The term 'cost-sharing' includes co-payment and coinsurance.

"(2) The term 'drug tier' means, with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage that uses a formulary or other cost-sharing structure, a category of drugs—

"(A) within such formulary or structure for which the total dollar amount of cost-sharing requirements for any drug does not vary by more than ten percent from the total dollar amount of cost-sharing requirements for any other drug; and

"(B) that are prescription drugs.

"(3) The term 'non-preferred brand drug tier' means, with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage that uses a formulary or other tiered cost-sharing structure, a category of drugs—

"(A) within a drug tier in such formulary or structure for which beneficiary cost-sharing

is greater than drug tiers for generic drugs or preferred brand drugs in the formulary or structure;

"(B) that are prescription drugs; and

"(C) that are not included within a specialty drug tier.

"(4) The term 'prescription drug' means—

"(A) a drug subject to section 503(b)(1) of the Federal Food, Drug, or Cosmetic Act; and

"(B) includes a drug described in subparagraph (A) that is a biological product (as defined in section 351(i) of this Act).

"(5) The term 'specialty drug tier' means, with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage that uses a formulary or other tiered cost-sharing structure, a category of drugs—

"(A) within a drug tier in such formulary or structure for which beneficiary cost-sharing is greater than drug tiers for generic drugs, preferred brand drugs, or non-preferred drugs in the plan's formulary; and

"(B) that are prescription drugs.".

(b) EFFECTIVE DATE.—Section 2719B of the Public Health Service Act, as added by subsection (a), applies

to plan years beginning on or after the date of the enactment of this Act.

○

C·H·I
CALIFORNIA HEALTHCARE INSTITUTE

Statement of the California Healthcare Institute (CHI)
Submitted to the
House Committee on Energy & Commerce
Subcommittee on Health

Hearing on "Examining Reforms to Improve the Medicare Part B Drug Program for Seniors"

June 28, 2013

CHI – California Healthcare Institute, the statewide public policy organization representing California's leading biomedical innovators – including over 275 research universities and private, nonprofit institutes, venture capital firms, and medical device, diagnostic, biotechnology and pharmaceutical companies – appreciates the opportunity to present its views and voice our opposition to any Medicare benefit redesign proposal that would seek to reduce payments for providers of drugs and biologics under Medicare Part B.

California's more than 2,300 biomedical companies and institutions, clustered throughout the state, lead the world in life sciences research and development, which has led to groundbreaking therapies and technologies to diagnose, treat and prevent conditions such as cancer, cardiovascular disease, diabetes, HIV/AIDS, chronic pain, Alzheimer's, Parkinson's Disease, and others. Just as important, the sector is an increasingly important component of our state's economic engine, employing nearly 270,000 people, paying $15.5 billion in wages and accounting for $20 billion in exports.

Timely and appropriate coverage and payment policies are critical to biotechnology innovation and, most important, patient care. That is why it is vital for Congress to protect programs that are working. Medicare Part B, which provides coverage for therapies that are physician-administered, injected or infused, is a program that is working well and that provides vital access to treatments for patients fighting debilitating and life-threatening diseases such as cancer and multiple sclerosis. As part of the *Medicare Modernization Act (MMA) of 2003*, Congress set the reimbursement rate for most Part B drugs at ASP plus six percent (ASP +6%) and since its implementation, Part B spending growth has been low, benefitting both patients and taxpayers.

ASP plus six percent reimbursement is designed to cover the costs of an efficient provider and according to a 2007 study by MedPAC, for most physicians it provides a "slim" difference between cost and reimbursement. ASP is – by definition – an averaging system and there are some providers whose costs will be higher than the average. For example, providers in small practices with low patient volumes and/or in rural areas may be less likely to have significant purchasing volumes. The additional reimbursement of six percent above ASP reduces the likelihood that these providers will face reimbursement below their acquisition costs. While ASP +6% has been working well, cuts to the six percent add-on could put small, independent or rural providers at risk, threatening access and care for extremely ill Medicare patients.

Compounding the problem for small and rural providers is a growing trend of certain health care services moving out of the community or individual clinic, and into the hospital outpatient setting. This is particularly true and troublesome with respect to oncology treatments. In addition to reports from CHI member companies, a 2013 report by the Moran Company on behalf of the US Oncology Network, Community Oncology Alliance, and ION Solutions found that chemotherapy treatments are moving into the hospital outpatient setting at a rate of 1.5 - 3.25 percent per year. Furthermore, a 2012 report by Avalere found that chemotherapy patients treated in the hospital outpatient setting cost on average 24 percent more than those receiving treatment received in a physician's office, regardless of the length of chemotherapy treatment. The result is increased costs for patients, as their out-of-pocket cost-sharing amount is determined by the reimbursed rate, which is higher in the hospital setting.

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CHI understands the pressures Congress faces as it considers ways to reduce the budget deficit. While reducing payments below ASP +6% may provide near-term costs savings on paper, any potential benefit from near-term savings will pale in comparison to the real-life impact on providers and the Medicare patients they serve. Already, cuts to Medicare Part B payments due to sequestration have forced some cancer clinics to turn away patients. Furthermore, the overwhelming majority of patients receiving treatments reimbursed under Part B are elderly, and critically ill – factors like a patient's comfort in being treated by their community physician's office, their proximity to those clinics, and the simple fact that immune-compromised people shouldn't be in the hospital where they are at increased risk for healthcare-acquired infections are also important considerations in determining the most appropriate site of care.

It is for these reasons that we are gravely concerned that the quality of care for our nation's seniors will not be well-served by continued erosion of the ASP reimbursement scheme, and urge you to resist any proposals that seek to further reduce payments for Medicare Part B drugs and biologics.

We would be pleased to provide additional information on the damaging impact of such policies in our state. Thank you again for the opportunity to present our views.

American Society of Clinical Oncology

Making a world of difference in cancer care

Statement of

The American Society of Clinical Oncology

for the record

House Energy and Commerce Committee

Subcommittee on Health

Examining Reforms to Improve the Medicare Part B Drug Program for Seniors

June 28, 2013

The American Society of Clinical Oncology (ASCO) thanks Chairman Pitts and Ranking Member Pallone for holding this important hearing on the Medicare Part B drug program and proposed Medicare reforms offered by members of the subcommittee.

ASCO is the national organization representing more than 30,000 physicians and other health care professionals who specialize in the treatment of patients with cancer. ASCO's core mission is to ensure access to high quality cancer care for all cancer patients and our comments are based on our goal to achieve that mission. We stand committed to working with you toward a more stable and rational system that ensures access to high quality cancer care for all Medicare beneficiaries.

Over 60 percent of all cancer diagnoses occur in individuals over 65 years old. Medicare beneficiaries with cancer depend on drugs administered in their physician's office to treat their diseases. Physician-administered drugs can help save the lives of people with cancer.

The Medicare Modernization Act of 2003 (MMA) set payment amounts for drugs administered in community-based physician offices at 106 percent of the manufacturer's average sales price (ASP). ASP is adjusted quarterly based on information collected from the manufacturers, and current pricing is based on data that is three to six months old. ASP includes sales to all buyers,

including very large buyers, and often does not reflect the prices available to typical community-based physician practices in oncology.

The calculation of ASP includes "prompt pay discounts" offered by manufacturers to wholesalers and distributors. Typically, prompt pay discounts are not passed along to community-based physician oncology practices. The ASP plus 6 percent formula, consequently, in many cases fails to cover actual costs incurred for procuring, storing, preparing and handling highly toxic agents. When ASP values are less than the prices available to many community-based oncology practices, it creates so-called "underwater" drugs. Increasingly, community-based practices are unable to cost-shift or otherwise absorb the financial losses that result from administering drugs that are underwater.

ASCO urges the subcommittee to pass H.R. 800, which would address this issue by excluding prompt pay discounts from manufacturers to wholesalers from the ASP calculation for drugs and biologicals under Medicare.

The application of sequestration cuts to payments for Part B drugs and to the 6 percent service payment is exacerbating the problem of "underwater drugs". Because the cost of the drug is fixed, the entire sequester cut comes out of the 6 percent, which translates to a reduction of 28 percent--not 2 percent. Sequestration has greatly impacted the ability of our members to treat Medicare beneficiaries with cancer.

A recent ASCO survey showed, in part, that while practices are working hard to continue providing care for Medicare patients, many are being forced to send patients to hospitals for chemotherapy and a smaller number are no longer able to see Medicare patients at all. All of these disruptions in care are the result of the automatic two percent cut due to sequestration. Over time, these changes may radically compromise the cancer care delivery system in the United States.

More than 500 ASCO members responded to the online survey, which was conducted April 23 – May 1, 2013 as Medicare began processing reimbursement claims under the funding cuts imposed by the Sequester. The survey results reflect a wide demographic mix of oncology practices with 44 percent in suburban settings, 41 percent in urban settings, and 16 percent in rural settings. Responding oncology practice ranged in size from 1 to 48 full-time medical oncologists.

Below are additional results from ASCO's survey on the impact of sequestration on oncology practices:

- 80 percent of survey respondents said that the sequestration cuts have affected their practices.
- Nearly 50 percent reported not being able to continue caring for Medicare patients unless they have supplemental insurance.

- 50 percent of respondents reported sending their Medicare patients elsewhere for chemotherapy, primarily to more expensive hospital outpatient infusion centers.
- Of those respondents sending Medicare patients elsewhere, the majority of practices reported between 10 percent and 50 percent of their patients were affected by this dislocation. However, some have had to redirect all of their patients.
- 25 percent reported no longer participating in clinical research.
- 14 percent reported having to stop taking Medicare patients altogether at the time of this survey.
- 74 percent of survey respondents reported having difficulty paying for chemotherapy drugs.
- 22 percent reported they have or will need to close satellite clinical or outreach clinics, assuming the sequester cuts remain in place.
- 27 percent of responding practices reported that they will no longer take Medicare Advantage patients.

The diversion of patients to hospitals or other facilities for chemotherapy could have a major detrimental impact on the care that cancer patients receive. ASCO is concerned that, in many areas of the country, this change will require significant travel and additional burdens for patients who are already struggling with the activities of daily living and the side effects of their cancer and its treatment.

ASCO urges the subcommittee to pass H.R. 1416 to help alleviate these problems by exempting physician-administered drugs from the Medicare sequestration.

We urge the subcommittee to provide payment stability for oncology drugs by passing H.R. 800 and H.R. 1416 and protecting against any additional reductions to the ASP methodology. ASCO looks forward to continuing to work with you to ensure that beneficiaries with cancer have access to high quality, patient-centered care.

AMERICAN COLLEGE OF RHEUMATOLOGY
EDUCATION • TREATMENT • RESEARCH

Statement for the Record

American College of Rheumatology

Hearing before the House Energy & Commerce Subcommittee on Health

"Examining Reforms to Improve the Medicare Part B Drug Program for Seniors"

June 28, 2013

The American College of Rheumatology applauds Chairman Pitts and Ranking Member Pallone for holding this hearing. We appreciate the committee's attention to the significant threats that imperil the ability of the Medicare Part B drug program to serve seniors. Representing more than 9,000 rheumatologists and rheumatology health professionals, the ACR is very concerned that sequestration cuts to physician-administered drugs, and other problems with the Part B drug reimbursement formula, are jeopardizing patients' ability to access critical drugs.

Many patients depend on their rheumatologists to administer infusion drugs that help prevent permanent disability. Even before the two percent sequestration cuts, many rheumatologists have been forced to stop providing these treatments because reimbursement for Part B drugs — calculated as the Average Sales Price plus six percent — often do not cover the actual costs of drug acquisition, storage, preparation, and handling. Most physicians pay more than ASP for physician-administered drugs covered under Part B. In addition, the inclusion of prompt-pay discounts and insurance company rebates in the payment formula often reduce reimbursement to one to two percent above cost, and sometimes less.

Sequestration has dramatically reduced Part B drug reimbursement to ASP plus 4.3 percent, a 28 percent cut, exacerbating an already precarious situation for vulnerable patients. Many rheumatologists have been forced to stop providing critical treatments, or choose between no longer providing certain medicines and limiting the number of Medicare patients they see.

This situation is forcing many patients to seek care in settings like hospitals, which are costlier and more difficult to access. In these settings, vulnerable patients experience significant burdens including higher copayments and longer travel times, and do not have their physician's supervision when complex treatments are administered. This circumstance is disturbing because rheumatology patients must adhere to treatment regimens or face debilitating pain in the short term and joint damage, disability, expensive surgeries, and higher health care costs and even death in the not too distant future.

The American College of Rheumatology strongly supports H.R. 1416 and H.R. 800. H.R. 1416 would terminate application of sequestration to payment for certain physician-administered drugs

under part B of the Medicare program. This legislation is essential to restoring patient access to treatments that can help prevent permanent disability and save lives. H.R. 800 would help to mitigate the effects of sequestration by excluding customary prompt pay discounts from the average sales price for drugs and biologics under Medicare Part B. Wholesale distributors benefit from these discounts – not physicians or patients. Prompt-pay discounts significantly reduce reimbursement for infusion drugs and they should be excluded from the payment formula.

The American College of Rheumatology requests that Congress take immediate action to protect access to critical treatments, by exempting physician-administered drugs from the sequestration cuts and eliminating prompt-pay discounts from the ASP formula.

Contact Information

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Contact E-mail Address: acooper@rheumatology.org

The US Oncology Network

August 5, 2013

Congressman Joseph R. Pitts
Chairman
House Energy and Commerce Committee Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Congressman Pitts,

Thank you for allowing me to testify before the Subcommittee on Health on Friday, June 28, 2013, at the hearing entitled, "Examining Reforms to Improve the Medicare Part B Drug Program for Seniors."

It was an honor and a privilege to address the committee on the current issues facing oncologists and Medicare Part B drugs. As requested I have attached to this letter responses to the additional questions submitted on behalf of the committee.

Thank you again for the opportunity, and should you need anything in the future feel free to contact me.

Sincerely,

Barry Brooks

Dr. Barry Brooks
Chairman
Pharmacy and Therapeutics Committee
The US Oncology Network

The Honorable Mike Rogers

1. **According to the recent analysis by the Moran Group, there has been a shift in the site of service for chemotherapy services in Medicare from the Physician Office Setting (POS) to the Hospital Outpatient Department (HOPD) over the 2005 to 2011 period.**

   According to the Community Oncology Practice Impact Report released this week, in the past year 288 clinics sites closed, 407 practices were financially struggling and 469 practices had entered into a contractual relationship of had been acquired by a hospital.

   What impact do you believe the shift in the delivery of cancer care from the community oncology clinic to the hospital outpatient has on (a) patient access to cancer treatment and (b) the cost of cancer treatment to patients?

   What change in Medicare payment policies do you believe would stem the tide of oncology clinic closures?

Answer:

Congressman Rogers, the 20% shift in site of outpatient cancer care over six years has had serious effects on cancer patients and on costs. When a community oncology clinic closes or physicians move into a hospital outpatient setting the patient is displaced from their current community clinic and forced to find a nearby hospital outpatient department for care. That patient will have to drive further, take off more time from work, spend more time away from their family, pay more in gas, wait in longer lines at the hospital, run the risk of acquiring more infections at the hospital, pay more in co-pays ($650 more a year per patient according to the 2011 Milliman Study I referenced in my testimony) , and may not get the same personal attention they were receiving in the community clinic. Over time, it will be harder and more expensive for patients to continue their cancer treatment. Additionally, if the site of service shift trend continues and intensifies, hospitals will not have the capacity to handle the influx of cancer patients and access to treatment for Americans fighting cancer will be imperiled.

To stem the tide, Congress should level the playing field between community oncology and the hospital outpatient department. The first step to a level playing field is equalizing Medicare payments for the same services regardless of setting. Congress should act on MedPAC's recent call for payment parity across outpatient settings. If a patient is receiving quality care in the community clinic, that practice should be receiving the same reimbursement as the hospital outpatient department. Today, Medicare reimbursement for oncology services is significantly higher in the hospital outpatient department, which tilts the competitive landscape unfavorably for both Medicare and seniors fighting cancer. The US Oncology Network applauds you and Congresswoman Matsui for your leadership in introducing HR 2869, the Medicare Patient Access to Cancer Treatment Act of 2013 which would address this issue; we look forward to working with you to enact this common sense approach. Additionally, Congress should pass (1) H.R. 800 to make reimbursement for Medicare Part B drugs more accurate by removing the prompt pay discount reduction from Average Sales Price (ASP); and (2) H.R. 1416, to eliminate the 2% sequestration cut on costs of the drugs physicians purchase on behalf of CMS.

These three legislative opportunities would go a long way toward the creation of a level playing field for community oncology, and ensure that in the future community cancer care is there for cancer patients when they need it.

The Honorable Cathy McMorris Rodgers

1. **In your testimony, you indicated that spending for cancer drugs is rapidly increasing in the hospital outpatient setting compared to the community setting, and you suggest that 340B program is contributing to this shift in care from the community setting.**

   Are many community –based oncologists choosing to affiliate with hospitals so they can continue to serve their patients in difficult circumstances?

   What market forces, irrespective of 340B, are causing oncologists and other physicians to move from individual or small group practices into hospital settings?

   Is there any data to suggest that 340B hospitals are buying oncology practices more rapidly than non-340B hospitals?

Answer:

Congresswoman McMorris Rodgers, there has been a 20% shift in site of outpatient cancer care over six years according to a recent analysis of Medicare data. This shift has had serious effects on patients and on costs. When a community oncology clinic closes or physicians move into a hospital outpatient setting the patient is displaced from their current community clinic and forced to find a nearby hospital outpatient department for care. That patient will have to drive further, take off more time from work, spend more time away from their family, pay more in gas, wait in longer lines at the hospital, run the risk of acquiring more infections at the hospital, pay more in co-pays ($650 more a year per patient according to the 2011 Milliman Study I referenced in my testimony) , and may not get the same personal attention they were receiving in the community clinic. Over time, it will be harder and more expensive for patients to continue their cancer treatment. Additionally, if the site of service shift trend continues and intensifies, hospitals will not have the capacity to handle the influx of cancer patients and access to treatment for Americans fighting cancer will be imperiled.

Right now oncologists all over the country are making difficult decisions regarding their practices and their patients. Depending on each of their situations some will merge/affiliate with a hospital, some will retire, some will eliminate staff, and some will stop seeing new patients or certain types of patients. Our mission as physicians is to take care of our patients, and we take pride in that mission, but when a practice is not sustainable due to the government rules, regulations and reimbursement issues, tough decisions must be made that impact the practice and the patients we serve. The bottom line is that the private practice of community oncology is no longer economically viable unless we receive prompt legislative relief.

While 340B pricing gives hospitals a substantial advantage in drug costs, it is only one of the issues driving physicians into the hospital setting. There are many factors driving this shift including: (1) Medicare doesn't cover the costs of community oncology, and (2) Medicare payments and rules are tilted to advantage the hospital. Low Medicare reimbursements, issues like the prompt pay discount, sequestration cuts to the underlying drug costs, being reimbursed for drugs on the basis of prices two quarters in arrears, and uncollectible beneficiary insurance leave us underwater on most of our Medicare patients. Currently, 50% of the patients I serve are Medicare eligible, which means I am losing money on 50% of my patients.

At the same time hospital outpatient departments receive anywhere from 50% to 300% more in reimbursement from Medicare and private payers for the same outpatient services, hospitals get reimbursed by Medicare for uncollectible coinsurance, and a third of hospitals with 340B pricing are able to buy cancer drugs at a 30-50% discount. For example, a dose of Rituxan can cost Texas Oncology, which is my practice, $10,000. On the other hand, 340B hospitals can buy this drug for $5000 and get reimbursed more than $10,000 by CMS.

Our observation is that over the past several years approximately 70% of the hospitals that have acquired community oncology practices are 340B hospitals, including all of the oncology practice acquisitions in Washington State over the past few years. This trend and the 340B hospital drug margin contributes to the decrease in cancer patient access to care and the increase in the overall cost of cancer care for Medicare, taxpayers, payers and patients alike.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
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Majority (202) 225–2927
Minority (202) 225–3641

July 23, 2013

Ms. Nancy Davenport-Ennis
President and CEO
National Patient Advocate Foundation
725 15th Street, N.W., 10th Floor
Washington, D.C. 20005

Dear Ms. Davenport-Ennis:

Thank you for appearing before the Subcommittee on Health on Friday, June 28, 2013, to testify at the hearing entitled "Examining Reforms to Improve the Medicare Part B Drug Program for Seniors."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, August 6, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to **Sydne.Harwick@mail.house.gov**.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

National Patient Advocate Foundation

The Patient's Voice | *since* 1996

July 31, 2013

The Honorable Joseph Pitts
Chairman
Committee on Energy and Commerce
Health Subcommittee
House of Representatives
Congress of the United States
2125 Rayburn House Office Building
Washington, DC 20515-6115

cc: Sydne Harwick
Legislative Clerk

Re: **Response to Additional Questions for the Record Relating to the Hearing Entitled "Examining Reforms to Improve the Medicare Part B Drug Program for Seniors"**

Additional Questions for the Record from the Honorable Cathy McMorris Rodgers

Question 1: In 1992, Congress created the 340B discount program to increase affordability and accessibility of pharmaceuticals for the nation's poor and unserved populations. It is my understanding that this is an important part of our medical safety net.

In your exchange with Congressman Cassidy during the hearing, you cite the 340B programs as having grown from 600 to 900 hospitals originally to about 6,000 hospitals today. Are you aware that there are only 2,000 hospitals in the program and 5,700 total in the United States?

Thank you for the opportunity to clarify the quoted statistics. According to Health Resources and Services Administration (HRSA) data cited in the September 2011 U.S. Government Accountability Office (GAO) Report "Manufacturer Discounts in the 340B program Offer Benefits, but Federal Oversight Needs Improvement," there were 1,233 hospitals participating in the 340B program in 2011.[1] Additionally, in 2011 there were 4,426 clinics and other sites affiliated with those hospitals, but physically separate from the hospitals themselves, that independently participated in the 340B program.[2] Together, they represent a total of 5,659 hospitals and their affiliated sites that participated in the 340B program in 2011, which is how I arrived at the 6,000 figure I stated during my testimony. Moreover, as of July 1, 2013, there were 22,641 covered entity sites (including all affiliated sites), up from 16,572 total covered entity sites in 2011, a 37% increase.[3]

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[1] GAO, Drug Pricing: "Manufacturer Discounts in the 340B program Offer Benefits, but Federal Oversight Needs Improvement," (Washington, D.C.: Sep. 2011) at 28, *available at* http://www.gao.gov/products/GAO-11-836.
[2] Id.
[3] Modern Healthcare, "Who benefits from drug discounts?" pg. 8-9 (Jul. 15, 2013).

725 15th St, NW, 10th Floor | Washington, DC 20005 | Phone (202) 347-8009 | Fax (202) 347-5579 | www.npaf.org

Congresswoman McMorris Rodgers is also correct: according to the American Hospital Association (AHA) there are 5,724 U.S. hospitals registered with the AHA.[4] Per a July 29, 2013 review of the HRSA 340B Covered Entity database, more than a third of those hospitals—2,015 hospitals to be precise—have currently enrolled one or more sites as a 340B Covered Entity.[5] Per the GAO in its September 2011 report entitled "Manufacturer Discounts in the 340B program Offer Benefits, but Federal Oversight Needs Improvement" referenced above, hospital participation in the 340B program grew nearly three-fold from 2005 to 2011.[6] I surmise that the number of hospitals participating in the 340B program has only continued to grow given that the Affordable Care Act expanded the program to four new eligible entities—certain freestanding cancer hospitals, rural referral centers, sole community hospitals and critical access hospitals.[7]

National Patient Advocate Foundation's (NPAF's) companion organization, Patient Advocate Foundation (PAF) is a national 501 (c)(3) non-profit organization which provides professional case management services to Americans with chronic, life threatening and debilitating illnesses. Through these coordination efforts, PAF case managers have assisted patients receiving care from hundreds of 340B Covered Entities, including hospitals, throughout the United States. I have attached a list of such 340B Covered Entities, including hospitals for your review and consideration. The interactions of PAF case managers with providers at such 340B Covered Entities, including hospitals, has influenced both my testimony and follow-up responses set forth herein.

Question 2(a): You indicated that you have data to show the 340B hospitals are using these drug discount savings to purchase community oncology practices. Can you provide me with that evidence?

As noted above, NPAF's companion organization, PAF, is a national 501 (c)(3) non-profit organization which provides professional case management services to Americans with chronic, life threatening and debilitating illnesses. PAF case managers serve as active liaisons between the patient and their insurer, employer and/or creditors to resolve insurance, job retention and/or debt crisis matters as they relate to their diagnosis. The PAF case managers collaborate with physicians and healthcare attorneys in achieving resolutions to specific cases when needed. As such PAF representatives regularly coordinate with oncologists in all fifty states caring for patients who have sought case management and cost-sharing assistance from PAF. Through these coordination activities and, as I highlighted in my original statement to the Committee on June 28, 2013, PAF has heard from patients identifying numerous oncologists throughout the United States who have either shifted Medicare patients (or all patients) to hospital outpatient departments for chemotherapy and/radiation services, or who have had their practices acquired or consolidated with hospitals due to decreases in reimbursement, most notably Medicare reimbursement, for oncology services provided in physicians' offices, including chemotherapy and radiation therapy services.[8] I have excerpted the examples of such site-of-service shifts from my June 28, 2013 testimony and attached them to this document for your consideration. In addition, I have also attached a communication from Zangmeister Cancer Center to its patients explaining its decision to shift Medicare patients to hospital outpatient departments for medication administration, including chemotherapy, for your review.

Industry associations and oncologists have indicated to various media outlets that hospital acquisition of oncology offices or the consolidation of hospitals and oncology practices have occurred, at least in part, due to the prevalence of hospital participation in the 340B program. In February 2012, the New York Times reported in an article entitled

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[4] See AHA Fast Facts on U.S. Hospitals, *available at* http://www.aha.org/research/rc/stat-studies/fast-facts.shtml last visited Jul. 29, *2013*.

[5] National Patient Advocate Foundation (NPAF) staff reviewed the HRSA 340B Covered Entity database (http://opanet.hrsa.gov/opa/CESearch.aspx) and accumulated the number of participating hospitals by consolidating all sites affiliated with each unique 340B identification number.

[6] GAO, Drug Pricing: "Manufacturer Discounts in the 340B program Offer Benefits, but Federal Oversight Needs Improvement," (Washington, D.C.: Sep. 2011) at 27, *available at* http://www.gao.gov/products/GAO-11-836.

[7] Section 7001 of the Affordable Care Act.

[8] *See* Statement of Nancy Davenport-Ennis, Founder and CEO, National Patient Advocate Foundation on "Examining Reforms to Improve the Medicare Part B Program for Seniors" before the United States house of Representatives Committee on Energy & Commerce Health Subcommittee on June 28, 2013.

"Dispute Develops over Discount Drug Plan," that "[s]ome oncologists say the 340B program is one reason that more than 400 practices have become part of hospitals in recent years."[9] Recently, MedPage Today quoted Ted Okon, Executive Director of the Community Oncology Alliance, in an article entitled "Oncology Clinics Caught in Financial Vase" published on July 27, 2013. In that article Mr. Okon states that in recent years "[w]e've seen almost an explosion in the number of nonprofit hospitals that have applied for and have been granted 340B status. As a result, with those deep discounts [on medicines under the 340B program], a lot of those hospitals have looked at increasing their inflow of drug revenue. The way to do that is to acquire an oncology practice, which has the largest flow of revenue attributed to chemotherapy."[10] In addition, just yesterday on July 30, 2013, The Wall Street Journal published an article by Dr. Scott Gottlieb entitled "How ObamaCare Hurts Patients" in which Dr. Gottlieb concludes that the 340B program is increasing the cost of cancer care and eroding its quality due to site of care shifts from physicians' offices to hospital outpatient departments. Dr. Gottlieb further states, as did Mr. Okon, Executive Director of the Community Oncology Alliance, in the MedPage Today article cited above, that "eligible [340B program] hospitals are buying private oncology practices so they can book more of the expensive cancer drug purchases at the discount rates. More than 400 oncology practices have been acquired by hospitals since ObamaCare passed. Acquiring a single oncologist and moving the doctor's drug prescriptions under a hospital's 340B program can generate an additional profit of more than $1 million for a hospital." I have attached the articles excerpted above and some additional articles from other news publications echoing the sentiment that many oncologists and industry associations have concluded that hospital acquisition of oncology offices or the consolidation of hospitals and oncology practices have occurred, at least in part, due to the prevalence of hospital participation in the 340B program.

In the absence of federal law or regulations dictating how 340B Covered Entities, including qualifying hospitals, may use revenues generated from the 340B program and oversight to monitor compliance with such restrictions, we can only rely on anecdotal evidence provided by physicians and other stakeholders as to how hospitals are funding their oncology practice acquisitions and why they are acquiring numerous oncology practices.

Question 2(b): Are 340B hospitals purchasing oncology practices at any greater rates than non-340B hospitals?

The acquisition of community oncology practices by 340B hospitals far exceeds the trend of consolidation of community practices into hospital systems generally. In fact, 70% of community oncology practices that were acquired over the 14 months ending in June 2013 were acquired by 340B hospitals, according to data from the Community Oncology Alliance. In addition, one group purchasing organization dedicated to specialty drug contracting and distribution to independent oncology practices and hospitals has stated that in 2012, of the independent oncology practices that were acquired by hospitals that were members of its organization, 75% of the practices were acquired by hospitals that participate in the 340B program. In 2013, of the independent oncology practices that were acquired by hospitals that were members of its organization, 61% of the practices were acquired by hospitals that participate in the 340B program.

Question 2(c): Is it plausible that 340B hospitals purchase these practices because the oncologists are seeking stable, reliable income in a difficult market for all independent physicians and they hope to ensure that their patients can still receive care despite their own economic uncertainty?

Yes, it is plausible. The Community Oncology Alliance (COA) has been tracking changes in the oncology treatment landscape for more than four years.[11] Its database quantifies the aggregate effects of all the factors contributing to the shift in cancer care services from community-based offices and treatment centers to hospital outpatient departments. COA's most recent Community Oncology Practice Impact report, released in June 2013, which we have

[9] New York Times, "Dispute Develops Over Discount Drug Plan." (Feb. 12, 2012).
[10] MedPage Today, "Oncology Clinics Caught in Financial Vase." (Jul. 27, 2013).
[11] Community Oncology Alliance, Community Oncology Practice Impact Report, "The Changing Landscape of Cancer Care" (June 25, 2013), *available at* http://www.communityoncology.org/site/blog/detail/2013/06/25/access-the-2013-community-oncology-practice-impact-report-showing-continued-cancer-care-consolidation.html.

attached hereto for your consideration, shows that 43 practices are referring all their patients elsewhere for treatment, 288 oncology office locations have closed, 131 practices have merged or been acquired by a corporate entity other than a hospital, and 469 oncology groups have entered into contractual relationships with a hospital, such as a professional services agreement, or been acquired outright by a hospital. Another 407 oncology practices report they are struggling financially. The latest COA report reflects substantial changes in the practice landscape from April of 2012. Specifically, it shows a year-over-year increase in clinic closings of 20% and an increase of 20% in practices with hospital arrangements. COA states affirmatively that "[t]he reasons for this consolidation are due to insufficient Medicare reimbursement to community oncology clinics and higher reimbursement and margins to hospital outpatient facilities, especially those eligible for 340B discounts."

Thus, oncologists are often forced to consolidate or enter into alternative arrangements with hospitals because their independent practices cannot financially compete with hospitals to provide chemotherapy, radiation therapy and other cancer treatments to patients because hospitals receive more favorable reimbursement from Medicare for many of the same treatments and procedures. (For example, 2013 payment rebates for common chemotherapy codes 96409 and 96413 in the hospital outpatient department are $146 and $231 compared with 2013 rates of ($109 and $132 in the physician office.) Those hospitals that participate in the 340B program also post significantly more favorable margins for separately reimbursable physician-administered drugs, such as chemotherapy, because they are able to acquire the drugs at substantial discounts—ranging generally from 20% to more than 50%—yet the Medicare reimbursement for the drugs---before sequestration, Average Sales Price (ASP) + 6%—is the same as that available to independent oncology practices that must purchase drugs at much higher commercial prices from wholesalers or distributors. Based on currently available data, media reports and the continued trend in declining Medicare reimbursement for chemotherapy and other services in physicians' offices,[12] one could surmise this trend will only continue.

Question 2(d): Could this trend be part of a general broader trend toward integration of health care systems, and not directly and solely attributable, as you suggest, to 340B hospitals?

In my testimony I did not address any potentially broader, general trend toward health system integration in the United States, nor did I solely attribute any potential trend related to hospital acquisition of oncology practices or arrangements between hospitals and independent oncology practices directly to 340B hospitals. Rather, I merely highlighted that "the 340B hospital structure now allows [hospitals] to offer very attractive packages to oncologists, for them to leave their practices and associate, or to bring their entire practices to the hospital setting."

Furthermore, 2012 data collected and analyzed by Jackson Healthcare suggests that independent oncology practices are being acquired by hospitals at a disproportionately high rate when compared to primary care practice acquisitions. Per Jackson Healthcare in its publication Trend Watch: "Physician Practice Acquisitions- Tracking Which Physician Practices Hospitals are Acquiring," attached hereto for your reference, Jackson Healthcare notes that in 2012, 44% of hospitals acquired physician practices.[13] Of those physician practices acquired, between 6% and 8% were oncology practices. However, per an American Society of Clinical Oncology (ASCO) 2006 workforce study, there are only 3.3-4 oncologists per 100,000 people in the United States, while there are 240 total physicians per 100,000 people in the

[12] *See* the Center for Medicare & Medicaid Services' proposed "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014 at 78 Fed. Reg. 43, 282 (Jul. 19, 2013) setting forth additional proposed cuts in Medicare reimbursement for oncology-related services in physicians' offices.

[13] Jackson Healthcare," Trend Watch: "Physician Practice Acquisitions- Tracking Which Physician Practices Hospitals are Acquiring." (2012).

United States.[14] As such, a 6%-8% acquisition rate seems disproportionately high given that oncologists represent less than 2% of physicians in the United States.

We at NPAF appreciate the Subcommittee's interest in improving the Medicare Part B program for beneficiaries. We specifically applaud the Subcommittee for exploring the impact of the 340B program on cancer care available to Medicare beneficiaries. Thank you for the opportunity to provide testimony during the June 28, 2013 hearing as well these additional, clarifying comments for the hearing record.

Respectfully submitted,

Nancy Davenport-Ennis
Founder and Chairman of the Board

Attachments

[14] *See* The Advisory Board Company, Oncology Rounds, "Estimating the Demand for Oncology Physicians," (Jun. 13, 2011), *available at* http://www.advisory.com/Research/Oncology-Roundtable/Oncology-Rounds/2011/06/Estimating-the-Demand-for-Oncology-Physicians (quoting the 2006 ASCO workforce study as to the number of oncologists in the United States); *see* The World Bank data for "physicians for 1,000 people" in the United States, *available at* http://search.worldbank.org/data?qterm=physicians+in+the+United+States (last visited Jul. 31, 2013) for the total number of physicians in the United States.

American Hospital Association

AHA Resource Center
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Fast Facts on US Hospitals

The American Hospital Association conducts an annual survey of hospitals in the United States. The data below, from the 2011 annual survey, are a sample of what you will find in AHA Hospital Statistics, 2013 edition. The definitive source for aggregate hospital data and trend analysis, AHA Hospital Statistics includes current and historical data on utilization, personnel, revenue, expenses, managed care contracts, community health indicators, physician models, and much more.

AHA Hospital Statistics is published annually by Health Forum, an affiliate of the American Hospital Association. Additional details on AHA Hospital Statistics and other Health Forum data products are available at www.ahadataviewer.com. To order AHA Hospital Statistics, call (800) AHA-2626 or click on www.ahaonlinestore.com.

For further information or customized data and research, call the AHA Resource Center at (312) 422-2050 for one-stop service.

Total Number of All U.S. Registered * Hospitals	5,724
Number of U.S. **Community** ** Hospitals	4,973
Number of Nongovernment Not-for-Profit Community Hospitals	2,903
Number of Investor-Owned (For-Profit) Community Hospitals	1,025
Number of State and Local Government Community Hospitals	1,045
Number of Federal Government Hospitals	208
Number of Nonfederal Psychiatric Hospitals	421
Number of Nonfederal Long Term Care Hospitals	112
Number of Hospital Units of Institutions (Prison Hospitals, College Infirmaries, Etc.)	10
Total Staffed Beds in All U.S. Registered * Hospitals	924,333
Staffed Beds in Community** Hospitals	797,403
Total Admissions in All U.S. Registered * Hospitals	36,564,886
Admissions in Community** Hospitals	34,843,085
Total Expenses for All U.S. Registered * Hospitals	$773,546,800,000
Expenses for Community** Hospitals	$702,091,034,815
Number of Rural Community Hospitals**	1,984
Number of Urban Community Hospitals**	2,989
Number of Community Hospitals in a System * **	3,007
Number of Community Hospitals in a Network ** **	1,535

*Registered hospitals are those hospitals that meet AHA's criteria for registration as a hospital facility. Registered hospitals include AHA member hospitals as well as nonmember hospitals. For a complete listing of the criteria used for registration, please see Registration Requirements for Hospitals.

**Community hospitals are defined as all nonfederal, short-term general, and other special hospitals. Other special hospitals include obstetrics and gynecology; eye, ear, nose, and throat; rehabilitation; orthopedic; and other individually described specialty services. Community hospitals include academic medical centers or other teaching hospitals if they are nonfederal short-term hospitals. Excluded are hospitals not accessible by the general public, such as prison hospitals or college infirmaries.

***System is defined by AHA as either a multihospital or a diversified single hospital system. A multihospital system is two or more hospitals owned, leased, sponsored, or contract managed by a central organization. Single, freestanding hospitals may be categorized as a system by bringing into membership three or more, and at least 25 percent, of their owned or leased non-hospital preacute or postacute health care organizations. System affiliation does not preclude network participation.

**** Network is a group of hospitals, physicians, other providers, insurers and/or community agencies that work together to coordinate and deliver a broad spectrum of services to their community. Network participation does not preclude system affiliation.

Updated January 3, 2013

Community Oncology Practice Impact Report

The Changing Landscape of Cancer Care

Issued June 25, 2013

Summary

- This is an update to the last Community Oncology Alliance (COA) *Practice Impact Report*, which was issued on 4/4/12. This report is derived from a tracking database on the changing oncology treatment landscape. The database is compiled from private and public sources. Included in this report are a table of numbers of impacted practices by state and a map depicting the impact.

- With this update, 1,338 clinics/practices during the past 6 years have been impacted as follows:
  - **288 Clinics Closed** — Denotes individual clinic sites that have closed.
  - **407 Practices Struggling Financially** — Denotes practices (possibly comprised of multiple clinic sites) that have financial difficulties.
  - **43 Practices Sending Patients Elsewhere** — Denotes practices (possibly comprised of multiple clinic sites) that are sending *all of their patients* elsewhere for treatment.
  - **469 Practices with a Hospital Agreement or Purchased** — Denotes practices (possibly comprised of multiple clinic sites) that have entered into contractual relationship with a hospital, such as a professional services agreement, or have been acquired by a hospital.
  - **131 Practices Merged or Acquired** — Denotes practices (possibly comprised of multiple clinic sites) that have merged together or been acquired by a corporate entity, other than a hospital.

Points to Note

- Relative to the last report issued 15 months ago, the data documents the following:
  - **20% Increase in Clinics Closed**
  - **8% Decrease in Practices Struggling Financially**
  - **9% Decrease in Practices Sending Patients Elsewhere**
  - **20% Increase in Practices with a Hospital Agreement or Purchased**
  - **1% Decrease in Practices Merged or Acquired**

  The decreases represent practices that have closed or have been acquired by hospitals.

- We continue to see consolidation in the cancer care delivery landscape, especially in terms of clinics being closed and practices being acquired by, or affiliating with, hospitals. A recent analysis by The Moran Group[1] confirmed this consolidation by reporting that physician-owned community oncology clinics administered 87% of the chemotherapy in 2005 (analyzing Medicare fee-for-service data). By the end of 2011, chemotherapy administration by community oncology clinics fell to 67%.

- The reasons for this consolidation are due to insufficient Medicare reimbursement to community oncology clinics and higher reimbursements and margins to hospital outpatient facilities, especially those eligible for 340B discounts. Studies by Avalere[2] and Milliman[3] have documented the higher cost of cancer care in the hospital outpatient setting. Medicare pays $6,500 more per patient (annualized) for chemotherapy administered in the hospital outpatient setting, and cancer patients on Medicare pay $650 more.

- This report does not reflect the adverse impact of the sequester cut to cancer drugs, which based on recent survey results[4], is expected to accelerate hospital acquisitions of community oncology clinics.

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[1] *Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries*, The Moran Group, May, 2013.
[2] *Total Cost of Cancer Care by Site of Service: Physician Office vs. Outpatient Hospital.* Avalere Health, May, 2012.
[3] *Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy.* Milliman, October, 2011.
[4] *National Medicare Sequestration Survey: Post: Follow-up*; Community Oncology Alliance, March 2013.

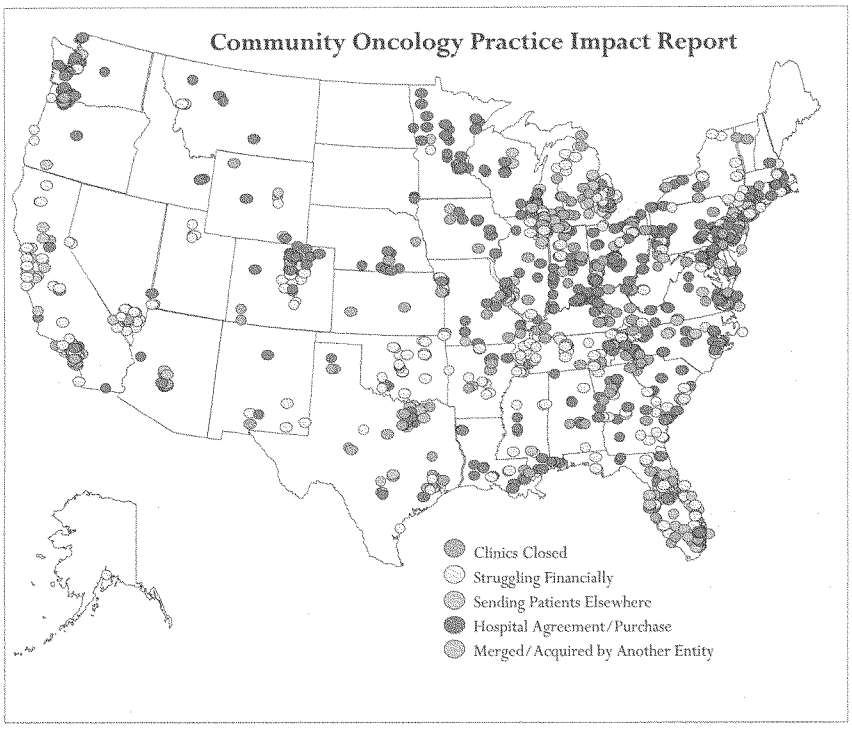
Community Oncology Practice Impact Report

Updated 6/20/13

State	*Total Sites/Practices*	*Clinics Closed*	*Practices Struggling Financially*	*Practices Sending Patients Elsewhere*	*Hosp. Agreement/ Purchase*	*Merged/Acquired by Another Entity*
Alabama	15	4	4	0	7	0
Alaska	2	0	2	0	0	0
Arizona	11	6	0	0	3	2
Arkansas	18	4	11	0	3	0
California	86	20	38	4	10	14
Colorado	42	7	15	1	19	0
Connecticut	10	1	0	0	9	0
DC	2	0	2	0	0	0
Delaware	4	4	0	0	0	0
Florida	122	32	26	0	27	37
Georgia	40	10	16	0	14	0
Hawaii	0	0	0	0	0	0
Idaho	2	0	0	0	2	0
Illinois	74	11	28	11	11	13
Indiana	37	10	5	2	19	1
Iowa	11	2	0	1	8	0
Kansas	4	3	0	0	1	0
Kentucky	34	15	2	0	17	0
Louisiana	18	3	4	0	11	0
Maine	12	3	4	0	3	2
Maryland	15	1	6	2	6	0
Massachusetts	0	0	0	0	0	0
Michigan	91	30	46	6	8	1
Minnesota	25	1	1	2	21	0
Mississippi	12	0	5	0	6	1
Missouri	39	8	9	2	19	1
Montana	7	0	3	0	4	0
Nebraska	9	2	0	0	7	0
Nevada	25	3	20	2	0	0
New Hampshire	1	0	0	0	1	0
New Jersey	39	4	12	0	13	10
New Mexico	7	1	4	0	2	0
New York	65	9	41	0	12	3
North Carolina	30	6	4	4	14	2
North Dakota	1	0	0	0	1	0
Ohio	51	11	9	0	29	2
Oklahoma	21	0	18	0	3	0
Oregon	19	1	3	1	14	0
Pennsylvania	62	6	9	0	44	3
Rhode Island	5	0	3	0	2	0
South Carolina	27	10	4	0	9	4
South Dakota	3	0	0	0	3	0
Tennessee	61	13	31	0	15	2
Texas	66	28	7	0	7	24
Utah	8	2	5	0	1	0
Vermont	1	1	0	0	0	0
Virginia	36	8	5	2	16	5
Washington	19	1	2	0	15	1
West Virginia	10	4	1	1	4	0
Wisconsin	33	2	0	2	28	1
Wyoming	6	1	2	0	1	2
Total	**1,338**	**288**	**407**	**43**	**469**	**131**

Clinics Closed denotes individual sites that have closed.
Practices Struggling Financially denotes practices (possibly comprised of multiple clinic sites) that have financial difficulties.
Practices Sending Patients Elsewhere denotes practices (possibly comprised of multiple clinic sites) that are sending all patients elsewhere for treatment.
Hosp. Agreement/Purchase denotes practices (possibly comprised of multiple clinic sites) that have a formal agreement/arrangement with a hospital or have been purchased by a hospital.
Merged/Acquired by Another Entity denotes practices (possibly comprised of multiple clinic sites) that have merged with other practices or have been acquired by a corporate entity, other than a hospital.

Source: Community Oncology Alliance practice impact database compiled and updated from data obtained from public and private sources.

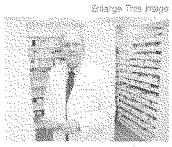

Community Oncology Practice Impact Report
Clinics Closed
Struggling Financially
Sending Patients Elsewhere
Hospital Agreement/Purchase
Merged/Acquired by Another Entity

Dispute Develops Over Discount Drug Program

By ANDREW POLLACK
Published: February 12, 2013

When a private oncology practice in Memphis formed a partnership with a nearby hospital in late 2011, the organizations proclaimed that the deal would "transform cancer care" in the region.

Enlarge This Image



Brent D. Bridges, the pharmacy director at a Georgia health system, says the hospital program is abused.

What they did not emphasize was that the deal would also create a windfall for them worth millions of dollars a year, courtesy of an obscure federally mandated drug discount program.

The program, known as 340B, requires most drug companies to provide hefty discounts -- typically 20 to 50 percent -- to hospitals and clinics that treat low-income and uninsured patients.

But despite the seemingly admirable goal, the program is now under siege, the focus of a fierce battle between powerful forces -- the pharmaceutical industry, which wants to rein in the discounts, and the hospitals, which say they might have to cut services without them.

One issue is that the program allows hospitals to us discounted drugs to treat not only poor patients but those covered by Medicare or private insurance. In those cases, the hospital pockets the difference between the reduced price it pays for the drug and the amount it is reimbursed.

That is what happened in Memphis. When the West Clinic teamed with Methodist Healthcare, the huge volume of chemotherapy drugs used by the clinic suddenly qualified for the hospital's discount, while reimbursement remained the same.

In a report issued on Tuesday, pharmaceutical industry trade groups say that some hospitals have gone overboard in using the program to generate revenue, straying from the original intent of helping needy patients. The report, which was supported by groups representing pharmacies, pharmacy benefit managers and oncology practices, called for the discounts to be more narrowly focused.

Some senior Republicans in the House and Senate are investigating the program, which they say has suffered from murky rules and lax enforcement.

"If 'nonprofit' hospitals are essentially profiting from the 340B program without passing those savings to its patients, then the 340B program is not functioning as intended," Senator Charles E. Grassley, Republican of Iowa, said in letters sent to three medical centers last October.

One reason for the scrutiny is that the program — named after the section in the law that created it in 1992 — now includes one-third of the nation's hospitals, triple the number in 2005. About $6.9 billion worth of drugs, or about 2 percent of the nation's total, are sold through the program annually, reducing revenue for the pharmaceutical companies by hundreds of millions of dollars a year.

The industry report says sales could grow to $12 billion by 2016. That is in part because the nation's new health care law will make more hospitals eligible for the discounts by increasing the number of Medicaid patients they treat, even as the need for the discounts should arguably diminish because fewer people will be uninsured.

Hospitals say 340B was never meant to merely provide cheap medicines to poor people. Rather, it was meant to help the hospitals that treat such patients, and to stretch federal resources. Making money from the spread helps keep the hospitals operating, which in turn helps needy patients, they say.

"If we didn't have our 340B program, I seriously doubt we could have our outpatient cancer center," said Burnis D. Breland, director of pharmacy at the Columbus Regional Healthcare System in western Georgia.

Nevertheless, with the program under scrutiny, the organization representing 340B hospitals, Safety Net Hospitals for Pharmaceutical Access, has warned companies that help those hospitals run their discount programs to avoid using terms like "increasing profits" and "revenue enhancement."

A 2011 report by the Government Accountability Office, the investigative arm of Congress, said that federal oversight of the program was insufficient to ensure that hospitals and drug companies were adhering to the rules.

In response, the Health Resources and Services Administration, which oversees the program using an annual budget of only $4.4 million, audited 51 hospitals last year, its first audits since the program began. It also made all hospitals recertify themselves as eligible for the program.

As a result, some 271 treatment sites belonging to 85 hospitals were ejected from the program, said Krista Pedley, the federal official in charge of the 340B program. She said that three hospitals acknowledged receiving discounts for which they were ineligible and were repaying manufacturers.

Some drug companies — Genentech is the only one that has publicly identified itself — are also auditing hospitals or considering doing so.

Previous studies have shown drug companies do not always offer the full discount, though no drug companies are being audited.

"Basically the pendulum has swung so aggressively toward oversight of the hospitals, with little concern about the drug companies," said Ted Slafsky, president of Safety Net Hospitals for Pharmaceutical Access.

With so much money at stake, the 340B program has given rise to a cottage industry of companies that help hospitals increase their savings, and two big conferences are held each year on the program. The most recent one, in San Francisco last month, drew 800 people and about 50 exhibiting companies.

Some oncologists say the 340B program is one reason that more than 400 oncology practices have become part of hospitals in the last several years. The 340B discounts apply to all drugs, but oncologists use a lot of costly ones, providing a potentially larger spread.

A single oncologist might use $2.5 million to $4 million in drugs a year, according to the Community Oncology Alliance. If those drugs can be acquired for a 25 percent discount, that is a potential profit of up to $1 million.

"It's the loophole that's made cancer drugs profitable again," said Dr. Peter B. Bach, director of the Center for Health Policy and Outcomes at Memorial Sloan-Kettering Cancer Center and a former adviser to Medicare.

Dr. Lee S. Schwartzberg, medical director of the West Clinic in Memphis, said the 340B program "definitely was a factor" in the decision to form the partnership with Methodist Healthcare.

The hospital and clinic say they will donate $5 million a year from the 340B proceeds to the University of Tennessee, which is building a cancer center with which they are affiliated.

The money is also being used to help pay for nursing and genetic counseling, Dr. Schwartzberg said.

Some prison systems, meanwhile, save on drug costs by making a 340B hospital their official health care provider.

If inmates "become 'patients' of the hospital, a 'win-win' arrangement can be negotiated with the state, county or city," said a slide from a 2010 presentation by Safety Net Hospitals for Pharmaceutical Access.

A big increase in the use of 340B occurred in 2010, when the government allowed hospitals to use an unlimited number of neighborhood pharmacies to fill 340B prescriptions. Before that, patients generally had to go to the hospital pharmacy, which can be inconvenient.

The University of California medical centers, which now have 240 pharmacies under contract, expect 35 percent of eligible prescriptions to go through the 340B program this year, up from only 10 percent in 2011, said Lynn Paulsen, director of pharmacy practice standards.

In these arrangements, needy patients typically get the drugs at little or no cost.

But if a patient is insured, the hospital keeps the difference between the reduced price it paid for the drug and the higher price reimbursed by the insurer, and pays the neighborhood pharmacy a dispensing fee.

There are already about 25,000 arrangements between a treatment site and a pharmacy, according to the Health Resources and Services Administration.

"It's morphed into a big revenue-capture game — how can we get as many 340B prescriptions filled at a 340B price," said Aaron Vandervelde of the Berkeley Research Group, a consulting firm to pharmaceutical companies.

It is too early to say what, if any, changes will be made by Congress.

Hospitals say that restricting the discounts to drugs actually consumed by poor patients would eviscerate the benefits of the program. The hospitals are hoping the program might be expanded to help balance the federal budget.

Ailing hospitals might garner more sympathy than profitable drug companies. It is perhaps telling that no Democrats have joined the investigation of the 340B program.

"It's saving the government money, so they don't have an incentive to change it," said

Carlton Sedberry, senior director at Medical Marketing Economics, a pharmaceutical industry consulting firm.

"It's making the hospitals money, so they don't have an incentive to change it." And patients, for the most part, are unaware of 340B.

"The only people this smacks are the manufacturers."

This article has been revised to reflect the following correction:

Correction: February 22, 2013

An article on Feb. 13 about a drug discount program for hospitals known as 340B misstated the target of a warning from an organization representing hospitals that use the program. The organization, Safety Net Hospitals for Pharmaceutical Access, warned companies that help the hospitals run their discount programs to avoid using terms like "increasing profits" and "revenue enhancement." It did not issue that warning to the hospitals themselves.

United States Government Accountability Office

GAO

Report to Congressional Committees

September 2011

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

GAO-11-836

GAO
Accountability * Integrity * Reliability
Highlights

Highlights of GAO-11-836, a report to congressional committees

September 2011

DRUG PRICING

Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement

Why GAO Did This Study

The Health Resources and Services Administration (HRSA), within in the Department of Health and Human Services (HHS), oversees the 340B Drug Pricing Program, through which participating drug manufacturers give certain entities within the health care safety net—known as covered entities—access to discounted prices on outpatient drugs. Covered entities include specified federal grantees and hospitals. The number of covered entity sites has nearly doubled in the past 10 years to over 16,500.

The Patient Protection and Affordable Care Act (PPACA) mandated that GAO address questions related to the 340B program. GAO examined: (1) the extent to which covered entities generate 340B revenue, factors that affect revenue generation, and how they use the program; (2) how manufacturers' distribution of drugs at 340B prices affects covered entities' or non-340B providers' access to drugs; and (3) HRSA's oversight of the 340B program. GAO reviewed key laws and guidance, analyzed relevant data, and conducted interviews with 61 340B program stakeholders selected to represent a range of perspectives, including HRSA, 29 covered entities, 10 manufacturers and representatives, and 21 others. Selection of stakeholders was judgmental and thus, responses are not generalizable.

What GAO Recommends

To ensure appropriate use of the 340B program, GAO recommends that HRSA take steps to strengthen oversight regarding program participation and compliance with program requirements. HHS agreed with our recommendations.

View GAO-11-836. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

What GAO Found

Thirteen of the 29 covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs, which includes the costs of purchasing and dispensing drugs. Of those remaining, 10 did not generate enough revenue to exceed drug-related costs, and 6 did not report enough information for us to determine the extent to which revenue was generated. Several factors affected 340B revenue generation, including drug reimbursement rates. Regardless of the amount of revenue generated, all covered entities reported using the program in ways consistent with its purpose. For example, all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients. Entities generating 340B program revenue that exceeded drug-related costs were also able to serve more patients and to provide additional services.

According to the 61 340B program stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. Specifically, 36 stakeholders, including those representing manufacturers, covered entities, and non-340B providers, did not report any effect on covered entities' or non-340B providers' access. The remaining 25, also representing a wide range of perspectives on the 340B program, reported that it affected access primarily in two situations: (1) for intravenous immune globulin (IVIG), a lifesaving drug in inherently limited supply; and (2) when there was a significant drop in the 340B price for a drug resulting in increased 340B demand. In both situations, manufacturers may restrict distribution of drugs at 340B prices because of actual or anticipated shortages. Stakeholders reported that restricted distribution of IVIG resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices. They also reported that restricted distribution when the 340B price of a drug dropped significantly helped maintain equitable access for all providers.

HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements—such as, entities' transfer of drugs purchased at 340B prices only to eligible patients, and manufacturers' sale of drugs to covered entities at or below the 340B price. HRSA primarily relies on participant self-policing to ensure program compliance. However, its guidance on program requirements often lacks the necessary level of specificity to provide clear direction, making participants' ability to self-police difficult and raising concerns that the guidance may be interpreted in ways inconsistent with the agency's intent. Other than relying on self-policing, HRSA engages in few activities to oversee the 340B program. For example, the agency does not periodically confirm eligibility for all covered entity types, and has never conducted an audit to determine whether program violations have occurred. Moreover, the 340B program has increasingly been used in settings, such as hospitals, where the risk of improper purchase of 340B drugs is greater, in part because they serve both 340B and non-340B eligible patients. This further heightens concerns about HRSA's current approach to oversight. With the number of hospitals in the 340B program increasing significantly in recent years—from 591 in 2005 to 1,673 in 2011—and nearly a third of all hospitals in the U.S. currently participating, some stakeholders, such as drug manufacturers, have questioned whether all of these hospitals are in need of a discount drug program.

Contents

Abbreviations

ADAP	AIDS Drug Assistance Program
CMS	Centers for Medicare & Medicaid Services
DSH	disproportionate share hospital
FQHC	federally qualified health center
GPO	group purchasing organization
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
IVIG	intravenous immune globulin
PHSA	Public Health Service Act
PPACA	Patient Protection and Affordable Care Act
PSSC	Pharmacy Services Support Center
PVP	Prime Vendor Program

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 23, 2011

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

Our nation's health care safety net provides services to low-income, uninsured, underinsured, and other individuals who experience barriers accessing care, regardless of their ability to pay. Certain types of providers within the safety net have access to discounted prices on outpatient drugs through the 340B Drug Pricing Program.[1] The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA),[2] requires drug manufacturers to give 340B discounts to entities covered under the law—known as covered entities—in order to have their drugs covered by Medicaid.[3]

Covered entities include clinics and hospitals that provide general health care services, as well as those that serve patients with specific conditions or diseases, and are typically eligible for the program because they receive some type of federal support, such as a federal grant. According

[1]Outpatient drugs covered under the 340B program may include: prescription drugs approved by the Food and Drug Administration; certain over-the-counter drugs provided as prescriptions; biological products, other than vaccines, that can be dispensed only by a prescription; and insulin approved by the Food and Drug Administration. 42 U.S.C. §§ 256b(b)(2), 1396r-8(k)(2). When payment for an outpatient drug is bundled with payment for other services, the drug is not covered by the 340B program.

[2]42 U.S.C. § 256b.

[3]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals. Medicaid programs vary from state to state.

to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services.[4] Covered entities' current spending on 340B drug purchases is estimated to be about $6 billion annually.

Participation in the 340B program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent off the cost of drugs, according to HRSA. In addition, covered entities can generate 340B revenue.[5] For example, covered entities can purchase drugs at the 340B price for all patients eligible under the program regardless of their income or insurance status, and generate revenue, such as through a patients' insurance reimbursement, that may exceed the 340B price paid for the drugs.[6] As of July 2011, there were more than 16,500 covered entity sites

[4]HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the PHSA. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act); *See also* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the PHSA).

[5]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs.

[6]In 1996, HRSA issued a definition of a 340B patient that defines the situations under which covered entities can use drugs purchased at 340B prices for their patients. While income and insurance status do not dictate whether a patient is eligible under the program, certain patients, such as those who do not receive health care services consistent with the scope of a grant that made an entity eligible for the program or those whose only service from the covered entity is the dispensing of drugs, are prohibited from receiving drugs purchased at the 340B price. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

enrolled in the program—about double the number reported in 2001.[7] Because they must participate in the 340B program to receive Medicaid reimbursement for their drugs, incentives for participation by drug manufacturers also are strong. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA requires program participants to meet certain conditions set forth both in law and agency guidance. For example, under the PHSA, covered entities are prohibited from transferring 340B drugs to individuals who are not eligible patients of the entities.[8] Similarly, to help ensure covered entities receive the discounts they are entitled to, HRSA has issued nondiscrimination guidance prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to other, non-340B healthcare providers.[9] This includes not conditioning the sale of drugs to covered entities on restrictive conditions, such as requiring them to commit to minimum purchase amounts, which would discourage entities from participating in the program. However, stakeholders, including both covered entities and drug manufacturers, have raised questions about the extent to which 340B program requirements are followed and the extent to which HRSA ensures compliance. Further, because the 340B program has no requirements on how 340B revenue can be used,[10] stakeholders, such as drug manufacturers, have raised questions about covered entities' generation of revenue and whether they are using it in ways consistent with the purpose of the program. Additionally, due to continued growth in the

[7]Data are the most recent available from HRSA's covered entity database and represent both unique covered entities and all their eligible sites, such as satellite clinics. According to HRSA, there are about 3,200 unique organizations currently participating in the program—the agency was unable to provide historical data on unique organizations for all entity types. Additionally, because a covered entity may enroll under any and all eligible grant types it receives, it is possible that certain unique organizations and eligible sites are reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[8]42 U.S.C. § 256b(a)(5)(B).

[9]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

[10]According to HRSA, while there are no 340B-specifc requirements, all covered entities eligible for the program based on their grantee status may be required to use 340B revenue in accordance with their grant requirements.

number of covered entities participating in the program, some stakeholders have raised questions about whether increased use of 340B discounts shifts a larger share of drug costs to others in the health care system.

The Patient Protection and Affordable Care Act (PPACA) amended the 340B program by expanding entity eligibility for the program to include additional types of hospitals.[11] PPACA also contained provisions to improve 340B program integrity, and included a provision explicitly prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, consistent with HRSA's nondiscrimination guidance.[12] The passage of PPACA has raised some questions for 340B stakeholders about the program. For example, although proponents of the explicit prohibition on manufacturers contend that it is necessary to prevent discrimination against covered entities, critics are concerned about how it could affect non-340B providers' access to drugs.[13] Additionally, PPACA extends health insurance coverage to more Americans, and some stakeholders, such as drug manufacturers, have questioned whether covered entities will need the discounts provided through the 340B program given this increased coverage.

PPACA directed us to address several questions related to the 340B program. In response to the mandate, we examined: (1) the extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program; (2) how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers; and (3) HRSA's oversight of the 340B program.

[11]Entities that became eligible for the 340B program through PPACA include certain critical access hospitals, sole community hospitals, rural referral centers, and freestanding cancer hospitals. See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082.

[12]Pub. L. No, 111-148, § 7102(b).

[13]For this report, we consider providers as having access to a drug if they are able to obtain the amount necessary to meet the needs of their patients—for covered entities this includes being able to obtain the drug at the 340B price.

To examine the extent to which covered entities generate revenue through their participation in the 340B program, factors that affect their revenue generation, and how entities use the program, we conducted interviews with a judgmental sample of 29 covered entity organizations primarily selected to represent five covered entity types located in five states. We selected entity types based on factors, including high levels of participation in the 340B program and variation in organizational structure and the types of services provided. We selected states based on factors, including geographic variation and the percentage of uninsured in the state. Specifically, we interviewed 7 federally qualified health centers (FQHC),[14] 5 family planning clinics, 5 AIDS Drug Assistance Programs (ADAP), 5 hemophilia treatment centers, and 5 general acute care hospitals with a Medicare disproportionate share hospital (DSH) adjustment percentage of greater than 11.75 percent[15]—in this report we refer to these hospitals as DSH hospitals.[16] These entities were located in Illinois, Massachusetts, Tennessee, Texas, and Utah. We specifically selected Massachusetts to gain a better understanding of the potential effect of PPACA's health insurance reforms on the 340B program.[17] In addition to interviewing covered entities located in the five states, we conducted interviews with 2 additional DSH hospitals located in other states, because of questions raised in stakeholder interviews about how these hospitals were using the program. When possible, we collected

[14]FQHCs are urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations and have received a "Federally Qualified Health Center" designation from the Centers for Medicare & Medicaid Services (CMS).

[15]General acute care hospitals are eligible for the 340B program when they have a Medicare DSH adjustment percentage of greater than 11.75 percent and meet certain other requirements. Medicare is the federally financed health insurance program for persons aged 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease. The Medicare DSH adjustment percentage is an additional Medicare payment to acute care hospitals paid under the inpatient prospective payment system—a Medicare reimbursement method based on a predetermined, fixed amount. A hospital's DSH adjustment percentage is generally based on its DSH patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients.

[16]While additional types of hospitals are eligible for the 340B program, we only interviewed DSH hospitals because the remaining hospital types had only recently started participating in the program.

[17]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

relevant documentation from covered entities. Although we selected covered entities to interview that represented a variety of entity types, not all covered entity types are represented. Further, our selection of covered entities was judgmental, and our sample is not generalizable. (See appendix I for more details on how we selected covered entities and appendix II for more information about the entity types eligible to participate in the 340B program.)

To examine how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers, we conducted interviews with 61 340B program stakeholders, including our judgmental sample of 29 covered entities, as well as 32 other program stakeholders representing a wide range of perspectives on the program.[18] Included were interviews with 6 drug manufacturers, selected based on factors such as having a large market share and producing drugs with reported challenges related to their distribution at 340B prices, and 6 organizations representing drug manufacturers and others involved in distributing drugs from manufacturers to providers. We also interviewed stakeholders representing providers, including 9 organizations representing covered entities, 2 organizations representing non-340B providers, and 5 organizations representing both covered entities and non-340B providers. Finally, we interviewed HRSA and the Centers for Medicare & Medicaid Services (CMS), as well as HRSA's 2 340B program contractors. (See appendix I for more details on interviewees and how we selected them.) Similar to our selection of covered entities, our selection of other program stakeholders was judgmental and, as such, responses are not generalizable. In addition, we reviewed relevant documentation from interviewees, and analyzed industry data as well as data from HRSA's covered entity database to determine the number of hospitals in the U.S. currently participating in the 340B program. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

To examine HRSA's oversight of the 340B program, we conducted interviews with the 61 program stakeholders discussed above and reviewed relevant documentation. We reviewed information from HRSA and other HHS agencies, including those that administer the grants that

[18]We conducted multiple interviews with certain organizations for a total of 65 interviews.

make entities eligible for the 340B program.[19] We also reviewed key laws, guidance, and relevant literature related to the program and to safety net providers. We analyzed data from HRSA's covered entity database to determine changes in 340B program participation among covered entity types since 2001. We reviewed data-related documentation and interviewed agency officials, and determined these data were sufficiently reliable for our purposes.

We conducted our performance audit from September 2010 through September 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B program was created in 1992 following the enactment of the Medicaid Drug Rebate Program and gives certain safety net providers discounts on outpatient drugs comparable to those made available to state Medicaid agencies.[20] HRSA, through its Office of Pharmacy Affairs, is responsible for administering and overseeing the 340B program,[21] which according to federal standards, includes designing and implementing necessary policies and procedures to enforce agency objectives and assess program risk. These policies and procedures include internal controls that provide reasonable assurance that an

[19]HHS agencies that administer the grants that make entities eligible for the 340B program include HRSA, Indian Health Services, Office of Population Affairs, and the Centers for Disease Control and Prevention. CMS calculates Medicare DSH adjustment percentages for hospitals.

[20]The Medicaid Drug Rebate Program was established through the Omnibus Budget Reconciliation Act of 1990 and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

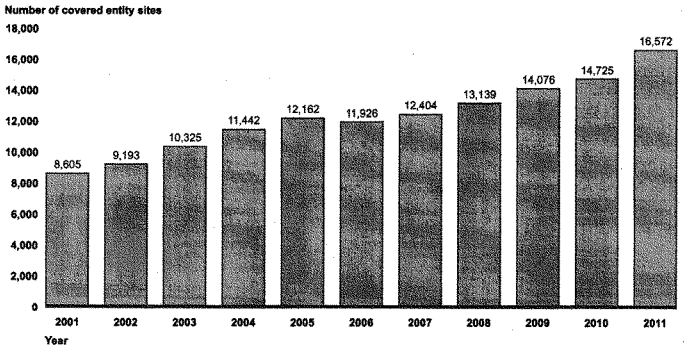
[21]The Pharmacy Services Support Center (PSSC) and the Prime Vendor Program (PVP) assist HRSA with the administration of the 340B program and are managed by contractors. The PSSC provides guidance and free technical assistance to covered entities and helps ensure that patients of covered entities receive comprehensive pharmacy services. The PVP establishes a distribution network for pharmaceuticals to covered entities and negotiates prices for a portfolio of drugs below the 340B price. Participation in the PVP is free and voluntary for covered entities.

agency has effective and efficient operations and that program participants are in compliance with applicable laws and regulations.[22]

Program Participants

Eligibility for the 340B program is defined in the PHSA. Entities generally become eligible by receiving one of 10 federal grants or by being one of six hospital types. (See appendix II for a complete list of covered entity types and their eligibility requirements.) To participate in the 340B program, eligible entities must register with HRSA and be approved. Entity participation in the 340B program has grown over time to include over 16,500 covered entity sites (see fig. 1).

Figure 1: Growth in Covered Entity Sites, 2001 to 2011



Source: GAO analysis of HRSA data.

[22]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

Federal grantees are eligible for the 340B program by virtue of receiving certain federal grants administered by different agencies within HHS. Eligible grantees include clinics that offer primary and preventive care services, such as FQHCs,[23] family planning clinics, and clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, such as hemophilia treatment centers. Participating clinics may offer eligible services at one or multiple sites. They also include state-operated ADAPs, which serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals.

Hospitals eligible for the 340B program include certain DSH hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. While DSH hospitals have been eligible for the program since its inception, children's hospitals became eligible in 2006, and the remaining hospital types became eligible through PPACA.[24]

Hospital eligibility for the 340B program has more elements than that of federal grantees, because unlike federal grantees, hospitals do not qualify for the program based on receipt of a federal grant. Rather, they must meet certain requirements intended to ensure that they perform a government function to provide care to the medically underserved. First, hospitals generally must meet specified DSH adjustment percentages to qualify; however, critical access hospitals are exempt from this requirement.[25] Additionally, all hospitals must be (1) owned or operated

[23]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[24]See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082. While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006) (amending 42 U.S.C. § 1396r-8(a)(5)(B)).

[25]To be eligible for the 340B program, rural referral centers and sole community hospitals must have a DSH adjustment percentage that is equal to or greater than 8 percent, and DSH, children's, and free-standing cancer hospitals must have a DSH adjustment percentage that is greater than 11.75 percent. Although children's and free-standing cancer hospitals do not receive payments under the Medicare inpatient prospective payment system, they must have a payer mix that would result in a DSH adjustment percentage of greater than 11.75 percent.

by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government,[26] or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital's most recently filed Medicare cost report.[27]

All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B program and must participate if they want their drugs covered by Medicaid. To participate, manufacturers are required to sign a pharmaceutical pricing agreement with HHS in which both parties agree to certain terms and conditions and submit this agreement to HRSA.

Program Structure and Operation

Covered entities typically purchase and dispense 340B drugs through pharmacies and can structure their programs in different ways. Entities can have (1) an in-house pharmacy model, in which the pharmacy is housed within the covered entity, (2) a contract pharmacy model, in which the entity contracts with an outside pharmacy to dispense drugs on their behalf, or (3) both. Historically, only covered entities that did not have an in-house pharmacy were allowed to contract with a single outside pharmacy to provide services. In March 2010, however, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies.[28] Some covered entities use HRSA's Pharmacy Services Support Center (PSSC) or private companies that provide technical assistance, information

[26]According to HRSA, a hospital is said to be "formally granted governmental powers" when the state formally delegates to the hospital a type of power(s) usually exercised by the state, for the purpose of providing health care services to the medically indigent population of the state.

[27]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 180, 47884 (Sept. 19, 1994).

[28]Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

technology, and other services to help develop, implement, and manage their 340B pharmacy program.

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities;[29] however, the provision establishing the 340B pricing formula indicates that manufacturers may sell a drug at a price that is lower than the ceiling price.[30] As such, covered entities may negotiate prices below the ceiling price. Manufacturers are responsible for calculating the 340B price on a quarterly basis. Occasionally the formula results in a negative price for a 340B drug.[31] In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA's penny pricing policy.

Key Program Requirements

Covered entities must follow certain program requirements as a condition of participating in the 340B program. For example, covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA's current definition of a patient. This definition was issued in 1996 and outlines three criteria which generally state that diversion occurs when 340B discounted drugs are given to individuals who are not receiving health care services from covered entities or are only receiving non-covered services, such as inpatient hospital services, from covered entities. (See table 1 for more information on HRSA's definition of a 340B patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.

[29]In general, the 340B price for a drug is calculated quarterly by subtracting the unit rebate amount used in the Medicaid Drug Rebate Program from the drug's average manufacturer price. See 42 U.S.C. § 256b (a)(1). Average manufacturer price is the average price paid to a manufacturer for drugs distributed to retail community pharmacies. It includes direct manufacturer sales to retail community pharmacies, as well as sales by wholesalers. 42 U.S.C. §§ 256b(b), 1396r-8(k).

[30]42 U.S.C.§ 256b(a)(10).

[31]When a drug's average manufacturer price increases more quickly than the rate of inflation, the government requires the manufacturer to pay an additional rebate amount. This may cause the drug's unit rebate amount to be greater than the drug's average manufacturer price, which would result in a negative 340B price.

Table 1: HRSA's Definition of a Patient Eligible for Discounted Drugs under the 340B Program

Criteria for patient eligibility[a]
1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.[b]
3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided.[c]

Source: GAO analysis of HRSA guidance.

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207, 55156 (Oct. 24, 1996).

[a]These criteria do not apply to ADAPs; rather, an individual will be considered a patient of an ADAP if enrolled in the ADAP program.

[b]An individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

[c]DSH hospitals are exempt from this requirement.

Covered entities also are prohibited from subjecting manufacturers to duplicate discounts whereby drugs prescribed to Medicaid patients are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program. To avoid duplicate discounts, covered entities can either purchase drugs for Medicaid patients outside the 340B program, in which case the state Medicaid agency may claim the rebate, or they can use drugs purchased at 340B prices, in which case the agency may not claim the rebate. Covered entities that decide to use 340B drugs for Medicaid patients must notify HRSA so that it can coordinate with state Medicaid agencies for billing purposes. Further, certain covered entities—DSH hospitals, children's hospitals, and freestanding cancer hospitals—are prohibited from purchasing outpatient drugs through any group purchasing organization (GPO).[32] However, they may purchase drugs through the specified HRSA contractor, the Prime Vendor Program (PVP). Rural referral centers, sole community hospitals, and critical

[32]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

access hospitals participating in the 340B program are allowed to purchase outpatient drugs through any GPO.

Drug manufacturers also must follow certain 340B program requirements. Specifically, they must sell outpatient drugs to covered entities at or below the statutorily determined price. In addition, HRSA's nondiscrimination guidance prohibits manufacturers from distributing drugs in ways that discriminate against covered entities compared to other providers. This includes ensuring that drugs are made available to covered entities through the same avenue that they are made available to non-340B providers, and not conditioning the sale of drugs to covered entities on restrictive conditions, which would have the effect of discouraging participation in the 340B program.

340B Revenue Generated by Covered Entities Varied, but All Entities Reported That the Program Was Used to Support or Expand Access to Services

About half of the covered entities we interviewed reported that they generated 340B program revenue that exceeded drug-related costs—the costs of purchasing and dispensing a drug—and revenue generation depended on several factors. Regardless of the amount of 340B revenue generated or the savings realized through 340B discounts, covered entities generally reported using the 340B program to support or expand access to services.

About Half of Covered Entities Reported Generating 340B Revenue That Exceeded Drug-Related Costs, and Revenue Generated Depended on Several Factors

Thirteen of the 29 covered entities we interviewed reported that they generated revenue through the 340B program that exceeded drug-related costs.[33] Of the 16 remaining, 10 did not generate enough 340B revenue to cover all drug-related costs, and 6 covered entities were unable or did not report enough information for us to determine the extent to which they generated 340B revenue due, in part, to their inability to track 340B-specific financial information.

In general, 340B revenue—whether exceeding drug related costs or not—was generated through reimbursement received for drugs dispensed by 340B in-house or contract pharmacies, though several factors affected the extent to which the covered entities we interviewed generated revenue through the program:[34]

- **Third-party reimbursement rates**: Eighteen of the 29 covered entities we interviewed generated 340B revenue by receiving reimbursement from third-party payers and tracked revenue by payer source. Of the 18, most reported that they generated more 340B revenue from patients with private insurance and Medicare compared to other payers.[35] However, a few of these covered entities reported that their ability to generate 340B revenue from private insurers, including Medicare Part D plans, was decreasing because some insurers were reducing contracted reimbursement rates for drugs based on the entity's status as a 340B provider. Of the 18 covered entities, most of those that used 340B drugs for Medicaid patients reported that state-determined Medicaid reimbursement rates for these drugs were generally lower, compared to private insurers and Medicare. For example, most reported that Medicaid reimbursement for a 340B drug was set at the price paid for the drug—the 340B price

[33]For this report, we define 340B revenue as all monies received by covered entities for drugs they purchase at the 340B price, whether or not the revenue meets or exceeds the costs paid for the drugs. When data provided by covered entities was used to determine revenue generation, the most recent year of reported data was used.

[34]Even though 6 covered entities were unable to report the amount of revenue they generated through the program, they were able to report what factors affected overall revenue generation.

[35]Medicare reimburses outpatient prescription drugs either through Medicare Part B or Part D. Part B covers drugs administered by physicians, such as chemotherapy drugs, and payment for those drugs is set by a fee schedule established quarterly by CMS. Part D sponsors are typically private insurers that contract with CMS to cover outpatient prescription drugs and negotiate reimbursement rates directly with health care providers.

or any lower price—plus a dispensing fee, the latter of which generally did not cover the costs of dispensing the drug.[36] This is typically referred to as reimbursement at actual acquisition cost, which reduces a covered entity's ability to generate revenue because the state, rather than the entity, benefits from any savings from purchasing drugs at the 340B price.[37] However, a few covered entities generated more 340B revenue through Medicaid than others because they had contractual agreements with their states to share 340B-related savings.[38] Covered entities in two of the five states included in our selection had such agreements. Finally, a majority of the 18 covered entities reported that revenue generated from uninsured patients was lower than that from all other payers.

- **ADAP status**: Factors that affected 340B revenue generation for the five ADAPs we interviewed were different than for other entity types, because unlike other covered entity types, ADAPs do not receive third-party reimbursement for drugs. Rather, ADAPs serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals who, for example, are uninsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs. ADAPs can choose to cover costs of drugs by either paying for the drugs directly or by assisting patients with the costs associated with health insurance, including payments for premiums and co-payments or deductibles. When ADAPs purchase drugs directly, they realize 340B savings on drugs—either at the point of purchase or after the fact through manufacturer rebates—but do not generate revenue through the program. When ADAPs assist with patients' health insurance by paying for co-payments or

[36]A dispensing fee is typically a set dollar amount per prescription that covers the overhead costs of dispensing a drug, such as pharmacy staff time.

[37]State Medicaid agencies may reimburse entities at actual acquisition cost, because when entities decide to use drugs purchased at 340B prices for Medicaid patients, the state can no longer claim Medicaid rebates for those drugs.

[38]These contractual agreements are commonly referred to as shared savings agreements. Shared savings agreements provide covered entities reimbursement above actual acquisition cost, for example, by paying a higher dispensing fee to covered entities than the fee paid to other providers. According to the HHS Office of Inspector General, states may be interested in shared savings agreements with covered entities because 340B prices can be considerably lower than states' standard Medicaid reimbursement rates and entering into such agreements could encourage entities to use 340B drugs for Medicaid patients while still saving money for states.

deductibles on a drug, they sometimes generate revenue by collecting the rebates representing the full 340B discount on a drug for which they may have only paid a portion of the price. Three of the five ADAPs we interviewed reported generating revenue this way.

- **Ability to leverage resources to access the lowest drug prices**: Some of the 29 covered entities we interviewed reported leveraging resources, such as through their larger parent organizations or the PVP, to access drugs at prices below the 340B ceiling price, potentially increasing the difference between the price paid for the drug and the reimbursement received. In addition, some covered entities said they had access to sophisticated information technology—for example by contracting with private companies—or had more staff to help ensure that they were obtaining the lowest priced drugs.

As more people gain insurance coverage under PPACA, covered entities may serve more patients with private insurance and Medicaid,[39] which may affect the extent to which they generate 340B revenue. One covered entity located in Massachusetts reported that after the state implemented universal health care, while they received more revenue from reimbursement for low-income patients that gained private insurance, these patients often could not afford associated co-payments or deductibles, and the entity covered these costs.[40] In addition, according to one ADAP we interviewed, as more individuals gain private insurance, the ADAP may increasingly choose to pay for health insurance for patients rather than paying for patients' drugs directly. This may enable it to generate revenue through the 340B program if it can claim more rebates for drugs for the newly insured patients. According to some covered entities, the impact of serving more Medicaid patients may depend on the Medicaid reimbursement rate that entities receive. For example, patients that gain Medicaid coverage may begin to seek services from covered entities, and for those entities that lose money on Medicaid patients, this may decrease their ability to generate 340B revenue. Conversely, for covered entities that have contractual agreements to share 340B-related

[39]PPACA contains provisions to expand private health insurance and Medicaid coverage to more Americans. See, e.g., Pub. L. No. 111-148, § 2001, 124 Stat. 119, 271.

[40]HRSA officials told us that this statement is consistent with their belief that low-income patients will continue to require assistance with health care costs after gaining insurance.

savings with their states, the increased Medicaid population may increase their ability to generate 340B revenue.

Covered Entities Reported Using the 340B Program to Support or Expand Access to Services

Regardless of the amount of revenue generated through the program, all of the 29 covered entities we interviewed reported that the 340B program, including the up-front savings they realized on the cost of drugs, allowed them to support their missions by maintaining services and lowering medication costs for patients, which is consistent with the purpose of the program. For example, some covered entities reported that they used the 340B revenue generated by certain patients to offset losses incurred from other patients, which helped support the financial stability of the organization and allowed them to maintain services. Further, one covered entity reported that without 340B revenue or the savings on drugs through its participation in the program, it would be unable to offer all the services it provides—both pharmaceutical and clinical—and another reported that it would have to close its outpatient pharmacy without the program. In addition to maintaining services, some covered entities passed 340B savings on to patients by providing lower-cost drugs to uninsured patients. For example, many covered entities determined the amount that a patient is required to pay based on the lower cost of 340B-priced drugs.

In addition, the 13 covered entities that generated 340B revenue that exceeded drug-related costs were able to use this revenue to serve more patients and to provide services that they might not have otherwise provided, including additional service locations, patient education programs, and case management, which is also consistent with the purpose of program. One covered entity, for example, reported that it used the revenue generated through the 340B program to provide additional service delivery sites in other parts of the state, which eliminated the need for some patients to travel more than 60 miles to receive services. A few covered entities reported using 340B revenue to support patient and family education programs, such as those where pharmacists provide education on drug interactions. Additionally, one covered entity reported using 340B program revenue to fund a case management program that did not generate any revenue on its own;[41] some services provided through this program included arranging

[41]Case management services facilitate access to appropriate health care, and are not typically reimbursed by payers.

transportation for patients to receive clinical services, coordinating necessary specialty care, and providing translation services.

Even though the uses of revenue generated through the 340B program were for similar purposes, some covered entities relied on the program more than others. For example, one FQHC reported that 340B revenue accounted for approximately 5 percent of its total budget, and was used to provide additional services within the organization. However, one hemophilia treatment center reported that 340B revenue accounted for about 97 percent of its total budget and was used to support all of its program operations.[42]

Manufacturers' Distribution of Drugs at 340B Prices Generally Did Not Affect Providers' Access to Drugs Except in Two Situations

According to stakeholders we interviewed, manufacturers' distribution of drugs at 340B prices generally did not affect providers' access to drugs. For example, 36 of the 61 program stakeholders we interviewed did not report any effect on covered entities' or non-340B providers' access to drugs related to manufacturers' distribution of drugs at 340B prices. These stakeholders represented a wide range of perspectives on the 340B program, including those representing manufacturers, covered entities, and non-340B providers.

The remaining 25 program stakeholders—also representing a wide range of perspectives on the 340B program—reported that manufacturers' distribution of drugs at 340B prices affected providers' access to drugs primarily in two situations.[43] The two situations were: (1) for intravenous immune globulin (IVIG), a lifesaving immune deficiency drug, the supply

[42]The organizational structure of hemophilia treatment centers we interviewed varied, and those that operated stand-alone programs were more dependent on 340B revenue than those that were integrated into hospitals.

[43]While stakeholders consistently reported two situations in which manufacturers' distribution of drugs at 340B prices affected providers' access to these drugs, some, such as covered entities, reported other situations that had effects on access, but it was not clear that the other situations were related to manufacturers' distribution of drugs at 340B prices.

of which is inherently limited;[44] and (2) when there was a significant drop in the 340B price of a drug, which may result in increased demand for the drug by covered entities. Both situations relate to the restricted distribution of drugs, which may occur during shortages or when shortages are anticipated.

Stakeholders reported that manufacturers' restricted distribution of IVIG at 340B prices resulted in 340B hospitals having to purchase some IVIG at higher, non-340B prices in order to meet their demand for the drug.[45] Manufacturers restrict the distribution of IVIG on an ongoing basis, because it is susceptible to shortages. Stakeholders, including five of the seven DSH hospitals we interviewed, reported that because of the restricted distribution of IVIG at 340B prices, 340B hospitals often must purchase some IVIG at higher, non-340B prices to meet their patients' needs. For example, DSH hospitals reported that when they were unable to access IVIG at 340B prices, additional IVIG was available for purchase at higher, non-340B prices directly from manufacturers, from specialty pharmacies,[46] or from GPOs.[47] Moreover, one DSH hospital reported that it had to purchase about one-third of the IVIG it needed at non-340B

[44]IVIG is primarily used to treat patients with immune deficiency diseases, a group of disorders in which the immune system fails to produce enough antibodies, thereby predisposing individuals to increased risk of infection. Factors inherent to the development and distribution of IVIG limit its supply making it susceptible to shortages, including that IVIG is made from human plasma, which is an inherently scarce resource, and that IVIG takes between seven and 12 months to manufacture. Additionally, only a few manufacturers develop and distribute these drugs in the United States.

[45]Hospitals are the primary purchaser of IVIG in the United States.

[46]Specialty pharmacies handle and distribute drugs that, among other things, have a high acquisition cost and require special handling practices.

[47]In general, 340B hospitals are prohibited from purchasing outpatient drugs through GPOs. While no DSH hospital we interviewed reported purchasing IVIG through GPOs, GPOs we interviewed told us that 340B hospitals have purchased IVIG through this avenue when they are unable to access it at the 340B price. During a December 2005 congressional hearing on the 340B program, an organization representing 340B hospitals argued that in situations when hospitals are unable to purchase IVIG at 340B prices, they are faced with either violating federal law by purchasing IVIG through GPOs, buying IVIG at cost-prohibitive retail prices, or denying their patients access to these drugs. See "Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency," Hearing before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, December 15, 2005. While 340B hospitals can receive the benefits of group purchasing through the PVP, the PVP does not have any contracts for IVIG.

prices—paying about $20,000 to $25,000 more per month than what it would have paid if it could have purchased it at 340B prices.

Although manufacturers' distribution of IVIG at 340B prices may not meet 340B hospitals' demand, some stakeholders, such as drug manufacturers, reported that changes in the amount of IVIG allocated for sale at 340B prices could negatively affect non-340B providers' access to these drugs. For example, one IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of the drug purchased by providers in 2004—allocating 95 percent of its projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B price.[48] This manufacturer stated that its distribution was fair, and that changing distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs. However, HRSA officials told us that the allocation of IVIG in this way is not sufficient or fair. Nearly a third of the nation's hospitals currently participate in the 340B program, and one large GPO we interviewed reported that 340B hospitals tended to be the bigger hospitals in the company's membership base.[49] Thus, if other manufacturers similarly restrict the distribution of IVIG at 340B prices, it is unlikely that covered entities' demands will be met at the 340B price.[50]

Stakeholders reported that manufacturers' distribution of drugs at 340B prices also affected providers' access to drugs when the 340B prices dropped significantly. In certain cases, when the 340B price of a drug dropped, some covered entities stockpiled the drug, which resulted in shortages in the supply for other providers, including other covered entities. For example, two covered entities we interviewed reported challenges accessing drugs when their 340B prices dropped, because other entities purchased large amounts of these drugs. In other cases

[48]This manufacturer reported that it based its allocation of IVIG on 2004 purchasing patterns, because this was the last period before demand exceeded supply for the product and an allocation system became necessary. While data on the number of hospitals participating in the 340B program in 2004 are not available, the number of 340B hospitals has grown from 591 in 2005 to 1,673 in 2011.

[49]While certain 340B hospitals are prohibited from purchasing outpatient drugs through GPOs, all 340B hospitals can purchase inpatient drugs through GPOs.

[50]The Department of Justice is examining the IVIG market in the United States, in part, due to concerns about the distribution of these drugs at 340B prices.

when the 340B prices dropped, manufacturers restricted the distribution of those drugs at 340B prices to ensure that all providers had equitable access. For example, one manufacturer reported that after the price of an oral contraceptive dropped to a penny as a result of HRSA's penny pricing policy, it received an order from a covered entity that exceeded the manufacturer's current national supply by 50 percent. In response, this manufacturer consulted with HRSA to ensure compliance with the agency's nondiscrimination guidance and restricted the distribution of drugs at 340B prices by allocating its supply based on the projected demand in the market and providers' past purchasing patterns.

HRSA's Oversight of the 340B Program Is Inadequate

HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance. Changes in the settings where the program is used may heighten concerns about the inadequacy of HRSA's oversight, and HRSA's plans for improving oversight are uncertain.

HRSA's Oversight Is Inadequate to Ensure Participants' Compliance with 340B Program Requirements

HRSA's oversight of the 340B program is inadequate because it primarily relies on covered entities' and manufacturers' self-policing—that is, participants ensuring their own compliance with program requirements. Upon enrollment, HRSA requires both covered entities and manufacturers to certify that they will comply with applicable 340B program requirements and any accompanying agency guidance. As part of this certification, agency officials told us that they expect participants to develop the procedures necessary to ensure compliance, maintain auditable records that demonstrate compliance, and inform HRSA if violations occur. For example, covered entities must develop adequate safeguards to prevent drugs purchased at 340B prices from being diverted to non-eligible patients, such as inventory tracking systems that separately purchase and dispense 340B drugs, and manufacturers must ensure that they properly calculate the 340B price of their drugs. In both cases, program participants must keep auditable records that can show that they have complied with program requirements and produce that documentation if requested by HRSA.

HRSA officials told us that covered entities and manufacturers can also monitor each other's compliance with program requirements, but in practice, participants may face limitations to doing so. For example, two covered entities we interviewed reported that it is difficult to determine whether they have been charged correctly for drugs because manufacturers' calculations of 340B prices are not transparent—namely,

there is no centralized list of 340B prices.[51] An organization representing covered entities also told us that its members had reported this difficulty. Similarly, three drug manufacturers we interviewed reported that, although they sometimes have suspected covered entities of diverting 340B drugs, it is difficult to prove diversion took place. An organization representing some manufacturers explained that, although manufacturers have the authority to audit covered entities, they have only conducted them in egregious circumstances, because agency requirements for these audits—such as a requirement to hire an independent third party to conduct the audits—are costly and administratively burdensome.

HRSA's guidance on key program requirements often lacks the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others' compliance and raising concerns that the guidance may be interpreted in ways that are inconsistent with its intent.[52] For example, HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly. Stakeholders we interviewed, including those representing covered entities and drug manufacturers, raised concerns that the guidance will be interpreted too broadly leading to cases of unintended diversion—that is, using 340B drugs for individuals who HRSA did not intend as eligible patients, but who may not be clearly prohibited in the guidance. However, one of these stakeholders representing covered entities also noted that, in order to ensure compliance, some entities may adhere to a narrow interpretation of the guidance and thus, limit the benefit of the program for their organization. The agency itself has recognized the need to further specify the definition of a 340B patient to ensure that it is interpreted correctly.

[51]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

[52]In May 2011, HRSA published its first proposed regulation on the 340B program, Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 76 Fed. Reg. 29, 183 (proposed May 20, 2011). Until this point the agency had provided program guidance through notices published in the Federal Register, which were typically finalized after a notice and comment period, as well as more informal guidance on its web site.

For example, HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through "other arrangements," as long as the responsibility for care provided remains with the entity. However, HRSA does not define "other arrangements," and officials told us that what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care.

In addition, HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program.[53] Rather, the agency bases eligibility for these hospitals on the application of broad statutory requirements that they are either formally delegated governmental powers by a unit of a state or local government or have a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. HRSA has stated that the determination of whether hospitals meet the first requirement is evaluated by the agency on a case-by-case basis. For the second requirement, HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals.[54] Therefore, hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended.

[53]We use the term hospitals that are not publicly owned or operated to refer to public and private, nonprofit corporations as well as private, nonprofit hospitals that may be eligible for the 340B program. The term does not include private, for-profit hospitals as these hospitals are not eligible for the 340B program.

[54]HRSA officials told us that contracts are selectively reviewed if further clarification is necessary.

Moreover, HRSA's nondiscrimination guidance is not specific in the practices that manufacturers should follow to ensure that drugs are equitably distributed to covered entities and non-340B providers when distribution is restricted. Some stakeholders we interviewed, such as covered entities, have raised concerns about the way IVIG manufacturers have interpreted and complied with the guidance in these cases, because covered entities have sometimes had to purchase IVIG at higher, non-340B prices. Additionally, given current guidance, one stakeholder reported that manufacturers can offer a certain amount of drugs at 340B prices, and while the distribution may not be equitable, still contend that they are complying with the guidance. Although PPACA included a provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, officials told us they do not have plans to provide any additional specificity to the nondiscrimination guidance.

Finally, in the case of HRSA's penny pricing policy, agency officials told us that it is well understood by 340B stakeholders and manufacturers we interviewed were generally aware of the policy. However, the agency has never formalized guidance in writing and there have been documented cases of manufacturers charging covered entities more than a penny for drugs when the policy should have been in effect.[55]

Beyond relying on participants' self-policing, HRSA engages in few activities to oversee the 340B program and ensure its integrity, which agency officials said was primarily due to funding constraints. For example, HRSA officials told us that the agency verifies eligibility for the 340B program at enrollment, but does not periodically recertify eligibility

[55]In a 2006 report, the HHS Office of Inspector General found that manufacturers did not always follow HRSA's penny pricing policy. Both in this report and in a 2005 report, the Office of Inspector General recommended that HRSA formalize its penny pricing policy in writing. See HHS Office of Inspector General, *Review of 340B Prices*, OEI-05-02 -00073 (Washington, D.C.: 2006); and HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

for all covered entity types.[56] As a result, there is the potential for ineligible entities to remain enrolled in the program. In addition, HRSA officials told us that they do not require a review of the procedures participants put in place to ensure compliance, and, although the agency has the authority to conduct audits of program participants to determine whether violations have occurred, it has never done so.[57] For example, officials said that they do not verify whether covered entities have systems in place to prevent diversion. Also, while HRSA encourages manufacturers to work with the agency to develop processes for restricting the distribution of drugs that are equitable to covered entities and non-340B providers, the agency only reviews manufacturers' plans to restrict access to drugs at 340B prices if a manufacturer contacts HRSA or concerns with a plan are brought to the agency's attention. Similarly, although HRSA calculates 340B prices separately from manufacturers, officials told us that, at this time, the agency does not use these calculations to verify the price that manufacturers charge covered entities, unless an entity reports a specific pricing concern.[58]

HRSA's oversight activities are further limited because the agency lacks effective mechanisms to resolve suspected violations and enforce program requirements when situations of non-compliance occur. If covered entities and manufacturers are not able to resolve conflicts on their own, HRSA has had an informal dispute resolution process in place since 1996 through which program participants can request that HRSA

[56]HRSA currently recertifies eligibility for sexually transmitted diseases, tuberculosis, and Ryan White grantees, consistent with requirements under the PHSA. In addition, HRSA verifies the grantee status of FQHCs as well as hospitals' DSH percentages on a quarterly basis. As resources allowed, HRSA has also periodically recertified 340B eligibility for other entity types. For example, HRSA recertified eligibility for family planning clinics in 2010. PPACA added a provision requiring HRSA to conduct annual recertification of eligibility for all covered entity types. HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[57]HRSA officials told us that while they do not conduct audits, if a potential violation of program requirements is brought to their attention, they will refer the matter to the HHS Office of Inspector General. Officials said that they have made two such referrals in the past year related to the diversion of 340B drugs.

[58]HRSA previously operated a voluntary pilot program with manufacturers to improve the integrity of 340B pricing calculations. Twelve manufacturers participated in the program, which was discontinued in March 2008 due to concerns regarding the confidentiality of drug pricing data and a lack of funding to run the program.

review evidence of a suspected violation and the agency then decides whether to initiate the process. However, despite reports by program participants about suspected violations they were unable to resolve on their own, HRSA officials told us that they have only initiated the dispute resolution process twice since its inception.[59] Additionally, HRSA has not issued regulations implementing monetary penalties for non-compliance established by PPACA, and HRSA has rarely utilized the sanctions that existed prior to PPACA. For example, participants found to be in violation of 340B program requirements face termination from the program. Yet according to HRSA officials, since the program's inception, only two covered entities have been terminated from the program due to findings of program violations and no manufacturer has ever been terminated for this reason.[60] Covered entities also are expected to pay back manufacturers for discounts received while out of compliance, and manufacturers are expected to pay back covered entities for overcharges. However, HRSA has not enforced these expectations and officials were unable to tell us the extent to which repayments have occurred.

Because of HRSA's reliance on self-policing to oversee the 340B program as well as its nonspecific guidance, the agency cannot provide reasonable assurance that covered entities and drug manufacturers are in compliance with program requirements and is not able to adequately assess program risk. As a result, covered entities may be inappropriately

[59]For example, a covered entity we interviewed said that it suspected certain drug manufacturers of implementing strategies to avoid offering drugs at correct 340B prices, but because of the lack of transparency in how 340B prices are calculated, could not determine this on its own. According to the entity, when it contacted HRSA about these strategies, agency officials said that they did not have the resources to help. However, HRSA officials told us that they were unaware of any instances where the agency has not helped a covered entity under these circumstances. Officials from one manufacturer reported that it provided HRSA with evidence that a covered entity had engaged in multiple instances of diversion, and after attempting to resolve the instances with the entity on its own, requested a hearing through the dispute resolution process in January of 2010. HRSA officials told us that the agency dismissed the manufacturer's request to initiate the process, because the covered entity disputed the manufacturer's claim that it had attempted to resolve the issue on its own, and that the agency is currently considering the manufacturer's appeal of this dismissal.

[60]In a 2005 report on the 340B program, the HHS Office of Inspector General noted that terminating a manufacturer from the 340B program also means that the manufacturer would be terminated from the Medicaid program, making it a difficult sanction to put into practice, given the effects on access to medications for Medicaid beneficiaries. See HHS Office of Inspector General, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Washington, D.C.: 2005).

claiming 340B discounts from drug manufacturers or qualifying for the program when they should not be, potentially increasing the likelihood that manufacturers will offset providing lower prices to covered entities with higher prices for others in the health care system. Additionally, manufacturers may be charging covered entities more than the 340B price for drugs, which would limit the benefit of the program for these entities.

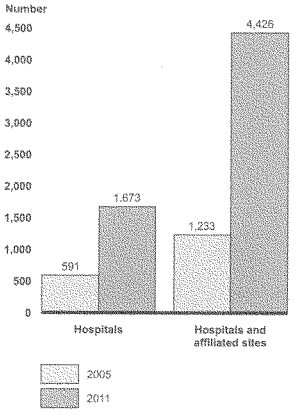
Changes in the Settings Where the 340B Program Is Used May Heighten Concerns about HRSA's Inadequate Oversight

Over time, the settings where the 340B program is used have shifted to more contract pharmacies and hospitals than in the past. According to HRSA officials, the number of covered entities using contract pharmacies has grown rapidly since its new multiple contract pharmacy guidance was issued in March 2010—as of July 2011, there were over 7,000 contract pharmacy arrangements in the program.[61] Hospitals' participation in the 340B program has also grown markedly in recent years. In 2011, the number of hospitals participating in the program was nearly three times what it was in 2005, and the number of these organizations, including their affiliated sites, was close to four times what it was in 2005 (see fig. 2).[62] Further, although participation in the 340B program has increased among other covered entity types over time, hospitals' participation in the 340B program has grown faster than that of federal grantees. In 2005, hospitals represented 10 percent of program participants, and as of July 2011, they represented 27 percent.

[61]HRSA was unable to provide the precise rate of growth of contract pharmacies within the 340B program due to data limitations. Specifically, HRSA currently only tracks contract pharmacy arrangements and is working to develop the ability to capture individual contract pharmacies. Data on the number of contract pharmacy arrangements are the most recent available from HRSA's covered entity database.

[62]One reason for hospital growth could be that more hospitals may have become eligible as a result of state-level Medicaid expansions in recent years. The number of Medicaid patients served by a hospital affects its DSH adjustment percentage, which helps determine hospital eligibility for the 340B program.

Figure 2: 340B Program Participation among Hospitals and Their Affiliated Sites, 2005 and 2011



Source: GAO analysis of HRSA data.

Note: 2005 was the earliest year data were reliable for hospitals without their affiliated sites.

Increased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program. Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies. For example, contract pharmacies are more likely to serve both patients of covered entities and others in the community; in these cases more sophisticated inventory tracking systems must be in place to ensure that 340B drugs are not diverted—intentionally or unintentionally—to non-340B patients.[63]

[63]Some covered entities have in-house pharmacies that also serve as retail pharmacies for the broader community. However, among the covered entities we interviewed, we found that this was not often the case.

Also, for a number of reasons, operating the 340B program in the hospital environment creates more opportunities for drug diversion compared to other covered entity types. First, hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed and must ensure that inpatients do not get 340B drugs. Second, hospitals tend to have more complex contracting arrangements and organizational structures than other entity types—340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. In light of this and given HRSA's nonspecific guidance on the definition of a 340B patient, broad interpretations of the guidance may be more likely in the hospital setting and diversion harder to detect. Third, hospitals dispense a comparatively larger volume of drugs than other entity types—while representing 27 percent of participating covered entities, according to HRSA, DSH hospitals alone represent about 75 percent of all 340B drug purchases.

The increasing number of hospitals participating in the 340B program has raised other concerns for some stakeholders we interviewed, such as drug manufacturers, including whether all of these hospitals are in need of a discount drug program. Nearly a third of all hospitals in the U.S. currently participate in the 340B program, and HRSA estimates that more may be eligible.[64] The number of hospitals eligible to participate may increase due to PPACA's Medicaid expansion, because the number of Medicaid patients served by a hospital affects its DSH adjustment percentage—one factor that determines hospital eligibility. Further, one organization we interviewed questioned whether the DSH adjustment percentage is the best measure to determine hospitals' eligibility for the 340B program, because of research indicating that it may not be an adequate proxy for the amount of uncompensated care a hospital provides.[65] The DSH hospitals we interviewed reported a wide range of payer mixes—with the percentage of Medicaid and uninsured patients ranging from about 15 percent of total patient volume for one hospital to about 85 percent for another. However, payer mix may not be the only factor to consider when identifying hospitals that provide care to the

[64]According to HRSA, over 400 additional DSH hospitals may be eligible for the 340B program based on their DSH adjustment percentage. This estimate does not include the additional hospital types made eligible for the program through PPACA.

[65]See MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: 2007), pp.78-79.

medically underserved and are part of the health care safety net. There is no established definition of a safety net hospital, and some researchers have argued that it should include factors other than payer mix, for example the disproportionate provision of critical services, that are either too expensive or unprofitable for other hospitals to provide, such as emergency room or trauma care.[66]

HRSA's Plans to Improve Oversight of the 340B Program Are Uncertain and May Not Address All Areas of Concern

While PPACA's 340B program integrity provisions address many of the deficiencies in HRSA's current approach to oversight, the agency has taken few steps to implement these provisions. PPACA requires HRSA to increase oversight of both covered entities and manufacturers, and outlines specific steps for HRSA to take in accomplishing this goal. (See table 2 for the 340B program integrity provisions included in PPACA.) However, according to officials, the agency does not have adequate funding to implement the integrity provisions. Officials also noted that once funding is secured, it could take several years to develop the systems and regulatory structure necessary to implement them.

[66]See for example, Barbara Wynn, et. al., "Analysis of the Joint Distribution of Disproportionate Share Hospital Payments," *PM-1387-ASPE* (Washington, D.C.: 2002); and Megan McHugh, Raymond Kang, and Romana Hasnain-Wynia, "Understanding the Safety Net: Inpatient Quality of Care Varies Based on How One Defines Safety-Net Hospitals," *Med Care Research and Review*, published online April 27, 2009.

Table 2: Key 340B Program Integrity Provisions Included in PPACA

Program participant	Requirements for HRSA	Required start date	Implementation status as of August 2011
Covered entities	Conduct annual recertification of eligibility for all covered entity types.	Not specified[a]	Developing implementation plan[b]
	Develop more detailed guidance on the procedures covered entities can follow to avoid the Medicaid duplicate discount.	Not specified[a]	Not started
	Establish a standard identification system for all covered entities by which each covered entity site can be identified for the purposes of ordering, purchasing, and delivery of 340B drugs.	Not specified[a]	Not started
	Impose certain sanctions on covered entities that knowingly and intentionally divert 340B drugs, by one or more of the following: • requiring a covered entity to pay manufacturers interest on the discounts they received for those drugs; • if the violation was also systematic and egregious, terminating the covered entity from the program and prohibiting re-enrollment for a period of time; and • referral to federal authorities.	Not specified[a]	Not started
Manufacturers	Improve mechanisms to ensure manufacturers charge the correct 340B prices on drugs, including: • making a centralized list of HRSA-verified 340B prices available to covered entities, • conducting selective audits of manufacturers, and • establishing procedures by which manufacturers repay covered entities for overcharges.	Not specified[a]	Not started
	Impose civil monetary penalties on manufacturers that knowingly and intentionally charge covered entities more than the 340B price.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking
Both	Develop a formal dispute resolution process, including: • establishing procedures for covered entities to obtain information from manufacturers,[c] and • requiring manufactures to audit covered entities prior to submitting a request to initiate the dispute resolution process.	Must issue regulations 180 days after enactment	Issued advanced notice of proposed rulemaking

Source: GAO analysis of Pub. L. No. 111-148, § 7102, 124 Stat. 119, 823 and interviews with HRSA officials.

[a]PPACA provides that these activities are to be conducted from amounts appropriated under a new authorization of appropriations. As of August 2011, no such appropriations have occurred.

[b]HRSA officials told us that the Office of Pharmacy Affairs' fiscal year 2011 budget allowed for the planning of a phased approach to recertification of all entity types, which is scheduled to begin in the fall of 2011. As of August 2011, officials were not able to tell us which entity types would be phased in first.

[c]Prior to PPACA, covered entities did not have access to 340B pricing data in order to monitor manufacturers because the Social Security Act prohibited the disclosure of the data by HRSA and state Medicaid agencies. 42 U.S.C. § 1396r-8(b)(3)(D). PPACA added a provision to Section 340B requiring that covered entities be allowed access to 340B pricing data. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 824 (adding 42 U.S.C. § 256b(d)(1)(iii)).

Independent of the provisions in PPACA, HRSA also has recently developed guidance to further specify the definition of a 340B patient. While the Office of Management and Budget completed its review of this definition in April 2011, as of August 2011, HRSA had not yet released it for stakeholder comment. In 2007, HRSA also proposed updating this guidance, but it was never finalized.[67]

Even if HRSA implements PPACA's provisions and updates its definition of a patient, these steps may not be sufficient to address all areas of concern. For example, PPACA specifically requires HRSA to conduct selective audits of manufacturers, but it did not establish the same requirement for audits of covered entities. As such, the effectiveness of HRSA's oversight of covered entities will, in part, be dependent on what additional steps the agency takes to ensure program integrity. Similarly, if in implementing PPACA's provision prohibiting manufacturers from discriminating against covered entities in the sale of 340B drugs, HRSA does not add specificity to the existing nondiscrimination guidance, it may be inadequate to ensure that all providers are able to equitably access drugs, particularly when manufacturers restrict the distribution of drugs at 340B prices. Also, as part of its 2007 proposed guidance on the definition of a patient, HRSA requested stakeholder comment on the elements that should be required in private, nonprofit hospitals' contracts with state or local governments as well as the different situations in which hospitals that are not publicly owned or operated should be formally granted government powers. However, HRSA officials told us that they have not issued additional guidance on these issues, and that they are not addressed in the clarifying guidance on the definition of a patient currently awaiting agency approval.

Conclusions

The 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services, and we found that the covered entities we interviewed reported using it for these purposes. However, HRSA's current approach to oversight does not ensure 340B program integrity, and raises concerns that may be exacerbated by changes within the program. According to HRSA, the agency largely relies on

[67]Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of a "Patient," 72 Fed. Reg. 1543 (Jan. 12, 2007).

participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers. As a result, HRSA may not know when participants are engaging in practices that are not in compliance. Furthermore, we found that HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements. There also is evidence to suggest that participants may be interpreting guidance in ways that are inconsistent with the agency's intent. Finally, participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance. With the program's expansion, program integrity issues may take on even greater significance unless effective mechanisms to monitor and address program violations, as well as more specific guidance are put in place. For covered entities, this may be particularly true in settings where there is heightened concern about the opportunities for the diversion of 340B drugs.

PPACA outlined a number of provisions that, if implemented, will help improve many of the 340B program integrity issues we identified. For example, PPACA requires HRSA to recertify eligibility for all covered entity types on an annual basis, which would help ensure entities that lose eligibility for the program do not remain enrolled. Additionally, PPACA requires HRSA to develop a formal dispute resolution process, including procedures for covered entities to obtain information from manufacturers, and maintain a centralized list of 340B prices—provisions that would help ensure covered entities and manufacturers are better able to identify and resolve suspected violations. PPACA also requires HRSA to institute monetary penalties for covered entities and manufacturers, which gives program participants more incentive to comply with program requirements. Finally, PPACA requires HRSA to conduct more direct oversight of manufacturers, including conducting selective audits to ensure that they are charging covered entities the correct 340B price.

However, we identified other program integrity issues that HRSA should also address. For example, the law does not require HRSA to audit covered entities or further specify the agency's definition of a 340B patient. While HRSA has developed new proposed guidance on this definition, it is uncertain when, or if, the guidance will be finalized. Because the discounts on 340B drugs can be substantial, it is important for HRSA to ensure that covered entities only purchase them for eligible patients both by issuing more specific guidance and by conducting audits of covered entities to prevent diversion. Additionally, while PPACA included a provision prohibiting manufacturers from discriminating against

covered entities in the sale of 340B drugs, HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance. Absent additional oversight by the agency, including more specific guidance, access challenges covered entities have faced when manufacturers' have restricted distribution of IVIG at 340B prices may continue and similar challenges could arise for other drugs in the future.

Also, current HRSA guidance may allow some entities to be eligible for the program that should not be. Hospitals qualify for the 340B program in part based on their DSH adjustment percentage. Even though the PHSA establishes additional eligibility requirements for hospitals that are not publicly owned or operated, these requirements are broad, and HRSA has not issued more specific guidance to implement them. We found that nearly a third of all hospitals in the U.S. are participating in the 340B program, more are currently eligible and not participating, and more may become eligible as Medicaid is expanded through PPACA. As the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system. As such, it is important that HRSA take additional action to ensure that eligibility for the 340B program is appropriately targeted. While HRSA officials reported that the agency does not have the resources to implement the PPACA provisions or otherwise increase oversight of the 340B program, limited resources could be prioritized to address areas of greatest risk to the program.

Recommendations for Executive Action

PPACA contained several important program integrity provisions for the 340B program, and additional steps can also ensure appropriate use of the program. Therefore, we recommend that the Secretary of HHS instruct the administrator of HRSA to take the following four actions to strengthen oversight:

- conduct selective audits of 340B covered entities to deter potential diversion;
- finalize new, more specific guidance on the definition of a 340B patient;
- further specify its 340B nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices; and

- issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program.

Agency Comments and Our Evaluation

In commenting on a draft of this report, HHS stated that it agreed with our recommendations. HHS also had additional comments on several content areas of the report, and we made changes as appropriate to address these comments. (HHS' comments are reprinted in appendix III.) Finally, HHS provided technical comments, which we incorporated as appropriate.

HHS stated that HRSA would continue to work on 340B program integrity efforts and prioritize these efforts based on available funding. HHS also outlined steps that HRSA plans to take in response to each of our recommendations. While we appreciate HHS' commitment to improving oversight of the 340B program, we are concerned that the steps are not sufficient to ensure adequate oversight.

With regard to our first recommendation that HRSA conduct selective audits of covered entities to deter potential diversion, HHS stated that HRSA will continue working with manufacturers to identify and address potential diversion and implement a plan to better educate covered entities about diversion. However, HHS did not state that HRSA will conduct its own audits of covered entities and we reiterate the importance of the agency doing so as part of its ongoing oversight responsibilities.

With regard to our second recommendation that HRSA finalize new, more specific guidance on the definition of a 340B patient, HHS stated that HRSA will review the draft of proposed guidance to update the definition and revise this guidance in light of changes in PPACA. While we agree that it may be important for HRSA to consider the impact of PPACA on the definition, given that PPACA became law more than a year ago, and the potential for broad interpretations of current guidance, we encourage HRSA to complete its review in a timely fashion.

With regard to our third recommendation, that HRSA further specify its non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices, HHS stated that HRSA will: implement a plan to specify existing policy regarding 340B non-discrimination and drug distribution; provide clearer guidance to manufacturers for working with HRSA and develop specific allocation

plans where needed; and continue to work with the Department of Justice when fair, voluntary allocation plans are not developed. However, we are concerned that these steps do not require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices. Without taking this step, HRSA may not know when manufacturers are inequitably distributing drugs to covered entities and non-340B providers.

With regard to our fourth recommendation that HRSA issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B program, HHS stated that HRSA will implement a plan to better educate covered entities on existing criteria for hospital participation in the program and initiate a phased approach to recertifying eligibility for all participating covered entities. Here, we are concerned that these steps do not include further specification of eligibility criteria for hospitals that are not publicly owned or operated, because we determined that additional specification of statutory requirements was needed to ensure that the 340B program is appropriately targeted.

We are sending copies of this report to the Secretary of HHS and appropriate congressional committees. In addition, the report is 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 contact me at (202) 512-7114 or at draperd@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 key contributions to this report are listed in appendix IV.

Debra A. Draper
Director, Health Care

Appendix I: Selection of Interviews with Program Stakeholders

Type of stakeholder	Number of stakeholders interviewed	Interview details

Covered entities	29	27 were selected to take into account certain criteria:
		• Entity Type:
		  • We selected five types of covered entities and specifically interviewed: 7 federally qualified health centers (FQHC), 5 disproportionate share hospital (DSH) hospitals, 5 hemophilia treatment centers, 5 family planning clinics, and 5 AIDS Drug Assistance Programs (ADAP). (See appendix II for a list of all entities eligible to participate in the program.)
		  • We picked these types based on:
		  • variation in operational structure,
		  • variation in services and drugs provided,
		  • high levels of 340B participation,
		  • experience with the program, and
		  • potential difficulty accessing drugs at 340B prices.
		• Location:
		  • We selected entities in five states: Illinois, Massachusetts, Tennessee, Texas, and Utah.
		  • States were selected based on variation in a number of factors, including: geography, percent of uninsured individuals, and Medicaid reimbursement policies.[a]
		  • We included Massachusetts to gain a better understanding of the potential effect of the Patient Protection and Affordable Care Act (PPACA) health insurance reforms on the 340B program.[b]
		• We used information provided by trade organizations representing covered entities to help select individual covered entities to interview.
		2 additional DSH hospitals were selected based on concerns raised in stakeholder interviews about how these entities were using the program.

Drug manufacturers	6	Selected based on market share and those that produce drugs with reported challenges related to their distribution at 340B prices.
Organizations representing drug manufacturers and others involved in drug distribution	6	Includes 4 manufacturer trade organizations, 1 distributor, and 1 pharmacy benefits manager.[c]

Type of stakeholder	Number of stakeholders interviewed	Interview details
Organizations representing providers	16	Includes organizations representing providers, including covered entities and non-340B providers: • 9 organizations that represent covered entities, including 6 trade organizations and 3 private companies that provide services and information technology to help covered entities establish and manage their 340B programs. • 2 organizations representing non-340B providers, including 1 trade organization and 1 non-340B provider. • 5 organizations that represent both covered entities and non-340B providers, including 3 trade organizations and 2 group purchasing organizations (GPO).[d]
Federal agencies and contractors	4	HRSA, the contractors that help administer the 340B program, and the Centers for Medicare & Medicaid Services.
Total	**61**	

Source: GAO.

[a]Medicaid is a joint federal-state program that finances health care for certain categories of low-income individuals.

[b]In 2006, Massachusetts implemented comprehensive state-level health insurance reform that was similar to PPACA's national-level reform.

[c]Distributors manage the sale of drugs to purchasers on behalf of manufacturers. Pharmacy benefit managers administer the prescription drug benefits of health insurance plans on behalf of plan sponsors.

[d]GPOs contract with providers, such as hospitals, and, on behalf of their members, aggregate purchasing volume to negotiate discounts on drugs from drug manufacturers or distributors.

Appendix II: Select Information on Entities Eligible to Participate in the 340B Program

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Federal Grantees					
Federally-qualified health center (FQHC)[b,c]	Receives a section 330 grant under the Public Health Service Act (PHSA) (42 U.S.C. § 254b); meets the requirements to receive such a grant; or is an outpatient health program or facility operated by certain tribal or urban Indian organizations	Urban or rural health centers that provide comprehensive community-based primary and preventive care services to medically underserved populations.	1992[d]	4,826	Health Resources and Services Administration (HRSA)
Urban Indian organizations[e]	Receives funds under title V of the Indian Health Care Improvement Act (25 U.S.C. §§1651 et seq.)	Provide a variety of health programs to eligible individuals.	1992[d]	26	Indian Health Service
Family planning clinics (Title X)	Receives a grant or contract under Section 1001 PHSA (42 U.S.C. § 300)	Provide comprehensive family planning services.	1992[d]	3,868	Office of Population Affairs
Sexually transmitted diseases grantee	Receives funds under Section 318 of the PHSA (42 U.S.C. § 247c) and is certified by the Secretary of HHS	Provide screening and treatment for sexually transmitted diseases.	1992[d]	1,472	Centers for Disease Control and Prevention
Tuberculosis grantee	Receives funds under Section 317E of the PHSA (42 U.S.C. § 247b-6) and is certified by the Secretary of HHS	Provide treatment for tuberculosis.	1992[d]	1,221	Centers for Disease Control and Prevention
Native Hawaiian Health Centers	Receives funds under the Native Hawaiian Health Care Act of 1988 (42 U.S.C. §§ 11701 et seq.)	Provide comprehensive health promotion and disease prevention services to Native Hawaiians.	1992[d]	11	HRSA
State-operated Ryan White AIDS Drug Assistance Program (ADAP)	Receives financial assistance under title XXVI of the PHSA (42 U.S.C. §§ 300ff-11 et seq.)	Serve as a "payer of last resort" to cover the cost of providing HIV-related medications to low-income individuals who are uninsured or underinsured and cannot afford to pay for drugs or who cannot afford their health insurance coverage for drugs.	1992[d]	90[f]	HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Other Ryan White grantees	Receives a grant under Part C of title XXVI of the PHSA or non-governmental grantees that receive any financial assistance under title XXVI of the PHSA if certified by the Secretary of HHS	Provide primary care and support services to individuals with HIV or AIDS.	1992[d]	520	HRSA
Hemophilia treatment centers	Receives a grant under section 501(a)(2) of the Social Security Act (42 U.S.C § 701(a)(2))	Provide medical care to individuals with hemophilia.	1992[d]	99	HRSA
Black lung clinics	Receives funds under Section 427(a) of the Black Lung Benefits Act (30 U.S.C. § 937(a))	Provide medical treatment to individuals disabled from pneumoconiosis (black lung) as a result of their employment at U.S. coal mines.	1992[d]	13	HRSA
Hospitals					
Disproportionate share hospitals (DSH)	DSH as defined under Section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B)) with a DSH adjustment percentage greater than 11.75[g]	General acute care hospitals paid under the Medicare inpatient prospective payment system.	1992[d]	3,061	Centers for Medicare & Medicaid Services (CMS)
Children's hospitals	Children's hospital as described under Section 1886 (d)(1)(B)(iii) of the Social Security Act with a DSH adjustment percentage greater than 11.75[g]	Primarily provide services to individuals under 18 years of age.	2006[h]	147	CMS
Critical access hospitals	Critical access hospital as determined under Section 1820(c)(2) of the Social Security Act (42 U.S.C. § 1395i-4(c)(2)) (no DSH requirement)[g]	Located in rural areas, provide 24-hour emergency care services, and have no more than 25 inpatient beds.	2010[i]	941	CMS and HRSA
Sole Community Hospitals	Sole community hospital as defined under Section 1886(d)(5)(D)(iii) of the Social Security Act (42 U.S.C. § 1395ww(d)(5)(D)(iii))with a DSH adjustment percentage equal to or greater than 8[g]	Isolated from other hospitals by distance, weather, or travel conditions.	2010[i]	200	CMS and HRSA

Entity type	How entity qualifies for 340B	Description of covered entity type	Year added to 340B program	Number of sites enrolled by entity type (July 1, 2011)[a]	Administering agency within the Department of Health Human Services (HHS)
Rural Referral Centers	Rural referral center as defined under Section 1886(d)(5)(C)(i) of the Social Security Act (42 U.S.C. §1395ww(d)(5)(C)(i)) with a DSH adjustment percentage equal to or greater than 8[g]	Large rural hospitals that provide services for patients from a wide geographic area.	2010[f]	72	CMS and HRSA
Free-standing cancer hospitals	Free-standing cancer hospital as described under Section 1886 (d)(1)(B)(v) of the Social Security Act (42 U.S.C. § 1395ww(d)(1)(B(v))with a DSH adjustment percentage greater than 11.75[g]	Not a unit of another hospital, has a primary purpose of treating or conducting research on cancer.	2010[f]	5	CMS
Total				**16,572**	

Source: GAO analysis of federal laws and regulations.

[a]Data are the most recent available from HRSA's covered entity database and represent both covered entities and their associated sites. Because a covered entity may enroll under any and all eligible grant types it receives, it is possible that a site is reflected in the database more than once. However, HRSA estimates that this overlap represents less than 5 percent of all listings in the database.

[b]Not all FQHCs receive federal grants. Providers that meet all of the requirements for the FQHC program but do not receive federal grants are referred to as FQHC look-alikes and are eligible to participate in the 340B program.

[c]This category includes: FQHC look-alikes; Consolidated Health Centers; Migrant Health Centers; Health Care for the Homeless; Healthy Schools/Healthy Communities; Health Centers for Residents of Public Housing; and Tribal Organizations created under the Indian Self Determination Act (Pub. L.. No. 93-638) and administered by the Indian Health Service.

[d]Eligible to participate in the 340B program from its inception. See Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967.

[e]Section 1905(l)(2)(B) of the Social Security Act includes outpatient health programs or facilities operated by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services in the definition of FQHCs.

[f]According to HRSA, some states have both direct purchase and rebate programs, which are counted separately in the 340B covered entity database, which is the reason for the difference in the number of ADAPs in the database versus the number of states that have ADAP programs overall.

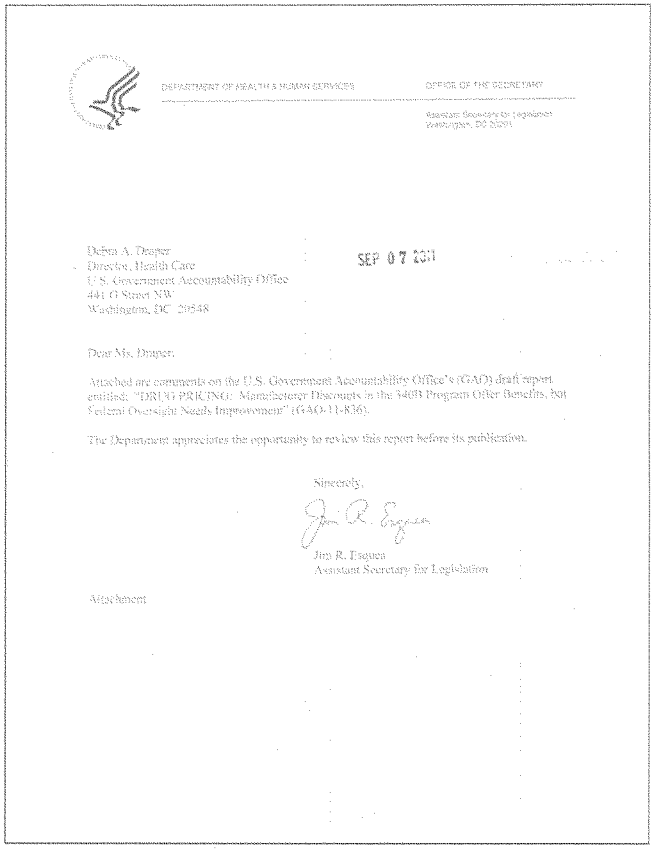
[g]Facility must also be (1) owned or operated by a state or local government, (2) a public or private, nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low income individuals who are not eligible for Medicaid or Medicare. Medicaid is the joint federal-state program that finances health care for certain low-income people, and Medicare is the federal health care program for the elderly and disabled. Children's hospitals and free-standing cancer hospitals do not receive payments under Medicare's inpatient prospective payment system; however, they must have a payer mix that would result in a DSH adjustment percentage greater than 11.75 percent. Facilities except critical access hospitals, Rural Referral Centers, and Sole Community Hospitals, must not obtain covered outpatient drugs through group purchasing.

[h]While PPACA explicitly added children's hospitals to the list of covered entities under the 340B program in the PHSA, they were originally made eligible under the Social Security Act through the Deficit Reduction Act of 2005. Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006).

[i]Became eligible to participate in the 340B program under PPACA. Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302,124 Stat.1029, 1082.

Appendix III: Comments from the Department of Health and Human Services

Note: Page numbers in the draft report may differ from those in this report.



DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 07 2011

Debra A. Draper
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Draper:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "DRUG PRICING: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement" (GAO-11-836).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

The Department appreciates the opportunity to review and comment on this draft report. We offer the following general comments on several content areas of the report.

The extent to which covered entities generate 340B revenue, factors that affect their revenue generation, and how entities use the program:

On Page 16, the report states that in Massachusetts where the state implemented universal health care, low-income patients gained private insurance, but "these patients often could not afford associated copayment or deductibles and the entity covered these costs". HRSA requests that the report reflect that this finding is consistent with the Health Resources and Services Administration's (HRSA) assessment that low-income patients will continue to require such assistance and the covered entities will provide valuable services to the safety net community.

On Page 18, the report states that "Even though the uses of revenue generated through the 340B Program were for similar purposes, some covered entities relied on 340B revenue more than others." The report goes on to state differences in revenue for FQHCs versus hemophilia centers. HRSA requests that the following explanation be incorporated into the report: Because each 340B entity type is unique in the types of services it provides and the patients it treats, the drug purchases of each entity type vary greatly (i.e., generics versus brand or certain specialty drugs); therefore, their savings will also vary greatly.

Regarding how manufacturers' distribution of drugs at 340B prices affects providers' access to drugs, whether those providers are covered entities or non-340B providers:

On Page 20, the report states that "One IVIG manufacturer reported that it restricted its distribution of IVIG by allocating its supply based on the amount of drug purchased by providers in 2004--allocating 95 percent of the projected monthly sales to non-340B providers and the remaining 5 percent to covered entities at the 340B Price" and "this manufacturer states that its distribution was fair and changing the distribution plans to increase the amount of IVIG drugs available at 340B prices could negatively affect non-340B providers' access to the drugs." HRSA requests that the report be edited to include:

> "HRSA does not believe that using the 2004 allocation of 95 percent to non-340B providers and 5 percent to 340B providers for a critical life saving drug is fair or sufficient. In 2005, there were 77 Hemophilia Treatment Centers and 591 Disproportionate Share Hospitals (DSH) purchasing IVIG through the 340B Program. This number has increased significantly to 99 Hemophilia Treatment Centers and

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

1,673 hospitals that now include children's hospitals, critical access hospitals, disproportionate share hospitals, free standing cancer hospitals, and rural referral centers. The allocation of IVIG drugs to 340B providers needs to be correlated to the increase in the 340B hospitals, as many of the same hospitals that purchased IVIG with no problems as non-340B providers in 2004 are now having tremendous difficulty in purchasing IVIG in 2011 as 340B providers. With 340B hospitals representing almost 33 percent of the hospitals of in the U.S. in 2011, 5 percent allocation for a life saving drug is not adequate."

On Page 21, the report states that some covered entities have stockpiled drugs when the price of a drug dropped. HRSA recommends that the report note that HRSA has worked with manufacturers in the past during an expected drop in price to develop an allocation process that is equitable across 340B and non-340B entities to prevent stockpiling. In addition, HRSA also encourages manufacturers to work with the agency to develop allocation processes to prevent issues with stockpiling.

HRSA's oversight of the 340B Program

On Page 24, the report states that HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program. HRSA requests that the report reflect that while HRSA has not published formal guidance in this area, HRSA has both criteria and a process in place to ensure hospitals satisfy 340B requirements. These criteria are utilized during the enrollment process and include:

- The criteria for hospital eligibility to participate in the 340B Program is outlined in section 340B(a)(4)(L)(i) which states the hospital "is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title." This information is on the HRSA Office of Pharmacy Affairs (OPA) website.
- Prior to enrolling a hospital into the Program, OPA verifies that the hospital meets the three statutory requirements for participation in the 340B program: 1) non-profit status is verified by IRS documentation; 2) DSH eligibility, if applicable, is verified by the Medicare cost report and 3) private hospitals must have a contract with state or local governments to provide health care services to low income

2

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan of Title XIX of the Social Security Act. As part of the registration process, the hospital must submit a form that attests to the aforementioned statement that is signed by both an authorized public official and a hospital executive. Contracts are selectively reviewed if further clarification is necessary.

- OPA provides hospitals a list of recommendations during the enrollment process that can be used in developing a contract. HRSA strongly recommends and encourages the covered entity to seek legal counsel when preparing these contracts.

On page 24, the report states that some stakeholders expressed concern about the application of the requirements against non-discrimination. The conclusion of the report states that absent additional guidance, "access challenges covered entities have faced when manufacturers' have restricted distribution of certain drugs at 340B prices may continue." The language in the conclusion suggests that several challenges are known and identified; however, in its report the only access challenges identified involved IVIG. HRSA has been working with the Department of Justice (DOJ) to evaluate and improve access to IVIG for 340B entities. HRSA recommends that GAO provide additional detail regarding the access challenges found in order for HRSA to address these concerns and take appropriate action.

On Page 25, the report states that HRSA verifies eligibility for 340B at enrollment, but does not periodically recertify eligibility for all covered entity types. HRSA requests that the report reflect that HRSA has been meeting the statutory requirement; HRSA recertified and continues to recertify STD, TB, and HIV/AIDS programs annually as expressly required under section 340B (a)(7) of the Public Health Services Act (42 U.S.C. 256b). These were the only entities that required annual certification by the Secretary prior to the PPACA. In addition, HRSA monitors DSH percentages and FQHC grant status on a quarterly basis. Each quarter OPA verifies the proprietary status of participating hospitals by matching its list of participating hospitals with CMS's list of hospitals to ensure that ineligible private hospitals are not participating. As a result of the PPACA, HRSA is required to annually recertify all 340B covered entities. OPA's FY2011 budget of $4.4M will allow for the planning of and initiation of a phased approach to recertification to begin in fall of 2011.

On Page 31, footnote (a) states that no appropriation has occurred for annual recertification. HRSA recommends that this statement be replaced with the following, "HRSA program FY2011 budget of $4.4M will allow for the planning and initiation of a phased approach to recertification to begin in fall 2011."

3

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

On Page 32, the report states that the PPACA specifically requires HRSA to conduct selective audits of manufacturers but it did not establish the same requirement for audits of covered entities. HRSA requests that the report clarify that the agency has had the authority to audit covered entities under section 340B(a)(5)(C) of the Public Health Service Act since the inception of the program.

GAO Recommendations

HRSA agrees with the recommendations and will continue to build on program integrity efforts and work to prioritize efforts based on funding. Implementation of a cost recovery fee as outlined in the FY 2012 President's budget would allow for the initiation of the implementation of all recommendations and program integrity provisions outlined in PPACA. The 340B Drug Pricing program integrity risk assessment is scheduled to begin in the fall of 2011.

GAO Recommendation #1: *Conduct selective audits of 340B covered entities to detect potential diversion.*

HRSA Actions:

- HRSA and the manufacturers have the authority to audit 340B covered entities. HRSA will continue to work with the manufacturers to identify potential diversion and work with manufacturers to develop audit plans where evidence suggests potential diversion may be occurring.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources, such as targeted webinars on diversion, peer to peer learning, FAQs, policy letters to covered entities, and more assistance to covered entities in assessing risk.

GAO Recommendation #2: *Finalize new, more specific guidance on the definition of a 340B patient.*

HRSA Actions:

- HRSA will review the draft of the proposed patient definition guidelines in view of PPACA changes and develop revised guidelines for publication.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "DRUG PRICING: MANUFACTURER DISCOUNTS IN THE 340B PROGRAM OFFER BENEFITS, BUT FEDERAL OVERSIGHT NEEDS IMPROVEMENT" (GAO-11-836)

Recommendation #3: *Further specify its 340B non-discrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices.*

HRSA Actions:

- HRSA will develop and implement a comprehensive educational and communication plan which will specify the existing policy regarding 340B non-discrimination and drug distribution to include, webinars, and policy letters to manufacturers regarding non-discrimination guidance.
- HRSA will continue to work with manufacturers to provide clearer guidance for manufacturers on working with HRSA and develop specific allocation plans where needed.
- HRSA will continue to work with DOJ when fair, voluntary allocation plans are not developed.

Recommendation #4: Issue guidance to further specify the criteria that hospitals that are not publicly owned or operated must meet to be eligible for the 340B Program.

HRSA Actions:

- HRSA will further publicize its existing criteria for hospital participation in the 340B program by placing the criteria and process on the program website and issuing policy letters to affected covered entities outlining these criteria.
- HRSA will initiate a phased approach to recertification for all participating entities, including hospitals, beginning in fall of 2011. This recertification process will enable HRSA to verify that hospitals continue to meet the statutory requirements for program participation.
- HRSA will develop and implement a comprehensive educational and communication plan which will build on existing tools and resources such as targeted webinars on the hospital criteria, peer to peer learning, FAQs, and letters to covered entities.

5

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact	Debra A. Draper, (202) 512-7114 or draperd@gao.gov
Staff Acknowledgments	In addition to the contact named above, Gerardine Brennan, Assistant Director; Jennie Apter; Kristin Ekelund; Kelli Jones; Dawn Nelson; Rachel Svoboda; and Jennifer Whitworth made key contributions to this report.

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Oncology Clinics Caught in Financial Vise

Published: Jul 27, 2013

By Charles Bankhead, Staff Writer, MedPage Today

save [A] [A]

Community oncology clinics continue to feel the squeeze of a changing reimbursement structure that has forced 288 clinics to close in the past 6 years.

If anything, the pace of closure, consolidation, and contraction has increased, with a 20% increase over the past year, which followed a 21% jump in closures between 2011 and 2012, according to the Community Oncology Alliance's (COA) Practice Impact Report.

Since the COA issued its first report in 2010, the number of community oncology clinic closures has increased by 67% (from 172).

An additional 43 oncology clinics have begun sending all of their patients elsewhere. All told, 1,338 community oncology clinics and practices have been adversely affected by changes in reimbursement practices, including 407 practices in financial straits, 469 that have entered into contractual arrangements with hospitals, and 131 that have merged or have been acquired by organizations other than hospitals.

"This is nothing new; it's been happening since 2005, when Medicare, which pays for roughly half of all cancer care, changed the way that they reimburse for cancer care," COA executive director Ted Okon told MedPage Today.

"You have two dynamics at work," he added. "Reimbursement was changed by Medicare, and over time, the private payers have followed suit. We've had reimbursement pressures that have put the pressure correspondingly on oncology practices. Those practices that have a large majority of patients who are Medicare beneficiaries simply have not been able to survive."

Rural Areas Hardest Hit

The pressures have disproportionately affected oncology clinics and practices in rural areas, which historically have been underserved.

However, other factors, some of them noneconomic, are at play, said Matt Farber, of the Association of Community Cancer Centers.

"The average age of physicians who are willing to be employees is declining," he said. "We are seeing more younger physicians coming into oncology who are happy to be an employee of a hospital or working within a system as opposed to being a partner or part owner or entrepreneur."

The current financial problems took root in 2003 with the Medicare Modernization Act, which introduced the Average Sales Price (ASP) to the reimbursement methodology associated with Medicare Part B drug coverage. According to the ASP formula, community oncology practices purchase the drugs, and Medicare reimburses the ASP plus a 6% service fee to cover the practices' acquisition and administration costs.

In congressional testimony in June, Barry Brooks, MD, of US Oncology, called the 6% add-on

"incredibly important because none of the work that must occur to prepare chemotherapy for administration to a patient is otherwise reimbursed by Medicare."

"Even in small clinics with one or two medical oncologists, the ancillary staff that do all of the above can be four to five highly trained professionals, and in larger clinics, the staffing is accordingly much larger," he added.

"Even if every drug were ready to be administered to a patient at the moment it arrived at the doorstep of the practice, paying exactly only acquisition for the drug would still be problematic and would not properly reflect the financial costs of inventory, as well as the significant infrastructure investment to manage and control this unique inventory."

Even with the 6% service fee, Medicare reimbursement has not kept up with rising costs, Brooks continued. Since 2006 Medicare part B reimbursement for drugs and biologics has remained essentially flat, whereas the Consumer Price Index has gradually increased, eroding the effective rate of the service add-on.

Hospitals Get More of the Money

Community oncology practices also have come out on the short end of a reimbursement disparity versus hospitals. Medicare has a substantially higher reimbursement rate for cancer drugs administered in a hospital outpatient clinic versus a community-based clinic. Not surprisingly, the disparity has driven more of the drug administration volume to hospitals.

In his congressional testimony, Brooks noted that the 2013 Medicare Physician Fee Schedule for a 1-hour intravenous infusion of chemotherapy was $143.24, compared with $230.50 allowed by the Hospital Outpatient Prospective Payment Schedule, a 61% difference.

Okon traces the pricing disparity to the 340B Drug Pricing Program enacted in 1992 to give "select safety net providers" a price break on drugs distributed and administered in the outpatient setting. Over the years, hospitals have become adept at taking advantage of the 340B program, which allows them to acquire drugs at discounts ranging as high as 60%.

"We've seen almost an explosion in the number of nonprofit hospitals that have applied for and have been granted 340B status," said Okon. "As a result, with those deep discounts, a lot of those hospitals have looked at increasing their inflow of drug revenue. The way to do that is to acquire an oncology practice, which has the largest flow of revenue attributed to chemotherapy."

Brooks told members of the House Energy and Commerce Health Subcommittee that 340B-certified hospitals have a margin in excess of 30% for Medicare drugs, whereas margin for community clinics typically ranges from 0 to -2.0%.

In late May, the Moran Company issued findings from a study commissioned by US Oncology, the COA, and ION Solutions. According to the report, hospitals' share of fee-for-service chemotherapy administration lines increased from 13.5% in 2005 to 33% in 2011. During the same period, Medicare payments for chemotherapy administration in hospitals went from $98.3 million to $300.9 million, whereas payments for physician office administration decreased by almost 15%.

The study also showed that:

- Hospitals' share of Medicare fee-for-service payments for chemotherapy administration increased from 16.2% in 2005 to 41.0% in 2011
- Hospitals' reimbursement for chemotherapy drugs more than doubled from $904.5 million to $2.03 billion versus a 32% increase in payments to physician offices ($2.63 billion to $3.47 billion)
- Hospitals' share of Medicare reimbursement for chemotherapy drugs increased from 25.6% to 37%
- Despite the reimbursement disparity, two-thirds of all chemotherapy for Medicare beneficiaries is delivered in physician offices

The latest financial body blow to community oncology clinics has come from the budget cuts mandated by sequestration. The 2% across-the-board cuts will affect the 6% service fee plus the acquisition costs for drugs purchased and administered to Medicare beneficiaries.

Brooks concluded his testimony by asserting, "Oncologists should not be put in the untenable position of continuing to treat patients at a loss, which will result in clinic closings or sending

seniors fighting cancer to the hospital for treatment in order to keep the clinic doors open."

Will Congress Bring Relief?

The community oncology industry has hopes of getting some relief from Congress. At least two pieces of legislation have been proposed to eliminate cuts to the service fees associated with chemotherapy administration and to ensure that community oncology providers benefit from any pricing discounts between drug distributors and manufacturers.

Stanching the flow of oncology practice from the community has to be a priority because once the change has occurred, the situation is unlikely to reverse itself, said Matt Brow, of McKesson Specialty Health and US Oncology. Any change of direction would require capital investment and other expenses that would put a start-up community clinic out of the reach of physicians and small organizations.

"It would be in the best interest of the government, the patients, the taxpayers, and the private payers over time to pay the same amount for the same service, regardless of the setting where it's provided," said Brow, adding that he expects to see legislation to that effect introduced in Congress in the near future.

Ultimately, patients will pay the price for the loss of community oncology services, said Okon. As more practices leave community settings, patients will have to travel longer distances to get cancer treatment and will have to pay more for that treatment.


TREND WATCH:
PHYSICIAN PRACTICE ACQUISITIONS
Jackson
HEALTHCARE

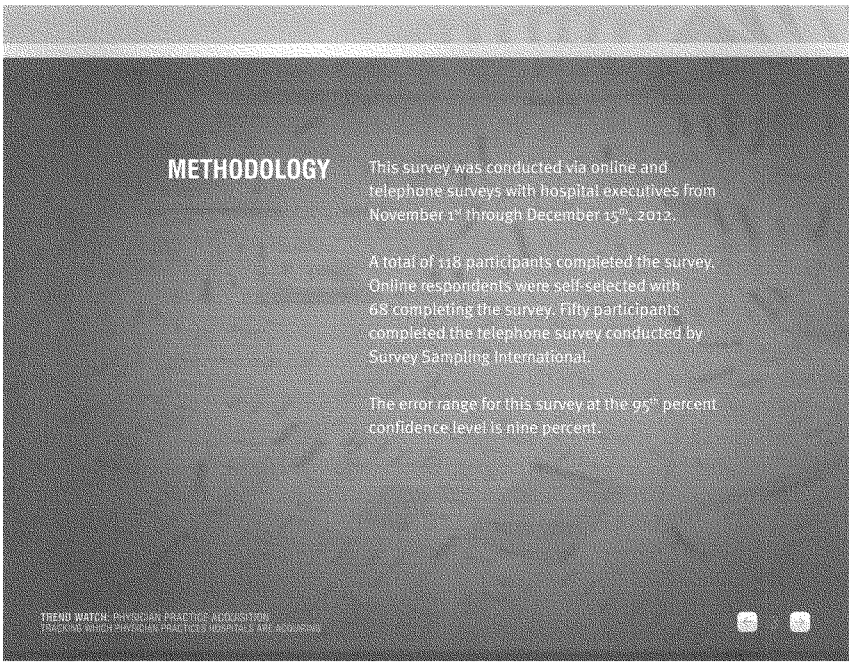
INTRODUCTION

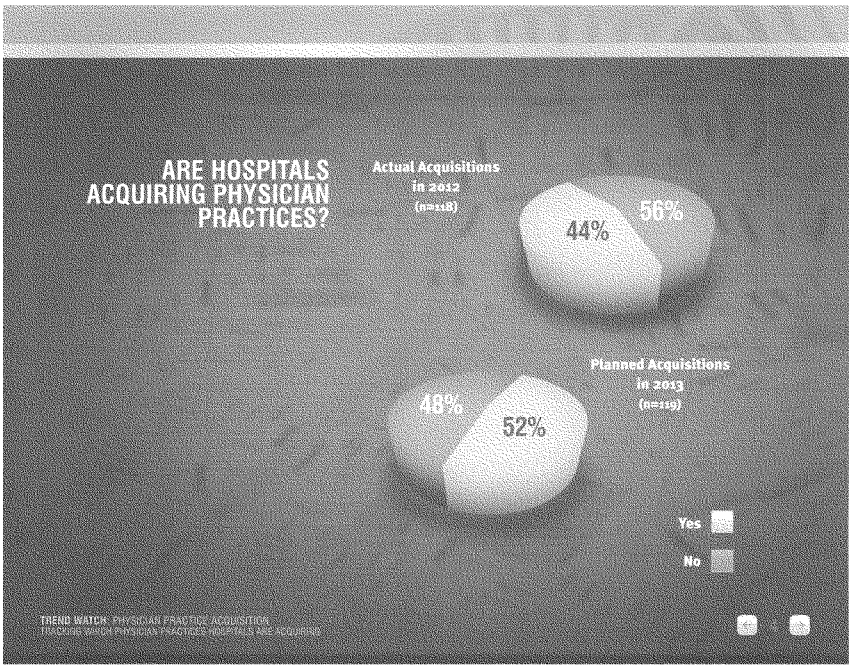
Are hospitals actively acquiring physician practices? If so, which specialties?

In this report, we share the findings of Jackson Healthcare's first national study of hospital practice acquisitions.

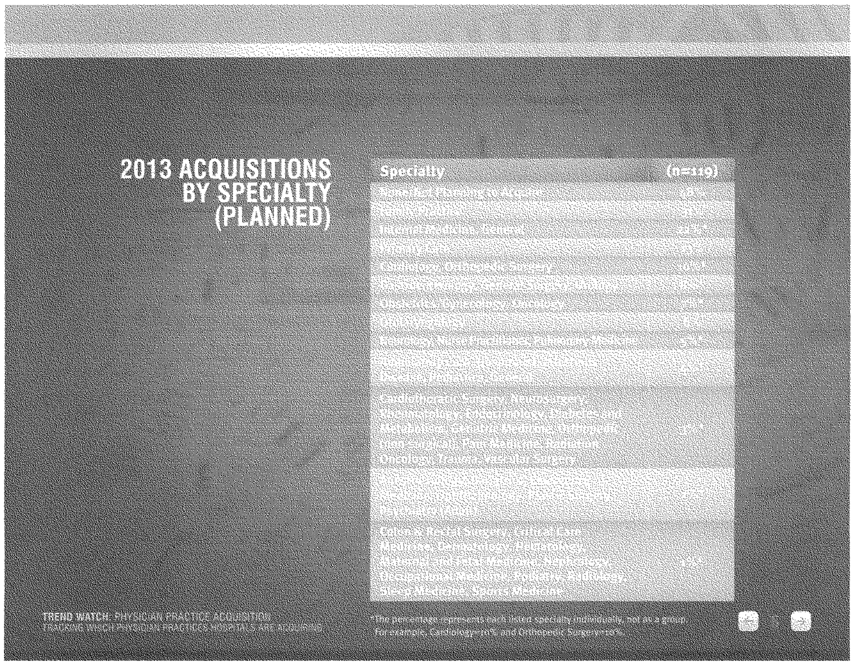
Key takeaways:

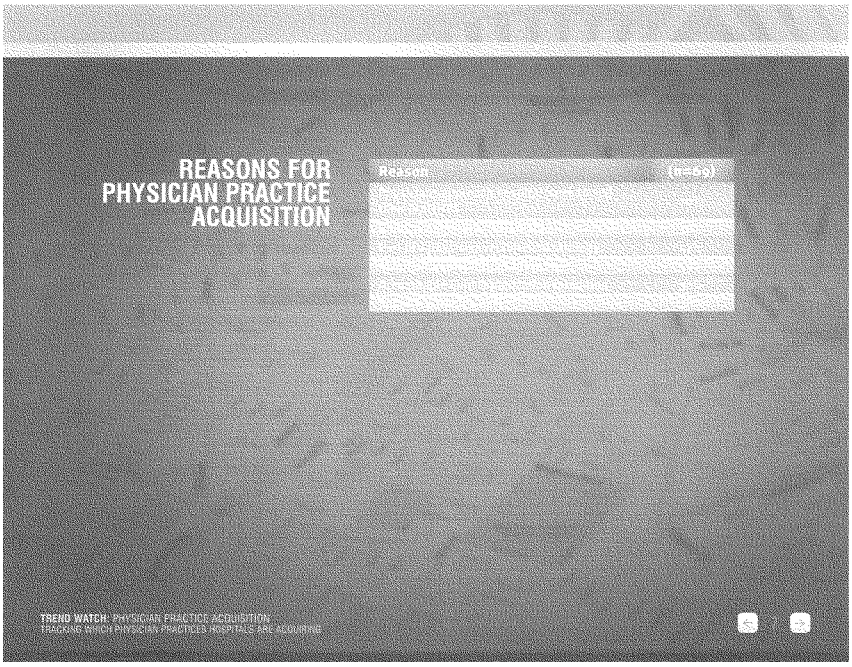
- ***Nearly half the hospitals surveyed are actively involved in physician practice acquisitions***
- ***Family practice and internal medicine are the primary targets***
- ***Hospitals acquire practices primarily for competitive positioning or through physician inquiries***

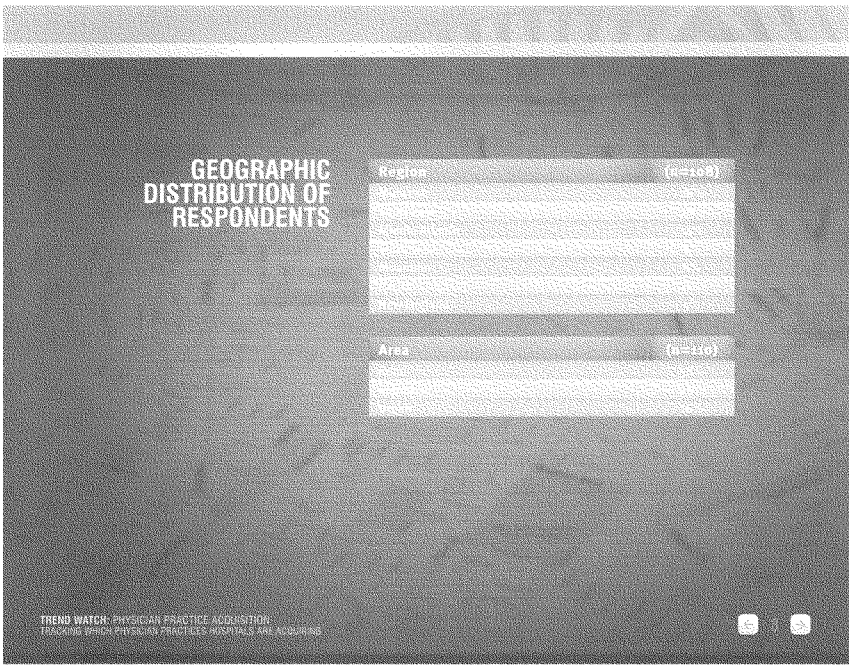

METHODOLOGY
This survey was conducted via online and telephone surveys with hospital executives from November 1st through December 15th, 2012.
A total of 118 participants completed the survey. Online respondents were self-selected with 68 completing the survey. Fifty participants completed the telephone survey conducted by Survey Sampling International.
The error range for this survey at the 95th percent confidence level is nine percent.
TREND WATCH: PHYSICIAN PRACTICE ACQUISITION
TRACKING WHICH PHYSICIAN PRACTICES HOSPITALS ARE ACQUIRING

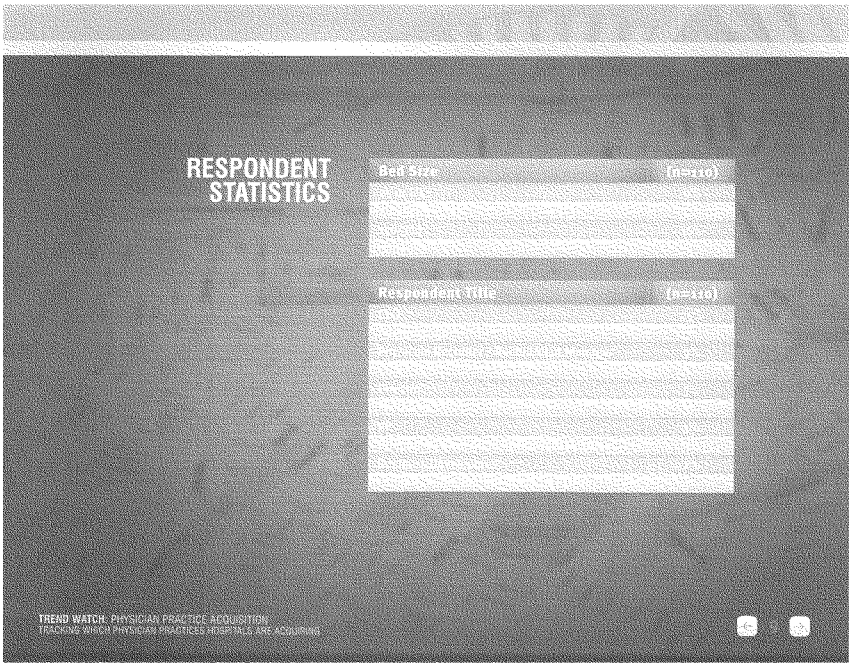

ARE HOSPITALS ACQUIRING PHYSICIAN PRACTICES?
Actual Acquisitions in 2012 (n=218)
44%
56%
Planned Acquisitions in 2013 (n=219)
48%
52%
Yes
No
TREND WATCH: PHYSICIAN PRACTICE ACQUISITION
TRACKING WHICH PHYSICIAN PRACTICES HOSPITALS ARE ACQUIRING

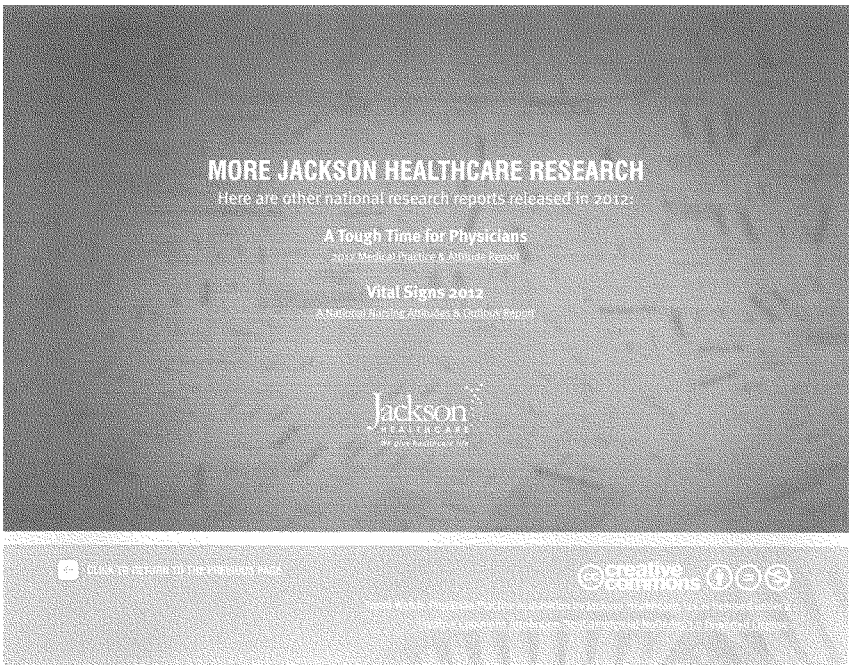

2012 ACQUISITIONS BY SPECIALTY (ACTUAL)
Specialty
(n=50)
Family Practice
Obstetrics Gynecology
Primary Care
Urology
Gastroenterology, Nurse Practitioner, Oncology, Orthopedic Surgery, Otolaryngology, Pediatrics, General
Neurosurgery, Physical Medicine & Rehabilitation, Psychiatry (Adult), Pulmonary Medicine
*The percentage represents each specialty individually, not as a group. For example, Gastroenterology=6%, Nurse Practitioner=6%, etc.
TREND WATCH: PHYSICIAN PRACTICE ACQUISITION
TRACKING WHICH PHYSICIAN PRACTICES HOSPITALS ARE ACQUIRING


2013 ACQUISITIONS
BY SPECIALTY
(PLANNED)
Specialty
(n=119)
Internal Medicine, General
Cardiology, Orthopedic Surgery
Obstetrics/Gynecology, Oncology
Cardiothoracic Surgery, Neurosurgery, Rheumatology, Endocrinology, Diabetes and Metabolism, Geriatric Medicine, Orthopedic (non-surgical), Pain Medicine, Radiation Oncology, Trauma, Vascular Surgery
Colon & Rectal Surgery, Critical Care Medicine, Dermatology, Hematology, Maternal and Fetal Medicine, Nephrology, Occupational Medicine, Podiatry, Radiology, Sleep Medicine, Sports Medicine
TREND WATCH: PHYSICIAN PRACTICE ACQUISITION
TRACKING WHICH PHYSICIAN PRACTICES HOSPITALS ARE ACQUIRING
*The percentage represents each listed specialty individually, not as a group.
For example, Cardiology=10% and Orthopedic Surgery=10%.


REASONS FOR PHYSICIAN PRACTICE ACQUISITION
Reason
(n=59)
TREND WATCH: PHYSICIAN PRACTICE ACQUISITION
TRACKING WHICH PHYSICIAN PRACTICES HOSPITALS ARE ACQUIRING


GEOGRAPHIC DISTRIBUTION OF RESPONDENTS
Region (n=168)
Area (n=110)
TREND WATCH: PHYSICIAN PRACTICE ACQUISITION:
TRACKING WHICH PHYSICIAN PRACTICES HOSPITALS ARE ACQUIRING


RESPONDENT STATISTICS
Bed Size (n=110)
Respondent Title (n=110)
TREND WATCH: PHYSICIAN PRACTICE ACQUISITION
TRACKING WHICH PHYSICIAN PRACTICES HOSPITALS ARE ACQUIRING



THE WALL STREET JOURNAL.
WSJ.com

OPINION | July 30, 2013, 7:16 p.m. ET

Scott Gottlieb: How ObamaCare Hurts Patients

The 340B program was meant to help about 90 hospitals buy drugs to treat the poor. Now 1,675 hospitals qualify.

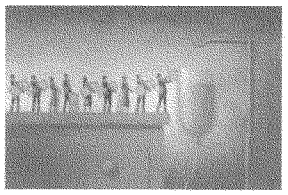
By SCOTT GOTTLIEB

President Obama promised to mend the failings in the American health-care system, and yet for cancer treatment, ObamaCare is taking a rotten feature of the old system and making it worse.

The Affordable Care Act expands a program called 340B, which siphons money from drug makers and insurers to subsidize certain hospitals. The program has been expanded as a way to offset some of the cuts that the law imposes on hospitals. One significant side effect: 340B is increasing the cost of cancer care—and harming its quality.

When the program began in 1992, its aim was to support hospitals that cared for many uninsured, indigent patients. Over the years, the program was radically broadened, gradually morphing into a government cash cow that hospitals of every description have learned to exploit.

Under 340B, eligible hospitals are allowed to buy drugs from drug companies at forced discounts of 25% to 50%. The hospitals can then bill government and private insurers for the full cost of the drugs, pocketing the spread. The arrangement gives 340B-qualified hospitals a big incentive to search for patients and prescribe lots of drugs. The costlier the drugs, the bigger the spread. So expensive cancer drugs are especially appealing.



Getty Images/Imagezoo

The original legislation creating 340B envisioned that only about 90 hospitals that care for a "disproportionate share" of indigent patients would qualify. But remember, this is a well-intentioned government program handing out money, with the usual result: By 2011, 1,675 hospitals, or a third of all hospitals in the country, were 340B-qualified.

Even flourishing hospitals like the Hospital of the University of Pennsylvania and Duke University Health System feed off the subsidies. In 2011, Duke bought $54.8 million in drugs from the discount program and sold them to patients for $131.8 million, for a profit of $76.9 million—a substantial portion of the health system's 2011 operating profit of $190 million. Only one in 20 patients served by Duke's 340B pharmacy is uninsured. The rest have their prescription costs covered by Medicare,

Medicaid or commercial insurers.

Now ObamaCare is encouraging even wider 340B abuses. The new health-care law expands 340B to cover cancer centers, new categories of hospitals and rural health centers. Since one of the ways that hospitals qualify for 340B turns on how many Medicaid patients they serve, ObamaCare's Medicaid expansion will also increase the number of 340B-eligible entities.

To goose the windfall, eligible hospitals are buying private oncology practices so they can book more of the expensive cancer drug purchases at the discount rates. More than 400 oncology practices have been acquired by hospitals since ObamaCare passed. Acquiring a single oncologist and moving the doctor's drug prescriptions under a hospital's 340B program can generate an additional profit of more than $1 million for a hospital. In the process, treatment of the doctor's patients is moved from an office setting to a hospital outpatient department.

As a result, between 2005 and 2011 the amount of chemotherapy infused in doctors' offices fell to 67%, from 87%, according to a new analysis of Medicare billing data done for community oncology groups. The share of Medicare payments for chemotherapy administered in hospitals (as opposed to outpatient oncology practices) increased to 41% in 2011, from 16.2% in 2005.

If these trends continue, the majority of cancer care will soon be delivered by hospitals. When the practice of oncology shifts to outpatient hospital clinics, the care is often less comfortable and convenient for cancer patients—and more costly.

Because the overhead for a hospital is higher than for a doctor's office, a patient treated in a hospital clinic incurs $6,500 more in costs than the same person treated in a private medical office, according to data from the Community Oncology Alliance. Patients who get chemotherapy at a hospital also face an additional $650 in co-pays and other out-of-pocket expenses. The price for infusing the drugs alone rises by 55%, according to an analysis of Medicare data. These inflated prices for cancer treatment inevitably drive up the cost of health insurance.

The Obama team has used informal "subregulatory guidance" to expand the 340B program still further. One big change came in March 2010 "guidance" that allows hospitals to contract with an unlimited number of neighborhood pharmacies to dispense drugs through them. There is no requirement that these "satellite" pharmacies have any geographic tie to the hospital.

This has created an industry of middlemen who build vast networks of pharmacies, all to expand the number of 340B prescriptions that a hospital can capture. There are now more than 25,000 arrangements between such satellite pharmacies and 340B-qualified treatment sites, according to the Health Resources and Services Administration.

The definition of a "covered patient" for 340B purposes is so murky under other guidance that hospitals are able to buy and bill discounted drugs for patients when the hospital merely serves as a conduit and doesn't give direct patient care.

The regulatory loosening has led to a proliferation of abuse. The Health Resources and Services Administration, the federal agency that (nominally) oversees the program, recently audited 340B-

eligible hospitals. The agency found "adverse findings" (like discounted drugs diverted or dispensed to ineligible patients) with almost half of the 34 institutions the agency examined.

A separate report by the General Accountability Office shows that the money isn't being targeted for indigent patients, as required. As profits from the program rose, and oversight remained lax, more of the money has instead become a general revenue source for 340B-eligible hospitals.

To combat this sort of gaming, drug makers are tightening how they distribute cancer drugs, to make improper diversion more difficult. This drug-company strategy may stem some of the most rampant abuses, but it adds to the cost and complexity of the pharmaceutical supply chain. It's another way that 340B increases costs.

The 340B program doesn't print free money. The cost of the discounts are foisted onto patients and insurers, who are forced to pay higher prices that drug makers establish to offset the cost of the forced discounts.

One of the rationales behind the Affordable Care Act was that the law would end the gimmicks that distort incentives and drive up costs. In the case of the 340B program and its effect on cancer treatment, the law has only further distorted an already expensive gimmick.

Dr. Gottlieb is a physician and resident fellow at the American Enterprise Institute. He consults with and invests in life-science companies.

A version of this article appeared July 31, 2013, on page A13 in the U.S. edition of The Wall Street Journal, with the headline: How ObamaCare Hurts Cancer Patients.

Oncology Rounds

Estimating the Demand for Oncology Physicians

on June 13, 2011 | **Permalink**

As frequent readers of this blog know, we often use it as a vehicle to share the answers to questions we receive frequently from our members. One question that has been coming across my inbox a lot recently, in various permutations, relates to the demand for key oncology physicians, particularly medical oncologists. Sometimes the questions is around estimating the true demand for physicians based on population and utilization, other times it's more specific to the volumes seen at a particular institution. While there is no perfect answer I thought I'd share a few numbers for those working through this issue.

Supply of physicians as a function of population

The most straightforward way to tackle this question is to take a supply side approach - the underlying assumption being that supply equals demand. I think we can all agree that this is flawed, but it's a helpful place to start. As most of you know, ASCO recently did a large workforce study, and they found there are approximately 10,000 medical oncologists and hematologists oncologistsin the US. If you add in pediatric oncologists and gyn oncs, the number is closer to 12,500. As a function of US population, this gets you to about 3.3-4.0 medical oncologists per 100,000 (assuming a US population of 308 million).

For radiation oncologists, the most comprehensive work I've seen completed is a study recently done at MD Anderson.They cite about 3,943 radiation oncologists nationally, equivalent to 1.28 per 100,000 US Population.

Supply does not equal demand

The challenge with this approach is that we all know that supply is not the same as demand. So the better question to look at is how many physicians do we actually NEED? This is a harder question to answer. The ASCO workforce study goes into detail on this at a population level, so I won't repeat their work here. But do look at the study if you haven't already. The MD Anderson study does not go into the same level of detail, but they do state that if the supply of radiation oncologists doesn't increase we will likely have a shortage given the fact that volumes are expected to rise based on demographics alone, and treatments are only getting more complex.

Translating to hospital specific demand

In terms of translating this to a specific hospital and how many they might need, here are a few thoughts. First, starting with medical oncologists. The most definitive data I have seen to date on patient load continues to be from Oncology Metrics recently published in the *Journal of Oncology Practice*. Their survey data indicates, that on average, a medical oncologist will see about 350 new patients annually (counted as new patients and consulations both in the office and the hospital). It's important to note that their survey focuses primarily on private practice physicians who may be more productive than those employed by a hospital. Some hospital administrators have told me they find that benchmark aggressive - in which case you may want to dial it back to 250 or 300. I think that one of the reasons this is high is the way they define new patients - it counts all new patient visits and consultations, both in the office and in the hospital.

For radiation oncology, we can take a similar approach. The average number of patients per radiation oncologist is about 250 (usually equal to one radiation oncologist per LINAC). This benchmark comes from a survey the Oncology Roundtable did of our membership 2-3 years ago.

Again, keep in mind these are estimates and will vary by practice structure, case mix etc. For instance, data in the ASCO study demonstrates that academic hem oncs spend only 47% of their time on patient care, while private practice physicians spend 76%. And men between the ages of 45 and 64 in private practice average over 100 visits per week, while women in that age group average only 90.

Why all the interest? Accountable care perhaps...

As I was pulling the data for the post I began thinking about why we've seen a huge surge in volumes of requests of this kind and I think it has to do with two major trends. First, the general uptick in interest in employment - more physicians are interested in employment and hospitals are trying to determine if they should take the plunge and employ and so they'll want to know if they have enough patients to support these physicians. A second, and related driver is accountable care. For those organizations setting up an ACO and striving to manage a population of patients, they'll want to know how many of each specialist they'll need to meet the demand of their specific patient population.

Learn more at our National Meeting

We'll be tackling both of these issues (amongst many others) at our 2011-2012 National Meeting series. The agenda and dates can be found here. Register now to save your seat!

Older Entries Newer Entries

Modern Healthcare

Article published July 13, 2013

Who benefits from drug discounts?

Drugmakers, hospitals battle over indigent-care program

By Jaimy Lee
Posted: July 13, 2013 - 12:01 am ET
Tags: Healthcare Reform, Hospitals, Medicare, Outpatient Care, Patient Care, Pharmaceuticals, Physicians, Purchasing, Suppliers, Supply Chain, The Week in Healthcare

Aspirus Ontonagon Hospital, a small not-for-profit hospital in Ontonagon, Mich., last year generated about $1 million in revenue from a federal program that allows safety-net providers to purchase deeply discounted drugs.

With improved margins due to savings from the 340B drug discount program since 2011, the 18-bed hospital prevented closures of its emergency department, family practice clinic and skilled-nursing facility. It also filled new positions and expanded services to offer oncology treatment for the first time.

"We would not have been able to start oncology without 340B," said William Wood, a board trustee for Aspirus Ontonagon Hospital, who called 340B participation a "major contributing factor" in the broader turnaround.

The hospital's turnaround is the kind of success story that makes the case for the 340B program, which was established by Congress in the early 1990s to help clinics and hospitals serving the poor and uninsured by allowing them to purchase certain outpatient drugs at up to a 50% discount and has since been expanded several times.

However, the 340B program has become controversial because of alleged misuse by some hospitals.

Critics say some hospitals may not be using the 340B savings and revenue they generate to improve care for the uninsured and indigent patients for whom the program was designed. Other providers have raised questions about whether physicians will alter prescribing patterns toward more expensive drugs to boost profit margins.

Hospitals in the 340B program purchase discounted drugs for any patient receiving medical care, not only those who are poor or uninsured, although Medicaid beneficiaries are excluded. The providers can then use savings or revenue generated from purchasing the discounted medications to enhance patient

care and services for all eligible patients. It's up to the providers to decide how to use the savings.

The number of providers participating in the 340B program has significantly increased in recent years, and roughly one-third of the nation's hospitals now participate in the program.

There were 22,641 covered-entity sites participating in the 340B program as of July 1, nearly 37% more than the 16,572 covered-entity sites in 2011, according to the Health Resources and Services Administration, which oversees the program.

That growth has fueled questions among 340B critics, notably drugmakers, who have said they don't want to see the 340B program expanded to include inpatient drugs.

But groups representing 340B-eligible hospitals say the program is operating as lawmakers intended and that the growth is tied to an expanded eligibility provision included in the 2010 healthcare reform law. The provision expanded 340B eligibility to critical-access hospitals, free-standing cancer hospitals, rural referral centers and sole community hospitals.

"There are a lot more rural hospitals in the program," said Ted Slafsky, president and CEO of Safety Net Hospitals for Pharmaceutical Access, a trade group that represents more than half of the participating 340B hospitals. "The evidence is that the hospitals are investing whatever savings they have from the program to help patients and to meet their indigent care needs."

As eligibility has widened in recent years, both the pharmaceutical industry and hospitals have said that some changes may be needed to reform the decades-old program and prevent abuse by providers, drug manufacturers and contract pharmacies.

"There's obviously a lot of potential for abuse, and that's not what anyone wants," said Lisa Swirsky, a senior policy analyst for Consumers Union.

The Government Accountability Office in 2011 recommended that HRSA tighten its oversight. That would allow the providers that need 340B savings to continue to operate, as well as prevent vulnerable patient populations from being negatively affected, she said.

But legislative changes such as requiring covered entities to use the drug savings directly on care for indigent patients "could hurt the folks they're trying to help," Swirsky added.

The drug industry, however, believes that the 340B statute requires the discount to be passed on directly to uninsured, indigent patients. The program, they say, should provide these patients with access to prescription drugs.

"While there remains a need for this safety net program, there are rising concerns about the program in its current form," said Matt Bennett, PhRMA's senior vice president of communications, in an e-mailed statement.

SNHPA and an alliance of trade groups representing drug manufacturers and others have recently published dueling websites addressing separate concerns about the 340B program.

The Alliance for Integrity and Reform—composed of drug companies and organizations, oncology groups and a pharmacy benefit manager—in May established

340Breform.org, which argues 340B savings should be used to directly boost access to medications for indigent and uninsured patients. SNHPA's Slafsky said the launch of that website contributed to SNHPA's decision to put together a report and publish its own website, 340Bfacts.com.

The organization issued its own recommendations for reforming the program. The recommendations included increased transparency of 340B prices and how hospitals use 340B savings, audits of drug

manufacturers and more scrutiny of contract pharmacies that participate in the program.

U.S. Sen. Charles Grassley (R-Iowa) has joined in the criticism of the 340B program. Over the past year, he has requested information from stakeholders ranging from pharmaceutical trade groups to hospitals that were reportedly charging a mark-up on drugs purchased through the 340B program.

"Even if the 340B program allows this kind of upselling, that doesn't make it right," Grassley said in a July 9 statement. "It also isn't right that we don't know how hospitals are reinvesting 340B revenue ... They could use the money for uninsured patients or they could use the money toward building a new wing.

Follow Jaimy Lee on Twitter: @MHjlee

(This article has been updated to correct that the 340B drug discount program excludes Medicaid beneficiaries, not Medicare beneficiaries.

Today's Headlines

Community Health Systems to pay $3.9 billion to buy HMA OIG wants skilled-nursing access for all Medicare beneficiaries Healthcare Reform Update: Public health organizations work to prepare providers for Medicaid expansion Northwestern to pay nearly $3 million to settle claims against cancer researcher
More Headlines

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Share your opinion. Send a letter to the Editor or Post a comment below.

Post a comment

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340B Covered Entities that have provided services to PAF patients

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Advocate Trinity Hospital
Albany Medical Center
All Children's Hospital
Arrowhead Regional Medical Facility
Asante Three Rivers Community Hospital
Athens Regional
Aurora Sinai Medical Center
Aurora St. Lukes, Milwaukee
Avera Medical
Azeala Health
Bakersfield Hospital
Ball Memorial Hospital
Banner Desert Medical Center
Banner Estrella Medical Center
Banner Gateway Medical Center
Banner Good Samaritan Medical Center
Banner Health
Banner MD Anderson Cancer Center
Banner Thunderbird
Baptist Bartlett Clinic
Baptist Health
Baptist Health Care West Florida Hospital
Baptist Health Medical Group
Baptist Hospital
Baptist Hospital Nashville
Baptist Hospital Nassau
Baptist Hospitals of Southeast Texas dba Memorial Hermann Baptist Beaumont Hospital
Baptist Medical Center
Baptist Memorial Hospital
Baptist South
Barnes-Jewish Hospital. St. Louis MO
Baton Rouge General Medical Center
Baxter Hospital
Bay Medical Hospital
Bayhealth Medical Center
Baylor Medical Center
Baylor Plano Hospital
Baylor University Medical Center
Baylor University Medical Center Dallas, TX
Baystate
Berlin Memorial
Beth Israel Deaconess Medical Center Boston, MA
Beth Israel Medical Center

Beth Isreal Hospital, NJ
Beverly Hospital
Binghamton General Hospital/UHS
Birhmingham Clinic
Bluestone Health Center
Bon Secours Hospitals - St. Francis Medical Center
Bon Secours Mary Immaculate
Bon Secours Maryview Medical Center
Bon Secours St Francis Health System
Brackenridge Hospital
Breast Cancer Specialist...as parnter of TX Oncology
Bridgeport Hospital
Brigham and Women's Hospital
Bringham Hospital in Boston
Bronx Lebanon
Brooklyn Hospital
Broward General Hospital
Brunswick Hospital Southeast Georgia Regional Medical Center
Bucyrus Community Hospital
California Hospital Medical Center
California Pacific Medical Center
Came Care
Cancer Center of Oxford
Cancer Therapy & Research Center at The University of Texas
Candler Hospital
Cape Cod Hospital TB02601
Cardinal Glennon Children's Medical Center
Carilion Roanoke Memorial Hospital
Carolina Coastal
Carolinas Medical Center
Cedar Sinai Hospital, Los Angeles, CA
Cedars-Sinai Medical Center
Central Baptist Hospital
Centura Health-Avista Adventist Hospital
Charleston Area Medical Center
Children's Hospital
Children's Hospital of King Daughter
Children's Hospital of Oakland
Children's Hospital of Pittsburgh
Children's Medical Center
Children's National Medical Center
Chippewa County War Memorial Hospital
CHOP
Christ Hospital
Christiana Care Health System
Christus Schumbert It is a 340B entity
Christus Spohn Hospital Corpus Christy South

Citizen's Baptist Medical Center
City of Hope Hospital
City of Hope National Medical Center
Claiborne County Hospital
Clara Maass Medical Center
Cleveland Clinic Florida
Cleveland Clinic Foundation
Cleveland Metro Health
CMC-Pineville
Community Care
Community Health Center of Greater Dayton
Community Health Center of Yavapai
Community Hospital
Community Hospital of San Bernadino
Community Regional Medical Center
Conemaugh Memorial Medical Center
Contra Costa Regional Medical Center
Conway Medical Center
Cook County Bureau of Health Services
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Cooper Green Mercy Hospital
Cooper Hospital
Covenant Michigan Avenue Clinic
Cox Medical Center
Cox Medical Center (Branson)
Cox Monett Hospital, Inc.
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Crouse Hospital Syracuse
Crozer Medical Center
Crozer-Chester Medical Center
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CTCA, WV
CTCA-MidWestern
Cullman Regional Medical Center
Dallas County Hospital District, Parkland Health and Hospital System
Dana Farber Cancer Center
Dartmouth-Hitchcock Hemophilia Center
Dartmouth-Hitchcock Medical Center
DCH Regional Medical Center
Dekalb Memorial
Dell Children Hospital-Cancer Center
Doctor's Community Hospital
Doctor's Renaissance Hospital
Dorminy Medical Center
Douglasville HealthCenter Hospital
Driscoll Children's Hospital
DSH Grady Memorial Hospital

DSH University Medical Center
Duke University
Duke University Hospital
Duke University Medical Center
E Alabama Cancer Center
E.A. Conway Medical Center
East Texas Medical Center
Edwards Cancer Center
Einstine Medical Center
El Rio Community Health Center
Ellis Fischel Cancer Center
Emory Clinic
Emory University Hospital Midtown
Erlanger Health System University of Tennessee College of Medicine
Erlanger Medical Center
Essentia Health
Family Cancer Center
Family Health Centers of Baltimore
Feather River Hospital Cancer Center
Florida Hospital Altamonte Springs
Florida Hospital South
Florida Medical Center
Forrest General Hospital
Forsyth Medical Center
Fort Sanders, TN
Fox Chase Temple Univ Hospital
Franklin Memorial Hospital
Fremont Rideout Hospital
Froedhert Hospital Milwaukee WI
GA Cancer Specialist
Gaston Memorial
Geisinger Medical Center
Genesis Good Samaritan Medical Center Zanesville
Georgetown Lombardi
Georgetown Memorial Hospital
Georgetown University Medical Center Lombardi Cancer Center
Glennwood Hospital
Good Samaritan Hospital
Good Shepherd Medical Center
Grady Hospital-Atlanta Georgia
Grant Medical Center
Greene Memorial Hospital Miami Valley South Sloan Kettering
Greenville Memorial Hospital
Guadalupe Regional Medical Center
Gwinnett Medical Center
Halifax Hospital
Harbor Hospital

Harbor UCLA
Harris County Hospital District
Hartford Hospital
Health Partnership Clinic
HealthPark Medical Center (Lee Memorial Hospital System)
Hennepin Medical Center
Henry Ford
Hermann Memorial
Hernando County Health Dept
Hershey Medical Center
Highland General Hospital
Highlands Medical Center
Hillcrest Baptist Medical Center
Hillman Cancer Center
Hillsbourough County Department
Hollings Cancer Center
Holy Cross Medical Center
Holy Redeemer Hospital
Homestead Hospital, Inc.
Hope Cancer Center
Huntsman Cancer Institute
Huntsville Hospital
Iberia Medical Center
Illini Hospital
Indiana health Center, South Bend
Indiana University
Inova Fairfax Hospital
Intermountain
Jackson General Hospital
Jackson Hospital
Jackson Memorial Hospital
Jackson Memorial, Miami
Jackson-Madison County Hospital
Jacobi Medical Center
James Care East Ohio East Hospital
James Factor Program of the Ohio State University
Jasper Memorial Hospital
Jefferson Hospital
Jefferson University
Jewish Hospital
John H. Stroger, Jr. Hospital of Cook County
John Muir Cancer Center
John Peter Smith Hospital
Johns Hopkins
Johns Hopkins Hospital
Johns Hopkins Hospital Mercy Hospital
Johnson City Medical Center

JPS Health Systems
Kaiser Permanente Hospital
Kaiser Permanente Medical Office
Kalispell Regional Medical Center
Karmanos Cancer Center
Kelsey-Seybold Clinic
Kern Medical Center
Kernersville Medical Center
Kevin Kellogg Mercy Health Partners-Hackley Campus
Kingman Cancer Center
Kings Brook Jewish Mediacl Center
Kings County Hospital
Kings Daughter and Univ of KY Lexington
L.A. Country Department of Health Services Antelope Valley Health Center
LA General
Lafayette General Medical Center
Lake Health
Lakeland Regional Med Center
Lancaster General Hospital
Lasalle County Health Department
Laughlin Memorial Hospital, Inc.
Leconte Medical Center
Lee Memorial Hospital
Lehigh Valley
Leo Jenkins Cancer Center (affiliated with Vidant Cancer Center)
Lexington Medical Center
Lincoln Medical Center
Loma Linda Cancer Center
Long Beach Medical Center
Long Beach Memorial
Long Island Jewish Hospital
Loyola University Medical Center
LSCC OB/GYN of Roundrock Texas
LSU Health Services Center, Shreveport
LSU Medical Center
Lynchburg General
Lyndon B Johnson Hospital
Magee Women's Hospital
Maimonides Medical Center
Maricopa Integrated Health Center Hospital
Maricopa Medical Center
Marivel Hospital-Maricopa Integrated Health Systems
Markey Cancer Center
Marshfield Clinic Medical Center
Martin Luther King Jr.
Mass General
Maury Regional Hospital

Mayo Clinic
Mayo Clinic Rochester, MN
McCleod Reginal Medical Center
McGee Women's Hospital. at UPMC
MCV Hospital
MD Anderson
MD Anderson, FL
MD Anderson, TX
Meadville Medical Center
Medical Center of Central GA
Medical Center of New Orleans
Medical College of Georgia
Medical University of SC
Memorial Cancer Institute
Memorial Health
Memorial Hermann Southeast Hospital
Memorial Hospital
Memorial Hospital at Gulfport
Memorial Hospital in Paolo Springs
Memorial Medical Center
Memorial Regional Hospital Cancer Instittute Hollywood, FL
Memorial Sloan Kettering
Mercer County Health Department
Mercy Cancer Center
Mercy Health Partners
Mercy Hospital
Mercy Hospital Breast Center
Mercy Hospital, Springfied
Mercy Medical Center
Mercy Medical Clinic
Mercy San Juan Hospital
Mercy Sleep Clinic (part of Mercy Medical Springfield)
Methodist Hospital
Methodist Hospital Brooklyn, NY
Methodist Hospital Indianapolis, IN
Methodist Methodist Center
Metrohealth Medical Center
Metropolitan Hospital
Miami Baptist
Miami Valley Hospital
Middleton Clinic/Meritor Hospital
Milton Hershey Medical Center
Mission Hospital - Saint Joseph's
Mission Memorial Hospital
Missouri Baptist Hospital
Moffitt
Montefiore Medical Center

Montefiore Wakefield Hem Onc Cancer Ctr.
Monter Cancer Center
Moses Taylor Scranton
Mother Frances Hospital
Mount Sinai Hospital
Mount Sinai Medical Center
Mount Vernon Hospital
Nash General Hospital
Nassau University Medical Center
Nebraska Medical Center
Neuroscience Institute of SHNDS
New Hanover Regional Medical Center
New River Health
New River Medical Center
New York Hospital
New York Presbytarian Hospital
New York Presbyterian
Newark Beth Israel Medical Center
North Broward Hospital
North Florida Regional Medical Center
North Mississippi Medical Center
Northside Hospital
Northwestern Memorial Hospital
Northwestern University
Northwestern University, Rehibilitation Institute of
Norton Cancer Institute
Novant Forsythe Medical Center
NYU
Oakwood Hospital
Ochsner Medical Center
Ohio County Hospital
Ohio State University
Okaloosa County Health Department
Oklahoma University
Olive View Medical Center
Onslow Memorial Hospital
Oregon Health and Science University
Oregon Health Science Center OHSU Center for Health and Healing
Orlando Health
Orlando Regional Medical Center
OSU James Cancer Center
Our Lady of the Lake Regional Medical Center
Ozarks Medical Center, West Plains, MO
Palmetto Baptist Health
Palo Pinto General Hospital
Palomar Hospital
Parkland Medical Center

Parkview
Peacehealth Southwest Medical Center
Peggy and Charles Stephenson Cancer Center
Pennsylvania Hospital
Phoebe Sumter Medical Center
Phoenix Children's Hospital
Piedmont West
Pinnacle Health
Planned Parenthood of Fairfield/Shasta
Presbyterian Hospital
Presbyterian Intercommunity Hospital
Provena United Samaritans Medical Center
Providence Alaska Medical Center

Providence Health System Southern California dba Providence Holy Cross Medical Center
Providence Holy Cross Medical Center, CA
Providence Hospital
Providence Regional Medical Center
Providence Sacred Heart
Queens Hospital
Rady Childrens Hospital
Rapid City Regional Hospital
Reading Hospital
Regional Cancer Center
Renown Regional Medical Center
Rhode Island Hospital
Rideout Memorial Hospital
Riley Hospital, Indiana University Health
Riverside County Medical Center
Riverside County Regional Hospital
Riverside Hospital
Riverside Shore Memorial
Rochester General, NY
Rocky Mountain CARES
Rogue Valley Medical Center
Ronald Reagan UCLA Medical Center
Roper St Francis Healthcare
Rush University
Sacred Heart Hospital & Lehigh Valley Hospital
Sacred Heart Hospital and Cancer Center
Sacred Heart Hospital of Pensacola
Sacred Heart Medical Center
Sacred Heart Riverbend Hospital
Saint Francis Hospital
Saint Helena Hospital
Saint Joseph Hospital, Orange
Salem Hospital

Salinas Valley Hospital
Samaritan Medical Center
Samaritin Pacific
San Francisco General Hospital
San Joaquin General Hospital
San Ysidro Health Center
Sanford Medical Center
Sanford USD Medical Center
Santa Clara Valley Medical Center
Scott and White Memorial Hospital
Scripps Memorial Hospital.
Scripps Mercy, CA
Seminole County Community Assistance
Sentara
Sentra Care Plex
Sequoia
Seton Medical
Shands Hospital, Gainesville, FL
Shands Hospital, Jacksonville
Shands Sleep Center
Shands Teaching Hopital and Clinics
Shands, University of Florida
Sharp Grossmont Cancer Center
Sharp Medical Center
Sharp Memorial Hospital
Shelby Baptist Memorial
Shivers/Brackenridge
Sinai Hospital
Singing River Hospital
Siteman CA Cente Barnes Jewish
Skagit Valley Hospital (Skagit Regional Clinic Mount Vernon)
Sleepy Hollow Open door
Smith Clinic
South Broward Hospital District dba Memorial Hospital
South Florida Baptist Hospital
South Georgia Regional Medical Center
South Jersey Hospital
South Seminole Hospital Orlando Health
Southeast Alabama Medical Center
Southern Regional Medical Center
Sparks Regional Medical Center
Sparrow Hospital
Spectrum Health/Butterworth Medical Center
spring hill regional
Springfield Regional Hospital
SSM DePaul
St. Anothony's Hospital

St. Anthony Hospital
St. Catherine Hospital
St. Christopher's Philadelphia
St. David's Medical Center
St. Dominic-Jackson Memorial Hospital
St. Elizabeth Hospital
St. Francis and University of St. Louis
St. Francis Hospital
St. Francis Medical Center
St. Francis Medical Center Peoria
St. John Hospital and Medical Center
St. John's Mercy Medical Center
St. John's Riverside
St. Joseph's Hospital
St. Jospeh Medical Center
St. Jude's Hospital
St. Louis University Hospital
St. Luke's Cedar Rapids, IA
St. Luke's Hospital
St. Luke's Hospital of Kansas City
St. Luke's Hospital, NY
St. Luke's Regional Medical Center Mountain State Tumor Institute
St. Mary's Pulmonary Care/Sleep
St. Mary's Health Care System, Inc.
St. Mary's Hospital
St. Vincent Charity Medical Center
St. Vincent Healthcare
St. Vincent Indianapolis
Stansbury Health Center/University of Utah
Staten Island University
Steward Health Care System
Stony Brook Hospital
Stormont-Vail Cancer Center
Strong Memorial Hospital, University of Rochester
SUNY Downstate
SUNY Upstate
Susquehanna Health Hospital
Sutter Hospital
Sutter Medical Center
Swedish American Hospital
Swedish Covenant Hospital
Swedish Medical Center
Tallahassee Memorial Healthcare, Inc.
Tampa Bay General
Tanner Medical Hospital Carrollton
Temple University Hospital
Tennova Healthcare

Terry Reilly Health Center
Texas Harris Methodist Hospital
Texas Medical Center
The Children's Hospital Association
The Gebhart Cancer Center at Fort Hamilton Hospital
The Medical Center of Bowling Green
Thomas Jefferson University Hospital
Tift Regional Medical Center
Tracy FAmily Clinic
Tri-City Medical Center
Trinitas Regional Medical Center
Trinity Hospital
Trintas Comprehensive Cancer Center
Truman Medical Center
Tuomey Healthcare System
Tuscon Medical Center
UAMS University of Arkansas Hospital
UMC of El Paso
UMPC McKeesport
Uniontown Hospital
United Regional Health Care System
Univeristy of Texas Medical Branch
University Health Center
University Health System
University Hospital
University Hospital Cleveland
University Hospital of Newark
University Hospital/Health System, San Antonio, TX
University Hospitals and Clinics
University Hospitals Case Medical Center
University Medical Association - University of Virginia Health System
University Medical Center in El Paso
University Medical Center of Southern Nevada
University of Alabama
University of Alabama at Birmingham
University of Arizona Health System
University of Arkansas for Medical Sciences Medical Center
University of California Irvine Medical Center
University of California Los Angeles Ronald Regan Medical Center
University of California San Diego
University of California San Diego Medical Center
University of California San Diego, La Joya
University of California San Francisco Hospital in San Francisco
University of California, Davis Medical Center
University of Chicago Medical Center
University of Cincinatti
University of Cinncinatti Hospital

University of Colorado
University of Florida
University of Illinois Hospital
University of Indiana Hospital
University of Iowa Hospital
University of Kansas
University of Kansas Medical Center
University of Kentucky Lexington
University of Loiusville James Graham Brown Cancer Center
University of Louisville
University of Maryland
University of Maryland Medical Center
University of Massachusetts Memorial
University of Medicine and Dentitry Hospital of New Jersey.
University of Miami
University of Miami Sylvester Cancer Center
University of Michigan
University of Michigan Health Systems
University of Minnesota
University of Mississippi Medical Center
University of Missouri Health System
University of New Mexico Hospital
University of North Carolina Chapel Hill
University of Pennsylvannia
University of Pennsylvannia Medical Center
University of Pittsbugh Medical Center Shadyside Family Health Center

University of Rochester Medical Center Strong Memorial Hospital Willmont Cancer Center
University of South Alabama Medical Center
University of South Carolina
University of Southern California
University of Tennessee Medical Center
University of Texas El Paso
University of Texas Galveston
University of Texas Health Center at Tyler
University of Toledo Medical Center
University of Utah Huntsman Cancer Hospital
University of Utah Medical Center
University of Virginia
University of Washington
University of Wisconsin Hospitals
UPMC
UPMC - West
UPMC Cancer Center
UPMC Greenville
UPMC Mercy
UPMC Shadyside

UPMC St. Margaret
Upstate University Hospital
USA Mitchell Center (Part of USA Medical Center)
USC Medical Center
USC-Kek Cancer Center
UT HealthScience Center
UT Southwestern Medical Cancer
VA Brooklyn
VA Hospital
Valley Baptist Medical Center
Valley Medical Center
Vanderbilt University
Vanderbilt University Hospital
VCU Medical Center
Ventura County Medical Center
Ventura Memorial Hospital
Veterans Administration
Veterans Administration Hospital in West Haven, CT
Via Christi Hospital Pittsburg
Villa Ricker
Virginia Commonwealth University
Virginia Commonwealth University Hospital, VA
Wade Family Medical Center
Wake Forest University Baptist Medical Center
Wake Medical Center
Waldo County General Hospital
War Memorial Hospital
Warren Hospital
Wellmont Health Systems
Wellstar Cobb
Wellstar Cobb (Kennestone)
West Clinic, Knoxville, TN
West Georgia Medical Center
West Jefferson Medical Center
Westchester Medical Center, NY
Western Maryland Health System
Western Pennsylvania Hospital
White County Medical Center
White Memorial Medical Center
Willis Knighton CC
Wilson Medical Center
Winston Salem Health Care
Winter Haven Hospital
Woodland Memorial Hospital
Wyckoff Hospital Brooklyn
Yale Medical Center
Yale New Haven Hospital

York Hospital
Zufall Health Center