MEDICARE PROGRAM EFFICIENCY AND INTEGRITY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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MEDICARE PROGRAM EFFICIENCY AND INTEGRITY

WEDNESDAY, APRIL 18, 2007

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

The subcommittee met, pursuant to call, at 2:35 p.m., in room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. (chairman) presiding.

Members present: Representatives Green, DeGette, Capps, Allen, Schakowsky, Solis, Hooley, Matheson, Deal, Cubin, Pitts, Murphy, Burgess, Blackburn and Barton.

Staff present: Erin Bzymek, Yvette Fontenot, Brin Frazier, Amy Hall, Christie Houlihan, Bridgett Taylor, Robert Clark, and Kristine Blackwood.

OPENING STATEMENT OF HON. FRANK PALLONE, JR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. I want to call this meeting to order.

Today we are having a hearing on "Medicare Program Efficiency and Integrity." I will recognize myself for an opening statement initially.

Since it was enacted, the Medicare Program has been a reliable source of health care for our Nation's seniors and disabled and it goes without saying that if it were not for the Medicare Program, some of our most vulnerable populations would have little, if any, way to access important medical care. Accordingly, we must make every effort to ensure that the Medicare Program remains intact and available for future generations who will undoubtedly come to rely upon its services, and part of our efforts must focus on ensuring that all of Medicare's payment policies are both fair and efficient. Currently, I don't believe that is the case. It should come as no surprise to anyone that many of us in Congress have strong concerns about payments to Medicare Advantage plans.

I have to admit, I am perplexed by the disparity in payments between these private plans and traditional Medicare. It makes little sense to me why Medicare payments for Medicare Advantage enrollees are on average 12 percent higher than what Medicare pays for beneficiaries enrolled in traditional Medicare. It flies in the face of the intent behind the program as I believe MedPAC, which has done substantial work in this area, will attest to later today. These excessive payments are wasteful and result in unnecessary costs

for the program as well as for its beneficiaries and the American taxpayers, and some of my good friends I assume on the other side of the aisle are going to argue that the Medicare Advantage Program provides value to the Medicare Program in the form of greater savings and enhanced benefits for enrollees but it seems to me that no matter how you try to sell it, it is just lipstick on a pig. The evidence just isn't there to back up these assertions.

The Medicare Advantage program is not the only area in which we would likely achieve greater value out of Medicare dollars we spend. I am looking forward to hearing from our witnesses today on what other areas we should focus our attention on improving payment efficiency within the Medicare Program.

But I do believe that eliminating overpayments and improper payments will only go so far. There is another side to this coin that involves ensuring the integrity of the Medicare Program. I admit my concern about ensuring Medicare Program integrity is somewhat parochial. This past year there were a couple of instances in my home State of New Jersey where providers were accused of improper billing which may have cost the Medicare and Medicaid programs hundreds of millions of dollars. In the first instance, the University of Medicine and Dentistry of New Jersey, UMDNJ, which is the Nation's largest health science university, overcharged Medicare and Medicaid to the tune of at least $4.9 million. Millions more could be owed. It was revealed by a Federal probe that the university was improperly billing for services at its outpatient clinics. As a result, the university could have been prosecuted, which would have made it ineligible for Federal funding and would have effectively shut down one of the largest health care providers in the State. Now, fortunately, this did not happen. In another instance last year, it was revealed that St. Barnabas Health Systems, which is the largest health care provider in the State of New Jersey, settled allegations that it inflated charges under the Medicare outlier payment system, which reimburses providers for patients whose costs are unusually high due to serious illnesses. Under this agreement, St. Barnabas has agreed to pay back $265 million.

It is important to note that the improper behavior is not all about the monetary cost to Medicare, it is about access as well. I think it is clear that when the integrity of the Medicare Program or participating providers are called into question, beneficiaries' access to care in jeopardized. In New Jersey, for example, if UMDNJ were forced to close, many low-income and elderly who rely upon the university for treatment services would have had nowhere else to turn.

That is why I think it is so important that we take the issue of Medicare Program integrity seriously. I will be interested to hear from our witnesses from both the Department of Health and Human Services Office of the Inspector General and the Department of Justice as to what steps they are taking to prevent similar circumstances from happening again. Needless to say, today's hearing is very critical. We have a responsibility to ensure the preservation of the Medicare Program for our Nation's seniors and disabled.

I would like to thank all of our witnesses for being here today. I look forward to your testimony. Obviously what you say is going

to be very important to what we do in the next few weeks, and thank you again for being here.

I now recognize our ranking member, Mr. Deal.

Mr. DEAL. Thank you.

OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

I think we all know that Medicare is a program that services about 44 million beneficiaries and costs about $450 billion. In a program of this size and importance, it is obviously vital that this committee maintain vigilant oversight to ensure that beneficiaries are being provided with high-quality health services and that the taxpayers are protected from funding fraud or abuse. During my tenure in Congress, we have certainly found areas in the program in need of reform and also tried to make changes to the program to help contain the exponential cost growth. Without reform, the projected growth of the program threatens Medicare solvency into the future absent a significant cost increase to the taxpayers. The efficiency of Medicare is important to ensure beneficiaries receive appropriate high-quality health care and that taxpayers and beneficiaries receive the maximum benefit from their dollars.

One area of inefficiency which has always been a concern for me is the area of imaging. MedPAC's March payment policy report summarized the problem well by stating, and I quote, "We have observed rapid and sustained growth in the volume of imaging services for Medicare beneficiaries which has led to concerns about quality and patient safety and potential overuse of imaging services." The volume of imaging services per Medicare beneficiary experienced a dramatic 9 percent growth in 2005. In a 2006 survey, 19 percent of physicians reported that their practice expanded imaging services in the last year. Additionally, MedPAC reports that the average annual growth and the volume of imaging services per beneficiary between 2000 and 2004 was 10.3 percent with the most dramatic growth occurring in MRI services. This kind of growth has been coupled with mounting concern about overutilization of imaging services and self-referrals.

A case being prosecuted by the Illinois attorney general highlights this very well. The attorney general contends that more than 20 Chicago-area radiology centers engaged in a widespread scheme to win referrals for MRIs by paying illegal kickbacks to doctors. Cases like this highlight the need for close scrutiny into the area of imaging to ensure fraud and abuse are not one of the contributing factors to volume growth.

It is my belief that the payment reductions made in the Deficit Reduction Act were a blunt instrument to address the imaging issue, and I hope the committee will take a more thorough look at this area to craft an imaging policy that prevents both overutilization and protects patients from receiving needless and potentially harmful scans.

I am sure today's witnesses will call attention to other areas within the Medicare Program in need of reform to ensure the program's effectiveness into the future. It is important that we continue to reform the Medicare Programs and ways to focus on providing beneficiaries with continued high-quality health services.

Hearings like this also highlight that despite our best efforts, there are some inherent weaknesses in Government-provided health care. Recognizing this, I hope the committee will look beyond Government provision of health care to broad-based patient-focused reforms which would improve health care delivery in both the public and he private markets.

I thank our witnesses for appearing today and I look forward to your testimony.

I yield back the balance of my time.

Mr. PALLONE. Thank you.

Next I would recognize our vice chair, Mr. Green, for 5 minutes.

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

Mr. GREEN. Thank you, Mr. Chairman, for holding this hearing on efficiency and integrity of the Medicare Program. I know the subcommittee is working hard to determine the best way to reform the physician payment under Medicare, and this hearing will provide us with important information on how we seek to accomplish that goal. The harsh budget realities dictate that any effort to reform this would have to be accompanied by increased efficiency within the Medicare Program and continued commitment to ensuring the integrity of the program.

I am pleased to see that MedPAC continues to press for care coordination and increased efficiency within Medicare. There is no question that care coordination would facilitate better health care outcomes for Medicare beneficiaries. A study published last year by Health Affairs concluded that nearly 20 million Medicare beneficiaries, or 50 percent of the beneficiary population, have five or more required medical treatments. We also know that 20 percent of the Medicare population has five or more chronic conditions and these beneficiaries account for two-thirds of all Medicare spending. Care coordination for these beneficiaries with multiple chronic conditions would improve efficiency within the Medicare Program and improve health outcomes for those beneficiaries who too often receive conflicting information and duplicative services from providers addressing different health care needs.

To address this issue, we are putting finishing touches on legislation that would provide a geriatric assessment and chronic care coordination benefit under Medicare part B. Under the bill, the high cost Medicare beneficiaries with multiple chronic conditions will be eligible to participate in a new voluntary care coordination benefit. A chronic care manager of the beneficiary's choosing would implement a care coordination plan with the beneficiary's other providers who would utilize clinical decision support, health information technology, medication management techniques and beneficiary education to ensure that the most appropriate health care is delivered with consideration given to the full range of the beneficiary's health condition. This legislation offers us a good start to begin addressing the structural problems of the current Medicare payment system and that has kept the Medicare Program from adapting to the chronic needs of our seniors.

To increase efficiency, we also have to take a look at the Medicare Advantage program. MedPAC's most recent report confirmed

that Medicare Advantage are paid on average 12 percent more than traditional Medicare with private fee-for-service plans under Medicare part C receiving 19 percent more than traditional Medicare payments. To be sure, MA plans are quick to point out that they offer additional benefits to their enrollees and that is true, but I remember vividly the deal we struck with the Medicare Advantage plans. All along Medicare Advantage plans claimed that they would provide additional benefits and increase efficiency at the same or lower cost than traditional Medicare. It was never meant to be part of the deal to pay them more for these services. All Medicare beneficiaries end up paying for these overpayments due to ever-increasing part B premiums. On behalf of all Medicare beneficiaries and the American taxpayer, I think it is high time we hold Medicare Advantage to the deal they made with us back years ago.

I thank our witnesses for being here, and I will yield back my time, Mr. Chairman.

Mr. PALLONE. Thank you.

I recognize our ranking member of the full committee, Mr. Barton.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Mr. Chairman. I sincerely want to compliment you on holding this hearing. This is the type of work that is not sexy, it is not seeking publicity, it is just doing the nitty-gritty nuts-and-bolts oversight and review of the ongoing programs of our Government and I want to honestly and sincerely commend you and Ranking Member Deal for doing this. It is very, very important.

As we go through today's hearing, I am going to be especially interested in hearing what the witnesses have to say about something that I have been promoting in Medicare for a number of years, that is, competitive bidding of durable medical equipment, prosthetics, orthotics and supplies. Price competition is almost always a good thing. There are some times that decisions have to be made in a crisis and once in a while there is something that is only by a single vendor but those times are rare. That is why I was the author of the competitive bidding proposal during consideration of the Medicare Modernization Act several years ago. I am pleased that the Centers for Medicare and Medicaid Services have just implemented this provision in a final rule. With the new rules come important accreditation and quality standards for suppliers, something that I think has been long overdue.

The Office of Inspector General will testify later this afternoon of its recent work reviewing suppliers in south Florida. According to the OIG, 45 percent of suppliers in three counties in south Florida did not meet one or more of five Medicare enrollment requirements. The accreditation and quality standards of the competitive bidding program will hopefully reduce such potential fraud and abuse, making suppliers more accountable and saving money for all our taxpayers.

The competitive bidding program that is being implemented will help sure that Medicare is paying the appropriate market-based price for these products. When fully implemented in 2010, competi-

tive bidding is projected to save Medicare over $1 billion a year. There will be savings to beneficiaries as well and it will improve people's access to quality suppliers, reduce out-of-pocket costs. Since beneficiaries pay a 20 percent co-pay, it is only fair to ensure that the beneficiary can realize the best price that is available that the market can offer.

I am also eager to hear the panel's testimony on improvements to the Medicare Program overall. I am concerned about a discussion around cutting the Medicare Advantage plans. Medicare managed care is not new to the Medicare Program. It has been offered a beneficiary choice in coverage since the inception of the Medicare Program. Over the past few decades we have tinkered with the managed-care option, adjusting the manner in which we reimburse plans in a number of major bills over the years. Plan participation has fluctuated. At time participation has been low, then it has been higher, then low again in the 1990's despite high enrollment numbers.

I remember what we experienced in the late 1990's and early part of this decade. I remember when our constituents were disenrolled and their extreme unhappiness at losing that particular option. You see, most of, if not all, beneficiaries like Medicare Advantage and they are willing to show it, so I am somewhat concerned with discussions of cutting over $60 billion out of this part of Medicare, which has such a high degree of universal satisfaction among the beneficiaries. There are currently over 8.3 million beneficiaries enrolled in Medicare Advantage plans and the number of beneficiaries choosing this option has increased by almost 54 percent in the last 2 years. So I have to ask, if it is working, why break it. And I understand that most of the discussion around cutting the rates is driven by the need to find a magic-bullet offset for spending on other health care programs, but if it is good policy, I don't see why we have to disrupt a benefit that is working well to great satisfaction of those that are enrolled in that particular option so that if we do that, we won't have to find an offset because we are going to keep spending the money where the people want it to be spent. It seems to me that we should do our jobs so that they can keep their benefits, not the other way around. If you don't believe the program is working, just ask the folks that have better access to enrolling in a plan today than ever before. These plans are an important option for low-income and minority beneficiaries. Fifty-seven percent of the enrolled beneficiaries have income of less than $30,000. These plans can reduce cost-sharing relative to traditional Medicare. It shows in the satisfaction numbers. Eighty-six percent of the enrollees have access to a plan that does not charge them a premium at all—86 percent. And it is not just the savings. It is about access to care afforded by these plans and beneficiary choice.

I could go on and on but my basic point is, that these Medicare Advantage plans are offering better access to care. More than 80 percent of them provide coverage for hospital stays beyond the traditional Medicare benefit. More than 75 percent cover routine eye and hearing tests. Over 98 percent of the beneficiaries can even enroll in a plan that offers preventive dental benefits.

Mr. Chairman, I share with you and Chairman Dingell and Ranking Member Deal a commitment to address the physician payment issue, which is a very costly item in Medicare. We need to work together, roll up our sleeves and look at that particular part of Medicare to see if there is not something that we can do to help our health care providers, all the various physician groups so that they will stay in the Medicare plan and give the benefits to our beneficiaries.

With that, Mr. Chairman, I yield back and look forward to the hearing and working with you and others as we try to come to solutions to some of the problems that we are going to hear about today.

Mr. PALLONE. Thank you.

I recognize the gentlewoman from California, Mrs. Capps.

OPENING STATEMENT OF HON. LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mrs. CAPPS. Thank you, Mr. Pallone, and I want to thank you as well for holding this hearing, a hearing which is long overdue.

Medicare is one of the most important benefits we provide to the elderly and the disabled. As a society, we have a responsibility; indeed, I would call it a privilege, to provide care for those who are most vulnerable. But what level of care can we provide when the program itself is fraught with wasteful spending and structural problems? It is my observation that we are looking for waste, fraud and abuse in all the wrong places. It is so obvious that priorities are being misplaced. We have a system that provides disincentives for preventive care, a system that picks and chooses treatments to cover, often at reimbursement rates with no clear connection to the actual cost of providing that care. What am I to say to a constituent who asks why her Medicare summary notices reflect a reimbursement to her provider for $2,000 more than the provider charged her for treatment, or to my constituent who asks why Medicare continues to pay maintenance fees on rented equipment that has never required maintenance, and when those fees have already total to several times more than the cost of purchasing the equipment outright? I will discuss those situations in more depth later but they are just two examples of wasteful spending in the same system that is underlying for primary care services in my district by as much as 5 percent, or why are certain private insurance plans receiving up to 12 percent more for the same services provided at a lower cost by other providers when there is no clear evidence of increased benefits to the beneficiaries? Why is Medicare reimbursing providers who perform certain diagnostic tests in their offices and ambulatory service centers at rates so low that it is driving their patients back to hospitals where the costs of providing these services are so much greater? Cost-saving services from diagnostic tests provide earlier screening and earlier intervention and treatment, saving both lives and Medicare dollars. Why is Medicare paying private contracts per audit they perform regardless of what the outcome is with no incentive to target bad actors over law-abiding ones?

As a health professional myself, it is so disturbing to see a health care program that thinks efficiency means immediately cost-cutting

instead of preventing disease and improving health. I am very anxious to hear what our witnesses today have to say about this, Mr. Chairman, and I am eager to work with our committee to address these pressing problems.

I yield back the balance of my time.

Mr. PALLONE. Thank you.

I know Mr. Murphy is just walking in, but you would be next if you like. I recognize the gentleman.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman. I appreciate it.

Our health care system is broken and must be reformed, and fixing the system is not about who is paying, it is about what we are paying for. A broken system is not fixed by just shifting additional payments to seniors, families, employers or taxpayers, but I believe affordability must begin with some fundamental reforms to quality, accessibility and safety for patients. Medicare spends about $372 billion annually and it is estimated that it will be bankrupt by 2019, 7 years earlier than previously expected, and 23 years earlier than Social Security, and I believe we need to transform our system to protect our seniors.

The Medicare Payment Advisory Commission recommends a number of suggestions from reducing payments to providers and Medicare managed-care plans to implementing pay for performance and care coordination programs. I believe care coordination can significantly reduce health care costs. For example, the University of Pittsburgh initiated a patient care management program for diabetes and reduced re-hospitalizations by 75 percent. Washington Hospital in Pennsylvania reduced re-hospitalizations for patients with heart disease by 50 percent, all from having folks monitor appointments, medications, diet, lab tests and treatment. These are real savings.

Recently we passed legislation providing a case manager to every wounded warrior in our military but we still don't have incentives for patient care management programs to reduce health care costs for out patients. I believe we can't continue to finance a broken health care system and expect different results, and I believe we need to transform our health care system and invest patient care management dollars to save billions of lives and thousands of dollars.

Any time we are faced with talking to folks from the Medicare Program and talking about efficiency and integrity. I believe these are the kind of things we need to be doing. After all, the sad truth of this is, is Medicare will reimburse doctors for sadly amputating the leg of someone with diabetes and severe problems but we haven't yet adjusted to the system of paying a few bucks each time to have a nurse call the patient and saying have you gotten your lab tests done, you haven't filled your prescription for insulin, how are you feeling today. We really need to make some major changes on that and I am so pleased that this committee is going to review these issues. I hope that we can review these and make some changes not only to such things as what I just mentioned but also

providing more allowance for doctors to volunteer at community health centers and by actively working to also eliminate infections from hospitals, because one of the sad truths too is, we also spend an awful lot of money reimbursing doctors and hospitals for an infection the patient picked up while they were there. As a matter of fact, some 2 million people a year contract an infection while in a hospital or health care center. It claims 90,000 lives and $50 billion a year. As we look at Medicare efficiency and integrity, I hope we are looking at these things too so we can look at fixing the system and not just financing it.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

The gentleman from Maine.

OPENING STATEMENT OF HON. TOM ALLEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MAINE

Mr. ALLEN. Mr. Chairman, thank you for calling this important hearing to examine efforts to improve the Medicare Program. Increasing efficiency and eliminating waste, fraud and abuse will keep the Medicare Program strong. Every dollar that we recover can provide additional services to beneficiaries. This committee needs to consider the improper payments recently reported by CMS in the fee-for-service program including $9.8 billion in overpayments and $1 billion in underpayments. We also need to examine the overpayments to private Medicare Advantage plans. They receive 12 percent more on average than traditional Medicare for treating comparable beneficiaries. While some Medicare advantage plans provide more services than traditional Medicare, their administrative costs are estimated to be 20 percent, much higher than traditional Medicare's 3 percent. If Medicare Advantage payment plans were brought in line with traditional Medicare, CBO estimates it would save $65 billion over 5 years.

I want to suggest a third issue to consider today: improving the evidence base for health care decision-making. Mr. Miller, I know you address this matter in your testimony. There is broad-based bipartisan agreement that we need to get better value for our Medicare dollar. Comparative effectiveness research involves evaluation of the relative safety and effectiveness of different pharmaceuticals, medical devices or medical procedures used to treat the same or similar illnesses or conditions. Comparative effectiveness research has great potential to improve health care quality and patient outcomes while ensuring that consumers receive the best care at the best value. The Effective Health Care program at the Agency for Healthcare Research and Quality, authorized under MMA, conducts systematic reviews of existing literature to identify what treatments work best, for whom, when and at what cost. AHRQ and its research partners synthesize the science and have built a meaningful evidence base. Working with a meager budget of $15 million, originally authorized at $50, AHRQ has completed seven reports on the treatment options for cancer-related anemia, low bone density, depression and gastroesophageal reflux disorder disease, among others. Seven additional studies are underway. The promise of comparative effectiveness research to improve care, patient outcomes and save Federal funds is significant. I will soon be

introducing legislation to bolster comparative effectiveness research, and I will be inviting my colleagues to join me as a cosponsor of the bill.

With that, Mr. Chairman, I thank the witnesses for being here and yield back the balance of my time.

Mr. BARTON. Mr. Chairman, could I just compliment the gentleman on his pronunciation. He did that very well.

Mr. PALLONE. I was listening to that also. I didn't know whether it was correct or not though.

Mr. BARTON. He said it like it is correct.

Mr. PALLONE. Gastro—what was it?

Mr. ALLEN. *Gastroesophageal*. I do not know if it is right either.

Mr. PALLONE. Very good. I will compliment you too.

I recognize Ms. Solis.

OPENING STATEMENT OF HON. HILDA L. SOLIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. SOLIS. Thank you, Mr. Chairman, and thank you for holding the hearing today.

In 1965, Congress created Medicare because seniors had difficulty obtaining affordable health care insurance. Seniors were promised that after a lifetime of working and paying into Medicare, they would have access to health care coverage during their retirement years regardless of their geographic location, their age and their income. Today more than 44 million seniors and people with permanent disabilities depend on Medicare to meet their health needs. In the coming decades, even more people will become beneficiaries of the program. I represent about 70,000 Medicare beneficiaries in my current district. They have entrusted the Government with their tax dollars and depend on us to oversee Medicare and to ensure that it runs efficiently.

In 2006, Medicare comprised 13 percent of the Federal budget and 19 percent of total health expenditures. Health care costs, as you know have skyrocketed and part B premiums are quickly becoming unaffordable. This is particularly troublesome, given the importance of access to quality affordable health care in minority communities, which often encounter greater burdens of disease. Unfortunately, low-income Medicare beneficiaries tend to be disproportionately Latino. Although Latinos make up only 6 percent of the Medicare beneficiaries, more than 14 percent are low-income seniors. Sixteen percent of Medicare beneficiaries in California alone are Latino. In 2006, a MedPAC report stated that 7.1 percent of Latino Medicare beneficiaries delayed getting care due to cost, proof that people with access to health insurance are not always able to receive services.

I have heard from my constituents that some California physicians have stopped taking new Medicare patients because of inadequate reimbursement. Given this existing reality, I am concerned about proposed cuts to Medicare providers. Less access to care will result in a disastrous increase in health disparities in our community. I am interested to hear MedPAC's view about payments to Medicare Advantage plans, especially since the private fee-for-service plans are paid 19 percent more than traditional Medicare.

I thank the witnesses for coming today and I look forward to hearing your response.

Mr. PALLONE. Thank you.

I recognize the gentleman from Utah.

Mr. MATHESON. Mr. Chairman, I have a written statement I will just submit for the record, and I will yield back.

[The prepared statement of Mr. Matheson follows:]

PREPARED STATEMENT OF HON. JIM MATHESON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF UTAH

Thank you, Chairman Pallone and Ranking Member Deal.

I want to thank you for holding this hearing today on the Medicare Program efficiency and integrity. This discussion today is a significant step in examining Medicare policy and one that requires a thorough review and consideration by Congress. I am happy that this hearing is being held at a time where we have the opportunity to improve health care reform for all Americans.

I also want to thank our distinguished guests. In my review of the testimony, I am looking forward to learning and identifying areas from our panel where the Medicare program is meeting the needs of the beneficiaries and investigating areas where reform needs to be made.

I am pleased to be a part of this committee and I am confident that due diligence will be given to the many health policy issues that continue to have long-term implications for the Medicare Program, including an issue that I am concerned with—the Medicare reimbursement for physician services. Having met with so many Utahns about the inadequacies of the current formula for determining physician reimbursement, it is my hope that we can make some progress on this issue during this session of Congress.

In addition, I am aware that we are looking to programs in Medicare to help supplement the State Children's Health Insurance Program. I hope to learn more regarding the options available to us to fully fund this significant, bipartisan partnership for children without negatively impacting services or access to programs that are successfully working for our Nation's seniors, especially those in rural or underserved areas. In 2007, 8.3 million beneficiaries chose to receive their health care benefits through a Medicare Advantage plan. Across the Nation, 85 percent of these chose a Medicare Advantage plan with prescription drug coverage. In my district, we have 19 percent of Medicare beneficiaries who have chosen a Medicare Advantage plan for their health insurance coverage and who rely on these programs for—vision, hearing, dental, fitness, mental health, and alternative health benefits.

I look forward to hearing the panel's views and expertise on a number of these issues within the Medicare program.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

The gentlewoman from Oregon.

OPENING STATEMENT OF HON. DARLENE HOOLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Ms. HOOLEY. Thank you, Mr. Chairman, for holding this hearing.

I have always firmly believed in the importance of building voters' faith in Government. Ensuring that Government programs provide services efficiently without waste, fraud and abuse is critical to that effort. We have a responsibility to provide quality health care for our citizens and seniors and an obligation to be good stewards of taxpayers' money.

As I have said before, Oregon physicians provide services more efficiently than those in many other parts of the country. They are so under-reimbursed to the point that many of them will not take new Medicare patients. As a consequence, I believe the physicians in Oregon welcome initiatives to improve efficiency in Medicare be-

cause the current system provides the most benefit to those providers who are least efficient.

The MedPAC recommendations to provide comparative research utilization measures to physicians would be a step in the right direction. Letting physicians with high resource use know how they compare to their fellow physicians would be a start in a positive conversation that currently does not exist. Another MedPAC recommendation, pay for performance in Medicare, has the potential to improve care and provide a better benefit for our seniors. However, just like with MedPAC's comparative resource utilization measures, it is critical to have appropriate risk adjustment measures in pay for performance. We do not want a pay-for-performance system that punishes physicians who care for older and sicker patients or those with more complex conditions. With any pay-for-performance system, we must make sure that all measures are clinically valid and that physicians play an integral role in developing and implementing appropriate standards. Physicians have the expertise in their area of specialty. We have to rely on that knowledge when creating a pay-for-performance system so that it works for both seniors and the providers.

In the area of program integrity, I am glad to see that progress has been made. A decline in payment error rates from over 10 percent in fiscal year 2004 to 4.4 percent in 2006 is a great accomplishment, and I congratulate you on that. The Department of Justice has similarly done an outstanding job of collecting $2.2 billion in judgments and settlements in fraud and abuse cases in 2006. However, the DOJ says in its testimony today that current funding levels are not sufficient to eliminate the backlog of fraud and abuse cases. The Office of the Inspector General, the Department of Health and Human Services said it recovers an average of $13 for every $1 spent on that office. We need to make sure that we are investing sufficient funds to stay aggressive in bringing cases against the small minority of providers that abuse the public's trust. We should also not punish those providers who are the most efficient.

Again, thank you, Mr. Chairman, for holding this hearing, and I am looking forward to our witnesses. Thank you.

Mr. PALLONE. Thank you.

The gentlewoman from Illinois, Ms. Schakowsky.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

I am so glad that we are holding this hearing on Medicare, which passed in 1965 and our chairman, Chairman Dingell, was not only a member of the House at that time, but as I understand it was actually presiding in the chair when Medicare passed, and since then it has been one of the most popular and effective and well-administered programs and most popular among our citizens, and so today we are here about how we can make Medicare even better, even more efficient.

I am very glad MedPAC, CMS, the DOJ and the Inspector General's Office are represented here today and I look forward to hearing those ideas on the use of comparative effectiveness, ways to re-

duce medical errors and inappropriate utilization and expanded access to preventive services. I also hope that we can focus on the inefficiencies involved in providing enormous subsidies to private plans in Medicare.

Marilyn Moon, a former public trustee of Social Security and Medicare trust funds, states in her recent book, Medicare: A Policy Primer, "Over the past 30 years Medicare has been more successful on a per capita basis of holding down the costs of health spending growth than has private insurance." Medicare also spends less on administrative costs. There are of course many ways to make Medicare even more efficient but moving more toward privatization of Medicare is not one of them. I wasn't here when Congress first created Medicare Plus Choice, the forerunner of today's Medicare Advantage programs, but as the executive director at the time of the Illinois State Council of Senior Citizens, I had many concerns about allowing private plans to infiltrate Medicare. The argument then was that Medicare private plans would cost less because of their greater efficiency, saving Medicare and taxpayers money while providing better benefits. But today it is clear that the theoretical promise has not been met. Medicare Advantage private plans on average cost 12 percent more than traditional Medicare and some plans are paying 40 percent more. When beneficiaries move from traditional Medicare to private plans, it costs us more, not less. We are paying billions of dollars each year to subsidize private plans that serve less than one in five beneficiaries while other important health needs are not being met. I find it hard to argue that that is an efficient or proper use of limited resources.

I am particularly interested in looking at the role of private fee-for-service plans, the fastest-growing sector of the Medicare Advantage market, which also happens to receive the highest level of excess payments. I believe there is little, if any, value added with these plans. I hope we will look into them more closely. The argument simply no longer stands that private plans will bring efficiency to the Medicare Program, and I really welcome the chance to investigate what has gone wrong here.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

The gentlewoman from Wyoming.

OPENING STATEMENT OF HON. BARBARA CUBIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WYOMING

Mrs. CUBIN. Thank you, Mr. Chairman.

Things are just not the same in rural America as they are in urban America, and our country has decided that there are certain things that everyone in this country should be allowed to have access to, whether it is postal delivery or whether it is public transportation, and it costs different things. We don't have public transportation in rural America like we do in urban America, and I think this health care debate will turn out to demonstrate the differences in why we need to take a good look at what we are doing here.

Our Nation's Medicare Program is an investment in the health of our Nation's seniors and we have a responsibility to the Federal taxpayer to ensure that it is a responsible investment. The 70,000

seniors in the State of Wyoming are best served knowing that Congress is doing what it can do to ensure the $425 billion spent in fiscal year 2007 are dollars well spent. The shear size of the Medicare Program is mind-boggling. Though overpayments, fraud, waste and abuse may seem inevitable in a program this large, we must rise to the challenge and act to protect the solvency of Medicare. I applaud the administration's proposal to rein in the growth of the Medicare Program and achieve a $65.6 billion in savings over 5 years. The Congressional Budget Office projects Medicare spending already estimated at $454 billion in fiscal year 2008 to double over the next 10 years. If we do not, we will face either a tax increase or rollback in benefits.

As this committee looks to find savings in the Medicare Program, I know there will be plenty of discussion surrounding the appropriateness of expenditures under Medicare Advantage program. Medicare Advantage replaced its predecessor, Medicare Plus Choice, in the Medicare Modernization Act of 2003. The program supports private plans that give Medicare beneficiaries more choices, additional benefits and coordinated care beyond traditional Medicare coverage. Enrollment in these plans has increased by almost 54 percent since 2004 but this number does not tell the whole story in rural areas like Wyoming. In every county in Wyoming, there is now access to a plan with a maximum out-of-pocket of $1,000 or less whereas prior to 2003 there was no access to these plans at all. There are now over 3,000 Medicare Advantage enrollees in Wyoming. Hundreds have written or e-mailed my office about how much they like their plans.

There is no doubt that we will need to make some difficult choices to preserve the long-term fiscal soundness of the Medicare Program. I am personally committed to addressing the negative physician fee schedule which represents an unacceptable situation, not just for Wyoming's beneficiaries but for the physicians they rely on. I would urge my colleagues, however, to consider the impact of our decisions on access to quality and affordable health care in rural areas like Wyoming and other places around the country.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

Any other statemets for the record will be accepted at this time.

[The prepared statement of Mr. Dingell follows:]

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

The Medicare Program is the most successful social program of our time. It has, in the course of more than 40 years, reduced unmet health needs among seniors and people with disabilities and has, together with Social Security, lifted tens of millions of elderly out of poverty by virtue of helping with the cost of their medical care. Without question, the Medicare program is essential to the fabric of our society and must be protected and preserved.

Part of protecting and preserving Medicare involves ensuring accuracy and efficiency in its payments. As the Medicare Payment Advisory Commission notes, the program should be neutral in its payments to providers—encouraging the right care at the right time in the right setting. This means constant oversight on the part of both Congress and the Centers for Medicare and Medicaid Services (CMS). And that is part of our goal here today.

In this fiscal year alone, Medicare will spend more than $425 billion on health care goods and services for its 44 million beneficiaries. Unfortunately, in a program of this size overpayments are inevitable. At today's hearing we will hear about fine

tuning Medicare's payment systems to improve efficiency and modifications that can be made to protect the integrity of the program as well.

Overpayments, or misaligned payments, can have a direct effect on beneficiary out-of-pocket costs, as well. Whenever there is an increase in part B spending, it automatically increases the part B premium beneficiaries pay. Misaligned payments can also cause beneficiaries to pay more than necessary in coinsurance. And in the overall context of the Federal budget, inappropriately spent funding reduces funds available for other priorities.

Our goal should be to increase the efficiency of the Medicare program to ensure the future stability of the program. For example, we now know MedPAC that private plans in Medicare are paid an average of 12 percent more for every Medicare beneficiary that chooses to enroll in one of those plans rather than remaining in traditional Medicare. These excess payments are funded by taxpayers and all beneficiaries—whether or not they enroll in private plans—in the form of higher Medicare part B premiums. These plans should be required to be operating more efficiently and I look forward to the MedPAC recommendations on this issue.

Similarly, providers who knowingly defraud the program should be identified and the Federal Government should work to recover overpayments from those providers and seek criminal charges if the case warrants.

Ensuring the efficiency and integrity of all of our public programs is among the top priorities of this Congress. That is the only way to ensure the continued existence and success of these programs. We in Congress want to work closely with those who advocate for beneficiaries and with those who represent the provider community, to protect Medicare fee-for-service for generations to come. I look forward to working with Chairman Pallone, as well as Ranking Members Barton and Deal, as we proceed in our efforts to improve Medicare.

Mr. PALLONE. We will turn to our witnesses now, and first of all, welcome. I understand that Ms. Norwalk can only stay until 3:45, so——

Ms. NORWALK. Yes. We are kicking off a prevention tour that a number of members of the committee have talked about. I have asked them to push it back a little bit so I can stay a little bit longer.

Mr. PALLONE. I thank you.

Ms. NORWALK. I will run and catch the bus.

Mr. PALLONE. All right. Well, let me quickly introduce you and also Dr. Miller. Leslie Norwalk is the acting administrator for the Centers for Medicare and Medicaid Services, and Dr. Mark Miller is executive director of the Medicare Payment Advisory Commission, or MedPAC. Thank you both for being here today. I will just mention that you can submit additional brief and pertinent statements in writing for inclusion in the record, and we will start with Ms. Norwalk.

STATEMENT OF LESLIE V. NORWALK, ACTING ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Ms. NORWALK. Good afternoon, Chairman Pallone, Representative Deal and distinguished members of the subcommittee. Thank you for inviting me here today to address the Centers for Medicare and Medicaid Services' efforts to promote efficiency and integrity in the Medicare Program.

The future of the Medicare Program depends in large part upon our ability to ensure the most efficient use of Medicare resources and that includes eradicating fraud at every possible opportunity. As the largest purchaser of health care in the world, CMS provides coverage to one in every three Americans. CMS covers 92 million beneficiaries, and the numbers and costs are growing. Medicare

outlays are projected to exceed $464 billion in the coming fiscal year with CMS accounting for nearly a fifth of the President's budget. National health spending is expected to average 6.9 percent annual growth over the next decade, and beginning this year it is projected to grow an average of 2.1 percentage points faster each year than gross domestic product. In the absence of fundamental reforms or unforeseen market changes, this trend will yield a health care of GDP that tops nearly 20 percent by 2016, going from $2 trillion in health care spending this year to $4 trillion in 2016.

Heeding the call of the Medicare trustees, the Federal Reserve Chairman, MedPAC and scores of other health and fiscal policy experts, the administration has proposed a fiscal year 2008 budget that tackles Medicare's long-term financial challenges and aims to transform it into a sustainable quality-based payment program. Clearly, the efficient and effective management of Medicare and its programs and operations is essential to that goal.

The Medicare trustees agree that prompt, effective and decisive action is necessary to address the exhaustion of the part A trust fund, which is currently projected to be depleted in a little more than a decade. Similarly, the trustees have urged that we take action to address the anticipated rapid growth in Medicare expenditures. Specifically, the trustees warn of a serious mismatch between the benefits and payments the program currently provides and the financial resources available for the future. Should these factors remain unchanged, the trustees note that over time the program would require major new sources of financing for part A. Medicare would also automatically require increased shares of general tax revenues for parts B and D, diverting resources from other Federal priorities. Projected levels of spending could also impose a significant financial liability on Medicare beneficiaries who pay premiums and cost sharing.

The President's budget proposes to build on past successes to further modernize Medicare, improve its quality and efficiency and secure its long-term future. On net, the Medicare proposals would reduce the rate of projected cost growth just shy of 1 percent over the 5-year window. The proposals aim to steer providers toward greater efficiency through payment policies that increase the role of competition and incentivize the slowing of cost growth through greater productivity and quality of care. In addition, payments would be tied in part to medical error reporting and value-based purchasing for hospitals would be expanded.

CMS recognizes the inherent potential of Medicare's payment system to encourage and reward quality in hospitals and other care settings. The Medicare Modernization Act and other recent legislation directed Medicare to increase payments when hospitals and other health practitioners report on quality measures that both empower providers and patients, arm them with raw materials necessary for informed decision-making and ultimately lead them to identify and pursue better care protocols. CMS is working toward greater transparency in physician and hospital pricing and quality data, providing consumers with better information about the treatment options available to them. The budget would take steps to encourage more appropriate payment for the five most common condi-

tions treated in post-acute care settings. The prospective payment system for hospital inpatient care implemented in 1983 slowed growth in part A spending as intended but it also had the effect of moving care to post-acute settings funded through a mix of part A and B and outpatient settings that are funded solely part B. Even with the criteria to direct patients to the most appropriate place for care, numerous factors such ad revisions of patient conditions and diagnoses cause overlap in the types of patients treated in these different post-acute settings. Exploring new evidence-based standards, more-accurate case mix measurements, improving patient assessment, CMS is working to ensure that patients receive the most appropriate care at the most appropriate time in most appropriate setting.

But regardless of the setting, CMS remains committed to improving the integrity of the Medicare Program and efficiency of its operations and expenditures. Central to our strategy for maintaining sound financial management, CMS has long used calculations of improper payments as a tool to preserve Medicare's fiscal integrity. Data collection and monitoring have enabled CMS to identify monies that have been inappropriately paid, to examine the causes of the inappropriate payment and ultimately strengthen the internal controls to minimize them as much as possible. Last year the paid claims error rate for Medicare fee-for-service was 4.4 percent, a sizable drop from the 5.2 percent reported in 2005, and significantly lower than the 10.1 percent in 2004. Next month CMS will announce the preliminary error rate for fiscal year 2007, and it appears that we will reduce the error beyond our expectation of 4.3 percent, so we continue to move in the right direction, but it will require continued monitoring and error-reducing efforts in order to continue this goal, and we are committed to do so.

CMS's financial management strategy prioritizes the detection and prevention of improper and fraudulent payments and to that end we have identified such activities over the past year. Our satellite offices and program safeguard and claims processing contractors are testing innovative approaches to detecting, investigating and prosecuting Medicare fraud. The Los Angeles Tax Project is a recent and telling example. With the L.A. County district attorney, our L.A. satellite office is conducting a unique pilot program to more effectively deal with health care fraud due to prosecution of providers for State income tax evasion, sort of the Al Capone approach. Relying on an elaborate communications network, the L.A. project offers a new tool for cracking down on health care providers suspected of committing insurance fraud in California. Over the past year CMS has seen a marked increase in fraud and abuse activities tied directly to provider enrollment. These activities are——

Mr. PALLONE. Ms. Norwalk, you are about a minute over, plus I know you want to get out of here, so——

Ms. NORWALK. Well, that is why I decided I will stay a little bit longer. The point I was making there is simply with fraud and abuse, we are seeing some specific targeted efforts, particularly even in organized crime in Los Angeles, Miami and Houston, and we are working diligently with both the OIG and DOJ, as I am sure they will testify to later, to go after this fraud in particular. And as Congressman Barton mentioned earlier, the DME accredi-

tation standards and the competitive bidding is yet another prong to go after some of the specific fraud to save billions of dollars.

Thank you very much. I look forward to working with MedPAC, the OIG and DOJ, and welcome any questions you may have.

[The prepared statement of Ms. Norwalk follows:]

Testimony of Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
On
Medicare Efficiency and Integrity
Before the
House Energy and Commerce Subcommittee on Health
April 18, 2007

Chairman Pallone, Representative Deal, and distinguished members of the Subcommittee, thank you for inviting me here today to discuss our efforts to promote efficiency and integrity in the Medicare program. The Centers for Medicare & Medicaid Services (CMS) has a track record of active engagement, ongoing through this day, with Congress, other state and Federal government partners, and the provider community with respect to these important issues.

At its inception, the fee-for-service (FFS) Medicare program was a mass purchaser of healthcare services, with CMS as a relatively passive payer. Given the size, broadened scope and impact of the program, both now and in the foreseeable future, CMS has begun to transform itself into a more active purchaser of high quality, efficient care for Medicare beneficiaries.

For the past six years, this Administration has made the efficient and effective management of Medicare and all of its programs an operational priority. Together with Congress, CMS has made great strides in modernizing and improving health benefits for people with Medicare. Central to its strategy for maintaining sound financial management, CMS has long used calculations of improper payments as a tool to preserve Medicare's fiscal integrity. Data collection and monitoring have enabled CMS to identify monies that have been inappropriately paid; to examine the causes of these improper payments, and ultimately, to strengthen internal controls to minimize them as much as possible.

The implementation of the Medicare Part D prescription drug benefit was a major step in modernizing Medicare and improving the quality of its services. Part D, enacted with passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implemented in January 2006, has been a resounding success. To date, more than 90 percent of Medicare beneficiaries have prescription drug coverage through Part D or another creditable source, including nearly 10 million low-income individuals receiving coverage with low or zero premiums and nominal cost-sharing. Beneficiary satisfaction with Part D is consistently at 75 percent or higher, exceeding 90 percent among low-income beneficiaries receiving extra help.[1] Equally important, Part D premiums and estimated program costs have been declining steadily thanks in part to market forces— encouraging strong competition among plans and smart choices by beneficiaries—and in part because of lower-than-expected growth in prescription drug spending. Since last year, projected payments to Part D plans for the ten-year period of 2007-2016 dropped by $113 billion—$96 billion of which can be directly attributed to competition and lower plan bids. The average beneficiary premium for basic benefits is estimated at $22 per month for 2007—roughly 42 percent lower than the original projected premium of $37 per month.

Further, we are seeing increased enrollment in Medicare Advantage, the program through which beneficiaries can access integrated health and prescription drug benefits, often with lower premiums and cost-sharing than under traditional fee-for-service Medicare. Medicare Advantage is particularly important for lower-income beneficiaries, who may have difficulty paying Medicare's cost-sharing or private supplemental insurance premiums. Fifty-seven percent of Medicare Advantage enrollees report income between $10,000 and 30,000, compared to 46 percent of those enrolled in fee-for-service.[2] Further, racial and ethnic minorities represent 27 percent of total Medicare Advantage enrollment, compared with 20 percent in fee-for-service.[3] Enrollment in Medicare health plans has reached an all-time high of 8.3 million beneficiaries, up from 5.3 million in 2003.

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[1] KRC Research survey for the Medicare Rx Education Network, conducted September 1-7, 2006.
[2] CMS analyzed the 2005 Medicare Current Beneficiary Survey (MCBS) to determine low-income and minority enrollment in Medicare health plans and in fee-for-service.
[3] CMS analysis of 2005 MCBS data.

Regardless of the care setting, CMS remains committed to improving the quality of patient care and to increasing the efficiency of Medicare expenditures. How Medicare pays for beneficiary services can significantly impact quality and medical costs not only for people with Medicare, but for our overall health care system. When payments are based primarily on admissions and procedures—rather than outcomes or efficiency—the system—our *current system*—risks paying for services that are ineffective, inefficient and/or inconsistent with best current information. CMS believes that a greater emphasis on recognizing and encouraging quality care would prevent complications and errors. That is why the Agency is modifying Medicare's FFS payment systems to improve quality, and at the same time, provide incentives for efficiency.

CMS recognizes the potential of the Medicare payment system to encourage and reward quality care in the hospital setting. This is particularly important, as it provides an opportunity to address quality concerns proactively. The MMA and Deficit Reduction Act of 2005 directed Medicare to pay more when hospitals and other health practitioners report on quality measures that empower both providers and patients, arm them with the raw material essential for informed decision-making, and ultimately, lead them to identify and pursue better care protocols. CMS is implementing several demonstration projects to encourage quality care and to lay the groundwork for value-based payments in the future. In addition, CMS is working toward greater transparency in physician and hospital pricing and quality data, providing consumers better information about treatment options available to them.

Fiscal Year 2008 Budget Proposals

The President's Fiscal Year 2008 budget proposes a plan for building on past successes to further modernize the Medicare program and secure its long-term future. Under current law, growth in net Medicare spending is approaching seven percent per year over the next five years and is anticipated to be higher than that over the next ten. Working closely with beneficiaries and providers, CMS believes it can improve the quality, efficiency and long-term viability of the Medicare program.

Federal Reserve Chairman Ben Bernanke, the Medicare Trustees, and the Medicare

Payment Advisory Commission (MedPAC) have underscored the importance of taking action *now* to address Medicare's long-term financial challenges. Chairman Bernanke warned the Senate Budget Committee at a January 18, 2007 hearing that "if early and meaningful action is not taken, the U.S. economy could be seriously weakened, with future generations bearing much of the cost." Voicing serious concern over Medicare's financial outlook in 2006, the Trustees insisted that "prompt, effective, and decisive action was necessary to address both the exhaustion of the Hospital Insurance Trust Fund and anticipated rapid growth in [Medicare] expenditures."[4]

The President's budget strives to induce providers toward greater efficiency with payment policies that increase the role of competition and create financial incentives for slowing cost growth through greater productivity and other improvements in care quality. Under current law, and based on the budgetary assumptions, the assets of the HI trust fund would start to decline in 2010. The Administration's proposals would improve the financial outlook of the HI Trust Fund throughout the ten-year window.
The net effect of the FY 2008 Medicare legislative and administrative proposals[5] is a reduction of nearly one percent in the rate of program growth over the five-year budget window. Specifically, they would save about $5.3 billion in FY 2008 and about $75.9 billion over five years.[6] Medicare's current average annual growth rate over the next five years is projected at 6.5 percent per year. Under the President's budget, the rate of growth would slow to 5.6 percent per year. Specifically, the budget would:

- **Foster Productivity and Efficiency:** Respond to inefficient health care delivery and rapid spending growth with provider payment adjustments that would account for expected productivity gains and induce providers to achieve efficiencies that restrain costs.
- **Rationalize Medicare Payment and Subsidies:** Tie payment to medical error reporting and expand value-based purchasing for hospitals; also

[4] 2006 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds at pp. 3-4.
[5] The Medicare budget assumes administrative savings of $1.0 billion in FY 2008 and $10.2 billion over five years. Savings will result from new efforts to strengthen program integrity in Medicare payment systems, correct for inappropriate provider payments, and adjust payments to encourage efficiency and productivity.

encourage appropriate payment for five common post-acute care conditions and address excessive Medicare payment and beneficiary coinsurance for power wheelchairs and oxygen equipment.

- **Improve Program Integrity:** Utilize a variety of data analysis tools to zero-in on the top ten vulnerabilities in the Medicare program, especially those with potentially high financial impact; and use such analyses to address and/or remedy the issues early in their lifecycle. An enhanced focus on data will enable CMS' program integrity efforts to be more proactive and less reactive, enabling a greater focus on actual fraud prevention rather than simply mitigation, after the fact.
- **Increase High-Income Beneficiary Responsibility for Health Care:** Eliminate annual indexing of income thresholds for reduced Part B premium subsidies, and extend the income-related Part B premium adjustment to Part D premiums.
- **Improve Long-Term Sustainability:** As a fall-back response in the absence of Congressional action, apply a -0.4 percent sequester to the Medicare payment amount for all providers in the first year that general revenue funding for the Medicare program exceeds 45 percent. The sequester reduction would grow by an additional 0.4 percent in each successive year that the general revenue funding remained above 45 percent.

Program Integrity in Fee-for-Service Medicare

Responsible and efficient stewardship of taxpayer dollars are critical goals of this Administration. Under the President's Management Agenda (PMA), a government-wide effort to improve financial management, federal agencies are mobilizing staff, resources and technology to identify improper payments in high-risk programs, establishing aggressive improvement targets, and implementing corrective actions to meet those targets expeditiously. Consistent with these efforts, CMS is committed to ensuring the highest measure of accountability within the Medicare program. Accordingly, the President's FY 2008 budget requests $183 million in discretionary HCFAC funding to build upon programs with a proven record for maintaining the integrity of the Medicare

Trust Funds. HHS plans to primarily use these funds for program integrity activities related to Part D and Medicare Advantage.

The majority of Medicare spending is in fee-for-service, with hospital and physician services currently representing the largest shares. The fee-for-service component also covers a range of other items and services, including home health care, medical equipment and ambulance and preventive services. CMS processes claims and makes payments for FFS Medicare benefits through contracts with private companies—Carriers, Fiscal Intermediaries (FIs) and Durable Medical Equipment Medicare Administrative Contractors (DME MACs).[7] These contractors review claims to ensure payment is made only for reasonable and necessary Medicare-covered medical services for eligible individuals. In addition, Quality Improvement Organizations (QIOs) are contractors that investigate beneficiary complaints about quality of care in hospitals and ensure payment is made for only medically necessary services.

The Improper Payments Information Act (IPIA) of 2002

Given the sheer size of Medicare program expenditures, even small payment errors can significantly impact the Federal Treasury and, by extension, taxpayers. As part of its longtime financial management strategy, CMS uses improper payment calculations to identify wrongdoing, strengthen internal controls, and ultimately, preserve Medicare's fiscal integrity.

Beginning in FY 2003, in concert with the Department of Health and Human Services Office of the Inspector General (OIG), CMS implemented a much more robust process—the Comprehensive Error Rate Testing (CERT) program—to assess and measure improper payments in the Medicare fee-for-service program. The CERT program not only produces a national paid claims error rate, but also very specific improper payment

[7] With the implementation of Medicare Contracting Reform (MCR) enacted by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Medicare contractor functions are being consolidated, and all contractors processing Medicare claims are called "Medicare Administrative Contractors" or "MACs." Although the durable medical equipment regional carriers (DMERCs) have been fully replaced by the DME MACs, while MCR implementation is underway, the original contractor terms – Carrier and FI – remain commonly used.

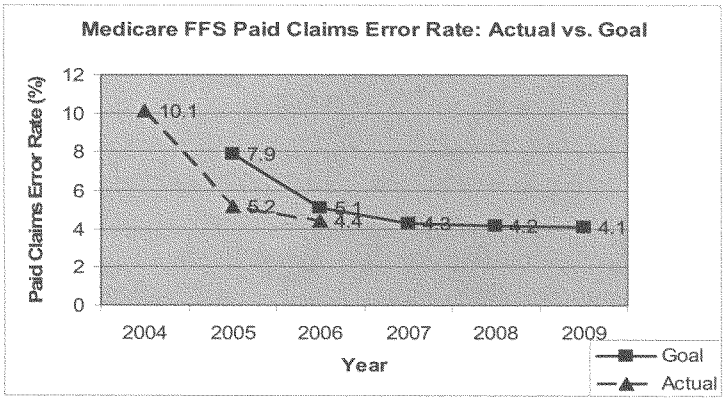
rates—contractor-specific, provider-type specific—and other management-related information, offering insight into payment errors by type and region.

Thus, in 2002 when the Improper Payments Information Act (IPIA) was enacted, CMS needed to make only minor changes to its ongoing processes for FFS Medicare to come into compliance with the Office of Management and Budget (OMB) guidance on the new law. In fact, CMS' efforts to crackdown on improper payments have gone *beyond* the scope of the IPIA requirements and Budget Office guidelines. This enhanced scrutiny reflects the Agency's increased commitment to use more detailed data and analysis to identify and eliminate improper payments.

Calculating improper payment rates is only one step in the process. Remediation is critical to CMS IPIA compliance activities. CMS, through its contractors, uses the error rates to identify where problems exist and to target improvement efforts. The cornerstone of these efforts is our annual Error Rate Reduction Plan (ERRP), which includes high-level strategies to clarify CMS policies and implement new initiatives to reduce FFS Medicare improper payments. In the past, ERRPs have included plans to conduct special pilot studies (i.e. electronic medical record submission pilot) and specific education-related initiatives. CMS also directs its contractors to develop local efforts to lower the FFS Medicare error rate by targeting provider education and claim review efforts to those services with the highest improper payments.

We believe our efforts in Medicare have been a success. In November 2006, HHS reported a Medicare FFS paid claims error rate of 4.4 percent, a significant decrease from the 5.2 percent reported in 2005, and significantly lower than the 10.1 percent rate reported in FY 2004. We have far exceeded our expectations, having reduced the error rate beyond the 2006 goal of 5.1 percent. With continued monitoring and error reducing efforts we aim to achieve our future targets of 4.3 percent in 2007, 4.2 percent in 2008, and 4.1 percent in 2009.

Figure 1:



Fraud, Waste and Abuse

CMS actions to safeguard Federal funds are not just limited to the error rate programs. Program and fiscal integrity oversight is an integral part of CMS' financial management strategy, and a high priority is placed on detecting and preventing fraud, waste and abuse. To that end, CMS has made significant changes to its program integrity activities in recent years.

The Program Safeguard Contractors (PSCs) are CMS' fraud, waste and abuse detection contractors. As of 2006, PSCs were established nationwide across all provider and supplier types in the Medicare FFS program. The PSCs perform data analysis to identify potential problem areas, investigate potential fraud, develop fraud cases for referral to law enforcement and coordinate Medicare fraud, waste and abuse efforts with CMS' internal and external partners (e.g., law enforcement, intermediaries, carriers, and MACs).

To further supplement the PSCs fraud identification efforts, CMS is making improvements to its own data analysis efforts. To achieve this, we are collecting vulnerability data from many of our partners, including Medicare contractors, and using a variety of data analysis tools to review claims data. Much of our work will focus on addressing vulnerabilities early on and those that have high estimated dollar impact to the

Medicare program. Our program integrity efforts will focus on the top ten vulnerabilities identified through our data analysis and on developing corrective actions to address these identified vulnerabilities.

Section 306 of the MMA gave CMS additional contracting authority to detect improper payments. The Secretary is directed to demonstrate the use of Recovery Audit Contractors (RACs) in identifying Medicare underpayments and overpayments, and collecting Medicare overpayments. CMS implemented RACs in three states – Florida, New York and California and in FY 2006, the RACs collected $68.6 million in overpayments and identified more than $300 million in improper payments.

The RAC demonstration is consistent with the President's Management Agenda (PMA) objective to prevent improper payments in federal programs. CMS designed the demonstration to accomplish two specific goals: to demonstrate whether RACs can identify past improper payments in the Medicare FFS program; and to determine whether the RACs can provide information to CMS that could help prevent future improper payments. It is clear that the RAC demonstration program accomplishes both of these goals. Given the success of this effort, Congress mandated the expansion of the RAC effort nationally in the Tax Relief and Health Care Act of 2006. CMS is now in the process of developing its expansion and implementation plans.

Provider Enrollment

CMS has seen a marked increase in fraud and abuse activities over the past few years that can be directly tied to provider enrollment issues. These activities are primarily focused in high vulnerability areas of the country such as Los Angeles, Miami and Houston where there are a large number of beneficiaries and providers/suppliers. CMS has undertaken numerous aggressive actions to tighten the provider enrollment process, provide more rigorous oversight and monitoring once a provider/supplier enrolls in the program, and strengthen the provider revocation process.

The fraudulent business practices of unscrupulous durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) suppliers continue to cost the Medicare program

billions of dollars. CMS is implementing new DMEPOS Accreditation Standards which will ensure DMEPOS suppliers meet CMS' supplier certification standards. All suppliers of DMEPOS must comply with the CMS quality standards in order to receive Medicare Part B payments and to retain a supplier billing number. The National Supplier Clearinghouse (NSC) will not be able to issue a supplier billing number to any non accredited supplier, thus any non-accredited supplier attempting to bill Medicare, will be automatically 'kicked-out' of the system.

To accommodate suppliers that wish to participate in the Medicare DMEPOS program, CMS will phase-in the accreditation process and require accreditation organizations to prioritize their surveys to accredit suppliers in the selected Metropolitan Statistical Areas and competitive bidding areas. All suppliers who require accreditation to bid in any CMS conducted DMEPOS competitive bidding need to be given priority by the approved accrediting bodies. Those suppliers in a non-competitive bidding area will be given a certain time frame in which to become accredited.

CMS is taking the following steps to better monitor a provider or supplier once it has entered the program:

- Implement claims specialty editing to ensure suppliers are only paid for items they are properly accredited to provide;
- Increase the number of random site visits to suppliers;
- Require greater claims scrutiny for high fraud risk suppliers;
- Deactivate providers with inactive provider numbers; and
- Provide additional resources for investigative staff to increase proactive initiatives by the NSC and the PSCs.

CMS is also implementing new strategies to remove fraudulent providers from the Medicare program. Our LA Satellite Office has recently identified situations in which some physicians are submitting claims for services that have not been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary was

not in the state or country when the services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred. We proposed through regulation that CMS have the authority to remove these abusive providers and suppliers from the Medicare program.

Conclusion

For eight fiscal years running, auditors have issued an unqualified opinion on CMS' financial statements. This accomplishment reflects the Agency's accountability for the public resources entrusted to us, and the dedication and commitment of our program and financial managers to achieve even stronger financial management.

The President's FY 2008 budget demonstrates a real commitment to improving America's health care system by further modernizing and improving Medicare. Steps taken now – or not taken – to adopt rational, responsible, and sustainable policies will directly impact our ability to preserve the promise of health care coverage for America's seniors, people with disabilities, and other vulnerable populations. We will continue to work to fully meet our fiduciary and operating responsibilities to our beneficiaries in years ahead.

Mr. PALLONE. Thank you.
Dr. Miller.

STATEMENT OF MARK E. MILLER EXECUTIVE DIRECTOR, MEDICARE PAYMENT ADVISORY COMMISSION

Mr. MILLER. Chairman Pallone, Ranking Member Deal and subcommittee, distinguished subcommittee members, MedPAC is a congressional support agency created to advice Congress on Medicare policy. MedPAC is uniquely structured. There are 17 commissioners that review the work that my staff does and shape the advice that we forward to the Congress. These commissioners include physicians, nurses, individuals who run hospitals, post-acute care facilities and managed-care plans. The commissioners include former policy officials, individuals trained as health economists and individuals trained as actuaries. Our work is largely directed towards improving efficiency and value of the traditional Medicare Program as well as managed-care plans. As we consider the advice that we give Congress, we keep certain principles in mind: assuring that beneficiaries have access to high-quality care, paying providers and plans fairly, assuring that each tax dollar is well spent.

There are other considerations that I know are on the minds of commissioners when they consider Medicare policy. First, there is a long-run sustainability problem facing Medicare. Medicare is growing faster than the budget, faster than the economy and faster than beneficiary incomes. This increase in spending, however, is not consistently accompanied by improvements in coordination or quality of care, and the commission believes that urgent attention is needed to improve the payment and delivery system incentives in Medicare. Second, Medicare policies must evolve to be more sensitive to the performance of providers. That is, Medicare needs to pay more to providers who have efficient practice styles and higher-quality care and less to those who do not.

The testimony I have submitted has a long list of ideas that the commission has recommended over the last several years, and I won't go through them but just to highlight a few. Regarding fee-for-service updates, each year we consider a range of factors such as supply of services and access to care for beneficiaries when we make recommendations on payment updates. If we determine that providers are more than adequately paid, the commission can make a recommendation to give the provider less than a full update. A recommendation of less than a full update usually results in savings to the Medicare Program if it is adopted. For our March 2007 report, recommendations would yield savings in Medicare for payments for home health agencies, skilled nursing facilities, inpatient rehab facilities and long-term care hospitals. Regarding Medicare Advantage plans, the commission has long supported the Medicare managed plans as an option for beneficiaries. The commission also supports the principle that Medicare payments should be neutral. That is, we should pay the same for a beneficiary regardless of which choice they make, fee-for-service or managed care. The current managed care payment system is not neutral to beneficiary choice and does not encourage efficiency. This is because it is based on an inflated set of administratively determined benchmarks. Under this system, we estimate that on average plans are paid 12

percent more than fee-for-service, and while it is true that most of this payment goes for additional benefits for beneficiaries, it is also important to bear in mind that these payments come from the trust fund, from general revenue and from premiums paid by all beneficiaries regardless of whether they are in managed-care plans or not.

Since 2002, the commission has recommended several changes to make Medicare payments more equitable between fee-for-service and managed-care plans as well as changes to make it more equitable among the managed-care plans because we think that certain types of managed-care plans are competitively advantaged over others. We believe that these recommendations will result in reduced Medicare expenditures, greater efficiency in care coordination for plans, and better information for beneficiaries in choosing their care options.

Regarding physician payment, the commission has made several recommendations to improve the value of physician services in Medicare. Again, I cannot go through all of the ideas. However, a couple to note, there is evidence that some physician services are unnecessary. In our March 2005 report, we recommended measuring physician practice styles, comparing them to their peers so that physicians could see how their practice styles differ significantly from the norm. Since that report, we have provided the Congress with detailed analysis on how to pursue this objective in a manner that is fair to the physicians. In its March 2006 report, the commission made recommendations that would improve the methods of establishing Medicare fees to make them more accurate and in so doing remove perverse incentives to over-provide certain services.

Regarding comparative clinical effectiveness, the commission believes that such information is critical to all health care in this country including Medicare because it will help us determine what works in health care and what does not work in health care. In its meeting last week, the commission called for the establishment of an independent entity to sponsor and disseminate such information to beneficiaries, providers and insurers.

I look forward to your questions.

[The prepared statement of Mr. Miller follows:]

MEDPAC Medicare Payment Advisory Commission

TESTIMONY

Improving Medicare Efficiency and Value

April 18, 2007

Statement of
Mark E. Miller, Ph.D.

Executive Director
Medicare Payment Advisory Commission

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

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Chairman Pallone, Ranking Member Deal, 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 perspectives on ways to bring greater efficiency to Medicare. MedPAC has sought improvements in Medicare efficiency above and beyond our legislative mandate over the last several years, evidenced in our ongoing work on payment adequacy for Medicare fee-for-service (FFS) payment systems and payments to managed care plans under the Medicare Advantage (MA) program, as well as specific work on pay-for-performance, coordination of care, bundling of medical services, comparative effectiveness, and a host of more targeted studies on specific elements of Medicare payment policy such as payments for imaging services and the sustainable growth rate under the Medicare physician fee schedule. I would like to discuss several of these areas in greater detail today.

There is currently a great deal of interest in improving the efficiency of the Medicare program. This interest is driven not only by the desire to make Medicare a better program but also by growing concern about the sustainability of Medicare spending. Medicare as a public payer has suffered from the same persistently high growth in health care cost that has plagued all sectors of the health financing community. Medicare spending grew 9.3 percent annually between 1980 and 2004, on average, considerably higher than the average annual rate of growth in gross domestic product (GDP) of 6.5 percent for that same period. While growth in GDP—the measure of goods and services produced in the United States—is used as a benchmark of how much additional growth in expenditure society can afford, other measures illustrate the more direct impacts of growth in Medicare spending on the program's beneficiaries. Between 1970 and 2005, the average monthly Social Security benefit increased by an inflation-adjusted average annual rate of 1.6 percent; during the same period, Medicare Supplementary Medical Insurance premiums grew by more than 4 percent annually. Recent Part B premium increases have offset 30 percent to 40 percent of the dollar increase in the average Social Security benefit. Yet, despite this rapid growth in spending, a large body of evidence suggests the increased cost of health care has not come with a corresponding increase in quality. The

Institute of Medicine, in its 2001 report *Crossing the Quality Chasm*, suggested that while care may be improving in many settings, significant gaps remain between what is known to be good care and the care delivered, and it is still all too common for beneficiaries not to receive high-quality health care.

Slowing the increase in Medicare outlays is important; indeed it is becoming urgent. Medicare's rising costs, particularly when coupled with the projected growth in the number of beneficiaries, threaten to place a significant burden on taxpayers. It is likely that all available tools (efficiency gains, efforts to combat fraud and abuse, tax increases, and benefit restructuring) will be necessary to address the financial pressures facing Medicare. Much of MedPAC's work focuses on improved efficiency—getting more in terms of quality and outcomes for each Medicare dollar spent—as a way to help address Medicare's growing financial crisis.

The Commission has implicitly or explicitly dealt with the role of efficiency in many aspects of its ongoing work:

- *Payment updates*. Ensuring that provider productivity is taken into account in estimating recommended payment updates for FFS providers and identifying situations when payments are more than adequate;
- *Payment accuracy*. Ensuring that payments for health care goods and services accurately reflect providers' costs so that adverse incentives are not created (e.g., to select patients and provide higher profit services in lieu of services that provide the best outcomes);
- *Bundling*. Creating larger units of payment to give providers flexibility in the efficient provision of care, while minimizing incentives to increase profits by providing additional services;
- *MA plans*. Ensuring that capitated rates paid to plans are neutral to Medicare FFS, so plans have the incentive to be efficient, and so that beneficiaries will

be able to make choices about their coverage options based on "apples to apples" comparisons;

- *Pay-for-performance programs.* Designing payment system incentives to provide high-quality, appropriate care;
- *Measuring provider resource use.* Using Medicare administrative data to let providers know how their service utilization compares with that of their peers;
- *Care coordination.* Increasing quality of care and decreasing costs when multiple providers are involved by implementing payment incentives that promote coordination and thus reduce adverse advents such as avoidable rehospitalizations following discharge; and
- *Comparative effectiveness.* Ensuring that new health care treatments and technologies represent advances in quality or efficiency in making health care decisions.

MedPAC believes there is considerable opportunity for improvements in program efficiency to increase the incentives for more efficient delivery of health care and, in so doing, help constrain the growth of program spending and increase the value of each dollar spent. Pricing policies can be powerful tools in creating these incentives; other program policies can complement changes to the payment systems. The likelihood of success of these measures in controlling spending will be enhanced if Medicare and other public programs can collaborate with private sector payers to ensure that these incentives are put in place across the board, rather than only in Medicare.

MedPAC believes it is essential to look hard at the value of the services Medicare pays for. For three-quarters of the program's existence, Medicare's reimbursement for services was relatively indifferent to the quality of care provided. In general, as long as claims were submitted in accordance with applicable administrative and policy requirements, Medicare paid them, regardless of whether the quality of the service (to the extent it was even a consideration) was in the top 10 percent or the bottom 10 percent, regardless of whether it resulted in an improved outcome for the patient, and regardless of whether the

service was the most appropriate for a given patient with a given condition. Persistent growth in Medicare spending led to passage of the watershed Balanced Budget Act of 1997 (BBA), which implemented a number of significant reforms to the program, most notably new prospective payment systems for providers that had previously been reimbursed on the basis of their costs and a new managed care program, Medicare+Choice. The rationale for the Medicare+Choice program was driven, at least in part, by the notion that managed care plans could deliver care to Medicare beneficiaries more efficiently than traditional FFS and thus in the long run would provide greater value for both the program and its beneficiaries. Such efficiencies would be leveraged even further by competition among plans, and one of the dimensions upon which plans were explicitly expected to compete was quality. Quality was also invoked in the BBA's authorization of a number of demonstration projects on the competitive acquisition of certain durable medical equipment.

The quality of care beneficiaries receive is not assured. Evidence shows that beneficiaries do not always receive the care they need and too often the care they do get is not high quality. There are also significant geographic variations in the amount of services beneficiaries receive, with little or no relationship to outcomes. This variation in care may expose some beneficiaries to unnecessary risk and is costly to beneficiaries and to the program.

Given the financial pressures facing Medicare, the program can no longer be indifferent to the value of the health care it pays for on behalf of its beneficiaries. The program must focus not only on achieving efficiency through calibrating payments, it must also pay much more attention to the quality and outcomes of the care its beneficiaries receive—in essence, looking not only at the price of health care but also at the value of the care that is purchased for that price.

Payment updates

Each year, the Commission recommends payment updates and other policy changes for FFS Medicare. To help determine the appropriate level of aggregate funding for a given

payment system, the Commission considers whether current Medicare payments are adequate by examining information about beneficiaries' access to care; changes in provider supply and capacity; volume and quality of care; providers' access to capital; and, where available, the relationship of Medicare payments to providers' costs. As mandated by the Congress, MedPAC explicitly considers efficiency in making these assessments: Ideally, Medicare's payments should not exceed the costs of the efficient providers. Efficient providers use fewer inputs to produce quality services. We then account for expected cost changes in the next payment year, such as those resulting from changes in input prices.

Improvements in productivity should reduce providers' costs in the coming year. Medicare's payment systems should encourage providers to reduce the quantity of inputs required to produce a unit of service by at least a modest amount each year while maintaining service quality. Thus, in most cases where payments are adequate, some amount representing productivity improvement should be subtracted from the initial update value, which is usually an estimate of the change in input prices. Consequently, we apply a policy goal for improvement in productivity. This factor links Medicare's expectations for efficiency to the gains achieved by the firms and workers who pay taxes that fund Medicare. Under this construct, MedPAC has identified instances in which payments are more than adequate and, on several occasions in recent years, has recommended no annual updates to provider payments. Most recently, in our March 2007 report to the Congress, we produced a number of update recommendations for the 2008 payment year cognizant of potential provider efficiency gains that will generate program savings if implemented:

- Skilled nursing facility (SNF) services. The Commission recommended that the Congress eliminate the update to payment rates for SNF services for fiscal year 2008;

- Home health services. The Commission recommended that the Congress eliminate the update to payment rates for home health care services for calendar year 2008;

- Inpatient rehabilitation facility (IRF) services. The Commission recommended that the Congress update payment rates for IRFs for fiscal year 2008 by 1 percent;

- Long-term care hospitals (LTCH). MedPAC recommended that the Secretary eliminate the update to payment rates for LTCH services for 2008.

Medicare should exert continued financial pressure on providers to control their costs, much as would happen in a competitive marketplace. We have found, for example, that hospitals under financial pressure tend to control cost growth better than those that have non-Medicare revenues that greatly exceed their costs. The Commission is striving to pursue innovative means to increase value in Medicare while maintaining financial pressure in all its payment systems to restrain costs.

Payment accuracy

Another component of encouraging efficiency through payment policy is to ensure that Medicare's payments for health care services are accurate. Misvalued services can distort the price signals for a wide variety of health care services. Some overvalued services may be overprovided because they are more profitable than others. Under Medicare Part B, mispricing may exacerbate the volume-inducing effects of the physician fee schedule. We identified similar situations in Part A. For example, our 2005 analysis of specialty hospitals showed that certain kinds of physician-owned specialty hospitals were extremely adept at identifying (and focusing on) more profitable diagnosis related groups (DRGs), and within those DRGs, the least sick (and most profitable) patients. By contrast, undervalued services may prompt providers to increase volume to maintain their overall level of payment. Conversely, some providers may opt not to furnish undervalued services, which can threaten access to care. For example, MedPAC has identified potential problems with Medicare's payment systems for both SNFs and hospices that may underpay and thus discourage these providers from accepting Medicare patients with complex medical conditions requiring expensive drug or nontherapy ancillary regimens as part of their treatment.

A service can become overvalued for a number of reasons. For example, under Medicare's physician fee schedule, the amount of physician work needed to furnish a service may decline as physicians become more proficient or when new technologies are incorporated. Services can also become overvalued when practice expenses decline. Likewise, services can become undervalued when physician work increases or practice expenses rise. Although CMS reviews the relative values assigned to physician services every 5 years, some services likely continue to be misvalued. In recent years, per capita volume for different types of services has grown at widely disparate rates, with volume growth in imaging and minor procedures outpacing that for visits and major procedures. Volume growth differs across services for several reasons, including variability in the extent to which demand for services can be induced and advances in technology that expand access and can improve patient outcomes. The Commission and others have voiced concerns, however, that differential growth in volume is due in part to differences in the profitability of services.

Differences in the profitability of services send signals to the market that go beyond incentives to over- or underfurnish services. For example, certain types of overvalued physician services may become more concentrated in some specialties than in others, such as primary care, that provide proportionately more low-profit services (such as evaluation and management services) that are less amenable to productivity gains. Facing these incentives, new physicians may be less willing to choose specialties that frequently provide undervalued services, resulting in reduced beneficiary access to certain physicians and certain services.

MedPAC has analyzed the issue of payment accuracy at great length in the context of Medicare's physician payment system. The Commission concluded in its March 2006 report to the Congress that CMS's process for reviewing the work relative values of physician services must be improved. To maintain the integrity of the physician fee schedule, we recommended that CMS play a lead role in identifying overvalued services

so that they are not ignored in the process of revising the fee schedule's relative weights. We also recommended that CMS establish a group of experts, separate from the Relative Value Scale Update Committee (RUC), to help the agency conduct these and other activities. This recommendation was intended not to supplant the RUC but to augment it. To that end, the group should include members who do not directly benefit from changes to Medicare's payment rates, such as experts in medical economics and technology diffusion and physicians who are employed by managed care organizations and academic medical centers. The Commission also urged CMS to update the data and assumptions it uses to estimate the practice expenses associated with physician services.

Ensuring the accuracy of payments to other providers—including hospitals and post-acute care providers—is also important. To this end, the Commission recommended refinements to the DRGs used in Medicare's hospital inpatient prospective payment system to capture differences in severity of illness among patients and thus reduce the potential for differential profitability of DRGs or individual patients within DRGs. We also recommended improving the case-mix systems used in Medicare's payment systems for post-acute care services, most notably the payment groups used under the SNF prospective payment system (PPS), to provide appropriate incentives for SNFs to treat patients requiring nontherapy ancillary services.

We recognize that CMS has many priorities and limited resources and that refinements to the various payment systems to ensure accuracy of payments will raise some difficult technical issues. These include the potentially increasing the number of payment groups, possible increases in spending from improvements in coding, and others. The Congress should take steps to ensure that CMS has the resources it needs to make the recommended refinements to Medicare's payment systems.

Bundling

Another way to promote efficiency through pricing in the delivery of health care services to Medicare beneficiaries is through "bundling." In bundling, a single payment is made for a group of related services, rather than making individual payments for each service

in the group. A larger unit of payment puts physicians and other providers at greater financial risk for the services provided and thus gives them an incentive to provide and order services judiciously. Medicare already bundles preoperative and follow-up physician visits into global payments for surgical services. Candidates for further bundling include services typically provided during the same episode of care, particularly those episodes for conditions with clear guidelines but large variations in actual use of service, such as diabetes treatment. In identifying the best candidates for bundling, one must consider that, while bundled payments could lead to fewer unnecessary services, they could also lead to stinting or unbundling (e.g., referring patients to other providers for services that should be included in a bundle). Medicare should explore options for increasing the size of the unit of payment to include bundles of services that physicians often furnish together or during the same episode of care, similar to the approach used in the hospital inpatient PPS.

MedPAC will be examining bundling the hospital payment and physician payment for a given DRG and for groups of DRGs, which could increase efficiency and improve coordination of care. This approach to bundling could be expanded in the future to capture periods of time (e.g., 1 or 2 weeks) after the admission but likely to include care (e.g., post-acute care, physician services) strongly related to the admission, further boosting efficiency and coordination across sites of care. We have also recommended broader bundling of services for patients with end-stage renal disease, most notably suggesting the inclusion of erythropoietin in the payment bundle (see above) to reduce the incentive to provide more of a given item or service to reap greater profits. Bundling services could be structured so that savings go to the providers, the program, or both.

Medicare Advantage

The Commission has discussed the concept of efficiency at great length with respect to the MA program. Many of the positions and principles the Commission has adopted with respect to increasing efficiency through pricing of individual services or groups of services also apply to the calculation of payments for even larger groups of services—to wit, the capitated payments paid to managed care plans under MA. The Commission has

always supported a private plan option in Medicare, given the potential savings and expanded beneficiary choice the private plans can bring to Medicare.

In our March report, the Commission presented recent findings on the MA plans beneficiaries can join in lieu of traditional FFS Medicare. While the initial intent of the MA program may have been predicated on the idea that managed care represented a less costly alternative to FFS Medicare, our most recent findings suggest that payments to plans are generally higher—in some cases much higher—than corresponding payments would have been on behalf of the same beneficiaries under traditional FFS. The Commission believes that greater efficiency is achieved when organizations face financial pressure. The Medicare program needs to exert consistent financial pressure on both the traditional FFS program and the MA program. This financial pressure, coupled with meaningful measurement of quality and resource use to reward efficient care, will maximize the value of Medicare for the taxpayers and beneficiaries who finance the program.

Medicare's private plan option was originally designed as a program that would produce efficiency in the delivery of health care. Efficient plans could be able to provide extra benefits to enrollees choosing to enroll in such plans, and better efficiency would lead to higher plan enrollment. Unfortunately, MA has instead become a program with few incentives for efficiency. Although MA uses "bidding" as the means of determining plan payments and beneficiary premiums, the bids are against benchmarks that are not competitively set. Setting benchmarks well above the cost of traditional Medicare signals that the program welcomes plans that are more costly than traditional Medicare. Inefficient plans—as well as efficient plans—are able to provide the kind of enhanced coverage that attracts beneficiaries to private plans because of generous MA program payments that are in excess of Medicare FFS payment levels. All taxpayers, and all Medicare beneficiaries—not just the 18 percent of beneficiaries enrolled in private plans—are funding the payments in excess of Medicare FFS levels.

Our analysis of MA payments shows that the benchmarks (which are the reference level for plan bids and the maximum program payment) now average 116 percent of traditional Medicare FFS levels, and payments average 112 percent. The ratio of benchmarks and payments varies by plan type, although it exceeds the expected Medicare FFS expenditures for those beneficiaries for all types of plans. Table 1 shows that payments to HMOs are 110 percent of expected FFS costs. Payments for private FFS (PFFS) plans are 119 percent of expected Medicare FFS costs, because they are located in areas of the country where benchmarks are much greater than FFS, and because they are relatively inefficient at returning benefits to their enrollees.

Table 1. Medicare Advantage benchmarks and payments in 2006 exceed expected Medicare fee-for-service expenditures for all types of plans

	HMO/POS/ PSO*	Local PPOs*	Regional PPO*	PFFS
Enrollment as of July 2006 (in thousands)	5,195	285	82	774
Enrollment as of February 2007 (in thousands)	5,063	333	109	1,328
Net enrollment growth	-3%	17%	33%	72%
Benchmark relative to FFS cost	115%	120	112	122
Payments relative to FFS cost	110%	117	110	119
Bid (for Medicare A/B benefit) relative to FFS	97%	108%	103%	109%

Note: POS (provider of service), PSO (provider-sponsored organization), PPO (preferred provider organization), PFFS (private fee-for-service), FFS (fee-for-service). Payments relative to expected FFS costs for the beneficiaries enrolled in Medicare Advantage plans.

* Data exclude special needs plans.

Source: MedPAC analysis of data from CMS on plan bids, enrollment, and benchmarks.

Private plans are given the flexibility and the incentives to improve the delivery of care and bargain with providers to negotiate payment rates that are expected to create program savings. However, the excess payments to private plans allow them to be less efficient than they would otherwise have to be, because inefficient plans can use the excess payments—rather than savings from efficiencies—to finance extra benefits that in turn attract enrollees to such plans. As shown in Table 1, enrollment has grown substantially

in MA as result of this situation. In 2006, 17 percent of beneficiaries were enrolled in MA plans, a level close to its all-time high.

Strikingly, almost half the growth in 2006 was in PFFS MA plans—the highest-paid and thus arguably least efficient—of the available types of MA plans. PFFS plans are nearly identical to Medicare FFS but with an added layer of marketing, operating and administrative costs, and profits. If the growth in enrollment in these plans reflected beneficiary preferences in the form of their willingness to pay higher premiums, such patterns would reflect a perceived benefit. However, it is likely that this growth has been fueled by program subsidies. PFFS plans primarily draw their enrollment from higher benchmark counties—specifically counties that were historically "floor" counties. MA benchmarks in these counties reflect a minimum payment level established by statute, resulting in benchmarks far above FFS expenditure levels in most cases. The statutory floor thus provides an implicit subsidy for these plans, and thus it is difficult to see the additional value such plans provide to Medicare beneficiaries for the additional cost to the program.

The Commission has always supported a private plan option in Medicare and has recommended lowering the MA benchmarks to help achieve a policy of financial neutrality between private plans and traditional Medicare FFS for several years. In addition to financial neutrality between MA and FFS, the Commission has also recommended neutrality between types of MA plans, including eliminating the stabilization fund for preferred provider organization plans and making bidding rules consistent across plan types. Further, the Commission has recommended a pay-for-performance program for MA plans, and calculating clinical measures for the FFS program that would permit CMS to compare quality in the FFS program with that in MA plans.

Obtaining greater value

Ideally, payment systems not only reflect efficient and accurate pricing, but also give providers incentives to furnish better quality of care, to coordinate care (across settings,

in chronic conditions), and to use resources judiciously. However, Medicare pays its providers the same regardless of the quality of their care, which perpetuates poor care for some beneficiaries, misspends program resources, and is unfair to high-performing providers. Medicare's payment system does not reward providers for coordinating patients' care across health care settings and providers, nor does it encourage the provision of preventive and primary care services, even though such actions may improve quality of care and reduce costs.

To change payment incentives, the Congress and CMS must adopt policies that link payment to the quality of care provided. MedPAC's pay-for-performance recommendations would go some way toward correcting the problem of lack of incentives for quality care. At the same time, Medicare needs to explore measuring provider resource use and to encourage coordination of care and provision of primary care.

Comparative effectiveness

Increasing the value of the Medicare program to beneficiaries and taxpayers requires knowledge about the costs and health outcomes of services. Until more information on the comparative effectiveness of new and existing health care treatments and technologies is available, patients, providers, and the program will have difficulty determining what constitutes good-quality care and effective use of resources.

Comparative-effectiveness information, which compares the outcomes associated with different therapies for the same condition, could help Medicare use its resources more efficiently. Comparative effectiveness has the potential to identify medical services that are more likely to improve patient outcomes and discourage the use of services with fewer benefits. CMS already assesses the clinical effectiveness of services when making decisions about national coverage and paying for some services, but to date FFS Medicare has not routinely used comparative information on the costs of services. Medicare Part D plans and other payers and providers, however, such as the Veterans Health Administration, do use such information—for example, in drug formulary

decision-making processes. Such information is critical for these entities, given the force of new technology in driving increased health care costs and the need for these payers to closely evaluate the comparative benefits of costly new technologies relative to existing treatments.

Private health plans and providers have not been at the forefront of effectiveness research. Private payers and providers may be reluctant to use comparative-effectiveness information extensively for fear that patients will criticize them as being more concerned about cutting costs than about patients' health. Litigation risks may also dissuade some private payers from using comparative-effectiveness information. In addition, private payers may anticipate problems keeping the information proprietary (thus aiding their competitors) and may fear that it would be difficult to capture the full return on their investment.

Medicare could use comparative-effectiveness information in a number of ways to improve the value of care beneficiaries receive. Medicare could use such information to inform providers and patients about the value of services, since there is some evidence developed by the Sacramento Healthcare Decisions group in 2001 and by Marjorie Ginsburg in 2004 that both might consider comparative-effectiveness information when weighing treatment options. Medicare might also use the information to prioritize pay-for-performance measures, target screening programs, or prioritize disease management initiatives. In addition, Medicare could use comparative-effectiveness information in its rate-setting process.

Given the potential utility of comparative-effectiveness information to the Medicare program, an increased role of the federal government in sponsoring the research may be warranted. Concerns have been raised by Moher and colleagues in the *Annals of Internal Medicine* about the variability and lack of transparency in methods and by Bekelman and colleagues regarding the potential bias of industry-sponsored researchers conducting

clinical- and cost-effectiveness research. MedPAC inventoried many of these concerns in our June 2006 report to the Congress.

A public-private partnership may more effectively address stakeholders' concerns about the use of comparative-effectiveness analysis than a noncollaborative process. A partnership that defines analytic standards would send researchers a clear, effective signal to improve their methods and develop valid and transparent comparative-effectiveness analyses. A partnership could help set priorities for clinical-effectiveness review and research. Services could be selected based on disease prevalence, high per unit cost, high total expenditures, and other factors.

Implementing the findings from comparative-effectiveness analysis may not save money for the Medicare program. Wider use of cost-effective, underutilized services could result in increased Medicare spending, which might not be offset with savings elsewhere. On the other hand, over the long run, comparative-effectiveness research could save the Medicare program money if it encourages manufacturers to develop services that are more cost-effective than current ones or if it helps inform providers and influences their patterns of care.

Pay-for-performance programs

Medicare has a responsibility to ensure that its beneficiaries have access to high-quality care. Yet beneficiaries receive care from a system known to have problems with quality. Beth McGlynn and fellow researchers have noted that care is improving in many settings, but significant gaps remain between what is known to be good care and the care delivered. For example, Cathy Schoen, Karen Davis, and coauthors reported in 2006 that only about half the adults in the United States receive all recommended clinical screening tests and preventive services, and many quality indicators vary widely across states.

Measures of quality and guidelines for appropriate care are increasingly available. The Medicare program has been a leading force in efforts to develop and use quality measures, often leading initiatives to publicly disclose quality information, standardize

tools for data collection, and give feedback to providers for improvement. CMS has also revised its regulatory standards to require that providers, such as hospitals and home health agencies, have quality improvement systems in place. CMS is conducting a number of demonstrations to explore whether financial incentives can improve the quality of care providers furnish. CMS's focus on quality provides a strong foundation for future initiatives.

While these tools can begin to improve quality, financial disincentives to improve quality allow the quality gap to persist. Medicare pays all health care providers without differentiating on the basis of quality. Those providers who improve quality are not rewarded for their efforts. In fact, Medicare often pays more when poor care results in complications that require additional treatment. The same negative or neutral incentives toward quality exist in the private sector. Many private purchasers and plans are experimenting with mechanisms to counterbalance these forces and reward those who provide high-quality care. Yet, they agree that Medicare's participation in these efforts is critical because of its market power and because private sector efforts alone may take a much longer time to show effects.

In a series of reports, we have recommended that Medicare change the incentives of the system by basing a portion of provider payment on performance. In our June 2003 report to the Congress, we established criteria for measures to compare providers to determine whether pay for performance is feasible in settings where Medicare beneficiaries receive care. The Commission also developed design principles to provide guidance on how to administer and fund a pay-for-performance program, which should:

- Reward providers based on improving care and exceeding certain benchmarks,
- Be funded by initially setting aside a small proportion of payments,
- Distribute all payments that are set aside to providers who achieve the quality criteria, and
- Establish a process through which measures can continue to evolve.

In our March 2004 report to the Congress, we found that MA plans and the facilities and physicians that care for dialysis patients were settings where pay-for-performance strategies could be implemented. In our March 2005 report to the Congress, we evaluated the available measures and measurement activities for physicians by our criteria and found useful structural, process, and patient experience indicators. Outcomes measures could be used with additional data and research. Therefore, we recommended that the Congress establish a quality incentive payment policy for physicians in Medicare. We also recommended pay-for-performance strategies for hospitals and home health agencies. While such efforts are important in increasing the quality of care provided to Medicare beneficiaries, it is important to note that MedPAC does not consider adjusting payments to reflect quality of care to be the end goal of pay-for-performance systems. Rather, we believe that once the link between payments and quality is well established, Medicare should then use the "payment" aspect of pay for performance to further drive increased efficiency—reflected by the combination of quality and cost—in delivering health care service.

Measuring provider resource use

In addition to implementing incentives via payment systems through pay-for-performance type mechanisms, Medicare could use other means of getting providers to think more consciously about the services they provide and thus enlist them as more active partners in the effort to ensure efficient care. One way to do this, as MedPAC has recommended previously, would be for the program to consolidate data on provision of services at the level of individual providers. Medicare could identify physicians and other providers with very high resource use relative to their peers. CMS could initially provide confidential feedback to these providers on an informational basis only. Once greater experience and confidence in resource-use measurement tools were gained, policymakers could use the results for additional interventions such as public reporting, targeting fraud and abuse, pay for performance, or differential updates based on relative performance.

Measuring provider resource use relative to a peer group, and providing such information to the providers, would promote individual accountability and would enable providers to more readily see a link between their actions and Medicare spending overall. However, a number of technical issues would need to be resolved. Providers will need to be confident that their scores reflect the relative complexity of their patient mix and that they are being compared with an appropriate set of peers. There would likely be considerable controversy around initial scores as some providers realized that their practice patterns were not in line with those of their peers.

MedPAC has made considerable progress in simulating how such a system might work in practice. In Table 2, we provide an example of comparing the resource use of an actual physician with the averages for his specialty within the market area. We demonstrate how the comparison can be broken down by type of case—both the stage of disease and the presence of comorbidities in patients. We then break down the comparison by the types of services that went into the selected episodes. The result is a comparison that can provide useful feedback to physicians about why their performance differs from that of their peers.

We use an individual cardiologist in Boston to compare a physician's clinical resource use with an overall expected value (an average across all specialties for the Boston metropolitan statistical area (MSA)) and with a specialty-specific expected value. We compare his actual clinical resource measurement with expected clinical resource measurement (based on the averages for all cardiologists treating hypertension in the Boston MSA) and calculate corresponding ratios. Ratios greater than 1.0 indicate higher than average values for clinical resource measurement (observed greater than expected) and ratios less than 1.0 indicate lower than average values for clinical resource measurement (observed lower than expected). When we use an expected clinical resource measurement value for cardiologists in Boston, his overall observed-to-expected ratio is 1.74, or not quite twice the average clinical resource measurement value.

Table 2: Selected Boston cardiologist has higher clinical resource measurement for hypertension than his peers

		Overall patient complexity level (low to high)				
	All episodes	1	2	3	4	5
Stage 1 hypertension						
Number of episodes	141	41	45	35	13	7
Clinical resource use						
Selected Boston cardiologist	$623	$453	$660	$814	$630	$410
Average for all Boston cardiologists	$357	$251	$307	$369	$409	$450
Selected cardiologist's resource use score	*1.74*	*1.80*	*2.15*	*2.21*	*1.54*	*0.91*

Note: Stage indicates progression of the disease, with 1 being the mildest form. Overall complexity level indicates the presence of other diseases. Resource use score is the ratio of the cardiologist's resource use to the average for cardiologists in Boston.

Source: MedPAC analysis of 100 percent sample of 2001–2003 Medicare claims using the Medstat Episode Group grouper from Thomson Medstat.

MedPAC believes there is tremendous potential in making these comparisons of resource use and has recommended that Medicare collect and consolidate information on provider resource use and provide feedback on resource use to individual providers. Physicians would then be able to assess their practice styles, evaluate whether they tend to use more resources than their peers (or what available evidence-based research recommends), and revise their practice styles as appropriate. Once greater confidence with the measurement tool was gained, Medicare could use the results for payments—for example, as a component of a pay-for-performance program that rewards both quality and efficiency. CMS could also use the measurement tool to flag unusual patterns of care that might indicate misuse, fraud, and abuse.

Care coordination

In recent years, the Commission has explored multiple strategies to provide incentives for high-quality, low-cost care and thus improve efficiency in the Medicare program. However, even if individual providers are efficient, a beneficiary may still receive less-than-optimal care if providers do not communicate well with each other or if they do not

monitor patient progress over time. To address this problem, we have considered ways to introduce care coordination and care management by creating incentives for providers to share clinical information with other providers, monitor patient status between visits, and fully communicate with patients about self-care.

The patients most in need of care coordination are those with multiple chronic conditions and other complex needs. Beneficiaries with chronic conditions represent a significant proportion of Medicare spending. In 2005, the Congressional Budget Office estimated that beneficiaries with more than one chronic condition made up 48 percent of the highest cost beneficiaries in 2001 but only 12 percent of the lowest cost beneficiary population. Yet, evidence continues to mount that beneficiaries with chronic conditions do not receive recommended care and may have hospitalizations that could have been avoided with better primary care. Researchers attribute this problem to poor monitoring of treatment—especially between visits—for beneficiaries and to a general lack of communication among providers. Coordinated care may improve patients' understanding of their conditions and compliance with medical advice and, in turn, reduce the use of high-cost settings such as emergency rooms and inpatient care. Ideally, care coordination will improve communication among providers, eliminating redundancy and improving quality.

Care coordination is difficult to accomplish in the FFS program because it requires managing patients across settings and over time, neither of which is supported by current payment methods or organizational structures. Further, because patients have the freedom to go to any willing physician or other provider, it is difficult to identify the practitioner most responsible for the patient's care, especially if the patient chooses to see multiple providers. The challenge is to find ways to create incentives in the FFS system to better coordinate care.

In our June 2006 report to the Congress, we outlined two illustrative care coordination models for complex patients in the FFS program: (1) Medicare could contract with providers in large or small groups that are capable of integrating the information technology and care manager infrastructure into patient clinical care, and (2) CMS could

also contract with stand-alone care management organizations that would work with individual physicians. In either model, payment for services to coordinate care would be contingent on negotiated levels of performance in cost savings and quality improvements. Given that Medicare faces long-term sustainability problems and needs to learn more about the most cost-effective interventions, the entities furnishing the care managers and information systems should initially be required to produce some savings as a condition of payment. Demonstrating continued savings may not be necessary or feasible once strategies for coordinating care are broadly used.

MedPAC has illustrated one of the ways in which lack of care coordination is manifested by low-quality, high-cost care in its recent discussion of hospital readmissions from a post-acute care setting. Under the inpatient hospital PPS, hospitals have a strong incentive to reduce their costs, which can be achieved in part by reducing patient length of stay. They have little, if any, financial incentive to invest in managing post-hospital discharge transitions. In some cases, hospitals may discharge patients prematurely, resulting in a readmission to the hospital in the event that the patient's condition deteriorates at home or in a post-acute care setting as a result of the premature discharge. Readmissions may also occur as a result of discharges hobbled by incomplete coordination with a post-acute care provider. In such events, not only does the beneficiary receive lower quality (and potentially even life-threatening) care, but additional costs are added to Medicare. The Commission is exploring a two-step means of reducing readmission rates, first by publicly reporting hospital-specific readmission rates for a subset of conditions, followed by an adjustment to the underlying payment method to penalize hospitals with higher readmission rates.

Conclusion

In addition to taking efficiency into account when calculating payment rates or assessing the amount of annual provider payment updates, Medicare should institute policies that improve the value of the program to beneficiaries and taxpayers. Those policies should reward providers and health plans for efficient use of resources and create incentives to

increase quality and coordinate care. Policies such as pay for performance that link payment to the quality of care physicians and other providers furnish should be implemented. At the same time, Medicare should encourage coordination of care and provision of primary care, bundle and package services where appropriate to reduce overuse, and ensure that its prices are accurate. To reduce unwarranted variation in volume and expenditures, Medicare should collect and distribute information about how providers' practice styles and use of resources compare with those of their peers. Ultimately, this information could be used to adjust payments to physicians. Findings from comparative-effectiveness research should be used to inform payment policy and furnished to beneficiaries and providers to inform decisions about medical care. Finally, concerted efforts should be made to identify and prevent misuse, fraud, and abuse by strengthening provider standards, ensuring that services are furnished by qualified providers to eligible recipients, and verifying that services are appropriate and billed accurately and that payments for those services are correct.

Because there are numerous payers in the U.S. health care system, achieving gains in efficiency is difficult for any one payer. To engender broader changes among providers, Medicare will likely need to collaborate with other payers but can take a leading role in driving change. But if we want Medicare to function more efficiently, the Congress needs to provide CMS with the necessary time, financial resources, and administrative flexibility. CMS will need to invest in information systems; develop, update, and improve measures of quality and resource use; and contract for specialized services. In the long run, failure to invest in CMS will result in higher program costs and lower quality of care.

Mr. PALLONE. Thank you, thank you both, and I will now start with the questions and I will recognize myself for 5 minutes initially.

I wanted to ask Dr. Miller, if the recommendations made by MedPAC regarding payments to Medicare private plans were enacted, do you believe that there are plans that can provide additional benefits to beneficiaries?

Mr. MILLER. Yes, and the 12 percent gets cited a lot but there is other work that we have done that shows that there are differences among the plans and their efficiencies. So for example, HMOs, which have more coordinated care and network types of approaches to care, actually can provide the traditional fee-for-service benefit more efficiently than the traditional Medicare Program. Those types of plans, the original intent of managed care was that plans like that would take those savings, use the additional savings to provide additional benefits and in turn attract beneficiaries to those plans. So yes, we do believe that there are plans who can provide—who are efficient enough to provide additional benefits to beneficiaries.

Mr. PALLONE. Obviously the private plans were introduced to save money through efficiencies and your recommendations—well, you can tell me. Do you think the current payment system for Medicare Advantage plans reward efficiency and would your recommendations still allow the most efficient plans to compete for Medicare beneficiaries by offering additional benefits and low premium? That is what I assume competition is all about.

Mr. MILLER. I think that is the intent of our recommendation is that right now, and I think the chairman said this in another hearing, that he feels that we are sending a signal that invites inefficient plans to come into the program, and I think our recommendations are directed toward encouraging efficiency among plans and encouraging those plans who can achieve those efficiencies to stay in the program, provide the extra benefit. Right now the way the payment system works is, it encourages plans that are not more efficient than the traditional Medicare Program and then when additional benefits are offered on top of that through the subsidies, obviously beneficiaries are attracted to those plans but not because of the efficiencies and the additional benefits through those but because of the additional benefits that are paid through the subsidy.

Mr. PALLONE. OK. Thank you. I have been bombarded recently with insurers who argue that low-income and minority beneficiaries disproportionately rely on Medicare Advantage plans for supplemental coverage, and you recently testified, however, that the best and most targeted approach for helping this population would be to strengthen the Medicare savings program within Medicaid that helps low-income beneficiaries pay for their premiums and cost sharing. Is that still your position?

Mr. MILLER. What we said in that hearing when we got this question was, this is an inefficient way of providing subsidies for low-income populations, and just think about it for a second. The way this work is, it is only available to someone who enrolls in a plan and whoever enrolls in that plan, whether they are low income or not, receives the benefit and so if we are spending dollars and our intent is to subsidize low-income beneficiaries, it is kind

of a messy way of doing it. There are a couple other examples out there of much more targeted ways to get at low-income beneficiaries and provide them subsidies. Inside the part D benefit, low-income subsidies are paid to the plan on the basis of the beneficiary qualifying through their income and assets, and so the plan doesn't get additional payments for everybody, they get additional payments for those beneficiaries that are low income. Additionally, the point that you made is in the traditional fee-for-service program under Medicaid, again if you qualify income and assets, Medicaid will assist you on your premium and depending, on your co-payment as well, and again, that is only available to people who are qualified and again a more targeted approach to that.

Mr. PALLONE. Thank you.

Ms. Norwalk, there are advocates and constituents who have complained of questionable marketing practices by prescription drug plans, especially certain Medicare Advantage prescription drug plans, and I would like to better understand what CMS is doing to address this matter. How many Medicare Advantage or Medicare Advantage prescription drug plans have been sanctioned for inappropriate marketing last year or this year and how many have been assessed a civil monetary penalty for violating marketing rules last year or this year, and then how many have been prohibited from enrolling new beneficiaries as a result of violations of marketing requirements, again last year or this year?

Ms. NORWALK. I don't have the numbers specifically at my fingertips but we will get them back to you for the committee for the record. I would say this, that in terms of marketing violations, one of the issues that we are dealing with is that marketing agents and brokers are regulated by the State. We recently have been working with the National Association of Insurance Commissioners and have signed MOUs with 17 States and Puerto Rico to ensure that when we see marketing violations, that we can report it to the State and the State can sanction the agent and broker, often who are independent. They may be an independent agent that is working on their own and actually marketing on behalf of a number of different plans. We are working with the plans to ensure that they are doing the appropriate training, and if they are employed by the plan would be able to sanction the plan for having had that agent or broker, but we think it is critical to work with the State insurance commissioners so that they can take the appropriate actions at the State level against the individual at the same time that we take action with the Medicare Advantage plan to ensure that the marketing that they are doing is appropriate. We also want to be careful of the beneficiary, ensuring that whatever happens that the beneficiary can have an open enrollment period and that beneficiary can change plans so if they have been put in a plan where they didn't understand, where they were fooled, if you will, we will let them change back with no financial penalty to them.

Mr. PALLONE. And if you can get back to me with the details. I appreciate it.

Mr. Deal.

Mr. DEAL. Thank you.

Ms. Norwalk, I understand that CMS has just recently issued its final rule on the competitive bidding provisions for durable medical

equipment. That provision had requirements for certification and accreditation in it. My understanding though is that CMS has granted a grace period for providers who are not accredited, a grace period in which they can get accredited, but will allow them to go ahead and participate in competitive bidding. My concern is that since the cost of accreditation is a rather sizable cost in some instances, will those unaccredited providers who are allowed to bid have an unfair advantage over accredited providers and what is CMS doing to try to make sure that doesn't happen?

Ms. NORWALK. You do have to be accredited in order to bid for the first 10 competitive bidding areas under our rules, so what we have done is, we have directed those who will be accrediting the suppliers to ensure that they start with the suppliers that work in these 10 areas to make sure that they have an ability or the time in which they can become accredited. All competitive bidders must be accredited by the end of the year and then all competitive bidders in the next 80 MSAs or the next 70 which need to be accredited by the end of next year so there should be no unfair advantage. Even physicians who don't have to bid must be accredited in order to provide DME supplies to Medicare beneficiaries. It is going to be done across the board.

Mr. DEAL. But if they are pending accreditation, they are still allowed to bid. Is that not true?

Ms. NORWALK. Well, the way that it will work is that you need to be accredited before the program is going to start. The program won't start until April 1, 2008, so we would actually not award anyone the ability to be a provider until that time, there is a quarter lag, if you will, between the time they need to be accredited by and the time we actually start competitive bidding so that we can make sure that no one has an unfair advantage.

Mr. DEAL. As my opening statement indicated, I have an interest in trying to monitor what we have done in the imaging area. Under the rules we put in place under the Deficit Reduction Act, we of course tried to equalize reimbursements for settings other than the outpatient hospital setting with equalization on a portion of the technical component of the reimbursement. Now, that has been in place for about 3 months now. Can you tell us if you have determined any effects of that and if so what they might be?

Ms. NORWALK. We are just starting to get in the quarterly data and I am happy to report back to you when we have a chance to analyze it in greater detail since the first quarter just ended. I get screen shots on my computer of what is happening with imaging. I took a look at it on the way over here. It is inevitable that when there are payment changes, it doesn't matter what the change is, it does impact utilization. The question is, is that impact in utilization appropriate, are we seeing a downturn simply because the payments are less or are we seeing a downturn because the payments are less and the services weren't necessary. So we will be taking a very close look at the interaction between both the quality and the utilization and I will be happy to brief you in greater detail.

Mr. DEAL. I think that would be critical for us to know what the next step might be. One of the concerns that I heard expressed in the imaging area is that overutilization of imaging might result in

some risk and harm to patients due to the iodizing radiation that occurs. Is CMS looking at that question of maybe a health concern for overutilization rather than just the purely economic overutilization? Is there a health risk and are you looking at that?

Ms. NORWALK. Well, I will certainly ensure that if we haven't been, I will ask my doctors to take a closer look. How is that?

Mr. DEAL. All right. That sounds good to me. I also made reference to the situation in Chicago about the sham lease arrangements and my understanding is that there were basically kickbacks being done by the providers of the services, billing it to the doctors, the doctors in turn seeking reimbursements. Have you all looked at that from the CMS level and are you working with the attorney generals in various States to look at that?

Ms. NORWALK. We spend a lot of time with our colleagues both in the OIG who implement the kickback statute for the Department as well as DOJ generally. I think there are a couple of things that I would point out here. A lot of what we are seeing are physicians buying this equipment and we may be well served in making sure that if they purchase the equipment, that the beneficiaries know that if they are getting a scan, part of the reason may be because they want to amortize the value of the equipment. Now, lots of physicians do the right thing all the time. The point is, let us get the right imaging service done whatever it happens to be without regard to the dollars in the provider's pocket.

Mr. DEAL. Very quickly, Dr. Miller, has your office looked at fraudulent or abusive behavior on these advanced imaging procedures as it relates to Medicare or Medicaid?

Mr. MILLER. Not so much at the fraud. We made a set of recommendations in trying to increase the standards for both the providers who are billing Medicare and the equipment to your point on the radiation, making sure that the equipment and the technicians that are running the equipment are as good as they can be. We did make some recommendations to reduce excessive billing through some billing code recommendations that we made and also made recommendations on some of the treatment of things under the star clause, that there were some loopholes that we felt existed in the star clause, and that is all detailed in our reports but we haven't done specific pursuit of fraud, that type of thing.

Mr. DEAL. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you.

Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman.

Ms. Norwalk, we just heard Mr. Miller testify that Medicare's payment system doesn't necessarily encourage primary or preventive care even though we know that primary and preventive care improves health outcomes and catches health care problems before they become costly emergencies. When our committee marked up the Medicare Modernization Act, our former colleague, Ernie Fletcher, and I included in the bill a diabetes screening benefit under part B. In our view, it didn't make a whole lot of sense for Medicare to pay for diabetes treatment but not pay for the beneficiaries to get screened for the disease. Since then we have heard CMS has done very little to promote the benefit and that take-up rates linger in the single digits. This is an alarming summation, es-

pecially since 60 percent of all Medicare beneficiaries have diabetes or pre-diabetes and could greatly benefit from the early detection. I know the American Diabetes Association has been unsuccessful in obtaining official utilization numbers from CMS and you and Secretary Leavitt will probably get a letter from me this coming week asking for that information. But in this venue, can you explain what steps CMS has taken for providers and beneficiaries to promote utilization of diabetes screening benefit and do you agree that the screening benefit for a disease is so prevalent among Medicare beneficiaries if implemented correctly could contribute increased efficiency in delivery of that health care under the Medicare Program?

Ms. NORWALK. You raise a terrific point. Without question, it is critical that we do more in terms of prevention. In fact, I am going to be missing the bus today but the reason I was going to leave early was to start a nationwide bus tour to focus with our partners including those in diabetes to go around the country, get people to sit down at the table to promote just this type of benefit. All of our prevention benefits but without question, the diabetes screening prevention benefit, is included in that. We have been working with all of our partners to make sure that we have the appropriate data so we can determine, have we been successful. But the focus of this bus tour—and the Secretary and I are doing a kickoff along with Julie Gerberding and others at HHS on Friday. We would love you to come down if you want to come and talk to us about prevention and its importance. We would love to have you there. But the whole point is to focus the attention on this benefit and how important it is, work with our partners but even people who aren't traditional partners including employers and others so we can get the prevention benefit out long before people ever get to the Medicare Program. I appreciate your highlighting the issue and can assure you that we are turning to it as soon as today to get this information out to make sure that we can increase those rates, and we will be happy to share the utilization data. We are hoping to make it better. I am a little concerned that what we have in-house is probably not sufficient. That is why we have been working with our partners.

Mr. GREEN. And that is what we need to know, is there a better way we can get that information out because it will save us Medicare dollars with that pre-screening. And again, that was one of the things we did in the Medicare Modernization Act that was bipartisan in hindsight.

Mr. Miller, I would like to explore MedPAC's recommendations on care coordination and there are a number of care coordination demonstration projects conducted by CMS in recent years. Last month an interim report was issued by the Medicare Coordinated Care Demonstration Project reporting limited benefits of the project. I would like to point out, however, that two of the 15 program hosts included Alzheimer's or dementia care in the benefit. By and large, they also failed to include the small and solo practitioners who we know provide the bulk of the care for our Medicare beneficiaries. We can imagine the importance of coordinating care for beneficiaries with dementia but we have numbers to back up that need. According to the Alzheimer's Association, the average

Medicare cost per beneficiary with dementia is $13,207 compared with $4,450 to the average annual cost in beneficiaries without dementia. Alzheimer's ranks up there with congestive heart failure and COPD in cost for the Medicare Program. Can you speak to what we have learned about care coordination from the various care coordination demos, specifically the importance of including proper populations and providers in that care coordination in a broader benefit?

Mr. MILLER. I can really speak to what MedPAC has talked about and care coordination, not so much the demonstrations and the findings there, although the commission has monitored and does think that there are some good ideas that are going on through the demonstrations. But to your point specifically, the two models that we have discussed in the commission about care coordination are the notion that you could give payments to groups of physicians who demonstrate a capacity to provide disease management and care coordination for chronic conditions, have some risk arrangement for it, not on the benefit, just the fee for administering it, and encourage groups that have that capacity, the IT the ability to make contact with patients and help them plan out their care and encourage it that way. For the solo practice, which you also raised, the other model that we talked about, they may not have the capacity to do that. They may not have the IT, they may not have the staff to contact the patients. The way you could think about a situation like that is, have a contract with a larger disease management entity with the solo practice so Medicare would make payments to the larger entity and then some payment to, say, perhaps on a per-month basis to the solo practice physician to manage the care for that patient. Just two other questions. We have also tried to look very hard at the prices and the fees that are being paid in the fee schedule to make sure that we are not discouraging primary care services and we have made some recommendations along those lines, and then finally we have been most recently talking about clinical comparative effectiveness as another way of trying to get information about what services help chronic care beneficiaries.

Mr. PALLONE. We are going to have to move on because we have six votes. There is only 10 minutes left and Ms. Norwalk is going to leave so I am going to recognize Mr. Barton and then we will see if we can get in Mrs. Capps.

Mr. BARTON. I will ask one question and then submit the rest for the record, Mr. Chairman.

Ms. Norwalk, can you talk, in the competitive bidding rule that just was announced, the protections are in place for small suppliers, the set-aside program to make sure that some of the competition goes to the mom-and-pop suppliers?

Ms. NORWALK. Absolutely. One of the concerns that was raised in doing this rule was that we might be putting a lot of small businesses out of business. Consequently, in each of the 10 competitive bidding areas, we set aside 30 percent of them to take into account small suppliers. Now, we define small suppliers as having $3.5 million in revenue, which is a smaller amount of revenue than the Small Business Administration, but wanting to be really focused on this area. Moreover, we heard a lot from the retail drugstores

about the ability of providing diabetic supplies so we focused initially on mail order. We have 60 percent of the diabetic supplies provided to Medicare beneficiaries through mail order so we still think we will get a pretty significant savings in that particular area.

Mr. BARTON. Thank you, Mr. Chairman. I will submit the rest of my questions for the record.

Mr. PALLONE. Thank you.

Mrs. Capps.

Mrs. CAPPS. Thank you, Mr. Chairman, Ranking Member, and thank you both for your testimony today.

Ms. Norwalk, in my district, I want to get out some issues that really important to some of my constituents and to me. In my district, we are fortunate to have an excellent facility called the Rehabilitation Institute of Santa Barbara and they have brought to my attention the burdensome auditing process being carried on by Medicare. Just for some historical context, briefly this is nonprofit institution, the only freestanding rehabilitation institution between Los Angeles and the Bay area. Speaking to the integrity of the institute, you should know that as a result of a probe audit, eight out of nine appeals by the Rehabilitation Institute were ruled in the institute's favor and several more are waiting final decisions. Meanwhile, Medicare is expanding the RAC process which rewards private contractors for identifying incorrect payments. When I heard about the way it is designed, I am sorry but I couldn't help but think of bounty hunters. I learned that yesterday alone, this nonprofit institution received 15 RAC requests. In fact, they have been asked for 116 claims for fiscal year 2003, 2004 and 2005. This institute has filed appeals on many of these but no decisions have yet been made. Each of these appeals though is required to be filed separately, which takes valuable time away from patients and costs extra money. This is not what they tell me, they would not be so bold—but I would say that this process is driving them to the brink of collapse.

This is my question. Will you tell me, please, what will happen if those appeals, all of these 116 claims and the appeals on them, are ruled in the institute's favor? Will Medicare recover the fees paid to the private auditors for each claim that they have incorrectly identified?

Ms. NORWALK. I don't expect the program works that way but I am more than happy to get the details from staff and sit down with your staff and talk about how the RAC program is constructed. Currently, what it is intended to do, and perhaps talk to the contractor more specifically about how they are paying for—what is going on with the rehab payments and I think the concern that ensuring that the—this is something that we mentioned earlier in terms of post-acute care services, making sure that the patient is provided right place, right time——

Mrs. CAPPS. But they have asked for all kind of guidance and information. There is a lot of integrity, and they wouldn't survive if it weren't for tremendous generosity of our local community in supporting them.

Mr. Chairman, I think we have identified what should be one of our first targets for eliminating wasteful spending, and let me fol-

low up with you. I want to ask if providers are able to recover the costs of filing these appeals. After all, it seems like the fees associated with filing appeals are deterrents from recovering payment for legitimate expenses. It is going to keep them from making appeals, finding out what is wrong. It is going to end up costing Medicare more money because they are going to avoid this whole process. It is so costly to them in time and energy, and in the meantime patients and their health providers suffer from these consequences while the private auditors are awarded in every case, even when they haven't found anything wrong at all.

Ms. NORWALK. My understanding in terms of how the RAC works is that they actually get a small portion of what recoveries they make and so the appeal would have to be denied by the provider in order for them to get increased payments. So in a sense, you are right in terms of how that works so if they are going after claims that are valid claims, then RAC itself would be penalized. So the intention is to sync those up.

Mrs. CAPPS. I know, but I can't tell you how demoralizing this process is to the providers in my district. I picked out one institution because I know it well. My husband was a patient there and they have done remarkable work in a multi-disciplinary way. But nursing homes have told me this, all kinds of facilities that receive Federal reimbursement, that they are going through this process, it is taking away from quality care to patients and they see it as the people coming in as very cynical, being not well versed in the nuances of the institution. I would just call them bounty hunters. We have got to find a better way to do this.

Ms. NORWALK. Well, I will take a look at it for you and we will report back.

Mrs. CAPPS. Thank you very much. Sorry for the diatribe, but I wanted to get that out on the record, because frankly, I know that you desire to do it to save money but in the end, I think it has really got some downsides that we should explore. Thank you.

Mr. PALLONE. Thank you. Thank you, Ms. Norwalk, for being with us here.

Now, Mr. Miller, we are going to come back. You are able to stay, right?

Mr. MILLER. Yes.

Mr. PALLONE. All right. We probably will be 45 minutes to an hour because there are six votes, so thank you.

[Recess]

Mr. PALLONE. I am not sure if other Members are going to come back so I am going to go back and ask Mr. Miller a couple of questions myself and then if we get other members, we will recognize them as well.

I am just going back to some of the questions I asked you before, some additional follow-up. Some of the private plans have disputed MedPAC estimates that Medicare Advantage plans cost 12 percent more on average than fee-for-service in 2006 and have claimed that their own estimates show little or no overpayments. I just wanted you to tell me what you think of these alternative estimates, if you would.

Mr. MILLER. And with all respect on that, I don't know exactly what you have seen but I have seen a piece of paper put together

by Blue Cross/Blue Shield and it has a little chart at the bottom that kind of goes six, one, three, two, that type of thing, and I have got to tell you, very little of that do we think is correct, and just to kind of walk you through it for just a second, they have 6 percent at the top and they are saying half of it accounts for this phase-out of the hold harmless. First of all, I think that number is wrong. I think it is smaller than that. And two, what they are conceptually saying is, what we are saying is, you are getting that money, and if you ask them pointblank, that is true, but they are saying it is going to go down in the future and so you shouldn't count it now, OK? So that is the first problem with their reasoning. The second problem is, if that is all that was going on, it might go down in the future but actually because enrollment has been moving so aggressively into the high benchmark counties, actually the 12, we are not clear whether it will go down or up in the future, so for that first piece, we just think it is wrong, and conceptually we are measuring what money they get and they are getting that money now. They are arguing it will go down in the future. We are not so sure. The second piece of it is a 1 percent that they say it should be—we didn't take into account the increased payments on the fee-for-service side for the physician fix that the Congress put in, and on that one it is almost but not quite. It is true that when we did the estimate, Congress had not acted, but when you do that you actually go back and you revisit the entire baseline, not just that component of it, and actually parts of the baseline went up and down. In the end, that is a wash, so the 1 percent we would also say is not correct. Then underneath that is 3 percent for IME, if I am not mistaken. We have been over this time and time again with the analysts who put this together. They know our methodology for doing this and I just don't know how to say it any differently. We do it correctly. We count it the same way on both sides. They are asserting that we are taking it out of one side and leaving it in the other and therefore creating a ratio that isn't true, and that is just not true. Then the very last thing at the bottom is, is they say OK, but the Congress wants these floors in place and these floors account for 2 percent. Here again there is a real dispute over the number. We think the floors probably account for 6 percent or so like half of this figure and of course, what we are recommending to the Congress is that we ought to be taking these benchmarks down and so they are saying but Congress has this payment system in place and we are saying right, we think that that payment system should change. So the last part of it is a philosophical difference.

Mr. PALLONE. All right. Well, thanks a lot. I have one more question and that is about the overpayments again to private plans. It is fair to say that overpayments to Medicare private plans advance the date when the Medicare part A trust fund becomes insolvent, and that curbing these overpayments would move back the date of insolvency?

Mr. MILLER. Yes, it does. Any time you are overpaying whether it is managed-care plans or anywhere else, and to the extent it comes out of part A it is going to affect the trust fund date. We believe it does affect the date. A very rough estimate is that if you implemented CBO's proposal where they estimated savings of $65

billion and then a different number over 10 which I can't remember off the top of my head, it would move the trust fund date back a couple of years.

Mr. PALLONE. OK. And do you think that these overpayments actually threaten the fiscal sustainability of the program?

Mr. MILLER. CBO is projecting very aggressive enrollment into managed-care plans over time and to the extent that every one of those enrollees means that Medicare pays more than it otherwise would have, it affects the long-run sustainability of the program.

Mr. PALLONE. Is there any way you can quantify the impact that overpayments would have on every Medicare beneficiary like every month or maybe get back to us?

Mr. MILLER. Actually I think I can quantify it for every month. Again, this is back the envelope, the actuaries are much more precise about it but we estimated about $2 per month in extra premium payments for all beneficiaries for the 12 percent overpayment.

Mr. PALLONE. OK. Thanks a lot. I appreciate it.

Dr. Burgess, do you want to ask questions of Mr. Miller?

Mr. BURGESS. Actually, I would prefer——

Mr. PALLONE. Oh, here comes Jan.

Ms. SCHAKOWSKY. I was mostly interested in how do we justify that we are paying the Medicare Advantage programs this higher price? How can that be sensible at all if we are talking about how we are going to save money?

Mr. MILLER. There is not a lot of disagreement here between you and the commission. The commission has looked at this problem and we have looked at it from a payer perspective and the dollars that leave the Treasury and arrive at the plans. We have calculated that they are more than 12 percent above average and we have noted that this comes out of the trust fund, general revenues and premiums for all beneficiaries whether they are in the plans or not.

Ms. SCHAKOWSKY. Right. And only one out of five is actually in one of these plans.

Mr. MILLER. Yes I think the enrollment is up to 18 percent, around there, but that is about right, one in five. So our posture is, if you are looking at this purely as a payer and an efficiency issue, efficiency and dollars leaving the treasury, there is not a lot of argument for doing this. Now, the counterargument by the industry is, but I give additional benefits to beneficiaries with this extra money, and I would just point out a couple things about that. They do get additional benefits but also in that extra money is administrative costs, marketing costs and profits to the plan and then I would just come back to the original argument. They are getting additional benefits with that money but those are benefits that are subsidized by all beneficiaries and going only to some beneficiaries who happen to be in those plans.

Ms. SCHAKOWSKY. And what about the private fee-for-service? That is even more.

Mr. MILLER. Yes, and that is actually a good question, and a clarification that I want to make for people because this gets misunderstood sometimes. It is not that private fee-for-service plans are paid more, it is that private fee-for-service plans locate in counties

where the payment rates are higher so that when you look at them, they are being paid more. Do you see what I mean?

Ms. SCHAKOWSKY. Yes.

Mr. MILLER. It is not that we pay private fee-for-service more, it is that where they are drawing their enrollment, the Medicare Program pays more. We pay about 19 percent more there. And the interesting thing about private fee-for-service plans is, it actually costs them 9 percent more to offer the standard benefit, the standard A-B benefit.

Ms. SCHAKOWSKY. Meaning if it were the Medicare fee-for-service?

Mr. MILLER. You got it, 9 percent more. Then the additional 10 percent is given to the beneficiaries in benefits. So there are two things to take away from private fee-for-service plans. As a group, and I am not saying every plan but as a group, they are much less efficient than standard Medicare fee-for-service and all of the extra benefits on average that go to beneficiaries are from extra money, are from subsidized dollars. No efficiency gains. Because remember, the basic argument, and you may have even said this, is, if they have efficiencies, they use that money to offer extra benefits. These private fee-for-service plans again as a group, not every private fee-for-service plan but as a group are not more efficient than fee-for-service and the extra benefits——

Ms. SCHAKOWSKY. So what is the justification for even allowing those to exist?

Mr. MILLER. Well, I am not sure I can tell you that. Let me try and answer the question this way. The private fee-for-service plans were actually conceived of in their original state—what was going on is, there was a big move in the country towards managed care and lots of increases in enrollment Medicare managed care and there was a concern on the part of Congress that some people might not want to be in managed-care plans and have potentially their care dictated by a coordinated care entity, so the thought behind private fee-for-service plans was, let us create plans where if they have an additional cost because they don't coordinate care, it is born entirely by the beneficiary. That was the thought behind them so that I have an uncoordinated plan, it is more extensive but the bennie pays the difference, but it hasn't worked out that way. Under the new payment system, the Federal—well, the Medicare Program and all bennies whether they are in the plan or not are paying that difference.

Ms. SCHAKOWSKY. And what is the rationale for allowing a Medicare Plus plan if we are paying those 12 percent more than Medicare fee-for-service and most beneficiaries end up subsidizing those plans?

Mr. MILLER. It just hit me again, what is the——

Ms. SCHAKOWSKY. I asked what is the justification for having the private fee-for-service? What is the justification for the Medicare Plus plans if they are being paid more and that money is coming out of beneficiaries and taxpayers?

Mr. MILLER. At the commission, we don't see a lot of justification. The counterarguments that people will ring to the table are, people are getting extra benefits from it, and then you have heard some of the other counterarguments that—and we have already had this

exchange, I think you were in the room for it, where it is well, low-income beneficiaries tend to be in these plans but of course our response to that is, there are more-efficient ways to help low-income beneficiaries.

Ms. SCHAKOWSKY. Right.

Mr. MILLER. I can't offer you a justification here. We are sort of raising that question ourselves.

Ms. SCHAKOWSKY. OK. Thank you. I appreciate it.

Mr. MILLER. No problem.

Mr. PALLONE. Thank you, and thanks, Mr. Miller, for staying here an extra hour, but we do appreciate it because we did want to ask you some additional questions. Thanks a lot.

Mr. MILLER. No problem.

Mr. PALLONE. And I am going to ask the second panel to come forward.

Thank you both for being here. Let me introduce you. First we have Stuart Wright, who is Deputy Inspector General for Evaluation and Inspections from the U.S. Department of Health and Human Services, and next to him is Daniel Fridman, who is Senior Counsel to the Deputy Attorney General and Special Counsel for Health Care Fraud within the Department of Justice. Thank you both for being here and we will start with Mr. Wright.

STATEMENT OF STUART E. WRIGHT, DEPUTY INSPECTOR GENERAL, EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. WRIGHT. Thank you. Chairman Pallone, Ranking Member Deal and members of the subcommittee, I am Stuart Wright, Deputy Inspector General for Evaluation and Inspections at the Department of Health and Human Services. I appreciate the opportunity to appear before you today to discuss our efforts to protect the integrity of the Medicare Program. My written statement provides an overview of our efforts to assess the appropriateness of Medicare payments and prices and our efforts to address quality of care and access issues for beneficiaries. In the interest of time, I will focus my remarks on our recent work related to durable medical equipment as a specific illustration of some of the program vulnerabilities we have identified and our recommendations to strengthen Medicare safeguards.

We have consistently found that the Medicare DME benefit is vulnerable to fraud and abuse. We have conducted numerous studies reviewing the appropriateness of payments and the prices Medicare pays. With respect to the pricing of medical equipment and supplies, we issued a report in September 2006 on the cost and servicing of oxygen equipment used in the home. In this review, we found that Medicare will allow $7,215 for a concentrator that costs about $600 to purchase new. Additionally, beneficiaries will incur $1,443 in coinsurance over a 36-month rental period. We noted that if Medicare payments were capped at 13 months as certain other DME items are capped, Medicare and its beneficiaries would save $3.2 billion over 5 years.

With respect to our investigative activities, from 2002 through 2006 we excluded 121 suppliers and 457 individuals associated

with suppliers, obtained 289 successful criminal convictions and achieved 76 civil settlements or judgments. Together, these criminal convictions and civil adjudications resulted in more than $796 million in restitution, fines and penalties. To help combat medical equipment fraud, OIG in conjunction with the U.S. Attorney's Office for the Southern District of Florida, the FBI and the Department of Justice launched an initiative designed to identify suspicious suppliers and review questionable financial activities. Since its inception, the initiative has recovered more than $10 million from entities which closed abruptly and abandoned their bank accounts.

Over the past decade OIG has also identified and reported on weaknesses in Medicare's enrollment process for suppliers. In our most recent work, we found that 45 percent of the suppliers in three south Florida counties did not meet one or more of the selected Medicare standards we reviewed. Working in collaboration with CMS and the National Supplier Clearinghouse, we conducted unannounced site visits to 1,581 suppliers in Miami-Dade, Broward and Palm Beach counties in late 2006. We focused on three supplier standards that could be verified quickly through direct observation and desk review. These three standards include five specific requirements which state that a supplier must maintain a physical facility, be open and staffed during business hours, have a visible sign, post hours of operation and maintain listed telephone numbers. During the site visits, we found that 31 percent of suppliers did not comply with the first two requirements of maintaining a facility at the business address that they had provided to Medicare. Specifically, 6 percent of the suppliers did not maintain physical facilities. In some cases, instead of finding operational facilities, we found vacant buildings or facilities in which another type of business was operating including a florist, a rental car company, a real estate office and an accountant's office. Twenty-five percent of suppliers were not accessible during reasonable business hours. We identified an additional 14 percent of suppliers that were open and staffed but failed to meet at least one of the three remaining requirements that we reviewed. For the period January through November 2006, Medicare allowed payments of over $97 million to the 491 suppliers who we identified as not maintaining a physical facility or were not open and staffed. We referred these suppliers to CMS for potential revocation of their Medicare billing numbers.

Our south Florida report and my written statement contained the recommendations we have made to strengthen Medicare enrollment standards including conducting more unannounced site visits and out-of-cycle inspections, requiring all suppliers to post a surety bond, and performing more-rigorous background checks of applicants. In response, CMS described several actions it has taken to implement our recommendations including revisiting contract requirements to increase the number of unannounced supplier site visits, drafting a proposed regulation requiring suppliers to post surety bonds, and considering targeted background checks of supplier applicants. In addition, CMS is also in the process of implementing accreditation standards and competitive bidding in selected parts of the country.

In conclusion, the OIG remains committed to protecting the integrity of the Medicare Program and ensuring that beneficiaries receive high-quality care. Within the DME benefit alone, we have identified numerous integrity problems and program inefficiencies. And in our most current work, we have also found that the Medicare supplier enrollment process is inadequate to prevent abuses such as those we found in south Florida.

I appreciate the opportunity to share with the subcommittee our efforts and would be happy to answer any questions.

[The prepared statement of Mr. Wright follows:]

Testimony of:
Stuart Wright
Deputy Inspector General for Evaluation and Inspections
U.S. Department of Health and Human Services

Good afternoon, Chairman Pallone, Ranking Member Deal, and distinguished members of the Subcommittee. I am Stuart Wright, Deputy Inspector General for Evaluation and Inspections at the Department of Health and Human Services (HHS). I appreciate the opportunity to appear before you today to discuss our work related to Medicare integrity and efficiency.

My testimony today will briefly describe the Office of Inspector General's (OIG) mission and role in protecting and promoting the integrity, efficiency, and effectiveness of the Medicare program. In addition, I will provide a general overview of our approach and work related to Medicare oversight touching on our efforts to assess the appropriateness of payments and prices, as well as addressing access and quality-of-care issues for beneficiaries. I will also discuss our recent work related to durable medical equipment as a specific illustration of some of the program vulnerabilities we have identified and our recommendations to strengthen Medicare enrollment safeguards. As part of that discussion, my testimony will provide details on our recent work in three South Florida counties, in which we determined that 45 percent of suppliers did not meet one or more of five Medicare enrollment requirements we reviewed.

Role and Responsibility of the HHS OIG

Our office was created in 1976 as the first statutory OIG in the Federal Government. Two years later, the Inspector General Act of 1978 (IG Act), modeled after the law creating the HHS OIG, established OIGs at other Cabinet-level departments of the Federal Government, as well as at some independent Government agencies. Congress created OIGs to be independent and objective units within Federal departments and agencies for the purposes of: (1) conducting audits and investigations of programs and operations; (2) coordinating and recommending policies to promote economy, efficiency, and effectiveness in the administration of programs; (3) preventing and detecting fraud and abuse; and (4) keeping the Department Secretary or Agency Administrator and Congress informed about the necessity for corrective action.

To achieve these important objectives, our office reviews programs to identify systemic vulnerabilities and makes recommendations to improve their efficiency and effectiveness; investigates specific instances of potential fraud or abuse and takes appropriate enforcement actions; audits specific payments, providers, and programs to identify and recommend recovery of overpayments; and promotes voluntary compliance by issuing guidance to the health care industry.

While we recognize that the majority of providers and suppliers are trustworthy and honest and strive to submit accurate and appropriate claims for payment, provider efforts alone are not sufficient to ensure the integrity of the program. OIG's oversight plays a key role in protecting program resources and the health and welfare of beneficiaries.

OIG's effectiveness in protecting the integrity of Medicare relies heavily on our partnerships with other law enforcement organizations. We work with the Department of Justice's Civil, Criminal, and Civil Rights Divisions, the U.S. Attorneys Offices, the Federal Bureau of Investigation, other Offices of Inspector General, and State and local law enforcement officials to investigate allegations of fraud cases and curb abusive behavior. We also frequently collaborate with the Centers for Medicare & Medicaid Services (CMS) to address mutual issues of concern.

Our staff expertise, national presence, organizational structure, ongoing identification of high risk areas, and collaboration with law enforcement partners enable OIG to leverage our resources to achieve maximum return for the dollars invested in our office. For the 3-year period from fiscal years (FY) 2004 through 2006, on average we reported savings of $13 for every dollar invested in our office.

OIG Priority Setting, Reporting, and Followup

Each year, OIG publishes a work plan, which outlines our activities for the upcoming fiscal year. Although resource constraints preclude us from reviewing all 300-plus programs of the Department annually, OIG engages in a comprehensive work-planning process to identify the most important and timely issues and to direct our resources accordingly. Additionally, as part of the Department's mandated Performance and Accountability Report, each year our office identifies, based upon OIG's body of work, the most significant management and performance challenges facing the Department. And, consistent with the requirements of the IG Act, OIG reports to Congress semiannually on OIG's audit, evaluation, and enforcement accomplishments during the prior 6-month reporting period.

Finally, OIG reports on all recommendations based on findings from OIG audits and evaluations that have not been fully implemented by the Department. To present one comprehensive listing of these recommendations, OIG is in the process of combining two documents that we have historically issued — the "Red Book" and "Orange Book" — into one publication that will be titled "Compendium of Unimplemented Office of Inspector General Recommendations." This document will serve as a useful tool for Congress, the Administration, and the Department in their respective efforts to identify ways to maximize the effectiveness of programs and services and to improve the efficiency of departmental programs. OIG expects to release this compendium in May 2007.

OIG Identification of Program Inefficiencies and Vulnerabilities

The Medicare program has grown dramatically since its inception in 1965 and currently provides health care insurance for more than 43 million persons. More than 1 billion fee-for-service claims are processed annually, and Medicare is the largest purchaser of managed care services in the country. Total Medicare expenditures have grown from $206 billion in FY 1996 to over $382 billion in FY 2006.

With increasing dollars at stake and a growing beneficiary population, the importance and the challenges of safeguarding this program are greater than ever. Fraud, waste and abuse schemes have become increasingly complex and constantly change in response to the latest oversight efforts by Congress, CMS, our office, and our law enforcement partners. With Medicare's expansive network of health care activities comes a tremendous responsibility to protect the program's integrity, promote efficiency in operation, and ensure effectiveness.

OIG is committed to identifying program weaknesses and vulnerabilities to help prevent fraud, waste, and abuse, promote economies and efficiencies, and to improve quality of care. Our work is aimed at identifying and recommending methods to minimize inappropriate payments, identifying ways to close loopholes that allow unscrupulous providers to defraud the program, and examining payment and pricing methods to ensure that Medicare, its beneficiaries, and taxpayers realize good value for program expenditures. Further, we routinely monitor quality controls and oversight to ensure that beneficiaries have access to and receive quality health care. To illustrate the variety of approaches we use in our oversight of the Medicare program, I have highlighted some of our significant work below.

Ensuring Appropriate Payments

In 1996, OIG estimated that over $23 billion (about 14 percent of expenditures) in improper payments had been made by the Medicare fee-for-service program. CMS, which is now responsible for determining the error rate, estimated that incorrect Medicare fee-for-service payments were reduced to $10.8 billion (4.4 percent of expenditures) in 2006.

Although the overall Medicare fee-for-service payment error rate has decreased in recent years, the increasing size and scope of the Medicare program continue to place it at high risk for payment errors in terms of both frequency and magnitude. Improper payments and problems in specific parts of the program continue to be identified by OIG audits and evaluations and by CMS's assessment of the Medicare payment error rate. These reviews have revealed payments for unallowable services, improper coding, and other types of improper payments. Improper payments range from reimbursement for services provided but inadequately documented and inadvertent mistakes to outright fraud and abuse.

For example, OIG identified $1.1 billion in improper payments in 1 year for services billed as consultations, a total of $676 million in improper payments in a series of

reviews for mental health services provided in various settings, $402 million in 1 year for inappropriately paid emergency and nonemergency ambulance transports, and $136 million in a 6-month period for inappropriately paid physical therapy services. Additionally, OIG determined that in 2001, Medicare and its beneficiaries paid an estimated $96 million for claims that did not meet Medicare's coverage criteria for any type of wheelchair or scooter and also spent an estimated $82 million in excessive payments for claims that could have been billed using a code for a less expensive mobility device.

To promote access to hospital care for patients with substantial medical needs, CMS makes additional payments called outlier payments. In a recent audit, OIG found that a major hospital chain took advantage of the Medicare outlier payment system by billing for and receiving hundreds of millions of dollars in outlier payments by merely increasing its charges for services. The hospital chain recently reached a $920 million settlement with the Government to settle allegations concerning the improper outlier payments, and, in addition, to settle allegations that it paid illegal kickbacks to doctors to refer Medicare patients to its hospitals and used improper billing codes to receive payments to which it was not entitled.

Ensuring Appropriate Prices

To further identify potential savings to the Medicare program, OIG has conducted extensive reviews of payment and pricing methodologies, which have determined that Medicare pays too much for certain items and services. For example, in a series of reports, OIG consistently found that Medicare's Part B drug reimbursement methodology led to overpayments and was vulnerable to abuse. In a 2001 review, OIG concluded that Medicare and its beneficiaries could save $761 million a year by paying for 24 drugs at the prices available to physicians and suppliers. Consistent with the recommendations in our body of work, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included provisions that instituted a new drug reimbursement methodology for Part B. Recognizing the extensive work by OIG on Part B drug reimbursement, Congress also included provisions in the MMA mandating that OIG monitor Part B drug reimbursement and certain market prices for Part B-covered drugs on an ongoing basis.

In another example, OIG issued a report in September 2006 on the cost and servicing of home oxygen equipment. This study built upon earlier work mandated by the MMA that compared Medicare reimbursement for home oxygen equipment to the prices paid by Federal Employees Health Benefits plans. In this review, we found that the program spent $2.3 billion in 2004 to rent oxygen concentrators, which are stationary equipment, for approximately 1.3 million beneficiaries. The Deficit Reduction Act of 2005 ended indefinite rental for oxygen equipment and established a rental cap of 36 months. Under the new rental cap, which beneficiaries will start to reach in January 2009, our report found that Medicare will allow $7,215 for a concentrator that costs about $600 to purchase new. Additionally, beneficiaries will incur $1,443 in coinsurance over the 36

months. We noted that if such payments were limited to 13 months, Medicare and its beneficiaries would save $3.2 billion over 5 years.

Ensuring Access and Quality of Care

OIG also conducts reviews to identify whether beneficiaries are able to promptly obtain needed health care services, and monitors oversight activities designed to ensure that beneficiaries receive quality services. In particular, OIG has long been concerned with the quality of care rendered in nursing facilities. Prior OIG work found an increase in the number of deficiencies, and a large number of nursing homes had been cited for substandard care. Recent work has focused on enforcement mechanisms against nursing homes that are out of compliance for designated time periods or have deficiencies that put residents in immediate jeopardy. For example, a recent OIG report found that for the majority of cases requiring mandatory termination of nursing facilities, CMS did not apply the remedy due to both late case referrals by States and CMS staff's reluctance to impose this severe remedy. In another recent review, OIG found that CMS did not investigate some of the most serious nursing home complaints within the required timeframe and that CMS's oversight of nursing home complaint investigations is limited.

We also recently conducted a review of quality-of-care data for End Stage Renal Disease facilities and found that limitations in data may limit quality oversight in these facilities. Another recent report examining the use of restraints and seclusion in hospitals found that CMS and survey agencies did not respond consistently to reported deaths in a timely manner and that CMS does not maintain comprehensive and reliable information about hospital deaths related to restraint and seclusion. We also recently examined beneficiary access to home health and skilled nursing facility care since the implementation of the prospective payment system and found that, while most Medicare beneficiaries have access to care, some with certain medical conditions, such as those needing IV antibiotics and/or expensive drugs and those with complex wound care needs, may experience delays in obtaining necessary care. Additional past work has included assessing the frequency of surveys of nonaccredited hospitals and CMS oversight of the Joint Commission on Accreditation of Healthcare Organizations performance.

Enrollment Vulnerabilities: Durable Medical Equipment Suppliers

Medicare Part B pays for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that are necessary and reasonable for the treatment of a beneficiary's illness or injury. These are items that can withstand repeated use and include oxygen equipment, hospital beds, wheelchairs, nebulizers, and other equipment that physicians prescribe for home use. Medical supplies include catheter, ostomy, incontinence, and wound care supplies. Medicare also covers braces and artificial limbs. In FY 2005, Medicare paid over $10 billion in claims for medical equipment and supplies.

OIG has consistently found that the Medicare DMEPOS benefit is vulnerable to fraud and abuse. Specifically, we have identified problems related to a wide range of items and

equipment, including orthotic body jackets, wound care supplies, incontinence supplies, lymphadema pumps, therapeutic shoes, enteral nutrition supplies, and, as provided in earlier examples, oxygen and power wheelchairs.

To ensure that payments are made correctly and services provided properly, it is essential that only qualified and trustworthy providers and suppliers are enrolled in the Medicare program. Our best strategy is twofold: to work to prevent these abuses from happening in the first place by ensuring that Medicare only does business with legitimate DMEPOS suppliers, and to pursue those unscrupulous providers who have exploited the current system.

Activities of such providers not only cost taxpayers billions of dollars, but also deprive vulnerable beneficiaries of the care and support they need as well as put them at financial risk. When fraud is perpetrated, such as an item being inappropriately billed on behalf of a Medicare beneficiary, the beneficiary is not only responsible for the copayments for unneeded or undelivered medical equipment, but may also face difficulties in obtaining medical equipment in the future if it appears that Medicare has already provided such equipment to that individual.

Fraudulent Activities

OIG has found that fraudulent suppliers continue to enroll and participate in the Medicare program. From 2002 through 2006, OIG excluded from the Medicare and Medicaid programs 121 DMEPOS companies and 457 individuals associated with DMEPOS. OIG has also aggressively investigated individuals and entities that have defrauded Medicare and Medicaid. Between 2002 and 2006, our investigations resulted in 289 successful criminal prosecutions of DMEPOS suppliers. During this same period, there were 76 civil settlements or judgments imposed. Together, these criminal convictions and civil adjudications resulted in more than $796 million in restitution, fines and penalties.

To help combat DMEPOS fraud, OIG, in conjunction with the U.S. Attorney's Office for the Southern District of Florida, the Federal Bureau of Investigation, and the Department of Justice launched a health care initiative designed to identify suspicious suppliers and review questionable financial activities. Since its inception, the initiative has recovered more than $10 million from nominee account holders who agreed to turn over the funds in the bank accounts when confronted by law enforcement officials. In most cases, the nominee account holders stated that they had no operational control of the businesses and had only lent their names in return for remuneration.

The DMEPOS fraud schemes we have uncovered generally fall into the following categories: (1) filing claims for equipment that was never delivered; (2) billing for high cost equipment when lower cost equipment was actually provided (upcoding); (3) billing for the component parts of a piece of equipment instead of the entire unit (unbundling); (4) delivering medical equipment to beneficiaries who do not need it; and (5) paying kickbacks to physicians and other sources in return for referring beneficiaries, access to beneficiaries Medicare numbers and/or signing certificates of medical necessity.

For example, an OIG investigation found that as part of a fraud scheme, a psychiatrist and his associates received kickbacks from DMEPOS suppliers for improperly certifying that many of their patients qualified for wheelchairs. The DMEPOS suppliers, in turn, supplied scooters to the beneficiaries but billed for the higher priced motorized wheelchairs or billed for wheelchairs that were never delivered. These fraudulent claims to Medicare were in excess of $50 million. Another investigation resulted in a DMEPOS company paying $8.4 million pursuant to its guilty plea to false statements relating to health care matters. Over a period of several years, the DMEPOS supplier billed Medicare and Medicaid for equipment provided to beneficiaries residing in assisted living facilites who did not meet coverage criteria, created false documents to support the false claims, and routinely misled assisted living facility personnel and physicians when marketing and servicing the equipment.

Supplier Enrollment Process

CMS contracts with the National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefits Administrators, to manage the enrollment of suppliers. To enroll in the program and apply for a Medicare billing number, suppliers must comply with 21 Medicare DMEPOS supplier standards. Suppliers must also report to CMS any changes in the information provided in the application, including change of address, within 30 days of the change. DMEPOS suppliers are required to reenroll with NSC every 3 years to maintain their Medicare billing privileges. If a supplier fails to comply with all standards at any time, CMS may revoke these privileges.

Over the past decade, OIG has identified and reported on weaknesses in Medicare's enrollment process for and oversight of DMEPOS suppliers. A 1997 report examined Medicare supplier enrollment practices in 12 large metropolitan areas in 5 States, including Florida. Based on unannounced site visits, we concluded that the enrollment process was unreliable for detecting unethical and improper practices of suppliers and recommended that CMS conduct site visits at the physical locations of DMEPOS supplier applicants. In a 2001 report assessing whether DMEPOS suppliers met the Medicare standards, OIG found that the expansion of the CMS site inspection program improved supplier compliance with Medicare standards. OIG made several recommendations to further improve the compliance rates, such as instituting random, unannounced site visits of DMEPOS businesses at times other than initial enrollment and reenrollment.

Consistent with prior OIG recommendations, the NSC now conducts site visits to verify that DMEPOS supplier applicants or reenrollees comply with the 21 Medicare supplier standards before assigning a Medicare billing number. After the initial site visit, suppliers are generally not visited by NSC inspectors until they are due for reenrollment after 3 years. An unannounced, out-of-cycle visit may occur if NSC becomes aware that a supplier may be in violation of one or more Medicare standards.

South Florida Suppliers' Compliance with Medicare Enrollment Standards

According to NSC supplier enrollment data, Miami-Dade County has the highest concentration of suppliers per Medicare beneficiary of any county in the Nation. Broward and Palm Beach Counties also have high concentrations of suppliers. NSC reported that during the last two quarters of 2005, Florida led the Nation in allegations of supplier noncompliance with Medicare standards. In the first quarter of 2006, the NSC initiated a project to conduct out-of-cycle visits to approximately 500 DMEPOS suppliers in Miami-Dade, Broward, and Palm Beach Counties. As a result of that project, NSC revoked the Medicare billing numbers for 286 of these suppliers. These revocations suggested that DMEPOS suppliers intent on defrauding the Medicare program could take advantage of the predictable site visit cycle by establishing businesses that do not maintain compliance with Medicare standards after NSC conducts the initial or reenrollment site visit.

Working in collaboration with CMS and NSC, OIG conducted unannounced site visits to 1,581 suppliers[1] in Miami-Dade, Broward, and Palm Beach Counties in the fall of 2006 to assess their compliance with selected Medicare supplier standards.[2] According to data from a CMS contractor, these three counties account for approximately 5 percent of total Medicare DMEPOS payments nationally. We focused on three supplier standards that could be verified quickly through direct observation and desk review and that are directly related to the ease of beneficiary access to DMEPOS services. These three standards include five specific requirements, which state that suppliers must: (1) maintain a physical facility, (2) be accessible during business hours, (3) have a visible sign, (4) post hours of operation, and (5) maintain listed telephone numbers.

During the site visits, OIG found that 31 percent of suppliers (491 of 1,581) did not comply with the first two requirements of maintaining a facility at the business addresses that they provided to Medicare and being open and staffed during business hours.

- Six percent of the suppliers (98 of 1,581) did not maintain physical facilities. In some cases, instead of finding operational facilities, site reviewers found vacant facilities or facilities in which another type of business was operating, including a wedding florist, a rental car company, a real estate office, and an accountant's office.

  We also visited one supplier location where there was no sign or any other information on the building, mail was stacked up outside, the door was open and there was no one there. At another supplier location, we found a nearly empty office space with a barely legible name printed on the door. There was a "Pharmacy is Closed" sign posted on the door along with several eviction notices,

[1] We did not visit suppliers associated with large chains, suppliers that were under investigation by OIG, or suppliers that had or were in the process of having their Medicare number revoked by NSC.
[2] "South Florida Suppliers' Compliance with Medicare Standards: Results From Unannounced Visits" (OEI-03-07-00150), March 2007.

including a final eviction notice. In addition, we saw several storefront locations that were empty inside and "For Rent" signs were posted.

- Twenty-five percent of suppliers (393 of 1,581) were not accessible during reasonable business hours. Of these suppliers, 385 were closed during unannounced site visits on a minimum of 2 weekdays during reasonable or posted business hours. For the remaining 8 suppliers, site reviewers found the door unlocked, but no one in the facility. Site reviewers observed some locations housing multiple suppliers that were either not open or not staffed during posted or reasonable business hours. For example, at one building, 15 suppliers were either not open or staffed. On the same street, another building housed nine suppliers that were not open or not staffed. Other locations had two to six suppliers that were not open or staffed.

We identified an additional 14 percent of South Florida suppliers that were open and staffed but failed to meet at least one of the three remaining requirements that OIG reviewed (having posted hours of operation, a visible sign, and a listed telephone number). Two hundred and six of these suppliers did not comply with one of these requirements and 10 suppliers did not comply with 2 or more of these requirements. The remaining 55 percent of suppliers we visited met all of the 5 requirements included in our review.

For the period January through November 2006, Medicare allowed over $97 million for DMEPOS to the 491 suppliers we identified as not maintaining a physical facility or were not open and staffed. We referred these suppliers to CMS for potential revocation of their Medicare billing numbers.

In a separate report, OIG documented the results of our out-of-cycle site visits to 169 DMEPOS suppliers in 10 States other than Florida. The report, titled "Medical Equipment Suppliers: Compliance with Medicare Enrollment Requirements," [3] notes that 10 of the 169 suppliers did not have a physical location and that an additional 6 of the suppliers existed at their stated business address but were closed during posted hours of operation. While this study did not uncover supplier noncompliance in all areas visited, our findings suggest that out-of-cycle visits of targeted DMEPOS suppliers may be warranted in other areas of the country.

Addressing Weaknesses in the Enrollment Process

Given our findings related to noncompliance with supplier standards, it is essential that additional system improvements and preventative practices be adopted to ensure the integrity of the Medicare program and to protect beneficiaries from potentially unscrupulous suppliers. Such changes must be made on a national level so that fraudulent activities are not simply shifted to another geographic area over time.

[3] "Medical Equipment Suppliers: Compliance with Medicare Enrollment Requirements" OEI-04-05-00380, March 2007.

Based on the findings of these two recent reports, OIG recommended that CMS strengthen the supplier enrollment process and ensure that suppliers meet Medicare standards through a number of actions, which include:

- conducting more unannounced site visits and out-of-cycle inspections,
- requiring all DMEPOS suppliers to post a surety bond,
- performing more rigorous background checks of applicants,
- increasing the prepayment review of DMEPOS claims,
- deactivating the Medicare billing numbers of DMEPOS suppliers that have been inactive for a 90-day period,
- implementing an enhanced review of all new enrollment applications by DMEPOS suppliers in South Florida,
- prioritizing processing reenrollment applications for current suppliers over processing new supplier applications,
- assessing the fraud risk of suppliers and target monitoring and enforcement on high-risk suppliers,
- implementing a competitive bidding acquisition program for DMEPOS within high-vulnerability areas,
- requiring suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years, and
- strengthening the Medicare supplier standards by establishing a minimum number of hours of operation required for each supplier and establishing minimum inventory requirements for product and service types provided by a supplier.

In response, CMS described several actions it is taking to implement these recommendations, including: revisiting contract requirements to increase the number of unannounced supplier site visits; drafting a proposed regulation requiring suppliers to post surety bonds; considering targeted background checks of supplier applicants; considering requiring greater claims scrutiny for high fraud risk suppliers; requiring suppliers to become accredited as meeting DMEPOS quality standards; and developing a proposal to revise deactivation requirements for inactive Medicare billing numbers. CMS is also implementing new DMEPOS Accreditation Standards to help ensure that DMEPOS suppliers meet Medicare supplier standards. Once the accreditation process is fully phased in, the NSC will not issue a Medicare billing number to a nonaccredited supplier.

Additionally, CMS has recently issued a final rule to implement the DMEPOS competitive bidding program required by the MMA. It will replace the current fee schedule payment amounts for specified DMEPOS items with payment rates established by the bidding process. In 2008, the competitive bidding program will operate within 10 of the largest Metropolitan Statistical Areas (MSA), including the Miami-Fort Lauderdale-Miami Beach area. Items in the initial phase of this program will include various types of oxygen equipment and wheelchairs, mail-order diabetic supplies, enteral nutrients, hospital beds, negative pressure wound therapy pumps, and walkers. In 2009, the program will be expanded to 70 additional MSAs and after 2009, CMS will expand

the program to additional areas and items. Suppliers must be accredited or have accreditation pending before they can submit bids.

Conclusion

Within the DMEPOS benefit alone, we have identified numerous integrity problems and program inefficiencies. And, in our most recent work, we have also found that the current Medicare supplier enrollment process is inadequate in identifying and preventing unscrupulous suppliers from participating in and billing the Medicare program. We are continuing our examination of enrollment, compliance, and oversight of DMEPOS suppliers, including collaborating with CMS and the Department of Justice on specific efforts in high risk geographic areas. We also have ongoing work to determine the appropriateness of Medicare payments for certain medical equipment and supplies, such as wound care equipment and pricing for wheelchairs.

In addition, OIG will continue our efforts to identify areas in rest of the Medicare program where program dollars are not being utilized efficiently or are vulnerable to fraud and abuse. We also maintain a commitment to ensuring that beneficiaries have access to, and are receiving, high quality care from honest and dedicated providers. We will continue to apply our comprehensive and multifaceted approach to carrying out our mission to protect the integrity of the Medicare program and its beneficiaries.

I greatly appreciate the opportunity to discuss our work to enhance the efficiency and integrity of the Medicare program. I would be happy to answer any questions.

Mr. PALLONE. Thank you, Mr. Wright.
Mr. Fridman.

STATEMENT OF DANIEL S. FRIDMAN, SENIOR COUNSEL TO THE DEPUTY ATTORNEY GENERAL AND SPECIAL COUNSEL FOR HEALTH CARE FRAUD, DEPARTMENT OF JUSTICE

Mr. FRIDMAN. Thank you. Mr. Chairman, Congressman Deal, members of the subcommittee, thank you for inviting the Department of Justice to discuss its work in an area of law enforcement that is of vital importance to our Nation's seniors and disabled persons, fraud in the Medicare Program. I am Assistant United States Attorney for Miami, a district which has made fighting health care fraud one of its top priorities. Presently I am on detail to main Justice, where I advise the Deputy Attorney General on health care fraud enforcement policy. In that capacity, I have a bird's eye view of what the Department's different components are doing to recover monies wrongfully taken from the Medicare Program and to prosecute those who defraud it. Within DOJ, health care fraud enforcement involves each of our 93 U.S. Attorneys Offices, the criminal division fraud section, the civil division, the civil rights division and the FBI.

Since the start of the Health Care Fraud and Abuse Control Program in 1997, the Department of Justice has recovered and returned a total of $10.4 billion to the Medicare trust fund with additional amounts going to other programs such as Medicaid and TriCare. We can conservatively say that for every $1 the Government spends on health care fraud enforcement in the HCFAC program, the Medicare trust fund gets at least $4 back in recoveries from civil litigation and criminal fines and forfeitures. This figure does not even capture the deterrent effect of our criminal prosecutions, which are harder to quantify but nevertheless save taxpayer money.

Mr. Chairman, this is good, basic good Government work, and as our record demonstrates, the department is committed to doing it. Over the last 10 years since the HCFAC program was created, we have significantly increased the number of civil cases we file and criminal convictions we obtain. In the last fiscal year 2006, we had 547 defendants convicted of health care fraud expenses, the highest number to date. Last year we filed or intervened in 217 new civil health care fraud cases, which represents an increase of 144 percent since the program started. Last year was also a record year for civil recoveries. Our civil division working with the U.S. Attorneys Offices obtained judgments and settlements totaling over $3.2 billion in fraud recoveries. Of that amount, $2.2 billion came from health care fraud cases.

Let me give you a couple of concrete real-world examples of the kinds of fraud schemes we are seeing today in our cases. Let met tell you about infusion fraud. In my home district, we have found that clinics pay recruiters to bring HIV or AIDS patients to the clinics to receive this infusion therapy. They pay each patient kickbacks of $100 to $200 per visit and the patients are given diluted drugs or simply no medication at all but Medicare is billed for the full price of the drugs. These schemes can harm patients because they are not getting proper treatments. In a recent case in my

home district, an individual was convicted of this scam with estimated Medicare losses of $5 million.

Let me tell you about power wheelchairs. We found a DME supply company that billed Medicare for expensive motorized wheelchairs that were not needed and not delivered. Medicare reimburses wheelchairs at about $7,000 each but the company actually delivered a less-expensive scooter that cost $1,000. Total loss to Medicare was about $1 million. We convicted the company's owner and also obtained convictions in separate cases of the physicians who signed the prescriptions for these motorized wheelchairs, people that did not actually need them.

Let us turn to pharmaceuticals. Serono was involved in off-label marketing violations. As the market for Serono's drug Serostim shrank, Serono resorted to trying to market its drug for unapproved purposes and paying doctors kickbacks in the forms of trips to France in exchange for the physicians writing up to 30 new prescriptions at about $21,000 a treatment. As a result of the Department's efforts, Serono paid $704 million to resolve criminal and civil liabilities.

The Department is committed to fighting fraud and abuse in the Medicare Program and devotes the necessary resources for this purpose. One of the most important sources of funding for the Department are the funds provided by the HCFAC program. Since 1997, these funds have helped the Department maintain dedicated prosecutors, litigators and FBI investigators who focus on health care fraud cases. In 2003, the Department received $49.5 million from the HCFAC program to support its litigators and prosecutors and the FBI received $114 million. However, those funds remained constant and without inflationary adjustment until this year when Congress passed and the President signed an inflationary cap adjustment to these funds each until 2010. The President's fiscal year 2008 budget requests $17.5 million to supplement DOJ's HCFAC funding allocation. We would appreciate this committee's support for full funding of the President's request so that we can continue pursuing these important cases.

In conclusion, I want to say a little something about the prosecutors and litigators who pursue these cases. Our attorneys are very dedicated to the work they do. They believe in it. They put in long hours to achieve justice for the beneficiaries and the taxpayers. I hope this testimony helps the subcommittee understand the kinds of fraud schemes the Department is seeing across the country and the role that the Department plays in fighting them. Working closely with our colleagues at HHS OIG and CMS, we will continue to build on our accomplishments and our resources and adjust our strategies as new fraud schemes develop.

Thank you, and I would be happy to answer any questions.

[The prepared statement of Mr. Fridman follows:]

Statement of
Daniel S. Fridman
Senior Counsel to the Deputy Attorney General &
Special Counsel for Health Care Fraud

Before the
Committee on Energy and Commerce
Subcommittee on Health

April 18, 2007

Mr. Chairman and distinguished members of the subcommittee, I appreciate the opportunity to appear before you to discuss Medicare program integrity. We are grateful for the leadership of your subcommittee on this important topic and to you, Mr. Chairman, for inviting us to discuss the Department of Justice's enforcement efforts.

I have been asked to provide testimony concerning the efforts of the Department of Justice to combat fraud and abuse in the Medicare program. Presently, I advise the Deputy Attorney General on health care fraud enforcement policy. In that capacity, I am responsible for coordinating the efforts of all the components within the Department of Justice that are charged with investigating and enforcing the civil and criminal laws concerning health care fraud. I am also responsible for high–level, inter-agency coordination with my colleagues at the Department of Health and Human Services Office of the Inspector General (HHS-OIG) and at the Centers for Medicare and Medicaid Services (CMS). Finally, I am an Assistant United States Attorney from the Southern District of Florida (SDFL), a district that is extremely engaged in investigating and prosecuting those who take advantage of seniors, endanger the health and lives of seniors, and defraud the Medicare program.

In my written testimony, I will describe the role the Department of Justice plays in Medicare program integrity, including the role of the Criminal and Civil Divisions of the Department of Justice, the Federal Bureau of Investigation, and the 93 U.S. Attorney's Offices across the country. I will address our sources of funding, our cooperative relationship with the Department of Health and Human Services, and our accomplishments. I will conclude by describing some of the particular initiatives we are launching in SDFL to fight fraud.

OVER $11 BILLION IN RECOVERIES RETURNED TO THE MEDICARE AND MEDICAID PROGRAMS SINCE 1997

The Department of Justice is committed to rooting out and punishing individuals and corporations who commit health care fraud, including providers and practitioners, equipment suppliers, and corporate wrongdoers. The Department of Justice is not alone in the fight to combat fraud and preserve the integrity of the country's health care system. We work closely with the Inspector General of the Department of Health and Human Services as well as our colleagues at the Centers for Medicare and Medicaid Services (CMS). We also work closely with the Food and Drug Administration, including its Office of Criminal Investigations (FDA-OCI), the Federal Employees Health Benefits Program (FEHBP) at the Office of Personnel Management and its Office of Inspector General, and with our State law enforcement partners in their Offices of Attorneys General and Medicaid Fraud Control Units.

Working with our colleagues, since the inception of the Health Care Fraud and Abuse Control (HCFAC) program in 1997, the Department has obtained, according to our preliminary estimates, $11.87 billion in total recoveries, which include criminal fines and Federal and State civil settlements in health care fraud matters, predominantly involving losses to the Medicare program. Of this total, $10.4 billion has been transferred or deposited back into the Medicare Trust Fund and $604 million, representing the federal share of Medicaid fraud recoveries, has been transferred to CMS. The monetary recoveries we achieve go right back into the Medicare and Medicaid programs to help fund the health care costs of the Americans who are enrolled.

These recoveries were made possible by the dedicated funding stream provided by the "HCFAC Program," which was established by the Health Insurance Portability and Accountability Act of 1996. This program provides the principal source of steady funding for Department of Justice efforts to combat Medicare fraud.

STATUTORY BACKGROUND AND FUNDING

Social Security Act Section 1128C(a), as established by the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191, HIPAA or the Act), created the Health Care Fraud and Abuse Control Program, a comprehensive program to combat fraud and abuse in health care, including both public and private health plans.

Under the joint direction of the Attorney General and the HHS Secretary, the HCFAC Program's goals are:

(1) to coordinate federal, state and local law enforcement efforts relating to health care fraud and abuse with respect to health plans;

(2) to conduct investigations, audits, inspections, and evaluations relating to the delivery of and payment for health care in the United States;

(3) to facilitate enforcement of all applicable remedies for such fraud;

(4) to provide guidance to the health care industry regarding fraudulent practices; and

(5) to establish a national data bank to receive and report final adverse actions against health care providers, and suppliers.

The Act requires the Attorney General and the Secretary to submit a joint annual report to the Congress which identifies both:

(1) the amounts appropriated to the Trust Fund for the previous fiscal year under various categories and the source of such amounts; and

(2) the amounts appropriated from the Trust Fund for such year for use by the Attorney General and the Secretary and the justification for the expenditure of such amounts.

The Act requires that an amount equaling recoveries from health care investigations -- including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties, but excluding restitution, compensation to the victim agency, and relators' shares -- be deposited in the Medicare Trust Fund.[1] All funds deposited in the Trust Fund as a result of the Act are available for the operations of the Medicare programs funded by the Trust Fund.

The Act appropriates monies from the Medicare Trust Fund to an expenditure account, called the Health Care Fraud and Abuse Control Account (the Account), in amounts that the Secretary and Attorney General jointly certify as necessary to finance anti-fraud activities. The maximum amounts available for certification are specified in the Act. Congress established the dedicated HCFAC resources to supplement the direct appropriations that HHS and DOJ otherwise devoted to health care fraud investigation and prosecution. The Act specifies the total annual maximum amount collectively available to HHS (including the HHS Office of Inspector General (OIG)) and DOJ for their health care fraud enforcement work, assigns specific authorities to the HHS OIG, and ,beginning with fiscal year 2007, specifies the minimum amount of funding OIG must receive each year.

In fiscal year (FY) 1997, HIPAA authorized HHS and DOJ to appropriate from the Account up to $104 million collectively, and allowed the Departments to increase that appropriated amount by up to 15% annually until FY 2003. HIPAA also provided $47 million in dedicated funding for the FBI's health care fraud investigations beginning in 1997 which also increased annually until 2003.

Since FY 2003, the maximum available for HHS and the Department of Justice (DOJ) collectively was fixed by statute at $240.558 million annually. Of this total, the OIG received the statutory maximum amount of $160 million annually. The DOJ litigating components and

[1]Also known as the Hospital Insurance (HI) Trust Fund. All further references to the Medicare Trust Fund refer to the HI Trust Fund.

other (non-OIG) HHS components split the remaining $80.558 million, which we refer to as the "wedge." Thus, of the $240.558 million maximum amount, the DOJ litigating components have received $49.415 million annually from FY 2003 through FY 2006. Separately, HIPAA appropriated $114 million annually to the Federal Bureau of Investigation (FBI) over this same time period to support the Bureau's health care fraud investigative activities.

Section 303 of Division B of the "Tax Relief and Health Care Act of 2006," signed by President Bush last December, provides for annual inflation adjustments to the maximum amounts available from the HCFAC Account and for the FBI starting in FY 2007 for each year through FY 2010. In FY 2010, a fixed funding level or "cap" is reinstated at the 2010 level. The annual inflationary adjustments in the Tax Relief and Health Care Act of 2006 will help sustain the Department's current level of criminal and civil health care fraud enforcement activities during the period of 2007-2010. We anticipate, however, that current funding levels alone will be insufficient to address the accumulated numbers of pending cases resulting from the cap on funding since FY 2003, the growth in the Medicare program due largely to the prescription drug benefit program (Part D), and an anticipated increase in referrals associated with the substantial increases in anti-fraud funding to HHS agencies from the Deficit Reduction Act of 2005. The President's FY 2008 budget includes an additional $183 million through a discretionary cap adjustment proposal for new program integrity work, predominantly for the Part D and Medicare Advantage programs, of which $17.5 million is designated for the Department of Justice.

HCFAC PROGRAM ACCOMPLISHMENTS IN FISCAL YEAR 2006

During Fiscal Year 2006, the Department "won or negotiated" approximately $2.2 billion in judgments and settlements, and it attained additional administrative impositions in health care fraud cases and proceedings.[2] The Medicare Trust Fund received transfers of nearly $1.55 billion during this period as a result of these efforts, as well as those of preceding years, in addition to $117.1 million representing the federal share of Medicaid money similarly transferred to CMS as a result of these efforts.[3]

In criminal enforcement actions during 2006, prosecutors for the Department and U.S. Attorneys' Offices:

- Opened 836 new criminal health care fraud investigations involving 1,448 potential defendants, and had 1,677 criminal health care fraud investigations involving 2,713 potential defendants pending at the end of the fiscal year; and

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2 Actual collections, transfers, and deposits that ultimately result from health care fraud judgments and settlements may not equal the total "won or negotiated" during FY 2006.

[3] Note that some of the judgments, settlements, and administrative actions that occurred in FY 2005 will result in transfers in future years, just as some of the transfers in FY 2005 are attributable to actions from prior years.

- Filed criminal charges in 355 health care fraud cases involving charges against 579 defendants and obtained 547 convictions for the year.

In civil enforcement actions during 2006, attorneys for the Department and U.S. Attorneys' Offices:

- Opened 698 new civil health care fraud investigations, and had 1,268 civil health care fraud investigations pending at the end of the fiscal year; and

- Filed complaints or intervened in 217 civil health care cases.

Since the inception of the HCFAC program in 1997, the Department's criminal and civil enforcement efforts funded through that program have returned nearly $11.87 billion total to the federal government, including more than $10.4 billion transferred to the Medicare Trust Fund and $604 million representing the federal share of Medicaid fraud recoveries transferred to CMS. We have secured more than 4,500 criminal convictions for health care fraud related offenses, the vast majority involving Medicare fraud.

INTER-AGENCY DOJ-HHS COOPERATION

Because the Department of Health and Human Services administers the Medicare Program and maintains all the payment records and data submitted by providers, successful prosecution of criminal cases and litigation of civil cases requires close cooperation between the Departments. Examples of this close cooperation include the following:

- Under auspices of HCFAC Program, DOJ and HHS hold senior staff-level meetings on a quarterly basis that include representatives from the Office of the Deputy Attorney General, Office of the Associate Attorney General, HHS Counsel to the Inspector General and Office of General Counsel, and CMS Program Integrity Director.

- Our agencies also hold quarterly CMS-law enforcement agency coordinating meetings among mid- and lower-level staff who work on specific collaborative initiatives, cases, and investigations.

- We hold monthly CMS-DOJ conference calls involving CMS Program Integrity and other staff with our USAO and FBI personnel nationwide.

- Interagency health care fraud task forces and working groups exist in a majority of federal judicial districts that consist of Assistant U.S. Attorneys, HHS and FBI investigative agents, CMS program agency personnel and Medicare Program Safeguard Contractors, Medicaid Fraud Control Units, state Attorney General staff, and some include private insurer investigators.

- The OIG shares summarized information about all Medicare contractor referrals for investigation with the FBI and DOJ, and the FBI exchanges copies of its health care fraud case opening memorandums with OIG.

- DOJ participated in the planning and presentation of a Medicaid Fraud training conference sponsored by the Inspector General of the Department of Health and Human Services, and it conducted a nationwide closed circuit training session for federal and state law enforcement officials on the HIPAA privacy rule and other privacy laws and regulations.

- Last year DOJ attorneys and support staff trained CMS regional and central office staff hired to administer the Medicare prescription drug benefit and monitor the prescription drug plans on federal health care fraud statutes and possible fraud schemes which may occur in the Medicare Prescription Drug (Part D) program. Department attorneys and staff also conducted two national training seminars for CMS Medicare Drug Integrity Contractor staff hired to conduct program integrity and anti-fraud work for the Part D program.

DEPARTMENT COMPONENTS INVOLVED IN MEDICARE ANTI-FRAUD ENFORCEMENT

Health care fraud enforcement involves the work of several different components of the Department, each of which receives funding from the HCFAC Program. I will briefly summarize the roles that different parts of the Department play in pursuing health care fraud matters.

Civil Division of the Department of Justice

The Department's Civil Division attorneys pursue civil remedies in health care fraud matters, using the False Claims Act, 31 U.S.C. §§ 3729-3733, as the primary statutory tool. The False Claims Act (FCA) prohibits knowingly submitting false or fraudulent claims for payment from the government, and knowingly making false records or statements to conceal or decrease an obligation to pay money to the government. The penalties under the FCA can be quite large because the law provides for treble damages plus additional penalties for each false claim filed. In addition, lawsuits are often brought by private plaintiffs, known as "relators" or "whistleblowers," under the *qui tam* provisions of the FCA, and the government will intervene in appropriate cases to pursue the litigation and recovery against the provider or company. The Civil Division also pursues many of these cases as criminal violations of the Food, Drug, and Cosmetic Act.

In FY 2006, the Civil Division opened or filed a total of 239 health care fraud cases or matters. In addition to any new cases that are filed, however, there remain a significant number of matters that the Division continues to move toward resolution. At the end of FY 2005, there remained 680 open cases. Many of these health care fraud cases, typically those involving corporate or institutional providers, involve millions of documents and hundreds of witnesses, require experienced litigation support personnel to amass and organize the evidence, and need knowledgeable consultants to provide their expertise about the fraudulent schemes.

Since the False Claims Act was substantially amended in 1986, the Civil Division, working with United States Attorney's Offices, has recovered $18.2 billion on behalf of the various victim federal agencies. Of that amount, $11.5 billion was the result of fraud against federal health care programs - primarily the Medicare program. Cases involving violations of the Food, Drug, and Cosmetic Act, or other types of fraud by pharmaceutical manufacturers in connection with federal health benefit programs, have resulted in total criminal and civil recoveries of over $5.2 billion since 1999.[4] The Civil Division's Office of Consumer Litigation works with many of the United States Attorney's Office on these prosecutions.

In addition to these accomplishments, the Department's Nursing Home and Elder Justice Initiative, coordinated by the Civil Division, supports enhanced prosecution and coordination at federal, state and local levels to fight abuse, neglect, and financial exploitation of the nation's senior and infirm population. Through this Initiative, the Department also makes grants to promote prevention, detection, intervention, investigation, and prosecution of elder abuse and neglect, and to improve the scarce forensic knowledge in the field. The Department additionally is pursuing number of cases under the FCA involving providers' egregious "failures of care."

United States Attorneys Offices

The 93 United States Attorneys Offices (USAOs) are the nation's principal prosecutors of federal crimes, including health care fraud. The USAOs pursue both civil and criminal cases and dedicate substantial resources to combating health care fraud. Each of the 93 districts has a designated Criminal Health Care Fraud Coordinator and a Civil Health Care Fraud Coordinator. HCFAC funding supports about 100 attorney and 81 support positions, and many USAOs supplement the HCFAC program funding they receive by providing for additional attorneys, paralegals, auditors, and investigators, as well as funds for litigation expenses for these resource-intensive cases.

In FY 2006, USAOs received 836 new criminal matters involving 1,448 defendants, and had 1,677 health care fraud criminal matters pending,[5] involving 2,713 defendants. USAOs filed criminal charges in 355 cases involving 579 defendants, and obtained 547 federal health care related convictions. During the last fiscal year, USAOs also opened 698 new civil health care fraud matters and had 1,268 civil health care fraud matters and cases pending.

USAOs receive referrals of health care fraud cases from a wide variety of sources, including the FBI, the HHS/OIG, state Medicaid Fraud Control Units, other federal, state, and local law enforcement agencies, and private insurers of medical services. The health care fraud coordinators often work with these partners in fighting health care fraud in local and regional

[4] A portion of this $5.3 billion is included in the reported False Claims Act recoveries for this same period.

[5] When a USAO accepts a criminal referral for consideration, the office opens it as a matter pending in the district. A referral remains a matter until an indictment or information is filed or it is declined for prosecution.

task forces and working groups, and these also can be the basis of case referrals. Cases are also obtained by USAOs by means of *qui tam* complaints. Under the False Claims Act, a *qui tam* plaintiff (a "relator") must file his or her complaint under seal in a United States District Court, and serve a copy of the complaint upon the USAO for that judicial district, as well as the Attorney General. The USAO must then decide whether the case warrants an intervention by the government to litigate the complaint.

The Executive Office for the United States Attorneys' (EOUSA) through the Office of Legal Education (OLE) provides training for AUSAs and other Department attorneys, as well as paralegals, investigators, and auditors in the investigation and prosecution of health care fraud. For instance, in FY 2006, EOUSA and the Civil Division participated in the planning and presentation of a Medicaid Fraud training conference sponsored by the Inspector General of the Department of Health and Human Services, and it joined with both the Civil and Criminal Divisions to conduct a nationwide closed circuit training for federal and state law enforcement officials on the HIPAA privacy rule and other privacy laws and regulations. EOUSA and the Office of Legal Education also sponsored the Health Care Fraud Coordinator's Conference for Civil and Criminal AUSAs, and Health Care Fraud for new AUSAs and Affirmative Civil Enforcement for Auditors, Investigators and Paralegals at the National Advocacy Center, and, most recently, it sponsored a Health Care Fraud Trial Practice Seminar for over 120 Department lawyers.

Criminal Division of the Department of Justice

The Criminal Division's Fraud Section develops and implements white collar crime policy, and supports the federal white collar crime enforcement community through litigation, coordination, policy, and legislative work. The Fraud Section is responsible for handling and coordinating complex health care fraud litigation nationwide. The Fraud Section also supports the USAOs with legal and investigative guidance, training, and, in certain instances, provides trial attorneys to prosecute criminal health care fraud cases.

In FY 2006, the Fraud Section provided guidance to FBI agents, AUSAs and Criminal Division attorneys on criminal, civil, and administrative tools to combat health care fraud, and worked at an interagency level through the following activities:

- coordinating large scale multi-district health care fraud investigations;

- providing frequent advice and written materials on confidentiality and disclosure issues arising in the course of investigations and legal proceedings regarding patient medical records, including HIPAA health information privacy requirements, compliance with the Substance Abuse Patient Medical Records Privacy Act and regulations, and coordinating referrals from the HHS Office for Civil Rights of possible criminal violations of HIPAA privacy provisions providing training and training materials for AUSAs, investigative agents, support staff, program agency officials, and state and local law enforcement on health care fraud enforcement and medical records privacy issues;

- providing training and training materials for AUSAs, investigative agents, support staff, program agency officials, and state and local law enforcement on health care fraud enforcement and medical records privacy issues;

- monitoring and coordinating Departmental responses to legislative proposals, major regulatory initiatives, and enforcement policy matters related to prevention, deterrence and punishment of health care fraud and abuse;

- reviewing and commenting on health care provider requests to the HHS/OIG for advisory opinions, and consulting with HHS/OIG on draft advisory opinions per HIPAA requirements;

- working with USAOs and CMS to improve Medicare contractors' fraud detection, referrals to law enforcement for investigation, and case development work;

- preparing and distributing to all USAOs and FBI field offices periodic summaries of recent and significant health care fraud cases; and

- organizing, overseeing and participating in interagency working groups formed to address specific cases and initiatives, often in conjunction with the Civil Division and Executive Office for United States Attorneys.

In FY 2006, the Fraud Section handled or was involved in cases and investigations of a defunct health maintenance organization; a financial service holding company that serviced hospitals, nursing facilities, and other health care providers; and of durable medical equipment (DME) suppliers and pharmacies. Along with the USAO for the Northern District of Ohio, Fraud Section attorneys indicted seven individuals in a scheme involving a financial service holding company. Through its subsidiary corporations, the company bought accounts receivable from hospitals, nursing homes and other health care providers and medical concerns, and company executives illegally diverted the money for other unrelated purposes. In another case, Fraud Section attorneys and the USAO from the Eastern District of Louisiana filed a superseding indictment of four corporate executives in a case involving the collapse of Louisiana's third largest HMO and its subsequent takeover and liquidation by the state Department of Insurance.

Civil Rights Division of the Department of Justice

The Civil Rights Division vigorously pursues the Department's goals of eliminating abuse and grossly substandard care in publicly-run Medicare (and Medicaid) funded nursing homes and other long-term care facilities. The Division undertakes this work pursuant to the Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997 (CRIPA). CRIPA authorizes investigations of conditions of confinement at publicly operated nursing homes and other residential institutions and authorizes the initiation of civil action for injunctive relief from violations of federal rights. In performing this work, the Division often collaborates with United States Attorneys around the country and with the Department of Health and Human Services.

Division staff conducted preliminary reviews of conditions and services at 29 health care facilities in 12 states during Fiscal Year 2006. The task in preliminary inquiries is to determine

whether there is sufficient information supporting allegations of unlawful conditions to warrant formal investigation under CRIPA. The Division reviews information pertaining to areas such as abuse and neglect, medical and mental health care, use of restraints, fire and environmental safety, and placement in the most integrated setting appropriate to individual needs. Separately, in Fiscal Year 2006, the Division opened or continued formal investigations, entered remedial agreements, or monitored existing remedial agreements regarding 45 health care facilities in 23 states, the District of Columbia, and the Commonwealth of Puerto Rico.

For example, in Fiscal Year 2006, the Division: (1) opened an investigation of a nursing home in South Carolina; (2) made findings that conditions and practices at another nursing home, Fort Bayard Medical Center, in Fort Bayard, New Mexico, violate its residents' federal constitutional and statutory rights; (3) entered a settlement agreement to remedy unlawful conditions at one of the largest public nursing homes in the country, A. Holly Patterson Extended Care Facility, in Uniondale, New York; and (4) monitored the implementation of remedial agreements for four nursing homes: Banks-Jackson-Commerce Medical Center and Nursing Home, in Commerce, Georgia; Nim Henson Geriatric Center, in Jackson, Kentucky; Reginald P. White Nursing Facility, in Meridian, Mississippi; and Mercer County Geriatric Center, in Trenton, New Jersey. More recently, in response to allegations of shocking mistreatment and neglect of elderly veterans, including an apparent homicide, the Division last month opened investigations of two veterans' homes in Tennessee.

The Division's recent findings regarding one nursing home are unfortunately illustrative. The investigation revealed a wide range of dangerously deficient medical and nursing care practices that not only failed to comply with federal regulations or meet professional standards, but were in fact aiding and contributing to the needless suffering and untimely deaths of residents. The Division found numerous situations where residents' last days of life were spent in misery, as they died from the effects of what appeared to be reckless and almost willful disregard to their health and safety. In fact, in virtually every record reviewed of deceased or current residents, the Division discovered life-threatening breakdowns of treatment that were substantial departures from the generally accepted standards in nursing home care. The Division is now negotiating an agreement to remedy these deficiencies.

Federal Bureau of Investigation

The FBI is the Department's primary investigative agency involved in the fight against health care fraud. The FBI leverages its resources in both the private and public arenas through investigative partnerships with agencies such as the HHS/OIG, the FDA/OCI, the Drug Enforcement Administration (DEA), the Defense Criminal Investigative Service, the Office of Personnel Management, the Internal Revenue Service, and various state and local agencies. In FY 2006, the FBI was allocated $114 million in HCFAC funds for health care fraud enforcement. This yearly appropriation was used to support 775 positions (455 Agent, 320 Support) in FY 2006. The number of pending investigations has shown steady increase from 591 cases in 1992 to 2,423 cases through 2006. FBI-led investigations resulted in 535 criminal health care fraud convictions and 588 indictments and informations being filed in FY 2006.

The FBI initiates health care fraud cases from various sources of information. Information can come from such sources as Medicare contractors, private insurance company Special Investigations Units, the National Health Care Anti-Fraud Association, employees of businesses providing medical services (hospitals, doctor's offices, clinics, medical equipment suppliers, nursing homes, etc.), confidential sources or cooperating witnesses with access to information and complaints from public citizens which are often beneficiaries of the health care services.

FRAUD SCHEMES

To give you a sense of the types of fraud schemes the Department has seen and the enforcement results the Department has achieved, I will outline below some of the significant Medicare fraud cases the Department pursued over the last year. This list is not meant to be exhaustive; it is meant to illustrate some of the fraud schemes we are seeing.

Hospital Matters

- **Tenet Healthcare Corporation**, the nation's second largest hospital chain, agreed to pay $920 million to settle allegations of fraud against Medicare and other federally insured health care programs. The settlement included $806 million to resolve claims that Tenet billed Medicare for excessive "outlier" payments. Federal health insurance programs, including Medicare, typically reimburse hospitals a fixed amount for treating a patient with a specific condition or illness, but will reimburse extraordinary "outlier" costs when they are reasonably incurred. Congress enacted the supplemental outlier payment system to ensure that hospitals possess the incentive to treat inpatients whose care requires unusually high costs. The United States alleged that Tenet artificially inflated its charges to make it appear that many of its patients received extraordinary care when, in fact, the treatment that was given was fairly standard and far less costly. The settlement also included $49 million to resolve claims that Tenet paid kickbacks to physicians for patient referrals, $48 million to resolve claims that Tenet billed the government at a higher rate than was justified by the services performed, and $20 million in pre-settlement interest.

  Government-initiated claims accounted for nearly $770 million of the settlement, with the remaining $150 million attributable to six *qui tam* suits. The relators who filed those suits will share $12 million of the settlement amount.

- **St. Barnabas Health Care System**, the largest health care system in New Jersey, paid $265 million to resolve allegations that nine of its hospitals fraudulently increased charges to elderly patients to obtain enhanced Medicare reimbursement for outlier claims. The United States alleged that between October 1995 and August 2003, Saint Barnabas and nine of its hospitals purposefully inflated charges for inpatient and outpatient care to make these cases appear more costly than they actually were, and thereby obtained outlier payments from Medicare that they were not entitled to receive.

Saint Barnabas entered into a Corporate Integrity Agreement with the HHS-OIG. The Corporate Integrity Agreement contains measures to ensure compliance with Medicare regulations and policies in the future.

- Following a three-week trial, the former owner and chief executive officer of the now defunct **Edgewater Hospital** in Chicago was found liable under the False Claims Act for engaging in an illegal kickback scheme at Edgewater. The court found that the defendant paid physicians for Medicare and Medicaid patient referrals in violation of federal law. The court held that the hospital's cost reports and individual patient claims for patients referred in connection with the scheme were false claims and awarded treble damages and penalties on just over 1,800 claims.

- Two owners of a former San Diego psychiatric hospital were found liable after trial for more than $15.7 million in damages and penalties for having included false claims in the hospital's cost report submitted to the Medicare program. Those cost reports sought reimbursement from the Medicare program for a variety of false costs, such as amounts for a fictitious lease, reimbursement for unused hospital space, and millions of dollars in costs that were actually attributable to the defendants' business enterprises unrelated to that hospital. The court awarded the United States $15,688,585 for treble damages and $31,000 in civil penalties.

Pharmaceutical Matters

- **Schering-Plough Corporation**, together with its subsidiary, Schering Sales Corporation, agreed to pay a total of $435 million to resolve criminal charges and civil liabilities in connection with illegal sales and marketing programs for its drugs Temodar, used in the treatment of brain tumors and metastasis, and Intron A, used in the treatment of superficial bladder cancer and hepatitis C. The resolution also pertained to Medicaid fraud involving Schering's drugs Claritin RediTabs, a non-sedating antihistamine, and K-Dur, used in the treatment of stomach conditions.

  Schering Sales Corporation agreed to plead guilty to charges that it conspired with others to make false statements to the FDA in response to the FDA's inquiry concerning certain illegal promotional activities by the company's sales representatives at a national conference for oncologists. Schering Sales also agreed to plead guilty to charges that it conspired with others to give free Claritin Redi-Tabs to a major health maintenance organization (HMO) to disguise a new lower price being offered to the HMO to obtain its business.

- **Eli Lilly and Company** agreed to plead guilty and to pay $36 million in connection with its illegal promotion of its pharmaceutical drug Evista. In pleading guilty to a criminal count of violating the Food, Drug, and Cosmetic Act by misbranding its drug Evista, the Indianapolis-based company agreed to pay a $6 million criminal fine and forfeit to the United States an additional sum of $6 million. In addition to the criminal plea, Lilly agreed to settle civil Food, Drug, and Cosmetic Act liabilities by entering into a consent

decree of permanent injunction and paying the United States $24 million in equitable disgorgement.

Evista is approved by the FDA for the prevention and treatment of osteoporosis in postmenopausal women. The government alleged that the first year's sales of Evista in the U.S. were disappointing compared to Lilly's original forecast; the company reduced the forecast of Evista's first year's sales in the U.S. from $401 million to $120 million. In order to expand sales of the drug, it was alleged, Lilly sought to broaden the market for Evista by promoting it for off-label uses, such as for the prevention and reduction in risk of breast cancer, and the reduction in the risk of cardiovascular disease. Lilly promoted Evista as effective for reducing the risk of breast cancer, even after Lilly's proposed labeling for this use was specifically rejected by the FDA.

- **Serono**, one of the world's largest biotech manufacturers, paid $704 million to resolve criminal charges and civil liabilities in connection with several illegal schemes to promote and sell its drug, Serostim, that resulted in the submission of false claims to Medicaid and Medicare. The FDA had granted accelerated approval for Serostim in 1996 to treat AIDS wasting, a condition involving profound involuntary weight loss in AIDS patients, then a leading cause of death in AIDS patients. Following the advent of protease inhibitor drugs, the incidence of AIDS wasting markedly declined, and Serono launched a campaign to redefine AIDS wasting to create a market for Serostim. Serono pled guilty to conspiring with RJL Sciences, a medical device manufacturer, to introduce on the market bioelectrical impedance analysis (BIA) computer software packages for use in measuring body cell mass and diagnosing AIDS wasting. The BIA software devices were adulterated medical devices in that FDA had not approved the devices for these uses. RJL and its owner also pled guilty to their roles in the conspiracy. In addition, Serono pled guilty to conspiring to offer doctors kickbacks in the form of free trips to Cannes, France, to induce them to prescribe Serostim.

Physicians

- An Ohio physician was convicted by a jury of 56 counts of mail, wire, and health care fraud, as well as illegal drug distribution and sentenced to life for operating "pain management" clinics in which he treated all patients with weekly injections and Schedule II and III narcotic drug prescriptions during visits that lasted no more than a few minutes, and then claimed thousands of dollars in insurance reimbursements per visit. He saw upward of 100 patients per day and submitted $60 million in fraudulent bills to the victim health care benefit programs. The physician was also convicted of health care fraud resulting in death in this case..

- A Tennessee oncologist was sentenced to over 15 years' imprisonment for defrauding Medicare, TennCare, and BlueCross BlueShield at the expense of cancer patients. The defendant mixed diluted versions of chemotherapy medications that were then given to patients, and instructed her nurses to draw up partial doses of one of the medications to administer to patients.

- From 1996 through 2003, a physician employed an individual to work at the physician's medical practice in Connecticut. Although the individual was not licensed to practice medicine, he nonetheless treated patients in the physician's medical practice. During this time, he was referred to as "Doctor" by the physician and he wrote prescriptions. The physician then billed insurance companies for services that were rendered by the individual, representing them as services rendered by a physician. They both pled guilty to conspiracy to commit health care fraud. The physician also entered into a civil settlement with the government and paid $160,000.

Hospice Care

- **Odyssey Healthcare, Inc.**, a Dallas, Texas-based hospice provider, agreed to pay the United States $12.9 million to settle allegations that the company billed the Medicare program for services provided to hospice patients who were not terminally ill and hence were ineligible for the Medicare hospice benefit. Odyssey Healthcare has also entered into a Corporate Integrity Agreement with the HHS-OIG. The Corporate Integrity Agreement addresses the company's practices regarding compliance with applicable Medicare regulations.

- **Faith Hospice, Inc.**, settled allegations that it submitted fraudulent claims to Medicare and Medicaid for ineligible hospice. The investigation was initiated when a review of a sample of its medical records showed that more than half of Faith Hospice's patients were ineligible for hospice care. Under the agreement, the owner and Faith Hospice forfeited $599,165.29 to the United States, one half of the funds seized pursuant to the civil forfeiture action. The case occurred in Alabama.

Skilled Nursing Facilities

- **USA Healthcare, Inc.**, (USAH) the owner of several skilled nursing facilities based in Cullman, Alabama, settled allegations of mischarging the Medicare Program by agreeing to pay the United States $1,217,808.00. The investigation arose out of an audit of cost reports filed by several of USAH's skilled nursing facilities which revealed that the company violated Medicare rules by failing to disclose that certain vendors were related to USAH by common ownership or control and therefore should have been reimbursed by Medicare at a lower rate based on actual costs and without inclusion of profit.

Medical Devices

- The owner and operator of **V&A Services**, a medical equipment supply company located in Stone Mountain, Georgia, was convicted by a federal jury of 11 counts of Medicare fraud in a motorized wheelchair fraud scheme. He was sentenced to 2 years and 3 months in federal prison to be followed by 3 years' supervised release. He was ordered to pay restitution of $164,590 in connection with the scheme. The judge entered an order of forfeiture at sentencing by which the defendant forfeited $36,416 from a seized bank account and durable medical equipment having a value of approximately $11,000

- The owner of a power wheelchair store was sentenced to 63 months in prison and ordered to pay over $4 million in restitution to the Medicare and Medicaid programs after he was convicted by a jury of paying recruiters to take beneficiaries to a medical clinic where a physician would perform medically unnecessary procedures and then sign false Certificates of Medical Necessity (CMN) forms authorizing the beneficiaries to receive motorized wheelchairs. The physician also was sentenced to 11 years and three months in prison for his participation in the scheme for receiving payment for signing the CMNs, and for submitting claims for services that either were not performed properly, or were not performed at all.

- The owner of a power wheelchair store pled guilty in Lynchburg, Virginia to conspiracy to commit health care fraud for his involvement in an intricate scheme involving power wheelchairs and "power chair scooters." Among the allegations were that items not needed and not ordered by the physician, were simply added after the physician signed the Certificate of Medical Necessity.

- In the Southern District of Texas, the owner of a Houston-based DME company was sentenced to 63 months in prison for his role in a motorized wheelchair scam. His company fraudulently billed Medicare and Medicaid for almost $5 million and defrauded these health care programs of at least $1.6 million.

SOUTH FLORIDA INITIATIVES

Because my colleagues at the HHS-OIG plan to discuss at the hearing the results of their investigation of South Florida DME vendors, I will discuss some of the initiatives being taken by the U.S. Attorney's Office in SDFL in conjunction with the Criminal Fraud Section and the OIG.

In late 2005, through the leadership of U.S. Attorney Alex Acosta, SDFL formed the South Florida Health Care Fraud Initiative to bring together the health care fraud prosecution resources of SDFL prosecutors, HHS-OIG and the FBI agents and Florida Attorney General's Office attorneys, cross-designated as Special Assistant United States Attorneys. Although still in its early phase, our Health Care Fraud Initiative has begun to pay dividends. Last fiscal year, we filed criminal charges against 111 defendants in 68 health care fraud cases, a 30% increase over the previous year. Our conviction rate was 97%. These cases typically involve at least one, and often several, million dollars in fraud.

Our prosecutors in South Florida are doing more than merely coordinating resources; they are developing and testing new law enforcement methods to add to our health care fraud litigation arsenal. I would like to describe two of these methods. The first concerns the use of civil complaints to freeze or seize money obtained through health care fraud as soon as our evidence will satisfy a civil standard.

"Operation Equity Excise" is an example. Working with HHS-OIG and the FBI, Operation Equity Excise identified clinics and DME companies that engaged in health care fraud. Often, these companies closed abruptly to avoid detection from law enforcement, and in that process abandoning their bank accounts, leaving behind substantial balances. Through this

Operation, federal agents attempted to locate the signatories on the bank accounts. Many of the signatories, who were also typically listed as the president of the company, denied knowledge of the operation of the company and denied having any claim or right to the funds in the accounts. Thirty-four individuals were located; they voluntarily surrendered the funds, resulting in approximately $10.5 million returned to the United States Treasury. The signatories on twenty-three accounts, with a total balance of over $30 million, have not been located. SDFL has filed civil health care fraud complaints against those individuals. We intend to provide notice through publication, proceed through default judgment, and return those funds to the Treasury as well. Importantly, our civil actions do not preclude a subsequent criminal prosecution. Where supported by facts, we continue to pursue criminal investigations of these companies. For now, at the very least, by seizing the bank accounts, we can recover some of the fraudulently paid moneys.

A second method is being refined through a recently-implemented short-term, proactive, surge operation that we are undertaking jointly with the Criminal Division, the FBI, HHS-OIG, and local law enforcement in Miami-Dade County. The surge operation uses proactive law enforcement methods adapted from experience fighting illicit drug trafficking along with real-time data review often used to fight credit card fraud. A typical health care fraud prosecution relies heavily on billing records and other historical evidence. In this operation, however, HHS-OIG agents are reviewing real-time billing patterns. In the few weeks of operation, our agents have identified patterns that standing alone reveal medically impossible claims. Our agents are visiting the offices and interviewing providers as the fraud is taking place. Such "caught-in-the-act" cases are often easier to prosecute than ones based solely on historical evidence.

Finally, to augment the cooperation between the prosecutors and agents, we have co-located the prosecutors and investigative agents in a "fusion center." Modeled after similar arrangements more traditionally used in drug and organized crime prosecutions, we hope that the proximity of the investigators and prosecutors, working closely together, helps foster strong working relationships and a more proactive investigative technique.

In order for the Subcommittee to better understand some of the fraud schemes we are seeing in Miami, I will present the facts of a typical case involving kickbacks and durable medical equipment. On March 22, 2007, Ricardo R. Aguera, a/k/a Pichi, the owner of three Miami durable medical equipment companies, was found guilty on all counts, following a week-long jury trial, of defrauding the Medicare Program of millions of dollars. He was charged with one count of conspiracy and four counts of soliciting and receiving kickbacks. Sentencing is scheduled for June 12, 2007. Four other defendants, Ivan Aguera, Robert Berenguer, Aristides Berenguer, and Carlos Berenguer, entered guilty pleas to all counts in the indictment without plea agreements prior to trial. All five defendants are related and run health care companies that were involved in the fraud scheme.

Previously convicted co-conspirator pharmacy owners, Henry Gonzalez and Alfonso Rodriguez, billed the Medicare program for over $20 million and reached agreements with DME owners, including the defendants, to kickback half of the money paid by Medicare in exchange for the DME owners bringing patients to the pharmacies. Testimony at trial revealed that the DME owners paid the patients to get access to their Medicare information so that the owners

could buy phony prescriptions from corrupt doctors to provide to the pharmacies. The heart of the conspiracy centered around three Miami pharmacies, Lily's Pharmacy, Unimed Pharmacy and Prestige Pharmacy, that illegally manufactured aerosol medications including albuterol, metaproterenol, and ipatropium bromide. These aerosol drugs are introduced into the lung through a piece of durable medical equipment known as a nebulizer. Medicare pays for such aerosol medication through the Part B program as it is taken through a nebulizer. Knowing this Medicare system rule, the pharmacy owners exploited the program by manufacturing the unnecessary, non-FDA approved medicine through a process known as "compounding." Evidence at trial established that at Lily's pharmacy, one of the men making the medicine was trained to repair air conditioners and was not a licensed pharmacist. The fraud scheme further relied on (1) paid patients who provided their Medicare cards and signed delivery receipts for medicine which the patients did not need and which they ultimately discarded, (2) doctors who signed fraudulent prescriptions which listed non-commercially-available medications, and (3) DME company owners that recruited and paid the patients to take the false prescriptions to the pharmacy owners.

At trial, evidence established that patients were paid $100 to $150 per month for the use of their Medicare cards. Pharmacy owners testified that the scheme of using "compounding" was designed from the beginning to defraud Medicare. Unwilling to buy FDA-approved medication to fill those prescriptions, pharmacies "compounded" the aerosol medications by the gallons and then billed Medicare. Patients testified at trial that they did not want the boxes of medicine and the only reason the patients visited the doctor with the DME owner was to receive cash kickbacks.

CONCLUSION

I hope my testimony has given you a comprehensive view of the Department's essential role in prosecuting and deterring fraud on the Medicare program, restoring funds illegally stolen from the Medicare program, and protecting our citizens from those health care fraud schemes which have caused physical harm and loss of life. The Department is committed to the ongoing success of the HCFAC program and will continue to marshal its resources, including those provided by the HCFAC program and its own discretionary funds, to prosecute fraud and abuse in the Medicare program and restore the recovered proceeds of fraud to the Medicare trust fund. The HCFAC program pays for itself many times over and helps ensure the safety and availability of medical services to all beneficiaries.

Mr. PALLONE. Thank you, thank you both, and let me yield myself 5 minutes or recognize myself for 5 minutes for questions, and I will start with Mr. Fridman. Let me say first of all that I certainly would support the full funding of what the President has proposed and I guess I can't speak for the others, I will just speak for myself.

I am concerned about oversight with some of the marketing with these Medicare private plans. We have been informed of a number of scams by agents working for Medicare private plans that they have recently victimized Medicare beneficiaries through false marketing practice. These agents provide misleading information to beneficiaries and have them sign false documents in order to get them enrolled in private plans. For example, I have a copy here, and I could show it to you, if you like, a recent press release from the Mississippi Insurance Department noting a number of scams in that State along these lines. We are told by the State that their ability to enforce the marketing guidelines that CMS has released does not exist because of the Federal nature of those guidelines. I would like to know, does the DOJ have any knowledge of these kinds of marketing abuses? Have you been involved in investigating any cases of wrongdoing by private insurance plans in Medicare and how many cases and what is the nature of the complaint?

Mr. FRIDMAN. Well, thank you for the question. Your staff was kind enough to share that press release with us and we are reaching out to the Mississippi Department of Insurance to find out more information about their allegations of fraud. I will say generally we have seen similar schemes such as the ones you have described in other contexts. For example, in part D enforcement, we have started to receive cases that show a scheme we call the 299 scam. Basically telemarketers are calling up senior citizens and offering to enroll them in a part D plan. They say it only costs $299, the typical scheme. They get their bank account information, their credit card information and then they just steal their money and they don't get enrolled in any plan. So we have seen things like this. We are keeping a close eye on these and we will pursue appropriate cases where there is Federal jurisdiction to pursue them.

Mr. PALLONE. It says in the Mississippi release, now that I know you have it, I am glad. It says companies offering Medicare plans are subject under Federal regulations to strict marketing guidelines for such plans which include prior approval of marketing material. So does that literally mean that if somebody takes out an ad on a radio or a newspaper that it has to be approved? Do you know?

Mr. FRIDMAN. Well, as Ms. Norwalk observed in her testimony, some of this is the purview of State insurance commissioners, there is no Federal jurisdiction there. I would defer to my colleagues at HHS OIG and CMS. They are more familiar with these kinds of regulations.

Mr. PALLONE. If you would, I know this sounds absurd but I always use an example when the HMOs started out that I would see these ads in my local newspapers where you go get a free lobster dinner if you came one night and they had these huge ads in the local papers in my district offering free lobster dinners. I don't

know, maybe that sounds absurd but I am just wondering what kind of things can they do?

Mr. WRIGHT. CMS does have marketing guidelines that apply to Medicare Advantage plans and we actually issued a report in August of 2006 in which we reviewed 36 plans' marketing material for calendar year 2005. For those 36 plans, we collected all advertisements, summary of benefit forms, enrollment forms and reviewed them to determine whether or not they met the requirements that CMS has imposed, and we did find some small problems associated with those marketing materials. I don't know that CMS reviews every single marketing piece issued by a Medicare Advantage plan, but there are guidelines and there is some review of those materials.

Mr. PALLONE. Now, I will go back to you because I only have 15 seconds. If DOJ, Mr. Fridman, were to find a large-scale organized attempt to defraud Medicare and Medicare beneficiaries by these private insurance plans, what type of remedies do we have against such actions and are they being used by CMS?

Mr. FRIDMAN. Well, we would evaluate each case for Federal jurisdiction and violations of Federal law and if we see those violations, we would certainly pursue them. I have an example of a case where we pursued a private insurer. It was called Employers Mutual. It was a recent case. They had established a similar kind of scheme in all 50 States where they fraudulently induced people to enroll in their insurance plan, called it an ERISA plan so they wouldn't be subject to regulation by State insurance commissioners and people wound up paying for premiums and getting stuck with the medical bills because the insurance company didn't actually cover anything. We prosecuted them and the owner of the company was convicted and sentenced to 25 years in prison. So we are serious about these kinds of fraud schemes and we will pursue them.

Mr. PALLONE. OK. Thank you.

Mr. Deal.

Mr. DEAL. Out of curiosity, in the south Florida examples that both of you have alluded to, what percentage of those were traditional Medicare plans as opposed to managed-care plans? Do you have any idea?

Mr. WRIGHT. With regard specifically to the suppliers and the site visits that we undertook, these were durable medical equipment suppliers on the fee-for-service side of Medicare so they didn't have anything to do with the Medicare Advantage.

Mr. DEAL. What about, Mr. Fridman, the examples other than the one that you have already alluded to? Were they traditional fee-for-service traditional Medicare situations?

Mr. FRIDMAN. Yes, I believe the durable medical equipment ones would be part B traditional fee-for-service.

Mr. DEAL. Here again, I guess the question becomes on the durable medical equipment, if these are basically nonexistent and 31 percent of them didn't meet the basic criteria, you said, how are people getting to these folks? There has got to be some linkage between a doctor saying you need a wheelchair or you need some other form of durable medical equipment. What was the linkage of a patient to get to those nonexistence folks?

Mr. WRIGHT. Well, that is the concern that we have, that there weren't patients getting to those entities because when we showed up on multiple site visits, they did not appear to be open for business as required.

Mr. DEAL. Well, was the fraud the fact that they weren't supplying anything and billing for it or that they were actually supplying something to folks but didn't meet the other criteria?

Mr. WRIGHT. The failure to comply with the supplier standards can result in the revocation of the billing number for those suppliers. As I mentioned in my oral statement, these entities billed $97 million. It is of concern to us whether or not the $97 million was for legitimate services to legitimate beneficiaries. We did not pull a sample of those claims so I cannot tell you that those claims were fraudulent, but given that the entities when we visited did not appear to be open and doing business, we are concerned.

Mr. DEAL. Mr. Fridman, you mentioned one case in which in the power wheelchairs that you say you convicted a physician who was part of this scheme, it appears.

Mr. FRIDMAN. Correct.

Mr. DEAL. How cooperative is the medical community in going after the doctors or those who are leading people in these directions who are complicit in it? How cooperative are they in working with you?

Mr. FRIDMAN. You mean in terms of giving us tips or leads?

Mr. DEAL. Yes.

Mr. FRIDMAN. I think that the medical community is a source of tips or leads for the Department. No profession wants bad apples ruining their reputations, and we expected them to be cooperative and give us information when they have it.

Mr. DEAL. But in the illustration that we have all heard about in Chicago with the State attorney general who I guess is under a Medicaid investigation he is conducting——

Mr. PALLONE. She.

Mr. DEAL. Beg your pardon?

Mr. PALLONE. She.

Mr. DEAL. She. I am sorry. Yes let us get it right. She. There the doctors were the ones who were all involved in the schemes. To what extent is the Department of Justice working with other attorney generals in looking at similar things, because if they do it in the Medicaid, they are bound to be doing it in Medicare, I would think as well.

Mr. FRIDMAN. The Department works very closely with the Medicare fraud control units in the different States to identify fraud. Many times there is overlap between the fraud committed in Medicare and it is also being committed in Medicaid in the same case so we often work very closely with them on the same cases, recover some share for the Medicare Program and recover some share for the Medicaid program as well.

Mr. DEAL. The imaging issue is one that has been of concern to me. Are you aware of any further investigations that are going on with regard to imaging overbillings, misbillings, fraudulent activities with regard to any investigations you can maybe tell us about?

Mr. WRIGHT. Not that I know of off the top of my head but I am happy to check with staff and report back to you in terms of the

investigative activities. We do have a couple of ongoing studies related to imaging services. I would be happy to tell you about them if that would be useful.

Mr. DEAL. Will these studies hopefully have recommendations as to any corrective action that we might need to take here?

Mr. WRIGHT. Yes, I hope that they do. I don't know that they will actually uncover inappropriate payments but they will look at some of the billing arrangements that exist with the provision of CAT scans, MRI and PET scans and they will present the data in terms of the trends. We have seen a dramatic increase in payments in that area in the recent past.

Mr. DEAL. Thank you both.

Mr. PALLONE. Thank you.

The gentlewoman from Illinois.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I wanted to connect something I asked earlier of Mr. Miller and something then that Mr. Pallone was asking about in terms of the marketing of these Medicare Advantage plans. Mr. Miller responded that one of the rationales for keeping these Medicare Advantage programs even though they are more expensive is because low-income beneficiaries use them despite the fact that they may not be the most efficient way to serve low-income people. So I am wondering if there is not a connection to marketing schemes that actually target low-income people who themselves might do better, because they are dual-eligible or whatever, to get more coverage, and if there has been a systematic review of who might be targeted by these kinds of advertising programs that aren't good for taxpayers or even the beneficiaries. Either one. I don't know where that would fall.

Mr. WRIGHT. It is my understanding that Medicare Advantage plans can't target on a specific population. I can't tell you anything in terms of the marketing material that we collected in terms of whether or not we saw anything geared towards specific cohorts of beneficiaries but in general plans are not supposed to market themselves to certain segments of beneficiaries. There are some things called special-need plans which are allowed to market and focus on discrete populations such as the disabled, low income, and that isn't something that we specifically looked at but we are thinking in terms of work planning on doing a study specifically on the special-need plans.

Ms. SCHAKOWSKY. Though they can't target special populations, are they allowed to target particular geographic areas or—I am just wondering how is it that—it sounded as if a disproportionate number of people who have these might be low-income people and so I am just wondering if there some way—they are often targeted in terms of predatory loans and all kinds of things. Well, I am glad that there is going to be some kind of investigation. I am wondering to what extent whistleblowers play a role in this at all and if there is a way that we could encourage that more, Mr. Fridman?

Mr. FRIDMAN. Well, I think the False Claims Act which Congress passed is one of the ways that we get case referrals. They are encouraged to file their cases and we pursue them. That is one of the ways, especially in the civil context, that we get our large dollar recoveries. We have whistleblowers inside the different companies

that file a complaint under seal. The Department of Justice then engages in a process to review the complaint, investigate it, see if there is evidence of a violation of Federal law and then we resolve—we decide whether or not to intervene.

Ms. SCHAKOWSKY. Are there protections for those whistleblowers?

Mr. FRIDMAN. Like retaliation kinds of things?

Ms. SCHAKOWSKY. Yes.

Mr. FRIDMAN. I believe there are. Yes, there are.

Ms. SCHAKOWSKY. OK. Good. You looked at the Florida—this is pretty amazing what you found in Florida, and they are the No. 1 supplier of durable medical equipment, I understand, right? They have the most number of outlets or whatever. But there is a No. 2 and a No. 3 and a No. 4. Have you followed up with some of these other places? It seems like a pretty lucrative thing to look at.

Mr. WRIGHT. Yes. The three counties that we reviewed in south Florida bill for 5 percent of the durable medical equipment nationally. Miami-Dade, one of the counties, has the highest concentration of suppliers of any county in the Nation. So we are now very much looking at other geographic areas to determine whether or not there might be similarly inappropriate businesses operating.

Ms. SCHAKOWSKY. And finally, you said you have adequate resources to do this job. It seems, if I could be so crude as to say profit centers in a way for the Government because we are doing well by doing good, and so are there enough resources? You are asking for more.

Mr. FRIDMAN. Correct.

Ms. SCHAKOWSKY. And is there enough staff to do this, Mr. Wright?

Mr. WRIGHT. I think there is. I think the additional resources will be very welcome. The President's budget, as previously mentioned, requests $183 million in a discretionary cap adjustment. We have had our HCFAC account frozen for 3 years and for the next couple of years it will be increased by inflation. In addition to that, the Congress did provide to our office $25 million a year until 2010 to specifically do Medicaid fraud work so we do have those added resources. But clearly we can use the additional resources and we similarly expect to continue the return on investment that, as I mentioned in my testimony, is about 13 to 1 over the last 3 years.

Ms. SCHAKOWSKY. And I am assuming you go after the big-ticket items here primarily in prioritizing where you do your investigations?

Mr. FRIDMAN. For the Department, I would like to address the resource issue as well, if I may?

Ms. SCHAKOWSKY. Sure.

Mr. FRIDMAN. Our HCFAC account has been frozen as well since 2003 at $49.5 million, the FBI at $114 million, and we have had some inflationary erosion as a result of that being frozen for the last 3 years. We are asking the committee to support the President's 2008 budget request of $17.5 million because that will allow us to make up for that inflationary erosion, and also plan for the influx of cases that we expect to see from anti-fraud funding that HHS has gotten in the area of part D and so forth. So that will help us build our resources for the future. In terms of—I am sorry——

Ms. SCHAKOWSKY. That you prioritize——

Mr. FRIDMAN. When we are looking at cases to take, when they come in we kind of triage them. We look at a variety of factors. We don't just take cases where there is going to be large monetary outcomes for us. We also look at factors like patient harm, where physicians are performing unnecessary surgeries. The dollar loss may be very small but we are going to pursue those cases because it benefits the public health. We have got to get those people off the streets so that is another factor that comes into our analysis.

Ms. SCHAKOWSKY. I am out of time so——

Mr. PALLONE. Yes, but I do intend to come back again with another round, so if you want to stay. And I know Dr. Burgess—I let my colleague go over 2 minutes so I am sure you will pay attention to that.

Mr. BURGESS. I will.

Mr. PALLONE. You are recognized.

Mr. BURGESS. I will make certain that there is equal distribution of extra minutes.

Mr. Wright, you alluded to a 13 to 1 return on investment for Medicare fraud. Can you estimate how much, what is the total dollar value of fraud within the Medicare system? The Federal program spends—what—$270 billion a year. Is there a percentage or a figure that you have in your mind as to what of that is spent inappropriately?

Mr. WRIGHT. There is no reliable estimate on the amount of fraud and abuse in the program. It just doesn't exist. We have no way of systematically measuring it. The Medicare fee-for-service does have an error rate but that is a payment error rate and we certainly have seen a dramatic decrease in that since it started in 1996, but in terms of fraud estimates, we don't have any reliable mechanism to measure it. So it is just sort of anecdotal.

Mr. BURGESS. The fee-for-service part, was that—I was a physician in private practice prior to coming to Congress so was that what we used to see as the compliance plan that we all to come up with sometime in 2000 or 2001?

Mr. WRIGHT. It is a random sample of claims and then a medical review of those claims to determine whether or not they in fact should have been paid.

Mr. BURGESS. And that is applied to——

Mr. WRIGHT. The total fee-for-service universe.

Mr. BURGESS. For physicians, for hospitals, for everyone?

Mr. WRIGHT. Yes.

Mr. BURGESS. A, B, C and D?

Mr. WRIGHT. Correct.

Mr. BURGESS. Are there certain segments of the Medicare Program that are more prone to fraud and abuse?

Mr. WRIGHT. Certainly. I think as we have seen with durable medical equipment, there are areas that are more problematic than other areas. That is correct.

Mr. BURGESS. And certainly the list you gave which was—or I guess Mr. Fridman gave that was pretty incredible. Is there—does this affect every part of Medicare A, B, C and D equally or is it a bigger problem in the Medicare Advantage plans or is it a bigger

problem in the physician's world or the hospital's world or the part B drug program?

Mr. WRIGHT. I think we have seen more problems with the durable medical equipment benefit, with independent diagnostic testing facilities, and some other ancillary services where there just aren't as many programmatic controls over provider entry. We certainly have fraud associated with hospitals but those are more secure entities and don't set up shop, bilk the Government for millions of dollars and shut down. So certainly on some of the ancillary services in part B, I think we have seen more problems.

Mr. BURGESS. And again, could you quantify that for part B?

Mr. WRIGHT. No. All we can do is refer to individual cases where we have done reviews. We did a specific medical necessary review of wheelchairs and isolated parts of the program we can tell you how much Medicare is paying inappropriately.

Mr. BURGESS. To what extent is the stage set for fraud by the way that Medicare is in fact administered, the fact that it is more lucrative for someone who provides wheelchairs to handicapped patients, it is more lucrative for that person to lease rather than just to sell the chair where the chair would be in the patient's realm for the rest of their life whereas a lease is something that is going to deliver dollars back to the business repetitively. Do we set ourselves up for this?

Mr. WRIGHT. I would say especially in the area of durable medical equipment that we have seen historically two problems. One is, we are overpaying for the equipment. Medicare should be an efficient purchaser of health care services.

Mr. BURGESS. And let me just stop you there. Whose fault is that? As legislators, if we want to get our arms around that part of the problem, where is the beef, where is the bank? How do we do that?

Mr. WRIGHT. You have to a certain degree—in the MMA a provision called for competitive bidding associated with durable medical equipment. The competitive bidding prices that suppliers submit in the geographic areas where there is competitive bidding will ultimately be used to set reimbursement rates nationally. The problem that we have seen historically in the area of DME is the fee schedules were based on 1986 charges to the program. Whatever claims suppliers submitted back in 1986 basically became the fee schedule. There wasn't a market-based price for the individual pieces of equipment. The competitive bidding provisions that you have enacted should in large part provide some kind of market check so that Medicare can be an efficient purchaser of the equipment.

Mr. BURGESS. And when will that begin to kick in?

Mr. WRIGHT. It begins to start next year.

Mr. BURGESS. Next year?

Mr. WRIGHT. Yes, in 2008.

Mr. BURGESS. Man, we are slow.

You are going to do a second round?

Mr. PALLONE. Yes.

Mr. BURGESS. I will yield back.

Mr. PALLONE. Thank you.

I was going to ask Mr. Wright a couple of questions here. Your testimony highlights vulnerabilities in Medicare oversight of dura-

ble medical equipment, prosthetics, orthotics and suppliers. Durable medical equipment coverage is very important for millions of Medicare beneficiaries. However, in order to protect the benefit and protect beneficiaries from excess out-of-pocket costs as a result of improper payments, obviously it is an important area. But why is it that this is a continuing area of vulnerability, Mr. Wright, when the Office of the Inspector General, CMS, DOJ have all been working on it for years? Are there changes we can make to the payment system to reduce the incentives for fraud and abuse in these various providers?

Mr. WRIGHT. I think again there are two primary reasons why we have seen the level of abuses that we have seen. As I mentioned earlier, one is the prices that we are paying for the equipment. The second area is the ease of enrollment. Prior to 1994, there were no DME supplier standards. At that time 11 standards were created. There are now 21 standards. There are soon to be 25 when accreditation comes in with the competitive bidding. Back when I started working for HHS, in order to get a provider number, all you needed to do was submit a claim and if you didn't have a provider number, the Government assigned you one. So we have come a long way, but given the findings that we have in south Florida, clearly there is still ease of entry and we are seeing suppliers come into the program, set up businesses and then, at least when we visited them appear, not to be operating as normal businesses. So I think some of the recommendations that are both in my testimony and in the report need to be visited in terms of tightening up supplier standards.

Mr. PALLONE. OK. Thanks. And the second thing I was going to ask you is, you gave us this testimony on the Office of the Inspector General's valued work on drugs that are paid for under part B and with the help of those reports were able to change the part B reimbursement system from a system where the drug costs set the price to a much more reasonable system based on the average sales price. These changes have been difficult for some providers to adjust to but the new system is saving both beneficiaries and taxpayers. But can you remind us of your findings regarding the adequacy of payments under the new average sales price plus the 6 percent reimbursement methodology, and why does the office believe we need to further refine the average sales price calculation? Do you have any estimate of how much these changes would save?

Mr. WRIGHT. I would certainly be happy to answer. We produced a large body of work over the years that showed that the prior reimbursement system used for Medicare part B drugs was systematically flawed. It was a system called average wholesale price and we found that the prices that Medicare paid based on average wholesale prices did not resemble prices available to physicians and suppliers in the marketplace. There was a large body of work produced by our office. In one report in 2001, we found that for 24 drugs Medicare would have saved $761 million. The Congress then subsequently in the MMA changed to average sales price methodology, which is an auditable number as reported by the manufacturers. We have taken issue with the way CMS calculates the ASP numbers. In a report that we issued last year, we said that the methodology that CMS uses to calculate volume-weighted ASPs

was mathematically flawed and we actually said in that report that the calculation difference resulted in a Medicare overpayment of $115 million. So we have taken that as sort of an issue with the way ASP is calculated, clearly a marked improvement over the prior system, but a little bit of a disagreement with CMS over the way it is calculated.

And then additionally, the MMA requires us to do comparisons between ASP and AMP, average manufacturer price, and ASP and widely available prices. We have done reports in both of those areas that have suggested some further savings could be obtained by implementing the authority Congress gave CMS to lower these prices when there becomes a big discrepancy between those two amounts.

Mr. PALLONE. OK. Thanks a lot.

Dr. Burgess.

Mr. BURGESS. Do you think that then gives any incentive when someone's reimbursement is based upon the average sales price plus six, if they have got a drug that has been around forever like 5-fluorouracil that costs pennies to administer or a newer drug that is still under patent that may be very expensive to administer. Is there any sort of bias in selection as to which drug might be better for that patient based upon the reimbursement value?

Mr. WRIGHT. I don't think that there is. The dispensing fee should be uniform and the ASP should be the average price that the manufacturers pay with some exceptions to calculate an average, and that is what we say that the Government will reimburse.

Mr. BURGESS. Some pharmacies will tell us that ASP plus six for medicines that are extremely low cost just simply are not worth their time to administer. Now we are not talking about infusion therapy, just something that might be sold off the shelves in the pharmacy as a prescription. Has that been a concern at all that there will be some medicines that are just simply no longer available to Medicare beneficiaries because the cost of carrying those medicines on the shelves is not fact made up by ASP plus six?

Mr. WRIGHT. I think that we want to continue to monitor the situation and to the extent issues are brought to our attention that there are access problems associated with ASP, we will want to go in and study that and provide CMS with information regarding how to structure the program so that in fact beneficiaries are able to get the prescription drugs needed.

Mr. BURGESS. OK. I have got to ask you this. I don't want to. What about the issue of upcoding? Has that been an issue in your investigations? I am briefly talking about physician practices.

Mr. WRIGHT. Certainly, upcoding is one of the fraud schemes that we see.

Mr. BURGESS. Well, wait a minute. It is sometimes in the eye of the beholder.

Mr. WRIGHT. Yes, that is where I was just about to go and——

Mr. BURGESS. Because we always feel like you guys downcode.

Mr. WRIGHT. Yes, and to the extent we have done the fee-for-service error rate, we have both reported—when we used to do that error report—we have reported both on upcoding and downcoding and netted the two out in terms of reporting any overpayments that the Government has made, and I believe that that is the way

that CMS continues to do that. So in terms of upcoding, it is more of an issue that we have seen when we have done medical necessity reviews and we have just said that certain procedures or services didn't meet the code that was billed and suggested that the Government overpaid the difference between the lesser code. But that is different from fraud where you have to demonstrate a pattern andmeet a different standard.

Mr. BURGESS. Well, an office, for example, that bought coding software, would that be evidence that they intended to defraud Medicare?

Mr. WRIGHT. Only if it is set in a way where they know that.

Mr. BURGESS. I knew I didn't want to ask that question. Is Medicare any more prone to this type of activity than, say, Medicaid, the Federal prison system, the VA, the Indian Health Service, all of the other ways that the Federal Government dispenses health care? Or is the same vulnerability present within other areas?

Mr. WRIGHT. Yes, I think it is probably the same vulnerability. To the extent the VA provides health care more directly, it is a different system, but certainly in terms of OPM and other Government programs, you see the same kinds of vulnerabilities. It is the shear size of Medicare that gets it the attention that it gets. We are talking billions of dollars, and even if fraud stays constant, as the dollars increase, you are talking about a large magnitude of a problem.

Mr. BURGESS. Mr. Fridman, let me just ask you in the limited time we have left, typically how will a case get initiated? Does someone bring it to your attention? Do you figure it out from billing records? Do you have computer flags? Do you have your own software that you employ?

Mr. FRIDMAN. We don't. We rely on HHS, specifically CMS, to provide us with data to back up our cases when it involves Medicare Program data, but to answer your question about where we get our cases from, basically there is three, maybe four main sources. One source is the FBI. The HCFAC program spends $114 million on dedicated FBI agents that are deployed across the country in task forces to look at health care fraud in different regions of the country so the FBI is a large source for case referrals for us. Another source is the HHS Office of the Inspector General. We get a lot of case referrals from them as well. Another source is whistleblower cases. Those provide another source of referrals. And then we also get referrals working other cases. We could be working a drug case and someone has information on a Medicare scam and so forth. So we work all our possible leads to take in cases.

Mr. BURGESS. That also worked for electronic media from Los Alamos as it turns out.

Before we close, can I just ask one question about the oxygen? Because you brought it up, Mr. Wright. We attempted to put some parameters, some boundaries around oxygen therapy, the length of time in the Deficit Reduction Act a couple of years ago and that was probably one of the most contentious parts of the conference committee and eventually we came up with a limit. Previously it was unlimited and we limited it to 36 months, and I get the impression from your testimony that 36 months is not going to do the

job, that that type of limitation is not going to provide the protections that the taxpayer needs in this regard.

Mr. WRIGHT. Yes. Clearly, based on the data in our report, we suggested that more than $7,000 over the span of 36 months for a piece of equipment that costs less than $600 and requires very minimal servicing is excessive. So we do think that there is room for the Congress to take further payments reductions associated with oxygen equipment, and that is what the report recommended, that CMS work with the Congress to consider further reducing the payment rate. The other capped rental categories have a payment rental of 13 months and then the Medicare payments stop.

Mr. BURGESS. Are there other areas that have this type of return available to them? Are there other areas that you have looked into besides just the home oxygen therapy?

Mr. WRIGHT. Over the years we have looked at wheelchairs in terms of the pricing and we did find in a report we issued in 2004 that Medicare was overpaying $284 million based on prices that were available on the Internet. You just go on the Internet and get a better price than Medicare. And going back further in time, we have looked at hospital beds. So we have sort of gone piece of equipment by piece of equipment and suggested that Medicare is paying too much. And hopefully, again, the competitive bidding will be a fix to get a market-based price.

Mr. BURGESS. What about in the case of nursing homes with providing services like physical therapy? Is there overutilization that is occurring there that is costing the taxpayers money?

Mr. WRIGHT. We have done reviews of physical therapy in nursing homes. It is a little dated at this point but we have specifically done random samples of physical therapy, occupational therapy, speech therapy in nursing homes.

Mr. BURGESS. And what type of conclusion did you draw?

Mr. WRIGHT. There were payment errors. I can't tell you off the top of my head what the numbers were but we were finding inappropriate physical therapy payments.

Mr. BURGESS. Just the last thing, is Medicare Advantage any more prone to any of these issues of fraud than the other traditional parts of Medicare, the fee-for-service, part A, part B, part D?

Mr. WRIGHT. You have different things to be concerned about because the program is fundamentally different. You don't have to worry as much about the payment side of things because in general Medicare is paying a capitated payment rate but you do have to worry about other abuses such as marketing and enrollment and underutilization because there is an incentive to underutilize.

Mr. BURGESS. I see. And you also talked about quality assurance. Is your office involved in the implementation of the quality assurance measures, the PVRP or whatever the heck we are going to call it when it comes out in June? Do you keep an eye on that as well?

Mr. WRIGHT. We do lots of work associated with the quality of care both in nursing homes, hospital quality oversight, ESRD quality oversight. We have looked into a number of areas looking at whether or not the oversight mechanisms are in place to ensure that beneficiaries get the care that we all want them to get.

Mr. BURGESS. And have you come to any conclusions about that?

Mr. WRIGHT. On the various systems that we have looked at, we have reported certain weaknesses.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. We are having such a good time here, we will just keep going.

Let me mention too, the members know that you can submit additional questions for the record and so you may get additional questions from us, and they will be submitted to the clerk within the next 10 days so you may get those additional questions.

Let me thank both of you again. Really, I think what you do is so important, and as you said, Mr. Wright, particularly when you are talking about Medicare, there is just so much money involved here that it not only gets the media attention but obviously it gets our attention because that money could be used for other purposes. So I really appreciate your being here today and taking our questions. Thanks a lot.

Without objection, the meeting of the subcommittee is adjourned. Thank you.

[Whereupon, at 6:20 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

August 6, 2007

The Honorable Leslie V. Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Norwalk:

Thank you for appearing before the Subcommittee on Health of the Committee on Energy and Commerce on April 18, 2007, at the hearing entitled "Medicare Program Efficiency and Integrity." We appreciate the time and effort you gave as a witness before the Subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the question, including showing the Member's name, and include the text of the Member's question along with your response. The Committee apologizes for the delay in forwarding this request to you, however, we believe your responses to these questions are important and they will be included in the hearing record. Your assistance with the request is appreciated.

To facilitate the printing of the hearing record, we ask that we receive your responses to these questions by the close of business on **Friday, August 17, 2007**. Please have your written responses delivered to **2125 Rayburn House Office Building** and faxed to **202-225-2525** to the attention of Sharon Davis, Chief Clerk. Please send, as well, an electronic version of your responses to Ms. Davis at **sharon.davis@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Ms. Davis at the Committee on Energy and Commerce at (202) 225-2927.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Hilda Solis, Member
Subcommittee on Health

The Honorable Barbara Cubin, Member
Subcommittee on Health

LESLIE V. NORWALK ANSWERS TO SUBMITTED QUESTIONS

THE HONORABLE HILDA SOLIS

The Private Fee-For-Service (PFFS) plans are paid the most even though they do not coordinate care for their beneficiaries. Most of these plans are found in rural areas. In your testimony, you state that racial and ethnic minorities represent 27 percent of total Medicare Advantage enrollment. What added benefit do these PFFS plans bring to patients? How many minorities are actually enrolled in these plans?

Rural beneficiaries traditionally have not had access to additional benefits offered via other MA products. On average, PFFS plans are providing beneficiaries with an added $63 each month in additional value. For example, PFFS plans use rebate dollars to offer additional benefits such as vision and dental care and cost sharing savings. The chart below illustrates some of the cost sharing savings that are offered to PFFS enrollees.

Percent of PFFS Beneficiaries Enrolled in PFFS Plans with Specific Attributes

Benefit Structure/Percent of PFFS Beneficiaries Enrolled in a PFFS Plan of this Type

Catastrophic cap between $1,001 and $5,000: 28 percent
$1,000 or less for a 90-day hospital stay: 81 percent
No premium beyond the Part B premium: 62 percent
Unlimited coverage for inpatient hospital days: 88 percent
No prior hospitalization requirement before a SNF admission: 89 percent
Primary care physician copayments of $20 or less: 94 percent
Prostate and cervical and cancer screening with no coinsurance: 99 percent

While the number of minorities enrolled in PFFS plans is not currently available, we do have data available on the percent of PFFS enrollees that live in rural areas. Approximately 31 percent of PFFS service enrollees live in rural areas. Whereas, only about 4.4 percent of MA enrollees in coordinated care plans live in rural areas. This difference highlights the important role that PFFS plans play in providing rural beneficiaries with choices in their health coverage.

In your testimony, you state that the President's proposed budget will save money. While I agree that Medicare needs to be efficient in its use of dollars, program efficiency should not result in less access to care for our seniors. I'm concerned about the effect of reduced Medicare payments to our hospitals, especially since many of our safety-net hospitals are already struggling to make ends meet. Even worse, many of the same hospitals are facing reductions in Medicaid payments. What will be the impact of reduced Medicare payments on our safety-net hospitals'especially the proposed rule that is supposed to take place in September will also result in fewer Medicaid dollars?

The Medicare Payment Advisory Commission (MedPAC) has noted that hospitals have been able to reduce costs under tighter price pressures. A modest reduction in the update of 0.65 percentage points would encourage efficiency, while maintaining access to care. It is vital that we do everything we can to maintain the solvency of the Medicare program and pay as efficiently as possible.

Since the implementation of the inpatient prospective payment system for acute care hospitals, the average actual increase in the market basket has been approximately 1.3 percentage points less than the average projected market basket increase (or only 66 percent of the average projected market basket increase). In light of these historical findings, and given hospitals' ability to adjust to market conditions, an on-going adjustment for productivity would likely not affect the ability of hospitals to furnish high quality inpatient services to Medicare beneficiaries.

We have great faith in the market's ability to adapt without reducing access. Since 2002, more hospitals have opened then closed each year, suggesting that while margins may be low, access to care is still improving.

THE HONORABLE BARBARA CUBIN

The Medicare Modernization Act of 2003 authorized a two percent Medicare home payment for ambulance trips in rural areas, as well as a five percent add-on payment for home health services in rural areas. Both programs were authorized to preserve access to care in rural areas, where

providers face unique geographic difficulties in providing these services. In Wyoming, roughly half a million people are spread out over almost 100,000 square miles. Both of these provisions have expired, and were not extended in the President's fiscal year 2008 budget. What is the Center for Medicare and Medicaid Services' justification for not proposing to extend these provisions, and do you have concerns about how it will affect access to care in rural areas?

The Centers for Medicare & Medicaid Services (CMS) has made a strong commitment to rural health issues and has made many significant regulatory and departmental reforms to address the needs of rural America.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a number of provisions to enhance beneficiary access to quality health care services and improve provider payment in rural areas. The provisions in the MMA included the continuation of two payment policy trends that have increased rural provider payment rates in recent years: (1) an expansion of opportunities for rural hospitals to receive cost-based payments from Medicare and (2) a number of PPS payment rate adjustments that benefit rural providers . As you mentioned in your question, these provisions included a two percent payment increase for ground ambulance trips that originate in rural areas and a five percent add-on payment for home health services furnished in rural areas.

A number of the provisions in the MMA were time limited but have been extended in later legislation, including the Deficit Reduction Act of 2005 (DRA) and the Tax Relief and Health Care Act of 2006 (TRHCA). CMS has worked expeditiously to implement all of the provisions in recent legislation, recognizing their importance to rural communities. Although the President's fiscal year 2008 Budget did not include proposals to extend the expiring rural provisions you mentioned in your question, CMS will continue to work with Congress to address disparities in rural reimbursement and to improve the quality and value of care delivered to all Medicare beneficiaries.

As always, I welcome your comments and suggestions to improve the quality of America's health care programs. I remain committed to ensuring equal access to high-quality, up-to-date care for Medicare beneficiaries residing in rural areas. You can be assured that this Administration will continue its efforts to help address the concerns of rural Americans.

July 25, 2007

Mark E. Miller, Ph.D.
Executive Director
Medicare Payment Advisory Commission
601 New Jersey Avenue, NW, Suite 9000
Washington, DC 20001

Dear Dr. Miller:

Thank you for appearing before the Subcommittee on Health on Tuesday, April 18, 2007, at the hearing entitled "Medicare Program Efficiency and Integrity." We appreciate the time and effort you gave as a witness before the Subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain Members of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the question, including showing the Member's name, and include the text of the Member's question along with your response. The Committee apologizes for the delay to you in forwarding this request to you, however, we believe your responses to these questions are important and they will be included in the hearing record. Your assistance with the request is appreciated.

To facilitate the printing of the hearing record, we ask that we receive your responses to these questions by the close of business on **Friday, August 10, 2007**. Please have your written responses delivered to **2125 Rayburn House Office Building** and faxed to **202-225-2525** to the attention of Christie Houlihan, Legislative Clerk. Please send, as well, an electronic version of your responses to Ms. Houlihan at **christie.houlihan@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Ms. Houlihan at the Committee on Energy and Commerce at (202) 225-2927.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Hilda Solis, Member
Subcommittee on Health

The Honorable Barbara Cubin, Member
Subcommittee on Health

MARK MILLER ANSWERS TO SUBMITTED QUESTIONS

REPLIES TO QUESTIONS FROM CONGRESSWOMAN HILDA SOLIS

MedPAC is an independent Federal body, and I thank you for coming today. In your testimony, you stated that Medicare Advantage plans are overpaid and that not all of these plans provide better care to their patients. I understand many low-income, minority populations are actually served by Medicaid. However, States such as California and Florida tend to have higher Medicare Advantage plan penetration rates and more minority populations. I am extremely concerned about any potential adverse consequences on minority populations. Will cuts to Medicare Advantage plans harm minority populations in States with high Medicare Advantage penetration rates?

Even before the 2003 Medicare Prescription Drug Improvement and Modernization Act introduced the Medicare Advantage (MA) program, private plans in many markets offered rich benefit packages. Plans often offered these extra benefits because they achieved efficiencies in delivering the basic Part A & B benefit. If payments to MA plans are reduced, we believe that beneficiaries in many market areas will continue to have MA plans available that provide coordinated care and extra benefits to enrollees. However, their benefit packages may be less generous than they are currently.

As we have pointed out in several of our reports, the Medicare program pays on average 12 percent more to MA plans than for FFS and this payment policy discourages efficiency. Using MA to provide low-income subsidies is unnecessarily costly. For example, one MA plan option private fee-for-service plans require 9 percent more in Medicare program payments than traditional FFS. The extra benefits PFFS plans offer to beneficiaries are financed entirely through higher Medicare program payments and beneficiary premiums (paid by all beneficiaries), rather than through efficiency gains. Moreover, providing low-income subsidies through MA plans is poorly targeted—reduced cost-sharing for example, is provided to everyone who enrolls in the plan, regardless of their income. In sum, Medicare Advantage plans are not an efficient vehicle for delivering benefits to low-income Medicare beneficiaries. Medicare savings programs, for example, may be a more effective way of targeting assistance to low-income populations.

The Private Fee For Service (PFFS) plans are paid the most even though they do not coordinate care for their beneficiaries. Most of these plans are found in rural areas. In your testimony, you state that racial and ethnic minorities represent 27 percent of total Medicare Advantage enrollment. What added benefit do these PFFS plans bring to patients? How many minorities are actually enrolled in these plans?

MedPAC does not currently have data on the number of minority enrollees in private fee-for-service (PFFS) Medicare Advantage (MA) plans. The most recent publicly available data on minority enrollment in MA overall are from 2004 and 2005—before the large growth in PFFS enrollment. We do not know whether PFFS enrollment patterns for minorities are similar to the patterns of plans that had Medicare contracts in 2004 and 2005.

PFFS plans are less efficient than traditional Medicare in terms of the cost of providing the Medicare Part A& B benefit package. PFFS plan bids show that on average their cost of providing Part A & B Medicare benefits is 109 percent of the cost in traditional Medicare. However, PFFS plans have been drawing their enrollment from counties with benchmarks well above Medicare fee-for-service (FFS) expenditure levels. This enables PFFS plans to generate "rebate" amounts (75 percent of the difference between plan bids and the county benchmarks) that are used to provide extra benefits. For example, under the current payment system and given PFFS plans bids, Medicare pays the plan 19 percent above FFS amount and 10 percent goes to the beneficiary in extra benefits. Bear in mind that these are "fully loaded" benefits. That is, even though 10 percent is provided in extra benefits, some percentage of this amount is consumed in administrative overhead (e.g., salaries); marketing costs; and plan profits.

The most common extra benefit is the reduction of average beneficiary cost sharing to levels below the average amount in Medicare FFS. PFFS plans also provide extra services (such as hearing aids, and dental and vision care), or reduced premiums. However, all of these extra benefits stem from plan overpayments (above Medicare FFS levels), not from PFFS plan efficiencies. Unlike other MA plan types, PFFS plans are not required to coordinate care for their enrollees, as noted in the

question, and they do not participate in the quality improvement activities required of other plans.

REPLIES TO QUESTIONS FROM CONGRESSWOMAN BARBARA CUBIN

While 28 percent of Medicare beneficiaries live in rural areas, it is my understanding that just one of the seventeen Medicare Payment Advisory Committee (MedPac) members has solid rural credentials. In fact, I am an original cosponsor of legislation (H.R. 1730) to ensure that rural experts are represented on MedPac as a percentage equal to their proportion of Medicare beneficiaries that live in rural areas. Could you detail how MedPac currently ensures that the unique needs of rural areas are taken into consideration when formulating recommendations to Congress?

Many of our Commissioners have solid rural credentials. Commissioners with specific rural experience and/or that are from rural areas include: Dr. Nick Wolter, Dr. Karen Borman, former Senator Dave Durenberger, and Dr. Thomas Dean (4 out of 17 Commissioners). In addition, there are other Commission members that have raised rural concerns during the Commission work cycle.

MedPAC staff also have extensive knowledge in rural issues and have traveled to many rural areas in recent years to study rural healthcare delivery and payment issues, including visits to rural areas in Oklahoma, Montana, North Dakota, South Dakota, Iowa, and Kansas. We have published three reports devoted to rural issues: Report to the Congress: Rural Payment Provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, December 2006; Report to the Congress: Issues in a Modernized Medicare Program, Chapter 7: Critical access hospitals, June 2005; and Report to the Congress: Medicare in Rural America, June 2001. In addition, we deal with rural issues regularly in our annual Congressional reports.

MedPAC has carefully evaluated the concerns of rural providers over the years and made a number of recommendations benefiting rural hospitals that Congress or CMS have implemented. In the MMA, Congress enacted our recommendations to increase the cap on rural disproportionate share (DSH) payments and to set the base payment amount for rural hospitals equal to that of urban hospitals. Between 2001 and 2007, we made several recommendations to improve the hospital wage index in ways that would help rural providers, and the Congress and CMS have implemented some of these. The resulting increase in payments to rural providers helps explain why rural hospitals achieved higher Medicare and all-payer margins than urban hospitals in 2005, and why rural hospital payments increased by $377 million, or 2.3 percent, in 2006 (MedPAC December 2006).

Given the breadth of our legislative mandate, you can be assured that rural issues will continue to be a significant part of MedPAC's agenda.

November 5, 2007

Mr. Daniel S. Fridman
Senior Counsel to the Deputy Attorney General and
Special Counsel for Health Care Fraud
Department of Justice
950 Pennsylvania Avenue
Washington, DC 20530

Dear Mr. Fridman:

Thank you for appearing before the Committee on Energy and Commerce on Wednesday, April 18, 2007, at the hearing entitled "Medicare Program Efficiency and Integrity." We appreciate the time and effort you gave as a witness before the subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from certain members of the committee. In preparing your answers to these questions, please address your response to the Member who has submitted the question, including showing the Member's name, and include any text of the Member's question along with your response. The committee apologizes for the delay to you in forwarding this request to you, however, we believe your responses to these questions are important and they will be included in the hearing record. Your assistance is appreciated.

To facilitate the printing of the hearing record, we ask that we receive your responses to these questions by the close of business on Monday, November 19, 2007.

Please have your written responses delivered to 2125 Rayburn House Office Building and faxed to (202) 225-2525 to the attention of Christie Houlihan, Legislative Clerk. Please send, as well, an electronic version of your responses to Ms. Houlihan at christie.houlihan @mail.house.gov in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Ms. Houlihan at the Committee on Energy and Commerce at (202) 225-2927.

Sincerely,

John D. Dingell
Chairman

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

December 21, 2007

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515-6115

Dear Mr. Chairman:

Please find enclosed a response to questions arising from the appearance of Former Senior Counsel to the Deputy Attorney General Daniel Fridman before the Committee on April 18, 2007, at a hearing entitled "Medicare Program Efficiency and Integrity".

We hope that this information is of assistance to the Committee. Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us that from the perspective of the Administration's program, there is no objection to submission of this letter.

Sincerely,

Brian A. Benczkowski
Principal Deputy Assistant Attorney General

Cc: The Honorable Joe Barton
Ranking Minority Member

"Medicare Program Efficiency and Integrity"

April 18, 2007

Questions for the Hearing Record
for
Daniel S. Fridman
Former Senior Counsel to the Deputy Attorney General
United States Department of Justice

QUESTION FROM CONGRESSMAN DINGELL:

1. **I understand that under HIPAA rules, providers are required to grant access to a patient's medical records upon the patient's request. If the provider fails to grant access to requested records within 30 days, HHS may impose civil penalties of $100 per violation, not to exceed $25,000. Patients were, however, significantly endangered by failure on the part of Imaging Services X to produce the results of their imaging tests in a timely manner. What enforcement authority does the Department of Justice have in a case like this?**

RESPONSE:

In enacting the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, Congress adopted two provisions which provide the basis for enforcement of the "Standards for Privacy of Individually Identifiable Health Information" (Standards), promulgated as a final rule by the Secretary of Health and Human Services on December 28, 2000 (65 Fed. Reg. 83462). These Standards, found at 45 C.F.R. Parts 160 and 164, include the requirement that covered health care providers grant a patient access to his or her medical records within 30 days of the patient's request, with certain exceptions, including a provision for the extension of the 30 day period by another 30 days, if the patient is informed in writing of the reason for the delay and the date by which the provider will complete its action on the request. 45 C.F.R. §164.524.

The two remedies for violation of the HIPAA Standards are found at 42 U.S.C. §§ 1320d-5 and 1320d-6. Section 1320d-5 empowers the Secretary to impose a civil monetary penalty of up to $100 for each violation of the Standards with a cap of $25,000 for aggregated fines for all violations of the same requirement or prohibition in a calendar year. The Secretary has the power to assess this penalty against a health care provider that violates the patient "access" provision of the Standards.

Section 1320d-6 provides criminal penalties for three enumerated illegal acts, the last two of which apply to personally identifiable health information related to an individual:

(a) Offense

A person who knowingly and in violation of this part –

(1) uses or causes to be used a unique health identifier;

(2) obtains individually identifiable health information relating to an individual; or

(3) discloses individually identifiable health information to another person,

shall be punished as provide in subsection (b) [of this section].

Thus, the only criminal offenses concerning personally identifiable health information which can be "enforced" by the Department of Justice through prosecution, relate to disclosing or obtaining such information. The HIPAA criminal provision does not cover violations where a health care provider fails to provide a patient access to his or her health care records, on request of the patient.

Nonetheless, in situations like the one described in this question, the Department will consider and evaluate whether the health care provider engaged in acts which may have violated another federal criminal statute. While a violation of another federal criminal statute might occur, for example, arising from the manner in which medical records are abandoned by a defunct medical provider, it does not appear that the Department of Justice would be able to pursue a HIPAA criminal case against a health care provider that has violated the Secretary's Standards by failing to provide access to patients' medical records when access is requested by those patients.

August 6, 2007

Mr. Stuart E. Wright
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, SW, 5th Floor
Washington, DC 20201

Dear Mr. Wright:

Thank you for appearing before the Subcommittee on Health of the Committee on Energy and Commerce on April 18, 2007, at the hearing entitled "Medicare Program Efficiency and Integrity." We appreciate the time and effort you gave as a witness before the Subcommittee.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached is a question directed to you from a Member of the Committee. In preparing your answer to this question, please address your response to the Member who has submitted the question, including showing the Member's name, and include the text of the Member's question along with your response. The Committee apologizes for the delay in forwarding this request to you, however, we believe your response to this question is important and it will be included in the hearing record. Your assistance with the request is appreciated.

To facilitate the printing of the hearing record, we ask that we receive your response to the question by the close of business on **Friday, August 17, 2007**. Please have your written responses delivered to **2125 Rayburn House Office Building** and faxed to **202-225-2525** to the attention of Sharon Davis, Chief Clerk. Please send, as well, an electronic version of your responses to Ms. Davis at **sharon.davis@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Ms. Davis at the Committee on Energy and Commerce at (202) 225-2927.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Joseph Pitts, Member
Subcommittee on Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

AUG 21 2007

The Honorable John D. Dingell
Chairman, Committee on Energy and Commerce
House of Representatives
Washington, DC 20215

Dear Mr. Chairman:

Thank you for your letter of August 6, 2007, addressed to Stuart Wright, Deputy Inspector General for Evaluation and Inspections. Your letter contained a question posed by the Honorable Joseph Pitts as a followup to the Subcommittee on Health's April 18, 2007, hearing on "Medicare Program Efficiency and Integrity."

I have enclosed a document containing the text of Mr. Pitts's question, followed by our response. Also enclosed is an Office of Inspector General (OIG) report that Mr. Pitts references in his question.

I very much appreciate the opportunity to further discuss OIG's role in ensuring the efficiency and integrity of the Medicare program. If you have any questions, please contact me or your staff may call Claire Barnard, Director of External Affairs, at (202) 205-9523.

Sincerely,

Daniel R. Levinson

Daniel R. Levinson
Inspector General

Enclosures

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

Question for Stuart E. Wright
from
The Honorable Joseph Pitts
regarding
HHS's IVIG Studies

Question: **According to data by consumer organizations, the current intravenous immune globulin (IVIG) provider reimbursement shortfall continues to affect patient access to this lifesaving medicine. Changes in Medicare provider payment rates to the Average Sales Price (ASP) plus 6 percent reimbursement methodology in January 2005 in the physician setting resulted in patient migration to the hospital outpatient setting. Because physicians were reimbursed at a rate lower than their purchase price, it has been reported that many were unable to perform IVIG infusions for their patients because it became economically unsustainable.**

Beginning in January 2006, a similar occurrence with Medicare reimbursement in the hospital outpatient setting has taken place where it has led in some instances to increased Medicare beneficiary IVIG access problems. The Medicare beneficiary IVIG access issue has still not been addressed by the Department of Health and Human Services (HHS) despite two outstanding agency directed IVIG marketplace studies.

The first study was initiated because various consumer organizations have reported that Medicare beneficiaries were experiencing significant difficulties accessing IVIG in their preferred site of service. The Committees on Energy and Commerce and Ways and Means jointly requested in the summer of 2005 that HHS Office of Inspector General (OIG) examine the current IVIG marketplace. In addition to assessing manufacturer pricing, this study is examining the role of distributors, Group Purchasing Organizations (GPOs), and physicians in the IVIG distribution channel.

On September 28, 2006, ASPE conducted a Town Hall meeting for the purpose of obtaining public comment on IVIG access problems. An overwhelming majority of those patients and physician commenting at the meeting argued that inadequate Medicare reimbursement for IVIG is the chief reason for IVIG access problems for Medicare beneficiaries. It has been reported to the IVIG community that both of these critical studies are nearly complete, but they have not been made available to policymakers or the IVIG community. These studies will give Congress important information regarding IVIG, including the impediments to access, and the impact of Medicare reimbursement on providers to offer the best IVIG therapies available for their patients. Finally, the release of these studies may afford an opportunity to provide potential solutions to this ongoing patient care dilemma.

It is imperative that they are released in a timely manner in order to give Congress information that might lead to solutions. When can we expect these studies so that we in Congress, the IVIG community and your agency can work together to find a solution to this patient access dilemma?

Answer: We are aware of the concerns of Congress, consumer groups, and the physician community about Medicare beneficiary access to IVIG. The Office of Inspector General (OIG) shares this concern. On April 24, 2007, our office released a final report titled "Intravenous Immune Globulin: Medicare Payment and Availability" (OEI-03-05-00404). This report summarizes the body of work we completed between June and December 2006 in response to an August 2005 written request from the chairs of the Subcommittees on Health of the Ways and Means and the Energy and Commerce Committees of the 109th Congress. A copy of this final report is enclosed. The report is also available on our Web site at http://oig.hhs.gov/oei/reports/oei-03-05-00404.pdf.

Briefly, based on data presented in this report, just over half of the IVIG sales to hospitals and physicians were at prices below the Medicare payment amounts in the third quarter of 2006, a substantial increase over previous quarters. In addition, most physicians and distributors surveyed by OIG reported problems with IVIG availability in 2005 and 2006. These physicians and distributors stated that problems with availability are typically related to Medicare payment.

In addition, as you reference in your question, the Department of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation recently completed a study on this same topic, available to you at http://aspe.hhs.gov/sp/reports/2007/IGIV/report.pdf.

I thank you for your interest in OIG's work on this topic and appreciate the opportunity to share this work with you.

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

INTRAVENOUS IMMUNE GLOBULIN: MEDICARE PAYMENT AND AVAILABILITY

Daniel R. Levinson
Inspector General

April 2007
OEI-03-05-00404

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

OBJECTIVE

1. To determine whether hospitals and physicians could purchase intravenous immune globulin (IVIG) at prices below the Medicare payment amounts in 2005 and 2006.
2. To determine whether IVIG was readily available to physicians and distributors in 2005 and 2006.

BACKGROUND

Members of the congressional subcommittees on Health within the Energy and Commerce and Ways and Means Committees requested that the Office of Inspector General (OIG) examine the current state of pricing and supply of IVIG. IVIG is a collection of antibodies derived from blood plasma fractionation and administered by infusion to patients with poorly functioning immune systems. Preliminary claims data indicate that Medicare and its beneficiaries paid approximately $74 million for IVIG administered in physicians' offices and home settings in 2006. Medicare paid an additional $130 million for IVIG administered in hospital outpatient settings based on claims processed from January through October 2006.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 changed the payment basis for most Part B prescription drugs, including IVIG, from the average wholesale price (AWP) to the average sales price (ASP) for physicians in 2005 and for hospitals in 2006. As a result, physician payment amounts fell 14 percent for powder and liquid IVIG between the fourth quarter of 2004 (the last quarter of AWP-based physician payments) and first quarter of 2005 (the first quarter of ASP-based physician payments). The Medicare payment amounts to hospitals fell 45 percent for powder IVIG and 30 percent for liquid IVIG between the fourth quarter of 2005 (the last quarter of AWP-based hospital payments) and first quarter of 2006.

The Centers for Medicare & Medicaid Services (CMS) established a temporary preadministration-related service payment (for both hospitals and physicians' offices) of approximately $70 per day of infusion during 2006 in response to concerns about beneficiary access and Medicare payment for IVIG. CMS recently stated that it would continue the add-on payment throughout 2007. In addition to the temporary add-on payment, the ASP-based Medicare payment during

the fourth quarter of 2006 was 17 percent higher for powder IVIG and 8 percent higher for liquid IVIG than it was at the close of 2005.

We conducted a review to examine IVIG availability and Medicare payment from the perspectives of: (1) manufacturers of IVIG, (2) distributors and group purchasing organizations (GPO) identified by the manufacturers as involved in the sale and distribution of IVIG, and (3) randomly selected physicians who billed Medicare for IVIG.

It is important to note that IVIG is a unique pharmaceutical product that presents payment and cost-related issues that may not be typical of other Part B-covered drugs (such as oral anticancer drugs and immunosuppressive drugs, drugs used in conjunction with durable medical equipment, and some vaccines). IVIG is a blood plasma derivative; the amount produced is dependent upon plasma collection and there is a finite amount of raw material. Therefore, the results of this review are applicable only to IVIG.

FINDINGS

In the third quarter of 2006, just over half of IVIG sales to hospitals and physicians were at prices below Medicare payment amounts, which represents a substantial increase over the previous three quarters. During the third quarter of 2006, 56 percent of IVIG sales to hospitals and 59 percent of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amounts. This represents a dramatic shift from the previous three quarters, when the percentage of IVIG sold at prices below the Medicare payment amounts was as low as 23 percent for hospitals and 4 percent for physicians.

The substantial increase in sales below the Medicare payment amounts appears to be the result of manufacturer price increases in January 2006 that were not reflected in increased Medicare payments until the third quarter of 2006.

Most physicians and distributors reported problems with IVIG availability in 2005 and the first quarter of 2006. The majority (57 percent) of responding physicians reported that they were unable to provide patients with adequate amounts of IVIG during the first quarter of 2006. In addition, distributors responding to our survey also reported problems with IVIG availability in 2005. According to their responses, none of the distributors were able to fulfill all customer requests for IVIG, and all responding distributors have asked

manufacturers for additional product. These respondents stated that problems with availability are typically related to Medicare payment.

CONCLUSION

Based on the data presented in this report, just over half of IVIG sales to hospitals and physicians were at prices below the Medicare payment amounts in the third quarter of 2006, a substantial increase over previous quarters. Distributors and physicians also reported problems with IVIG availability.

The interaction of manufacturer pricing decisions and certain ASP-related issues could partially explain our findings regarding IVIG pricing and availability. Because manufacturer price increases for IVIG in early 2006 were not reflected in Medicare reimbursement until the middle of that year, hospitals and physicians were initially charged more for IVIG without a corresponding increase in payment. If manufacturers were to implement another across-the-board price increase, hospitals and physicians might face issues similar to those that they faced in the first two quarters of 2006.

It is important to note that additional factors, including off-label use, coding, and plasma industry economics, may drive the difficulties with IVIG pricing and availability. Reported recent increases in the use of IVIG for off-label indications may strain the tight supply of this product. Each IVIG product is a unique brand drug, yet Medicare payment is based on a weighted average price of all products. The production of IVIG requires substantial resources not typically associated with other pharmaceutical products. However, this review did not include an in-depth examination of these factors.

AGENCY COMMENTS

CMS commented that this report provides initial information on the availability and pricing for IVIG and sets the stage for further review of certain issues (e.g., off-label use, payment lags, and distributor markups) that can bring greater understanding of how the marketplace operates for this unique product. CMS also noted that the time lag is a feature of the ASP system and applies to all Part B drugs and biologicals. CMS stated that the substantial increase in the percentage of IVIG sold to hospitals and physicians at prices below the Medicare payment amounts is an important development and noted that these findings indicate that Medicare payment has adjusted to increases in

IVIG market prices over time. CMS stated, "We will carefully consider this report as we continue our dialogue with manufacturers, patient groups, and stakeholders to better understand marketplace developments and issues impacting beneficiary access to quality care. We strongly encourage the OIG to further study some of the issues raised [in CMS's comments to the draft report]."

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVE

1. To determine whether hospitals and physicians could purchase intravenous immune globulin (IVIG) at prices below the Medicare payment amounts in 2005 and 2006.
2. To determine whether IVIG was readily available to physicians and distributors in 2005 and 2006.

BACKGROUND

Sections 1847A (d) (1) and (2) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108-173), directs the Office of Inspector General (OIG) to undertake pricing studies and compare average sales prices (ASPs) with widely available market prices. Related to these provisions, members of the congressional subcommittees on Health within the Energy and Commerce and Ways and Means committees requested that OIG determine the current market prices for IVIG and investigate the current state of IVIG pricing and supply. We previously provided the congressional requestors with the results of our work.

Intravenous Immune Globulin

Patients with poorly functioning immune systems receive IVIG infusions to temporarily replace missing antibodies, thus helping to protect them against infectious agents that cause various diseases. IVIG is produced in both powder and liquid form through fractionation of human blood plasma. Fractionation is the process whereby plasma proteins are separated in a purified and concentrated form. Each IVIG product has a distinct brand name.

The Food and Drug Administration (FDA) has approved IVIG to treat several conditions. One condition is primary immune deficiency disease, a group of disorders in which the immune system fails to produce enough antibodies, thereby predisposing individuals to increased risk of infection. Additional FDA-approved indications for IVIG use are acute and chronic idiopathic thrombocytopenia purpura, B-cell chronic lymphocytic leukemia, Kawasaki syndrome, pediatric

human immunodeficiency virus, and bone marrow transplantation.[1] Some providers have reported that the majority of their IVIG use is for off-label (non-FDA-approved) indications (e.g., multiple sclerosis, rheumatoid arthritis, infections in low-birth-weight newborns). Off-label use may have increased, contributing to rising demand.[2]

IVIG is a unique pharmaceutical product; as a blood plasma derivative, the amount produced is dependent upon plasma collection. Production increases require substantial time and resources not generally associated with other drug products.

Sources of IVIG

Physicians, hospitals, and other providers purchase IVIG through distributors, group purchasing organizations (GPO), and directly from manufacturers.

Manufacturers establish relationships with distributors to sell IVIG to providers. Distributors purchase IVIG from manufacturers and then independently resell IVIG to providers or work in conjunction with GPOs to provide IVIG to GPO members.

GPOs generally provide their members with access to lower-cost products by negotiating prices for specific drugs from manufacturers. GPOs do not purchase drugs themselves; rather, they enter into group purchasing contracts with manufacturers on behalf of their members. The contracts prescribe the prices, conditions, and terms under which GPO members can purchase drug products. GPO members then purchase drugs from distributors or manufacturers at the price specified in the GPO contracts. Distributors do not determine GPO contract prices; they only provide drugs to GPO members at the contract prices.

Medicare Payment for IVIG

According to Medicare claims data, Part B and its beneficiaries paid approximately $74 million for IVIG administered in physicians' offices and patients' homes in 2006.[3] Medicare paid an additional $130 million

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[1] Department of Health and Human Services Advisory Committee on Blood Safety and Availability, "Status of Immune Globulin Intravenous (IVIG) Products." Available online at http://www.hhs.gov/bloodsafety/igiv.html. Accessed April 24, 2006.

[2] Ibid.

[3] Medicare Part B Extract and Summary System, updated through December 2006 (90 percent of claims reported), accessed March 26, 2007.

for IVIG administered in hospital outpatient settings from January through October 2006.[4]

The MMA changed the basis of physician payment for most Medicare Part B prescription drugs, including IVIG, to ASP, effective January 1, 2005.[5] There is a two-quarter lag between the time manufacturers report ASPs to CMS and the time those prices become the basis for Medicare payment. For example, first-quarter 2006 ASP submissions from manufacturers served as the basis for third-quarter 2006 Medicare payment for most covered drugs. Prior to 2005, Medicare generally used the average wholesale price (AWP) as the basis for Part B payment for prescription drugs. Numerous reports by OIG and the Government Accountability Office found that the AWP is often significantly higher for Part B drugs than the prices that drug manufacturers, wholesalers, and similar entities actually charge the physicians who purchase these drugs.

Medicare continued to use AWPs to pay hospitals for outpatient drugs in 2005. However, since January 1, 2006, Medicare payment for most drugs and biologicals, including IVIG, administered in hospital outpatient departments has been based on 106 percent of the manufacturer's ASP, an amount identical to the physician payment amount.[6]

A previous OIG review examined the adequacy of Medicare's new payment methodology among certain specialties (hematology, hematology/oncology, and medical oncology). This review determined that physician practices in these specialties could generally purchase drugs, including IVIG, at less than the MMA-established payment

[4] This figure is based on hospital claims processed from January through October 27, 2006. This figure includes Medicare and beneficiary payments.

[5] Pursuant to section 1847A (c) of the Act, the ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States (with certain exceptions) 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 obtained through the Medicaid drug rebate program.

[6] "Medicare Announces Payment Rates and Policy Changes for Hospital Outpatient Services in 2006." Available online at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1711. Accessed April 24, 2006.

rates.[7] An additional review conducted by the Medicare Payment Advisory Commission similarly found that oncologists could purchase most drugs at prices below Medicare's payment amount.[8]

Concerns Over Medicare Payment and Product Availability

Medicare payment for IVIG. After the MMA changed the basis of physician drug payment from AWPs to ASPs, patient advocacy groups and physicians expressed concerns over Medicare's reduced payment amount for IVIG.[9] Their concerns centered on the claim that, under the new payment methodology, the cost for physicians to acquire IVIG would exceed Medicare's payment amount. As a result of changes to Medicare's payment methodology, the physician payment amounts fell 14 percent for powder and liquid IVIG between the fourth quarter of 2004 (the last quarter of AWP-based physician payments) and the first quarter of 2005 (the first quarter of ASP-based physician payments).[10] In addition, manufacturers expressed concern over the fact that the codes used for Medicare payment are based on a weighted average of all liquid or all powder IVIG products.

Similarly, hospital payments also decreased as a result of the shift to ASPs in January 2006. The Medicare payment amounts to hospitals fell 45 percent for powder IVIG and 30 percent for liquid IVIG between the fourth quarter of 2005 (the last quarter of AWP-based hospital payments) and the first quarter of 2006.

IVIG availability. In addition to issues with pricing, it has been reported in the media that there is an inadequate supply of IVIG.[11] FDA's Center for Biologics Evaluation and Research, which has procedures for determining and reporting a shortage, indicates on its Web site that "along with other HHS [Department of Health and Human Services] agencies, the FDA has received reports from stakeholders, patients, and health care providers regarding difficulty in obtaining [IVIG] products.

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[7] "Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients." Department of Health and Human Services, OIG (A-06-05-00024). September 2005.

[8] "Effects of Medicare Payment Changes on Oncology Services." Medicare Payment Advisory Commission. January 2006.

[9] "Law Impedes Flow of Immunity in a Vial." New York Times. July 19, 2005.

[10] The Medicare physician payment amounts were identical for powder and liquid IVIG in the fourth quarter of 2004 as well as in the first quarter of 2005.

[11] "Law Impedes Flow of Immunity in a Vial." New York Times. July 19, 2005. "IVIG Shortage Driving Patients to Hospitals." Drug Topics. August 22, 2005.

From discussions with manufacturers, distributors, providers, and consumers, it is clear that availability and treatment patterns have shifted; but we did not find clear evidence that there is currently a shortage. This is a multi-faceted and fluid situation."[12] Further, HHS officials have told Congress that, among other factors, because IVIG is derived from human plasma, it takes significant startup time to increase supply, and supply has historically been cyclical.[13]

This is not the first time patient advocacy groups and physicians have expressed concern over IVIG availability. According to a media report, as well as an OIG interview with a manufacturer, there was a shortage of IVIG in the late 1990s after two companies halted production in their factories to make changes in order to meet new quality standards.[14] When the factories came back online, production increased, leading to excess product and reduced prices. At that time, three manufacturers left the business. Other issues with IVIG availability surfaced in 2003 when one manufacturer, while staying in business, reportedly closed dozens of plasma collection centers.[15]

Recent Increases in Medicare Payment for IVIG

In response to concerns about beneficiary access to IVIG and Medicare payment, CMS established a temporary preadministration-related service payment (for both hospitals and physician offices) of approximately $70 per day of infusion during calendar year 2006. This additional payment covers the preadministration-related services required to locate and acquire adequate IVIG product and prepare for an infusion of IVIG.

In a press release dated November 2, 2005, CMS stated "that the pricing for IVIG is accurate, and that there is no overall product shortage. However, in the face of such factors as increasing IVIG demand . . . physician office staff has to expend extra resources on locating and obtaining appropriate IVIG products and scheduling patient infusions." CMS went on to state that "for calendar year 2006

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[12] "Biological Product Shortages." Available online at http://www.fda.gov/cber/shortage/shortage.htm. Accessed February 6, 2007.

[13] Testimony of Herb B. Kuhn, CMS, before the Subcommittee on Health of the House Committee on Ways and Means, July 13, 2006. Available online at http://waysandmeans.house.gov/hearings.asp?formmode=view&id=5108. Accessed November 28, 2006.

[14] "Law Impedes Flow of Immunity in a Vial." New York Times. July 19, 2005.

[15] Ibid.

only, physicians and hospitals will be permitted to bill this add-on code to compensate for the administrative burdens associated with IVIG administration during this time of some volatility in IVIG product availability."[16] CMS recently stated that it will maintain the add-on payment for IVIG in 2007 to help ensure appropriate patient access to IVIG.[17]

In addition to the temporary add-on payment, the Medicare payment amounts for IVIG rose in 2006. The ASP-based payment during the fourth quarter of 2006 was 17 percent higher for powder IVIG and 8 percent higher for liquid IVIG than it was at the close of 2005.[18]

SCOPE AND METHODOLOGY

Scope

We conducted this review to examine the pricing and availability of IVIG from the perspectives of: (1) manufacturers of IVIG, (2) distributors and GPOs identified by the manufacturers as involved in the sale and distribution of IVIG, and (3) randomly selected physicians who billed Medicare for IVIG.

IVIG is a unique pharmaceutical product that presents payment-related issues that may not be typical of other Part B-covered drugs.[19] IVIG is a blood plasma derivative; the amount produced is dependent upon plasma collection and there is a finite amount of raw material. Therefore, the results of this review are applicable only to IVIG. This review did not examine the availability of or Medicare payment for any other drug products.

[16] The full text of the press release is located on CMS's Web site: http://new.cms.hhs.gov/apps/media/press/release.asp?Counter=1709. Accessed February 9, 2006.

[17] Final Rule, 71 Federal Register 69624, 69679 (December 1, 2006).

[18] In the fourth quarter of 2005, the Medicare physician payment amounts were $43.10 per gram of powder IVIG and $56.30 per gram of liquid IVIG. For the same quarter, the Medicare hospital payment amounts were $80.68 per gram of liquid and powder IVIG. In the fourth quarter of 2006, the Medicare payment amounts were $50.53 per gram of powder IVIG and $60.65 per gram of liquid IVIG.

[19] Medicare Part B covers only a limited number of outpatient prescription drugs. Covered drugs include injectable drugs administered by a physician; certain self-administered drugs, such as oral anticancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

Methodology: Data Sources and Sample

Manufacturers. We collected 2005 sales prices, sales volume, and production volume from the five IVIG manufacturers producing IVIG at the time of the review (December 2005). These manufacturers also completed a written survey on IVIG pricing and availability.

Distributors. From August to October 2006, we collected sales and pricing data from the three largest distributors for the first three quarters of 2006 to gather IVIG sales prices to hospitals and physicians.[20] In addition, between January and April 2006, we collected sales prices and sales volume for 2005 from 13 distributors (including the 3 largest distributors) identified by IVIG manufacturers.[21]

Physicians. In April 2006, we sent written surveys on pricing and availability to 255 randomly selected physicians who billed Medicare for IVIG. We asked the physicians how much they paid for IVIG during the first quarter of CY 2006, taking into account discounts and rebates. We also asked them to submit invoices to document all IVIG purchases. Between May and August 2006, 157 physicians (62 percent) responded to our written survey and 100 physicians (39 percent) provided their purchase volume and acquisition costs for IVIG.

Data Analysis: Pricing and Sales Data From 2006

Distributors. We examined 2006 sales and pricing data from the three largest IVIG distributors for the first three quarters of 2006. We calculated the percentage of IVIG sales to hospitals and physicians at prices above and below the Medicare payment amounts for the first three quarters of 2006.

Physicians. Based on the information provided by responding physicians, we calculated the percentage of IVIG purchased at prices above and below the first-quarter 2006 Medicare physician payment amounts. We also determined the percentage of IVIG purchased by physicians that was subject to discounts and rebates and examined physician responses to our written survey.

[20] Based on data obtained from all distributors, OIG determined that the three largest IVIG distributors accounted for approximately 90 percent of distributor-reported sales in the fourth quarter of 2005.

[21] The sales volume and pricing data presented were provided by distributors and include IVIG sales and prices to GPO and non-GPO members.

FINDINGS

In the third quarter of 2006, just over half of IVIG sales to hospitals and physicians were at prices below Medicare payment amounts, which represents a substantial increase over the previous three quarters

During the third quarter of 2006, 56 percent of IVIG sales to hospitals and 59 percent of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amounts.[23] This represents a dramatic shift from the previous three quarters, when the percentage of IVIG sold at prices below the Medicare payment amounts was as low as 23 percent for hospitals and 4 percent for physicians. As Tables 1 and 2 illustrate, the percentage of IVIG sold at prices at least 10 percent above the Medicare reimbursement amount declined substantially in the third quarter of 2006 as well.

Table 1. Distributor Sales to Hospitals From Fourth Quarter of 2005 to Third Quarter of 2006

IVIG Price Range	4th Quarter 2005	1st Quarter 2006	2nd Quarter 2006	3rd Quarter 2006
Below Medicare payment	37.3%	25.5%	22.8%	56.0%
0.01%–5.00% greater than Medicare payment	51.2%	30.7%	31.4%	6.1%
5.01%–10.00% greater than Medicare payment	2.7%	11.5%	9.6%	33.6%
10.01%–20.00% greater than Medicare payment	6.5%	5.1%	5.2%	3.2%
20.01%–25.00% greater than Medicare payment	0.4%	25.1%	29.7%	0.7%
More than 25.01% greater than Medicare payment	1.9%	2.1%	1.4%	0.5%

Source: IVIG pricing and sales data from the three largest distributors.
Note: Totals may not add because of rounding.

Table 2. Distributor Sales to Physicians From Fourth Quarter of 2005 to Third Quarter of 2006

IVIG Price Range	4th Quarter 2005	1st Quarter 2006	2nd Quarter 2006	3rd Quarter 2006
At or below Medicare payment*	33.0%	10.5%	3.5%	58.6%
0.01%–5.00% greater than Medicare payment	48.5%	44.4%	53.9%	8.3%
5.01%–10.00% greater than Medicare payment	0.1%	7.0%	0.9%	14.0%
10.01%–20.00% greater than Medicare payment	11.0%	11.6%	18.8%	15.8%
20.01%–25.00% greater than Medicare payment	1.2%	18.0%	15.4%	2.4%
More than 25.01% greater than Medicare payment	6.3%	8.4%	7.6%	1.0%

Source: IVIG pricing and sales data from the three largest distributors.
Note: Totals may not add because of rounding.
*Less than 1 percent of sales to physicians during this quarter were at the same price as the Medicare payment amount.

[23] The three largest IVIG distributors accounted for approximately 90 percent of distributor-reported sales in the fourth quarter of 2005, including 97 percent of sales to hospitals and 66 percent of sales to physicians. Because these distributors account for almost all hospital purchases, these data are representative of hospital costs. Most sales by these distributors were to GPO members at contract prices. Virtually no IVIG sold by the remaining 10 distributors was subject to GPO contracts. However, 34 percent of physician purchases came from smaller distributors at noncontract prices, and the percentages in Table 2 may overestimate actual amounts of IVIG sales below Medicare payment amounts.

Purchase prices and invoices supplied by responding physicians for the first quarter of 2006 corroborate the distributor data presented in Table 2. The pricing data illustrate that approximately 10 percent of physician purchases (after subtracting discounts and rebates) were made at prices below the Medicare physician payment amounts in the first quarter of 2006.[24]

The substantial increase in sales below the Medicare payment amounts appears to be the result of manufacturer price increases in January 2006 that were not reflected in increased Medicare payments until the third quarter of 2006

According to data provided by manufacturers, all planned to increase IVIG prices at the beginning of 2006. The data provided by distributors indicate that these price increases were then passed on to customers. However, Medicare payment amounts in the first two quarters of 2006 were still based on older sales prices from 2005. Therefore, even though hospitals and physicians had to pay more for IVIG in early 2006, their Medicare payment did not increase at the same time. It appears that payment amounts for IVIG started to "catch up" with actual sales prices during the third quarter of 2006, and this is reflected in the increase in the percentage of sales at prices below the Medicare payment amounts shown in Tables 1 and 2. Table 3 below illustrates that Medicare payment amounts for IVIG have risen over the last four quarters. The largest increase in Medicare payments occurred between the second and third quarters of 2006, reflecting manufacturer price increases from two quarters prior.

Table 3. Medicare Payment for IVIG From the Fourth Quarter of 2005 to the Third Quarter of 2006

IVIG Form	4th Quarter 2005[25]	1st Quarter 2006	2nd Quarter 2006	3rd Quarter 2006
Liquid IVIG (1 gram)	$56.30	$56.72	$58.18	$60.23
Powder IVIG (1 gram)	$43.10	$44.44	$44.52	$49.80

Source: CMS 2005 and 2006 ASP drug pricing files.

[24] Approximately 90 percent of physician-reported purchases were at prices above the Medicare payment amount in the first quarter of 2006. In addition, 133 of 157 responding physicians (85 percent) reported that they could not purchase either liquid or powder IVIG at a price below the Medicare payment amount for that quarter.

[25] These are the Medicare physician payment amounts for the fourth quarter of 2005. The Medicare hospital payment amount for this quarter was $80.68 per gram.

In the fourth quarter of 2005, IVIG obtained by hospitals and physicians through GPO contracts was more likely to be sold at prices below the Medicare payment amounts than IVIG not obtained through GPO contracts. Physicians are less likely than hospitals to obtain IVIG through GPO contracts. Most distributor sales to hospitals (87 percent) were at contract prices in the fourth quarter of 2005; however, a much smaller portion of distributor sales to physicians (44 percent) were at contract prices during the same quarter.[26]

According to sales data collected from 13 distributors (including the 3 largest IVIG distributors), 39 percent of contract sales were at prices below the Medicare payment amounts during the fourth quarter of 2005 (see Table 4 on the next page). In contrast, only 2 percent of noncontract IVIG was sold at prices below the Medicare physician payment amounts during the same quarter. Furthermore, almost one-third of noncontract sales exceeded Medicare payment amounts by at least 20 percent. Less than 1 percent of contract sales exceeded the Medicare payment amounts by that amount.

Noncontract prices may be higher than contract prices because they are subject to additional distributor markups.[27] Distributors typically mark up manufacturer sales prices prior to reselling IVIG to customers, such as physicians or hospitals. Distributor markups have a greater effect on noncontract prices because contract prices are set, prenegotiated prices between the GPO and manufacturers. Distributors do not determine these prices, and any markup is limited by the terms of the contracts. The markup limitations do not typically apply to IVIG sold outside of a GPO contract, although some manufacturers place limits on distributor markups. In the fourth quarter of 2005, distributor markups for noncontract sales ranged from 5 to 49 percent.

[26] For the purposes of this review, IVIG sales to GPO members at the contract prices by distributors are considered "contract" sales. Not all sales by distributors are subject to GPO contracts. In contrast to the contract sales, sales of IVIG by distributors to providers are considered "noncontract" sales. Distributors typically mark up manufacturer sales prices prior to reselling noncontract IVIG directly to customers, such as physicians or hospitals.

[27] We are defining markup as the difference between how much a distributor pays the manufacturer for IVIG and how much the distributor charges customers for IVIG.

Table 4. Contract and Noncontract Sales Prices for IVIG in the Fourth Quarter of 2005

IVIG Price Range	Percentage of Contract Sales	Percentage of Noncontract Sales
Below Medicare physician reimbursement	39.2%	1.7%
0.01%–5.00% greater than Medicare physician reimbursement	55.9%	24.6%
5.01%–20.00% greater than Medicare physician reimbursement	4.7%	40.5%
20.01%–50.00% greater than Medicare physician reimbursement	0.2%	24.9%
More than 50.01% greater than Medicare physician reimbursement	0.0%	8.3%

Source: IVIG pricing and sales data from distributors.
Note: Totals may not add because of rounding.

Most physicians and distributors reported problems with IVIG availability in 2005 and the first quarter of 2006

The majority (57 percent) of responding physicians reported that they were unable to provide patients with adequate amounts of IVIG during the first quarter of 2006. These physicians stated that problems with IVIG availability were typically related to Medicare payment.

A small number of responding physicians said that they had stopped providing IVIG to Medicare beneficiaries altogether. One responding physician stated that payment issues led him to turn patients away: "The reimbursement from Medicare does not cover the cost of medication. We are unable to provide care for new patients." Another physician added: "We can no longer treat [Medicare] patients with IVIG due to losing hundreds of dollars each time." A third physician cited supply issues for the inability to treat patients: "Due to insufficient supply, we are forced to turn away patients requiring IVIG."

All 13 distributors responding to our January 2006 survey also reported problems with IVIG availability. One summarized the situation by stating: "Customers have requested more product, but we are unable to obtain the extra product needed from the manufacturer." According to their responses, none of the distributors were able to fulfill all customer requests for IVIG, and all distributors have asked manufacturers for additional product. Most distributors reported that manufacturers were unable to provide them with additional IVIG.

One important reason distributors are unable to obtain additional IVIG from manufacturers is that manufacturers are contractually obligated to fulfill their GPO allocations first, and, when additional product is available, manufacturers reportedly provide it to GPO members first (at a noncontract price). Therefore, hospitals and physicians who are not GPO members do not have the same access to IVIG products.

Manufacturers, distributors, and physicians reported that patients were being shifted from physicians' offices to hospitals to receive IVIG

Manufacturers responded that they received reports in 2005 of some patients being moved from physicians' offices to hospitals for IVIG treatment because of payment differentials between the settings at that time. Similarly, in responses to our January 2006 survey, a majority of the distributors noted that patients were being moved from physicians' offices to hospitals to receive IVIG treatment because of changes in Medicare's physician payment amounts. Physicians also noted in their response to our April 2006 survey that an increasing number of patients were receiving IVIG treatment in hospitals. Sixty-one percent of responding physicians indicated that they had sent patients to hospitals for IVIG treatment because of their inability to acquire adequate amounts of IVIG or problems with Medicare payment. The most common explanation for the shift to hospitals was Medicare payment, specifically the inability of physicians to purchase IVIG at prices below the Medicare payment amounts.

Distributor sales data support this claim and indicate that hospitals received more IVIG in the fourth quarter of 2005 than in the fourth quarter of 2004, while sales to physicians decreased. At that time, prices to hospitals were generally lower than prices to physicians, while Medicare payment to hospitals for IVIG administered in an outpatient setting was substantially higher than Medicare payment to physicians in 2005.[28] In keeping with the payment reforms in the MMA, CMS began paying for most Part B drugs and biologicals administered in hospital outpatient departments based on 106 percent of the manufacturer's ASP on January 1, 2006.[29] Despite the reduction in hospital payments following the change in payment methodology, data from the three largest distributors indicate that total sales to hospitals continued to increase through the first half of 2006.

The priority given to GPO contract customers is related to the shift in patients to hospitals, because the GPO market comprises primarily

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[28] In 2005, CMS reimbursed hospitals for outpatient drugs at 83 percent of the AWP. The CMS hospital payment for both powder and liquid IVIG was $80.68 per gram in the fourth quarter of 2005, compared to 56.30 (liquid IVIG) and $43.10 (powder IVIG) for physicians.

[29] "Medicare Announces Payment Rates and Policy Changes for Hospital Outpatient Services in 2006." Available online at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1711. Accessed April 24, 2006.

hospitals and nursing homes (although some physicians can purchase IVIG through GPOs). According to distributor data, most hospitals receive IVIG through their GPO memberships and, as previously stated, contract prices are generally lower than noncontract prices. One distributor summarized the potential problems with hospitals acquiring larger portions of available IVIG by stating: "The product [IVIG] allocation is normally based on historical usage data. To meet the new increased demands in the hospital outpatient setting, [the distributor] used noncontract product to meet those needs. This decreased the amount of IVIG available to the noncontract market (e.g., physicians, home care and pharmacies)."

CONCLUSION

Based on the data presented in this report, just over half of IVIG sales to hospitals and physicians were at prices below the Medicare payment amounts in the third quarter of 2006, a substantial increase over previous quarters. Distributors and physicians also reported problems with IVIG availability.

The interaction of manufacturer pricing decisions and certain ASP-related issues could partially explain our findings regarding IVIG pricing and availability. For example, the results of this review indicate that the two-quarter lag between manufacturer price increases and corresponding increases in Medicare payment amounts may have played a major role in substantially increasing the percentage of IVIG sales at prices below the Medicare payment amounts in the third quarter of 2006.

Because manufacturer price increases for IVIG in early 2006 were not reflected in Medicare reimbursement until the middle of that year, hospitals and physicians were initially being charged more for IVIG without a corresponding increase in payment. If manufacturers were to implement another across-the-board price increase, hospitals and physicians might face issues similar to those that they faced in the first two quarters of 2006.

Furthermore, ASPs include manufacturer sales to all classes of trade and do not explicitly include distributor markup, which may cause the actual acquisition cost of IVIG to exceed the Medicare payment amount (especially in a time when increased demand creates incentives for distributors to increase markups on noncontracted sales). In the case of IVIG, the combination of the two-quarter lag and distributor markups could result in a gap between provider acquisition costs and Medicare payment amounts, which could lead providers to shift patients to other sites of service. When this occurs, beneficiaries may have difficulty obtaining treatment in their preferred settings.

It is important to note that additional factors, including off-label use, coding, and plasma industry economics, may drive the difficulties with IVIG pricing and availability. Reported recent increases in the use of IVIG for off-label indications may strain the tight supply of this product. Each IVIG product is a unique brand drug, yet Medicare payment is based on a weighted average price of all products. The production of

IVIG requires substantial resources not typically associated with other pharmaceutical products. However, this review did not include an in-depth examination of these factors.

AGENCY COMMENTS

CMS commented that this report provides initial information on the availability and pricing of IVIG and sets the stage for further review of certain issues (e.g., off-label use, payment lags, and distributor markups) that can bring greater understanding of how the marketplace operates for this unique product. CMS also noted that the time lag is a feature of the ASP system and applies to all Part B drugs and biologicals. CMS stated that the substantial increase in the percentage of IVIG sold to hospitals and physicians at prices below the Medicare payment amounts is an important development and noted that these findings indicate that Medicare payment has adjusted to increases in IVIG market prices over time. CMS stated, "We will carefully consider this report as we continue our dialogue with manufacturers, patient groups, and stakeholders to better understand marketplace developments and issues impacting beneficiary access to quality care. We strongly encourage the OIG to further study some of the issues raised [in CMS's comments to the draft report]."

APPENDIX A

DETAILED SCOPE AND METHODOLOGY

Detailed Scope

We conducted a multiphase review to examine the pricing and availability of intravenous immune globulin (IVIG) from the perspectives of: (1) the manufacturers of IVIG, (2) distributors and group purchasing organizations (GPOs) identified by the manufacturers as involved in the sale and distribution of IVIG, and (3) randomly selected physicians who billed Medicare for IVIG.

Manufacturers. We collected data from the five IVIG manufacturers producing IVIG at the time of the survey (December 2005). We did not include the American Red Cross in this study because it announced its exit from the plasma therapeutics business in July 2005.

Distributors and group purchasing organizations. Based on information collected from the 5 IVIG manufacturers, we identified 17 distributors and 7 GPOs involved with the sale and distribution of IVIG. We collected data only from distributors and GPOs identified by the manufacturers. IVIG manufacturers identified four additional companies as distributors in their responses to the Office of Inspector General (OIG). We did not include three of these in our analysis because these companies do not consider themselves distributors, as none of them resells IVIG. The fourth company identified itself as a "small independent distributor" and "was not set up to breakout the kind of information [OIG] is requesting."

For the three largest IVIG distributors, we collected sales and pricing data for the first three quarters of 2006. We did not collect any 2006 sales and pricing data from smaller distributors, who tend to charge customers more for IVIG.

Physicians. We randomly selected physicians who billed Medicare for two IVIG procedure codes during the third quarter of 2005. The procedure codes are: Q9941—injection, immune globulin, intravenous, lyophilized (powder), 1 gram; and Q9943—injection, immune globulin, intravenous, nonlyophilized (liquid), 1 gram. These two codes accounted for the majority of Medicare payment for IVIG during the last three quarters of 2005 (the effective dates of these codes). There were two additional IVIG procedure codes in effect during 2005: Q9942 and Q9944, which were 10-milligram doses of powder and liquid IVIG, respectively. We did not include these two codes in our analysis.

Effective January 1, 2006, CMS replaced these four procedure codes with two new codes: J1566 and J1567.

Detailed Methodology: Data Sources and Sample

Manufacturers. The five manufacturers producing IVIG at the time of the survey (December 2005) provided OIG with 2005 IVIG sales prices and sales volume. In addition, we asked manufacturers to complete a written survey about IVIG access and availability, distribution methods, resale policies, customers, and future production plans.

Distributors and GPOs. Manufacturers identified 17 distributors and 7 GPOs involved with the sale and distribution of IVIG. Between January and April 2006, 14 distributors and 6 GPOs completed a written survey concerning IVIG. Two of the seventeen distributors submitted survey responses after the deadline for data collection. The remaining distributor and one GPO did not complete the survey or provide sales and pricing data. Based on manufacturer sales data, these nonrespondents made up a very small portion of IVIG sales.

Thirteen of these distributors also provided us with their sales prices and sales volume for 2005. The sales volume and pricing data were provided by distributors and include IVIG sales and prices to GPO and non-GPO members.

Based on distributor-reported data, we determined that the three largest IVIG distributors accounted for approximately 90 percent of distributor-reported sales in the fourth quarter of 2005. We collected sales and pricing data from these three largest distributors for the first three quarters of 2006.

Physicians. We extracted all paid Medicare Part B physician claims for two IVIG procedure codes from CMS's 2005 National Claims History File with dates of service in the third quarter of 2005 (the most recent claims data available at the time we selected our sample). We summarized the claims by the physician's Unique Physician Identification Number (UPIN) and profiling identification number. After we summarized third-quarter 2005 claims data by UPIN and profiling identification number, there were 1,111 observations for Q9941 and 1,350 observations for Q9943.

We then selected a simple random sample of 130 physicians for each of the two procedure codes. OIG investigative concerns prevented us from contacting a small number of physicians; we excluded these physicians from our sample. The final sample contained 129 physicians for

procedure code Q9941 and 126 physicians for procedure code Q9943, for a total of 255 physicians.

In April 2006, we sent written surveys on pricing and availability to the 255 randomly selected physicians in our sample. We asked physicians how much they paid for IVIG during the first quarter of 2006, taking into account all discounts and rebates. We asked physicians to submit invoices to document all IVIG purchases. We also asked physicians how available and accessible IVIG is, what happens when they are unable to provide patients with adequate amounts of IVIG, and from what sources they purchase IVIG products.

Between May and August 2006, 157 physicians (62 percent) responded to our written survey and 100 physicians (39 percent) provided their purchase volume and acquisition costs for IVIG. Some respondents reported IVIG purchases and purchase prices for individual physicians in our sample, while others provided IVIG purchases and prices for physicians' group practices. We could not identify fundamental differences between responding and nonresponding physicians.

Data Analysis: Pricing and Sales Data From 2006

Distributors. We examined sales and pricing data for the first three quarters of 2006 from the three largest IVIG distributors. We calculated the percentage of IVIG sales to hospitals and physicians at prices above and below the Medicare payment amounts and identified trends in IVIG availability related to increases in IVIG purchase prices and Medicare payment.

Physicians. Based on the information provided by the responding physicians, we calculated the percentage of IVIG purchased by responding physicians at prices above and below the first-quarter 2006 Medicare physician payment amounts, which were based on average sales prices reflecting manufacturer sales from July through September 2005. For this analysis, we compared physician-reported prices that take into account discounts and rebates with the Medicare physician payment amounts. We also determined the percentage of IVIG purchased by physicians that was subject to discounts and rebates. We examined physician responses to our survey to identify what product availability issues exist, what concerns physicians have about Medicare payment, from what sources physicians purchase IVIG products, how physicians use IVIG, and any other specified issues.

A P P E N D I X - A

Pricing and Sales Data From 2005

Manufacturers. Based on the information provided by the five manufacturers, we identified the amount of IVIG sold in 2005 to each type of customer (e.g., distributor, GPO member, direct customer, and home care company). In addition, we analyzed manufacturer responses to questions about IVIG access and availability, distribution methods, resale policies, customers, future prices, and future production plans.

Distributors and GPOs. We identified the amount of IVIG sold in the fourth quarter of 2005 to each type of customer (e.g., hospital, physician, clinic, home care company, etc.). For sales to hospitals, we determined the percentage of IVIG sold at prices above and below both the Medicare outpatient hospital payment amount and the Medicare physician payment amount for the fourth quarter of 2005. We also calculated the percentage of sales to hospitals and physicians at contract and noncontract prices. For physicians, sales prices were compared only to the fourth-quarter 2005 physician payment amounts.

We identified the amount of IVIG sold in the fourth quarter of 2005 at contract and noncontract prices, regardless of customer type. For the purposes of this review, IVIG sales to GPO members at the contract prices by distributors are considered "contract" (encumbered) sales. One distributor that works extensively with GPO members summarized the relationship in the following way: "The GPO sends [distributor] the allocation spreadsheets that list their members along with the IVIG allotment that is agreed upon between the provider and the GPO . . . The GPO members call to order their IVIG and [the distributor] ships product to the GPO members based on the allocation spreadsheets."

Not all sales by distributors are subject to GPO contracts. In contrast to the contract sales described above, sales of IVIG that distributors independently resell to providers are considered "noncontract" (unencumbered) sales. Distributors typically markup manufacturer sales prices prior to reselling noncontract IVIG directly to customers, such as physicians or pharmacies. Each manufacturer allows distributors to sell a portion of their IVIG at noncontract prices.

We also examined distributor and GPO responses to the pricing and availability survey to identify distribution methods, manufacturer relationships, resale policies, product availability, pricing, and other specified issues.

APPENDIX ~ B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

APR 12 2007

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq.
Acting Administrator

SUBJECT: Office of Inspector General's Draft Report: "Intravenous Immune Globulin: Medicare Payment and Availability" (OEI-03-05-00404)

Thank you for the opportunity to review the above referenced report. We appreciate the Office of Inspector General's (OIG) efforts to provide information about the supply chain for intravenous immune globulin (IVIG). We believe this report provides some initial information on the availability and pricing for this product and as discussed below, sets the stage for further review of key issues that can bring greater understanding of how the marketplace operates for this product.

Beginning in 2005, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required Medicare to pay physicians for most drugs and biologicals, including IVIG, based on 106 percent of the average sales price (ASP + 6 percent). In 2006, Medicare also began paying hospital outpatient departments for IVIG, as well as other drugs and biologicals, based on ASP + 6 percent.

Studies by Medicare Payment Advisory Committee and OIG indicate that physicians are generally able to acquire most drugs and biologicals at prices below the ASP + 6 percent payment rate. While these studies suggest that the supply chain system for ASP is generally working well, we are concerned about reports of problems with product availability and Medicare payment rates for IVIG. We take these reports seriously. The Centers for Medicare & Medicaid Services (CMS), along with the Food and Drug Administration and other components within the Department, continue to actively work with manufacturers, health care providers, patient groups, and others to better 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.

As the report points out, IVIG is a unique product. Since IVIG is derived from blood plasma, the amount produced depends on plasma collection. With constraints on the amount of raw material available, there are constraints on the amount of IVIG that can be produced.

The demand for IVIG has grown significantly in recent years, as off-label use of the product has increased dramatically. While demand has increased, so too has supply.

APPENDIX - B

The availability for IVIG has historically been cyclical. There have previously been both periods of abundant and tight IVIG supply. The report found that all distributors surveyed indicated that they were not able to obtain additional IVIG from any source and that most distributors were unable to obtain additional IVIG from manufacturers. There are a limited number of IVIG manufacturers, with three companies accounting for 85 percent of IVIG production. This can have significant implications for pricing and the availability of IVIG. In a tight market, increased demand generated by factors, such as additional off-label use, has an impact on IVIG availability for Medicare beneficiaries. It would be helpful to know more about the surge in off-label use, it's effectiveness, and the current and planned research in this area.

IVIG products have been put on allocation by manufacturers and thus most IVIG product is not for sale on the open market. Instead, IVIG has been obligated for delivery to Group Purchasing Organizations (GPOs), distributors, and other end purchasers based on long-term contracts with the manufacturers. Higher prices for IVIG obtained outside a GPO or not via a contract may impact access and product availability for some Medicare beneficiaries. Your report also indicates: "Noncontract prices may be higher than contract prices because they are subject to additional distributor markups".

The report contains important information about the key role of distributors, a major player in the supply chain. Your report specifically discusses distributor mark-ups for IVIG. Your report found: "In the fourth quarter of 2005, distributor mark-ups for noncontract sales ranged from 5 to 49 percent." This range contains what some might consider excessive mark-ups and is substantially higher than commonly thought to be typical for other drugs and biologicals. The report did not examine how distributor mark-ups for IVIG compare to distributor mark-ups for other drugs and biologicals where payment is successfully made at ASP plus 6 percent. If distributor mark-ups are materially higher for IVIG than for other drugs and biologicals, it could have a significant impact on IVIG availability.

It would also be useful to know whether the mark-ups charged by the same distributor vary over time. For example, if a distributor increases mark-ups when supply gets tighter, and that mark-up is unrelated to the price the distributor has to pay the manufacturer for IVIG, the mark-up could have an impact on IVIG availability and patient access.

There is also an issue about the role of the secondary market in IVIG pricing and availability. Some believe that the secondary market accounts for 10 percent or more of IVIG distribution. Not only does a significant secondary market raise product integrity issues, but also secondary markets are often characterized by fluctuating prices and product availability, particularly where there is a tight supply of IVIG.

In addition, the OIG report analyzed the difference between distributor sales to physicians and hospitals and Medicare payment amounts. We note that any increase in

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Medicare payment amounts would increase payments to all purchasers, including those purchasers who can currently obtain product at or below Medicare payment amounts.

The study suggests that the two quarter lag in the ASP system and the exclusion of distributor mark-up from ASP may have led to differentials between the Medicare payment amount and providers' acquisition costs for IVIG. We note, however, that these features of the ASP system apply to all Part B drugs and biologicals. Yet, the OIG has found that other drugs and biologicals are generally faring well under the ASP system. It would be helpful if this issue, as it relates to IVIG and distributer mark-ups, were explored further.

With respect to the lag, we note that payment rates under all Medicare payment systems, other than for Part B drugs and biologicals, are adjusted once per year. In contrast, Medicare payment rates for Part B drugs are adjusted quarterly. This system works for other Part B drugs and biologicals. We are concerned that some may misinterpret the information about the relationship between actual sales and Medicare payment amounts to suggest eliminating the lag. We are not sure what it would mean to eliminate the lag or how Medicare payment rates would be determined. We are not sure how Medicare could operate a payment system that would change payment amounts more frequently or with a shorter time lag between data collection and implementation.

In the typical market for a product, an increase in price would lead to an increase in supply. However, given the unique characteristics of IVIG and production issues, it is not clear that an increase in Medicare payment amounts would lead to an increase in IVIG supply. If there is a higher payment amount that would lead manufacturers to increase supply, it is not clear what that higher payment amount is, how it would be determined on a one-time or regular basis, and whether it would increase supply sufficiently for both physicians and hospitals.

In the report, it is encouraging that increasing numbers of physicians and hospitals are able to purchase IVIG below the Medicare ASP+6 payment rates despite these issues. In the third quarter of 2006, Medicare payment rates were higher than 59 percent of sales to physicians and 56 percent of sales to hospitals, a substantial increase in these percentages over the prior 3 quarters. We consider this increase to be an important development, as it suggests that although your report cannot determine the underlying reasons physicians and hospitals have had issues with IVIG product availability, Medicare payment rates, under the ASP+6 system, have adjusted to substantial increases in IVIG market prices over time.

We appreciate the OIG's work in this complex area. We will carefully consider this report as we continue our dialogue with manufacturers, patient groups, and stakeholders to better understand marketplace developments and issues impacting beneficiary access to quality care. We strongly encourage the OIG to further study of some of the issues raised in these comments in order to better understand the IVIG market. Any solution needs to address the underlying problem, otherwise the action could be ineffective, and could lead to severe access problems.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director, Prescription Drug Pricing Unit.

Edward K. Burley served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to this report include Roman Strakovsky and Kriti Sehgal; other central office staff who contributed include Linda B. Abbott, Scott Horning, and Barbara Tedesco.

STATEMENT OF THE POWER MOBILITY COALITION

The Power Mobility Coalition (PMC), a nationwide association of suppliers and manufacturers of motorized wheelchairs and power operated vehicles, applauds the House Energy and Commerce Subcommittee on Health for holding a hearing examining ways to identify and eradicate fraud within the Medicare program.

The PMC has long supported efforts aimed at removing unscrupulous actors from the Medicare program. In fact, it was several PMC members who first identified pockets of suspicious activity in the delivery of power mobility devices (PMDs) in Harris, Country Texas and then brought these concerns to the attention of the Centers for Medicare and Medicaid Services (CMS) as early as April, 2003. The PMC, along with other leaders of the durable medical equipment (DME) industry, then partnered with CMS in the implementation of the "Wheeler Dealer" program that sought to root out fraudulent activity in the Medicare PMD benefit.

The PMC was very supportive of anti-fraud initiatives contained in the Medicare Modernization Act (MMA), including the requirement that a Medicare beneficiary see a health care practitioner for a face-to-face examination prior to the submission of a PMD claim, increased quality standards for PMD suppliers, and the provision that requires all DME supplies to be accredited by a nationally recognized accreditation body. While these are all positive steps in efforts to clean up the Medicare program, the PMC feels that more could be done and, as a result, offers the following recommendations to the subcommittees:

ALL NEW DME SUPPLIERS OR DME SUPPLIERS WHO ARE RENEWING THEIR SUPPLIER NUMBER MUST BE ACCREDITED

CMS has released the new quality standards for all DME suppliers and has named the nationally recognized accreditation bodies that have "deemed status" to ensure Medicare quality standards are being met. Since all the pieces of the accreditation puzzle are now in place, CMS must insist that all new DME suppliers become accredited before they can be awarded a Medicare supplier number. Further, DME suppliers who have to recertify for a supplier number should also be immediately subject to the accreditation requirement.

ACCREDITATION MUST HAPPEN PRIOR TO IMPLEMENTATION OF COMPETITIVE BIDDING

Program integrity is paramount to ensure Medicare beneficiaries receive the highest quality of products and services from lawful suppliers. Stringent quality standards coupled with mandated accreditation of suppliers will rid the Medicare program of unscrupulous actors and reinforce the integrity of those suppliers who play by the rules.

Implementing competitive bidding and allowing non-accredited suppliers to participate in the bidding process is contrary to CMS' priority to safeguard Medicare resources and beneficiaries. Allowing non-accredited suppliers to bid and be awarded contracts will cause major disruption if the contracted supplier cannot obtain accreditation and the contract must then be terminated and subject to a "rebid." In addition, non-accredited suppliers would have lower overhead and, as a result, would be able to submit lower bids which could artificially lower the single payment amount for accredited contracted suppliers.

While CMS has recently notified DME suppliers that they must be accredited by August 31st in order to be considered in the initial round of competitive bidding, there will still be many instances and many areas of the country where non-accredited suppliers could be serving Medicare beneficiaries. Even in competitive bidding areas (CBAs), non-accredited suppliers who are "grandfathered" and allowed to serve beneficiaries in CBAs are under no pressing mandate to become accredited.

ESTABLISH A DME PROGRAM INTEGRITY ADVISORY GROUP

DME manufacturers and suppliers know their business better than anyone and are constantly monitoring the marketplace. Lawful DME suppliers and manufacturers are anxious to share intelligence about potential fraudulent actors with CMS. The PMC recommends that CMS establish an advisory group comprised of DME suppliers, manufacturers and beneficiaries to work with CMS officials on developing proactive solutions to help detect and eliminate fraud.

REQUIRE PHYSICIAN CERTIFICATION ON DOCUMENTATION SUPPORTING A PMD CLAIM

As part of recent administrative changes to the Medicare PMD benefit, while a physician must provide a prescription for PMDs, CMS no longer requires that the

physician certify the need. The PMC recommends that the algorithmic formula contained in the PMD National Coverage Determination be codified in a form that will then need to be certified, under penalty of law, by the physician. Such certification will strengthen the role of the physician as gatekeeper of the Medicare PMD benefit and put the physician in a position to ensure that the beneficiary meets the requirements necessary under the Medicare program to qualify for PMDs. A physician-certified document will also provide some much needed objectivity to the PMD claims process.

The PMC appreciates the opportunity to comment on efforts to strengthen Medicare program integrity and provide recommendations for additional tools to help identify and prevent fraud. We, however, must raise caution when Medicare adopts overly restrictive anti-fraud measures that fail to distinguish between lawful suppliers and unscrupulous actors. These measures will only serve to further restrict access to PMDs, drive up program costs and deny needy beneficiaries high-quality PMDs.

The Medicare PMD benefit provides thousands of beneficiaries with freedom, independence and the ability to live more healthier and active lives. PMDs save the Medicare program money by keeping beneficiaries with compromised or limited mobility out of more costly institutional settings and decreasing the need for hospitalizations. We look forward to working with the committee to ensure that appropriate program safeguards are in place to protect both the Medicare trust fund as well as Medicare beneficiaries.

Respectfully submitted,

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