

**MEDICARE REIMBURSEMENT OF
PHYSICIAN-ADMINISTERED DRUGS**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
ONE HUNDRED NINTH CONGRESS

SECOND SESSION

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**MEDICARE REIMBURSEMENT OF
PHYSICIAN-ADMINISTERED DRUGS**

THURSDAY, JULY 13, 2006

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 1:08 p.m., in room 1100, Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee), presiding.
[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
July 06, 2006
HL-16

CONTACT: (202) 225-3943

Johnson Announces Hearing on Medicare Reimbursement of Physician-Administered Drugs

Congresswoman Nancy L. Johnson (R-CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on Medicare reimbursement of physician-administered drugs. In addition, the hearing will examine physician reimbursement for administration of these drugs. **The hearing will take place on Thursday, July 13, 2006, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 1:00 p.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include representatives from the Centers for Medicare & Medicaid Services (CMS), the Office of Inspector General of the Department of Health and Human Services, the Medicare Payment Advisory Commission, the Government Accountability Office (GAO), and representatives from provider and patient groups. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Under the Medicare program certain categories of physician-administered outpatient drugs, including drugs used in cancer treatment, and certain drugs used with durable medical equipment are covered under Part B.

The Balanced Budget Act of 1997 (P.L. 105-33) specified that Medicare payment for covered outpatient drugs would equal 95 percent of the average wholesale price (AWP). However, AWP's are not defined by law or regulation. The AWP for a product is often far greater than the acquisition cost paid by suppliers and physicians. In addition, the AWP's do not reflect the discounts, rebates or "charge backs" that manufacturers and wholesalers offer to providers. In 2001, according to the GAO and the CMS, Medicare overpaid for Part B drugs by more than \$1 billion annually.

As a result, Congress significantly reformed the way Medicare pays for physician-administered drugs in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (P.L. 108-173) from the AWP methodology to an average sales price (ASP) methodology plus 6 percent. The ASP represents an average of all manufacturers' final sales prices in the United States, net of rebates or other discounts and excluding certain sales at nominal charges. The ASP is calculated quarterly by CMS from data submitted by manufacturers. The Secretary of the Department of Health and Human Services has the authority to adjust reimbursement for a drug when he finds that the ASP does not reflect widely available market prices.

Physicians can also choose to receive physician-administered drugs through a Medicare contractor. The competitive acquisition program (CAP) was established through the MMA. Through CAP, physicians write a prescription to be filled by a Medicare-contracted supplier that would then dispense the product to the doctor on a timely basis. The supplier, not the physician, would be reimbursed by Medicare for the drug, and the physician is reimbursed for drug administration. The supplier would be responsible for collection of the 20 percent coinsurance on the drug pay-

ment, lowering the bad debt exposure and liability of the physician and significantly reducing their paperwork burden.

The MMA also significantly increased the physician fee schedule payments for oncologists and other specialists by revising and creating codes. There were also transitional payments for oncologists and other affected specialists for 2004 and 2005. In 2005 and 2006, CMS implemented a demonstration program for oncologists in order to assess and provide support for the quality of care for patients undergoing chemotherapy. Additional payments per encounter were paid to physicians who participated in the demonstrations.

In announcing the hearing, Chairman Johnson stated, "The AWP process was seriously flawed. The revised payment methodology fundamentally changes the way Medicare pays for drugs and physicians services. Congress should continue its oversight and monitor implementation of the law to ensure that patients have access to high-quality cancer care and that physicians are reimbursed appropriately."

FOCUS OF THE HEARING:

Thursday's hearing will focus on implementation of the revised payment methodology for reimbursement of physician-administered drugs, and examine the effects of this new payment system on providers and beneficiaries.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, <http://waysandmeans.house.gov>, select "109th Congress" from the menu entitled, "Hearing Archives" (<http://waysandmeans.house.gov/Hearings.asp?congress=17>). Select the hearing for which you would like to submit, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the on-line instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You **MUST REPLY** to the email and **ATTACH** your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business Thursday, July 27, 2006. **Finally**, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225-1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at <http://waysandmeans.house.gov>.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman JOHNSON OF CONNECTICUT. The hearing will come to order. Thank you all for being here.

I am pleased to Chair the second hearing on the Medicare reimbursement for physician-administered drugs. The Medical Modernization Act (MMA) (P.L. 108-173) includes very complicated and significant changes to reimbursement for these drugs and the services required to deliver them. These changes were made in order to better align for the reimbursements for the cost of acquiring and administering drugs.

The purpose of this hearing is to evaluate whether or not the reimbursement changes have corrected for historic overpayments in this area, while at the same time maintaining patient access to these drugs, which include treatments for oncology, reconstituted human epithelium (rhe), immune deficiency disorders and some vaccinations. Prior to the MMA, Medicare only covered drugs that were covered incident to physician services or administered through covered durable medical equipment items. These drugs were covered in Medicare and reimbursed 95 percent of the average wholesale price. Additionally, Medicare beneficiaries were responsible for 20 percent coinsurance on the drug payment.

As recently detailed in an article of USA Today, beneficiaries are often held responsible for many thousands of dollars of cost sharing for oncology therapies throughout the course of cancer treatment. Seniors without secondary insurance are simply unable to afford cost sharing of this magnitude. Uncollected coinsurance is becoming an increasing financial burden on providers, and many have reported that it is affecting treatment location decisions for seniors. These medications treat life-threatening illness; however, it is unclear how Medicare or certain beneficiaries that are responsible for coinsurance can be prepared to pay for therapies costing \$100,000 a year.

Finally, Congress chose to place a limit on out-of-pocket expenditures for any seniors under the Medicare Part D program to avoid the financial devastation from illness, and yet, part B, does not have any similar kind of limit. It is now unclear how to address this issue, and I intend to work with my colleagues and Centers for Medicare and Medicaid Services (CMS) and others to evaluate policy remedies.

In addition to changes in Medicare, reimbursement for part B drugs, the MMA increased reimbursements for chemotherapy administration. Since 2003, Medicare reimbursement has fluctuated in this area due to transitional prices which came to significant—sorry—transitional increases in payments which were phased out in 2006. Despite the absence of these transitional payments, the highest volume code, the intravenous fusion for first hour is 200 percent more than in 2003.

The MMA also mandated the evaluation of drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account complexity and resource consumption, and to appropriately adjust the relative value units for these codes. I considered this review and subsequent changes extremely significant to ensuring that providers were adequately reimbursed for the cost of administering these drugs and look forward to hearing from providers and CMS regarding the outcome of this process, because that seems to me, one of the really big issues that we need to open up at this hearing outside the claims to traditional reimbursement to provide for the cost of drugs.

The Medicare Modernization Act also included alternative methods to purchase and bill for drugs, the Competitive Acquisition Program, or CAP program. This program is just beginning its support and clinical impacts on treatment and the finances of practices that elect to participate.

The Medicare Modernization Act reforms—the payment system first by setting drug reimbursements at 106 percent of the average sales price (ASP). We are going to hear a lot of testimony on the studying of that average price and its strengths and weaknesses and what it does and does not take into account, and that is an important aspect of this hearing. So, I am going to skip over the details which you are, frankly, all familiar with.

I would rather get on to the controversy, but I am pleased to welcome the panel. I am pleased to welcome Herb Kuhn, Director of the Center for Medicare and Medicaid Services, to testify about the agency's perspective on the adequacy of the current payment system and early experiences with competitive acquisition price (CAP). I am also interested to hear about CMS's efforts to work with providers and oncologists in particular to evaluate reports in the field.

The Medicare Modernization Act required the Department of HHS Office of Inspector General (IG) to conduct a study on physicians' offices of varying sizes and their ability to acquire drugs at 106 percent of ASP. Robert Vito, Inspector General for Evaluations and Inspections, will testify on the finding of his study.

Additionally, Mark Miller, Executive Director of the Medicare Payment Advisory Commission, MedPAC, will also testify regarding the Commission's finding on their January 2006 report titled Effects of Medicare Payment Changes on Oncology Service. In particular, he will speak to us on the beneficiary access to oncology treatment and the adequacy of the 106 of ASP as a payment methodology.

Bruce Steinwald, Director of Health Care at the U.S. Government Accountability Office (GAO), will speak to the adequacy of reimbursement in the hospital outpatient department and CMS's ability to collect data on drug acquisition costs.

On the second panel, I would like to welcome Dr. Joseph Bailes, executive vice president of the American Society of Clinical Oncology, which represents 24,000 members worldwide and medical oncologists, from Houston, Texas, will testify on both reimbursement for drugs and for administrative payments.

Marcia Boyle, president of the Immune Deficiency Foundation and the mother of a son with primary immune deficiency (PID),

will speak from the patient perspective about the importance and accessibility of intravenous immunoglobulin (IVIG) to treat PID.

Also, Richard Friedman, chief executive officer of BioScrip, will testify about the CAP program. BioScrip was recently awarded a contract to be the vendor for the CAP program.

Finally, Dr. Jordan Orange, of the Primary Immunodeficiency Disease Committee of the American Academy of Allergy, Asthma and Immunology, will testify on accessibility and use of IVIG. IVIG is a plasma-derived product used to treat PID and is indicated by the Food and Drug Administration for five other diseases. However, IVIG has been found to be useful treatment in many, more non-indicated diseases and ailments. There have been numerous reports of patients, physicians and hospitals either having difficulty accessing the drug or significant shifts inside of care. Dr. Orange has provided research on IVIG.

Dr. Frederick Schnell, an oncologist from Macon, Georgia, and the upcoming president on the Community Oncology Alliance, will testify on community practices', especially small practices' or geographically isolated practices', experiences with a new reimbursement system.

I want to thank all of the witnesses for participating in today's hearing. It is of vital importance for Congress and CMS to be vigilant in our oversight of the implementation of the Medicare Modernization Act and ensure access to vital and life-saving treatment is maintained.

Mr. Kuhn, if you will start, please. Excuse me. I yield to my colleague Mr. Stark.

Mr. STARK. Thanks for holding the hearing. I want to particularly mention, Madam Chair, that I was pleased to see our staffs working together on such a bipartisan way in this hearing. While I am not always sure that I want to take credit for this, I don't mean to shortchange Bart Miller, but I have a hunch that I was one of the first people to raise the question of replacing the average wholesale price (AWP) with reimbursements that had reflected more accurate acquisition costs. The average wholesale price scandal, I think, came to light following investigations from some whistleblower cases, and we had, I think, such outrageous abuses that would make Halliburton blush. That raised questions about inappropriate care, perverse financial incentives on the physicians, and plain old profiteering at the expense of Medicare and patients and taxpayers.

I introduced the average acquisition price bill in 2002, and it was based on the corporate integrity agreements between Office of the Inspector General (OIG) and some of the drug manufacturers. The MMA average sales price provisions were based in large measure on that legislation and those agreements. We are going to hear some facts today from our distinguished first panel about how this average sales price system is working, and I appreciate all the research that all of you have done on part B drugs, and I urge CMS to utilize the resources, the other resources that tabled as they continue working on this program.

We will hear anecdotes claiming physicians can't afford to provide part B-covered drugs, and I appreciate that there may be issues with the formula, but I am quite skeptical that the claims

made by the groups in the second panel in particular are groups that are funded largely by drug manufacturers. So, we basically have a second panel made up of people showing for the drug manufacturers, and I tend to view that with some skepticism.

I have never quite understood why, although they do it in Japan, we could do it here, why physicians should be in the position of trying to make profits as pharmacists. Perhaps they can explain that to us today. The—on the other hand, I think that there is no question that physicians should be paid fairly and adequately, but I always felt that should be left to them, and in programs like the Report Benefit Savings (RBS), Medicare Payment Advisory Commission (MedPAC) and others who could tell the difference between an oncologist and a carbuncle, which I can't do, and I think we need to have people with the proficient staff and experience to understand the procedures, the complications and how they should be paid.

I am dubious as to whether paying people to make a profit on drugs that they prescribe and administer is in the best interest of the free market which we are trying to stimulate here. I think it is clear that ASP reimbursement is more accurate and, therefore, better than the old wholesale price system. I want to take seriously the questions of adequate reimbursements of the doctors and the reduced access, and, again, I hope that our first panel is prepared to advise us and recommend to us changes that should be made. So, I want to thank you for the opportunity, Madam Chair, to examine the average sales price system and look forward to seeing what we can do to make it more fair and equitable for all people concerned. Thank you.

Chairman JOHNSON OF CONNECTICUT. Thank you, Mr. Stark. Mr. Kuhn.

STATEMENT OF HERB B. KUHN, DIRECTOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. KUHN. Chairman Johnson, Representative Stark, Members of the Subcommittee, thank you for the opportunity to discuss with you the way Medicare pays for drugs covered under part B. As you are aware, the MMA substantially revised Medicare payment for part B drugs and their administration. part B Medicare covers a limited number of prescription drugs. In 2005, carriers paid \$10 billion for part B drugs, and intermediaries paid another \$5 billion.

Prior to the MMA, Medicare paid for these drugs at 5 percent of the average wholesale prices we heard earlier. This methodology, however, created incentives for manufacturers to establish a high wholesale price, while at the same time selling to physicians at a lower price in order to create a profit margin or a spread. This resulted in excessive payments by Medicare and our beneficiaries. The MMA, we believe, as a large measure successfully addressed this situation, providing for more appropriate payment for drugs while at the same time addressing concerns about inadequate payments for drug administration.

Studies by MedPAC, the U.S. Department of Health and Human Services (HHS), OIG and the GAO suggest that oncologists who are responsible for the large share of part B drug expenditures can

purchase drugs for the treatment of cancer at less than the Medicare payment amount. These studies indicate that the ASP-based system is working appropriately.

In discussions leading up to the passage of the MMA, many physicians argued that the excess payment of these medications have subsidized inappropriately low fees for their administration. Physicians argued that lowering payments for drugs required increases in the payments for administering the drugs.

The MMA significantly revised Medicare payments for administrative drugs. MMA made several permanent changes to coding in and—I am sorry, in 2004 and 2005, and CMS implemented all of these particular provisions. Over all, as a result of all of these changes, Medicare payments for drug administration in 2006 are 117 percent higher than they were in 2003. Payment amounts for oncology drug administration codes in 2006 are more than 200 percent higher than in 2003. In addition, payment is 192 percent higher for the Code accounting for the most spending. I would note that utilization of part B drugs has been increasing very rapidly. In our April 2006 letter to MedPAC, we pointed out that the volume and intensity of part B drugs increased 20 percent per year in 2003, 2004 and 2005. Growth in the volume and intensity of drugs more than offset the 2005 revisions in pricing that occurred when this ASP system was implemented in 2005.

Our preliminary review is that there was an almost 20 percent increase in total Medicare payments to oncologists. This is including both drugs, drug administration, medical visits and other services between 2003 and 2005, again, the first year of ASP in 2005. I would also point out that on Tuesday of this week the administration released the mid-session review of the budget. Medicare part B expenditures are now expected to be significantly higher as a result of rapid growth in the use of physician-related services and hospital outpatient services, including the volume and intensity of drugs.

For a moment now I would like to say a few words about IVIG, which was raised earlier. CMS and other components of the Department of Health and Human Services have heard concerns from some providers and the beneficiaries community about the adequacy of IVIG supply and Medicare reimbursement. Access to care is very important to the Medicare Program, and we are very, very concerned about these reports. During the past year we have taken several actions to refine Medicare payments rates for IVIG that could be accomplished within our existing authority. We established, for example, separate payment amounts for liquid and powder IVIG in the beginning of April of 2005. For 2006, we created special preadmission handling fees for both physician offices as well as outpatient departments, and for the third quarter of 2006, the quarter beginning July of this month, the Medicare payment amount increased 11.9 percent for the powder form and 3.5 percent for the liquid form.

There are a number of other factors that are contributing to the IVIG situation. We have also heard, and I know on the second panel you will hear from folks about off-label use of the product and the surge in that area. Manufacturer consolidations and changes in business practices have also been occurring in the mar-

ketplace. Also, we are seeing and hearing many reports about diversion of the product into the secondary or resale market where the product is being reportedly sold at extremely high markups. To better understand the market for IVIG and elevated access and reimbursement concerns for patient and physicians, HHS has commissioned an independent expert study to assess these factors and others. We want to maintain access to IVIG, but it is important to determine the causes of the concerns so we can implement appropriate measures to achieve this goal. In conclusion, we feel confident that the changes to the MMA, the way we reimburse for drugs under part B, has done much to ensure the payment both for drugs and the administration. The Department plans to continue monitoring payments, adequacy and access to care for part B drugs. I look forward to your questions.

Chairman JOHNSON OF CONNECTICUT. Thank you, Mr. Kuhn.

[The prepared statement of Mr. Kuhn follows:]

Statement of Herb B. Kuhn, Director, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services

Chairman Johnson, Representative Stark, distinguished members of the Subcommittee, thank you for the opportunity to discuss with you the way Medicare pays for drugs covered under Part B. These drugs are not covered under the new Part D prescription drug benefit. As you are aware, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) substantially revised Medicare payment both for Part B drugs and their administration. The goals of the MMA changes were to have Medicare pay appropriately for both Part B drugs and their administration, and to create a choice for physicians about buying and billing for Part B drugs or having those drugs furnished to a physician upon submission of a prescription order. We believe that those goals have largely been accomplished.

Medicare Part B Drugs

Part B of Medicare covers a limited number of prescription drugs. These Part B drugs generally fall into three categories: drugs furnished incident to a physician's service; drugs used as a supply to durable medical equipment (DME); and certain statutorily covered drugs. Medicare Part B drug coverage has not been changed by implementation of the new Medicare Part D drug program. Drugs that were covered by Medicare Part B before the Part D prescription drug program became operational continue to be covered under Medicare Part B.

Drugs covered under the "incident to" benefit are injectable or intravenous drugs that are administered as part of or "incident to" a physician's service. The statute limits Part B coverage to drugs that are not usually self-administered unless the physician participates in the Competitive Acquisition Program (CAP) for Part B drugs. Under the "incident to" provision, the physician must incur a cost for the drug, and must bill for it. Examples include injectable prostate cancer drugs (lupron acetate for depot suspension (Lupron & Eligard), goserelin acetate implant (Zoladex)), injectable drugs used in connection with treatment of cancer (epoetin alpha (Procrit) and darbepoetin alfa (Aranesp)), intravenous drugs used to treat cancer (paclitaxel (Taxol) and docetaxel (Taxotere)) and to treat non-Hodgkin's lymphoma (rituximab (Rituxan)), injectable drugs used to treat rheumatoid arthritis (infliximab (Remicade)), injectable anti-emetic drugs used to treat the nausea resulting from chemotherapy, and other drugs furnished by physicians, such as intravenous immune globulin (IVIG).

Part B also covers drugs that are administered through a covered item of DME such as a nebulizer or pump. Inhalation drugs, such as albuterol sulfate and ipratropium bromide, are frequently administered through a nebulizer. The Medicare statute requires Part B to cover certain other specific drugs, including immunosuppressive drugs for beneficiaries with a Medicare covered organ transplant; hemophilia blood clotting factor; certain oral anti-cancer drugs; oral anti-emetic drugs; pneumococcal, influenza and hepatitis vaccines; antigens; erythropoietin for trained home dialysis patients; certain other drugs separately billed by end stage renal disease (ESRD) facilities (for example, iron dextran, vitamin D injections); osteoporosis

drugs; and home infusion of intravenous immune globulin for Primary Immune Deficiency.

In 2005, the preliminary estimate of allowed charges for the approximately 550 drugs paid for by Medicare Part B carriers is \$10 billion. The majority of these expenditures were for drugs administered incident to a physician's service and drugs furnished in conjunction with DME. Much of the current spending for carrier paid drugs is concentrated in relatively few of the approximately 550 covered drugs. For example, of the \$10 billion for carrier paid drugs, 11 drugs account for 50 percent of spending, 27 drugs account for 75 percent of spending, and 65 drugs account for 90 percent of spending. The top two drugs, darbepoetin alfa (Aranesp) and epoetin alpha (Procrit), account for 17 percent of carrier spending. Three prostate cancer drugs, lupron acetate for depot suspension (Lupron and Eligard) and goserelin acetate implant (Zoladex), account for four percent of carrier spending. Infliximab injection (Remicade), for rheumatoid arthritis treatment, accounts for five percent of spending. Rituximab (Rituxan), for cancer treatment accounts for eight percent of carrier spending. Inhalation drugs account for eight percent of carrier paid drugs (not taking into account the inhalation drug dispensing fee). Spending of \$161 million for intravenous immune globulin accounts for 1.6 percent of carrier paid drugs; the total for IVIG increases to approximately \$378 million when preliminary data for hospital outpatient departments are included. In 2005, roughly 50 percent of spending for carrier paid drug went to oncologists. Another five percent went to urologists and four percent went to rheumatologists.

Intermediaries rather than carriers, process claims from both ESRD facilities and hospital outpatient departments including for Part B covered drugs. The figures discussed in the previous paragraph do not include spending for drugs paid for by intermediaries to hospital outpatient departments, or to ESRD facilities for drugs paid outside the ESRD composite rate. The preliminary estimate of 2005 allowed charges for separately billed Part B covered drugs paid to ESRD facilities is \$2.9 billion and \$2.0 billion for hospital outpatient departments.

Payment for Medicare Part B Drugs

Prior to the MMA, Medicare paid 95 percent of the Average Wholesale Price (AWP) for Part B drugs as reflected in published compendia. Numerous reports by the Office of the Inspector General and the General Accountability Office indicated that Medicare's payment was significantly higher than physician acquisition costs for the drugs. The difference between Medicare's payment and acquisition costs has come to be referred to as "spread." Physicians have long indicated that they used the spread to cross-subsidize payments for administering drugs.

The MMA revised the system, changing Medicare's payment both for Part B drugs and their administration. The MMA created two choices for physicians for payment of Part B drugs. First, a physician may choose not to buy and bill Part B drugs, but rather obtain such drugs from a competitively selected vendor upon submission of a prescription order for specific drugs for a particular beneficiary. This Competitive Acquisition Program became operational on July 1, 2006. Second, a physician may choose to purchase drugs in the market and bill Medicare for them, in which case the MMA specifies that Medicare's payment for most Part B drugs be 6 percent above the Average Sales Price (ASP). The ASP-based payment rates became effective January 1, 2005.

ASP

The ASP is the average sales price from a manufacturer to all entities who purchase the drug from the manufacturer (such as wholesalers and distributors), except for certain low price sales. The ASP is net of discounts, rebates and other price concessions. The ASP is calculated from data submitted by manufacturers on a quarterly basis. CMS takes the manufacturer's reported average sales price for each specific National Drug Code (NDC) in a billing code (billing codes, known as HCPCS codes, frequently include more than one NDC) and weights it by the volume of sales to determine the ASP for the billing code for a drug. The statute requires that the Medicare payment amounts are updated each quarter based on data from the second previous quarter. For example, Medicare ASP payments for the quarter beginning July 1st are based on manufacturers' average sales prices during the January to March quarter submitted by April 30th. After receiving data by April 30th, CMS has just a few weeks to compile the data, calculate the rates, check potentially erroneous data submissions with manufacturers, make corrections, publicize the rates, and load the new pricing files into each of the claims processing contractors' systems. The ASP system represents the only Medicare payment system where rates are updated as frequently as quarterly and this allows the Medicare payment rate to more accurately reflect the most current market conditions. We continue to work

closely with manufacturers to expedite data submission and ensure adherence with ASP guidance.

Comparing the July 2006 and January 2005 quarters for the top 50 drugs, Medicare payment amounts (ASP plus six percent) are higher for 36 drugs, lower for 13 and the same for one. Payments for five drugs increased by ten percent or more, while payments for six drugs decreased by ten percent or more. The biggest decrease, 93 percent, was for carboplatin, a drug with many generic entrants since 2004. Two competitor drugs, Aranesp and Procrit, experienced decreases in payments of 14.6 percent and 11.3 percent respectively. There were double digit increases and decreases for a number of inhalation drugs (duoneb: -17.5 percent; budesonide: 12.7 percent; levalbuterol: 17.7 percent; albuterol: 26.2 percent; ipratropium bromide: -27.5 percent). Other double digit payment increases occurred for bortezomib injection (Velcade) (12.4 percent) used to treat multiple myeloma, and epoprostenol injection (Flolan) (12.8 percent) used to treat pulmonary hypertension. Milrinone lactate injection, another drug with new generic offerings which is used to treat congestive heart failure, was the only other drug that experiences a double digit payment decrease (-13.9 percent).

Overall, Medicare payments for drugs did not change substantially between January 2005 and July 2006. The weighted average payment change was negative-four percent. Payment decreases, both among drugs for which there were new generic entrants and among other drugs that had direct competitors, accounted for much of this decrease. If recent generic drugs carboplatin, paclitaxel, and milrinone are eliminated from the total, the weighted average payment change was -1.3 percent. In addition, if competitor drugs Procrit and Aranesp are also eliminated from the total overall Medicare payments actually increased by two percent between January 2005 and July 2006.

CAP

The MMA established an alternative method for physicians to obtain many drugs covered under Part B, called the Competitive Acquisition Program for Part B drugs. Beginning in July of this year, physicians have the option of making an annual election as to whether they wish to purchase these drugs on their own, and be paid based on the ASP rate, or obtain them from a vendor who will then be responsible for supplying the drug to the physician, billing Medicare for the drug, collecting the coinsurance from the beneficiary, and coordinating secondary payer issues. Participation in CAP is voluntary and physicians who elect into CAP must abide by their choice for the year, except for certain rare exceptions. The benefit of participating for physicians is that they do not incur the expense of purchasing and billing for these medications. Nor do they have to concern themselves with the Medicare payment rate for these products and trying to acquire them at the best possible prices in the market.

Vendors who bid to participate in CAP must meet certain criteria outlined in the statute and CMS regulations. These include among other things, issues of: management and operations; experience and capabilities; licensure; record of integrity; adequacy of internal controls; and financial performance and solvency.

Potential vendors are required to bid on a particular category of drugs within a given geographic region. For the first round of CAP, CMS determined through regulation that there would be only one competitive acquisition geographic area, which includes all 50 states and territories, and one category of drugs comprised of approximately 180 of the most common physician administered drugs. Potential vendors' bids could not exceed the volume weighted average ASP plus six percent of the full list of drugs. The actual payment rates under CAP are based on the median of the successful bids. For the first round of CAP, CMS contracted with BioScrip, Inc. as the CAP vendor.

The first physician election for CAP began in May and concluded at the end of June. Elections are effective either July 1, or August 1, depending on when the completed election form was received by the physician's local carrier, and extends through the remainder of this calendar year. For 2007 and subsequent years, the physician election will occur for 45 days in the fall for elections effective for the subsequent calendar year.

Once a physician has elected to participate in CAP, they must obtain all drugs on the CAP drug list from their chosen drug vendor with exceptions in emergency situations and for prescriptions where the physician explicitly requests that it be furnished as written. Physicians continue to purchase and bill Medicare under the ASP system for those drugs that are not furnished by the physician's CAP vendor.

CMS has established a number of information sources for physicians and other prescribing professionals who have the opportunity to participate in the CAP. CMS also conducted outreach to the physician community working with national and

local organizations and specialty societies. On May 11 and again on June 12, CMS hosted national “Ask the Contractor” conference calls during which providers had the opportunity to learn more about the CAP and ask questions about participation. Local carriers were also required to provide information to physicians in their regions.

This initial phase of CAP is providing CMS with the opportunity to gain valuable experience as a launching pad for future enrollment. We look forward to expanding the CAP to more categories of drugs in the future and widening the pool of vendors and interested physicians.

Payments for Administration of Drugs

The MMA required four permanent changes in the data and methodology used to determine Medicare payments to physicians for administering drugs. These changes, all implemented on January 1, 2004, permanently affect Medicare’s payment for drug administration services. In addition to these permanent changes, MMA also provided for transition payments increasing the underlying drug administration payment by 32 percent in 2004 and 3 percent in 2005.

- One significant change was to require use of data from a survey conducted by the American Society of Clinical Oncologists (ASCO) on the costs of running a practice. These data are now used in the methodology to calculate Medicare payments for drug administration services. MMA excluded these increased expenditures from the budget neutrality requirement so that these changes did not reduce payments for other services under the physician fee schedule.
- Another MMA change required the Secretary to set work relative value units for drug administration services at the same level as the lowest level office visit billed by a physician.
- Still another MMA change required use of data on compensation of oncology nurses from the ASCO survey in the methodology to calculate practice expense relative value units for drug administration services.
- Finally, MMA required the Secretary to review and make appropriate changes in payment for multiple chemotherapy drugs furnished on a single day through the push technique.

In addition to the above changes, in order to ensure that drug administration codes accurately reflect services furnished, the MMA required prompt evaluation of existing codes used by physicians to bill for administering drugs to patients. The MMA also required the Secretary to use existing processes and authority to expedite consideration of coding changes and new relative value units. Changes in expenditures resulting from this review of codes were exempt from the budget-neutrality requirement that would otherwise apply. Because Medicare uses the American Medical Association’s Current Procedural Terminology (CPT) system for coding of physicians’ services, the CPT Editorial Panel undertook an expeditious review of drug administration codes. The CPT Editorial Panel adopted some new drug administration codes and refined several existing codes. The AMA’s Relative Value Update Committee (RUC) made recommendations to CMS on the relative values for new drug administration codes.

The new codes made changes to address concerns that physicians had raised about the drug administration codes. In particular, a new code was established to reflect the higher resource costs associated with infusing a second cancer drug on the same day. In addition, oncologists and other physicians can now bill Medicare for more than one administration of a non-chemotherapy drug as they can do currently for chemotherapy drugs.

These new and refined CPT codes became operational in 2006. However, in order to make them operational in 2005, in advance of their formal inclusion in the CPT system, we established temporary codes that were used during 2005. We used the RUC recommended values for the new and refined drug administration codes. The MMA specified that the changes in expenditures resulting from this review of codes were exempt from the budget-neutrality requirement that would otherwise apply.

Overall, as a result of all these changes, Medicare payments for drug administration in 2006 are 117 percent higher than they were in 2003. Payment amounts for four oncology drug administration codes in 2006 are more than 200 percent higher than in 2003. In addition, payment is 192 percent higher for the code accounting for the most spending—chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug.

Other Changes Affecting Payments to Oncologists

Concurrent with implementation of the ASP system and increased payments for drug administration codes, we also made other changes and clarifications affecting

oncologists and other physicians. Prior to 2005, injections furnished on the same day as other physician fee schedule services were bundled in to payment for the medical visit and not paid separately. Beginning with 2005, Medicare made separate payment for injections furnished on the same day as other physician fee schedule services.

Considerable physician effort may be required to monitor and attend to patients who develop significant adverse reactions to chemotherapy drugs, or otherwise have complications in the course of chemotherapy treatment. Some physicians are not aware of their ability to bill for these services. We clarified that these services can be billed appropriately using existing CPT codes, including, depending on the services involved: billing for a physician visit; billing for a higher level physician visit; billing using a prolonged service code; and billing using a critical care service. Billing for services relating to a significant adverse reaction to chemotherapy drugs would be in addition to billing normally allowed for the physician's care of a cancer patient. We issued coding guidance to assure appropriate billing for these services, potentially providing additional revenues for practices that had not used these billing codes appropriately in the past.

In order to assess the quality of care for cancer patients undergoing chemotherapy, Medicare initiated a one-year nationwide demonstration project during 2005. The demonstration collected data on three patient assessment elements for each day that chemotherapy was administered. We established 12 new billing codes, four in each of three patient status categories: (i) nausea and/or vomiting; (ii) pain; and (iii) fatigue. Physicians reported one of the four different levels in each of these three categories. The demonstration project was open to all oncologists. Payment of \$130 was made to physicians who submitted the three codes in conjunction with each day of chemotherapy administration. We are using a contractor to evaluate this demonstration and the evaluation is ongoing.

For 2006, we are conducting a one-year demonstration where physicians treating cancer patients are routinely consulting clinical practice guidelines, and comparing management of their patients to that recommended in the guidelines. As part of this demonstration they are also reporting on the patient's disease status, and the focus of their visit with the patient—all data not routinely captured in the claims processing system. Participating oncologists and hematologists qualify for additional payments if they submit data from each of the three categories when they bill for an evaluation and management (E&M) visit of level 2, 3, 4, or 5 for established patients. Practices reporting data on all three categories qualify for an additional payment of \$23 in addition to the E&M visit.

The evaluation of the 2006 demonstration will use a combination of quantitative and qualitative methods to examine the impact of the demonstration on: Medicare spending; beneficiary outcomes; physician practice adherence to clinical guidelines; and financial status of physicians' practice. In addition, through field assessments and physician surveys, the evaluation will examine how the demonstration impacted the way physicians delivered care to beneficiaries, and the types of modifications they needed to make in order to be able to report the data. The evaluation will include a validation study of physician-reported adherence to guidelines developed by the American Society of Clinical Oncology and the National Comprehensive Cancer Network. The evaluation of the 2006 demonstration is being managed jointly by CMS' Office of Research, Development and Information (ORDI) and the National Cancer Institute (NCI). Contractor bids have been submitted for the evaluation and an award is expected to be made by Fall 2006.

IVIG

CMS and other components of the Department of Health and Human Services (HHS) have heard concerns from some providers and beneficiary groups about the adequacy of the intravenous immune globulin (IVIG) supply and Medicare reimbursement for these products. Access to care is very important to the Medicare program and we are concerned about these reports.

During the past year, we have taken several actions to refine Medicare payment rates for IVIG that could be accomplished within our existing authorities. We established separate payment amounts for liquid and powder IVIG beginning April 2005. For 2006, we created special pre-administration handling fees of about \$72 for physicians and \$75 for hospital outpatient departments that administer IVIG. At the same time we have continued to work with manufacturers to ensure that they accurately calculate the ASPs that they report to us since these data are used to determine Medicare's payment amounts. The Medicare payment rate for IVIG is updated quarterly based on the most recent data reported by manufacturers. For the third quarter of 2006, the Medicare payment amount increased 11.9 percent for lyophilized IVIG (powdered form) and 3.5 percent for liquid IVIG.

The current IVIG market involves a complex set of demand, supply and other factors. Demand for IVIG has grown significantly in recent years, as off-label use of the product has increased. Because IVIG is a product derived from human plasma, supply increases require significant start-up time. Supply availability for IVIG has historically been cyclical. IVIG production capacity contracted somewhat in 2004 but increased again in 2005, and manufacturers indicated that they expect supply to increase further in 2006. The industry barometer of supply adequacy for May 2006 indicates that "inventory levels are between 2–5 weeks and supply is still adequate."

In addition, there are a number of other factors contributing to the complex IVIG situation. Manufacturer consolidations and changes in business practices have occurred, such as placing IVIG on allocation. Allocation means that a substantial portion of the IVIG distributed in the United States is not for sale on the open market, but has been obligated for delivery to Group Purchasing Organizations (GPOs), distributors, and end-users based on long-term contracts with manufacturers. There are also reports of some IVIG product being diverted to the secondary (resale) market where product is reportedly being sold with extremely high markup.

A number of components of HHS continue to work together, and with manufacturers, providers, patient groups, and stakeholders to understand the present situation and to assess potential actions that will help to ensure an adequate supply of IVIG and patients receiving appropriate and high quality care. To better understand the market for IVIG and evaluate access and reimbursement concerns from patients and physicians, HHS has commissioned an independent, expert study to assess these factors. We want to maintain access to IVIG, but it is important to determine the causes of the current concerns so we can implement appropriate measures to achieve this goal. We plan to continue to work with all stakeholders to understand the forces causing IVIG concerns and to help craft effective solutions.

Summary

The intentions of the MMA changes were to rationalize how Medicare pays for both Part B drugs and their administration, and also to create options for physicians to either buy and bill for Part B drugs, or to have those drugs furnished to a physician from a qualified vendor upon submission of a prescription order. Payments for drug administration codes have increased significantly from levels under the AWP payment system.

Studies by MedPAC, the Office of the Inspector General (OIG) and the Government Accountability Office suggest that oncologists can generally purchase drugs for the treatment of cancer at less than the Medicare payment amount. Furthermore, the OIG study found that this was true for both large and small practices. These studies suggest that the ASP system has helped Medicare payments for oncology drugs covered under Part B move closer to actual market prices. We are hopeful that the initial success of the CAP program will encourage additional physician enrollment.

The Department plans to continue monitoring payment for and access to Part B drugs. CMS and other agencies within HHS are continuing to work with manufacturers, providers, patient groups, and stakeholders to ensure that patients receive appropriate and high quality care. I look forward to answering any questions you may have.

Chairman JOHNSON OF CONNECTICUT. Mr. Vito.

STATEMENT OF ROBERT A. VITO, REGIONAL INSPECTOR GENERAL FOR EVALUATIONS AND INSPECTIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. VITO. Good afternoon, Madam Chairman. I am Robert Vito, Regional Inspector General for Evaluations and Inspections at the U.S. Department of Health and Human Services Office of Inspector General. I appreciate the opportunity to appear before you today to discuss our work regarding Medicare part B reimbursement for prescription drugs. In the past, Medicare part B reimbursed for most covered drugs based on their average wholesale price, or AWP. However, this system was fundamentally flawed, causing the Medicare Program and its beneficiaries to overpay by hundreds of

millions of dollars a year. To help bring reimbursement more in line with the actual cost, Congress created the average sales price, or ASP, methodology.

Unlike AWP, ASP is defined by law and based on actual sales transactions. Recent data on Medicare expenditures show that the move to ASP in January of 2005 has lowered inflated reimbursement amounts. As a result, the part B expenditures for drugs in 2005 fell by almost 1 billion from the previous year. To help monitor the new reimbursement system, the MMA expanded the OIG's role. The OIG was required to conduct a study on the adequacy of ASP-based reimbursement amounts for cancer drugs as well as to perform comparisons of ASP to other pricing points. Through this we identified a small number of instances where Medicare reimbursement may exceed certain prices in the marketplace.

Our first study on ASP addressed the ability of physician practices in three cancer-related specialties to obtain drugs at 106 percent of ASP. We found that the average prices paid by physicians for 35 of the 39 drugs we reviewed were less than the ASP-based reimbursement amounts. Additionally, we found that in most cases larger practices purchase drugs for less than the smaller practices. The next three studies involved the comparison of ASP to average manufacturer prices, or AMPs, and ASP to widely available market prices, or WAMP. When the OIG finds that the ASP of the drug exceeds the AMP or WAMP by 5 percent, the MMA gives the Secretary the authority to reduce the Medicare reimbursement amount for the drug. In the first of these comparisons we found for the first quarter of 2004 some Medicare reimbursement for 51 of the 364 drugs included in our review had an ASP that exceeded AMP by at least 5 percent. If reimbursement for these 51 drugs had been lowered to 103 percent of AMP, Medicare expenditures would have been reduced by an estimated 164 million in 2005.

Last week my office released a second report on the subject finding that, for the second quarter of 2006 Medicare reimbursement amounts, ASP exceeded AMP by at least 5 percent for 46 of the 341 drugs reviewed. If its reimbursement amount for the 46 drugs had been based on 103 percent of AMP, the Medicare expenditures would have been reduced by 64 million in 1 year. The OIG also issued a report comparing ASP to WAMP for a small number of drugs that we expected would meet the criteria for the price reduction. We found that the prices for five of the nine drugs we reviewed did indeed surpass the threshold, with ASP exceeding WAMP by 17 percent to 185 percent. Medicare expenditures would be reduced as much as \$67 million in 2006 if reimbursement amounts for these five codes were lowered to the WAMP.

In addition to the mandated work I have described, we have also issued a report on CMS's flawed methodology for calculating ASP. This flaw stems from the fact the CMS does not consistently weight the number of units of the drugs that were sold in its calculation. As a result, in the first quarter of 2005, reimbursement amounts for 46 percent of the drugs were too high, and reimbursement amounts for 13 percent of the drugs were too low, leading to 110 million in excessive reimbursements that year.

I want to conclude my testimony by stressing that the new ASP system represents a marked improvement over the old AWP meth-

odology. Under this new system, we have seen a substantial reduction in the reimbursement amounts for many products, bringing a decade-long trend of increasing expenditures for part B drugs to a halt. However, like any new reimbursement system, we realize that its implementation must be continually monitored to ensure that the payment levels are appropriate. To this end we are committed through our oversight work to continue to provide CMS and the Congress with timely information on ASP-related issues. This concludes my testimony, and I welcome your questions.

Chairman JOHNSON OF CONNECTICUT. Thank you, Mr. Vito. [The prepared statement of Mr. Vito follows:]

Statement of Robert A. Vito, Regional Inspector General for Evaluations and Inspections, U.S. Department of Health and Human Services

Good afternoon, Madam Chairman. I am Robert Vito, Regional Inspector General for Evaluation and Inspections in Philadelphia at the U.S. Department of Health and Human Services' Office of Inspector General (OIG). I appreciate the opportunity to appear before you today to discuss OIG's most recent work regarding Medicare Part B reimbursement for prescription drugs and the average sales prices (ASP) used to set this reimbursement.

In short, the new system appears to have lowered the previously inflated Part B reimbursement amounts and, in turn, reduced overall Medicare expenditures for prescription drugs. Even so, OIG's work has identified a small number of instances in which the reported ASPs, and the resulting Medicare reimbursement amounts, may still be higher than certain other prices in the marketplace. We have also identified an issue with the method CMS uses to calculate reimbursement amounts.

Flaws in the Previous Reimbursement System

Prior to 2004, Medicare Part B reimbursed for most covered drugs based on the lower of either the billed amount or 95 percent of the average wholesale price (AWP) as published in national pricing compendia. The AWP is not defined by law or regulation, nor is it typically based on actual sales prices. As numerous reports by OIG and the Government Accountability Office have illustrated, the AWP-based reimbursement amounts for most covered drugs were significantly higher than the prices that drug manufacturers, wholesalers, and other similar entities actually charged the physicians and suppliers who purchase these drugs. Consequently, under this flawed system, the Medicare program and its beneficiaries were overpaying by hundreds of millions of dollars per year for prescription drugs.

To help align reimbursement amounts with actual acquisition costs, Congress included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provisions to reform Part B drug reimbursement. The MMA specified that reimbursement amounts for most outpatient prescription drugs furnished in 2004 be set at 85 percent of the AWP, until a new methodology could be implemented on January 1, 2005. This new methodology based reimbursement amounts on manufacturer-reported ASPs rather than AWP. Unlike the AWP, an ASP is defined by statute and based on actual sales transactions. The MMA defines an ASP as a manufacturer's sales of a drug to all nonexempt purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those paid under the Medicaid drug rebate program.^{1,2} Under this new methodology, Medicare reimbursement for most Part B drugs is set at 106 percent of the drugs' volume-weighted ASPs.³

¹Section 1847A(c) of the Social Security Act, as added by the MMA.

²Pursuant to section 1847A(c)(2) of the Social Security Act, sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" for Medicaid drug rebate purposes.

³Although manufacturers submit an ASP and sales volume for each individual drug product they sell, CMS does not establish a reimbursement rate for each specific drug product. CMS uses ASP data for individual drug products to calculate an overall ASP for the procedure code. The ASP for an individual drug product is weighted by the amount of that drug sold during the quarter. This means that the ASP for a drug with a high volume of sales should have greater influence on the reimbursement amount for a procedure code than an ASP for a drug with a low volume of sales.

Impact of ASPs On Medicare Reimbursement

The Congressional Budget Office estimated that the changes enacted by the MMA would save Medicare almost \$16 billion over 10 years by reducing excessive Medicare reimbursement amounts for Part B-covered drugs. Recent data on Medicare reimbursement and expenditures provide evidence confirming that the ASP-based reimbursement system has substantially lowered reimbursement amounts for numerous drugs. For about one-quarter of the drugs covered under Part B, Medicare reimbursement amounts have been reduced by at least 50 percent when compared to pre-MMA levels. For example, in 2003⁴ (when reimbursement was set at 95 percent of the AWP), Medicare paid almost \$120 for a month's supply of the inhalation drug albuterol; today, Medicare pays \$20.⁵ For the cancer drug Zoladex, Medicare paid almost \$450 per dose in 2003; Medicare currently pays \$196 per dose.

The reductions in the reimbursement amounts for individual drugs have had a substantial effect on overall Part B expenditures. Before the MMA was enacted, CMS data indicated that Medicare expenditures for Part B drugs had increased by at least 20 percent annually every year since 1994. By 2004, Medicare was paying almost \$11 billion for covered drugs, up from \$4 billion just 6 years earlier. Due to changes made by the MMA, this trend has reversed, with Medicare Part B spending close to \$1 billion less on covered drugs in 2005 than in 2004. This decrease occurred despite rising utilization for the drugs.

OIG Work Involving Medicare Part B Drugs

Prior to the passage of the MMA, OIG's primary role in Medicare drug pricing involved identifying and reporting on flaws in the AWP-based system that left the program vulnerable to fraud, waste, and abuse. In more than a dozen reports, we repeatedly found that Medicare paid too much for prescription drugs due to inflated AWPs. In addition, working with our many law-enforcement partners, we assisted in investigations of pricing issues that resulted in significant civil and criminal settlements.

The MMA established two mandates for OIG that changed and expanded our role in monitoring Medicare drug pricing. First, the MMA mandated that OIG conduct a study on the adequacy of ASP-based reimbursement amounts for certain cancer drugs. Second, the MMA required OIG to perform an ongoing monitoring function that compares ASPs to other pricing points. As discussed below, we have recently completed studies that address both of these mandates.

OIG Work Required by the MMA

Adequacy of ASP-Based Reimbursement for Certain Cancer Drugs

The MMA required that OIG conduct a study on the ability of physician practices of different sizes in the specialties of hematology, hematology/oncology, and medical oncology to obtain drugs and biologicals at 106 percent of the ASP. This requirement responded to concerns that the new reimbursement amounts based on ASPs may be lower than the drug acquisition costs for physicians in these specialties. OIG completed this study in September 2005.⁶

We compared the average prices paid by physicians for drugs represented by 39 procedure codes to Medicare reimbursement amounts and concluded that physician practices in the three specialties could generally purchase drugs for the treatment of cancer patients at less than the MMA-established reimbursement rates (i.e., 106 percent of the ASP). Overall, the report found that the average prices paid for 35 of the 39 drugs under review were less than the Medicare reimbursement amounts. Larger physician practices purchased drugs at greater discounts (i.e., at least 15 percent below Medicare reimbursement) for more drugs than smaller practices. In addition, we also estimated that for 35 of the 39 codes, physician practices could purchase drugs for less than the reimbursement amounts during at least half of the months reviewed.

OIG Comparisons of ASPs to Other Pricing Points

The MMA also mandated that OIG conduct studies that determine whether the ASP exceeds certain other prices. Specifically, the MMA required OIG to compare

⁴All data and methods described in the testimony refer to calendar years.

⁵These figures relate only to reimbursement for the drugs themselves. They do not include the dispensing fees paid to the supplier.

⁶"Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients," A-06-05-00024.

manufacturer-reported ASPs to both average manufacturer prices (AMP)⁷ and widely available market prices (WAMP).⁸ In certain situations where the ASP of a drug exceeds the AMP or the WAMP by a certain threshold, the MMA gives the Secretary the authority to reduce the reimbursement amount for the drug to either 103 percent of the AMP or 100 percent of the WAMP. Currently, the threshold amount is 5 percent, although the Secretary has the authority to raise or lower this percentage in the future.

- *Comparisons of ASPs to AMPs.* OIG completed the first of its studies comparing ASPs to AMPs and issued a report earlier this year.⁹ We found that in the third quarter of 2004, 51 of the 364 procedure codes (14 percent) included in this review had an ASP that exceeded the AMP by at least 5 percent. If reimbursement amounts for these 51 codes had been lowered to 103 percent of the AMP, Medicare expenditures would have been reduced by an estimated \$164 million in 2005.

In response, CMS stated that the information in the report was helpful in its continuing efforts to monitor payment adequacy under the ASP methodology. However, CMS noted that OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology. Although CMS acknowledged the Secretary's authority to adjust ASP payment limits when certain conditions are met, it believed that other factors should be considered, including the timing and frequency of pricing comparisons, stabilization of ASP reporting, the effective date and duration of rate substitution, and the accuracy of ASP and AMP data.

In June 2006, OIG released a second report comparing ASPs to AMPs.¹⁰ We found that for 46 of the 341 procedure codes (13 percent) included in this review, ASPs exceeded AMPs by at least 5 percent in the fourth quarter of 2005.¹¹ Twenty of these codes were identified in OIG's previous report as having ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2004. If reimbursement amounts for the 46 codes had been based on 103 percent of the AMP, we estimate that Medicare expenditures would have been reduced by \$64 million in one year.

- *Comparison of ASPs to WAMPs.* In addition to the comparisons of ASPs and AMPs, OIG released a report comparing ASPs to WAMPs in June 2006.¹² For this analysis, we specifically selected a purposive sample of nine procedure codes for which we suspected that the ASP might exceed the WAMP by at least 5 percent. The purposive sample was based on the results of the September 2005 OIG report on adequacy of reimbursement for cancer drugs.

We found that 5 of the 9 procedure codes included in this review met or surpassed the 5-percent threshold defined by the MMA. For these 5 codes, the ASPs exceeded the WAMPs by a range of 17 to 185 percent. We estimate that Medicare expenditures would be reduced by as much as \$67 million in 2006 if reimbursement amounts were lowered to the WAMPs for these 5 codes. In addition, the prices that physicians pay for these drugs may be even lower than the WAMPs that were calculated, as all of the responding distributors offered price discounts to physician customers that were not reflected in the calculation of WAMPs.¹³

⁷ AMPs, also reported by drug manufacturers to CMS, are used in the determination of rebates in the Medicaid program. As defined in section 1927(k)(1) of the Social Security Act, the AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts.

⁸ Section 1847A(d)(5) of the Social Security Act generally defines widely available market price to be the price that a prudent physician or supplier would pay for the drug, net of any routinely available price concessions.

⁹ "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices," OEI-03-04-00430, May 2006.

¹⁰ "Comparison of Fourth Quarter 2005 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for the Second Quarter of 2006," OEI-03-06-00370.

¹¹ Fourth-quarter 2005 ASPs are used to set second-quarter 2006 reimbursement amounts.

¹² "A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005," OEI-03-05-00340.

¹³ The most common type of price discount offered to physician customers was a prompt pay discount. Three of the five companies that responded to our request for information offered this type of incentive, with percentage discounts ranging from 1 to 3 percent, depending on the time of payment.

Additional OIG Work Involving ASP

CMS's Calculation of ASPs

For the most part, the Medicare Part B reimbursement amount for a drug is now based on a volume-weighted ASP that CMS derives from the underlying ASPs for individual drug products reported by manufacturers. In the process of conducting the mandated price comparisons, we identified a problem with the method CMS uses to calculate volume-weighted ASPs. We alerted CMS to the problems with its calculation and issued a report on this subject in February 2006.¹⁴ We found that CMS's method for calculating a volume-weighted ASP is mathematically flawed because CMS does not consistently weight the number of units of a drug that were sold throughout its equation. As a result, many procedure codes have a reimbursement amount that is higher or lower than the amount that would have been calculated if the weighting were applied consistently.

According to OIG's analysis of prices published in the first quarter of 2005, the flawed calculation caused 46 percent of procedure codes to be reimbursed at amounts that were higher than they should have been, resulting in an estimated \$115 million in excessive Medicare reimbursements in 2005. For 13 percent of procedure codes, CMS's reimbursement amount was lower than it should have been, representing an estimated \$5 million loss to providers in 2005. The flawed calculation did not affect reimbursement amounts for the remaining 41 percent of procedure codes. OIG recommended that CMS change its calculation of volume-weighted ASPs. Although CMS stated that it may consider altering the ASP methodology in the future, the agency has yet to make any changes to its calculation of volume-weighted ASPs.

Drug Manufacturers' Calculations of ASPs

OIG is currently auditing eight drug manufacturers to evaluate their methodologies for calculating ASPs for individual drug products. Several more audits are planned in the near future.

Adequacy of Reimbursement for Intravenous Immune Globulin

This Subcommittee and the House Committee on Energy and Commerce Subcommittee on Health requested that OIG evaluate the current state of pricing and supply for one specific drug, intravenous immune globulin (IVIG). Patient advocacy groups and physicians have repeatedly expressed concerns that, under the ASP-based reimbursement methodology, the cost for physicians to acquire IVIG exceeds Medicare's reimbursement amount. OIG's work in this area is ongoing. A final report that addresses Medicare reimbursement for IVIG, provides perspectives on the supply and distribution of this unique product, and makes any recommendations that are warranted will be issued in the near future.

Dispensing Fees for Inhalation Drugs

In tandem with the reimbursement reductions resulting from the MMA, CMS raised the dispensing fee paid by Medicare in 2005 for inhalation drugs from \$5 to an interim amount of \$57 for a 30-day drug supply. It did so based in large part on industry statements claiming that beneficiaries receive numerous, important services from their suppliers. Last year, OIG issued a report that reviewed the nature and extent of dispensing services that Medicare beneficiaries received from inhalation drug suppliers in 2003. OIG found that the most common service beneficiaries received was contact for drug refills. Few beneficiaries received more intensive services such as education, care plan revision, or a respiratory assessment, and 16 percent of beneficiaries received no services at all. The most common way beneficiaries received services was by telephone; only 1 in 10 beneficiaries received a home visit.

Conclusion

Prior to the passage of the MMA and the implementation of the new ASP-based methodology, Medicare reimbursed for many prescription drugs at prices that did not reflect actual acquisition costs for physicians and suppliers. Under the new system, there has been a substantial reduction in reimbursement amounts for many high-dollar products, causing the decade-long trend of increasing Part B expenditures for prescription drugs to reverse. Building on OIG's existing work that identified weaknesses in the old system, we have responded to new mandates under the MMA by taking on a more extensive role in helping to ensure the appropriateness of Medicare payments under the new methodology. As a result, OIG has already

¹⁴"Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs," OEI-03-05-00310.

identified a few instances where the reported ASPs, and the resulting Medicare reimbursement amounts, may still be higher than certain other prices in the marketplace. In addition, OIG has undertaken nonmandated audits and evaluations of issues that we have identified as important to ensuring the integrity of Medicare Part B drug payments, such as the methodology used by CMS to calculate Medicare reimbursement amounts, and the methodologies used by drug manufacturers to calculate ASPs.

It appears that the new ASP methodology represents a marked improvement over the old AWP system. However, like any new reimbursement system, we realize that its implementation must be continually monitored to ensure that payment levels are appropriate. To this end, we are committed through our oversight work to provide CMS and Congress with timely information regarding ASPs and other drug reimbursement issues.

This concludes my testimony, and I welcome your questions.

Chairman JOHNSON OF CONNECTICUT. Dr. Miller.

**STATEMENT OF MARK MILLER, PH.D., EXECUTIVE DIRECTOR,
MEDICARE PAYMENT ADVISORY COMMISSION**

Mr. MILLER. Chairman Johnson, Ranking Member Stark and distinguished Subcommittee Members, I am Mark Miller, Executive Director of the Medicare Payment Advisory Commission. I will apologize here. I think you are going to hear some things that you have already heard. Medicare part B, that pays for—part B drugs that are used to treat patients with very serious medical conditions such as cancer, hemophilia and rheumatoid arthritis. Under Medicare's old system, the AWP, Medicare expenditures were growing rapidly at annual rates of 20 and 25 percent. This is because AWP was inflationary and paid well above what physicians paid to purchase the drug. Physicians argued that they needed this spread in order to cover the cost of administering these drugs.

The MMA changed both the way that Medicare pays for the drug as well as the way physicians are paid to administer drugs. The new system, the ASP, has resulted in substantially lower Medicare expenditures. As you have just heard, in 2005 there was actually a reduction in expenditures. This is because Medicare has realized lower prices for these drugs. For example, we looked at the volume and mix of drugs provided in 2004 under the old payment system and determined that if they had been paid under the new payment system, Medicare would have paid 22 percent less.

Congress asked MedPAC to examine the impact of these policy changes on oncology practices and on Medicare beneficiaries receiving cancer treatments. Before I go through these results, I want to make one caveat. We were asked to report in January of 2006, which we did, but, of course, many of the policy changes were still coming into effect. We analyzed national claims data. We made several site visits to communities to talk to oncology offices, to outpatient departments, hospitals, physicians, and we also ran focus groups on beneficiaries. This is what we found. The volume of services going to beneficiaries continued to increase after the implementation of the policies. Between 2004 and 2005, cancer chemotherapy sessions in physicians' offices increased by 13 percent. The number of beneficiaries receiving cancer chemotherapy sessions increased by at least 7½ percent. As you have already heard mentioned, the actual Medicare reimbursements to support the admin-

istration of the drugs increased significantly over those time periods.

There is also a long-running trend in the provision of these services toward the use of the latest drugs in order to give patients new options to treat their cancer. These drugs, because they are new, are often very expensive. That trend continued after the implementation of the policies. So, all of these data don't point to the lack of access problem, but there is one issue I want to bring to your attention. In a couple of the communities that we visited, we found that beneficiaries who did not have supplemental insurance were being referred to hospital outpatient departments for the infusion of their drug. The issue breaks down like this. If the physician gets reimbursed for cancer chemotherapy drugs, the physician is getting a payment from the program and from the beneficiary. If the beneficiary is unable to make that payment, the physician may determine that they can't afford to purchase that drug, send the patient to the outpatient department for the infusion, and bring them back to the office for the remainder of their care.

So, there is no access issue per se. The beneficiary still gets the infusion, but there is clearly a convenience issue and other issues that attach here, of program payment issues as well. Practices were able to purchase most Medicare—most, not all—but most Medicare drugs at or below Medicare's payment rate. Oncologists did change the organization of their practices. They hired staff and engaged in more aggressive price negotiation tactics, and also kept lower inventory in order for them to take advantage of changes in prices.

I will conclude my testimony by saying we think that ASP is not a perfect payment system, as well as some of the other statements that were made here, but we think it is a vast improvement over the AWP, and also, like you have heard, we believe it needs continued monitoring in order to be sure that the prices—prices are tracking the payment, the prices that physicians are actually paying to get the drug. I look forward to your questions.

Chairman JOHNSON OF CONNECTICUT. Thank you, Mr. Miller.

[The prepared statement of Mr. Miller follows:]

Statement of Mark Miller, Ph.D., Executive Director, Medicare Payment Advisory Commission

Chairman Johnson, Ranking Member Stark, distinguished Subcommittee members. I am Mark Miller, executive director of the Medicare Payment Advisory Commission (MedPAC). I appreciate the opportunity to be here with you this morning to discuss MedPAC's work on Medicare Part B drugs and oncology.

Before 2006, Medicare covered few outpatient drugs but those medications that were covered under Part B were used to treat patients with very serious medical conditions like cancer, hemophilia, and rheumatoid arthritis. Medicare expenditures for these drugs were growing rapidly, rising from \$2.8 billion in 1997 to \$10.3 billion in 2003, representing about 4 percent of Medicare spending. Although policymakers agreed that payment rates for Part B drugs were too high, providers argued that the high rates were necessary to offset drug administration fees that were too low to cover the costs of administering those drugs to beneficiaries.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) changed the way Medicare pays for both drugs and drug administration services under the physician fee schedule. As intended by the policy, payment rates for drugs were reduced to levels closer to the prices providers were paying while payment rates for drug administration increased. As a result of the payment changes, Medi-

care spending for Part B drugs declined in 2005 despite increases in the volume of drugs used and the substitution of newer drugs for older less expensive products.

The Congress directed MedPAC to study the effect of these changes on beneficiary access and quality of care. Our first report, completed January 2006, focused on services provided by oncologists. We found that, in general, beneficiary access to chemotherapy drugs remained good and we found no evidence that quality of care declined. For our second mandated report, due in January 2007, we are studying the effects of the payment changes on drug administration services provided by other specialties, such as urologists and rheumatologists.

Although no payment system is without drawbacks, the current system has resulted in Medicare payments that are closer to the price physicians pay and has reversed spending trends for Part B covered drugs. However, the Commission believes that it is important for the Secretary to continue monitoring physician acquisition costs to test the accuracy of Medicare drug payments as the new payment system evolves over time.

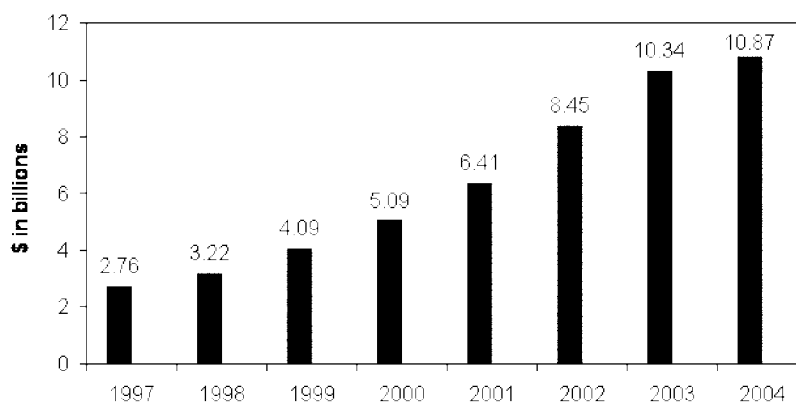


Chart 1. Medicare spending and annual growth rates for Part B drugs.

Source: MedPAC analysis of CMS data, 1997–2004

Background

Under Part B, Medicare covers drugs administered in physician offices, including drugs used for chemotherapy, drugs used as part of durable medical equipment, blood clotting factor, erythropoietin used to treat anemia in end-stage renal disease patients and cancer patients, and some oral medications such as immunosuppressive drugs used following organ transplants. These drugs are not usually purchased at retail pharmacies. Providers buy the products and then bill Medicare as they administer them to patients. Physician claims account for the majority of Medicare expenditures for Part B outpatient drugs. Physicians in only two specialties—hematology oncology and medical oncology—submitted claims for almost 50 percent of total billing for Part B drugs in 2004, not including drugs provided in dialysis facilities.

Expenditures for Part B drugs increased rapidly, more than 25 percent every year from 1998 to 2003. One of the most significant factors driving spending growth was the payment method. Following the Balanced Budget Act (BBA) of 1997, the Medicare payment rate for covered drugs was set at 95 percent of the average wholesale price (AWP). Despite its name, AWP does not represent the average wholesale price. Rather, it can be thought of as a manufacturer's suggested list price. It does not have to correspond to any transaction price or average transaction price, which often reflect substantial discounts. Every drug has its own AWP. Individual AWP's are compiled and reported in compendia like the Red Book and First Databank largely on the basis of information supplied by the manufacturers. A series of investigations by the Department of Health and Human Services Office of the Inspector General (OIG) and the Government Accountability Office (GAO) showed that Medicare payment rates were well above providers' acquisition costs.

Policymakers discussed a number of ways to reform the payment system, including continuing to pay based on AWP but requiring a steeper discount, setting payment to a different benchmark tied to transaction prices like the average sales price

(ASP) or the average acquisition price (AAP), or using competitive bidding to lower prices. In its June 2003 Report to Congress, the Commission examined these policy options.

Our analysis suggested that continuing to use AWP as a benchmark but requiring steeper discounts would lead to limited savings for Medicare. In many cases, the additional discount would still result in payments substantially higher than acquisition costs. AWP would still not correspond to any transaction price and could not be audited. Providers would continue to have an incentive to switch to drugs with higher AWP's to maximize their profit.

Next, we examined the potential effects of a payment method based on a computed average transaction price such as the average sales price (ASP), or the average acquisition price (AAP). Both of these methods depend upon calculated average transaction prices for products. Although in theory calculations based on ASP and AAP should result in the same payment rate, ASP is based on data collected from pharmaceutical manufacturers while AAP data is collected from physicians and suppliers. Differences might reflect inclusion of the wholesalers' fees in AAP and differences in the way manufacturers and physicians would report the data. Since manufacturers are already reporting average price data to CMS in order to determine Medicaid drug payment rates, the data needed to calculate ASP is more readily available than the data needed to determine the average acquisition price.

We concluded that a competitive system or use of either benchmark (ASP or AAP) would reduce Medicare payments. We recognized that there were drawbacks to every proposed reform of the payment system but that all options were likely to reduce Medicare payments compared to the AWP system then in place.

All proposals based on these benchmarks anticipated paying providers a specified percentage above the calculated price although they differed as to how high to set the additional payment. The Commission did not recommend that the payment rate be set at any specific percentage above the benchmark. We said that beneficiary access would not be affected as long as the payment rate was set high enough to meet the costs of efficient providers. We also said that payments set too high above the benchmark would encourage price increases and reduce Medicare savings.

Following passage of the MMA, Medicare significantly changed the way it pays providers for physician-administered drugs and drug administration services, generally reducing the payment rate for drugs while increasing payments for drug administration services. In 2005, Medicare began paying for Part B drugs based on 106 percent of the average sales price (ASP). ASP represents the weighted average of manufacturers sales prices for each product that falls within a Medicare billing code. (Medicare billing codes are used for multiple products.) It is based on data submitted quarterly by pharmaceutical manufacturers, net of price concessions such as rebates and discounts and is limited to sales in the United States. The ASP payment rate is set prospectively based on these transaction prices from two quarters prior. Thus, if manufacturers raise prices in the succeeding quarters, purchasers may have difficulty purchasing products at the Medicare payment rate until the ASP "catches up." On the other hand, if prices go down, either because of competition between therapeutically equivalent branded drugs or because a generic version of a branded drug becomes available, purchasers may buy products at prices significantly below the payment rate until the ASP "catches up."

MedPAC study

Concerned that the payment changes not affect beneficiary access to needed medical care, the Congress directed the Commission to complete two studies on the effects of the new payment system on beneficiary access, quality of care, and physician practices. Our first report, delivered January 2006, analyzed the effect of the payment changes on beneficiary access to chemotherapy. We are currently conducting a second study on the effect of the payment changes on services provided by other specialties including urologists, rheumatologists, and infectious disease specialists.

Because the legislated changes had not yet been fully implemented and we only had partial data for 2005, the Commission had limited ability to analyze the impact of the changes. We undertook a series of qualitative and quantitative analyses to assess beneficiary access and quality of care.

- We analyzed expenditures and changes in volume for chemotherapy services using Medicare claims data.
- We analyzed a commercial database with prices for drugs used by oncologists to see if prices physicians paid were below the Medicare payment rates, and we measured the variation in prices different physician practices paid.
- We visited community oncologists, hospital outpatient departments, and health plans in five markets to discuss the effects of payment changes on practices.

- We conducted four focus groups with Medicare beneficiaries receiving chemotherapy during 2005 to see how the payment changes affected their experiences.
- We interviewed stakeholders to gain their perspective on how the payment changes affected the buying and selling of physician-administered drugs.
- Finally, we reviewed the literature on pricing for Part B drugs and studies of quality-of-care indicators for chemotherapy.

We found that the payment changes did not affect beneficiary access to chemotherapy services. Physicians provided more chemotherapy services and more Medicare beneficiaries received services in 2005 than in 2004. We saw no indication that quality of care was affected, and patients continue to be satisfied with the care they are receiving. We found no indication of access problems in any region of the country. In general, large practices were able to purchase chemotherapy drugs at lower prices than small practices, but all could buy most drugs at prices below the Medicare payment rate. However, there is one issue to report. In some areas, beneficiaries without supplemental insurance were receiving chemotherapy in hospital outpatient departments rather than physician offices.

Medicare spending on chemotherapy drugs and services

To measure the impact of the 2005 Medicare payment change to ASP, we analyzed carrier claims for the first six months of 2005. We compared our results to spending and volume claims for the same period in 2003 and 2004. We found that beneficiaries received more drug administration services in 2005 than 2004, but that spending remained constant. Medicare expenditures for chemotherapy drugs declined in 2005 because of the change to payment based on ASP. The change to pricing based on ASP also narrowed the gap between the prices paid by the providers who negotiated the best and worst deals with drug manufacturers.

Preliminary estimates by CMS indicate that spending for all Part B drugs in 2005 declined by 3 percent. Drug spending is determined by volume, drug mix, and the payment rate for the drugs. In the case of Part B drugs, volume increases were offset by changes in the payment rate.

To demonstrate the effect of pricing changes from 2004 to 2005, we estimated what Medicare would have paid if the volume of all the specific Part B drugs billed in 2004 were paid according to the Medicare payment rates for October 2005. Using this methodology, we calculated that expenditures for all Part B drugs used in 2004 would have cost 22 percent less in 2005.

However, the spending decrease was not as great as the decrease in prices would have suggested because the mix of drugs used in 2005 was different from the mix used in 2004. In a continuation of previous trends, physicians substituted newer, more expensive single source drugs for older drugs. Many of the new drugs are produced through the use of biotechnology. Not only are these products expensive when initially marketed, they face only limited competition over time because the FDA does not yet have an approval process for generic versions of biologicals. Many of these biologicals are used in the treatment of cancer. Of the ten drugs that accounted for the largest share of Part B drug spending, four received FDA approval in 1996 or later. Additionally, spending on injectables too new to have received their own payment codes accounted for 3 percent of Part B drug spending.

Both the volume and payments for chemotherapy administration increased in 2005. We estimate that physicians provided 13 percent more chemotherapy sessions in 2005 than in 2004. CMS changed its rules to allow physicians to bill more codes for each chemotherapy session, so the number of services has increased faster than the number of sessions, by 33 percent from 2003 to 2005. In addition, the Congress made two, one-year payment increases for drug administration: in 2004 it increased payments by 32 percent and in 2005 it increased payments by 3 percent over what would otherwise be paid under the fee schedule. Taken together, the volume and payment increases led spending for chemotherapy administration services to rise 182 percent from 2003 to 2005.

We also compared the number of Medicare beneficiaries receiving chemotherapy in physician offices in 2003, 2004, and 2005. We estimate that the number of beneficiaries receiving chemotherapy in physician offices increased 7.5 percent in 2005, based on the most conservative assumption. No matter what set of assumptions we used, Medicare beneficiaries received an increasing number of chemotherapy sessions in physician offices from 2003 to 2005.

In 2005, CMS provided another source of payments for chemotherapy in physician offices. In addition to paying for drugs and drug administration services, CMS implemented a one-year demonstration project to evaluate how chemotherapy affects the level of fatigue, nausea, and pain experienced by patients. All oncologists were eligible to receive \$130 per patient per day for asking chemotherapy patients three questions about how they had responded to treatment. (Beneficiaries were charged

\$26 copayments for this demonstration.) We estimate that this demonstration project increased Medicare expenditures by more than \$200 million, further increasing drug administration payments by more than 70 percent over 2003 levels. (In 2006, CMS implemented an alternative demonstration project. The agency required oncologists to provide information on treatment patterns for patients with different cancers at different disease stages. Physicians reporting the required data receive \$23 per patient visit.) The addition of the demonstration project funds complicated MedPAC's ability to evaluate fully the effects of the payment changes.

Payment adequacy

In the course of our site visits, the Commission found that most oncologists could purchase most drugs at rates below the Medicare payment level, but profit margins on these drugs generally were low, as the policy change anticipated. Every practice reported that they could not buy some drugs at the payment rate. A study by the Office of Inspector General (OIG) (September 2005) indicated that oncologists could still purchase most drugs at rates below the payment level, although specific drugs posed a problem for some practices. In general, larger practices paid lower prices than smaller practices for the same drugs.

The Commission analyzed the data presented in the OIG report to determine what kinds of drugs provided higher or lower payment margins compared to the Medicare payment rates. We found that the highest payment margins occurred when generic alternatives, such as carboplatin and cisplatin, became available. Purchasers also were able to buy brand name drugs at prices well below Medicare payment rates if the drugs had therapeutic substitutes available. One example would be dolasetron mesylate, one of a number of drugs used to treat nausea in chemotherapy patients.

As providers moved to purchase less costly alternatives, competition between buyers and sellers resulted in lower Medicare payment rates in the following quarters. We found that when the January Medicare payment rate for a drug was more than 15 percent higher than the average price providers paid, the Medicare payment rate fell sharply by October. In particular, payment rates for chemotherapy drugs with high margins in January declined by as much as 72 percent in October.

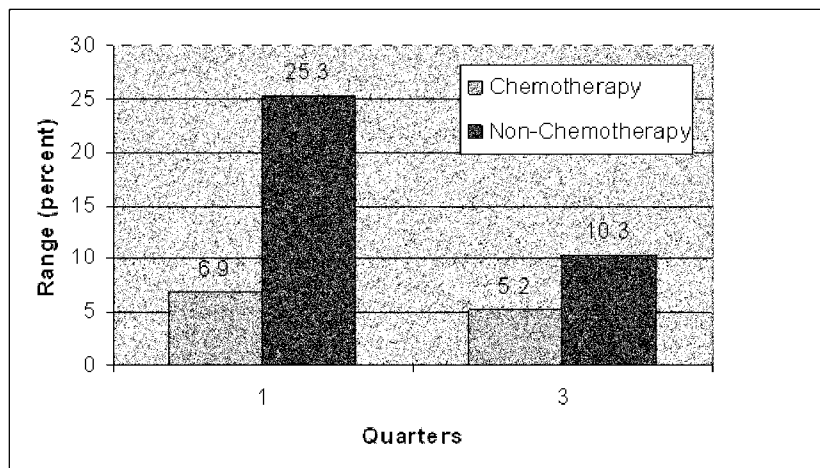
Changes in both pricing and purchasing patterns may affect the accuracy of drug payments over time. For this reason, the Commission has recommended that the Secretary continue to monitor provider drug acquisition costs in both physician offices and dialysis facilities.

Price variation

Under the ASP method, pharmaceutical manufacturers might narrow the range of discounts offered to purchasers to ensure that all physicians could purchase their products at the Medicare payment rates. Since the market for chemotherapy drugs is limited, manufacturers would want to maximize their customer base. To track changes in oncology prices over time, the Commission acquired pricing information from a commercial data source. (Our contract with the vendor does not allow us to present prices for specific drugs.) Prices are net of discounts but do not include rebates provided by manufacturers after the sale. The database shows variation between the lowest and highest prices the purchaser paid. The Commission purchased data on 26 drugs billed by oncologists for one month of each of the first three quarters of 2005. Drugs include chemotherapy agents and medications used to treat the side effects of chemotherapy. Many overlap with the drugs identified in the OIG report. The 26 drugs accounted for more than 50 percent of physician-administered Part B drug spending in 2004.

Our analysis of prices paid by physicians showed that price variation for our basket of drugs declined between the first and third quarters of 2005. Next, we looked to see if the decline in price variation was more pronounced for any particular types of drugs. We grouped our drugs in two ways. First, we classified them based on whether they were single source branded drugs or had generic alternatives. Next, we looked at whether the drugs were chemotherapy agents or prescribed to treat the side effects of chemotherapy. For all four categories, the range, defined as the variation between the best and worst price obtained by physicians, narrowed between the first and third quarters of 2005. The range for single source chemotherapy drugs—small to begin with—narrowed least, falling from 6.9 percent to 5.2 percent. The biggest change was in the range for drugs used to treat the side effects of chemotherapy. That range declined 25.3 percent in the first quarter to 10.3 percent in the third quarter (chart 2). In other words, for this group of drugs there was a difference of about 10 percent between the highest and lowest prices available to physicians.

Chart 2. Change in price variation by chemotherapy and non-chemotherapy drugs
June 2005–December 2004



Note: Two drugs have been excluded because generic alternatives became available during the four quarters. Two others have been excluded because of crosswalk problems. The range measures the percent of variability among the prices paid by clinics. It is measured by subtracting the price paid by the 25th percentile from the price paid by the 75th percentile, dividing by the price paid by the 50th percentile, and multiplying by 100. MedPAC's contract with IMS Health does not allow the prices of drugs to be named individually.

Source: MedPAC analysis of IMS Health data 2004–2005.

Changes in physician practices

The Congress required the Commission to examine the effect of the payment changes on physician practices. During our site visits, we asked physicians how they responded to the Medicare payment changes. Of course, their answers were subjective. Physicians told us they considered the payment changes significant and changed their practices to get better drug prices, lower costs, and boost revenue. All practices changed their drug purchasing activities. Some also changed their use of drugs, office staffing, mix of services offered, and patient mix.

All the physicians we visited reported that they spent more time and resources shopping for lower prices for drugs than they did before the payment changes. Their choice of ancillary drugs for treating chemotherapy side effects was more likely to be based on price. Many practice managers reported that they routinely purchased only one drug to treat nausea and one erythroid growth factor to treat anemia for all the physicians in the practice. Physicians also reported that they kept smaller inventories of drugs on hand than previously. This allowed them to respond quickly to price changes and avoid tying up large sums of capital.

Many offices have hired employees to work with patients when they begin treatment to ensure that they can pay their out-of-pocket expenses. This financial adviser estimates the beneficiary's potential liability based upon the treatment plan. If the beneficiary does not have supplemental insurance, the adviser determines whether she qualifies for other assistance, including Medicaid and assistance programs maintained by individual pharmaceutical manufacturers. The beneficiary may be given a payment schedule to make copayments over time.

Practices reported that differences in local coverage policies affected their treatment decisions. Physicians were reluctant to use expensive new therapies that they thought the local carrier might not cover. For example, a carrier might cover a new drug for treatment of one cancer while the physician wanted to use it to treat a patient with another type of cancer. One practice reported sending a patient to the hospital outpatient department for treatment because the local intermediary covered a particular drug and the carrier did not. Practices reported they were less likely to appeal local coverage decisions. They found the appeals process too expensive and time-consuming and the outcome of the appeal uncertain.

Physicians took other actions to reduce costs or improve efficiency. For example, some practices reduced costs by changing their mix of employees, replacing full-time employees with part-time employees or replacing nurses with pharmacy technicians. Similarly, many practices reported that they reduced health and pension benefits for their employees. One practice reported increasing efficiency by hiring workers to do the coding for oncology nurses and freed up their time for patient care. Several practices reported hiring a pharmacist to purchase and mix drugs as well as recommend drugs to the practice based on price and clinical effectiveness.

Some practices tried to increase revenues by providing more services in their offices. For example, some physician practices purchased positron emission tomography (PET) scanning technology in the past few years and increased imaging in their offices. However, this was only possible for practices with large facilities. Many practices reported they did not have the space or capital to expand in this way.

No physician or office manager reported that the payment changes affected the quality of care in their office. No beneficiary who participated in our focus groups reported that she had seen a decline in the quality of care she was receiving.

Beneficiaries without supplemental insurance

While the new Medicare payment system has reduced prices for existing drugs, it does not have any mechanism to affect prices for new single source branded drugs as they enter the market. New products have become increasingly expensive in the past few years. Beneficiary copayments for these drugs (20 percent of the total payment) are high, and physicians who cannot collect coinsurance from beneficiaries will receive only 80 percent of the Medicare payment rate. Medicare has no limit on the out-of-pocket costs that beneficiaries may face. Medicare beneficiaries without supplemental coverage may be transferred to hospital outpatient departments (HOPDs) and face higher copayments there. However, if beneficiaries who cannot pay cost sharing in physician offices go to HOPDs for chemotherapy infusion, they are unlikely to be able to pay the higher cost sharing there. Instead, their unpaid bills would become bad debt. Medicare pays 70 percent of hospitals' bad debt.

Although we did not find any cases in which beneficiaries could not get chemotherapy services, Medicare beneficiaries without supplemental insurance have more limited choices in some areas of the country. These individuals are more likely than other beneficiaries to receive chemotherapy in HOPDs. In 2004, the Commission found that in some markets, oncology practices had stopped treating Medicare patients without supplemental insurance in their offices. Patients were sent to hospital outpatient departments or safety-net facilities. When we returned to these practices in 2005, we found they were sending more patients to the HOPD. (Hospitals in these markets also reported they were treating more patients with supplemental insurance who required expensive new drugs.)

When patients are sent to the hospital for chemotherapy, the physician continues to manage their care. Physicians still provide evaluation and management visits, some lab work, and other services in the office setting. The patient only receives the chemotherapy infusion in the hospital. Although quality of care may be equivalent in hospitals and physician offices, beneficiaries face higher copayments in HOPDs and treatment usually takes longer. For example, chemotherapy drugs must be mixed in the hospital pharmacy, where pharmacists are preparing medications for all the other hospital patients. The chemotherapy patient will wait longer until the medication is prepared. Only a few beneficiaries who participated in our focus groups had been referred to the HOPD from physician offices. They emphasized the duplication of tests and increased time commitments caused by the switch. One individual complained about the higher copayments.

As the price of new single source cancer drugs continues to rise, beneficiaries without supplemental insurance may have an increasingly hard time paying their 20 percent coinsurance. Although most physician practices have continued to treat all beneficiaries in their offices, beneficiary inability to meet cost-sharing requirements creates a financial liability for the practices. Many practices have begun to counsel beneficiaries on their estimated out-of-pocket liabilities before treatment begins. A few practices reported instances in which beneficiaries refused treatment because they did not want to travel to a hospital or leave her family with debts caused by her out-of-pocket liability.

We cannot quantify the number of beneficiaries who need help paying their coinsurance for chemotherapy. We have no source of data to determine the number of Medicare beneficiaries without supplemental insurance who are receiving chemotherapy services. Data on supplemental insurance are not captured on Medicare claims. The oncology practices we visited estimated between 5 and 20 percent of their Medicare patients have no source of supplemental coverage. Estimates varied depending on the demographic structure of the market and the availability of Medi-

care Advantage and retiree health insurance. The Commission (MedPAC 2005a) estimates that, in general, 9 percent of beneficiaries have no source of supplemental coverage. Beneficiaries without supplemental coverage are not the only individuals facing high copayments. Some cancer patients who participated in beneficiary focus groups were concerned that they might exceed lifetime caps on their retiree coverage.

Many pharmaceutical companies offer patient assistance programs to help patients with the cost of their medications. In 2003, pharmaceutical companies provided patients with medications valued at \$3.3 million. However, this assistance is not readily available for Medicare beneficiaries without supplemental insurance. Most of the assistance goes to patients without any insurance. Less aid is available for individuals needing help with copayments. Yet this cost may be beyond the means of many beneficiaries. For example, one new cancer drug costs Medicare an average of \$12,000 every two weeks. Beneficiaries face copayments of \$2,400 monthly for this medication. They continue taking the medication until the patient's condition worsens.

The Commission is concerned about the burden of cost sharing for beneficiaries with cancer and other catastrophic conditions. We intend to explore the general issue of unlimited beneficiary out-of-pocket liability, which can affect cancer patients and patients with other illnesses, in future work.

Chemotherapy and quality of care

The Congress directed the Commission to report whether quality of care was affected by Medicare payment changes for chemotherapy services. Based on our interviews and site visits, we found no indication that quality of care has been affected by the payment changes. However, few consensus quality indicators for chemotherapy-related services exist and data to evaluate indicators that do exist are limited.

We discussed perceptions of differences in quality of care with physicians and patients in the course of our site visits and focus groups. Not surprisingly, clinicians we interviewed think the quality of services they provide is quite high. We found that physicians' evaluation of differences in quality across settings was subjective and seemed to be dictated by where they practiced. Oncologists in single-specialty practices felt they had more experience in educating patients about their condition and were more likely to hire oncology-certified nurses. They felt they provided more continuity of care and greater convenience for patients. By contrast, physicians practicing in hospital settings pointed to the availability of staff pharmacists to mix drugs, maintaining that this resulted in higher quality and fewer medical errors. They also pointed to greater use of safety guidelines and standard treatment protocols as indicators of higher-quality care.

Beneficiaries who participated in our focus groups received treatment in a variety of settings, including single-specialty oncology offices, outpatient departments of community hospitals, outpatient departments in university hospital cancer centers, and infusion centers of integrated health plans. Almost without exception, beneficiaries praised the quality of care they received. (The one exception was a beneficiary dually eligible for Medicare and Medicaid who received treatment in the HOPD of a safety-net institution.) None experienced changes in the quality of care received in the past year. Two focus group participants had switched to HOPDs for chemotherapy administration from physician offices in 2005. Neither felt quality of care suffered, although both felt there was less coordination of care and greater out-of-pocket expense in the hospital.

In general, further work is needed to determine quality chemotherapy care. Current public and private initiatives to define and measure quality of cancer care can provide the framework for a pay-for-performance oncology quality initiative. However, there is one instance where the Commission finds that CMS can take action now to monitor the quality of care beneficiaries are receiving.

Erythroid growth factors (Erythropoietin alpha and darbepoetin alpha) are used for the treatment of anemia following chemotherapy as well as some other indications. Medicare expenditures for these products account for the highest percentage of Medicare Part B drug spending. Although the shift to ASP resulted in lower payment rates for both products, volume and expenditures continued to increase in 2005. At the same time, concerns have been raised about drug safety and potential under- and overuse of these products. In 2004, the Food and Drug Administration (FDA) responded to safety concerns about the use of growth factors by issuing new prescribing information. Although some local carriers have attempted to limit the use of erythroid growth factor in accordance with FDA regulations and clinical guidelines, carriers are hampered by their lack of access to all relevant clinical data. In our January 2006 report, the Commission recommended that the Secretary re-

quire providers to enter patients' hemoglobin level on all claims for erythroid growth factors. This data should be used as part of Medicare's pay-for-performance initiative.

Conclusion

Policymakers had long agreed that Medicare did not pay accurately for Part B drugs or drug administration services and suggested different alternatives. Although the Commission did not recommend any particular new payment method, our analysis showed that several of the proposed methods would improve the accuracy of the payment system. Following passage of the MMA, Congress reduced payments for drugs and increased payments for drug administration services. In 2005, Medicare began using ASP to set payment rates for Part B drugs. This change lowered the payment rate for most drugs and decreased Medicare spending for Part B drugs. Payment for drug administration services increased.

Part B drugs are used to treat patients with very serious medical conditions including cancer, hemophilia, and rheumatoid arthritis. The Congress directed MedPAC to study the effect of the payment changes to ensure that access and quality of care for individuals with these illnesses were not harmed. We found that that, in general, beneficiary access to chemotherapy services remained good. Physicians provided more chemotherapy services to Medicare beneficiaries in 2005 than in 2004.

The ASP payment method has generally lowered beneficiary cost sharing for Part B drugs. However, beneficiaries without supplemental insurance may face high out-of-pocket spending, particularly if they need new single source drugs. These drugs are expensive and Medicare has no limit on the out-of-pocket costs that beneficiaries may face. Some physicians are sending individuals without supplemental insurance to hospital outpatient departments for chemotherapy infusions where they face still higher copayments. The Commission is concerned about the burden of cost-sharing faced by beneficiaries with cancer and other catastrophic conditions and we intend to explore this issue in future work.

We found no evidence that the quality of care received by Medicare beneficiaries has declined. However, we are concerned that the continuing increase in use of erythroid growth factor should be monitored to make sure that use falls within accepted clinical guidelines. The Commission has recommended that the Secretary require providers to enter patients' hemoglobin level on all claims for erythroid growth factors. This data should be used as part of Medicare's pay-for-performance initiative.

Overall we found that access to care and quality of chemotherapy services were not harmed in 2005. However, we recognize that no payment system is without flaws. Changes in both pricing and purchasing patterns may affect the accuracy of drug payments over time. For this reason, we have recommended that the Secretary continue to monitor provider drug acquisition costs in both physician offices and dialysis facilities.

As directed by the Congress, MedPAC is currently studying the effect of the Medicare payment changes on services provided by other specialties including urologists, rheumatologists, and infectious disease specialists. In this report, due January 1, 2007, we will analyze if beneficiary access, quality of care, or physician practices have been affected following an additional year of experience with the new payment system.

Chairman JOHNSON OF CONNECTICUT. Mr. Steinwald.

STATEMENT OF BRUCE STEINWALD, DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. STEINWALD. Thank you, Mrs. Johnson, Mr. Stark and other Members of the Subcommittee. I am pleased to be here with you this afternoon, and I commend you for scheduling this hearing, because given the fiscal crisis facing the Medicare Program, it is essential that the payments be based on accurate information and incentives for providers to operate as efficiently as possible. I will skip over the part of my testimony that relates to how we got to ASP because that has been covered.

My remarks this afternoon are based on work that we did in response to several MMA requirements related to the study of payment for separately billable part B drugs delivered in the hospital outpatient setting. Cutting right to the bottom line, we found that compared with alternative payment methods, ASP is a practical basis for payment for the following reasons.

First, ASPs are based on actual transaction prices and are a better proxy for provider acquisition costs than average wholesale prices or provider charges included on claims for payment, neither of which is based on real transactions. Second, ASPs, which manufacturers update quarterly, offer information that is relatively timely for rate setting. In comparison, rates for other Medicare payment systems are based on data that are not so current. Third, using manufacturers as the data source for drug prices is preferable to collecting such data from providers, because the manufacturers have data systems in place to track prices, whereas providers generally do not.

We learned from our survey of hospitals on how much they paid for part B drugs that obtaining price data was very burdensome on hospitals, and, by the way, on us as data collectors as well, and we recommended against using such surveys as a regular data source. So, for these reasons, we concluded that ASP is a practical source of data from the standpoint of collecting data for rate-setting purposes. Practical does not imply perfect or even optimal, as has been already suggested.

When CMS proposed to use ASP for hospital outpatient drugs in 2006, we commented that ASP is what we called a “black box” because of the lack of information on how manufacturers calculate average drug prices. For example, the law appropriately requires that average prices to be net of rebates. Rebates are price concessions granted by manufacturers sometime after the purchase and delivery of the drugs. We learned from our hospital survey that it is very difficult to deduct a rebate amount from an individual drug purchase because rebates are often granted for a collection of drugs and other products over a period of time.

While most of the hospitals we surveyed reported receiving one or more rebate checks, they were unable to tell us how rebates affected the individual drug prices. Some hospitals even deposited their rebate checks in non-patient revenue accounts along with gift shop and parking lot revenues because their accounting systems were unable to accommodate those payments elsewhere. Our experience with the hospitals we surveyed made us wonder how manufacturers would account for rebates when they reported average sales price to CMS, and we were concerned to learn that CMS does not provide specific guidance to manufacturers on how to account for rebates. Nor do they have information to determine whether rebates are handled consistently and appropriately across manufacturers and across drugs.

There are other reasons to want to peer into the ASP black box. For example, CMS does not instruct manufacturers to provide a breakdown of price and volume data by purchaser type; that is, by physicians, hospitals and other health care providers, and by wholesalers, which purchase drugs for resale to health care providers. As a result, CMS cannot determine how well the average

price data represent actual acquisition costs for different purchaser types. In particular, to the extent that some of the sales are to wholesalers that subsequently mark up manufacturers' prices in their sales to providers, the ASP representation of provider acquisition cost is attenuated.

Finally, there is the plus factor, the 6 percent add-on to ASP. I can't tell you whether the 6 percent is the right amount or not, but our experience with hospital outpatient drug prices may be instructive. Our survey of hospital acquisition costs found that paying for such drugs at ASP plus 6 percent would have been excessive in 2006. Although the law requires CMS to pay hospitals their average acquisition costs, our survey found that hospitals' payments for the drugs were somewhat below ASP plus 6 percent. In its final rule, CMS did settle on ASP plus 6 percent, reasoning that part of the payment was for handling costs as opposed to acquisition. Our conclusion from this experience, and looking at part B drug payments more generally, is that the empirical foundation for plus 6 percent or any other percentage add-on is insufficient, and once again we believe that a better understanding of the components of ASP would be a worthwhile beginning to determine an appropriate plus factor. Mrs. Johnson, I will end my remarks with that, and I would be happy to answer any of your questions or those of other Members of the Subcommittee.

Chairman JOHNSON OF CONNECTICUT. Thank you very much.

[The prepared statement of Mr. Steinwald follows:]

**Statement of Bruce Steinwald, Director, Health Care, U.S. Government
Accountability Office**

Madam Chairman and Members of the Subcommittee:

I am pleased to be here as you discuss Medicare's method of paying for outpatient drugs covered under the program's Part B, the part of Medicare that covers a broad range of medical services, including physician, laboratory, and hospital outpatient department (HOPD) services and durable medical equipment (DME). Part B-covered drugs are typically administered by a physician or other medical professional rather than by patients themselves. In contrast, drugs covered under the new prescription drug benefit, known as Part D, are generally self-administered by patients.¹ In 2005, Medicare paid more than \$9 billion for Part B drugs furnished in conjunction with physician services, HOPD services, dialysis services, and services performed using DME, such as nebulizers.^{2,3}

Until 2005, Medicare's method of paying physicians for Part B drugs was based on the drug's average wholesale price (AWP), which, despite its name, was neither an average nor what wholesalers charged.⁴ It was a price that manufacturers derived using their own criteria; there were no requirements or conventions that AWP reflect the price of an actual sale of drugs by a manufacturer.⁵ An analysis we conducted in 2001 on Part B drug prices found that Medicare's AWP-based payments

¹ Medicare Part A covers inpatient hospital services; Medicare Part C, known as Medicare Advantage, covers beneficiaries enrolled in managed care plans.

² In this testimony, we will refer to physicians, hospital outpatient services, dialysis services, and durable medical equipment suppliers collectively as providers.

³ A nebulizer is a device driven by a compressed air machine. It allows the patient to inhale medicine in the form of a mist.

⁴ Until 2004, Medicare paid physicians 95 percent of AWP. Legislation changed Medicare's payment to 85 percent of AWP in 2004.

⁵ Manufacturers reported AWP's to organizations that published them in drug price compendia, and the Medicare claims administration contractors that pay claims for Part B drugs based physicians' payments on the published AWP's.

often far exceeded market prices that were widely available to health care providers.⁶

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that, beginning in 2005, payments for physician-administered drugs be based on the drug's average sales price (ASP)—that is, an average, calculated from price and volume data reported by drug manufacturers, of sales to all U.S. purchasers.⁷ The law directed that ASPs be net of rebates and other price concessions and that 2005 payments to physicians for these drugs be set at 106 percent of ASP.⁸

The MMA took a different approach to setting rates for a subset of Medicare Part B drugs delivered in the HOPD setting. Prior to the MMA, Medicare paid HOPDs for Part B drugs based on hospitals' 1996 median costs for these drugs. In response to concerns that payments would not reflect the cost of newly introduced pharmaceutical products—such as those used to treat cancer or rare blood disorders—1999 legislation authorized augmented payments for these drugs on a temporary basis.⁹ Subsequently, the MMA defined a new payment category for these drugs called specified covered outpatient drugs (SCOD). The MMA required the Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services (HHS) to set rates for this subset of Part B drugs. Specifically, it directed CMS to set 2006 payment rates for SCOD products equal to hospitals' average acquisition costs—the cost to hospitals of acquiring a product, net of rebates. Subsequently, CMS selected ASP as the basis to pay for SCODs provided at HOPDs.

In several related requirements, the MMA directed us to provide information on SCOD costs and CMS's proposed rates. Among them was a requirement to conduct a survey of a large sample of hospitals to obtain data on their acquisition costs for SCODs and provide information based on these data to the Secretary of Health and Human Services for his consideration in setting 2006 Medicare payment rates.¹⁰ We were also required to evaluate CMS's proposed rates for SCODs, comment on their appropriateness in light of the survey we conducted, and advise on future data collection efforts by CMS based on our survey experience.¹¹ We issued reports in 2005 and 2006 in response to these requirements, and my remarks about ASP are based on that work. Specifically, my remarks today will focus on (1) ASP as a practical and timely data source for use in setting Medicare Part B drug payment rates and (2) components of ASP that are currently unknown and implications for Medicare rate-setting. Our work was conducted in accordance with generally accepted government auditing standards.

In summary, using an ASP-based method to set payment rates for Part B drugs is a practical approach compared with methods based on alternative data sources, for several reasons. First, ASP is based on actual transactions and is a better proxy for health care providers' acquisition costs than AWP or health care providers' charges included on claims for payment, neither of which is based on transaction data. Second, ASPs, which manufacturers update quarterly, offer information that is relatively timely for rate-setting purposes. In comparison, rates for other Medicare payment systems are based on data that may be at least 2 years old. Finally, using manufacturers as the data source for prices is preferable to collecting such data from health care providers, as the manufacturers have data systems in place to track prices, whereas health care providers generally do not have systems designed for that purpose.

⁶ GAO, Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs, GAO-01-1118 (Washington, D.C.: Sept. 21, 2001).

⁷ Certain prices were excluded, including prices paid to federal purchasers and prices for drugs furnished under the Part D program.

⁸ The term rebates refers to price concessions given to purchasers by manufacturers subsequent to receipt of the product.

⁹ See the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, app. F, § 201 (b), 113 Stat. 1501A-321, 1501A-337—1501A-339.

¹⁰ We provided information from this survey in two reports—one on drugs and another on radiopharmaceuticals. See GAO, Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate Setting, GAO-05-581R (Washington, D.C.: June 30, 2005), and GAO, Medicare: Radiopharmaceutical Purchase Prices for CMS Consideration in Hospital Outpatient Rate Setting, GAO-05-733R (Washington, D.C.: July 14, 2005). The Secretary of HHS considered the price data we provided but elected not to use these data as the basis for 2006 rates.

¹¹ We provided our comments on the proposed rates in 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). We provided information on our data collection experience in GAO, Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS, GAO-06-372 (Washington, D.C.: Apr. 28, 2006).

Despite these advantages, CMS lacks certain information about the composition of ASP that prompted us, in our report commenting on CMS's proposed 2006 SCOD rates, to call ASP "a black box."¹² Significantly, CMS lacks sufficient information on how manufacturers allocate rebates to individual drugs sold in combination with other drugs or other products; this is important, as CMS does not have the detail it needs to validate the reasonableness of the data underlying the reported prices. In addition, CMS does not instruct manufacturers to provide a breakdown of price and volume data by purchaser type—that is, by physicians, hospitals, other health care providers, and wholesalers, which purchase drugs for resale to health care providers. As a result, CMS cannot determine how well average price data represent acquisition costs for different purchaser types. In particular, to the extent that some of the sales are to wholesalers that may subsequently mark up the manufacturer's price in their sales to health care providers, the ASP's representation of providers' acquisition costs is weakened. Additionally, a sufficient empirical foundation does not exist for setting the payment rate for Medicare Part B drugs at 6 percent above ASP, further complicating efforts to determine the appropriateness of the rate. Given these information gaps, CMS is not well-positioned to validate the accuracy or appropriateness of its ASP-based payment rates.

Background

CMS calculates payment rates for each Part B drug with information on price data that manufacturers report quarterly to the agency. In reporting their price data to CMS, manufacturers are required to account for price concessions, such as discounts and rebates, which can affect the amount health care providers actually pay for a drug.

ASP Is a Price Measure Established in Law and Calculated with Manufacturers' Data

The MMA defined ASP as the average sales price for all U.S. purchasers of a drug, net of volume, prompt pay, and cash discounts; charge-backs and rebates. Certain prices, including prices paid by federal purchasers, are excluded, as are prices for drugs furnished under Medicare Part D. CMS instructs pharmaceutical manufacturers to report data to CMS—within 30 days after the end of each quarter—on the average sale price for each Part B drug sold by the manufacturer. For drugs sold at different strengths and package sizes, manufacturers are required to report price and volume data for each product, after accounting for price concessions. CMS then aggregates the manufacturer-reported ASPs to calculate a national ASP for each drug category.¹³

Varying Payment Arrangements Affect the Price Purchasers Pay at the Time of Sale

Common drug purchasing arrangements can substantially affect the amount health care providers actually pay for a drug. Physicians and hospitals may belong to group purchasing organizations (GPO) that negotiate prices with wholesalers or manufacturers on behalf of GPO members. GPOs may negotiate different prices for different purchasers, such as physicians, suppliers of DME, or hospitals. In addition, health care providers can purchase covered outpatient drugs from general or specialty pharmaceutical wholesalers or can have direct purchase agreements with manufacturers. In these arrangements, providers may benefit from discounts, rebates, and charge-backs that reduce the actual costs providers incur. Discounts are applied at the time of purchase, while rebates are paid by manufacturers some time after the purchase. Rebates may be based on the number of several different products purchased over an extended period of time. Under a charge-back arrangement, the provider negotiates a price with the manufacturer that is lower than the price the wholesaler normally charges for the product, and the provider pays the wholesaler the negotiated price. The manufacturer then pays the wholesaler the difference between the wholesale price and the price negotiated between the manufacturer and the provider.

ASP Is a Practical Payment Approach, Given the Limitations of Other Data Sources Available for Rate-Setting

Using an ASP-based method to set prices for Medicare Part B drugs is a practical approach compared with alternative data sources for several reasons. First, unlike

¹² GAO-06-17R.

¹³ Manufacturers' reported price data are based on the Food and Drug Administration's (FDA) system of National Drug Codes, while the ASP that CMS calculates for each drug is based on the agency's Healthcare Common Procedure Coding System, which uses categories that are broader than the FDA's coding system.

AWP, ASP is based on actual transactions, making it a useful proxy for health care providers' acquisition costs. Whereas AWP's were list prices developed by manufacturers and not required to be related to market prices that health care providers paid for products, ASPs are based on actual sales to purchasers. For similar reasons, payments based on ASPs are preferable to those based on providers' charges, as charges are made up of costs and mark-ups, and mark-ups vary widely across providers, making estimates of the average costs of drugs across all providers wide-ranging and insufficiently precise. In addition, basing payments on charges does not offer any incentives for health care providers to minimize their acquisition costs.

Second, ASPs offer relatively timely information for rate-setting purposes. Manufacturers have 30 days following the completion of each quarter to report new price data to CMS. Before the end of the quarter in which manufacturers report prices, CMS posts the updated Part B drug payment rates, to take effect the first day of the next quarter. Thus, the rates set are based on data from manufacturers that are, on average, about 6 months old. In comparison, rates for other Medicare payment systems are based on data that may be at least 2 years old.

Third, acquiring price data from manufacturers is preferable to surveying health care providers, as the manufacturers have data systems in place that track prices, whereas the latter generally do not have systems designed for that purpose. In our survey of 1,157 hospitals, we found that providing data on drug acquisition costs made substantial demands on hospitals' information systems and staff. In some cases, hospitals had to collect the data manually, provide us with copies of paper invoices, or develop new data processing to retrieve the detailed price data needed from their automated information systems.¹⁴ Hospital officials told us that, to submit the required price data, they had to divert staff from their normal duties, thereby incurring additional staff and contractor costs. Officials told us their data collection difficulties were particularly pronounced regarding information on manufacturers' rebates, which affect a drug's net acquisition cost.¹⁵ In addition, we incurred considerable costs as data collectors, signaling the difficulties that CMS would face should it implement similar surveys of hospitals in the future.

CMS Lacks Information on ASP Necessary to Monitor Payment Rate Accuracy and Appropriateness

Despite its practicality as a data source, ASP remains a "black box." That is, CMS lacks detailed information about the components of manufacturers' reported price data—namely, methods manufacturers use to allocate rebates to individual drugs and the sales prices paid by type of purchaser. Furthermore, for all but SCODs provided in the HOPD setting, no empirical support exists for setting rates at 6 percent above ASP, and questions remain about setting SCOD payment rates at ASP+6 percent. These information gaps make it difficult to ensure that manufacturers' reported price data are accurate and that Medicare's ASP rates developed from this information are appropriate.

Significantly, CMS has little information about the method a manufacturer uses to allocate rebates when calculating an ASP for a drug sold with other products. Unlike discounts, which are deducted at the point of purchase, rebates are price concessions given by manufacturers subsequent to the purchaser's receipt of the product. In our survey of hospitals' purchase prices for SCODs, we found that hospitals received rebate payments following the receipt of some of their drug purchases but often could not determine rebate amounts. Calculating a rebate amount is complicated by the fact that, in some cases, rebates are based on a purchaser's volume of a set, or bundle, of products defined by the manufacturer. This bundle may include more than one drug or a mixture of drugs and other products, such as bandages and surgical gloves. Given the variation in manufacturers' purchasing and rebate arrangements, the allocation of rebates for a product is not likely to be the same across all manufacturers. CMS does not specifically instruct manufacturers to provide information on their rebate allocation methods when they report ASPs. As a result, CMS lacks the detail it needs to validate the reasonableness of the data underlying the reported prices.

In addition, CMS does not require manufacturers to report details on price data by purchaser type. Because a manufacturer's ASP is a composite figure representing prices paid by various purchasers, including both health care providers and wholesalers, CMS cannot distinguish prices paid by purchaser type—for example, hospitals compared with other institutional providers, physicians, and wholesalers. In

¹⁴The burden was more taxing for some hospitals than for others. Many hospitals were able to rely on price data downloaded from their drug wholesalers' information systems.

¹⁵Typically, hospitals did not systematically track all manufacturers' rebates on drug purchases, although nearly 60 percent of hospitals reported receiving one or more rebates.

particular, to the extent that some of the sales are to wholesalers that may subsequently mark up the manufacturer's price in their sales to health care providers, the ASP's representation of providers' acquisition costs is weakened. Thus, distinguishing prices by purchaser type is important, as a central tenet of Medicare payment policy is to pay enough to ensure beneficiary access to services while paying no more than the cost of providing a service incurred by an efficient provider. In our 2005 report on Medicare's proposed 2006 SCOD payment rates, we recommended that CMS collect information on price data by purchaser type to validate the reasonableness of ASP as a measure of hospital acquisition costs.¹⁶

Better information on manufacturers' reported prices—for example, the extent to which a provider type's acquisition costs vary from the CMS-calculated ASP—would help CMS set rates as accurately as possible. For most types of providers of Medicare Part B drugs—physicians, dialysis facilities, and DME suppliers—no empirical support exists for setting rates at 6 percent above ASP. In the case of HOPDs, a rationale exists based on an independent data source—our survey of hospital prices—but the process of developing rates for SCODs was not simple. In commenting on CMS's proposed 2006 rates to pay for SCODs, we raised questions about CMS's rationale for proposing rates that were set at 6 percent above ASP.¹⁷ CMS stated in its notice of proposed rulemaking that purchase prices reported in our survey for the top 53 hospital outpatient drugs, ranked by expenditures,¹⁸ equaled ASP+3 percent on average, and these purchase prices did not account for rebates that would have lowered the product's actual cost to the hospital.¹⁹ We noted that, logically, for payment rates to equal acquisition costs, CMS would need to set rates lower than ASP+3 percent, taking our survey data into account. In effect, ASP+3 percent was the upper bound of acquisition costs. Consistent with our reasoning, CMS stated in its notice of proposed rulemaking that "Inclusion of . . . rebates and price concessions in the GAO data would decrease the GAO prices relative to the ASP prices, suggesting that ASP+6 percent may be an overestimate of hospitals' average acquisition costs." In its final rule establishing SCOD payment rates, CMS determined that our survey's purchase prices equaled ASP+4 percent, on average, based on an analysis of data more recent than CMS had first used to determine the value of our purchase prices. CMS set the rate in the final rule at ASP+6 percent, stating that this rate covered both acquisition costs and handling costs.²⁰ We have not evaluated the reasonableness of the payment rate established in the final rule.

Lacking detail on the components of ASP, CMS is not well-positioned to confirm ASP's accuracy. In addition, CMS has no procedures to validate the data it obtains from manufacturers by an independent source. In our 2006 report on lessons learned from our hospital survey,²¹ we noted several options available to CMS to confirm the appropriateness of its rates as approximating health care providers' drug acquisition costs. Specifically, we noted that CMS could, on an occasional basis, conduct a survey of providers, similar to ours but streamlined in design; audit manufacturers' price submissions; or examine proprietary data the agency considers reliable for validation purposes. HHS agreed to consider our recommendation, stating that it would continue to analyze the best approach for setting payment rates for drugs.

Concluding Observations

Because ASP is based on actual transaction data, is relatively timely, and is administratively efficient for CMS and health care providers, we affirm the practicality of the ASP-based method for setting Part B drug payment rates. However, we remain concerned that CMS does not have sufficient information about ASP to ensure the accuracy and appropriateness of the rates. To verify the accuracy of price data that manufacturers submit to the agency, details are needed—such as how manufacturers account for rebates and other price concessions and how they identify the purchase prices of products acquired through wholesalers. Equally important is the ability to evaluate the appropriateness of Medicare's ASP-based rate for all providers of Part B drugs over time. As we recommended in our April 2006 report, CMS should, on an occasional basis, validate ASP against an independent source of price data to ensure the appropriateness of ASP-based rates.

¹⁶GAO-06-17R.

¹⁷GAO-06-17R.

¹⁸These drugs accounted for 95 percent of Medicare spending on all SCODs in the first 9 months of 2004.

¹⁹The purchase prices hospitals reported to us took account of discounts but not rebates.

²⁰Handling costs include providers' expenses associated with storing, preparing, and disposing of drugs.

²¹GAO-06-372.

Madam Chairman, this concludes my prepared statement. I will be happy to answer any questions you or the other Subcommittee Members may have.

Chairman JOHNSON OF CONNECTICUT. Mr. Steinwald, I appreciate your comments in regard to the black box of ASP. I do think the ASP system is a better system than the AWP system, but I am concerned about some of the weaknesses that are inherent to it, at least the way we interpret it now.

What I understand you saying is that we ought to know, at least somebody ought to know, what purchasers do to get that automatic 2 percent cut in volume purchasing and what payers don't. It may be that one of the reasons we are hearing such varied comments and the adequacy of this system is that small practices have less access to the volume discount that big purchasers are able to negotiate. Do you think that may be a problem?

Mr. STEINWALD. Yes, ma'am. We don't know at present whether those average prices are wide-ranging across different purchasers or very tightly distributed. In our survey of hospitals, though, we did find that different hospitals were paying different amounts for the same drugs. Teaching hospitals tend to pay less because they are large purchasers, and the manufacturers like to expose their products to doctors in training in the hope of building some brand loyalty, and rural hospitals tend to pay more because they tend to be more isolated and are small purchasers. So, we have that information from our survey, but we don't know, as far as I am concerned, anything about the variability in prices paid across the different kinds of providers whose prices are averaged in the ASP.

Chairman JOHNSON OF CONNECTICUT. It is an interesting thought that you are finding small hospitals pay more, big hospitals pay less. If the same is true for small practices versus large practices, we ought to at least know it.

Mr. STEINWALD. Yes, ma'am.

Chairman JOHNSON OF CONNECTICUT. Dr. Miller, in the work that MedPAC has done on this issue, you concluded in one of your reports that pharmacy handling costs were about 25 percent, 28 percent, as I recall.

Mr. MILLER. I don't recall the exact percent. What I do recall concluding is that we thought there was a substantial cost there because of the way hospitals had chosen to do their accounting and charging practices. It was hard to tease out of the data precisely what those costs were, and we made a recommendation that we move toward a fee schedule that attaches a handling fee to how complex it is to administer a drug, an oral drug obviously a lot less than a radiopharmacy drug.

Chairman JOHNSON OF CONNECTICUT. Did you look at that issue in community practices?

Mr. MILLER. In community practices? I am sorry, the study was about hospital outpatient.

Chairman JOHNSON OF CONNECTICUT. Because that same issue is there in community practices where they have to handle the drugs where they have to buy them, store them, so on and so forth. The U.S. Department of Labor Occupational Safety and

Health Organization (OSHA) required a \$25,000 investment last year because they wanted a different kind of hood, yet that isn't taken into account in the coding. We worked hard during the coding process to get that taken into account, but it explicitly wasn't. May that have some effect on whether or not small practices are doing well under this system?

Mr. MILLER. It may have an effect. I know that several steps were taken to change the rules and the coding that allowed physicians in their practices to more comprehensively bill for the administration of services; for example, when multiple chemotherapy agents are introduced into the patient, the ability to bill separately for each of those infusions. The only thing I can speak to directly is in our work we did not find that there was a loss of access in a physician's office. We were finding the administration of those drugs were increasing even after the implementation of the policy.

Chairman JOHNSON OF CONNECTICUT. You do find a difference in access for those who had no insurance?

Mr. MILLER. Absolutely. I tried to be very on point on that. If you don't have supplemental insurance, a Medigap policy or employer wraparound, in some communities those patients were being sent to the hospital outpatient.

Chairman JOHNSON OF CONNECTICUT. It is also very important to note for the record that in some communities there is no alternative. You can't send patients to the hospital. There isn't one nearby. So, the fact that patients who don't have coinsurance and can't afford the coinsurance get moved to settings where it is less of a problem, that is a real thing that is happening, and it is a real problem that is developing in communities where there is no other place to refer those patients. Wouldn't you guess that is a growing problem in those areas?

Mr. MILLER. In those instances if we are talking about rural areas, patients will have to travel.

Chairman JOHNSON OF CONNECTICUT. Mr. Kuhn, in discussing the coding situation, you know, originally we said ASP would be this and that. We would adjust the administration payments to oncologists to take into account the legitimate cost of delivering the drug, which had, before the reform, been paid through the drug price itself. We were very careful instructing that coding process because I personally had arranged for whatever costs came out of it to be allowed and not to be held to the budget-neutral standard, because we were saving the money in the drug pricing, and we wanted it to go into coding.

It was very discouraging to me that we allow radiologists, radiology oncologists, a management fee, and we don't allow radiology—I mean, chemotherapy oncologists a management fee, but we lost that. We also lost any recognition of these pharmacy costs. We did get—but we did get some adjustments through the coding system, but they were put into temporary D codes. Now, several times I have sent over to your office and personally handed to Dr. McClellan analyses that have been done in the last few months of what has happened to those G codes as they got merged the next year into C codes, and some of them, while they were supposed to get increases, actually then began to get decreases. So, knowing

how hard it is to look for any—at any one thing, I had them accommodate it, group things by treatment.

I would think we all really do have to take seriously that the combined codes that you would—that you would bill to treat breast cancer or colorectal cancer or lung cancer, that the group of codes—and, for example, colorectal cancer has declined from 2004 to 2006, very significantly down 36 percent. That reflects—I mean, that really is concerning to me. If you go through all of the chart that you will see in every area and then anecdotally from individuals' practices, you see some of these same things affirmed. So, when you begin to hear then that since January 1, 2006 oncology offices are closing satellite offices, that is another aspect. If you can move people to the hospital, that is an aspect of strain on the system. Closing satellite offices is something that is of concern to me, because in rural areas that has made access to cancer care—very great in Medicare, greater in our country than in any other country—and as you close those satellite offices, you do contract access. Then depending on what kinds of cancer you treat—and so therefore, whether you are using drugs on which there is a loss or drugs which there is a profit, we are hearing more and more about cancer practices that are reducing their—the number of Medicare patients they can afford to take and so on. That anecdotal evidence, it is very strong now.

I am very concerned that my personal office has not been contacted about how you explain this kind of thing and how you explain the clear evidence. When I say clear evidence, you know, I am not talking the studies and the general stuff that we do from Washington. I am talking decoders. People who do this for a living, and who struggle with this across the country, and who, when they try to code for the same treatment, are coming out with a lower payment. Now, we expected some lowering from the first year because we had that demonstration project that plugged \$300 million into the system, but I wouldn't have expected to lose it all. I wouldn't have expected to lose it all plus the transition payment. I wouldn't have expected to actually go from G codes to a lower code payment. That is what we seem to be seeing.

I think—I hope that you and your staff will look carefully at the testimony and Exhibit A under the Code testimony because we have got to get this right. If we don't get the administrative payments right—and I appreciate all of your big-sounding percentages, but remember, that is a percentage increase from an administrative payment that was never intended to cover the costs of 6 hours of monitoring—of delivering a highly toxic substance into someone's body. So, we don't know whether it is adequate just because it sounds big. If we don't get this right, we will lose the access to cancer care that we have developed to a greater extent than any other Nation, and with it we will lose the ability to do clinical trials and research that has kept us at the cutting edge of cancer care. This isn't just about big money fleeing someplace. This is about little people having access to care, and oncologists who have been creative enough and willing to put themselves out to have satellite offices to reach elderly out in rural areas being able to continue to do.

I am not pleased that I have never had—this has been months, you know. Never had anyone come and sit down and explain to me why this isn't logical, when this is what people who are living, are saying they are living. I think when you look back at MedPAC's analysis of its true hospital delivery of chemotherapy, they saw big pharmacy costs, and these individual practices are handling those pharmacy costs, struggling under nonpayment of copayments by those who don't have coverage and so on. We don't have time to go into all of the problems here, but I thank Mr. Steinwald for his testimony because that may begin, if we begin to look—if you begin to look at the reported prices in terms of volume buyers and non-volume buyers, maybe we can find out what the problems are. If we look honestly at pharmacy management, we might be able to look at—we might be able to find that aspect of the problem.

I am going to turn now to Mr. Stark, but I did want to get clearly on the record that there are issues being raised by practitioners who are honest, hard-working folk out there that we are unable to answer from our general studies, but which some of the work that is being done does suggest that there are problems in the system that could be lethal to small practitioners, and they are crucial to access to care for our seniors. Mr. Stark.

Mr. STARK. Thank you, Madam Chair. Dr. Miller, I thought that in your testimony you indicated that while most drugs could be purchased by physician offices regardless of size at or below the reimbursement rate, there may be some that cannot. Now, it also sounds like that may be some single-source, brand-name drugs, but maybe I am reading something into your testimony that doesn't exist. Could you—perhaps you could do this later in letter. Could you codify as best you can how many of these drugs fall below the reimbursement rate and whether that is a disproportionate share of the demand of utilization? I think there is—that your answer may determine how radical a change we need.

I wanted to ask also at the same time that whether you or any of the others know how the prices that we pay in Medicare for these drugs compare with the Federal fee schedule. Does the Veterans Affairs (VA) get them for half what we are paying, roughly? Does anybody know?

Mr. KUHN. I don't think we have ever done a cross-walk on that so I couldn't answer that question.

Mr. STARK. You want to make a guess?

Mr. KUHN. I wouldn't even hazard a guess.

Mr. STARK. Anybody know? Okay. That would be interesting. We seem to—the VA seems to pay half of what everybody else in the world pays. I would presume they are also getting the same break on these. I won't tell you where that leads me to go. What about the small practitioners who may not be able to get some drugs?

Mr. MILLER. So, I think that the question was along the lines of can you quantify, be a little bit more precise, about this statement of who can buy and who can't buy. You know, first thing just by way of caveat to keep in mind here is, you know, we haven't done a national study. We went out and visited some seven-some-odd communities, and this is what we are bringing back. So, I can't truly quantify it. The types of examples that we found out there

were things like this. Oddly enough, you know, your instinct would take you to a single-source drug, but sometimes it was old generics because the fee of purchasing it from a wholesaler exceeded the price of the drug. So, you know, you found anomalous situations like that.

You also find situations where a drug may be extremely expensive, and now you might be over here in the sole-source situation, and let us say a provider wants to buy it, but wants to get the prompt pay discount. That may literally create cash flow issues, and so they may choose to not purchase the drug under that circumstance. Those were the kinds of things when we were sitting around with the oncology offices and talking to the nurses and so forth and the managers, the types of things that arose there, but I don't have a quantification of this.

Mr. STARK. Could I just follow on and talk about the other side of this equation? The adequacy of the rates for physician administration. Your testimony, Mr. Kuhn, indicates that reimbursement has gone up considerably since the drug payment changes. I assume that still holds even after they lose the 130 bucks per patient that they got for the so-called demonstration. I don't know what it demonstrated except that they were happy to take the 103 bucks per visit.

Do—can you comment, and I hope you can—now, what do you need to be able to recommend to us, because it is basically MedPAC that recommends. OIG, they would rather have their tongues fall out than make a recommendation. They might tell us what exists, but they are very careful about not recommending and CMS is 50–50. Dr. Miller, we depend on to bring us the technical expertise of his panel. Do you have enough information to tell us about the adequacy of the rates for physicians? If not, what do you need to get that, and can we look forward to it?

Mr. MILLER. I think there is probably a couple of things, and I am sorry that this is coming so much to me, because I can't give you exactly an answer on this. I mean, one caveat, again, is that the demonstration was still in play when we were looking at things, so giving you a definitive answer is hard. I think one key thing that you need to keep—that we all need to keep track of, and we can keep track of this as well, is whether the access to the services, are you seeing it. One place you can look is to continue to look at the claims data to see whether the services are being provided in the physician's office. We found that that continued to increase. They continued to buy the most expensive and the latest drugs, and that it seems to be, at least so far, adequate payment.

I think those trends need to continue to be tracked, because if that turns around, you will start to see it in the data. I think also—I mean, ideally what you want here is to know the cost of what the practice is incurring and how carefully that is tracking, you know, both the administration of the drug. Frankly, that data doesn't exist in the Medicare system that I am aware of—the ability to look at the physician's specific cost for the administration of the drugs and compare that to Medicare's payment.

Mr. STARK. Would it help if the physicians submitted it? They are the ones that are asking for more money. I think it would be incumbent to give the data you need.

Mr. MILLER. I think the issue there is defining the data that you want and the Medicare Program wants, and then the burden that it would produce in order to generate that data, and then, of course, the lag in collecting it before it could be analyzed. Sort of the usual problems.

Mr. STARK. Are you going to try that?

Mr. MILLER. What we are doing right now is we have another report due to you in January, I believe on January 1st of 2007, in which we are going to be looking at other specialties as well to ask the same questions that we asked oncology. We will be taking another look, looking at the flow of data to have some more information on where the major access problems have appeared. We have not specifically contemplated the notion of collecting cost data from physicians.

Mr. STARK. My time is up. I will come back.

Chairman JOHNSON OF CONNECTICUT. Mr. McCrery.

Mr. MCCRERY. Mr. Kuhn, you mentioned that HHS is undertaking an independent study of the IVIG issue. Is that different from the OIG's office study that they are doing?

Mr. KUHN. That is correct, Mr. McCrery.

Mr. MCCRERY. Who is doing that?

Mr. KUHN. The Assistant Secretary for Planning Evaluation, also known as ASPE, is taking that on. We are going to look at three principal activities here when they go forward in this. One, they want to do a supply analysis, really kind of understand what the supply looks like. Are there indeed ample product in the marketplace? Are there shortages? Because we have had some contractions in this industry in the past. They also want to do a demand analysis and understand that much better. Including that, they want to look at our reimbursement levels and the way we calculate reimbursement in this area. They want to look at product differentiation, and they want to look at access issues thoughtfully. Finally, they want to conduct a series of public meetings as well to make sure that the public understands and participates fully in this process, with the target, as I understand right, now to report out sometime this fall.

Mr. MCCRERY. This fall?

Mr. KUHN. That is the current target.

Mr. MCCRERY. Now, Mr. Vito, the OIG report, your testimony, you say on IVIG it should be out soon. Can you give me a little sharper definition of soon?

Mr. VITO. Yes. This Committee, along with the Commerce Committee, asked us to look at IVIG for access and pricing. We delivered the first phase to this Committee and the Commerce Committee in June of this year. We are in the second phase, which is looking at the Government Pension Offsets (GPOs) and the distributors to find out what they are paying for the product. We have completed our data collection. We are in the analysis and report writing section of our work now. We hope to have that to you within the next month or two. As far as getting the information from the physicians, we have surveyed the physicians. We are requesting that they provide the information to us. We have been working hard to get a good response rate and have gone back on at least a number of occasions to get the information from the physicians.

So, that is a little bit longer out, but we do hope to have the next phase to you shortly.

Mr. MCCRERY. I appreciate that. I do appreciate your getting the first phase of that report to us on the manufacturers. We don't have any manufacturers here today, Madam Chairman. That is unfortunate, I wish we could have had some manufacturers here. Before I get to that, Mr. Kuhn, you said in your testimony that CMS has taken steps to try to assure that there is supply in the market and that patients have access, and that providers can get adequate reimbursement for providing and administering this life-saving drug. Just so everybody here knows, if a severe immunodeficient patient does not get this drug, he will die. That is how important this is. It is not a matter of it is better than some other drug or makes his quality of life better. He will die if he does not get this. So, this is a critical, critical question for all of us to make sure we get it right.

You mentioned, Mr. Kuhn, that you have taken steps to try to ensure that access. One of those steps will expire at the end of this year. It is the add-on pre-administrative fee that you call it. Are you waiting until the OIG report and your independent study before you decide to extend that? Or have you thought of some interim steps to take prior to getting the results that you are looking for?

Mr. KUHN. We are currently evaluating the effectiveness of that particular step, whether it really did help both physicians as well as hospitals in terms of their search for the product, because, again, there has been some reported shortages. People have reported to us that they have had difficulty finding the product. So, we wanted to enable them even more with this step to help them out in that area.

We are doing evaluation whether it is appropriate to extend it in some other form, make other recommendations possibly for 2007, how we want to go forward. I think our current analysis that we are doing right now and the report by ASPE is going to help us in making those decisions. The work that the IG is doing is going to help us in that as well as our outreach with the stakeholder community, because we do want to engage them about that and have discussions about that. It is a work in progress that hopefully we will have more information soon on what kind of recommendations we want to make.

Mr. MCCRERY. Just very quickly. I know you understand this. You understand the critical nature of this question. We just can't abide patients not having access to this until we figure out why. We have to make sure that they have access. So, I appreciate the steps you have taken, Mr. Kuhn—CMS has taken so far. I hope you will stay on top of it not at the end of the year, but tomorrow, and make sure that we are doing all we can to ensure patient access to this drug. I have got some other questions later for Dr. Orange about the supply problem, but I will talk about that then. Thank you, Madam Chairman.

Chairman JOHNSON OF CONNECTICUT. Mr. Johnson.

Mr. JOHNSON of Texas. Thank you, Madam Chairman. Mr. Vito, I have a good friend who was diagnosed with an autoimmune disease earlier this year, and 2 weeks ago she was give an infusion

of IVIG. Condition greatly improved, whereas before she had weakness affecting eyesight, speech, swallowing and others, she is now able to see clearly and speak at length without slurring her words. You know, there are hundreds of stories like that out there, and it is of critical importance that miracle drugs like that remain available to those who really don't have anywhere else to turn.

The OIG, as you know, has been tasked to evaluate the current state of pricing and supply for IVIG. Based on preliminary results from your study, do you believe the administrative changes taken by CMS to increase the reimbursement of IVIG have alleviated some of the concerns expressed by patient advocacy groups and physicians?

Mr. VITO. Based on the work that we have done so far, we cannot answer that question. As we get more data from the other two sources, we might be in a better position to provide some information to you.

Mr. JOHNSON of Texas. You don't have any ideas yourself? Let me just ask you, in your opinion, what more can be done to ensure that patients receive the treatment in the most cost-effective setting, that is doc's office or the hospital? Do you have a preference, or have you formed an opinion?

Mr. VITO. I work for the Office of Inspector General. We were asked to do specific work for this Committee and the other Committee, and we are focusing on that work. I do not have an opinion on that. I could tell you that we are trying to get the work done in the most expedient manner so that we will have some information to help you make decisions on how to move forward.

Mr. JOHNSON of Texas. You said that two or three times. In other words you don't want to go on the record with your own opinions.

Mr. VITO. No, sir.

Mr. JOHNSON of Texas. Do any of you?

Mr. KUHN. Mr. Johnson, I would just say, Mr. McCrery identified one of the actions that we have taken already in terms of trying to help with this issue. There has been some others that the agency has taken, and obviously we want to look further to make sure we do right for these patients, because I think your point about the patient and how this product—it is a remarkable product that makes all the difference in the world for these people in their lives, and we need to make sure that there is uninterrupted access to them and to the clinicians for getting this product.

In addition to the pre-administration fee, we have also worked closely with, hard with the manufacturers to make sure that they are reporting to us as accurately as they possibly can on their ASP pricing. We want to make sure when we do the quarterly updates, we are on the spot in terms of what the pricing is so that there is no deviation whatsoever, to make sure that works. Likewise, last year, at the request of the stakeholder community, we began splitting the Codes out. Up until then we had one code for this product. It comes in two different forms, liquid and powder, and we split that apart in order to help them differentiate and work in that area as well. Also, we are working very hard with the Public Health Service and the Food and Drug Administration (FDA). FDA is doing a lot of good surveillance in terms of working with the

manufacturers dealing with supply issues to help them where there might be regulatory issues. We have a pretty enterprise-wide action plan within the agency to do this. I think the study is going to help us understand if there are more things that we ought to be doing to make sure that we get this product to the people that need it.

Mr. JOHNSON of Texas. Thank you, sir. Appreciate your comments. I yield back the balance of my time.

Mr. MCCRERY. Would you yield?

Mr. JOHNSON of Texas. I yield to you.

Mr. MCCRERY. Just in case you are looking for some other tool, you already have one at your disposal, I think. Blood-derived products you reimburse at 95 percent of AWP, which I assume would be higher if you applied that to IVIG, which is a plasma-based product you could describe as a blood-derived product. I assume that would be a higher reimbursement than the current reimbursement rate, wouldn't it?

Mr. KUHN. That is correct. If blood and blood products are currently reimbursed at 95 percent of AWP. The issue with this particular product, however, in the MMA Congress did designate this product as not a blood and blood product separately from that. So, in terms of our discretionary authority to make that adjustment, we don't believe we have that authority.

Mr. MCCRERY. Madam Chairman, maybe that is something we need to look at and give CMS the flexibility to make that change. Thank you.

Chairman JOHNSON OF CONNECTICUT. Mr. Ramstad.

Mr. RAMSTAD. Thank you, Madam Chairman. Thank you also, Madam Chairman, for highlighting the fact that one of the key areas impacted by recent changes in the Part B drug reimbursement certainly has been the practice of oncology. I don't think it is hyperbole to state categorically that our cancer care delivery system is facing a crisis. Now, I have heard concerns expressed here today in the exchanges, heard concerns from numerous cancer patients back home, from countless oncologists and others that when you analyze this, drug administration has dropped by over 20 percent in terms of reimbursement just in the last 2 years. At the same time reimbursement for acquiring the drugs has decreased by over 30 percent.

Then when you look at the recent findings of the study done by PricewaterhouseCoopers, they estimate that cancer care payments will be cut by almost \$14 billion 2004 to 2013. Congressional Budget Office (CBO) had estimated a \$4.2 billion reduction in payments over that period. We all know CMS, Director Kuhn, has drastically reduced the demonstration project that was supposed to make up for shortfalls. Why in the world have there been no permanent solutions to maintain critical Medicare funding for cancer care? Why not, for example, add payment codes for treatment planning as has been suggested earlier?

Mr. KUHN. Those are all good questions, Mr. Ramstad, and here is where we are in the sequence, and I would like to walk the Committee through these because—

Mr. RAMSTAD. I want to know why there hasn't been permanent solutions for maintaining critical Medicare funding for cancer

care? That is the question that needs to be broached, needs to be answered. Why specifically not add payment codes for treatment planning? Please answer those two questions.

Mr. KUHN. Sure. From 2003 to 2006, administration codes are up 117 percent across the board is where we are right now. Those are permanent changes over those 3-year periods as we move forward. Administrative utilization for cancer care from 2003 to 2004 is up 21 percent; from 2004 to 2005 it is up 31 percent. So, we are seeing real increases in this area as we go forward. In terms of planning codes, when we went through this process, and we did 2 successive years and both 2004 and 2005 in terms of making changes, and the 2004 changes we used the actual data that oncology physicians gave us, their survey data, in order to make the permanent changes in the Codes. In 2005, the changes we made were put to us by the current procedural terminology (CPT) editorial Committee, which is run by the American Medical Association (AMA). At that particular Committee they did not recommend that there be any planning code, that that function is already captured in the evaluation and management (E&M) codes that are out there. We use used the oncologist data, and then we used the regular order in terms of the process that exists with existing Committees to drive these codes forward, and the results are there: 117 percent increase.

Mr. RAMSTAD. Well, I am looking at an average per-treatment basis, why has Medicare reimbursement decreased by over 20 percent the past 2 years?

Mr. KUHN. The data that I have and that I see from 2003 to 2005 shows that overall payments to oncologists are up 20 percent.

Chairman JOHNSON OF CONNECTICUT. Would the gentleman yield on this?

Mr. RAMSTAD. I yield to the Chairman.

Chairman JOHNSON OF CONNECTICUT. When you use those dates, you include that big demonstration payment year. Yes, the providers were kept whole that year. It is when you withdrew the 30-percent increase and the 300 million in demonstration and the small transition payment—when you say 117 percent increase across the board, that was 117 percent of a little, tiny payment that was for administration. It was never intended to cover the costs of a whole staff, of pharmacy costs and all the other things associated with delivering the care. That was never the point of that original administration fee.

We grew a big cancer care capability because the drug companies paid for administration, but they did not have to turn to the government. So, that 117 percent does not really mean anything. It does not tell us anything. Most of that is the result of the fact that we included in the law that you pay for oncology nurses when originally you were going to pay the average nurse salary. So, his question which he originally asked, why are we seeing this decrease, is the question we need you guys to answer. That goes for anyone at the table.

Mr. KUHN. I appreciate that, and I would just say again that the 117 percent increase is based on the factual data that we got from oncologists in terms of practice experience and then the work changes were based on the CPT panels. It sounds like information

that you all have that you referenced earlier in your comments, Mrs. Johnson, and you, Mr. Ramstad, is new data that we need to look at to make sure that we can reconcile that you as the Committee, as you do your appropriate oversight work here, can have apples-to-apples comparisons to make sure that you make the decisions that you need to. We will look at that and work with your staff on that.

Mr. RAMSTAD. I thank the Chairwoman—reclaiming my time—for providing the proper context for that question. We need to have further discussions, and certainly within the parameters of our 5-minute exchanges here today we did not sufficiently cover that. I want to ask one final question, Mr. Kuhn, and this really was a MedPAC finding and corroborated, I think, by the colloquy that the Chairwoman had with Dr. Miller. MedPAC found that pharmacy facility costs are a substantial part of total drug costs, and the Chairman verified that in terms of 25 to 28 percent of total drug costs. My final question, Mr. Kuhn, why has no pharmacy facility code been created?

Mr. KUHN. On the issue of pharmacy handling fee, and the physician community has talked a lot of issues about storage, waste, you know, managing these complex drugs that are out there, but, again, when we looked at the data that the oncologists presented themselves to us where they really did look at the issues of practice expense, we used the data that they provided because it looked at the entire practice expense, it brought the issues to the table, and we incorporated those to the new relative value units (RVUs) that we have in the Code. We believe that we have captured that information already in the existing payments without having to create new codes.

Mr. RAMSTAD. Let me ask you this, a final question, and thank you for your indulgence, Madam Chairman. Mr. Kuhn, I hope you do sit down with some of the oncologists from Minnesota, from the Mayo Clinic, University of Minnesota Hospital, Fairview and others, Northwestern. I hope you do have a sit-down with us and discuss your figures as well as their national association. I would like to facilitate that meeting and get you on the record as saying you would be happy to meet us.

Mr. KUHN. Absolutely be happy to meet with you.

Mr. RAMSTAD. Thank you very much. I yield back.

Chairman JOHNSON OF CONNECTICUT. I do want the record to note that we have sat down with that kind of group with Dr. Bark and never gotten any response. I handed the very charts that he is referring to Dr. McClellan and others in your office, and we have not gotten the response. We do need to understand this because your testimony does not correlate with our experience as Members of what is happening in our districts of cancer care, and this is too important for that divide to be there.

Mr. RAMSTAD. Madam Chairwoman, I promise to invite you to the meeting.

Chairman JOHNSON OF CONNECTICUT. Thank you. Mr. Hulshof.

Mr. HULSHOF. Thank you, Madam Chair. I also want to associate myself with Mrs. Johnson's comments at the beginning. We asked you specific things to do in research and reports to do, and

you have done that. Of course, some of you have gone very close to the line in the report, and I can appreciate the potential dilemma that you are in. On the other hand, as those of us who return to our respective districts every week and we hear, and, yes, perhaps anecdotally, but absolutely what Mr. Ramstad said and what Ms. Johnson said is the real world. You know, we know how we have gotten here. I remember in 1998 under the previous administration, HHS—Health and Human Services Secretary Shalala was talking about AWP and the abuse of it, so there was a move afoot then. So, then we began to come up with this formula.

Let me just say for the record the reason that we have ASP plus 6 percent is because of the gentlewoman from Connecticut, because there was some discussion about not including the practice expense, and it is only because of her tenacity is the reason we have the plus 6 percent. Putting that aside, we recognize, just as we have with the 1997 Balanced Budget Act (BBA), (P.L. 105-33), that well-intentioned ideas sometimes have very unintended consequences. That is why I hope you aren't feeling, all of you, particularly you, Mr. Kuhn, that this intensity from this side—and the record unfortunately will not demonstrate the passion and the emotion with which we bring these questions to you. It is not an attempt to put any of you on the spot or to embarrass, but it is passion that—because there are some people doing some lifesaving things back home, and they want to continue to do it.

The fact is that 84 percent of cancer patients in this country are seen at community clinics. This is not any judgment toward those treatments that are done within the hospital setting. Again, let me get off my soap box. Some of the unintended consequences, for instance, on the prompt pay, the community clinics are having to actually carry on their books until they get reimbursed. They are required to pay. They don't get the negotiated discounts between the manufacturers and the wholesalers, and so then they are actually reimbursed for something less than what they actually have to pay. So, one of the suggestions, I think, from a later witness is to eliminate prompt pay discounts from the ASP calculation. You may want to comment on that.

You know, Missouri Cancer Associates in Columbia, Missouri, opened their books. I requested they open their books and in the month of March of this year, Mr. Kuhn—and I will pick on you a little bit. They had a negative cost. Their clinic was in the red for the month of March. So, when you project this out then, you have retiring oncologists who are going to leave the practice early, and then you have incoming residents who aren't going to choose the field of oncology because they see the current state of affairs, and so it is much more lucrative in some other area of expertise. I think we are right on the cusp of something that could be dire. So, again, that is my editorial comment.

Let me ask you this specific question, Mr. Kuhn. I think Mr. Steinwald in the report—I am not sure that he said it in his oral testimony—GAO has expressed concern that CMS does not require manufacturers to report ASP information by purchaser type. Is it your opinion that CMS has the administrative authority to require manufacturers to report this information? That is question number one. Question number two: Would it be helpful to better assess

claims that you stated, that 106 percent of ASP is insufficient—or perhaps our claims that 106 percent of ASP is insufficient? Let me go with those two. Do you have the administrative authority to require that information from manufacturers?

Mr. KUHN. On that one, I would have to get back to you, Mr. Hulshof. I don't know whether we can collect the data in that manner or not, but I would like to get back to you for the record on that one.

Mr. HULSHOF. Do you wish to opine this further question as far as how much of an administrative—

Mr. STARK. Would the gentleman yield for a moment?

Mr. HULSHOF. Sure.

Mr. STARK. I would like to join you in that. I thought that was a question we would like to see that information as well, and I commend the question.

Chairman JOHNSON OF CONNECTICUT. Return that to the whole Committee, Mr. Kuhn.

Mr. KUHN. We would be happy to.

Mr. HULSHOF. As a quick follow-up along this line, and perhaps you could do this in writing, not to put you on the spot, I would anticipate that the manufacturers would say, well, there is an administrative burden. So, I would like any opinions you might have as far as an administrative burden that this would represent, given the turnaround time that is required. Again, I thank the Chairman for her indulgence.

Chairman JOHNSON OF CONNECTICUT. I would like to recognize Mr. Camp.

Mr. CAMP. Thank you, Madam Chairman. Mr. Kuhn, in the Medicare Modernization Act there was a provision requiring CMS to conduct a demonstration project for self-administered drugs that were previously available only through a physician's office. Congress also directed the department to submit a report on the demonstration evaluating patient access to care, outcomes, as well as an analysis of any cost savings to the Medicare Program attributable to reduced needs for infuse-related services. Can you tell me if this report has been provided yet or when we can expect to receive CMS's evaluation?

Mr. KUHN. That particular provision was section 641 of the MMA, and that report is currently in clearance within the department. I wish I could give you a projected date when we would have this up to Congress, but it is working through the process, and we hope to have it to you very soon.

Mr. CAMP. At some point it would be interesting to know how the agency would use these findings if, in fact, they found that the use of self-administered alternatives led to improvements in patient health outcomes and cost savings to the Medicare Program to improve care for patients as well as utilizing the program more efficiently. CMS has implemented a new national coverage determination for physician-administered drugs under Part B. Once a national coverage determination (NCD) has been adopted by CMS, my understanding is that local carrier coverage determinations are not relevant. If that is the case, there is a carrier that is being permitted to circumvent the intent of the NCD for a particular drug, and the situation causes undue hardships for those dialysis pa-

tients that fall within the region in which this carrier operates. Does CMS have the authority to enforce NCDs once adopted, or can any carrier ignore the intent of the NCD? Can you tell me what steps are being taken to correct situations like these? Problems—how long will it take to have problems like these addressed?

Mr. KUHN. I am somewhat familiar with this one, when you mentioned that it was an end-stage renal disease (ESRD) facility. I think it is a drug called Levocarnitine.

Mr. CAMP. Yes, it was.

Mr. KUHN. In 2002 or 2003, we did have an NCD, or national coverage determination, on that particular product. My understanding is that it is being implemented by our contractors as implemented by the NCD. What I also understand is that with varying practices' patterns by different ESRD facilities, they run into issues in terms of how they come up against this NCD. What I think this one takes, and what I understand this one to be, there needs to be some further education with the carrier, with the systemic autoimmune rheumatic diseases (SARD) facilities so they understand exactly what the standards are of the NCD, so that they understand how it is being implemented as we go forward.

Two things. One, we will go back and be absolutely sure that it is being implemented appropriately in terms of how the NCD is put forward; but secondly, and more importantly, that we have that communication and education between our contractor and ultimately the providers to make sure that they understand exactly the appropriate criteria as well.

Mr. CAMP. I certainly appreciate that because this situation has led some beneficiaries in parts of the United States to not have access to this particular drug, but also as a result makes their dialysis treatments less effective. It is very critical care. We have heard a lot about cancer treatment which is critical, but dialysis treatment is critical as well.

Mr. KUHN. We will look at this, and I will also bring this to the attention of our chief medical officer at CMS, who also happens to be a nephrologist. We will have some first-line expertise to look into this for you.

Chairman JOHNSON OF CONNECTICUT. Mr. Foley.

Mr. FOLEY. Thank you, Madam Chairman. I appreciate first and foremost yours and Mr. McCrery's and other's work on IVIG. It is critically important. Critically important. I repeat that not only for effect, but for the understanding that this is about 2 years old this problem. I am not on the Health Subcommittee, and that is why I appreciate the gentlewoman giving me a chance, because for a long time I thought the failure to respond to some of our inquiries was only because I wasn't on the health Committee. So, I am going to suggest, and I have heard it repeatedly by members of this panel, that they, too, have had trouble getting their calls returned.

This is an issue where people are dying. I came from a Committee hearing with Mr. Camp, and we were talking about the esoteric nature of the Tax Code. Nobody is going to die over the Tax Code, but people are dying over IVIG. I can't seem to get an answer. I keep hearing we are going to have facts from manufacturers. We are going to have facts from doctors. I know one thing:

There is a critical crisis. Hospitals are stopping providing it. We get various determinations of price, it is this, it is that, but nobody can put their hands on this issue, 2 years old. Mr. Kuhn, I have a question. Based on your discussions with FDA and others in HHS, do you believe there is an IVIG product shortage?

Mr. KUHN. I will tell you, Congressman, an honest answer. It will go week to week. FDA feels like there is a sufficient supply, and it depends who you talk to last on this issue. I will talk to one manufacturer who will say there is plenty of supply. I will talk then to a distributor who will say that there is insufficient supply. Right now, from what I can tell from not only the manufacturing community, their trade association, and the information we see from FDA, it looks like there is sufficient supply in the marketplace right now, though, however. . . .

Mr. FOLEY. Okay. Given that fact, sufficient supply in the market, which would not be a supply/demand concern, why do you think providers and distributors are selling their products 40, 50, 80 percent over ASP?

Mr. KUHN. This has been one of the most frustrating things about this product, different from anything we have seen before. What we have is a lot of it is encumbered. It is under contract with different distributors who have it under contract with various providers that are out there in the community. This really seems to have restricted the free flow of product within the marketplace, and what you see is the product moving to the secondary market as a result of that with enormously high markups, and it has created in some situations, some inappropriate shortages.

For example, if a physician has a part of the supply himself, and then he or she decides to send his patients over to the hospital, and he keeps that supply of the product, he is not shipping it with the patients, and we lead to dislocations here. Again, what we understand is there is plenty of supply in the marketplace. What we really see is this allocation problem seems to be getting in the way of free flow of product in the marketplace and helping it find its equilibrium so that everybody gets the treatment they need and deserve.

Mr. FOLEY. Let me ask, if the doctor is holding back the product in shipping his patient, what benefit is that on the doctor?

Mr. KUHN. There might be a chance to deliver that product to another patient that might have a private payer that might pay at a higher rate, for example, might be one of the advantages there. We have heard that some manufacturers who have done a very good job in terms of trying to make sure that the product is getting to people that they have, they have seen evidence of some of their products getting into secondary markets. When they do, I think they are taking actions to make sure that the product goes to patients and not to the secondary market so that people can profiteer on this product in one way or another.

Mr. FOLEY. So, let me get this straight. You are suggesting that this doctor is shipping his patient to the hospital so that they can provide the IVIG, and he is selling it to somebody else for more money?

Mr. KUHN. I am saying there have been instances where this has occurred. I would like to believe, and I think the evidence is

there, that this is truly the exception to the rule. What we are seeing is that, as I think you indicated earlier, there are a number of factors that are driving to again having this product difficulty finding its equilibrium in the marketplace.

Mr. FOLEY. You mentioned at some point somebody did off-market use or off-label use?

Mr. KUHN. Yes. There is a big surge in demand in terms of off-label use. In Medicare we saw enormous increase in usage between 2002 and 2004, a significant amount of usage. I think what has happened is it is a wonderful product, and I think others have mentioned that for the people who really need it, it is absolutely essential. We are finding, and I think the clinical evidence, and you will hear from the second panel, there are new opportunities for use of this product that can be very important and therapeutic to individuals, so that, too, is exacerbating our problems as well.

Mr. FOLEY. I think you know now by the tone of the Committee we are all very, very interested in this, and waiting to the fall for answers is getting a little late.

Mr. KUHN. I hear you loud and clear.

Chairman JOHNSON OF CONNECTICUT. Thank you very much. As we dismiss this panel, I would like to submit for the record and call to your attention, Mr. Kuhn, the letter that I am sending to Dr. McClellan today asking that CMS analyze claims dated from 2003 to 2005 to see if there has been a change in the proportion of cancer care provided in physicians' offices compared to the hospital outpatient department, and then to do the same with 2006 data when it comes in.

[The letter from Chairman Johnson follows:]

July 13, 2006

Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Hubert Humphrey Building, Room.314-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan,

The Medicare Modernization Act (MMA) included significant changes in Medicare reimbursement for cancer drugs and the costs associated with administering these drugs. These changes were the result of studies that concluded that the Medicare Program was overpaying for cancer drugs. Since this time, there have been numerous changes to oncology reimbursement including moving to an Average Sales Price (ASP) methodology for the payment of drugs, an increase in chemotherapy administration reimbursement rates, and two different demonstration projects supplementing administration payments.

All of these changes have resulted in a reimbursement environment that is in flux and uneven. I have received impressive reports from oncologists that they are shifting the site of care for Medicare beneficiaries without secondary insurance from the physician office to the hospital outpatient department because there is no longer the ability to absorb the 20% copayment loss in the individual practice. Congress must know if this is in fact occurring, to what degree, and if it is a result of reimbursement changes.

Consequently, I ask that CMS analyze claims data from 2003 to 2005 to determine if there has been a change in the proportion of cancer care provided in the physician office compared to the hospital outpatient department and report to me in writing on the findings. Additionally, 2006 has resulted in another round of reimbursement changes and I request that CMS also analyze and report the claims on the first two quarters of 2006 as soon as this information is available.

I believe that this information is important to assessing the appropriateness as well as the cost effectiveness of the current reimbursement system and I look forward to reviewing CMS' s analysis of the claims data,

Very truly yours,

Nancy L. Johnson
Member of Congress

Chairman JOHNSON OF CONNECTICUT. So, I think the Committee could benefit from having that information in terms of trying to find out what really is going on. As Dr. Miller recognized— noted, those without secondary coverage do appear to be moved to hospital settings, and since in some areas those settings are not available, we need to understand whether we need to take action to deal with this copayment problem. Do you think you have the administrative action to deal with the copayment issues that are coming forward?

Mr. KUHN. We do not believe we have the authority now for the copayment issues and basically Medicare bad debt. It is statutorily defined for hospital skilled nursing facilities. There is nothing on the physician's side that gives us the authority to do that at this time.

Chairman JOHNSON OF CONNECTICUT. Do we have the authority to deal with the issue of lag, the difference between with when prices change? Could you require that price could only be changed at certain periods so that there wouldn't be this lag?

Mr. KUHN. I think we are pretty quick in terms of information as it comes forward. Under most of the Medicare payment systems, we do updates on an annual basis. On this one we are doing it on a quarterly basis. We get the information—the payment rates that we are using right now under ASP is information that—from pricing from January, February, and March of this year. So, right now it is pretty quick turnaround, and compared to the other payment systems under the Medicare Program, this is almost real-time data, at least for the Medicare Program.

Chairman JOHNSON OF CONNECTICUT. Do you think people are getting the payment if the price goes up within 3 months?

Mr. KUHN. We believe that the manufacturers understand how to report the ASP data now. We are now into our seventh quarter of it, and we think we are getting very accurate information from them so that as prices move and change, I think they are pretty reflective pretty quick. I think that is evidence in terms of current ASP information that is out there. If you look at the data, and some people look at it and go, oh, gosh, look at the increases that we are seeing in July. Well, that is because a lot of people raised prices in January.

Chairman JOHNSON OF CONNECTICUT. That is not a 3-month lag, that is a 6-month lag, and you are absorbing that loss for 6 months, and if it happens to be one of the high cost and it happens to be a high user, we can't just let the statistics drive this. If it is a drug that is seldom used, it probably does not matter much, but if it is a drug that is used frequently, it could matter a lot. I think getting at some of the things that Mr. Steinwald raised, but also looking at this issue of frequency abuse. Why can't

we make it? If we know the information after 3 months, why can't we get the payments out there in 3 months?

Mr. KUHN. When we get the reporting information—to give a sense of the timetable, January, February, March of this year. By the third or fourth week of April. We have the information from the manufacturers in terms of reporting for that period of time, and within 2 months those prices were posted. So, it is a pretty quick turnaround.

Chairman JOHNSON OF CONNECTICUT. It is a total of 6 months lag. We need to look at how you could shrink that down.

Mr. KUHN. We will look and see—

Chairman JOHNSON OF CONNECTICUT. You need look at who needs to report when to get it shrunk down. Thank you very much. I thank the panel for your attention and welcome the second panel to testify. We will have votes coming up, so we will go through the panel and then have questions. Dr. Frederick Schnell, Dr. Joseph Bailes, Marcia Boyle, Richard Friedman, and Dr. Jordan Orange. Dr. Schnell, if you would begin as soon as the name plates are distributed.

**STATEMENT OF FREDERICK M. SCHNELL, M.D., PRESIDENT,
COMMUNITY ONCOLOGY ALLIANCE**

Dr. SCHNELL. Madam Chairman, Ranking Member Stark and distinguished Members of the Ways and Means Subcommittee on Health, good afternoon. My name is Fred Schnell, and I am a practicing community oncologist from Macon, Georgia, and I volunteer as the president of the Community Oncology Alliance (COA). We believe that the cancer care delivery system in this country is in grave danger of being dismantled. Changes in Medicare reimbursement for cancer care brought about by the Medicare Modernization Act of 2003 we believe to be too severe. Community cancer clinics were shielded from the full impact of these changes until 2006. Now reimbursement for both drugs and services in many cases is less than our costs.

COA has reports of patient access problems from 37 States, especially among seniors without adequate secondary insurance who are unable to pay the 20 percent Medicare coinsurance obligation. There are four simple solutions to correcting this problem. First, eliminate prompt payment discounts from the calculation of average sales price so that ASP is not artificially lowered by financial discounts between manufacturers and wholesalers. Second, remove the 6-month lag in ASP so that community cancer clinics are not unfairly subsidizing the Medicare system for such price increases. There have already been over 35 price increases this year alone. Third, create payment codes for essential services that Medicare does not currently reimburse, most specifically for treatment planning and pharmacy facilities. Fourth, restore appropriate payment for drug administration and deal with the reality of bad debt.

By not addressing the problem with Medicare reimbursement, we are jeopardizing the future of cancer care in America and threatening to undo all of the notable progress accomplished in the war on cancer. The combination of earlier diagnosis, more effective therapy, and widely accessible care has contributed to the decreasing cancer mortality rate. Today, 84 percent of people with cancer are

treated in community cancer clinics just like ours in Macon. No longer do cancer patients have to travel great distances and bear economic hardships to be treated in distant institutions. Instead they receive care in their own communities close to home, family and friends. Prior to the MMA, Medicare payments for cancer care were unbalanced. Reimbursement for drugs subsidized a severe underpayment for drug administration and essential medical services that cancer patients require. However, the current reality with the MMA is a significant difference between actual implementation and what Congress had intended.

The CBO estimate for the MMA was a \$4.2 billion reduction in Medicare payments for cancer care from the year 2004 to 2013. Earlier this week, PricewaterhouseCoopers released a revised analysis that estimates that \$13.8 billion will actually be cut from cancer care payments over this same time period. This far exceeds congressional intent. What then explains this sizable discrepancy of actual implementation and congressional intent? The answer is threefold. First, Medicare reimbursement for drug administration was initially increased in 2004, but, as stated, has since actually decreased by a factor of over 20 percent. The MMA increased reimbursement for drug administration by 110 percent in 2004 as well as mandated an additional one year 32 percent transition increase. This appears to be a substantial increase; however, it was an increase to an extremely low reimbursement rate and paled in comparison to the cut in drug reimbursements.

Unfortunately, CMS did not create any new major payment codes for unreimbursed services such as treatment planning. What CMS did do was devalue payment for drug administration. This devaluation has been compounded by the drastic cut to drug reimbursement. Second, certain essential components of cancer care are not reimbursed at all. For example, an essential part of my day-to-day work involves the development of complex treatment plans for my patients. Currently, no Medicare payment exists for medical oncology treatment planning, although there is reimbursement for treatment planning developed by radiation oncologists. Another example is that the cost of pharmacy facilities are not reimbursed. These include storage, inventory, pharmacy operations and waste disposal. These types of services are subsidized by drug payments under the old Medicare reimbursement system.

Third, drug reimbursement barely covers drug acquisition costs and has decreased over 30 percent. Studies completed by the OIG and the GAO on the adequacy of Medicare reimbursement for cancer drugs ignore the reality that drug acquisition costs is just a portion of total drug costs. In addition to pharmacy facility costs, we incur bad debt from patients who lack adequate secondary insurance and are unable to pay their 20 percent Medicare coinsurance. Bad debt, which averages 5.3 percent nationwide, is a growing reality for community cancer clinics, especially as the cost of cancer drugs increases. Whereas the patient copay for a high blood pressure medication might be \$5 or \$10, the Medicare copay obligation for cancer treatment can easily reach \$5,000 to \$10,000. We are ignoring the fact that approximately 20 to 25 percent of Medicare beneficiaries do not have adequate secondary insurance that covers the expense of cancer treatment.

Furthermore, as I previously stated, the inclusion of prompt pay discounts artificially lowers ASP, and community cancer clinics are subsidizing Medicare for every price increase. The Competitive Acquisition Program is not the answer to the problems associated with Medicare drug reimbursement. The oncology community at large use CAP as an untried and untested experiment. We will not expose our patients to the risks it presents. CAP will force the creation of individual patient inventories, and increase the likelihood of treatment errors and delays, and place new and unreimbursed administrative burdens on our clinics.

In conclusion, community cancer clinics cannot operate when reimbursement continues to be ratcheted down while operating costs are increased by at least 4 percent per year. In 2006, the impact of insufficient reimbursement has resulted in more patients not being able to be treated because clinics cannot afford to provide treatment that is reimbursed less than cost. Seventy percent of the clinics from 37 States reporting are not able to treat an increasing number of patients. As an example, we just received notice from a clinic in Kentucky that is unable to treat 25 to 30 patients per month due to, and I quote, an overwhelming percentage of 20 percent coinsurance turning into bad debt.

Unfortunately, the local hospital can treat only a very limited number of patients, and treatment is being delayed by a week or two. Additionally, clinics report closing satellite facilities and practices often in underserved communities, reducing professional staff, and very unfortunately being pressured to factor economic decisions into cancer treatment planning. If the situation continues without relief, we will lose oncologists to attrition and retirement while seeing increased rates of practice closings.

On behalf of every American with cancer, or caring for someone with cancer, I implore the Congress to address the growing deficiencies in the Medicare reimbursement for cancer care. The problem that community cancer clinics face is exacerbated by Medicare artificially setting the bar too low and inviting private payers to cut their payments for cancer care as well. We are already seeing this happen in my State of Georgia. I finish with a question: As a nation, are we willing to risk the future of the cancer care delivery system in this country for an expense of less than half a penny per day per American? Let us work together to finish the promise of balanced reform promised in the MMA for cancer patients and the community cancer clinics that provide them with the highest quality care. Thank you, Madam Chairman, and your Committee for allowing me to testify today.

Chairman JOHNSON OF CONNECTICUT. Thank you, Dr. Schnell.

[The prepared statement of Dr. Schnell follows:]

**Statement of Frederick M. Schnell, M.D., President,
Community Oncology Alliance**

Medicare Part B reimbursement for cancer care is insufficient in 2006. The implications of insufficient reimbursement are that community cancer clinics report sending more patients to the hospital for treatment, closing satellite facilities and practices, reducing staff, and being pressured to factor economic decisions into the cancer treatment plan in order for clinics to continue treating patients. Additionally, clinics report considering dropping out of the Medicare program. Already, in 2006,

there are reports about access problems from community cancer clinics in over 37 states.

The fundamental problem with Medicare Part B reimbursement in 2006 is that drug administration reimbursement has decreased by over 20% since 2004 while drug reimbursement has decreased by over 30%. So, during a time period when underlying medical costs are increasing approximately 4% per year, reimbursement for both essential services and drugs required to treat seniors covered by Medicare Part B continues to decrease. Relating to services reimbursement, certain services such as cancer treatment planning and pharmacy facilities are not reimbursed. Relating to drug reimbursement, Medicare reimbursement of Average Sales Price (ASP)+6% appears in cases to cover drug acquisition costs. However, reimbursement for most cancer drugs is actually less than cost when including the realities of pharmacy facilities, prompt pay wholesaler discounts, bad debt, and manufacturer price increases. Community cancer clinics, where 84% of the cancer patients in the United States are treated, cannot continue to operate in an environment where costs are exceeding reimbursement.

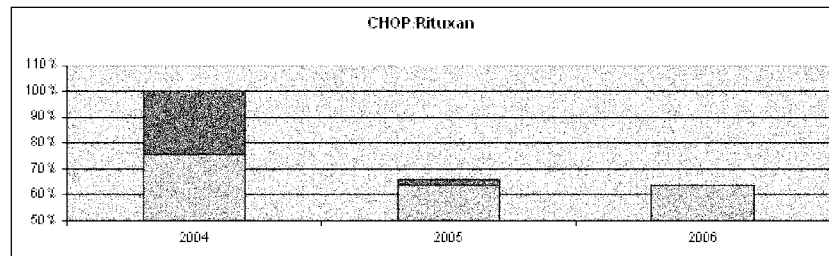
The specific problems with Medicare reimbursement are three-fold.

Problem #1. Medicare payment for drug administration is inadequate and is decreasing.

The Medicare Modernization Act (MMA) increased drug administration payments by 110% starting in 2004. The MMA also created a lump-sum transition increase of 32% that further raised drug administration payments in 2004. This transition increase decreased to 3% in 2005 and was eliminated in 2006. The purpose of this transition increase was for the Centers for Medicare & Medicaid Services (CMS) to ascertain the adequacy of existing payment codes and to create new codes for unreimbursed services, such as treatment planning.

Unfortunately, in 2004 no new major payment codes were created by CMS for 2005; only temporary “G codes” were created. Instead, CMS developed a chemotherapy demonstration project for 2005 that retained at least \$300 million in Medicare funding for cancer care. This stopgap funding, along with the 3% transition fee and averted cut in the physician fee schedule, minimized any impact on community oncology during 2005. However, the chemotherapy demonstration project and transition increase both expired at the end of 2005, which resulted in lower Medicare reimbursement in 2006. Additionally, CMS replaced the temporary “G codes” with new codes at a lower relative value unit (RVU) rate and with no clear “cross walk” (i.e., translation) from the “G codes.” This resulted in an additional decrease in drug administration reimbursement. Exhibit A shows a coding analysis performed by expert coders from around the country. Analyzing some commonly used cancer treatment regimens, it is clear that reimbursement for drug administration only (*this analysis excludes drug reimbursement*) on a treatment-by-treatment basis has decreased substantially from 2004 to 2006. This decrease is estimated to be in excess of 20% overall.

The graph below illustrates the components of declining drug administration for the CHOP/Rituxan treatment regimen presented in Exhibit A. The purple portion of the bar in 2004 and 2005 illustrates the impact of the transition increases—32% in 2004 and 3% in 2005. The blue portion represents the underlying RVU-based payment.



It is illogical that Medicare drug administration reimbursement has decreased over 20% from 2004 to 2006 in light of the fact that medical human resource and supply costs have actually increased by approximately 4% per year during this period. It must be noted this has occurred when drug reimbursement has decreased by over 30% with the change from the prior AWP system to the new ASP-based reimbursement system.

Problem #2: Certain essential cancer care services and costs are not reimbursed.

The prior AWP-based reimbursement system resulted in drug reimbursement overpayments that subsidized essential cancer services that were either under-reimbursed or not reimbursed. Under the ASP-based system there is neither a subsidy nor a direct or indirect reimbursement for certain essential services. For example, cancer treatment planning is not reimbursed as part of any existing Medicare payment mechanism. It is ironic that radiation oncology treatment planning, which is typically part of the overall cancer treatment plan, is reimbursed by Medicare, whereas medical oncology treatment planning is not reimbursed. As another example, all of the direct drug costs of a pharmacy are not reimbursed. These include storage, inventory, pharmacy operations, and waste disposal. In light of increasing regulations dealing with chemotherapy and other toxic drug handling, the costs of maintaining a pharmacy are increasing. However, these costs are not reimbursed directly or indirectly.

Although some argue that many costs are “bundled” in the drug administration payment codes, there is no evidence that this is true or that these costs are appropriately covered by payment codes. In fact, the existing codes for drug administration have not been updated—even with the 2004 MMA 110% increase—to reflect the increasing costs of simply administering cancer drugs, much less cover any other facets of cancer treatment, such as treatment planning.

Problem #3: ASP+6% may only barely cover drug acquisition costs. It does not cover all direct drug costs.

A clinic’s total drug costs are comprised of drug acquisition costs, pharmacy costs, billing and overhead, and bad debt. Analyzing a clinic’s drug acquisition costs in comparison to ASP+6% reimbursement and concluding that reimbursement covers cost is a faulty analysis, which is the problem with studies completed by the Office of the Inspector General (OIG) and the Government Accountability Office (GAO). The table below shows both OIG’s estimated purchase price by drug (column a) along with the corresponding drug reimbursement rate (column b). If all of the patient’s co-insurance was paid, most of the drug acquisition cost is covered by the reimbursement (column c). However, factoring in bad debt of 5.3% most of the drug acquisition costs are not covered by the reimbursement (column d). On a case-by-case basis, the impact of non-payment of the 20% co-insurance is substantial (column e). If you factor in bad debt and selected other direct drug costs, the result is a further under-reimbursement of drug costs.

Drugs	Q1 Estimated Average Purchase Price	4th Quarter Medicare Payment Rate	If Total Amount Paid	Bad Debt Factor of 5.30%	If No Co-pay Collected	Bad Debt Factor and Other Drug Costs
Carboplatin	16.24	35.25	19.01	17.14	11.96	14.67
Dexamethasone	0.05	0.11	0.06	0.05	0.04	0.05
Cisplatin	2.05	2.37	0.32	0.19	(0.16)	0.03
Vinorelbine	35.71	42.83	7.12	4.85	(1.45)	1.85
Dolasetron Mesylate	4.04	6.52	2.48	2.13	1.18	1.68
Cyclophosphamide	2.03	2.12	0.09	(0.02)	(0.32)	(0.47)
Epoetin Alfa	9.20	9.22	0.02	(0.47)	(1.82)	(1.11)
Filgrastim	245.46	279.57	34.11	19.29	(21.80)	(0.28)
Darbepoetin alfa	15.81	15.06	(0.55)	(1.36)	(2.65)	(0.46)
Fluorouracil	1.49	0.64	(0.85)	(0.98)	(0.98)	(0.97)
Leucovorin	1.16	1.32	0.16	0.09	(0.10)	(0.90)
Palonosetron hydrochloride	16.38	17.99	1.61	0.66	(1.99)	(0.30)
Granisetron hydrochloride	6.39	7.14	0.75	0.37	(0.66)	(0.13)
Vincristine	3.18	3.60	0.42	0.23	(0.40)	(0.03)
Pegfilgrastim	2,080.71	2,078.07	(2.04)	(112.78)	(918.25)	(282.24)
Etoposide	0.46	0.49	0.03	0.00	(0.07)	(0.03)
Doxetaxel	280.71	293.64	12.93	(2.63)	(90.60)	(63.10)
Pamidronate disodium	56.50	40.63	(15.87)	(16.52)	(24.06)	(20.87)
Gemcitabine hydrochloride	111.40	115.89	4.49	(1.65)	(18.69)	(9.76)
Fludarabine	263.12	262.87	(0.25)	(14.13)	(52.62)	(32.66)
Bevacizumab	55.27	57.11	1.84	(1.19)	(3.49)	(2.16)
Zoledronic acid	192.96	200.03	7.08	(3.62)	(32.93)	(17.82)
Trastuzumab	51.80	54.39	2.59	(6.09)	(8.26)	(4.10)
Oxaliplatin	8.07	8.53	0.46	0.01	(1.75)	(0.66)
Irinotecan	123.00	126.92	3.92	(2.81)	(21.45)	(11.69)
Mitoxantrone	316.10	323.90	7.70	(6.46)	(57.08)	(32.12)
Doxorubicin J9001	353.30	354.53	11.23	(8.92)	(61.66)	(33.61)
Topotecan	730.68	753.80	32.92	(7.66)	(119.64)	(91.07)
Ocrototide	84.40	87.31	2.91	(17.2)	(14.55)	(7.63)
Diphenhydramine	0.93	0.72	(0.21)	(0.25)	(0.35)	(0.30)
Sargramostim	21.44	21.87	0.43	(0.73)	(3.34)	(2.26)
Amifostine	414.00	439.31	25.31	2.03	(62.65)	(28.73)
IVI non-lyophil	56.26	56.30	0.04	(2.64)	(11.22)	(6.58)
Fulvestrant	79.97	81.33	1.36	(0.92)	(14.81)	(9.64)
Rituxan	440.10	456.92	16.82	(8.94)	(76.36)	(50.25)
Paclitaxel	16.71	13.33	(3.38)	(4.99)	(6.65)	(5.62)
Leuprolide	279.94	224.42	(54.92)	(69.31)	(99.60)	(92.82)
Enoxaparin Sodium	6.45	5.45	(1.00)	(1.28)	(2.00)	(1.97)
Doxorubicin J9000	5.48	5.94	0.36	0.05	(0.31)	(0.36)

It is unreasonable to simply look at drug acquisition costs in isolation without considering all direct drug costs. The stated Medicare reimbursement rate is ASP+6%. However, factoring in other costs, the effective real rate is ASP-3.8%. These include the MMA-mandated inclusion of prompt payment discounts between the pharmaceutical manufacturer and the wholesaler into the ASP calculation; the impact of the lag between a manufacturer's price increase and inclusion in the drug reimbursement rates; and the bad debt factor.

Stated Medicare Drug Reimbursement Rate	ASP+6%
Less Prompt Pay Discount	2.00%
Less Price Increase Lag	2.50%
Less Bad Debt	5.30%
Effective Medicare Drug Reimbursement Rate	ASP-3.8%

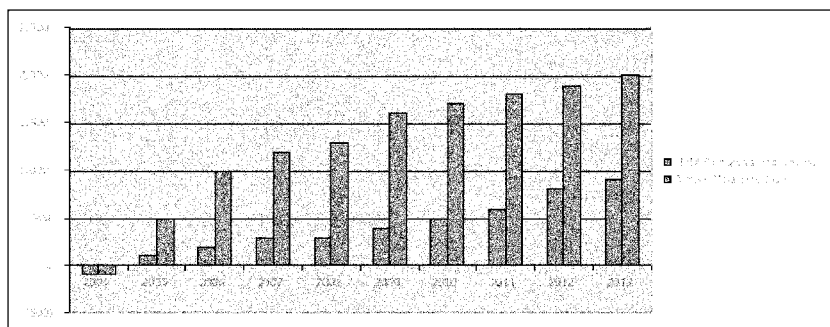
Bad debt is a real cost incurred by community cancer clinics. COA estimates bad debt at 5.3% nationally. An estimated 12% of patients have no secondary co-insurance and in many states Medicaid—as the secondary insurer—does not cover the patient's co-insurance obligation. As the cost of cancer drugs escalate, patients are increasingly unable to cover co-insurance payments that can run over \$20,000. Bad debt is a reality of operating a community cancer clinic, yet it is ignored as a reality by CMS. Community cancer clinics historically have been willing to treat patients rather than turn them away or hand them over to a collection agency. However, community cancer clinics now are increasingly unable to subsidize cancer care for seniors covered by Medicare with no secondary insurance coverage.

This analysis does not include pharmacy costs. MedPAC estimated pharmacy costs at 26-28% of total drug costs in analyzing actual costs from outpatient facilities in Maryland. This analysis also does not include the cost of capital in purchasing very expensive cancer drugs or the costs of billing and overhead. Once

again, under the AWP-based system these costs were part of drug reimbursement. However, under the ASP-based system only acquisition cost is reimbursed.

Some believe that the Competitive Acquisition Program (CAP) is a solution to drug reimbursement problems. However, CMS has struggled to find only one CAP vendor—after delaying the program because initially there were no vendors—and few if any community cancer clinics will trust an unproven, untested system to deliver the correct drugs on time to their patients. The CAP will create multiple patient inventories, risk treatment errors, and result in treatment delays. Additionally, the CAP will actually increase pharmacy and billing costs because of the procedures, tracking, and record keeping requirements. Analyzing the top reimbursed cancer drugs, COA estimates that Medicare will actually pay over 3% more for drugs to the CAP vendor than to community cancer clinics.

These three problems have resulted in Medicare now becoming the lowest payer for cancer care services. Medicare, with its considerable market clout, has set reimbursement rates artificially low for private payers to follow. In many cases, this is exactly what is happening.



The congressional intent of the MMA was to save Medicare \$4.2 billion from 2004–2013 by changing the reimbursement system for cancer care, according to the Congressional Budget Office in a letter dated November 20, 2003, to Chairman Thomas. Unfortunately, actual implementation by CMS is resulting in substantially more cuts to Medicare reimbursement for cancer care. Exhibit B is a report from PricewaterhouseCoopers that estimates the cuts to cancer care reimbursement to be \$13.8 billion, far in excess of the \$4.2 billion intended by Congress. The graph below shows this discrepancy in projected cuts (congressional intent) versus actual implementation by CMS. The reasons for this discrepancy are the three problems previously outlined in this document.

There is bipartisan recognition of this problem in both the House and the Senate. The entire cancer community supports solutions to this problem. There are currently three bills in the House addressing aspects of this overall problem, including one with over 70 sponsors that was introduced by Congressman Jim Ramstad, a member of the Ways and Means Subcommittee on Health. There is an identical Senate bill that was introduced by Senator Arlen Specter.

Some have suggested waiting to see more substantial patient access problems before fixing the problems with Medicare Part B reimbursement for cancer care. That is simply not acceptable because actual lives of Americans are already being negatively impacted. Furthermore, we risk dismantling a system of cancer care that has been built during the past 15–20 years. Rescuing the cancer care delivery system when it is too late will not be feasible because the damage will be done. Already, the incidence of cancer is increasing while the number of oncologists is flattening. Reimbursement problems should not be motivating older oncologists to retire, which is starting to happen, or discouraging new physicians from pursuing a specialty in oncology, which is also happening at the medical school and fellowship levels.

On behalf of community oncology, we ask the Congress to immediately fix the problems of insufficient Medicare reimbursement for cancer care by at least accomplishing the following:

- Eliminate “prompt payment” discounts from pharmaceutical manufacturers’ calculation of ASP. Prompt payment discounts are financing discounts between the manufacturer and the wholesaler—these are not incentive purchasing discounts to community cancer clinics. Inclusion of these discounts in the ASP calculation artificially lowers Medicare drug reimbursement by approximately 2%.

- Immediately increase Medicare reimbursement for those drugs increased in price by the manufacturer. Community cancer clinics are currently subsidizing Medicare for all drug price increases for 6 months, on average.
- Create payment mechanisms for un-reimbursed services such as treatment planning and pharmacy facilities. Medicare reimbursement needs to more realistically cover the essential services provided to seniors by community cancer clinics.
- Reevaluate existing drug administration payment codes to restore adequate reimbursement that covers the costs of the materials and human resources required to administer drugs.
- Address the growing bad debt problem of Medicare patients without adequate secondary insurance.

An independent analysis of the plight facing community oncology appeared as a research article in the Journal of the National Comprehensive Cancer Network (*Surviving the Perfect Storm: An RVU-Based Model to Evaluate the Continuing Impact of MMA on the Practice of Oncology*; Volume 4, Number 1, January 2006). The authors write, "The emotional and financial pressures facing the medical oncologist in private practice are enormous, with no relief in sight. The complexity of managing private practice oncology rivals that of managing cancer care." "Will the planned changes in Medicare reimbursement, exacerbated by the loss of operational inefficient medical oncology practices, lead to irreparable changes in the oncology delivery system (e.g., access, availability, continuity, and quality)?" "Will the United States abrogate its leadership in clinical cancer care and research and default to a specialty of algorithm followers rather than algorithm creators? Are the unintended consequences of changes in regulation and reimbursement fully appreciated? And last and most importantly, what are the risks to the cancer patient resulting from the heuristic approach promulgated by regulators and legislators?"

Exhibit C presents a sample of quotes received from community cancer clinics across the country.

Exhibit A

HCP/CS	Treatment Description	Total Dose Based 1.75SAAS/kg	Admin. Time	Administration Code Description	2009 and 2004 Administration Code	2006 Administration Code	Reimb. 2004	Reimb. 2006	2004 2006 Diff	2004 2006 % Diff	
	Non-Hodgkins Lymphoma										
J6000	Adriamycin 60mg/m2	60mg	10m r/12h	Sequential Chem IV P	96408	96411	\$154.76	\$70.37	-\$83.39	-54.21%	
J6370	Vincristine 2mg	2mg	10m r/12h	Sequential Chem IV P	96408	96411	\$154.76	\$70.37	-\$83.39	-54.21%	
J6070	Cytosar 750mg/m2	1275mg	1hr	Initial Chemo inf	96410	96413	\$217.35	\$172.31	-\$44.54	-20.46%	
J69510	Rituxan 375mg/m2	837.5mg	3hrs	Seq. IV Chemo inf + 2hrs	96412 + 9	96417 9641502	\$144.90	\$162.57	\$17.67	12.19%	
J2469	Alloxi 0.25mg	0.25mg	16m r/12h	Injection nose push	90730	90774	\$117.79	\$26.91	-\$90.38	-77.15%	
J1100	Decadren 20mg	20mg	15m r/12h	In same bag with Decadren	Not coded	One per day	\$0.00	\$0.00	\$0.00		
	Colorectal Cancer										
	Folfox 6 + Avastin										
J6200	Oxaliplatin 100mg/m2	175mg	2hrs	Initial Chem IV P	96410 96412	96413 96416	\$225.00	\$211.34	-\$13.31	-20.20%	
J6530	Leucovorin 400mg/m2	650mg	2hrs	Concurrent IV Infusion	Not coded	90763	\$0.00	\$24.63	\$24.63		
J6190	5FU 400mg/m2	650mg	10m r/12h	Sequential Chem IV P	CCU visit	96411	\$0.00	\$70.37	\$70.37		
J6190	5FU 400mg/m2	1050mg	16hrs	Continuous Chem IV inf.	96411 50	96416	\$250.00	\$192.76	-\$57.24	-31.12%	
J6255	Avastin 6mg/kg	240mg	1hr	Seq. IV Chemo inf.	96412	96417	\$19.50	\$0.00	-\$19.50	-100.00%	
J2469	Alloxi 0.25mg	0.25mg	10m r/12h	Injection nose push	90730	90774	\$117.79	\$26.91	-\$90.38	-77.15%	
J1200	Benadryl 50mg	50mg	20m r/12h	Seq. IV Infusion	Not coded	90767	\$33.00	\$12.14	-\$20.32	-38.00%	
J1100	Decadren 20mg	20mg	20m r/12h	Piggy Backed	Not coded	90763	\$0.00	\$24.63	\$24.63		
	Carbo/Taxol Low Dose										
J6045	Carboplatin AUC 2	175mg	1hr	Initial Chemo inf	96410	96413	\$217.35	\$172.31	-\$44.54	-20.46%	
J6265	Taxol 80mg/m2	135mg	1hr	Seq. IV Chemo inf	96412	96417	\$42.30	\$80.63	\$38.33	90.39%	
J2469	Alloxi 0.25mg	0.25mg	10m r/12h	Injection nose push	90730	90774	\$117.79	\$26.91	-\$90.38	-77.15%	
J1200	Benadryl 50mg	50mg	20m r/12h	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.44	\$42.44		
J1100	Decadren 20mg	20mg	20m r/12h	Piggy Backed	Not coded	90763	\$0.00	\$24.63	\$24.63		
J2780	Zantac 50mg	50mg	20m r/12h	Piggy Backed	Not coded	One per day	\$0.00	\$0.00	\$0.00		
	Carbo/Taxol q3weeks										
J6045	Carboplatin AUC 5	425mg	1hr	Initial Chemo inf	96410	96413	\$217.35	\$172.31	-\$44.54	-20.46%	
J6265	Taxol 175mg/m2	297.5mg	3hrs	Seq. IV Chemo inf + 2hrs	96412 + 9	96417 9641502	\$144.90	\$162.57	\$17.67	12.19%	
J2469	Alloxi 0.25mg	0.25mg	10m r/12h	Injection nose push	90730	90774	\$117.79	\$26.91	-\$90.38	-77.15%	
J1200	Benadryl 50mg	50mg	20m r/12h	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.44	\$42.44		
J1100	Decadren 20mg	20mg	20m r/12h	Piggy Backed	Not coded	90763	\$0.00	\$24.63	\$24.63		
J2780	Zantac 50mg	50mg	20m r/12h	Piggy Backed	Not coded	One per day	\$0.00	\$0.00	\$0.00		
	Carbo/Taxol q4weeks										
J6045	Carboplatin AUC 5	425mg	1hr	Initial Chemo inf	96410	96413	\$217.35	\$172.31	-\$44.54	-20.46%	
J6265	Taxol 175mg/m2	297.5mg	3hrs	Seq. IV Chemo inf + 2hrs	96412 + 9	96417 9641502	\$144.90	\$162.57	\$17.67	12.19%	
J2469	Alloxi 0.25mg	0.25mg	10m r/12h	Injection nose push	90730	90774	\$117.79	\$26.91	-\$90.38	-77.15%	
J1200	Benadryl 50mg	50mg	20m r/12h	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.44	\$42.44		
J1100	Decadren 20mg	20mg	20m r/12h	Piggy Backed	Not coded	90763	\$0.00	\$24.63	\$24.63		
J2780	Zantac 50mg	50mg	20m r/12h	Piggy Backed	Not coded	One per day	\$0.00	\$0.00	\$0.00		
	Carbo/Taxol q6weeks										
J6045	Carboplatin AUC 5	425mg	1hr	Initial Chemo inf	96410	96413	\$217.35	\$172.31	-\$44.54	-20.46%	
J6265	Taxol 175mg/m2	297.5mg	3hrs	Seq. IV Chemo inf + 2hrs	96412 + 9	96417 9641502	\$144.90	\$162.57	\$17.67	12.19%	
J2469	Alloxi 0.25mg	0.25mg	10m r/12h	Injection nose push	90730	90774	\$117.79	\$26.91	-\$90.38	-77.15%	
J1200	Benadryl 50mg	50mg	20m r/12h	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.44	\$42.44		
J1100	Decadren 20mg	20mg	20m r/12h	Piggy Backed	Not coded	90763	\$0.00	\$24.63	\$24.63		
J2780	Zantac 50mg	50mg	20m r/12h	Piggy Backed	Not coded	One per day	\$0.00	\$0.00	\$0.00		

HCPCS	Treatment Description	Total Dose Based 1.7 BSA/68 kg	Administration Time	Administration Code Description	2004 Administration Code	2006 Administration Code	Reimb 2004	Reimb 2006	2004 2008 Diff	2004 2008 Diff
	Docu Descrip AD Taxol	Breast Cancer					USA			
90000	Adriamycin 50mg/m2	102mg	15 minutes	Seq. Chemo IVP	96408	96411	\$154.76	\$70.89	\$83.88	\$4.21%
90070	Cytosan 600mg/m2	1020mg	1hr	Initial Chemo inf.	96410	96413	\$217.35	\$172.81	\$44.54	20.46%
J9265	Taxol 175mg/m2	297.5mg	3hrs	Seq. IV Chemo Inf + 2hr	96412 & 9	96417 & 96415 & 2	\$144.96	\$162.57	\$17.61	12.19%
J3499	Aloni 0.25mg	0.25mg	10 minutes	Infusion slow push	90780	90776	\$117.79	\$28.94	\$88.85	77.15%
J1100	Decadron 20mg	20mg	20 minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.46	\$42.46	
J2780	Zantac 50mg	50mg	20 minutes	Piggy backed with Decadron	Not coded	90768	\$0.00	\$24.63	\$24.63	
							\$634.80	\$500.24	\$134.56	21.20%
	TAC	Breast Cancer								
J8170	Taxolite 75mg/m2	127.5mg	1 hr	Initial IV Chemo inf.	96410	96413	\$217.35	\$172.81	\$44.54	20.46%
90000	Adriamycin 50mg/m2	85mg	15 minutes	Seq. Chemo IVP	96408	96411	\$154.76	\$70.89	\$83.88	54.21%
90070	Cytosan 600mg/m2	850mg	1hr	Seq. Chemo Inf.	96412	96417	\$26.20	\$20.69	\$5.51	21.03%
J2499	Aloni 0.25mg	0.25mg	10 minutes	Infusion slow push	90780	90776	\$117.79	\$28.94	\$88.85	77.15%
J1100	Decadron 20mg	20mg	10 minutes	In bag with Aloni	Not coded	Not billed	\$0.00	\$0.00	\$0.00	
							\$539.20	\$489.10	\$50.10	9.29%
	Herceptin	Breast Cancer								
J0385	Herceptin 2mg/kg	135mg	1hr	Initial Chemo inf.	96410	96413	\$217.35	\$172.81	\$44.54	20.46%
	Taxol/Herceptin	Breast Cancer								
	Taxol 50mg/m2	135mg	1hr	Initial IV Chemo inf.	96410	96413	\$217.35	\$172.81	\$44.54	20.46%
	Herceptin 2mg/kg	135mg	1hr	Seq. Chemo Inf.	96412	96417	\$46.30	\$36.51	\$9.79	21.14%
J1200	Benadryl 50mg	50mg	15 minutes	Infusion slow push	90780	90776	\$117.79	\$28.94	\$88.85	77.15%
J1100	Decadron 20mg	20mg	15 minutes	In bag with Benadryl	Not coded	One per day	\$0.00	\$0.00	\$0.00	
J2780	Zantac 50mg	50mg	15 minutes	In bag with Benadryl	Not coded	One per day	\$0.00	\$0.00	\$0.00	
							\$353.44	\$284.25	\$69.19	19.58%
	Taxol/Gemzar	Lung Cancer								
J9265	Taxol 175mg/m2	297.5mg	3hrs	Seq. IV Chemo Inf + 2hrs	96410 & 96412 & 2	96417 & 96415 & 2	\$213.95	\$162.57	\$51.38	24.02%
J9201	Gemzar 1250mg/m2	2125mg	1hr	Initial IV Chemo inf.	96412	96413	\$46.30	\$172.81	\$126.51	273.78%
J3499	Aloni 0.25mg	0.25mg	8 minutes	Seq. IVP	Not coded	90776	\$0.00	\$28.94	\$28.94	
J1200	Benadryl 50mg	50mg	20 minutes	Seq. IV Infusion in one bag	90780	90768	\$117.79	\$24.63	\$93.16	79.09%
J1100	Decadron 20mg	20mg	20 minutes	Seq. IV Infusion in one bag	Not coded	One per day	\$0.00	\$0.00	\$0.00	
J2780	Zantac 50mg	50mg	20 minutes	Seq. IV Infusion in one bag	Not coded	One per day	\$0.00	\$0.00	\$0.00	
							\$480.04	\$355.92	\$124.12	25.85%
	Gemzar	Pancreatic Cancer								
J9201	Gemzar 1250mg/m2	2125mg	1hr	Initial IV Chemo inf.	96410	96413	\$217.35	\$172.81	\$44.54	20.46%

Exhibit B

President Bush signed the Medicare Modernization Act (MMA) on December 8, 2003. This legislation made significant changes in payment for Part B prescription drugs. Under Section 303 (oncology) of the MMA, Part B drugs, which previously were reimbursed at 95 percent of Average Wholesale Price (AWP), were reimbursed at 85 percent of AWP in 2004 and then, in 2005, reimbursed at a new pricing system called "Average Sales Price" (ASP), under which reimbursement was set at ASP+6 percent. Finally, in 2006 and beyond, physicians will have a choice between providing the drugs and being reimbursed at ASP+6 percent or having these drugs provided by vendors selected in a competitive bidding process.

PricewaterhouseCoopers (PwC), at the request of the Community Oncology Alliance, estimated savings to the Medicare program from changes in Part B reimbursement rates for covered outpatient oncology drugs and oncology-related services under the MMA. Based on the most recent information from the Medicare program, we estimate the savings of \$4.1 billion for the five-year period of 2004–2008 and \$13.7 billion for the ten-year period of 2004–2013 (as shown in Table 1 below).

These estimates are considerably higher than those estimated by the Congressional Budget Office (CBO) in 2003 at the time of enactment of the MMA. CBO estimated savings from Section 303 of the MMA at \$0.9 billion for the 2004–2008 period and \$4.2 billion for the 2004–2013 period, or about one-third PwC's estimate for the same period.¹ The differences in estimates are not surprising. CBO's 2003 estimate was based on their best information at that time, which did not include any specific information on ASP. In constructing our estimate, we had access to actual ASP information for 2005–2006 from the Centers for Medicare and Medicaid Services (CMS).²

Table 1. Federal Budgetary Cost of the MMA Payment Changes to Oncology Outpatient Drugs and Biologicals (Fiscal Years 2004–2013, in \$ billions)

	2004	2005	2006	2007	2008	2004– 2008	2004– 2013
PwC's 2006 estimate	0.1	(0.5)	(1.0)	(1.3)	(1.4)	(4.1)	(13.7)
CBO's 2003 estimate	0.1	(0.1)	(0.2)	(0.3)	(0.3)	(0.9)	(4.2)

¹ Congressional Budget Office. *H.R.1 Medicare Prescription Drug, Improvement, and Modernization Act of 2003*. November 20, 2003.

² Our savings estimate does not include indirect effects on the federal outlays for the Medicare Part B premium, Medicare Advantage, and the Medicaid program. CBO did not show these off-sets separately for individual sections of the MMA but, instead, folded together all the off-sets of dozens of other programs and reported the overall offset.

Table 1. Federal Budgetary Cost of the MMA Payment Changes to Oncology Outpatient Drugs and Biologicals (Fiscal Years 2004–2013, in \$ billions)—Continued

	2004	2005	2006	2007	2008	2004— 2008	2004— 2013
Difference	(0.0)	(0.4)	(0.8)	(0.9)	(1.1)	(3.2)	(9.5)

PricewaterhouseCoopers estimate, July 10, 2006.

Methodology

In 2004, Part B oncology drugs were reimbursed at 85 percent of AWP under the MMA, compared to 95 percent of AWP in absence of the MMA. To calculate the spending after the change in drug pricing, we took the drug portion of the baseline and applied the 85 percent in place of the previous 95 percent for branded drugs. This reduced drug spending by \$0.5 billion. However, the reduction in drug payments was offset by the increase in payments to physician fee schedules under the MMA. Consequently, estimated payments in 2004 were virtually unchanged by the MMA.

In 2005, we estimated the new ASP+6 percent pricing system would reduce oncology drug payments by about 30 percent, based on new information from CMS. We applied this percentage to the baseline 2005 drug spending. This price reduction resulted in savings of \$1.8 billion in drug spending. In the meantime, physician fees spending was increased by \$0.4 billion. The combined impact of the MMA on oncology Part B spending would be gross savings of \$1.4 billion. These gross savings would result in fiscal year savings of \$0.5 billion to the Medicare program for 2005 after accounting for behavioral offsets, cost sharing, and conversion from calendar year to fiscal year.

Starting in 2006, physicians will have a choice of whether they purchase drugs and receive the ASP pricing system or have the drugs distributed by vendors selected through a competitive bidding process. We have assumed that all physicians will be reimbursed by the ASP pricing system. This is a conservative estimate of potential savings because our assumption is that Medicare would pay ASP+6 percent rather than the lower competitive amount. In 2006, the reduction in drug spending was estimated at about 35 percent, based on the first three quarters of ASP+6 percent information. Total impact of the MMA on oncology Part B spending was estimated to be gross savings of \$2.2 billion, or \$1.0 billion in fiscal year savings to the Medicare program after accounting for behavioral offsets and cost sharing.

In 2007 and thereafter, the reduction in drug spending was assumed at 32 percent, the average of that of 2005 and 2006. We have also incorporated in our estimate proposed changes by CMS in work relative value units (RVUs) and practice expense (PE) RVUs affecting payments to physician services. These revisions are proposed to be effective starting January 1, 2007. Specifically, CMS estimated that the combined impact of work and PE RVUs changes would increase oncology physician fee schedules by 3 percent in 2007 (first year of PE transition) and by 2 percent in 2010 with full PE implementation.

We estimated the total savings over the five-year period (2004–2008) to the Medicare program would be about \$4.1 billion and the ten-year period (2004–2013) would be about \$13.7 billion, as reported in Table 1.

EXHIBIT C

“On an average we are sending 25–30 patients to the hospital a month for their chemotherapy treatment and growth factor support due to an overwhelming percentage of 20% coinsurance turning into bad debt. Facilities, however, are providing a very limited number of open chairs for patients which means patients are being delayed a week or two waiting on an open chair.”

“We have only been able to send one patient to our local hospital due to the fact that they are refusing to accept Medicare, Medicaid, self pay, and managed care Medicaid patients based on the following factors: they are not set up for chemotherapy infusion; they do not have the staff needed; and last, they are not budgeted for the additional financial burden. We are still in negotiations with these hospitals and will let you know when/if we have a resolution.”

“We have a practice that is unable to take on every referral. Two years ago we stopped doing second opinions, and rarely had to turn down new patients. This year we have turned down more new patients than ever in the history of our 15 years in this town—we no longer do self-referred patients, and cannot always take on new patients referred by physicians. Thus, we do not take any HMO’s or any MediCal. Be-

cause chemotherapy is so expensive, we have stopped taking any dual eligibles. Many more patients have been hospitalized for chemo in our town than were three years ago, and that clearly is because the drugs are unaffordable, both to patients and doctors. If one of five Avastin patients fails to pay their 20%, our practice could go out of business."

We are looking toward closing one of our offices. We can no longer cover the overhead of the practice due to the inadequate payments of ASP+6%. The other reimbursement schedules are grossly inadequate. We have already cut staff. Medicare D for oncology patients is a catastrophe. Most cannot afford the co-pays on these very expensive drugs. They are priced out of effective medications such as the TK inhibitors, Revlamid, etc. **THERE IS A NEW WRINKLE!** Medicare is now not denying our claims but "PENDING" all claims for Rituxan, Aranesp, and Herceptin—thus they delay payment for three to four months. This has wiped out all of our money. We cannot purchase any more drugs! We will now be sending all patients to the hospital 10 miles away for chemotherapy. Does Medicare wish to eliminate the private practice of Medical Oncology?

"It seems that CMS excluded our specialty number 98 from yet another fix in their system. We still have not been paid from the first oversight which was the 2006 demonstration project, but to add insult to injury, a much worse problem has occurred and it seems that I cannot make any progress no matter what I do. Medicare has been pending all of our claims that include Aranesp, Procrit or Neulasta charges. They request medical records. They pend the entire claim to include any chemo drugs that may be included. We have not been paid this entire year for these drugs. I have stopped sending my claims for these services hoping to prevent this process and hold up on any additional claims."

"We did cost analyses on each chemo protocol based on each drug cost and overhead. This was done using our most common secondary reimbursements. Based on this, a list was sent to staff indicating which protocols were underwater. These are the treatments sent out. What was found was that without a secondary, in most cases with Medicare, we were underwater with some exceptions."

"We can't afford to treat patients that cannot pay their 20%. Right now 26 of 64 drugs we commonly give are underwater at 100% of Medicare. Also, the hospitals are seeing more and more patients in their outpatient units. We are in a high competition area, and a lot of the Oncologists in this area are sending patients to the hospital for treatment."

"When we treat patients without secondary coverage we put a financial burden on these patients. This is not the time to cause more stress; this is the time to allow the patient to heal. One example of financial stress is colon cancer; the treatment cost is \$8,000 every two weeks for 12 treatments. Patient responsibility is 20%, or \$1600 per treatment or \$3,200 per month. If they cannot afford secondary insurance, how can they afford \$3,200 per month for six months (\$19,200)? The clinic is to collect this amount. The clinic is not a collection agency. A pharmacist once said to me as I tried to call in a drug that cost \$1,200, why would I loan the patient a thousand dollars while the government decides to pay me? This \$19,200 is a loan that many times is paid in \$50 and \$100 installments. Maybe the government could loan the money to these patients so we can go back to assisting the patient in health care."

"We do see the Medicare only patients for OV and labs but refer them to the hospital for any treatment because most of our drugs will be in the red if we receive only 80% of the Medicare allowable. Most of our patients who only have Medicare do so because they cannot afford a secondary/supplemental—thus, cannot afford or will not pay the co-pay. We service western Kentucky which has a lot of the "working poor" who cannot even afford their employer's healthcare premiums and southern Illinois that is just poor with a very high percentage of Medicaid.

Chairman JOHNSON OF CONNECTICUT. Dr. Bailes.

STATEMENT OF JOSEPH S. BAILES, M.S., EXECUTIVE VICE PRESIDENT, AMERICAN SOCIETY OF CLINICAL ONCOLOGY, ALEXANDRIA, VIRGINIA

Dr. BAILES. Thank you. Good afternoon. I am Dr. Joseph Bailes, a medical oncologist from Houston, Texas, representing the American Society of Clinical Oncology, or ASCO. ASCO is the medical society for physicians and other health care professionals involved

in cancer treatment and research, with more than 24,000 members worldwide, a third of whom are practicing community oncologists in the United States. ASCO has for many years been concerned about imbalance in Medicare payment methodology, with emphasis on drug payment and too limited emphasis on payment for services. With the passage of MMA, Congress moved toward resolving these imbalances, but problems remain which are causing disruptions in care, and we believe that more needs to be done.

ASCO believes that the average sales price, or ASP, system has the potential to reflect appropriately the cost of acquiring drugs. As currently structured, however, the system does not ensure that all physicians can purchase chemotherapy drugs without suffering financial loss that would threaten the access of patients to some therapies. Although last year's inspector general report characterized reimbursement as generally adequate, the report shows that for about half of the drugs reviewed, at least 20 percent of physicians incurred out-of-pocket loss to obtain the drugs. ASCO believes that this shortfall in Medicare payments will create access problems; therefore, ASCO supports creating a floor for Medicare payments to ensure that it is not lower than the widely available market price.

In addition, ASCO supports excluding prompt pay discounts to wholesalers and distributors from the calculation of ASP. Including prompt pay discounts received by wholesalers and distributors distorts the calculation, and it contributes to situations in which individual physicians are unable to obtain some chemotherapy drugs at or below the Medicare payment rate. It is for these reasons that ASCO strongly supports H.R. 5179, introduced by Representative Ralph Hall, as a means of bringing Medicare payments into better alignment with market prices and thus avoiding access challenges for patients.

To be complete, reimbursement reform must address not only overpayment for drugs, but also underpayment for physician services. While MMA made some adjustments to payment for services, we believe that further changes are required to recognize services not currently reimbursed by Medicare. ASCO supports the establishment of a new Medicare service for comprehensive care planning and coordination at the time of diagnosis, at the end of active treatment, or when there is a change in the cancer survivor's condition or care. Such a service is supported by a series of recommendations by the Institute of Medicine. H.R. 5465, introduced by Representatives Davis and Capps, proposes such a service and ASCO is supporting that bill as well.

ASCO continues to be concerned about the CMS methodology for determining practice expense relative values. Both the GAO and the Lewin Group, a CMS contractor, have issued reports concluding that the CMS methodology of allocating practice expense relative values for indirect costs is biased against services that do not involve physician work. We are also concerned by the proposal published by CMS on June 29, 2006, in which CMS would disregard certain survey data in determining practice expense relative values. We urge the Committee to review carefully the CMS proposal and offer guidance to the agency regarding alternative approaches that will sustain necessary cancer care services.

The oncology demonstration projects administered by CMS in 2005 and 2006 provide additional resources for oncology practices, but are also yielding data contributing to quality improvement efforts, including CMS's development of future pay-for-performance programs in cancer care. It has been suggested by cancer experts and third-party payers that the current demonstration project will have value only if it provides sufficient longitudinal data to enable meaningful analysis and direction for future quality improvement efforts. We urge the Committee to support a multiyear extension of the demonstration project to enable collection of enough data to guide quality enhancement initiatives.

Patient coinsurance, as you have heard, is an issue for Part B drugs. ASCO agrees with MedPAC that the coinsurance problem needs to be addressed. The 20 percent coinsurance requirement is frequently an unreasonable burden on cancer patients who are treated with state-of-the-art medicines. Congress should resolve this issue by eliminating, or at least significantly reducing, the patient burden of coinsurance for Part B drugs. We appreciate the interest of the Committee in scheduling the hearing, and we anticipate working with you to continue improvements in reimbursement and quality of care for the benefit of our patients and enhanced efficiency of the Medicare Program. Thank you, Madam Chairman.

[The prepared statement of Dr. Bailes follows:]

Statement of Joseph S. Bailes, M.D., Executive Vice President, American Society of Clinical Oncology, Alexandria, Virginia

Good afternoon, I am Dr. Joseph Bailes, Interim Executive Vice President and CEO of the American Society of Clinical Oncology, or ASCO, and a medical oncologist from Houston, Texas. I am pleased to be here on behalf of ASCO to address issues related to Medicare payment for Part B drugs and related services.

ASCO is the medical society for physicians and other health care providers involved in cancer treatment and research. With more than 24,000 members worldwide—and a third of those members in private practice in the United States—ASCO is the leading voice of oncology professionals on matters of quality cancer care and access.

The issues under consideration today are familiar to ASCO. We have been engaged in the debate over reform of reimbursement for cancer therapy for at least 15 years, since around the time that ASCO first established a Washington office. We have long been concerned about imbalances in payment methodology, with too much emphasis on drug payment and too little on payment for services.

With the passage of the Medicare Modernization Act of 2003, or MMA, Congress attempted to resolve those imbalances. However, with a change of this magnitude it is not surprising that there are some problems. This hearing provides an opportunity to air some of the continuing concerns under MMA so that we can work together to assure both quality cancer care for our patients and responsible reimbursement policy for the federal Medicare program. We are here to share with you our thoughts about how to achieve both.

Payment for Drugs

We appreciate that the “average wholesale price,” or AWP, system was an unbalanced method of compensating oncologists for cancer care under Medicare. As currently structured, however, the system of “average sales price,” or ASP, does not ensure that all physicians can purchase chemotherapy drugs without suffering financial loss that threatens the access of patients to some therapies.

In September 2005, the HHS Office of Inspector General (“OIG”) issued a report finding that reimbursement for drugs under the ASP system was “generally adequate.” The report found that, for 35 of the 39 drug codes analyzed, the *average* amount paid for drugs was less than the Medicare reimbursement amount. For 4 of the 39 drugs, the average amount paid for drugs exceeded the reimbursement amount.

The OIG’s conclusion that reimbursement was “generally adequate” and its analysis based on average drug costs to physicians do not appropriately consider the

many situations faced by particular physicians in which the Medicare payment amount does not cover the cost of the drugs. Although the OIG's conclusions did not highlight this problem, the report shows that for 17 of the 39 drugs reviewed, at least 20 percent of physicians incurred an out-of-pocket loss. Only 3 of the 39 drugs could be obtained by all physicians at the Medicare payment amount or less. The OIG's conclusion fails to acknowledge that out-of-pocket losses are incurred by physicians in many circumstances, a situation that threatens access to care for some cancer patients. In some of those circumstances, practices are referring patients to hospital outpatient departments. We have received reports from ASCO members that, in some instances hospitals are not accepting those patients. This is a particular challenge to patients without secondary insurance.

To avoid the potential access problems created by this shortfall in Medicare payment, ASCO supports legislation that would ensure that the Medicare reimbursement amount is sufficient to cover what physicians have to pay to obtain drugs. Legislation introduced by Representative Ralph Hall, H.R. 5179, would create a floor for Medicare payment to ensure that it is not lower than the "widely available market price." The Medicare statute is currently asymmetrical in that it allows the Centers for Medicare & Medicaid Services ("CMS") to lower the payment rate when it exceeds the widely available market price but does not permit raising the payment rate when it is less than the widely available market price. This inconsistency should be rectified immediately.

The statute defines the widely available market price as "the price that a prudent physician or supplier would pay." We believe that a physician who shops among the distributors of oncology drugs for the lowest price is a prudent buyer. If that physician cannot obtain a drug for the Medicare payment amount through that process, Medicare needs to revise the payment amount.

H.R. 5179 would also exclude prompt pay discounts to wholesalers and distributors from the calculation of ASP. This change is analogous to the change in the definition of "average manufacturer price" that was enacted by section 6001(a)(2) of the Deficit Reduction Act of 2005 ("DRA"). Under the DRA, average manufacturer price will be used beginning in 2007 to set the upper payment limit for reimbursement to pharmacies for drugs reimbursed by Medicaid.

The DRA, however, excluded prompt pay discounts extended to wholesalers from the calculation of average manufacturer price of this purpose, presumably because pharmacies do not receive those discounts. The same principle should apply under Medicare Part B. Including prompt pay discounts received by wholesalers and distributors distorts the calculation and contributes to situations in which individual physicians are unable to obtain some chemotherapy drugs at or below the Medicare payment rate.

We strongly support H.R. 5179 as a means of bringing Medicare payment into better alignment with market prices and thus avoiding access challenges for patients.

Payment for Related Services

The MMA made some adjustments to payment for services but they were not sufficient to cover the cost of providing the full range of services required for comprehensive cancer care. Further legislative changes beyond those in MMA are required to recognize services not currently reimbursed by Medicare. In addition, CMS must revise the manner in which it is calculating the practice expenses associated with particular services.

Payment for Coordination of Cancer Care

One very important payment reform is embodied in legislation introduced by Representatives Lois Capps and Tom Davis. Inspired by a series of recommendations from the Institute of Medicine ("IOM"), H.R. 5465 would establish a new Medicare service for comprehensive cancer care planning and coordination at the time of diagnosis, at the end of active treatment, or when there is a change in the cancer survivor's condition or care.

The care planning service was recommended by the original IOM cancer care quality report in 1999, and the most recent report on adult survivorship issues in 2005 underscored the importance of coordination of care as the survivor moves from active treatment to a period of monitoring side-effects of treatment and possible second cancers. By paying oncologists for comprehensive care planning, the quality of cancer care will be enhanced, patient satisfaction will be boosted, and cancer care resources will be more efficiently utilized.

Practice Expense Relative Value Methodology

ASCO continues to be concerned about the CMS methodology for determining practice expense relative values consistently with MMA. A CMS contractor, the Lewin Group, and the Government Accountability Office have both issued reports

concluding that the CMS methodology of allocating practice expense relative values for “indirect” costs is biased against services that do not involve physician work. We believe that drug administration services, which are considered to involve little or no physician work, are adversely affected by the current methodology. CMS, however, has not revised its method of calculating practice expense relative values to remedy this bias.

Our concern about the calculation of practice expense relative values has been heightened by the proposal published by CMS on June 29, 2006. The MMA required CMS to use the supplemental survey of oncologists’ expenses sponsored by ASCO to determine practice expense relative values. However, under CMS’s proposal, surveys would no longer be used to determine the practice expense relative values attributed to the “direct” costs of clinical staff, supplies, and significant equipment. In addition, CMS is proposing to change the method of determining the practice expense relative values attributable to the “indirect” costs of administrative staff and overhead. We do not believe that CMS has discretion to discount or disregard this survey data in determining practice expense relative values for drug administration services performed by oncologists.

ASCO has just begun its analysis of CMS’s proposed changes, but we are concerned about proposed decreases in payments for many drug administration services. For example, the practice expense relative value units assigned to the key service of a chemotherapy infusion (first hour) would decline by 13 percent. It is important that the CMS methodology result in appropriate payment amounts for drug administration services that are adequate to support the services and consistent with the intent of Congress in MMA. We urge this Committee to review carefully the CMS proposal and offer guidance to the agency regarding alternative approaches that will sustain necessary cancer care services.

Demonstration Projects and Quality Cancer Care

The oncology demonstration projects administered by CMS in 2005 and 2006 have provided additional resources to permit oncology practices to provide high quality cancer care. In addition, these projects have yielded useful data for assessing the quality of cancer care and contributing to quality improvement efforts. The current demonstration project assesses compliance with cancer guidelines, an initiative that holds promise not only for enhancing cancer care quality this year but also in guiding the development of future “pay-for-performance” in cancer care.

ASCO is collaborating with CMS, other government agencies, patient advocates, and third-party payers in the Cancer Quality Alliance, a voluntary alliance that addresses issues of quality care in oncology. In this setting, it has been suggested by experts that the demonstration project will have value only if it provides sufficient longitudinal data to enable meaningful analysis and direction for future quality improvement efforts. We would urge the Committee’s support for a multi-year extension of the demonstration project to enable collection of enough data to support well-informed quality enhancement initiatives.

Competitive Acquisition Program

The MMA also enacted a Competitive Acquisition Program (“CAP”) under which physicians can obtain drugs from a Medicare contractor for specific patients, and the contractor is responsible for billing the Medicare program and the patient. One purpose of the CAP was to meet the needs of individual physician practices that, for whatever reason, find themselves unable to purchase drugs through traditional channels at acceptable prices. We believe there may be a legitimate role for the CAP, but as currently configured, there are still significant issues that need to be addressed with the program.

A primary concern is the fact that the rules permit CAP vendors to terminate access to drugs for patients who fail to pay their coinsurance within 45 days. This provision is an unexpected and unwelcome burden for cancer patients. Oncologists in practice frequently face the necessity to deal with unpaid coinsurance, sometimes absorbing the loss, sometimes extending payment terms, and sometimes referring patients to charitable organizations. All these options are open to CAP vendors, and they should not be absolved from those options any more than oncologists. Arguably, one of the reasons oncologists may avoid CAP is the potential harm to their patients from this provision, which should be revisited without delay.

Another potentially inhibiting factor for oncologists is the failure of CAP to reimburse practices for the administrative costs associated with the program. Our members tell us that there would be a significant new administrative burden in dealing with the CAP contractor. Since there would be no additional reimbursement to cover these costs, that factor may be discouraging for practices as they decide whether to enroll in the program.

Other issues of concern include the rule that a physician may not transport CAP drugs from one practice location to another. This rule can interfere with the operation of practices with multiple offices. Also, the CAP rules establish a vague negotiation process for the physician and the CAP vendor to work out the disposition of unused drug. It would probably encourage enrollment in the CAP if this process were clearer.

Patient Coinsurance

Patient coinsurance is an issue not just in CAP but also in Part B generally. Cancer drugs can be very expensive, and the 20 percent coinsurance can amount to many thousands of dollars for a course of treatment. Patients who lack secondary or supplemental insurance are often hard pressed to pay the coinsurance involved.

In a report issued by the Medicare Payment Advisory Commission ("MedPAC") in January 2006, however, MedPAC noted that patients who are unable to cover their coinsurance are increasingly being referred to hospitals. Medicare pays 70 percent of the bad debt incurred by hospitals. MedPAC also stated that it plans to study long-term solutions to this problem.

ASCO agrees with MedPAC that this problem needs to be addressed. Although the 20 percent coinsurance requirement is appropriate for many types of services covered by Medicare, it is frequently an unreasonable burden on cancer patients who are treated with state-of-the-art medicines. Congress should resolve this issue by eliminating, or at least significantly reducing, the patient burden of coinsurance for Part B drugs.

* * * * *

As the issues raised in this hearing amply reflect, Medicare reimbursement for cancer care is as complex and challenging as ever. ASCO has provided its members a wide range of tools and services to help them adjust to this rapidly changing environment. Among these are the Quality Practice Oncology Initiative, practice management workshops, practice guidelines, and a hotline for Medicare policy questions. We are happy to share information about these and other similar efforts at a later time.

There remain many potential pitfalls before we achieve a reimbursement system that ensures comprehensive quality cancer care. We appreciate the Committee's interest in scheduling this hearing and are committed to working with you to continue improvements in reimbursement and quality of care for the benefit of our patients.

Chairman JOHNSON OF CONNECTICUT. Thank you. Ms. Boyle.

STATEMENT OF MARCIA BOYLE, PRESIDENT, IMMUNE DEFICIENCY FOUNDATION, TOWSON, MARYLAND

Ms. BOYLE. Chairwoman Johnson, Ranking Member Stark and Members of the Subcommittee, thank you for inviting me today to testify on behalf of patients who depend on intravenous immunoglobulin, or IVIG, for their very lives. I would like to especially thank Congressman McCrery for his long-time support of our patient community. As president of the Immune Deficiency Foundation, I represent approximately 50,000 patients across America who need IVIG as their only lifesaving therapy. However, today, I am speaking on behalf of all patients who need IVIG.

My son John is one of those patients. He was born without the ability to produce antibodies. Fortunately, he receives IVIG, a plasma-derived therapy, every 3 weeks to replace this essential component of his immune system. How good is this treatment? At 28 years old, with regular infusions of IVIG, he is married, has a demanding career and is a healthy and productive member of society. Meeting him and others like him, you would never know there was a problem. Without this therapy, he would probably not be alive or he would be severely disabled. IVIG prevents infections in the im-

mune-compromised, and there is no alternative therapy. The thought of his not having access to IVIG is a nightmare. Unfortunately, patients have been living this nightmare and are in despair. When the new ASP formula went into effect on January 1, 2005, my office started hearing from several thousand Medicare patients and physicians who could no longer receive or administer IVIG because physicians could not afford to continue treating at the reduced Medicare rates.

During 2005, many of the Medicare patients were shifted to hospitals, away from their physicians, their trained nurses and their usual brand of IVIG, and many suffered serious reactions to different brands. Some were hospitalized and many had increased infections. When you think about it, the worst place for an immune-compromised outpatient is in the hospital exposed to infections. In fact, I believe it is the most expensive site of therapy. Patients who were not successfully transferred to hospitals were denied access to IVIG altogether, particularly those without Medigap or secondary insurance. We don't even know what has become of many of these patients. Those that we do know of have been seriously ill.

Working with other concerned groups last year, we advocated for access in all sites of care and begged Congress and CMS to not reduce the reimbursement rates for the hospitals to the levels of the physician outpatient setting because that would remove the last site of care. However, on January 1, 2006, hospitals were also switched from the AWP to the ASP formula. Although we hoped our predictions would not be true, many hospital outpatient clinics have stopped treating with IVIG because it is too costly to continue treating. Patients in some States have been particularly devastated, particularly those in Texas, Nebraska and Florida, where few hospitals remain that treat with IVIG. The impact of Medicare reimbursement doesn't stop with Medicare patients. In recent months, we have heard of more private insurance carriers reducing their rates to those of Medicare, now endangering the lives of children. While the medical details are different, the medical outcome is the same as taking chemotherapy away from a cancer patient or insulin away from a diabetic.

The HHS Blood Safety Advisory Committee in May of 2005 recommended that the Secretary declare a public health emergency to restore access to IVIG. He did not. Sadly, Pam Way, one of the patients who testified about losing access to IVIG and literally begged for her life, has died as a result of this situation. In September of 2005, the advisory Committee once again recommended that the Secretary declare a public health emergency. In response to the two recommendations, 28 Members of Congress sent a letter to Secretary Leavitt requesting that he declare a public health emergency. Once again, IVIG access was not restored.

A few weeks ago, 58 Members of Congress sent a letter to Secretary Leavitt requesting that he declare a public health emergency. I thank Congressmen McCrery and Foley for their leadership in this effort, as well as the Members of the Subcommittee who signed onto this letter. It is truly a national disgrace that this problem has persisted for more than a year and a half and government has done nothing to restore access to our patients. Members of this Committee, how many more patients have to suffer, how

many more patients have to die, for the government to recognize this public health emergency? I implore the Committee to take emergency action today to restore access to IVIG in all sites of care. Please end the nightmare that has devastated our community. Once again, thank you for including the problem of IVIG in today's hearing.

[The prepared statement of Ms. Boyle follows:]

**Statement of Marcia Boyle, President, Immune Deficiency Foundation,
Towson, Maryland**

Chairwoman Johnson and Members of the Subcommittee, thank you for inviting me to testify on behalf of patients who need Intravenous Immunoglobulin replacement in order to stay alive. I would like to specially thank Congressman McCrery for his long-time support in helping to improve the lives of patients with primary immune deficiency diseases. Please know that although I represent the primary immune deficiency community, today I am speaking on behalf of all patients who require IVIG as their lifesaving therapy.

As president of the Immune Deficiency Foundation, I represent more than 50,000 patients across America who need IVIG as their only lifesaving therapy. My son is one of these patients. Like other PID patients, he was born without the ability to produce antibodies. He receives IVIG every three weeks to replace this essential component of his immune system. How good is the treatment? At 28 years old, with regular infusions of IVIG, he is married, has a demanding career, and is a healthy and productive member of society. Without this plasma-derived therapy, he would not be alive, or would be kept alive through antibiotics fighting infection after infection, and be severely disabled with a poor quality of life. IVIG prevents infections in the immune-compromised. There is no alternative therapy. The thought of his not having access to IVIG would be an unacceptable nightmare.

Unfortunately, many patients have been living this nightmare. Since January 2005, IDF has received thousands of calls, emails and letters from Medicare patients and physicians, who have not been able to receive their IVIG infusions at their physicians' offices, outpatient infusion suites, home care settings and hospitals. About 20% of our patients are on Medicare. During 2005, many of the Medicare patients were shifted to hospitals where many were admitted for 23 hours and most were not receiving the most appropriate brand of IVIG, but rather, the brand the hospital had accessible. Patients who had not been successfully transferred to hospitals, especially those who did not have Medigap or secondary health insurance policies, were denied access to IVIG altogether. Here is a quote from a physician in New York the sums up the flavor of our calls in 2005: "I cancelled all of my Medicare patients. The price of IVIG has increased and I can no longer sustain the loss. I do not know what to do and I am in total despair."

We received a call from a patient in Missouri, typical of many others, who said: "I am an 81 year old Medicare PID patient—I am sick all the time, and am not sure if I will be able to live long enough to get my next infusion. I had an infusion scheduled at the hospital. As I was leaving for the hospital, they called to cancel my appointment. They told me that they will not be able to infuse me. Can you help me?"

It does not make sense to move a primary immune deficient patient out of a closely monitored infusion suite, physician's office, or home care environment—with nurses who are trained in the administration of IVIG—to a hospital where an immune-compromised patient can be exposed to an opportunistic infection. I cannot believe it was any policymaker's intention to shift all patients to hospitals, which is, in fact, the most expensive site of care.

IDF and other groups spent a great deal of time communicating to Congress and CMS the devastating impact of Medicare Reimbursement reductions on our community. IDF conducted a national survey of Medicare patients, which provided quantitative data on the impact of the reimbursement changes. 39% of these patients had problems because of reimbursement, and 40% of these patients suffered negative health outcomes as a result of reimbursement.

We begged that the reimbursement rates for the hospitals not be reduced as dramatically as they had for the physician outpatient setting.

However, on January 1, 2006, hospitals were also switched from the AWP to the ASP formula. Even faster than expected, many outpatient hospital clinics eliminated IVIG infusions to patients because it was too costly to continue treating at the current reimbursement rates. CMS did implement a temporary preadministration fee for the physician's office and hospital, but it was not enough to offset the

reduction in reimbursement from the ASP formula and the reduced administration fees.

Patients in some states have been devastated. For example, the state of Nebraska has only one hospital treating on an outpatient basis with IVIG; the state of Florida has a handful of hospitals left, and in the state of Texas, most Medicare patients in Dallas, Houston and Irving cannot receive IVIG in a hospital. We have reports of patients not receiving IVIG since last November. Without IVIG they will eventually become disabled and die prematurely.

The impact of Medicare reimbursement does not stop with Medicare patients. During the past year, we have heard of more private insurance carriers reducing their reimbursement rates to those of Medicare—with even children being denied therapy! Our patient community has always dealt with an unusual burden of insurance problems because of the nature of their chronic illness and the cost of the expensive therapies—but the recent changes are unnecessarily devastating.

While the medical details are different, the medical outcome is the same as taking chemotherapy away from a cancer patient or insulin away from a diabetic. IVIG has been taken away from patients who will die without it. Are these patients not important to our society?

I am going to share a story of a patient who was personally affected by the changes to reimbursement after being denied access to IVIG. Her name is Pam Way. I met Pam at the Department of Health and Human Services Advisory Committee on Blood Safety and Availability meeting last May 2005. Pam had Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and Myositis, disorders for which IVIG is recognized as medically indicated. When Pam was treated with IVIG, she was walking and fairly healthy. But when the Medicare Modernization bill was enacted, she was shifted from her doctor's office to the hospital. At the hospital, she was unable to get the brand of IVIG that she required. In addition, she could not receive her infusions on a regular basis.

Patients with immune problems require brand-specific IVIG, because each product is different. Patients treated with brands their bodies don't tolerate can suffer life-threatening anaphylactic reactions. I once saw my son collapse after receiving a new product. Product choice for IVIG is critical for patients.

Congress understood this and exempted IVIG from the competitive acquisition program. Although it was Congress' intent to ensure that patients have access to all brands of IVIG, the opposite has occurred, because the reimbursement rate for IVIG is too low.

Due to the changes in reimbursement, Pam stopped receiving her IVIG infusions on a regular basis and her health deteriorated to the point that she was becoming nonfunctioning. Eventually, it took all the strength she had, when she appeared in a wheelchair to speak before the Advisory Committee in May of 2005. She literally begged for her life. The Committee recommended that the Secretary declare a public health emergency. Pam was one of thousands of patients across the country that was too sick to fight for themselves, but she tried.

Although the Committee tried to help, Secretary Leavitt did not take action. Last year, a letter signed by 28 Members of Congress was sent to Secretary Leavitt requesting that he declare a public health emergency. Once again, nothing happened. A few weeks ago, 58 Members of Congress sent a letter to Secretary Leavitt requesting that he declare a public health emergency. I would like to thank Congressman McCrery and Foley for their leadership on this effort, as well as the Members of this Subcommittee who signed on to this letter, which include: Congressman Camp, Congressman Ramstad, Congressman English and Congressman Hayworth.

In the meantime, the public health emergency has not been declared, reimbursement remains inadequate and Pam never got the continuity of treatment she needed. Pam was only able to receive IVIG when she was admitted to the intensive care unit and it was too late. Pam died in April of this year. And we will have more deaths while the government continues to study the problems of the marketplace and supply.

When will someone say that the lives of these patients are important? We continue to share stories of patients suffering, but no one takes action to restore access to IVIG.

Even with the newest reimbursement rate increases effective July 1, only one immune globulin brand will become affordable and available to some patients.

It is a national disgrace that this problem has persisted since January 2005, and nothing has been done to help save these patients lives. The long-term effects to patients who were already on disability or elderly are immeasurable.

Chairwoman Johnson, how many more patients have to suffer, how many more patients have to die to acknowledge the public health emergency that has been allowed to continue since January 2005?

I implore of the Subcommittee today, to take emergency action to restore access to IVIG.

Once again, thank you for including the IVIG patient community in today's hearing.

Chairman JOHNSON OF CONNECTICUT. Thank you, Ms. Boyle. Mr. Friedman.

**STATEMENT OF RICHARD FRIEDMAN, EXECUTIVE CHAIRMAN,
BIOSCRIP, ELMSFORD, NEW YORK**

Ms. FRIEDMAN. Chairman Johnson, Representative Stark and distinguished Members of the Subcommittee, I am Richard Friedman, Chairman and CEO of BioScrip. Thank you for the opportunity to testify today on the Medicare part B Competitive Acquisition Program. As the sole vendor for this program, we believe that BioScrip's testimony will provide the Subcommittee with insight into the CAP program.

My testimony today will focus on CAP implementation and structural barriers to physician election and proposed solutions. BioScrip provides pharmaceutical care solutions with a primary focus on specialty medication distribution and clinical management services. Our specialty medication distribution services include condition-specific clinical management programs to improve the care of individuals with complex health conditions such as HIV/AIDS, cancer, Hep-C, rheumatoid arthritis, hemophilia, MS, transplantation or conditions requiring immunosuppressive medications.

Through our National mail order facility and 31 community pharmacies in 26 U.S. cities, BioScrip provides local specialty pharmacy and infusion support to patients and prescribers. We partner with healthcare payers, pharmaceutical manufacturers, government agencies and physicians to manage patient outcomes and control costs. Since the CAP began, BioScrip has shipped 354 drug orders to 41 physicians throughout the United States. We have made a significant initial investment in new infrastructure and physician education initiatives and have been closely working with CMS. We have created a list of drug assistance programs and foundations to support Medicare beneficiaries who cannot afford the 20 percent co-payment.

Since being announced as a sole CAP vendor, BioScrip has been working hard to make sure the transition is smooth for both physicians and beneficiaries. The July 1, 2006, operational startup was successful. However, there are several structural challenges that we believe is part of the reason for which physicians have not enrolled. In March 2006, BioScrip, along with other vendors, were offered the CAP contract. BioScrip believed, based on our expertise in management and distribution of specialty medications, the CAP program was a good fit. BioScrip was already involved in similar programs in the private sector.

BioScrip's bid was less than ASP plus 6 percent and a final rate of ASP plus 4.4 percent was offered to BioScrip by CMS based upon the competitive pricing process. To prepare for the CAP implementation, BioScrip made significant investments. We retained 90 new dedicated people in operations to support an estimated 2,000 physi-

cian practices. We recovered accrument fees for these hires. We utilized 55 sales professionals to educate physicians across the United States. We developed educational support, including print and media, and we invested in facility upgrades.

We believe that many physicians still have unanswered questions regarding the benefits of the CAP. Educational outreach needs to continue by CMS, Noridian and BioScrip. BioScrip has made physician education and outreach a priority in its implementation strategy. To date, we have contacted 265 national, regional and State associations and related organizations and 19,182 physicians. We have faxed 34,000 physician practices and e-mailed 25,000 physicians. We met with 45 pharmaceutical manufacturers, either in person or by phone, and established a toll-free BioScrip CAP information specialist call center. We developed a dedicated CAP page on BioScrip's Web site. We hosted two audio conferences to present a program to 400 physicians and we continue to provide ongoing physician support for election and operational issues.

Chairman JOHNSON OF CONNECTICUT. Mr. Friedman, I neglected to say your entire statement will be submitted for the record, but the opening statements are 5 minutes. If you could kind of move more rapidly through your last couple of pages.

Ms. FRIEDMAN. Sure. To go through what we believe are the barriers and the solutions for them, first is a lack of on-site inventory. The physician orders for CAP drugs are patient-specific and have to be made in advance. Physicians complain that this system allows for limited flexibility to adjust treatment to shifting disease states or accommodate unanticipated therapeutic needs. Our solution is to supply physicians' offices with limited inventory to meet emergency therapy changes.

The second barrier is the requirement to ship to the site of drug administration. Our solution is to permit shipments to multiple locations designated by the physician.

The third barrier is the added billing requirements for the physician. Our solution is to simplify the physician billing practice. Physicians would bill for the administrative fee only and not have to change their billing systems, and we could monitor that program.

The fourth barrier is the physician concern over co-pay. Our solution is to give physicians the option to support the copay for non-paying beneficiaries on a patient-specific basis.

Finally, the last barrier is physician education as to the benefit of the CAP program within the limited election period. Our solution is to continue the education and allow for an open enrollment period for physicians.

In closing, BioScrip would like to once again thank the Subcommittee for this opportunity to testify. We have made a significant financial investment to ensure the success of this program. Based upon the small number of physicians that have initially enrolled, we will not recognize a return on our investment. We firmly believe that CAP can be a successful long-term program, as proven in the private sector. I believe that in coordination with CMS and Congress, we can make this a reality. Thank you for your time.

[The prepared statement of Mr. Friedman follows:]

**Statement of Richard Friedman, Executive Chairman, Bioscrip,
Elmsford, New York**

I. INTRODUCTION

Chairman Johnson, Representative Stark, distinguished members of the Subcommittee, I am Richard Friedman, CEO of BioScrip, Inc. and my esteemed colleague to my right is Russ Corvese, BioScrip's Senior Vice President of Operations. We would like to thank you for the opportunity to testify today on the Medicare Part B Competitive Acquisition Program (CAP). As the sole vendor for this program that was launched just 13 days ago, BioScrip's testimony will provide the subcommittee with insight into the CAP program and some of our early successes and challenges.

My testimony today will focus on four topics:

- Benefits of the CAP for Medicare beneficiaries and physicians
- CAP implementation dates and entities involved
- CAP structural barriers to physician election and solutions to improve the CAP
- Financial implications to the vendor

BioScrip, Inc. provides pharmaceutical care solutions with a primary focus on specialty medication distribution and clinical management services, and pharmacy benefit management services. Its specialty medication distribution services include condition-specific clinical management programs to improve the care of individuals with complex health conditions, such as HIV/AIDS, cancer, hepatitis C, rheumatoid arthritis, hemophilia, multiple sclerosis, and transplantation, or conditions requiring immunosuppressive medications. Through 31 community pharmacies in 26 U.S. cities, BioScrip provides local specialty pharmacy and infusion support to patients and prescribers. It partners with healthcare payors, pharmaceutical manufacturers, government agencies, and physicians to manage and control costs.

We appreciate this opportunity to testify on the Medicare Part B CAP and its role in providing savings for the Medicare program and beneficiaries, while maintaining access and easing the burden on physicians. We applaud Congress for authorizing this important new program as part of the Medicare Modernization Act of 2003 (MMA). In less than two weeks since the CAP began, BioScrip has already shipped 113 drug orders to 26 physicians. We made a significant initial investment in new infrastructure and physician education initiatives and have been closely working with the Centers for Medicare and Medicaid Services (CMS) and the designated CAP carrier, Noridian, to resolve any technical issues that impact the CAP. We have created a list of drug assistance programs and foundations to support Medicare beneficiaries who cannot afford the 20% co-payment. Since announced as the sole CAP vendor, BioScrip has been working hard to make sure the transition is smooth for both physicians and beneficiaries. We believe that the July 1, 2006 operational start up was successful; however, there are several structural challenges that will need to be addressed before developing the CAP into a real alternative to the "buy and bill" system, as provided by the statute.

II. BENEFITS OF THE CAP

The MMA established a new methodology for Medicare Part B reimbursement of most covered drugs. Effective January 1, 2005, reimbursement to physician practices for drugs was changed from 95% of the average wholesale price (AWP) to 106 percent of the average sales price (ASP). The MMA also mandated the implementation in 2006 of a competitive acquisition program (CAP) for part B drugs and biologicals, as a second step in reducing Medicare overpayments. The program would represent an alternative to the "buy and bill" system for acquisition of drugs administered in physician offices. More specifically, the CAP has the potential to:

- Eliminate manufacturer incentives that increase the spread between Medicare payments and the physician purchase price
- Eliminate overspending Medicare's limited resources
- Reduce costs for Medicare beneficiaries who are responsible for a 20% copayment of the total cost
- Reduce time and resources utilized by physician practices for drug acquisition
- Reduce physicians' administrative costs and financial liability by moving the responsibility to collect beneficiary deductibles and coinsurance from the physician practice to the CAP vendor

III. CAP IMPLEMENTATION

CMS published the CAP proposed rule in March 2005, followed by the interim final rule on July 6, 2006. The initial vendor bidding process was cancelled before the scheduled deadline (August 5, 2005) and the program start was delayed. On November 21, 2005 CMS published some final CAP provisions as part of the final rule

on the 2006 physician fee schedule. The CAP vendor bidding process closed on December 22, 2005. In late March 2006, CMS offered CAP contracts to five vendors. On April 21, 2006, CMS officially announced BioScrip as the sole CAP vendor. The initial physician election period was scheduled for May 8—June 2, 2006 and subsequently extended through June 30, 2006. BioScrip started shipping CAP orders on June 28, 2006, for a July 1, 2006 program start date.

The CAP reimbursement rate of 104.4% of average sales price (ASP) was driven by competition among the five bidders who were offered CAP contracts. However, BioScrip, the only CAP vendor, bore the entire burden of program implementation and the lion share of physician education and outreach.

Based upon estimates of 2,000 physicians electing to participate in the CAP, we made a significant initial investment in new infrastructure and physician education initiatives and have been closely working with CMS and Noridian to resolve technical and operational issues. BioScrip has created a list of drug assistance programs and foundations to support Medicare beneficiaries who cannot afford the Medicare part B cost-sharing (deductible and 20% co-payment). Since announced as the sole CAP vendor, BioScrip has been working hard to make sure the transition is smooth and does not affect beneficiaries' access to prescription drugs.

To prepare for the CAP, BioScrip has invested significantly in infrastructure and human resources:

- Retained up to 90 dedicated people in operations to support an estimated 2,000 physician practices
- Incurred recruitment fee for 90 individuals
- Invested in technology
- Initiated sales initiatives across the U.S. utilizing 55 sales professionals
- Developed marketing support including print and media
- Invested in facility upgrades (Columbus facility solely for the CAP)
- Expended executive time and travel to organize and promote CAP

BioScrip understands that, given the short time frame allowed for physician CAP election, it is essential that physicians are properly educated and informed about the program before they decide if the program addresses their needs. The initial physician election period was restricted to 26 days, and then extended through the month of June, 2006. BioScrip believes that many physicians and practices still have unanswered questions regarding the benefits of the CAP. Despite the regulatory mandate, the Medicare part B local carriers have been involved in minimal CAP educational activities. The outreach efforts of CMS and Noridian, we believe, need to significantly continue. BioScrip has made physician education and outreach a priority of its implementation strategy.

Physician education activities have been a priority for BioScrip and included:

- Outreached and/or presented to 265 national, regional, state associations, professional societies and related organizations
- Outreached to 19,182 physicians via phone and/or in-person meetings
- Faxed 34,000 physician practices
- E-mailed 25,000 physicians
- Met with 45 pharmaceutical manufacturers either in person or by phone
- Received over 2,000 Web Hits to BioScrip CAP web page
- Established toll-free BioScrip CAP Information Specialist Call Center
- Developed technical language on dedicated page on BioScrip's web site
- Trained entire sales force/representatives regarding CAP and the benefits to physicians
- Created multiple educational materials utilized in initial CAP launch and physician outreach education
- Purchased physician list of approximately 40,000 names
- Provided ongoing physician support for election and operational issues
- Hosted two audio conferences to present the program to 400 physicians, to educate on the operational process and answer practice questions

Based on the actual physician election numbers received from CMS and Noridian, the physician participation levels came significantly below the expected program target of 1,500 to 2,000 physicians. BioScrip prepared for 2,000 physicians submitting orders on July 1, 2006. To date, we have a total of 307 CAP physicians, with 664 practice locations. A breakdown of election numbers by specialty is provided in Appendix B. Physician specialties with the highest Medicare part B allowed charges—see Appendix B—are the least represented among this group. Physicians

who joined the CAP repeatedly specified that they wanted to leave the “buy and bill” system and are happy with the reduced administrative burden.

IV. CAP STRUCTURAL BARRIERS

BioScrip appreciates that physician CAP election is essential to make CAP a viable alternative to the current “buy and bill” system, achieve savings for the Medicare program and beneficiaries. From discussions with physicians who would consider CAP but have not yet elected to participate, BioScrip has found that there are still structural barriers that affect physicians’ decision to sign up for the CAP. Among the most frequently cited barriers are:

A) Lack of On-Site Inventory

Unlike the “buy and bill” system, physician orders for CAP drugs are patient-specific and have to be made in advance. Many physicians complain that this system allows for limited flexibility to adjust treatment to shifting disease states or accommodate unanticipated therapeutic needs.

SOLUTION: Supply physicians’ offices with limited inventory to meet emergency/therapy changes

Having an adequate drug inventory stocked in physician offices will provide needed flexibility and increase beneficiary access to the drugs. BioScrip is already using “loaned inventory” practices for its commercial side of the business, and could logistically accommodate this request. Drug orders will still be submitted for each patient, but the physician will use existing CAP drug stock for administration. BioScrip will follow-up and replace the drugs used.

However, from a cash-flow perspective, BioScrip cannot afford to maintain this inventory in physicians’ offices and wait to be reimbursed after the administration of the drug. One option to address this issue would be a pre-payment or advanced payment from Medicare that will then be periodically reconciled against submitted claims. This option would be budget-neutral. Other options include the creation of a supply fee that would allow BioScrip to accumulate the necessary capital to support this “loaned” inventory.

B) Requirement to Ship to Location

The CAP vendor has a regulatory obligation to ship any CAP drug to the location where the drug is administered to the patient. Many physician practices have satellite locations opened only one or two days each week, to serve patients in rural or remote areas. These practices have expressed concern that shipping drugs to those locations will require additional resources and coordination to receive drugs and maintain inventory at multiple locations. Moreover, BioScrip has heard from physicians who have already enrolled in the CAP but did not realize they had to sign up for all locations.

From the vendor’s perspective, shipping to multiple locations and the need for additional coordination will increase costs. In addition, by having to ship and store multiple-use vials to more locations, the potential for drug waste—and BioScrip’s financial liability—will increase.

SOLUTION: Drug-shipping to location selected by physician

To implement the CAP as an equivalent alternative to the current “buy and bill” system and ensure adequate and timely access to the drugs for Medicare beneficiaries, a similar process should be adopted to deal with physician practices with multiple locations. Thus, drugs would be shipped to the location chosen by the physician, including the practice central office, and then transported and prepared at the location of administration by the physician or other authorized health provider.

C) Burdensome Claims Processing

Physicians are required to bill for the administration fee within 14 days from the drug administration date. The claim would include, in addition to information about physician services provided, detailed information about the drugs administered (including unique identifiers, J-code and NCD code, and dosage) identical to the information submitted by the vendor in the parallel claim for the drug. Physicians are complaining that this process is increasing rather than reducing paperwork and that there is not sufficient time for physician offices to change their billing systems to accommodate the new requirements before the program start-up.

SOLUTION: Simplifying physician billing process

One of the stated goals of the CAP is the potential to reduce physician practice administrative workload and associated costs. While we understand the need to implement upfront checks to allow CMS to match drug and physician service claims and eliminate fraud and abuse, this complex new process represents a significant

burden for physicians and a barrier to enrollment in the CAP. Physicians would prefer to continue billing for the administration fee only and not have to change their billing systems to incorporate new information such as the unique identifier. CMS could continue to use audit and compliance programs implemented under “buy and bill” to ensure accuracy of claims and payments to both physicians and the CAP vendor.

D) Beneficiary Co-Pay Collection

Medicare beneficiaries are, in general, responsible for 20% co-pay on part B drugs and biologicals. Under the CAP, responsibility for collecting co-pays will shift from physician practices to the CAP vendor, BioScrip. The CAP reimbursement rate set through competitive bidding results in a net CAP profit estimated at 1% or less. Thus, BioScrip will depend on co-pay collection to make sure it can continue as a CAP vendor. At the same time, physicians are worried that patients who cannot pay the 20% co-pay will be cut-off from the drug supply.

BioScrip has been partnering with associations, foundations, and drug manufacturers to find solutions to help beneficiaries who cannot afford the co-pays. However, many physician practices are still concerned they will lose patients who are not eligible for these assistance programs.

SOLUTION: Physician option to offer cost-sharing support for co-pay for non-paying beneficiaries

Under the “buy and bill” system, many physician practices provide financial support for some of the beneficiary cost-sharing (co-pays and deductible), particularly for low-income beneficiaries. Under the CAP, beneficiaries will have expanded access to prescription assistance programs, but would no longer benefit from this support offered by their physicians. If co-pays remain unpaid despite access to assistance programs and attempts to schedule a payment plan with the beneficiary, the CAP vendor is allowed to stop providing CAP drugs for that particular beneficiary. Some physicians are worried about these situations and would like to see more flexibility in the co-pay collection process, such as an option given to the physician to offer cost-sharing support for these non-paying beneficiaries, similarly to the current practice.

E) Limited Physician Election Period

The initial CAP enrollment period began May 8, 2006, two weeks after the CAP vendor was announced and 3 days before the first CMS conference call aimed at educating physicians about the new program. The first announcement about the CAP enrollment was sent to CMS physician listserv subscribers and posted on the CMS website on May 5, 2006. CMS extended the initial election period until June 30, 2006, to allow more physicians to learn about the CAP and decide if they want to join.

BioScrip has made a significant upfront investment to prepare for the CAP implementation, particularly for education and outreach to physicians and physicians' practices. BioScrip found that one-on-one encounters were the most effective in educating physicians and physician groups about program operations and benefits. Since the potential pool of CAP physicians is about 40,000, these education and outreach efforts will take time and go beyond the extended enrollment deadline of June 30, 2006. At the same time, many physicians would apparently wait to see how the CAP works in the first month or so before making a decision about enrollment. The limited enrollment period will not allow these groups to participate in the CAP before January 1, 2007.

SOLUTION: Maintain open-enrollment period for physicians

There is no ‘hard’ deadline in the statute that would limit the physician enrollment period. Adoption of an open enrollment period, at least for this first year of CAP implementation, would allow more physicians to sign up for the program and more time for education and outreach.

V. FINANCIAL IMPLICATIONS TO THE VENDOR

BioScrip has invested significant financial resources to ensure the success of this program. Based upon the number of the physicians that have initially enrolled in the program, BioScrip—or any vendor—cannot keep investing in the CAP where it will not recognize the return on investment. To continue these efforts, particularly physician education and outreach, BioScrip needs congressional support to remove barriers to physician election and ensure that the CAP is viable.

VI. CONCLUSION

In closing—BioScrip would like to once again thank the Subcommittee for this opportunity to testify on the newly implemented CAP program. We share the subcommittee's desire to eliminate excess cost and waste from Medicare and we strongly support the CAP, which we believe is a viable program that has the potential to save money while maintaining quality of care and beneficiary access to life-saving prescription drugs. Although I indicated a number of concerns and structural barriers to the CAP program—I believe that in coordination with CMS and the U.S. Congress—these current barriers can be immediately addressed and resolved. We are very committed to continue working with this committee, CMS, and all other germane partners to implement a viable CAP.

If you have questions concerning BioScrip's written or verbal testimony, please do not hesitate to contact me or my Washington Legislative Counsel, the Dumbarton Group, for additional assistance.

Thank You.

APPENDICES

Appendix a—Important CAP dates

- December 2003—The Medicare Modernization Act (MMA) is passed; Provisions referring to the implementation of the CAP for the acquisition of part B drugs and biologicals are included in section 303 (d).
- March 4, 2005—CMS releases the CAP proposed rule
- July 6, 2005—CMS releases the CAP interim final rule
- August 2005—Initial CAP bidding process cancelled
- September 6, 2005—CMS releases technical updates to the CAP interim final rule that changes the CAP implementation dates
- November 21, 2005—CMS releases some final CAP provisions as part of the 2006 physician fee schedule
- November 15—December 22, 2005—CMS accepts vendor bids for the CAP program
- March 31, 2006—BioScrip receives CAP award letter from CMS
- April 7, 2006—BioScrip signs the offered contract
- April 18, 2006—BioScrip is informed of sole vendor status
- April 19–20, 2006—BioScrip meets with CMS and Noridian in Baltimore
- April 24, 2006—BioScrip establishes a CAP help desk
- April 28, 2006—BioScrip starts creating CAP educational materials, website
- May 4, 2006—BioScrip starts making capital investments to prepare for the CAP
- May 5, 2006—Physician election period is announced on CMS physician listserv
- May 8, 2006—Initial physician CAP election period starts
- May 11, 2006—First CMS call on CAP for physicians
- May 31, 2006—First BioScrip call on CAP for physicians
- Early June—BioScrip starts one-on-one physician outreach efforts
- June 1, 2006—The new 90 BioScrip employees for the CAP start training
- June 2, 2006—Initial CAP physician election period ends; extended election period is announced
- June 2, 2006—BioScrip meets with CMS to discuss CAP structural and operational issues
- June 19, 2006—Second CMS call on CAP for physicians
- June 22, 2006—Second BioScrip call on CAP for physicians
- June 22, 2006—BioScrip receives the first physician election file (partial data)
- June 23, 2006—BioScrip starts making welcome calls to physicians (ongoing process)
- June 28, 2006—BioScrip starts shipping product to physicians' offices
- June 29, 2006—BioScrip receives the second physician election file
- June 30, 2006—Extended physician election period ends

Appendix B—Number of CAP physician elections

Specialty	Number of CAP physicians
Allergy/Immunology	69
Cardiology	6

Appendix B—Number of CAP physician elections—Continued

Specialty	Number of CAP physicians
Clinic or group practice	1
Critical care	5
Dermatology	1
Endocrinology	23
Family practice	1
Geriatrics	1
Infectious disease	4
Maxillofacial surgery	2
Medical Oncology	18
Neurological surgery	19
OBGYN	1
Oncology	4
Ophthalmology	77
Optometrist	1
Orthopedic surgery	6
ORL	27
Pathology	11
Plastic surgery	1
Proctology	10
Psychiatry	3
Pulmonology	1
Rheumatology	14

Source: BioScrip physician election data, valid as of July 10, 2006.

Medicare part B allowed charges for part B drugs and biologicals administered in physicians' offices, 2003

Specialty group	Number of claims	Allowed charges
Oncology	7,311,248	\$5,647,268,606
Ophthalmology	169,061	154,720,837
Psychiatry	43,752	3,626,108
Rheumatology	952,381	404,027,916
All other specialties	12,034,708	1,369,525,241

Source: CMS claims data, 2003. CAP Interim final rule, July 6, 2005.



Chairman JOHNSON OF CONNECTICUT. Thank you very much. Dr. Orange.

STATEMENT OF JORDAN S. ORANGE, M.D., PH.D., CHAIR, PRIMARY IMMUNODEFICIENCY DISEASE COMMITTEE, AMERICAN ACADEMY OF ALLERGY, ASTHMA AND IMMUNOLOGY, ASSISTANT PROFESSOR OF PEDIATRICS, UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE, PHILADELPHIA, PENNSYLVANIA

Dr. ORANGE. Chairwoman Johnson and Members of the Subcommittee, I thank you for inviting me to testify as a practicing immunologist with expertise in the safe and effective administration of intravenous immunoglobulin, or IVIG. I am also currently the Chairman of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology, or quad A-I. The quad A-I is our country's largest professional organization for allergists and immunologists, with over 6,000 members. My clinical practice is limited to patients with primary immunodeficiency diseases, or PIDs.

PIDs result from inherent defects in a patient's immune defense, leaving gaping holes that make the patient susceptible to recurring, severe and unusual infections. Some of these are life threatening and others result in chronic deterioration of organ function, leading to disability and premature death. Fortunately, treatments have been developed for some PIDs, the crown jewel of which is IVIG. IVIG contains antibodies obtained from the plasma of thousands of volunteers to assure a broad array of protection for patients who have an inability to make useful antibodies of their own. The ability to safely and effectively provide IVIG to PID patients is essential for their survival and well-being.

Immunologists across our country are deeply concerned that current reimbursement processes are endangering our patients. A recent membership-wide survey of the quad A-I ascertained that 95 percent of respondents feel current reimbursement standards present risk to the health of patients with PIDs. As a result, the quad A-I has been firmly committed to understanding the issues underlying the current IVIG debate and working to provide physicians the necessary resources to ensure safe and effective therapy for their patients. As an example, this manuscript published in the *Journal of Allergy and Clinical Immunology* entitled "Use of IVIG in Human Disease, a Review of Evidence By Members of the PID Committee of Quad A-I." Herein, we review the clinical evidence underlying the six FDA approved indications and nearly 100 off-label uses of IVIG. Some are supported by clinical evidence of the highest order, while others are only anecdotally supported or not supported at all.

This document, however, is only a review of evidence and does not represent a prioritization of indications based upon medical necessity or lack of alternative therapies. To contend with these issues, my hospital convenes all specialties prescribing IVIG to prioritize usage based upon our inventory. We have over 30 indications for which we allow IVIG treatment and divide these into four categories of priority. These are based upon a combination of the clinical evidence underlying the indication, the therapeutic alter-

natives for that particular diagnosis and the seriousness and severity of the condition. I believe this type of assessment is essential to ensure that patients who most desperately require IVIG will receive it.

Our published evidence review also does not comprehensively address the utilization of IVIG within specific indications. This issue requires careful consideration to prevent waste and will benefit from the development of indication-specific guidelines. The quad A-I has been addressing this from a PID standpoint. The quad A-I has also generated a site of care guideline. This effort reflects the complexity of administering IVIG to PID patients, which is a feature of it being a biological response modifier, or BRM. A BRM is defined by the National Library of Medicine as “a treatment intended to stimulate or restore the ability of the immune system to fight infection and disease.” This is exactly what IVIG does for PID patients.

As currently the administration of IVIG is viewed as low complexity and is reimbursed using non-chemotherapy administration codes, as is saline and antibiotics, we fear that reformulated reimbursements will no longer support the safest and thus the most effective administration of IVIG to patients. Finally, as clinical research uncovers new uses for IVIG, it appears that utilization is on the rise. Thus, it is critical to continually reevaluate the appropriate use of and indications for IVIG to ensure that patients who will benefit the most from therapy and have the least therapeutic alternatives will have access. I speak for the quad A-I to say that as academic immunologists, we are grateful for the invitation to be heard today and for our opportunities to work with HHS. We look forward to working with your Committee and with HHS in the future to benefit the patients whose lives depend upon IVIG therapy. Thank you.

[The prepared statement of Dr. Orange follows:]

Statement of Jordan S. Orange, M.D., Ph.D., Chair, Primary Immunodeficiency Disease Committee, American Academy of Allergy, Asthma and Immunology, Philadelphia, Pennsylvania

Chairwoman Johnson and Members of the Subcommittee, I thank you for inviting me to testify as an academic clinical immunologist with expertise in the safe and effective administration of intravenous immunoglobulin (IVIG). I am a practicing physician scientist at the Children’s Hospital of Philadelphia with an appointment as Assistant Professor of Pediatrics at The University of Pennsylvania School of Medicine.

I am also currently the chairman of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology or AAAAI (“quad A-I”). The AAAAI is our country’s largest professional organization for allergists and immunologists certified by the American Board of Allergy and Immunology, a sub-board of the American Board of Medical Specialties. The AAAAI has more than 6,000 members and has the goals of educating its members and the public to ensure the provision of safe and effective care to patients affected by allergic and immunologic diseases.

My clinical practice is limited to patients with disorders of immunity and specifically those with primary immunodeficiency disorders. These diseases result from inherent defects in a patient’s immune defenses resulting in gaping holes that leave a patient susceptible to recurrent, severe, and unusual infections. Some of these infections are life threatening in and of themselves and others result in chronic deterioration of organ function leading to disability and premature death. Fortunately, medical science has developed treatments for some of the primary immunodeficiency diseases, the crown jewel of which is IVIG. The criteria for primary immunodeficiency diseases (PID) diagnoses as well as the evidence underlying treatment

with IVIG have been recently published in the *Annals of Allergy, Asthma and Immunology* as the Practice Parameter of the Diagnosis and Management of Primary Immunodeficiency, on which I am an author.

IVIG are antibodies purified from the plasma of thousands of U.S. volunteers. I describe antibodies to my patients as unique “sponges” that float around in the bloodstream having the ability to “soak up” different types of infections. The large number of plasma donors is necessary to insure a broad array of antibody specificity for patients who have an inability to make specific antibodies of their own.

The ability to safely and effectively provide IVIG to patients with primary immunodeficiency is essential for their survival and well-being. Immunologists across our country are deeply concerned that current reimbursement processes are endangering our patients. In fact a recent membership-wide survey of the AAAAI (completed March 2006) has ascertained that 95% of the more than 400 respondents feel current reimbursement standards present at least some risk to the health of patients with primary immunodeficiency diseases and more than half estimate this risk as serious or extreme.

Building upon these concerns, the AAAAI has been firmly committed to understanding the issues underlying the current IVIG debate and working to provide prescribing physicians the necessary resources to ensure safe and effective therapy for their patients. I would like to highlight several of these efforts for you.

The first is a manuscript published as a supplement to the April 2006 issue of the *Journal of Allergy and Clinical Immunology* entitled: “Use of intravenous immunoglobulin in human disease: A review of evidence by members of the primary immunodeficiency committee of the AAAAI.” This document, of which I am the lead author, reviews the clinical evidence underlying the six FDA approved indications and nearly 100 off-label uses of IVIG. These indications range from extremely rare conditions to those that are relatively common. Some indications are supported by clinical evidence of the highest order, while others are only anecdotally supported, or are not supported at all. This document, however, is only a review of published research and expert opinion. It does not represent a prioritization of indications based upon medical necessity or lack of alternative therapies. For example, toxic epidermal necrolysis is a very rare disease that is nearly uniformly fatal without IVIG therapy. As a result, high-quality, placebo-controlled trials of IVIG in this disease will never be possible. For these reasons these diseases will never be able to attain the highest strength of recommendation, but the utility of IVIG is the standard of care.

To contend with these issues my hospital regularly convenes all medical services prescribing IVIG to prioritize our usage based upon our inventory. We have approximately 30 indications for which we will allow IVIG treatment and have divided these into 4 categories of priority. The prioritization is based upon a combination of: the clinical evidence underlying the indication; the therapeutic alternatives available for use in that particular diagnosis; and the seriousness and severity of the condition. I believe this type of assessment is essential to ensure that patients who most desperately require IVIG will receive it.

Our published evidence review also does not comprehensively address the utilization of IVIG within specific indications. This issue requires careful consideration to prevent waste and will benefit from the development of indication-specific guidelines.

In this light the AAAAI has developed an IVIG “tool kit” to address the specific use of IVIG in primary immunodeficiency. This document includes eight guiding principles for IVIG use. They are explained in the document in more detail, but are outlined here in brief:

- 1) *Indication*—IVIG therapy is indicated as replacement therapy for patients with PI characterized by absent or deficient antibody production. This is an FDA-approved indication for IVIG, which all currently available products are licensed.
- 2) *Diagnoses*—There are a large number of PI diagnoses for which IVIG is indicated and recommended. This includes some with normal or abnormal total levels of IgG.
- 3) *Frequency of IVIG treatment*—IVIG is indicated as continuous replacement therapy for primary immunodeficiency. Treatment should not be interrupted once a diagnosis has been established.
- 4) *Dose*—IVIG is indicated for patients with primary immunodeficiency at a starting dose of 400–600mg/kg every 3–4 weeks. Less frequent treatment of use of lower doses is not substantiated by clinical data.
- 5) *IgG trough levels*—IgG trough levels can be useful in some diagnoses to guide care but are NOT useful in many and should NOT be a consideration in access to IVIG therapy.
- 6) *Site of care*—The decision to infuse IVIG in a hospital, hospital outpatient, community office, or home based setting must be based upon clinical characteristics.
- 7) *Route*—Route of immunoglobulin administration must be based upon patient characteristics. The majority of patients are appropriate for intravenous and a sub-

set for subcutaneous therapy. 8) *Product*—IVIG is not a generic drug and IVIG products are not interchangeable. A specific IVIG product needs to be matched to patient characteristics to insure patient safety.

Also included in the AAAAI IVIG “tool kit” is the IVIG site of care guideline. This document outlines certain criteria that should justify a patient receiving IVIG in a particular site of care. It was designed with primary immunodeficiency diagnoses in mind, but does apply to certain other diagnoses for which IVIG is indicated.

Just as important, this effort also highlights the fact that administering IVIG to patients with PI can be a complex process. Certain patients require physician supervision during infusion and need a sophisticated approach to their treatment. This is an essential element of safe and effective clinical care and one that depends upon substantial expertise. In part, this relates to the role that IVIG serves as a biological response modifier (BRM). A BRM is defined by the National Library of Medicine and National Cancer Institute as: “a treatment intended to stimulate or restore the ability of the immune system to fight infection and disease.” IVIG is a BRM for patients with PI as it enhances the defective components of immunity to fight and protect against infection and complications of infection. In PI, and in other indications, IVIG also modifies aberrant immune response to protect, maintain and restore normal physiology to prevent disease. As is commonplace with BRM therapy, adverse events occur frequently, and the risk of severe adverse events (AEs) is real. For example, the FDA licensing studies of IVIG for patients with PI (for which all currently available IVIG products are licensed), include an occurrence of total AEs as high as in 72% of patients. There are also numerous severe AEs many of which are acute and include thromboembolism, hypotension, seizures, aseptic meningitis syndrome, anaphylaxis, acute respiratory distress syndrome (ARDS), pulmonary edema, apnea and transfusion associated lung injury (TRALI). All IVIG products also include a black box warning regarding acute renal failure. The incidence of moderate and severe AEs associated with IGIV infusions is not infrequent and is documented for one recently licensed product as 34% and 8% respectively. If nothing more, this underlines the complexity of PID patients specifically who are being treated with IVIG.

A reimbursement-related fear is that the reformulated strategy may no longer support the highest quality, safest and most effective approach to patients who require IVIG. Currently, administration of IVIG is viewed as low complexity and is reimbursed using non-chemotherapy administrative codes. Given the aforementioned concerns, and what we as experts define as the standard of care this policy will fail to support proper practice. In fact it will not even meet nursing labor expense in many centers. Properly categorizing IVIG, as a high complexity administration and reimbursement using the chemotherapy administration codes will represent a substantial step in the direction of acceptable practice and patient safety. I hope the committee will support the comprehensive understanding of the requirements for safe and effective infusion to ensure the safety and well-being of our patients.

Finally, as clinical research uncovers new uses for IVIG, it appears that utilization is on the rise. For these reasons it is critical to continually reevaluate the appropriate use of, and indications for IVIG to ensure that patients who will benefit the most from IVIG therapy and have the least therapeutic alternatives will have access. Thus, judicious use must be promoted and practiced now and in the future.

I know I can speak for the AAAAI that as academic physicians we are grateful for the invitation to be heard today and for our opportunities to have worked with HHS. We look forward to working with your committee and with HHS in the future to benefit the patients whose lives depend upon IVIG therapy.

Chairman JOHNSON OF CONNECTICUT. Thank you. Dr. Orange, to what extent does the problem reflect the expanded application of IVIG to other situations, to other medical problems?

Dr. ORANGE. Well, it is actually hard to estimate to what extent that reflects the problem, because we actually don't know how the usage of IVIG is divided in this country. There really hasn't been an effective survey of indications and numbers vary widely. However, it is certainly very clear from the patient organizations that uses in indications that are not FDA approved are definitely in-

creasing. Given how labor intensive the production of IVIG is, it is a catchup process. So, I think this does factor into it.

Chairman JOHNSON OF CONNECTICUT. We don't track the off-label uses and whether they are effective or not?

Dr. ORANGE. We certainly track—there certainly is published research whether or not the off-label uses are effective. Some of them are extraordinarily effective, as proven by meta-analysis data, the highest level of medical evidence. What we don't know is how much of the total IVIG pool goes to these different indications. That is not in the public record.

Chairman JOHNSON OF CONNECTICUT. You say it is a labor intensive production drug. Do you think the supply is the problem?

Dr. ORANGE. I think I would refer back to Mr. Kuhn's comments, which I think are very well placed, which is it is a very delicate balance—the production of the product and the distribution of the product. Once again, it is difficult to say where the problem lies, but there certainly are patients not receiving immunoglobulin who need it.

Chairman JOHNSON OF CONNECTICUT. I must say, this Subcommittee has had repeated briefings on this situation over the years. I have never faced anything quite so frustrating. Ms. Boyle, it is terribly disappointing to hear that people have really died because our reimbursement structure seems to be failing. On the other hand, we haven't been able to really identify what is the supply problem, what is the payment problem and what is the role of these off-label uses. So, we do have some very good work going on now, and I hope we will be able to move forward. We have a lot of interest on the Committee. So, we will press hard. I don't want you to think we haven't been paying attention for a year. It has been very frustrating. Your testimony has been very helpful.

Dr. Schnell and Dr. Bailes, Dr. Bailes, your organizations have about one-third of its members community oncologists. A lot of its members are academic oncologists and have a different perspective and a little different access. Do you see a difference between your community oncologist members' access to drugs at a price that they can afford that is under the reimbursement?

Dr. BAILES. Maybe I don't understand your question, Madam Chairman. You mean as far as the size of the practice, or the price of the drug? In my analysis of the OIG's report, at least half of the drugs they reviewed, there were at least 20 percent of physicians could not obtain them at the Medicare payment rate. We hear that repeatedly.

Chairman JOHNSON OF CONNECTICUT. What I am asking you, since your organization includes a membership that is broader in scope, are you hearing from your community practice physicians a different concern, a greater concern, a more urgent and dire need than from your institutional providers?

Dr. BAILES. I would say that is correct, but we also hear from institutional providers, too. Not to the extent we hear from community providers.

Chairman JOHNSON OF CONNECTICUT. Dr. Schnell, you mentioned you have heard from community providers that they are actually closing satellite offices, shifting care of some patients that don't have coverage to the hospital. Some, I understand, are consid-

ering no longer caring for Medicare patients. Is this information that you are receiving from your members pre-January of this year, post-January of this year, in the last 3 months, as people have sort of looked at the system as it is developing? What are you giving us, anecdotal evidence that is just coming up now?

Dr. SCHNELL. Madam Chairman, we began tracking this as a grassroots organization around the first of the year, so the majority of the anecdotes and stories and quotes that we have received and reports of these activities have been in 2006. I would contend and submit to you that the majority of the problems are because of the financial aspects of care that are ambient in 2006 and were actually not present last year. We lost, in terms of the outpatient treatment clinic income, we lost the entire demonstration project at the end of last year, plus we lost the 3 percent transition fee that has been already reported upon by Members of your Committee, plus factually we are seeing reductions, as you alluded to earlier, in services in aggregate because of the lack of these replacement codes we had anticipated for the last 28 months.

Chairman JOHNSON OF CONNECTICUT. How do you respond to CMS's comment that they used your survey data and your survey data included the cost of pharmacy?

Dr. SCHNELL. We have sent them our data approximately 3 months ago and have had no response. I gather that is not an isolated experience, after sitting through this.

Chairman JOHNSON OF CONNECTICUT. It is true that they used your data, and this was earlier on in the first round. It is separate from the coding process. We do need to know the extent to which that data did reflect pharmacy costs in the local practices.

Dr. SCHNELL. Pharmacy cost data estimates come from an analysis of practices that we did internally, but they fit very nicely with what was reported in a recent immediate PAC study that is in their written testimony that estimates that to be 26 to 28 percent in the State of Maryland.

Chairman JOHNSON OF CONNECTICUT. Mr. McCrery.

Mr. MCCRERY. Dr. Orange, before I get to you, Ms. Boyle, I want to say thank you for the work you do on behalf of immunodeficient patients. Your organization has certainly been at the forefront of bringing attention to this whole issue, and, were it not for your efforts, I suspect we wouldn't be nearly as far along as we are in addressing the problem. So, thank you.

Ms. BOYLE. Thank you.

Mr. MCCRERY. Dr. Orange, you seem to me to be particularly well situated to provide some insight into this problem, and yet your testimony is not very clear. You say, for example, that you prioritize; you meet, your staff meets, and you prioritize patients, I assume you are talking about from neediest to least neediest, and you start at the top I guess with your supply, and you give that to number one and number two until you run out. Is that basically what you do?

Dr. ORANGE. It is a matter of prioritizing diagnoses, but, yes, exactly.

Mr. MCCRERY. Why do you run out?

Dr. ORANGE. Fortunately, we have not. I think that that is due to some particularly—first, we are a large institution. This is refer-

ring to my hospital. We have a good supply of immunoglobulin, but we have actually had to suffer some of the consequences of the current environment and we have had to actually change—my hospital purchases one product to try to make ends meet. We have exceptions for patients who need other products. We purchase one product in the majority, and we have had to change our product that we use twice in the past 12 months, which requires increased precautions. As one of the immune deficient foundation surveys show, 34 percent of the adverse reactions that occur during IVIG administration, occur during a product change. We have had to go through this process with all of our IVIG patients twice in the last year.

Mr. MCCRERY. Why have you changed products?

Dr. ORANGE. We don't buy IVIG through a purchasing organization, we buy from a distributor. I cannot speak for our pharmacy department here—I am not involved with this, but the distributor has informed the pharmacy department that an adequate supply of the product we are purchasing will not be available. So, to make sure we will at least have—

Mr. MCCRERY. You just buy another kind?

Dr. ORANGE. Yes.

Mr. MCCRERY. Well, have you pressed your pharmacy department to press your distributor for reasons why the kind that you like is not available?

Dr. ORANGE. I certainly don't know about it. I think in some ways we are happy to have IVIG.

Mr. MCCRERY. That would be helpful to this Committee, and you seem, again, particularly well situated to do that. Surely you have some relationship with your distributor, your pharmacy department has some relationship with your distributor. They spend a lot of money with them. So, use the marketplace to demand an answer. Why can't you—what is the reason that you can't supply what we prefer for our patients? See what they say. It would be nice if you could let us know, or let CMS know. Which gets me to my next question. Are you hopeful, let me rephrase that, of course you are hopeful. Do you believe that the two studies going on, one from the Office of Inspector General and the other from the Assistant Secretary for Planning and Evaluation of HHS, will bear fruit in terms of identifying the reasons for at least anecdotally spot shortages or shortages of one particular kind or another in the market and problems with reimbursement levels?

Dr. ORANGE. I was very enthused by some of the studies that are ongoing and particularly look forward to the results of Mr. Kuhn's.

Mr. MCCRERY. Have you been contacted by either HHS or the Office of Inspector General? Would you like to be?

Dr. ORANGE. I think a dialog, ongoing dialog is essential. We have met with Mr. Kuhn before. I wasn't aware of his study per se, but I am thrilled to hear about it. With what he proposed, the one concern I do have is that we are not going to identify the specific administration costs of safely and effectively giving IVIG through that study; although it will give incredibly valuable information. Once again, for a variety of reasons, IVIG is reimbursed as a low complexity administration. With the reformulation of re-

imbursement you have to pay attention to how the different services are supported.

Mr. MCCRERY. In your view, would that be a good solution to the reimbursement problem, to separate the cost of the drug from the complexity or time involved in administering the drug? In other words, do you have a separate payment to the provider for administering the drug?

Dr. ORANGE. There already is an administration code that does support the provision of IVIG. It is just the way it has been classified as a non-chemotherapy administration, I fear that with everything being itemized at this point, that doesn't support the safe and effective administration. We at the quad A-I are working together with the Immune Deficiency Foundation to try to ascertain some hard objective data, but don't have that right now.

Mr. MCCRERY. Well, it seems to me, Madam Chairman, we ought to write Mr. Kuhn or Dr. McClellan and advise them to contact Dr. Orange's organization, both the association and maybe his hospital, and seek their input. They have got some good data. I don't know why they haven't contacted you so far. What are they doing? Who are they contacting? Do you know, Dr. Orange?

Dr. ORANGE. Through the quad A-I we actually have had dialog with CMS and it has been very—

Mr. MCCRERY. You said that before. You said also you weren't aware of the study that HHS was doing. Okay. Thank you.

Chairman JOHNSON OF CONNECTICUT. Mr. Hulshof.

Mr. HULSHOF. Thank you, Madam Chairman. I appreciate all the witnesses that are here, and I appreciate the Chairman bringing this issue forward. Again, I think it is because of a lesson that we learned after 1997 with the balanced budget agreement, in a bipartisan way, in fact, some of those probably here in the room who remember the markup, there were 39 Members of the full Committee back then in 1997, and the Medicare changes, if memory serves, passed by a 36 to 3 vote. The reason I remember is because I was a freshman and I remember everything that went on that first year that I was here.

I think what happened, of course, as we look back at BBA was perhaps we weren't as diligent in overseeing those changes that were made, because it had some real difficult challenges, it provided real difficult challenges for a number of sectors, and I think Congress was slow to respond to those unintended consequences. That is why I think this is so important, because, again, with the Medicare Modernization Act, and as these changes are being implemented, it is important to do just what you have done, and that is provide us with the information and the follow up.

Please let me suggest to you don't let today be the end of your journey, but, again as Mr. McCrery talked about, continue to provide us information. I would probably say, Mr. Schnell, as you were sitting through the first panel, you had to take at least some encouragement from at least the tone of questions from those of us up here, because as I look at Exhibit C of your testimony, which you call quotes, we call verbatim, what have you, it was as if I was, again, at the community cancer clinic in Columbia, Missouri, listening to some very dedicated individuals who said almost ver-

batim these same things. So, I appreciate the dilemma or where we are moving.

Again, if we could make those changes. If Mr. Kuhn tells us in some aspects it doesn't take an act of legislation, but they can be done administratively, we will learn that as well. I do want to ask you, having sat through the previous panel, one of the suggestions you have made in your written testimony on page 5 is to reevaluate existing drug administration payment codes. As you probably heard, I think not only Mr. Kuhn, but Dr. Miller said, and I know MedPAC actually in their report has shown an increase in the utilization of drug administration codes. So, are we saying the same thing, or help clarify then maybe what MedPAC or what Mr. Kuhn has overstated, if in fact they have overstated the use of these administration codes?

Dr. SCHNELL. Yes, sir, I would be glad to speak to that. We believe that MMA held immense promise for our community. The problem is they didn't deliver in developing codes that address the magnitude, intensity and complexity of service that we provide. I have been asked to add that we are highly supportive of H.R. 4098, the Community Cancer Care Preservations Act, sponsored by your colleague Mr. Ramstad. We have 74 sponsors on that and it contains a majority of things we would like to see happen. I might also add that the exhibit to which you referred contains anecdotes from a small number of people. We have many more, but, I truly dare say that if I pulled any community oncologist that I know in any part of the country, we would come up with similar quotes.

Mr. HULSHOF. I appreciate that. For the record, I think I misspoke earlier when I said Secretary Shalala in 1998 talked about the average wholesale price. I think it was actually the year 2000. I remember it had been an election year. I just remembered the wrong election. I remember visiting with our local cancer oncologists, or community oncologists too about the concern about even changing AWP to this new methodology. So, I appreciate that your organization agrees that something needed to be done, because obviously within AWP you were picking up the practice expense and you were dealing with, for instance, the very technical requirements for oncological nurses and technicians and what have you. I think this is—the intent, at least, is to have a better, more transparent system, so that you are reimbursed for the drugs adequately and that there is a practice expense specifically within this. Insofar as this is deficient, we hope to continue to have this dialog so that we can make whatever corrections are necessary. Again, I appreciate all of you being here today. Thank you, Mrs. Johnson.

Chairman JOHNSON OF CONNECTICUT. Thank you. Dr. Schnell, I agree that it was the coding process that fell down, and I want Mr. Hulshof to know that it is part of that problem of the changes in medicine up against a very old law and a very old process. The idea of practice expense was kind of stuck in the old world of receptionists and nurses and delivering chemotherapy is much more of a clinic operation. It requires a lot more overtime capability, and we could never get that picked up, even though we worked hard on trying to get oncologists involved in that process. So, it was a disappointment. It is very hard to get back at it now, but that is something that I hope that as we get them focused on

how the payments per treatment type have declined, we will begin to be able to get at that.

Mr. Friedman, if you are going to get reimbursed at ASP plus 4.4 percent, what gives you confidence that you can deliver these drugs to community oncologists for under ASP plus 6 or plus whatever they are going to get paid? How are you going to manage this problem that they won't get paid ASP plus 6, they will get paid ASP plus 4 at the best, because they aren't going to get some of the discounts that bigger purchasers can get? How will you be able to serve them in a way that will actually save them money?

Ms. FRIEDMAN. We actually don't manage that end of it. Our job is to deliver the product and then get reimbursed ourselves from CMS and the co-pay side.

Chairman JOHNSON OF CONNECTICUT. I see. Of course.

Ms. FRIEDMAN. So, we are not involved in the pricing part of what happens within the oncologist's office or any other specialist, or any other physician that signs up for the program. Our job solely is to make sure that the drugs are there for the patient.

Chairman JOHNSON OF CONNECTICUT. You certainly had a lot of experience in this line of distribution, and I am glad someone is out there to try the CAP initiative, and it is surprising that only one vendor was willing to take it on. Dr. Bailes and Dr. Schnell, why don't you see this as a positive possibility? It eliminates your doctors' exposure to loss on the price of drugs.

Dr. BAILES. Well, ASCO does not have a formal position on the Competitive Acquisition Program. That is an individual practice decision. There are issues with it, Madam Chairman, that need to be addressed, we believe, in addition to the administrative issues that were mentioned. For instance, one is the ability of a vendor to seize shipment of drugs if a patient or cancer patient or any patient is 45 days or more late on payments. There is also the inability to take a CAP drug from one office to another for those practices that have multi-site jurisdictions, and patients are often treated in different sites in those areas. So, those we see are two major issues, in addition to the extra administrative activity in the practice that is required because the drugs are specific to the individual patient when they are shipped.

Chairman JOHNSON OF CONNECTICUT. Mr. Friedman, do you care to comment?

Ms. FRIEDMAN. I happen to agree. It is part of our testimony as well that we should be able to send drugs to where the physician wants, even in multiple locations. Part of the problem that we see is in the rural locations where the physician only attends that office maybe 1 day a week. How do you get the drugs there? There is no staff to accept the drug. So, having the drug sent to the main office and then carried there we see is not an issue as well. We appreciate the point on the co-pay. We are concerned about that as well. In past, I believe the physicians did have the ability to step in, if they wanted to, and we would like to open that up again.

Chairman JOHNSON OF CONNECTICUT. Any other comments on the subject of the CAP program? Thank you very much for your testimony. These are difficult problems to work out, but I am glad to have heard all of the parties today and hope we will make some

real progress over the next couple of months. Thanks. This hearing is adjourned.

[Whereupon, at 3:35 p.m., the Subcommittee was adjourned.]

**Statement of J. Jay Baker, Greenbrier Oncology Clinic,
Lewisburg, West Virginia**

I am a board certified medical oncologist who has been in practice for thirty years, the last fifteen years as a solo practitioner in a rural community in West Virginia. There is a very large population of retirees here, which helps explain the fact that approximately seventy percent of my patients are insured through Medicare, many without co-insurance. In the same medical complex there is a freestanding radiation therapy facility. Together, we provide what is felt by the community to be excellent cancer care. The nearest facility to offer this type of care is 55 miles away, while chemotherapy alone is offered a bit closer, 45 miles away in Virginia.

Since January 2006 when the latest Medicare changes were put into full effect, I have lost money each and every month . . . totaling nearly \$125,000 thus far. I can say that nearly all of this loss has come as a result of changes in reimbursement from Medicare, especially the underfunding of the administrative costs incurred when treating patients. I have tried to eliminate overhead as much as possible in hopes of finding a way to keep this office open. As you are aware, many offices are sending their Medicare patients to the hospital for treatment, but in this small community hospital, that is simply not an option.

As a consequence of the above, I am being forced to shut the doors to this office and close down my practice, thereby depriving this area of quality medical oncology service. I see no other way out of this. I do not believe that medical oncology can survive in a rural setting in the present circumstances, and I am a prime example of this. It is my hope that this committee will somehow see the errors of the present situation and take appropriate steps to correct them. It will, of course, be too late for this practice, but perhaps others can be saved and thereby continue to offer quality care to patients who don't happen to live near a population center or cannot afford to drive 50 miles one way to receive care. I know you have received reports of practices closing "satellite" clinics in some areas, but this is a report of one entire practice being forced out of business totally . . . and I dare say that I am not the first, nor will I be the last if Medicare remains unchanged.

Thank you for your attention to this testimony.

PS . . . I have not drawn a paycheck for the past month and a half!

**Statement of Steven H. Collis, AmerisourceBergen Specialty Group,
Addison, Texas**

Madam Chairman and members of the Committee,

AmerisourceBergen Specialty Group and its affiliates provide pharmaceutical services to pharmaceutical manufacturers and healthcare providers in the United States and Puerto Rico, and Canada. We distribute brand name and generic pharmaceuticals to various healthcare providers, including acute care hospitals and health systems, independent and chain retail pharmacies, mail order facilities, physicians, clinics, and other alternate site facilities, as well as skilled nursing and assisted living centers.

At ABSG, our emphasis is bringing specialty pharmaceuticals from the manufacturer to the physician to the patient. We help manufacturers improve their product launches and expand their markets. We ensure that provider organizations receive the specialty products they need, when they need them most. We give physicians the resources that improve their practices and patients the medicines that improve their lives. In addition to delivering products, that means related services such as reimbursement and consulting services, logistics services, and physician education.

In short, your hearing today is to examine the costs for physician-administered drugs. That's something we know about because providing these drugs to physicians is what we do.

1. CAP Program Design Places Unrealistic Burdens

The design of the program places unrealistic burdens on competitive access program providers (CAPs), burdens that have already discouraged entry by many prospective CAPs.

Geographic Scope. The geographic area that each CAP must serve is too large. The additional requirement to serve U.S. territories imposes a significant burden with higher risk of co-pay issues. In order to enhance the likelihood that the CAP program will meet Congress' goals, we recommend you *revise the requirements so that CAPs are only required to serve physicians in the 50 states and Washington DC.*

Inexpensive, Low-Margin Drugs. The CAP program tries to do too much and, in doing so, it forces too many low-cost drugs (for which physicians face relatively less economic risk) into the program. While the average bid NDC was about \$280.00, the median bid NDC was only about \$59.00. If there were an average 6% gross profit, that would mean the CAP would have gross margins less than about \$3.50 on one-half of its products. That is not adequate. We recommend that you *eliminate any NDC with reimbursement under \$200.00.*

Risk of Unprofitable Orders. The cost to process and ship an order will vary by the size of the order but, on average, it will be proportionately more for small-dollar orders. We recommend that you *establish a minimum size for all orders, at least \$15,000.00 for oncology drugs and \$5,000.00 for all others. Additionally, we recommend that you allow CAPs to establish a per-order charge of at least \$50.00 to compensate CAPs for their additional dispensing costs.*

Too Many Specialties. Again, the CAP program design tries to do too much and, in overreaching, it makes failure more likely. We recommend that *the CAP program focus on key specialties: Oncologists, Rheumatologists, Urologists, and Ophthalmologists.*

Problems Collecting Co-Pays. Challenges in collecting co-payment after administration of the drugs to patients makes the CAP program operationally unattractive. Outside the CAP program, physicians and specialty pharmacies collect co-payment before services are performed and drugs are dispensed to the patient. Doing so allows the provider to minimize its economic risk. If there's no payment, there's less risk because the drugs won't be dispensed. We recommend that you *allow CAPs to collect co-payments from patients (either directly or through the physician) before services are provided in order to mitigate the high potential for uncollectible payments from patient, especially those without co-insurance.*

Risk of Waste. There is a significant potential for waste, especially with some of the high-cost specialty drugs (e.g. *Erbix, Velcade, Alimta, etc.*).

Single-Use Units. With single-use vials, a physician might prescribe 3.1 vials of an expensive drug and the CAP would dispense 4 vials. If CMS, after the fact, decides that use of a large single-dose vial was inappropriate and the physician did not act in good faith to reduce waste, the 0.1 would be deemed waste. Not only would the CAP not be reimbursed for the 0.1 vial, it would be denied reimbursement for the entire vial. Also, it's not clear how CMS determines good faith from the physician and, if CMS decides the physician did not act in good faith to minimize waste, the economic risk falls on the CAP—a party with only limited ability to control or prevent such waste. Even when doing so was completely appropriate, the remaining 0.9 of the vial will be truly wasted unless the physician has another patient immediately in need of the same medicine. We recommend that you *allow CAPs to enter into agreements with physicians to require that the physician reimburse the CAP if CMS determines the physician acted inappropriately.*

Multi-Use Packs and Units. There is also a significant potential for waste with multi-pack NDCs (e.g. *Procrit, Neupogen, etc.*) and multi-dose vial NDCs (e.g. *Herceptin, etc.*) because, by design, there is more than one discrete dose per NDC. CMS has indicated that any remaining doses can be re-directed to other patients based on an agreement between the CAP and the physician. However, CMS defines CAP's shipments as prescription orders. Prescription orders are subject to state pharmacy laws. And, state pharmacy laws generally prohibit doing so.

Conflicts with State Pharmacy Laws. Design of the CAP program does not properly recognize the inherent incompatibility with state pharmacy laws. That is, distributors and pharmacies operate under different restrictions. Drugs sold by a distributor to a physician may be readily dispensed to any appropriate patient. However, drugs dispensed by a pharmacy for one patient cannot be re-directed to a different patient. A physician cannot simply use extra drugs—whether remaining in a single-use vial, a multi-use vial or a multi-pack—on a patient other than the patient for whom the pharmacy dispensed the drug. We recommend that you *recognize the distinctions between distribution and pharmacy and either avoid conflating incompatible activity or expressly override contrary state law. Additionally, we recommend that making it clear that any agreement between a CAP and a physician allowing drugs to be re-directed from one patient to another will not violate Medicare/Medicaid fraud and abuse/anti-kickback rules or other laws.*

Risk from Providers. The CAP program model introduces a significant new economic risk. With product purchased by a physician, the owner of the product has

possession of it. And, its owner is the person deciding how it will be dispensed to patients. Under the CAP program model, physicians have custody of product they do not own and they decide when and how much the CAP will need to dispense for each patient. There's no question the vast majority of physicians are honest. Only a few would over-prescribe a drug or inappropriately use drugs dispensed for one patient for another. However, CAPs should be able to monitor use of product for which they have the economic risk. We recommend that you *allow CAPs to audit the use by physicians of drugs dispensed by the CAP and to correct any problems that arise.*

Incentives Not Aligned. The economic incentives of a CAP are not aligned sufficiently with those of the physicians it serves. For example, for high-cost drugs, a physician will have relatively much less economic risk because administration fees will be substantially lower than the cost of the drugs, not to mention the fact that the CAP will have hard-dollar losses for product and shipping it has purchased and paid for, not the softer losses that a service provider has in not being paid for lost staff time. We recommend that you *allow CAPs to require that physicians collect co-pays on their behalf.*

2. CAPs Have Little Negotiating Leverage

We believe that the CAP program was designed with an incorrect assumption that specialty distributors and specialty pharmacies have a high degree of negotiating leverage with drug manufacturers and with physicians. This is simply not borne out by the facts. More to the point, CAPs do not have negotiating leverage with drug manufacturers or physicians—which was clearly shown when the CAP awards were made. The net result from CMS's competitive bidding was a composite cost reduction of 0.40% when compared to ASP+6% in Q4 2004 before application of the PPI—basically no savings. And, actual CAP rates will be 4.85% higher than ASP+6% in Q4 2004 after the PPI is applied—making drugs dispensed by CAPs *more expensive* than those reimbursed under the ASP system. We recommend that you *allow CAPs greater ability to negotiate with drug manufacturers and with physicians they serve.*

3. Current CAP Program Model Unrealistic

The fatal flaw of the current CAP program design was that its model does not correspond to any existing or viable specialty distribution or specialty pharmacy economic model. That is, the model seeks to have CAPs provide services like those provided by a specialty pharmacy but to do so at margins similar to those in the specialty distribution industry. There is simply no compensation for the additional risks and costs inherent in the current CAP program model.

Specialty Distribution. Specialty distribution is:

- **Low Margin.** Operating profit margins are typically in the low single digits.
- **Low Service.** Many orders are placed electronically through websites.
- **Short DSO Payment Terms.** Typically, physicians pay for product within 10–30 days.
- **Low Bad Debt.** Physicians are typically very good credit risks. Moreover, most physicians purchasing product are repeat customers who will not be served if they do not timely pay their bills.
- **Efficiency Is Key.** Specialty distribution is very efficient, with frequent inventory turns and low costs.
- **Minimal Returns.** While physicians typically return very few drugs, there are some. Low returns helps keep operating costs low. However, allowing returns also keeps costs low because unused saleable product can be re-sold, helping minimize waste.

Specialty Pharmacy. Specialty pharmacy is:

- **Higher Margin.** Operating profit margins are typically in the high single digits.
- **Higher Service.** Pharmacists typically spend significant time providing phone consultation, patient specific dosing, etc.
- **Longer DSO Payment Terms.** Typically, full payment is not received for 1½ to 2 months. Often there is a need to coordinate benefit payments from more than one insurance company or other third-party payor. And, the pharmacy will typically need to collect a co-payment from the patient.
- **Higher Bad Debt.** Even with the ability to collect co-payments and deductibles before services are provided and drugs are dispensed, specialty pharmacies will typically have more bad debt than a specialty distributor.
- **Lower Efficiency.** While specialty pharmacies are typically less efficient, consuming greater working capital than distribution, they can profitably serve their patient because they typically have higher operating margins.

- No Returns. Under most state pharmacy laws, a patient cannot typically return drugs once they are dispensed.

Additional Economic Burdens for CAPs. Under the current design, CAPs have additional economic burdens without additional compensation.

- Consigned Inventory. Product owned by the CAP is placed on consignment in the offices of physicians where the CAP has no direct control over the consigned inventory.
- Inefficiency. CAPs must own more inventory to meet the same level of patients' needs because, when inventory is dispersed, a CAP cannot readily shift it to physicians and patients who need it when inventory has been consigned to another physician's office.
- Co-Payments. CAPs have no ability to collect co-payments and deductibles before services are provided and drugs are dispensed. This increases their bad debt risk and increases their expenses to collect payment.
- Greater Cost. The per-dose cost is typically lower when purchased in multi-packs or multi-dose vials. Under the CAP program, there will be greater reliance on single-dose vials, which will tend to increase overall costs.
- Greater Waste. When multi-packs and multi-dose vials are used by CAPs, it will tend to increase the amount of drugs that is wasted.
- Minimal Negotiating Leverage. CAPs have little real ability to negotiate favorable terms with manufacturers and little real ability to require physician and patient compliance.

4. Conclusion

For the CAP program to succeed, it's essential that Congress implement reforms that will remove the economic and structural barriers of the current design. We at AmerisourceBergen Specialty Group are available at any time to work with you in helping enhance this program so it will better serve patients and their physicians.

Thank you, again, Madam Chairman and members of the Committee.

RECOMMENDATIONS

- Revise the requirements so that CAPs are only required to serve physicians in the 50 states and Washington, DC.
- Eliminate any NDC with reimbursement under \$200.00.
- Establish a minimum size for all orders, at least \$15,000.00 for oncology drugs and \$5,000.00 for all others.
- Allow CAPs to establish a per-order charge of at least \$50.00 to compensate CAPs for their additional dispensing costs.
- Focus on key specialties, including oncologists, rheumatologists, urologists, and ophthalmologists.
- Allow CAPs to collect co-payments from patients (either directly or through physicians) before services are provided in order to mitigate the high potential for uncollectible payments from patient, especially patients who do not have coin-surance.
- Allow CAPs to enter into agreements with physicians to require that the physician reimburse the CAP if CMS determines the physician acted inappropriately.
- Recognize the distinctions between distribution and pharmacy and either avoid conflating incompatible activity or expressly override contrary state law.
- Ensure that agreements between a CAP and a physician that allow re-directing product from one patient to another will not violate Medicare/Medicaid fraud and abuse/anti-kickback rules or other laws.
- Allow CAPs to audit the use by physicians of drugs dispensed by the CAP and to correct any problems that arise.
- Allow CAPs to require that physicians collect co-pays on their behalf.
- Recognize the increased costs and lower margins that CAPs face when compared with specialty distribution and specialty pharmacy.
- Allow CAPs greater ability to negotiate with drug manufacturers and with the physicians they serve.
- Recognize that CAPs have additional economic burdens that justify additional compensation and remove economic and structural barriers from the current design.

Statement of Appearance and Representation

Pursuant to the Committee's rules for appearances, Steven H. Collis, AmerisourceBergen Specialty Group and AmerisourceBergen Corporation submit the following information.

Steven H. Collis is Senior Vice President of AmerisourceBergen Corporation and President of AmerisourceBergen Specialty Group. His appearance is solely on behalf of ABSG and its affiliates and not on behalf of or otherwise representing any client, other person or organization.

AmerisourceBergen Corporation, a publicly traded company (NYSE:ABC), is one of the world's largest pharmaceutical services companies serving the United States, Canada and selected global markets. AmerisourceBergen Corporation has more than \$58 billion in annualized revenue, employs more than 13,000 people and is ranked #27 on the Fortune 500 list. For more information, see www.amerisourcebergen.com.

ABSG is a wholly owned subsidiary that provides manufacturer services, distribution services and physician and patient services through its nine specialty pharmaceutical services divisions, including:

Manufacturer Services

- ICS—Customized outsourcing partner, whose services include outsourced logistics, contract services, clinical services and medical education.
- Imedex—An industry leader in providing continuing medical education to healthcare professionals worldwide, Imedex organizes more than 80 conferences and projects worldwide each year.
- Lash Group—One of the largest reimbursement consulting firms in the nation, serving pharmaceutical, biotech and medical device companies with a range of consulting and reimbursement services.
- NMCR—International source for analytical research into medical decision-making and provider of medical education programs

Distribution Services

- ASD Healthcare—A leading supplier to physicians in nephrology, oncology, plasma, primary care and vaccine healthcare.
- Besse Medical—One of the largest nationwide distributors of vaccines, biologicals and injectables.
- Oncology Supply—One of the largest nationwide distributors of oncology products and practice management solutions.
- Physician & Patient Services.
- International Oncology Network (ION)—A group purchasing and medical education organization serving more than 3,000 community-based oncologists.
- U.S. Bioservices—A specialty pharmaceutical services company dedicated to helping pharmaceutical manufacturers and physicians improve patient's lives through evidence-based medicine.

Connecticut Oncology Association
South Windsor, Connecticut 06074
July 27, 2005

Congresswoman Nancy Johnson, chairwoman,
Committee on Ways and Means Health Subcommittee
U.S. House of Representatives
1102 Longworth House Office Building
Washington D.C. 20515

Dear Chairwoman:

Thank you for the opportunity to comment on the impact of the MMA upon community oncology in support of the hearing held on July 13, 2006 by the House Ways and Means Subcommittee on Health.

The impact upon patients and physicians in the state of Connecticut has been dramatic. In 2004, the combined net payments from both drugs and professional fees as well as the 32% transitional payment were sufficient for oncology practices to continue to care for Medicare cancer patients at close to a breakeven level. Most practices care for Medicare patients as 40—50% of their patient mix, so changes in Medicare reimbursement have significant to the financial stability of these small businesses.

In 2005, the transitional payment decreased to 3% and the drug payments changed to an ASP basis. From the first day these rates were in place, practices found themselves unable to care for Medicare patients who could not afford to carry supplemental insurance and could not afford to pay the 20% Medicare co-payment. These patients were referred to local hospital outpatient facilities (which were not locally available in several communities because those hospitals had long before closed their own outpatient infusion centers since care had shifted to the more cost-

efficient physician office sites). Additionally, Medicare patients from Skilled Nursing Facilities in need of cancer treatment were also being shifted to any available hospital facility (even inpatient if the patient's condition warranted) because of Medicare policy changes making the Skilled Nursing Facilities responsible for an illogical and incomplete list of cancer treatments. The Skilled Nursing Facilities refused that responsibility so physicians were forced to refer such patients to the more-costly hospital facilities when cancer care was needed. This shifting of patients without supplemental insurance and those from Skilled Nursing Facilities has resulted in a real but as yet uncounted additional financial burden upon the Medicare Part A system, as well as a hardship and quality of care burden upon the Medicare cancer patients and their families, which in some cases has adversely affected their care.

Two specific examples: In southern CT, a Medicare woman without supplemental insurance could not afford to pay the required 20% copayment for her treatment after Jan 1, 2005, and the ASP+6% payment was significantly below the practices' costs of purchase and acquisition of the drugs in that regimen. The practice offered to refer her to the local hospital (which in this case was accepting patients). She refused to go, stating that she had been there before and felt the care, experience and skill level of the non-oncology specific nurses employed at the hospital was inadequate for her needs, so she also decided to then forego that treatment completely. THIS WAS AN ACCESS ISSUE CAUSED BY THE MMA JUST 30 DAYS INTO 2005!

The second example occurred in another town further west, still in the south of CT. A patient had been receiving her care from the practice despite being unable to meet her copayment obligations. The practice was able to continue her care under the old Medicare payment structure because they could still afford to accept a certain level of bad debt. Under the 2005 payment schedule, the inability of the ASP+6% payment to cover their costs of purchase and pharmacy acquisition meant that the practice was facing more than \$10,000 in annual losses for her care. They were forced to refer her for treatment to the local hospital.

There are no longer dedicated oncology divisions in this hospital. Like most community hospitals across the nation, when the most appropriate cost-effective care setting became the physician office, oncology units were closed and oncology-certified nurses migrated to the physician offices. Nurses on the general medicine floors or even in the few hospital owned infusion centers are not as familiar with the complications of caring for cancer patients, especially with the newer drugs and nursing shifts frequently change during the course of a day's treatment, creating lack of continuity in what is already extremely complex care. This patient was referred to the hospital outpatient infusion center, and the nurse from the physician office called the hospital nurse to give her information on the specific drug being used. This drug was very toxic, and even the physician office nurse had checked with the manufacturer before administering it to learn of any new information on managing patient comfort and reactions. The hospital nurse never bothered to follow up on the office nurse's suggestion that she also could get updated information before administering this treatment. The patient did suffer complications and reactions, requiring hospitalization for those symptoms, which led to clinical depression. Medicare Part A was now incurring costs of the hospitalization, and the additional medical and mental complications from the differences between her physician office based treatments in 2004 and this new locus for treatment in 2005. THIS IS A DIRECT EXAMPLE OF THE ACCESS AND QUALITY ISSUES RESULTING FROM MMA WHEN PATIENTS ARE REQUIRED BY POLICY CHANGES TO SEEK TREATMENT IN SETTINGS OTHER THAN THE PHYSICIAN OFFICE, WHICH HAS BECOME THE GOLD STANDARD FOR MANAGING CANCER CARE.

One solo oncologist in CT closed his practice and was packing boxes and moving them out as the MMA was being signed into existence.

Another solo oncologist, the only practicing oncologist in the town, closed first his infusion center in February of 2005 because of the inadequacy of the ASP+6% formula to cover his costs of both purchase and acquisition, and then his full practice in May of 2005 because the remaining professional rates were inadequate to sustain a practice without infusion services. Patients are now driving almost an hour on back winding roads to seek treatment in the nearest town.

Several respected oncologists have moved forward their retirement plans, some well below retirement age, because of the significance of Medicare patients in their patient mix and the fact that in 2004, net net Medicare payments were close to breakeven, in 2005, they dropped below breakeven unless you were careful to manage your patient bad debt potential and evaluate treatments and refer patients elsewhere for treatments that would have incurred significant financial losses, and by 2006, there is no practice that is not losing money on every Medicare patient they treat, for both professional and drug services. One of those physicians just retired

on July 1, 2006, in the prime of his career, because of the financial burden as well as the emotional toll of not only caring for cancer patients, but the added toll of explaining and guiding them through a system that he feels has let them down.

The testimony of the Community Oncology Alliance and ASCO have highlighted the specific problems with the ASP+6% methodology and the fact that professional services required for the safe and effective delivery of cancer care are not reflected in the professional codes or reimbursement rates set by CMS. The Relative Value Units and practice expense bases were created decades ago when the majority of current cancer treatments did not even exist, and the physician offices were not the efficient models of acute care and even emergency care service for cancer treatment that they are today. I testified before CMS and the RUC review committee as to the inadequacy of these codes and base rates in 2004, and those issues have not been addressed fully to this day.

Even large medical groups in CT are writing to me now, citing the impact they are seeing on their private reimbursements when insurers are mimicking the flawed 2006 Medicare payment system. When large medical groups in the center of the state are joining private oncology practices of all sizes across the state in a common message "We cannot hold on much longer, we are worried about our ability to continue to stay in practice," THIS INDICATES A SEVERE ACCESS ISSUE CAUSED BY FLAWS IN THE MEDICARE PAYMENT SYSTEM.

Bridgeport Hospital announced in 2004 that there were specific drugs, without generic alternatives and essential parts of standard cancer treatment regimens, that they were no longer to provide in the hospital, since they could not afford to provide these drugs: among them were Avastin, Rituxan, and Erbitux. This created problems with access for patients in 2005, and by 2006, when local physician practices also became financially vulnerable for all levels of Medicare patients, even those with supplemental insurance, THIS HAS CREATED AN ACCESS PROBLEM FOR PATIENTS WHO NOW HAVE TO TRAVEL WELL OUT OF THEIR AREA, IF THEY CAN, TO SEEK CARE.

I appreciate your time and am happy to discuss the situation in CT with you should you wish. Please heed these messages. Oncology care is in crisis due to the flawed methodology used for the ASP policy as well as the continued lack of recognition of the costs and resources required to provide care in the most cost-effective and medically efficient setting, the physician office.

Sincerely,

Dawn Holcombe, MBA, FACMPE, ACHE
Executive Director

The West Clinic
July 18, 2006

The House Committee on Ways & Means Health Subcommittee
Room 1102 Longworth House Office Building
Washington, DC 20515

Dear Chairman Johnson & Members of The Ways & Means Health Sub-Committee:

The changes under MMA have put our clinic into a significantly compromised situation. As a result, we are no longer able to treat all of our cancer patients in our facility. Many are being shifted to hospital settings—nearly ten times the amount that were shifted last year. The hospitals have placed significant limitations upon their willingness or ability to accept them. Thus, patient treatments are being delayed or shifted outside the communities that we serve.

The West Clinic has offices in Tennessee and Mississippi and serves a patient base within 150 mile radius of Memphis, Tennessee—including West Tennessee, North and Central Mississippi, Eastern Arkansas, Southeastern Missouri, Southwestern Kentucky, Northeastern Alabama, and Northern Louisiana. Last year we had over 110,000 patient encounters and nearly 500,000 phone calls. Our clinic sites intervened to prevent thousands of emergency room visits and hospital admissions. That was our story in 2005.

In 2006, the full impact of MMA has hit and we are no longer able to care for our patient population as before. Major shifts of patient care are now occurring and proactive interventions that avoid ER visits and hospital admissions are now more limited.

The vast majority of the best treatments for colon cancer, lung cancer, breast cancer, lymphoma, and many other diseases are now reimbursed significantly below cost. For the first time in the 27 year history of our clinic we are facing a serious

deficit situation. How can this be? First, the bad debt scenario. In our communities nearly 4 out of 10 Medicare patients have either Medicaid, no secondary, or insufficient co-insurance. The net effect is the inability to collect the full 20% co-pay on nearly 30% of our Medicare patients. This alone puts our reimbursement for drugs below ASP. Secondly, the real costs of delivering 21st century cancer care are not covered. We have sophisticated pharmacy operations in all of our sites. Yet, the cost of the storage, preparation, inventory, safety, and other essential pharmacy operations is not reimbursed. Third, we have faced over 35 drug price increases since January 1st of this year. Thus, we have to wait at least six months for the Medicare reimbursement to reflect these increases. Fourth, neither our oncologists nor our nurses are fully reimbursed for the work that they do. Currently, there is no reimbursement for oncology treatment planning. Our oncologists are the point person on the management of patient care—including chemo, surgery, radiation, home health, hospice, and every aspect of the entire continuum care. Also, the essential work of our nurses is enormously undervalued. Most noteworthy is the pittance that is paid for the second and subsequent hours of chemotherapy. Given the sophisticated and complex nature of the many of the new chemotherapy regimens the focused intensity of the second and subsequent hours of chemo is equal (and at times more) than the initial hour. Fifth, the prompt pay discount inclusion in ASP lowers our effective reimbursement by at least 2 percent.

Meanwhile, commercial insurers are now pushing for setting their reimbursement based upon the current Medicare model. Should they succeed, we will essentially have to cease operations. This will leave thousands of cancer patients fending for themselves and over 300 employees out of work. As the largest and leading cancer provider in the 150 mile radius of Memphis we consider this a tragedy.

On July 13, 2006 your committee held hearings on the salient concerns resulting from MMA. Your efforts to look into this matter are most appreciated. Clearly, this was a step in a positive direction. As one who sits in the clinic—time is of the essence—regarding real solutions to these concerns. Cancer clinics operate as month-to-month businesses relying solely on the revenue for providing care. We have no endowments, foundations, or corporate investors. We can only go so much longer getting paid less than it costs us to provide care.

Some may say, why then, are you not going to be a CAP provider? Very simply, CAP will lead to major disruptions of care (as 35% or more treatments change the day of the visit) and secondly, CAP will actually cost us more—given the added administrative expenses. Thirdly, CAP will create such confusion with individual patient inventories that the costs will increase as will the likelihood of medical errors. Given our annual malpractice bill of \$555,000, we cannot afford to increase our risks. Most importantly, we will not subject our patients to the medical risks associated with CAP or the harassment they will receive from the CAP vendor when they cannot afford the 20% co-pay and they end up being sent to a collection agency or the threat of having their treatment discontinued. CAP is a great idea of maintenance medications—terrible for oncology.

Anyway, where does this leave all of us?

The time and need for solutions is now. Many sound and reasonable solutions for balanced and permanent reform for cancer care reimbursement have been proposed. We hope that the committee will move legislation and that CMS will move forward with administrative fixes before the crisis exacerbates to a point where like the crisis in IVIG, patients lives are at risk. I am afraid that we are just a few months away—at most—from this happening.

Sincerely,

Steven M. Coplon, MHA, CMPE
Chief Executive Officer

Dear Sir:

I am practicing medical oncologist, and I have been in practice in Tyler, Texas for 22 years. Tyler is a city of 80,000 and is a regional referral center for most of East Texas' rural citizens.

The MMA and its attendant cuts in reimbursement have a terrible impact on the quality of care we can offer our Medicare patients. As background, let me state that to provide high quality cancer care in the community setting (and 80% of all American cancer patients receive their care in this setting) we have to endure an enormous overhead. We require a highly trained staff (a pharmacist, 2 "chemo" nurses, 2 physician's assistants to support the patients of a 2 doctor oncology practice: annual salary for these employees alone exceeds \$350,000), sophisticated billing and coding staff and equipment, and the drug bills which are in the millions. Our cog-

nitive services are reimbursed on the same scale as primary care physicians who have an overhead which is but a fraction of ours. To fund this quality of service, we must have some other source of revenue. One would think that source would be chemotherapy administration, yet; Medicare reimbursement for our chemo drugs is less than our cost for 38 of the 42 drugs which we purchase regularly. Only if the patients have a supplemental insurance which will pay the 20% difference between actual Medicare payment and the Medicare “allowable” charges can we treat our patients in our own clinic. If we treated Medicare patients without supplementary insurance, we would be hundreds to thousands of dollars “in the red” on each treatment. Our only alternative is to send outpatients with “Medicare only” insurance to the local hospital’s outpatient chemo units for treatment.

We are fortunate to have two hospitals in Tyler that are willing to help our patients, but the hardship to these individuals can be significant: 1. JW is a 70 year old widower who is virtually paralyzed by a disease called chronic inflammatory demyelinating polyneuropathy. He lives alone, and his very function depends on monthly infusions of IVIG (intravenous immune globulin.) He has Medicare “only” insurance, so with the institution of ASP-based reimbursement and the further cuts in reimbursements for infusions in 2006, we have been forced to send Mr. W to the hospital outpatient setting for treatment. He now sits in a wheelchair for 10 hours taking a treatment he could complete in our office in 4 hours. 2. EF is a 68 year old retired nurse with “Medicare only” needing chemotherapy for high risk stage 3 colon cancer. She spent 11 hours on the fourth of July at the hospital taking what would have been a 3 hour treatment in our office. The next available appointment time for her treatment would have been 2 weeks later, and that was simply too long to wait. I could offer you several other examples. Our patients are educated and well aware of what is at stake. JW has written letters to Congressman Gohmert, our Senators, and President Bush. Our patients are angry!

Please fix the problem. Clinic based oncology care is the best in the world. Don’t let it disappear. Please deal with the flaws in ASP (prompt-pay discounts, several month delays till increased drug prices are reflected in the ASP, etc.). Please enhance E and M reimbursement for oncologists. The intensity and the overhead of our job are not like that of other physicians who are not reimbursed for procedures. Please save community oncology.

Thank you,

Gary E. Gross, MD, FACP

**Statement of Arlette J. Holland, Practice Administrator,
Chestnut Hill, Massachusetts**

To Whom It May Concern:

As Practice Administrator for a small oncology practice I see the day to day impact and ripple effect of reduced Medicare reimbursement. Two of our oncology nurses are commenting, under separate cover, on the impact on treatment accessibility, the impact on our nursing staff and the time it takes to assist patients to get the care they need. I will be focusing my comments on the effect of reduced revenue on the practice itself.

Since we are a small practice we do not have the luxury of purchase power when it comes to buying drugs and medical supplies. We do the best we can by joining every Group Purchasing Organization we can and by taking advantage of rebate programs and contract pricing. In the past we were able to earn early pay discounts from our drug vendors—but now with the reduction in our reimbursement and it’s direct impact on our cash flow we cannot pay early to receive said discounts. In fact, the majority of time we are paying our vendors late and incurring late fees and service charges—sometimes in excess of \$5000 a month! Over time we have lost the ability to purchase from some of our drug distributors because of late payments and over extending our credit limits—the result for us is we have fewer opportunities to shop for best drug pricing. If you factor all of this together and compare it to ASP+6%, we are on the losing end. We are NOT able to purchase drugs at or below ASP+6.

In some instances where we have been able to earn a small profit on a drug—those few pennies are still not enough to cover the underreimbursed cost of administering the drug. We are not adequately reimbursed (sometimes not at all) for IV bags, tubings, dressing supplies, etc., so those few pennies are not even enough to cover supplies. You must also look beyond that to other expenses oncology practices incur—office rent, salaries, employee benefits like health and dental insurance, mal-

practice insurances, telephone and computer systems, office supplies, hazardous waste expenses, medical supplies, clinical education, licensure and hospital dues for the physicians, leases on photocopiers and faxes, transcription services, utilities, postage, lab coat and laundry services—the list could go on and on but these are things that are necessary to run a safe medical practice that offers quality care to its patients. How do these things fit into the pennies we are reimbursed for drugs, administration services and E & M charges?

Practices like ours are fronting the money for all of these things and are quickly falling behind! Some weeks we don't even meet payroll and our physicians then do not get paid AND our vendors don't get paid—putting us farther and farther behind.

Our practice, with three treatment facilities, is like many others across the country—we are not extravagant. We run bare bones. There are no frivolous expenses, we have not had salary increases for our staff in three years. We are in fact understaffed—our nurses travel to all three locations to treat patients because we cannot afford adequate staffing. In some offices we are unable to treat patients on certain days because our nurses are required to travel to another of our sites. Our nurses not only treat our patients but also assist our billing department in screening patients' insurances for coverage and preauthorization requirements. The nurses are our social workers and patient advocates, they expend a huge amount of their time assisting patients in prescription coverage, copay assistance and patient education. How is this reimbursed? Our billing and secretarial staff are down to the bare minimum; often having to cross cover for each other on busy days or vacations. Because we are not being able to afford adequate staffing in any department, the patients sometimes feel the impact on the quality of their care—some days there just are not enough staff and not enough hours to accomplish all that is required for patients and thus patients sometimes experience a delay in services.

The Cancer Center of Boston has always prided itself on the ability to see new patients within 24 hours of initial contact—we still strive to meet that but find that treating the patient the same day as we had in the past is no longer a reality in our practice. Not only do we clinically review the appropriate treatments for patients but now these treatments must be analyzed for reimbursement. Will we be reimbursed at all? Will we be under reimbursed? We can no longer afford to stock our pharmacies for “potential” treatments but are forced to order daily for treatments that have been prescheduled.

We have yet to send our patients elsewhere for treatment. Ethically we feel we can't turn patients away and thus extend every effort to find an affordable and clinically appropriate treatment. Another consideration is that the hospitals at which our physicians are on staff have NO oncology services.

To date we have not closed any of our offices BUT are tenants at will in two (2) out of three (3) because signing extended leases seems a poor business decision in view of current reimbursements and future trends.

Medicare is not the only payor at fault here but are the catalyst for other payors to follow suit.

On behalf of The Cancer Center of Boston I ask the Committee to continue to review and appropriately adjust reimbursement to adequately match the reality of cancer care today and to plan for cancer care in the future.

Statement of Horizon Hematology-Oncology, Spartanburg, South Carolina

The current methodology of drug reimbursement is devastating to small physician practices. For small practices, with one-two physicians, drug pricing reflects high cost and big loss because we do not have large volume. This is not taken into consideration, and in fact it is a benefit to big facilities and a penalty for small practice. The big volume buying power of large facilities skew the reimbursement. The large facilities buy large quantities at lower prices and reap the reward of purchasing under reimbursement while for small practices current drug pricing reflects a substantial loss, as we do not have the large volume purchasing power.

Promoting American small business the government should be paving the way versus making it hard to collect the reimbursement due. For example, 14-day payment on electronic claims and 29 days with a small business waiver actually penalizes small business and 6% of ASP doesn't cut it when this payment postponement penalty costs to borrow. Knowing that the “Wal-marts” of oncology can buy anything cheaper than small business.

A flat 6% tips the scale heavily against small business entities. Realize when patients are strapped for cash and use a credit card to pay their coinsurance there

is a minimum processing fee of 2+%. So the reality is that we are not getting ASP+6% when all factors are considered. This is just another example of the reality of how inadequate the calculation for reimbursement truly is.

Additional Comments:

CMS is taking more money out of Community Cancer Care.

The 2005 and 2006 Demonstration was put in place by our legislators and CMS to offset the drastic reimbursement cuts made to oncologist. As we all know the 05' demonstration translated into an additional \$130 for each chemotherapy infusion for each Medicare Beneficiary and in 06' an additional \$23 for physician evaluation of Medicare Beneficiary with certain cancers.

This is not happening! *CMS has given Medicare Advantage Plans a pass.*

Change Request 3634 Transmittal # 12 from CMS, which states that "only Medicare beneficiaries who are not enrolled in a Medicare Advantage plan are included with the demonstration."

Shocking! So Medicare beneficiaries are receiving inferior benefits and oncologists are receiving inferior reimbursement. This is no Advantage Plan at all!

In 2005 each time an oncologist gave chemotherapy to a Medicare Beneficiary with a replacement plan they **lost \$130 each time** and are **losing \$23 per physician encounter** in 2006. On a national scale how many millions/billions does this constitute? And this savings is passed on to private insurance companies.

I doubt this loss revenue is being considered in the figures that the legislators are touting around Washington. Shocking isn't it!

Hunterdon Hematology Oncology
Flemington, New Jersey 08822
July 13, 2006

Thank you for giving me this time to share how I feel about this issue. If you need further information please feel free to call.

I came into oncology management 6 years ago. At that time, I too thought that the way reimbursement by AWP was incorrect because there were a handful (5) of generic drugs that were paid at brand name prices.

The MMA has turned a Molehill into a Mountain- Act.

Each drug, brand or generic, is assigned a separate NDC number. The simplest solution would have been to reimburse a % by billing the NDC #. There would never have been an issue of any drug being reimbursed disproportionately.

I had mentioned this 3 years ago to Steven Phillips at CMS and was told how the computer system would need to be changed in order to handle 11 digits. I believe it would have been more cost effective to change the system to handle NDC#'s and there would not be any issues of drugs "Below Water."

We have 29 drugs "below water" in this 3rd quarter. Admin fee do not cover the difference between cost and reimbursement. Where do I make up the difference?

example: Neulasta costs 2366.84 we are reimbursed 2148.71 if we do not reach our goal we are minus 218.13. If we reach our goal we could make 1% over cost! That's it!! Admin code pays 21.52. This does not even cover the cost to see this patient!

We have to check each patient's regimen before treatment to see if we can afford to treat them here or if we need to send the patient to the hospital for their treatment.

Administration fees must be increased to cover the true expenses.

What are we saying to our seniors? That they are not worth receiving the best care possible? Our seniors have worked hard for their benefits and to be turned over to an all day treatment that could have been 2 hours in the outpatient setting is atrocious.

I spend my day looking at websites shopping for better drug prices because everyday there are price increases from the pharmaceutical companies. The pharmaceutical companies are not even allowed to help Doctors office as they did in the past. Educational grants and any help they could have provided has been eliminated.

Next solution, we tack on 6% to our invoice amount. This way everyone would be paid fairly regardless of the size of the practice. It would be easier and more cost effective to send in prove of purchase.

I am not naive. I realize that the method that is being used forces us to find the "Best" prices but there are so many flaws that will never be remedied with the system the way it is. We can not purchase drugs at some of the discounted prices be-

cause of volume. Also, hospital prices, incentives, and rebates should not be included in the averaging. If I can pay my bills on time I should be able to enjoy a % off my bill just like any other business. If I meet a quota for a rebate I should be entitled to that rebate. This is part of running a business. If I can not reach the levels I shouldn't be penalized by having to pay more for the drug! That does not make any business sense.

Sincerely,

Luanne Lange
Practice Manager

**Statement of Samuel W. Needleman, Oncology Associates of Stephenville
Hematology-Oncology, Stephenville, Texas**

I have a rather short reply. I am a compassionate, Triple Boarded Hematologist who came to a Texas Town of 25,000. The CEO of the local hospital had done a study that showed a need for one full time Oncologist. I have been very well received and see about 300 consults a year. My start up was underwritten generously by the hospital. I collect over a million dollars a year, but we lose so much on chemotherapy that the hospital has cut my salary from \$300K to 50K, and I shall be forced to leave this community. I was very happy here and it will hurt the community. The current system of reimbursement does not allow small groups without super specialist billing experts to operate without losing money. It has driven me away from a small community I have loved and served well.

Submitted by Physicians of Southeastern Gynecologic Oncology

We are writing to let you know of the impact of the reimbursement changes resulting from the implementation of the Medicare Modernization Act (MMA). As you are aware, the intention of the MMA was to correct over-reimbursement for chemotherapy drugs and under-reimbursement (or no reimbursement) for essential services relating to administration of the drugs. In the planning phase, it was estimated that the reduction to community cancer care would be about \$4.2 billion over 10 years. **A more recent estimate using real world figures from community oncologists shows the impact to be more than three times that—\$13 billion over 10 years.**

For lawmakers used to the realities of large numbers in budgeting, this may sound feasible. But on the local level, it is untenable. **Just two years into implementation, the implications are far-reaching, severe, and at a precipice.**

In our gynecologic oncology practice where we care for women diagnosed with ovarian, uterine, cervical, vaginal and vulvar cancers (about a third of whom are Medicare beneficiaries), we have seen precipitous drops in Medicare reimbursements. In fact, **our reimbursement rates for Medicare beneficiaries have dropped by 30%** since the phased MMA changes begin to be implemented in 2004. Although many sources have painted oncologists as making huge profits on drug reimbursement, the reality is that oncologists have huge outlays for administering chemotherapy drugs; staff pharmacists; highly trained and experienced oncology nurses (often with special certification); time for treatment planning (changing dosages based on side-effects; changing regimens based on efficacy for that particular patient; changing treatment dates for emergencies, etc.); special equipment in the office for preparing chemotherapy safely; charges for safely disposing of chemotherapy-related waste and more. **These costs are not accounted for in any Medicare reimbursement rates or methodology.**

Any business with such a dramatic decrease in income must adapt. We are no exception. In order to keep our doors open, we have had to change the way we do business. In the past, our patients received chemotherapy in our office. This enabled us to provide excellent care for our patients: they could see the physician on the same day as their chemotherapy (reducing trips for patients who are already exhausted from their disease and treatment); providing continuity of care (the same oncology nurse provided their chemotherapy at each visit, making the patient comfortable enough to voice important concerns that they wouldn't "bother the doctor with" and allowing the nurse to notice changes in patient's clinical status); and providing quicker care (patients who must register in the hospital face considerably

longer wait times). Now, **Medicare beneficiaries without a secondary insurance must be treated in the hospital, increasing their treatment time and travel time, requiring multiple visits for physician follow up and treatment, and decreasing continuity of care.** We cannot risk their inability to pay their copayments as this could put us in jeopardy financially. They cannot have labs drawn in our office, receive important supportive care injections in our office or see the physician on the same day as treatment. This, of course, is just the first step. **We have already considered sending *all* Medicare patients regardless of secondary insurance to the hospital. We have not done this because it is important to us to continue to provide our patients with the best care we can. But this may become necessary in the not distant future.**

As we said at the beginning of this process, changes to Medicare are only the beginning. Private insurers follow Medicare's lead. This summer, **Blue Cross Blue Shield of Georgia announced that they would be reducing our reimbursement rates by 11%**, effective July 1, 2006. This affects another 30 percent of our patient base. We expect other large private insurers to follow, compounding the problems set into motion by the MMA.

If reimbursement rates continue to drop from government and private payors, our practice will have no choice but to send *all* of our patients to the hospital for their chemotherapy. We are not the only practice facing this reality. Transferring all the patients who currently receive chemotherapy in a community oncologist's office into the hospital will overwhelm the system. This is already happening in some locations.

On a larger scale, inadequate reimbursement for chemotherapy affects cancer care throughout the country:

- Older oncologists are retiring.
- Fewer new physicians are choosing oncology as a specialty.
- Satellite offices serving rural communities close to patients' homes are closing making cancer treatment more difficult if not impossible for some patients.
- Most research protocols are administered in community clinics. Disabling these clinics hinders the pace of oncology research and the delivery of life-saving treatments to the patients who need it.
- Hospital infusion centers will likely be overwhelmed by the sudden demand when a practice must stop providing chemotherapy or worse, must close its doors. This causes unacceptable treatment delays that harm patients.

Fortunately, this scenario does not have to occur. Legislation in the House and Senate (**HR 4098 and S 2340**) includes provisions to solve the problems with drug reimbursement created by rushed implementation of the ASP system, create payment codes for essential services that Medicare does not currently reimburse for (i.e., treatment planning and pharmacy facilities), and restore appropriate payment for drug administration and deal with the reality of bad debt. These provisions will not make oncologists wealthy, but will allow them to continue to provide world-class cancer care to all Americans. ***We implore you to save cancer care; the situation is urgent and deteriorating. Congress must act now to preserve the best cancer care system in the world.***

Medical Specialists of Fairfield
Fairfield, Connecticut 06824
July 26, 2006

To Whom It May Concern:

I am the managing partner for a group of five hematologists and medical oncologists in Fairfield, Connecticut. We perform about 90% of our chemotherapy infusions as an outpatient in our private office and about 10% in the infusion center of the hospital. Over the last seven months, it is obvious that we are sending more patients to the infusion center because of pharmacoeconomic issues. The ASP reimbursement system for drugs clearly has flaws that need correcting. The Medicare Reimbursement Policy of ASP plus 6% is clearly not adequate when we factor in bad debt, collection costs of 2% to 5%, and the low rates involved.

To show a specific example, we are sending patients who receive Neulasta white blood cell factor support injections to the hospital if they have Medicare or private payer Medicare Choice plans. The reimbursement for Neulasta is \$400 less than our costs, per injection.

We have made it an office policy to send all Medicare patients without supplemental insurance to the hospital infusion center because drugs for these patients

are “underwater” and do not cover our costs. Many patients have experienced delays in their chemotherapy because of staffing and scheduling issues to the hospital, as well as an inconvenience factor, having both to go to the infusion center and then come to see me for followup, whereas other patients with adequate insurance and adequate reimbursement are being seen the same day as chemotherapy. This reduces the strain both on the patient and the loved ones, significant others, or friends who escort these patients who can seldom come alone.

I hope this is helpful and allows you to see the wisdom of increasing reimbursement for things like pharmacy handling, patient coaching and counseling, medical treatment planning, supplies and regulatory compliance costs, equipment costs, and increased staff costs that we are now bearing the brunt of and are not being covered in the professional services.

Thank you for your attention to this matter.

Sincerely,

Glen A. Reznikoff, M.D., F.A.C.P.

The Cancer Center of Boston
Plymouth, Massachusetts 02360
July 27, 2006

This communication is being written to express my concern for the reimbursement formula currently used to calculate payment for oncology drugs in the community office setting.

As an oncology nurse in a small community office, I am very involved in the purchasing, dispensing, and billing of oncology drugs within our practice. I cannot fathom that the committee in charge of developing, implementing, and evaluating reimbursement formulas for community oncology practices have any working knowledge of how these oncology offices function.

Our physicians used to be able to decide upon a treatment for their patients based on what chemotherapy drugs and supportive drugs were the most appropriate for each patient; however, now the physicians are sometimes forced to alter treatment regimens based on insurance coverage. I am appalled that patients may be denied the most effective, possibly life-saving, medications because they do not have the correct health insurance coverage.

Even patients with primary and secondary health insurance coverage are not always able to receive the most appropriate medications because some of those medications cost our practice more to purchase than Medicare reimburses for the drug. Since the reimbursement is based on average sale price (ASP) plus 6%, I am left to wonder who determines what the average sale price should be. Having purchased chemotherapy drugs for the past fifteen years, I can tell you for a fact that the average sale price for small community oncology practices is not the same as the average sale price for large offices or huge buying conglomerates. Since we do not have the ability to obtain volume discounts due to the size of our practice, we pay a much higher price than buying groups pay for the exact same drug. Thus, when the medication costs our office more than we are reimbursed, the patient may not have the option of receiving that medication. This fact constitutes denial of access to care for our senior citizens, those who have built this country into what it is today.

In addition to medication reimbursement, another factor is the cost of administration of the medications. Medicare does not reimburse for the intravenous bags or any of the supplies and equipment necessary for the administration of the chemotherapy drugs. All of these items must be purchased and paid for, whether or not they are reimbursed. Nursing staff, an integral part of the administration of chemotherapy, must be paid for their time. What part of the reimbursement covers the cost of nursing coverage? The reimbursement for the administration codes does not cover supplies, equipment, salaries, compliance with regulations, etc. that are a part of the total functioning of a community oncology practice.

Congress must take into account that small community oncology practices do not have the available cash flow that larger practices have. We are usually unable to pay the wholesalers according to the terms outlined and therefore often incur later fees and service charges, another cause for decreased cash flow. What are community practices to do when they are unable to pay their bills? What are they to do when they are reimbursed less for a drug than the purchase price? Let me tell you that, community practices are beginning to do one of two things. These practices are either sending the patients to local hospitals for the more expensive treatments or deciding to treat patients with the second best treatment available. Many local hos-

pitals do not offer oncology services; therefore some patients may even be denied that option. Does this seem like the way you, as Congressmen and women, would want to be treated or have your parents treated if you or they had the misfortune to be covered by the Medicare system?

Please do not hesitate to contact me for further information as I would welcome the chance to discuss this issue in greater detail.

Thank you for your time and your interest in this very important issue,

Respectfully,

Donna J. Strong, RN OCN BS

Statement of Talecris Biotherapeutics, Research Triangle Park, North Carolina

Chairman Johnson, Ranking Member Stark, and distinguished subcommittee members, thank you for the opportunity to provide the following statement regarding Medicare reimbursement of physician-administered drugs. Talecris Biotherapeutics manufactures Gamunex®, an intravenous immunoglobulin (“IVIG”) product, a critically important therapy for many patients.

Our approach to patient care is simple. We support giving each patient and his or her physician access to the IVIG brand most effective for that patient in a setting best suited for his or her individual needs. As such, we focus our comments on the Average Sales Price (“ASP”) methodology and its impact on the pricing and availability of IVIG therapy.

We support the ASP methodology as a means to reimburse adequately physicians for the cost of acquiring the therapy. Unfortunately, two coding-related IVIG reimbursement issues are contributing in a substantial manner to situations where providers and patients are not able to acquire some IVIG products at a price that is consistent with the Medicare reimbursement.

To ensure ample access to IVIG across all sites of service we encourage CMS to commit to a long-term solution by (1) issuing separate Healthcare Common Procedure Coding System (“HCPCS”) codes to IVIG products and (2) increasing the payment for administration services to adequately reflect the cost of providing the service, based on a thoughtful and careful review of the costs associated with those services. Our recommendations are completely consistent with the ASP methodology, and with the letter and spirit of the Medicare Modernization Act (“MMA”).

We ask Congress to encourage CMS to this action at the earliest opportunity to address the access issues that currently exist for Medicare patients.

I. Our Commitment to IVIG Access

Talecris Biotherapeutics is a new company that is proud to have inherited a legacy of more than 60 years of providing lifesaving and life-enhancing plasma-derived therapeutic proteins. Following its acquisition of the assets of Bayer Biological Products’ plasma business, Talecris is maintaining and building on a heritage of patient care innovations in therapeutic proteins that dates back to the early 1940s. Our products have long been recognized in the industry as innovative and of the highest quality. Talecris, having inherited a solid foundation of unparalleled expertise and experience, is now uniquely positioned to create a new standard of excellence in the field of biotherapeutics.

Normal human blood contains antibodies, which help to protect us from a wide spectrum of pathogens. However, some individuals are unable to make functional antibodies, which renders them susceptible to recurrent and life-threatening infections. Treatment with IVIG provides immune-deficient individuals with the antibodies needed to prevent potentially fatal infections.

IVIG is produced from plasma pooled from thousands of blood plasma donors, which is processed to provide a high concentration of antibodies. Talecris is one of a handful of manufacturers who produce IVIG.

As you review this issue, we encourage you to be mindful of the special commitments and efforts that Talecris has made. Talecris has taken extraordinary steps to substantially improve production of IVIG, dramatically increase investment in production facilities, ensure the availability of an emergency supply of product for needy patients, and conduct important scientific research. *Despite the incredible costs involved in these efforts, we have not, over the last five years, increased our prices at a rate that has even kept pace with the rate of inflation.* That is an extraordinary commitment to our patients, and we are justifiably proud of our record.

II. Understanding the Access Issue

The chronology of the development of the IVIG access issue reveals its substantial link to Medicare reimbursement. Pursuant to the MMA, the ASP payment system first became the basis of Medicare reimbursement for services in physicians' offices in January 2005. Reports of IVIG beneficiary access problems in physicians' offices surfaced shortly thereafter and were, based on the information that we have received from patient groups, essentially localized in that site of service.

Significantly, throughout 2005, Medicare continued to reimburse hospital outpatient facilities without using the ASP methodology, while Medicare services in the physician office setting were being transitioned to the ASP methodology. It is important to note that the patient groups did not report any significant access issues at the time in the hospital outpatient setting. Indeed, the patient groups reported a migration of a significant number of patients from the physician office setting to the hospital outpatient setting.

In January 2006, however, Medicare hospital outpatient reimbursement did transition to the ASP payment system. Soon after, patient groups began to report that Medicare beneficiaries were experiencing IVIG access problems in hospital outpatient departments. It is important to note that reports of IVIG access issues have been primarily focused on Medicare beneficiaries, although some commercial payer coverage changes have been responsible for some additional issues.

Although some appear to be inclined to see the access issues as supply-driven, and not reimbursement-related, we do not believe that this is correct, particularly when we examine the evidence related to our product. Over the last 5 years, we have increased the amount of IVIG we make available to patients in the United States by 85 percent. In anticipation of, and in response to, the considerable need for IVIG over the last decade, Talecris has dedicated significant resources to meet the needs of the IVIG community. Talecris, for instance, has invested more than \$250 million to build a highly efficient, state-of-the-art manufacturing facility in Clayton, North Carolina—the only facility of its size dedicated to IVIG production.

In addition to our dramatic efforts to increase production, we have established the Gamunex® Emergency Supply Program for patients who might be facing a critically urgent situation related to their IVIG therapy. As part of our overall commitment to help meet patients' needs, Talecris holds 2 percent of its inventory in reserve just for the Emergency Supply Program. Through the program, Gamunex® is provided on a first-come, first-served basis to patients in emergency situations. We have never come close to exhausting our emergency supply. This suggests that the nature of the access issues is not supply, but reimbursement, related.

Further, as noted above, Talecris has approached pricing issues with restraint and a sincere interest in limiting price increases. Our price increases have been quite limited despite increased production costs, significant investments in additional manufacturing capacity, and large investments in producing a new IVIG product, which we believe has clinical advantages. Again, since 2000, Talecris has *not* increased prices at a rate that keeps pace with the rate of inflation, as determined by the Consumer Price Index-Urban. To date we have taken just 15 percent in total price increases over the last 5 years.

We are committed to ensuring access to this life-saving therapy. Accordingly, we continue to take reports of IVIG access issues seriously, and we are committed to working openly with the subcommittee to ensure adequate access to IVIG therapies for the thousands of Medicare beneficiaries who rely on this important therapy.

III. Proposed Solutions

Talecris is committed to a long-term solution for IVIG access. We understand how challenging the current market environment is for the IVIG community, and we plan to continue delivering on our commitment to do everything possible to meet the needs of IVIG patients. We ask Congress to urge CMS to do the same by (1) issuing separate HCPCS codes to IVIG products and (2) increasing the payment for administration services.

A. Issuing Separate HCPCS Codes to IVIG Different Products

CMS calculates the ASP for drugs based in part on what HCPCS code those drugs are assigned to using the standardized coding system utilized for outpatient billing. Each quarter CMS computes an ASP for each HCPCS code typically based on the volume-weighted average of the applicable manufacturer's average sales prices. Where there is only one product in a HCPCS code, which is the case for the vast majority of drugs, ASP is equal to the price of that product's manufacturer reported ASP. This system generally makes ASP predictable and the resulting reimbursement stable and consistent with acquisition prices. This is, we believe, exactly what Congress intended when it mandated ASP as a methodology.

Unfortunately, because all of the IVIG products are treated as multiple source products by CMS, notwithstanding that they are not in any way bioequivalent, IVIG ASP reimbursement is based on the weighted average of the ASPs of multiple IVIG products. *Accordingly, this necessarily means that some IVIG products will have reimbursements that are based on a class ASP that is below the product's actual ASP. The inevitable consequence of this, we believe, is that there will be situations where a Medicare provider is forced to provide critically necessary IVIG services at a reimbursement rate that is below the provider's acquisition cost.*

CMS normally groups only products into one HCPCS code when the affected products are rated therapeutically equivalent, pharmaceutically equivalent and bioequivalent by the Food and Drug Administration ("FDA"). The IVIG products, however, are *not* therapeutically equivalent, pharmaceutically equivalent or bioequivalent, as we have indicated above. There is no debate about this critical point.

IVIG products differ in terms of the amount of sugar, osmolality, volume, sucrose, immunoglobulin A, and pH. In addition, products differ according to donor pools, manufacturing process, and final product formulation. These differences provide the clinical basis for physicians to prescribe specific brands of IVIG. When a patient is administered a brand that is not appropriate for him or her, problems can arise. This is particularly true for patients with diabetes, congestive heart failure, and compromised renal function, among other conditions.

Fortunately, CMS has the authority to code and reimburse all IVIG products separately. We believe that this change is integral to solving the IVIG access issue, and we believe it is entirely consistent with the ASP methodology. We ask only that IVIG products be treated like the vast majority of other drugs and the way that any unique, distinct product should be treated.

B. Increasing the Payment for Administration Services

In addition to the coding problem, we believe that IVIG access is also compromised due to inadequate reimbursement for administration services. Where some have suggested that the ASP multiplier should be increased above 106 percent to address this issue, we do not support this option, because we do not believe that it is consistent with the ASP methodology.

However, the MMA, in decreasing drug reimbursement, did contemplate that administration service reimbursement could and should be altered where additional administration reimbursement was shown to be necessary. We ask that CMS do only what Congress contemplated as part of its consideration of the MMA. We ask that CMS review the extraordinary costs inherent in the administration of IVIG and make all appropriate adjustments that are supported by the evidence presented.

The safe and effective administration of IVIG is extremely complex. We understand that the infusion times for IVIG range from 2 to 8 hours. A nurse to patient ratio is set at 1:1, with immediate availability of a physician for assessment of potential complications. In addition to a physician's evaluation of a patient, the administration service includes the complete evaluation of vital signs and neurological status by a highly trained infusion nurse, pre-medication by an infusion nurse, and complete assessment of vital signs and neurological status every 15 minutes. To account for all of these factors, we support an increase in the payment for administration services.

CMS has the authority to make this increase without Congressional action. We urge them to act accordingly.

IV. Commitment to Long-term Solution

One of the most important aspects of a solution to the IVIG access issue is a long-term commitment by Congress and CMS to keep a constant methodology in place for IVIG reimbursement.

Various factors make a stable market critical to the decision to invest in increased production. The manufacture of IVIG includes more than 400 steps from pooling through fractionation, purification, inspection, and packaging. To ensure additional investment in IVIG capacity to meet the increasing demand for this life-saving therapy, predictable demand and long lead times are required because the manufacture of IVIG takes approximately 8 months from plasma collection at a donor center to lot release, and purchase commitments for raw plasma must be made 1–2 years in advance. Furthermore, in order to ensure compliance and regulatory approval, manufacturers must allow up to 5 years to expand production facilities and modify processes.

Talecris may not continue to make additional investments to increase IVIG production in an environment where reimbursement is uncertain or subject to change. We fear that a number of the temporary or emergency solutions being discussed will only

add to unpredictability of the marketplace, having the unintended result of discouraging future investments by manufacturers, like Talecris.

We understand that CMS may be contemplating a National Coverage Determination (“NCD”) restricting the coverage of IVIG. We feel compelled to call your attention to the significant number of Medicare beneficiaries who could be negatively impacted by a NCD. We are concerned that CMS may be attempting to address what are predominately reimbursement issues by limiting coverage. Unfortunately, because it would likely take a year or more for an NCD to evaluate the various uses of IVIG, the inevitable consequence of an NCD will be to interject tremendous uncertainty into the IVIG marketplace that may prevent Talecris and other manufacturers from making the additional investments in production capacity that are so clearly needed.

We appreciate that CMS has some questions about the level of evidence supporting some uses of IVIG. Accordingly, we support the further use of the local coverage determination process to address any such issues, but we believe that these decisions should be made by the carriers in a manner that will permit local standards of practice to be fully considered and where the process for review can be quicker than it could, in connection with this product, through an NCD process. The local coverage process is the process that has generally determined IVIG coverage in the past and it should continue to be the process used in the future.

Many immunocompromised patients rely on this essential therapy to treat and prevent fatal infections. Accordingly, we ask you to urge CMS to proceed with caution as it considers coverage issues and to weigh heavily the long-term implications of restricting the coverage of an often life-saving therapy in a precipitous manner through a “one size fits all” NCD.

We are sensitive to the complicated nature of the IVIG issue, and we continue to look forward to the results of the on-going Office of the Inspector General (“OIG”) study of IVIG access. *Talecris was pleased to meet with the OIG last year and assist with its survey. In responding to the survey questions, however, it became clear to us that the study contained a number of design flaws, which may compromise the results and diminish the OIG’s ability to compare data accurately and ultimately the aggregate value to the information assembled.* As the date of the release of the report is extended, we also have concerns about whether the data collected is still relevant.

In addition, we have some concerns about the limited scope of the parties surveyed. We believe that a complete picture of the IVIG marketplace includes not only manufacturers and distributors, but also a robust sample of hospital outpatient departments, group purchasing organizations, physicians, and patient advocates. Broad participation and comment are key to an accurate report. We have encouraged the OIG to work with all of the key stakeholders involved, but we do not believe that OIG has fully adopted our and others’ suggestions in this regard.

V. Conclusion

Talecris thanks you again for this opportunity to provide input to your review of Medicare reimbursement of physician-administered drugs, specifically the impact of ASP reimbursement on the pricing and availability of IVIG therapy. We respectfully ask Congress to urge CMS to facilitate beneficiary access to IVIG by (1) issuing separate HCPCS codes to IVIG products and (2) increasing the payment for administration services. We strongly urge you to consider the lasting policy implications of Congressional and administrative decisions as CMS negotiates the delicate balance between appropriate reimbursement and access to care. We hope that Congress will urge CMS to exercise restraint in considering any number of policy options that could negatively impact the long-term sustainability of access to IVIG within the United States, such as a precipitous NCD process. As the subcommittee continues to review this issue, we welcome the opportunity to provide additional information.

U.S. Oncology
July 13, 2006

The Honorable Nancy Johnson
Chair, Subcommittee on Health
Committee on Ways & Means
U.S. House of Representatives

Dear Congresswoman Johnson,

U.S. Oncology is pleased to submit this testimony for the record for the Committee on Ways & Means Health Subcommittee Hearing scheduled for July 13, 2006 on Medicare Reimbursement of Physician-Administered Drugs.

U.S. Oncology, headquartered in Houston, Texas, is one of the nation's largest community cancer treatment and research networks. U.S. Oncology provides extensive services and support to its affiliated cancer care sites to help develop the most advanced treatments and technologies, build integrated community-based cancer care centers, improve therapeutic drug management programs and participate in many of the new cancer-related clinical research studies. The network consists of nearly 1000 physicians, based at over 450 service sites in 34 states. U.S. Oncology serves as a strong advocate for community-based cancer care providers, at whose offices approximately 83.4 percent of all cancer treatment encounters occur in the United States.

Over the past several years, U.S. Oncology and community cancer care providers have advocated for a balanced and sustainable reform of the Medicare reimbursement structure for physician-administered drugs with the goal of preserving and strengthening Medicare beneficiary access to cancer care services. U.S. Oncology shared the general concern with the prior system used to pay for chemotherapy drugs and related drug infusion services: overpayment on drugs was used to subsidize underpayment on drug administration services.

The Prescription Drug, Improvement and Modernization Act of 2003 (MMA) replaced the flawed system with a new payment structure Congress intended to more accurately match reimbursement for cancer-fighting drugs and the delivery of those drugs to the costs of providing those services. However, in several key areas, the implementation of the MMA changes to reimbursement of physician-administered drugs has failed to meet Congressional intent of fair and adequate reimbursement.

Prompt Pay Discount

Prompt pay discounts are discounts typically offered by pharmaceutical manufacturers to pharmaceutical distributors on direct sales of prescription drugs. Wholesalers typically do not share manufacturer's prompt pay discounts with providers. Direct sales by manufacturers are made to full-service or specialty distributors that buy in bulk, consolidate orders and make just-in-time deliveries to providers across broad geographical areas. The prompt pay discount compensates wholesalers for the time-value of money and the assumption of credit risk associated with sales to downstream purchasers.

Prompt pay discounts offered to distributors and not passed on to providers are typically around two (2) percent of the sales price. According to the Healthcare Distribution Management Association, the net profit margin for full-service healthcare distributors is about 0.75%. A significant part of a wholesaler's margin comes from manufacturer to wholesaler prompt pay discounts.

Congress intended under the MMA for ASP to match providers' acquisition costs. However, CMS has netted a 2% distributor prompt pay discount out of ASP calculations even though the discount is not received by providers. As a result, the CMS-computed starting point for ASP of a drug that costs \$100 when purchased by a physician practice is actually only \$98, or 98% of the provider's cost to purchase the drug. When wholesaler prompt pay discounts are netted out of ASP, Part B reimbursement to physicians and pharmacies is effectively reduced by 2% to provider cost+4%.

In recognition of the role that prompt pay discounts play in wholesaler compensation, Congress excluded customary prompt pay discounts extended to wholesalers when it redefined Average Manufacturer Price (AMP) under the Deficit Reduction Act of FY 2006. The redefined AMP will be used by the Medicaid program as a metric both for retail pharmacy reimbursement and Medicaid rebate calculations.

U.S. Oncology strongly urges Congress to apply the same formula to the Average Sales Price (ASP) metric used to compensate physicians and pharmacies for drugs reimbursed by Medicare Part B as physicians and pharmacies cannot buy these drugs at prices net of customary wholesaler prompt pay discounts. Removing customary prompt pay discounts to wholesalers from the ASP calculation under Medicare Part B would:

1. Make ASP more reflective of pricing actually available in the marketplace to the physicians and pharmacies that buy and administer or dispense Part B drugs;
2. Better align manufacturer's calculation methodologies for ASP and AMP, thus simplifying manufacturers' price reporting burden; and
3. Ensure consistency in the way prompt pay discounts are handled in the calculation of the reimbursement metrics that determine government payments to

pharmacies that dispense outpatient drugs regardless of whether Medicaid or Medicare Part B is the government payer.

Removing customary prompt pay discounts to wholesalers from the ASP calculation under Medicare Part B would better reflect the Congressional intent behind the ASP payment methodology. As noted above, a key objective of MMA was to match reimbursement for Part B drugs with the drugs' actual acquisition costs in the market. Subtracting customary wholesaler prompt pay discounts when ASP is calculated artificially distances reimbursement from cost and is inconsistent with the Congress' intent to ensure patient access to higher cost drugs in hard-to-serve areas.

Two-Quarter Lag

Currently, there is a six-month, or two-quarter, lag between manufacturer reporting and updating of ASP for physician reimbursement under Medicare Part B. The practical implication of this two-quarter lag is that a provider's drug cost increase experienced today will not be recognized by CMS for six months.

Approximately 90% of oncology drug expenditures are made for single source drugs, which leaves manufacturers little incentive to reduce drug prices over time. For some commonly prescribed and expensive, single source cancer drugs and certain other injected or infused products that are standard of care, ASP has been rising rapidly, frequently on a quarterly basis. Examples include 4.3% and 2.6% increases in Aloxi and Eloxatin ASP values, respectively, between 2q06 and 3q06.

The two-quarter lag means the effective payment for drugs with rapidly rising prices can be below current acquisition cost, not ASP+6%, exclusive of the prompt pay discount reduction and other issues. The reverse is true when prices are falling, as can happen when an innovator drug comes off patent.

U.S. Oncology believes that in a rapidly changing market, reducing the lag time between the reporting and use of ASP would better align reimbursement with physician acquisition costs. We urge the Committee to work with the cancer care community to develop a system that ties physician reimbursement to monthly ASP reports as opposed to quarterly ASP reports. Manufacturers must begin reporting AMP monthly as of Jan. 1, 2007 under the DRA. Simultaneously requiring monthly ASP reporting beginning Jan. 1, 2007 could effectively reduce the lag between ASP reports and physician payments by 2–3 months beginning in the third quarter of 2007.

If the lag time were materially reduced, providers would experience fewer cash flow dislocations due to rising ASP. For the same reasons, Medicare would benefit more quickly when prices are falling.

Medicare Bad Debt

When taken in combination, netting out wholesaler prompt pay discounts and the two-quarter lag result in effective reimbursement for physicians of provider cost plus 2% assuming all allowable costs can be collected by the provider. Our historical experience has been that approximately 25% of Medicare's 20% patient co-insurance is uncollectible bad debt. Medicare bad debt results in an additional loss equating to approximately 5% of Medicare allowable costs and drives the actual reimbursement received by community cancer care providers for drugs provided to Medicare beneficiaries down to three percent below provider cost on average.

The Medicare bad debt faced by community cancer care providers is primarily attributable to uncollectible patient co-insurance of Medicare beneficiaries who cannot afford or choose not to purchase secondary insurance. With the patient co-insurance portion of many drug regimens costing thousands of dollars, a large portion of Medicare beneficiaries without secondary insurance will never be able to pay any more than a trivial portion of their co-insurance. As the Committee considers the effects of the Prompt Pay Discount and the Two Quarter Lag discussed above, it is important to recognize the reality that Medicare makes no provision for the bad debt experienced by community cancer care providers. This reality will continue to negatively impact patient access to quality care.

Adopting and adjusting these provisions would lead to a reimbursement that would be more consistent with the 6% of ASP cushion Congress intended to ensure patient access and protect rural physicians from underpayments because reimbursement based on monthly ASPs would reflect more current pricing.

Drug Administration Services

U.S. Oncology does not believe that drug reimbursement and the transition to an ASP-based reimbursement structure are properly viewed in the absence of a discussion of reimbursement for the administration of the same drugs to Medicare beneficiaries. U.S. Oncology remains extremely concerned about the underpayment of drug administration services under both the current and proposed Physician Fee Schedule Practice Expense methodologies.

MMA established a framework and direction to CMS to fully cover drug administration practice expenses that were previously covered through drug product payments. Congress recognized the inadequate drug administration payment system by creating drug administration transition payments (32% add-on in 2004 and 3% add-on in 2005) to allow CMS time to build in these new payments into the practice expense reimbursement system.

Additionally, Congress created a budget neutrality waiver for CMS, extending through 2006, to ensure that these new practice expense reimbursements necessary to cover the costs of drug administration would not adversely impact other specialties.

Despite clear intent of Congress through MMA to more accurately match practice drug acquisition and drug administration reimbursement with the costs of providing those services, our practices have experienced practice expense reimbursements that have declined by 20% since 2004 and CMS recently proposed a new Practice Expense methodology that will further exacerbate the under funding of drug administration services in 2007 and beyond.

Medicare currently reimburses less than 60% of practice drug administration costs even for the mythical provider who collects 100% of the patient co-insurance. U.S. Oncology's analysis indicates that community cancer care providers are paid more than \$900 below the cost of drug administration for **each** Medicare beneficiary and this underpayment rises to nearly \$1000 below cost net of bad debt.

Please see **Exhibit A—U.S. Oncology Comments Regarding Practice Expense Methodology Submitted to CMS March 28, 2006**—for further detail relating to continuing underpayment of drug administration services.

Competitive Acquisition Program (CAP)

In December of 2005, U.S. Oncology informed CMS that it would not participate as a vendor in the Competitive Acquisition Program (CAP) due to continuing concerns about the potential negative impact the program may have on the ability of the cancer care community to deliver high-quality cancer care services to patients in a safe and cost-effective manner. Subsequent developments have strengthened our belief that CAP is fatally flawed for both vendor and physician and does not constitute a realistic or viable alternative to the reimbursement challenges facing community cancer care providers.

Please see **Exhibit B—U.S. Oncology Comments Regarding the Competitive Acquisition Program (CAP) Submitted to CMS December 22, 2005**—for further detail relating to problems with CAP.

Thank you for the opportunity to provide this written testimony for inclusion in the Committee Record. U.S. Oncology looks forward to working with the Committee to construct an adequate and sustainable reimbursement system that appropriately values the needed and life-saving services provided to Medicare beneficiaries by the cancer care community.

Sincerely,

Dan Cohen
Senior Vice President

West Michigan Regional Cancer and Blood Center
Free Soil, Michigan 49411
July 18, 2006

I would like to add my comments to The Ways & Means Health Subcommittee on the subject of Medicare Reimbursement for Physician Administered Drugs. As a medical oncologist practicing in a community cancer center in rural northern Michigan, I have experienced firsthand the devastating effects caused by the change in the formula for calculating Medicare reimbursement for treatment provided at our cancer center.

Currently, of the 61 drugs that we routinely use, our profit margin on 38 of them is less than 6%, which was not the premise of the ASP+6% calculation. Additionally, because we are located in a rural area, our surrounding community hospitals are small and refuse to treat our patients at their facilities, citing that their staffs are untrained in oncology administration and that the cost of providing oncology services would cause an unsustainable financial burden.

Because of these issues, there are drugs that I must discontinue using in my practice, due to the severe negative financial impact. Sandostatin, for example, which is approved by Medicare for chemotherapy-induced diarrhea, costs me \$2603.09 per dose. We bill Medicare and four weeks later receive 80% of the ASP+6%, which

amounts to \$2082.47. Until we receive the co-pay from the patient, or from their supplemental insurance, we are “underwater” by \$520.62.

Another example is the use of Rituxan, a monoclonal antibody routinely used to treat and cure lymphoma. The average dose of Rituxan costs me \$3726.00 and I get reimbursed 80% of the ASP+6%, which is \$2980.00 per dose. Again, I carry the financial burden of the 20% (\$746) while waiting for secondary insurance or patient payment. It doesn't take long for these underpayments to add up and cripple my financial viability.

The true absurdity of the situation is that while these drugs can reduce hospital admissions, morbidity and mortality rates, I am forced to use alternatives for these drugs, even when they are suboptimal. Ultimately, the patient suffers and Medicare often pays more due to hospital admission and extended illness.

The above examples are just two of the 38 drugs that are not adequately reimbursed by Medicare. Changes must be made to compensate for this deficit in reimbursement for drugs, whether it is increasing chemotherapy administration payment or providing reimbursement for the other costs of administering treatment.

There are many costs related to providing chemotherapy services that are not compensated, for example pharmacy costs, which include procurement of the drugs, secure storage and inventory control, treatment preparation, and pharmaceutical spoilage or wastage.

I trust that you understand the ramifications these reimbursement reductions have on our patients, your constituents, and that you will move swiftly to correct these inadequacies.

Thank you for your attention to this important issue. If I can be of further service and provide additional information from a rural cancer center perspective, please do not hesitate to contact me.

Sincerely,

A. Soliman Behairy, MD

Western Washington Medical Group
Departments of Hematology & Medical Oncology
July 17, 2006

Committee Members;

I would like to take this time to explain how very difficult it is becoming for our office to provide good quality cancer care to our Medicare/Medicaid patients. Due to the ASP methodology, in the second quarter of 2006, I was buying 12 drugs for more than CMS allows for reimbursement. I do not have a concise total as of yet for the third quarter because I am still getting many price increases from pharmaceutical companies, but I assume it will be similar. In order to obtain the best pricing I can, I pay for our drugs through direct debit the day I receive them, causing a financial hardship to our practice when we have not yet had time to be reimbursed for those drugs. I also shop around to find the best prices through a variety of oncology specific vendors, of which I might add, takes too much of my time. On other drugs, we might get reimbursed \$.01 more than we pay, so as you can see, we are certainly not covered for our cost of storage or for bad debt.

We are not adequately reimbursed for the special space we are required to have in our office to safely store and mix these toxic drugs or for the specialized personnel it takes to administer these drugs.

We have had to resort to sending some patients to the hospital for treatment and have not found this very optimal as we find the hospital personnel are not as proactive in assuring the patient has all that they need in the way of take home drugs and/or prescriptions necessary in the event they should have some common side effects.

Due to Part D, those patients that are in a low income level, that qualified for assistance through the pharmaceutical companies for their oral agent treatments, are no longer eligible and consequently some have chosen not to be treated.

In all, we feel we are working harder and taking more financial risk to care for this group of patients and are reimbursed less, to the point of jeopardizing our practice, of which 45% is Medicare and 5% is Medicaid. Especially when you consider that some commercial payors are trying to emulate the ASP system.

We have considered CAP, but in analyzing all that would be entailed in that program, we found it to be even less of an option.

These physicians, as I am sure is true of most Oncologists, became Oncologists in order to help these patients who are fighting for their lives, but today they find themselves having to weigh the financial reality of caring for these very patients.

We sincerely hope that you will find some way to alleviate the hardship MMA has put upon us as well as our patients and rectify these issues.

Respectfully,

Julie MacDougall
Practice Administrator

Community Oncology Alliance
July 17, 2006

The Honorable Nancy Johnson
Chairwoman, House Ways and Means Subcommittee on Health
U.S. House of Representatives
2113 Rayburn HOB
Washington, D.C. 20515-0521

Dear Madam Chairman:

For the record, I am submitting this written testimony on behalf of the Community Oncology Alliance (COA) and to supplement my testimony before the Ways and Means Subcommittee on Health at the hearing on July 13th.

I would like to clarify my misunderstanding and incorrect answer relating to a question you asked me concerning CMS using oncology data.

For the record, from the official transcript just released you asked the following question:

REP. JOHNSON: How do you respond to CMS's comment that they used your survey data and your survey data included the cost of pharmacy?

To this question, I responded:

DR. SCHNELL: We have sent them our data and have—effectively approximately three months ago and have had no response. I gather that's not an isolated experience after sitting through this.

Unfortunately, I was referring to analyses that we supplied to CMS relating to the coding of certain cancer treatment regimens, which show that on the treatment level services reimbursement has decreased from 2004 to 2006. What I did not understand is that you were asking me if it is correct if CMS used oncology survey data, specifically in capturing the cost of pharmacy-related expenses.

Yes, in a manner that we cannot determine, CMS has used 2001 data provided in 2002 by the American Society of Clinical Oncology (ASCO). Unfortunately, we have maintained to both ASCO and CMS that this data was fundamentally flawed and is now outdated. In summary,

- data was collected at the oncologist level (and only from oncologists who were “full or part owners” of their medical practice) not at the practice level, thus making it virtually impossible to accurately capture all practice/clinic expenses;
- only 8 data elements (i.e., practice expense dollar amounts) were collected (*see Exhibit A in the enclosed document*) making it impossible to attribute expenses to specific services such as treatment planning and pharmacy facilities;
- much of the data, including high dollar expense items, were seemingly arbitrarily discarded by CMS, thus decreasing total practice expenses attributed to oncology; and
- the practice expense data from 2001 is now obsolete, especially given treatment advances and reimbursement changes over the past 5 years, which have increased expenses.

We have attached a brief background piece on this that provides more detailed information on why “the oncologists’ own data” is not valid and reflective of actual community oncology practice.

We suggest that it would be very helpful if CMS could provide information on “unbundling” some of the most frequently used drug administration codes. Let me explain. We constantly hear the argument that all expenses for essential services we provide are “bundled” together and therefore paid under the most common billing codes we use. However, we are not able to obtain a breakdown, or “unbundling,” for these codes from CMS. We would appreciate help in obtaining this information from CMS. This will then allow us to compare these component expenses, and the corresponding “unbundled” reimbursement, with actual practice costs.

Regardless of this “bundling” issue, in the spirit of paying appropriately for drugs and specific services, we believe that there should be separate payment codes for drug administration, treatment planning, and pharmacy facilities, in addition to the evaluation and management (E&M) codes used by all medical specialties. CMS could easily accomplish this administratively, as we believed this was supposed to happen per the Medicare Modernization Act of 2003.

I trust that this clarifies my response to your questions.

Sincerely,

Frederick M. Schnell, MD, FACP
President

Analysis of the ASCO/Gallup/Lewin Oncology Survey Data Used by CMS
Prepared for Congresswoman Nancy Johnson

SUMMARY:

Data was collected by the Gallup Organization on behalf of the American Society of Clinical Oncology (ASCO), submitted to CMS, and analyzed by the Lewin Group. This is “the oncologists’ own data” that CMS references as being used in justifying the current level of reimbursement for all services provided by community oncologists. There are fundamental flaws with the way the data was collected, the way it was analyzed, and the conclusions drawn from it. The specific problems are summarized as follows:

- Data was collected at the individual oncologist level and not at the medical practice level; that is, the data could only be submitted for full—or part-time physician owners of the practice as opposed to all other physicians, nurse practitioners, oncology nurses, and staff that composed the entire community oncology clinic. Given the comprehensive nature of community oncology clinics, even the smallest clinics, it is extremely difficult, if not impossible to attribute expenses to an individual oncologist. This approach will result in artificially lower practice expenses.
- The actual practice expense data captured is attached as Exhibit A. Only 8 practice expense dollar amounts were collected via phone survey. This made it impossible to value any costs relating to specific functions such as treatment planning and pharmacy facilities. At best, the data could be used in a collective manner to attribute some practice expense component to the drug administration codes.
- The calculation of hours Lewin made about the time oncologists spend in direct patient care is inordinately high. This resulted in lower expenses attributed per hour (because the hour denominator was artificially high) and, therefore, resulted in lower total practice expenses.
- It is impossible to ascertain if the final data accepted by CMS is representative of actual community oncology. Lewin even questions the representative nature of the sample given the low survey response rate. Furthermore, it appears that data outliers were arbitrarily excluded from the final data accepted.
- There was great concern expressed by CMS over high “clerical” salaries. The data and cost from larger practices that employ more highly compensated administrators, CEOs, CFOs, etc., were therefore excluded from the survey thus giving an unfair representation of salary cost across the board from smaller to larger clinics.
- The data used is from 2001 and is therefore obsolete. This information is prior to the availability of newer treatment protocols and changes to Medicare reimbursement for cancer care.

What follows are specific facts and problems associated with this data being used in any way by CMS to draw accurate conclusions about appropriate levels of services reimbursement.

FACTS:

The Gallup Organization, which was contracted by ASCO to collect community oncology practice expense data, started with the AMA MasterFile of 5,574 oncologists. Out of the 5,574, Gallup attempted to contact 2,356 oncologists. Out of the 2,356, there were 999 responses collected by Gallup and submitted to CMS. The Lewin Group, which was contracted by CMS to analyze the data (see Recommendations Regarding Supplemental Practice Expense Data Submitted for 2003, Centers for Medicare and Medicaid Services, #500-95-0059/TO#6, September 17, 2002) eliminated 416 responses because these were responses from oncologists that were not

owners of their practice. CMS edits eliminated an additional 338 responses leaving a usable sample of only 245 physician responses.

PROBLEMS:

- The AMA MasterFile clearly does not include all of the office-based oncologists in the United States. There is no way of knowing how representative the AMA MasterFile is in terms of office-based community oncology practice. *With the elimination of data, there is no way of knowing how representative the 245 physician responses are of nationwide community oncology practice.*
- *Lewin questioned if the final sample was indeed representative* (“This low response rate may indicate that the responses are not representative of the population of oncologists.”).
- *The 245 responses represent individual physicians, not necessarily individual practices. We know of instances where two or more physician owners from the same practice submitted data.*

FACTS:

The survey was at the physician level, not at the practice level. Only individual oncologists who are owners of their practice were eligible to submit data for their “share” of practice expenses. Oncologists who are not owners were excluded from the survey. The survey requested only 8 data elements of practice expenses (see Exhibit A).

PROBLEMS:

- There are numerous problems associated with determining the oncologist’s “share” of practice expenses, especially specific to the oncologist who is a partial and/or full “owner” of the practice. Is the “share” what the oncologist is legally liable for as a shareholder or is his/her “share” the amount of expense attributable to his/her particular practice from an accounting standpoint? We polled clinic practice administrators who responded to the survey and the interpretation varies. It is virtually impossible to assume that the data was consistent and representative of total practice expenses.
- No data were collected relating to specific functions performed by the oncologists, nurses, or staff or to specific components of overhead. Therefore, it is impossible to draw any conclusions about expenses attributed to such specific components of care such as treatment planning or pharmacy facilities.

FACTS:

CMS disputed and originally rejected the ASCO data as too high because the salaries reported for “clerical” personnel were calculated as being higher than that for “clinical” personnel. Lewin reports that the average clerical person makes \$87,253 per year and the average clinical person makes \$71,014 per year. Lewin questions the accuracy of the abnormally high clerical salaries.

PROBLEMS:

- In the data collected, there was only one question pertaining to the salaries of “administrative, secretarial, or clerical” personnel. Yet, because community oncology practices function more as clinics than simple physician offices, they typically have more experienced practice administrators and related staff (CEOs, COOs, CFOs, etc.). It appears that either data was eliminated or adjusted, thus artificially lowering overall practice expenses.