

**MEDICARE PRESCRIPTION DRUG BENEFIT:
MONITORING EARLY EXPERIENCES**

HEARING

BEFORE THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

ONE HUNDRED TENTH CONGRESS

FIRST SESSION

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MEDICARE PRESCRIPTION DRUG BENEFIT: MONITORING EARLY EXPERIENCES

WEDNESDAY, MAY 2, 2007

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:07 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Max Baucus (chairman of the committee) presiding.

Present: Senators Kerry, Lincoln, Stabenow, Grassley, Snowe, and Crapo.

OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR FROM MONTANA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order.

Earlier this year, the Medicare prescription drug program turned 1 year old. Like all 1-year-olds, it grew at a rapid pace, and, like all 1-year-olds, it needs careful monitoring and guidance to ensure that it matures properly.

The book of Proverbs says that "Children are a crown to the aged." We are here today to see to what extent this 1-year-old is a blessing to America's seniors. We are also here to see to what extent this 1-year-old needs greater direction.

I have heard from many seniors in Montana and across the country about how pleased they are with the drug benefit. They are getting real help buying their medicines. Eighty percent of seniors are satisfied with the new benefit. That is good, but it is not good enough.

I have also heard from seniors who are not satisfied. One out of every five seniors enrolled in the benefit is not satisfied. Many were overwhelmed by the number of plans, many were perplexed by the formularies or, worse yet, many are still not able to afford medicine.

I helped write the law. We, on this committee, can feel toward it much like a parent. Like any parent of an active 1-year-old, we need to spend a lot of time watching over the benefit as it develops. That is why I convened this hearing. It is time for us to hear how the drug benefit is working.

We are here today to identify the problems, and we are here today to begin solving them. The Finance Committee has an ongoing obligation to do oversight, and we have an obligation to ensure that the Medicare drug program works well for everyone.

I have heard disconcerting reports from people involved in the program. I have heard concerns about the program from seniors,

from people who are advocates for them, and from providers. We have representatives from each of these groups here today, and we need to hear from folks who can share views from the front lines.

More than 5 million seniors without drug coverage did not enroll in the program. Many of them are eligible for the extra financial help in the program, but they may not know it. We need more outreach to them. We need to know what obstacles are standing between these seniors and the drug coverage that they need. Are Medicare and private plans effectively reaching out to everyone? Are there unnecessary complications that we can simplify?

Also, choosing the best plan has proven to be a daunting task. The Centers for Medicare and Medicaid Services approved more plans than we anticipated. Some plans used marketing tactics to attract seniors that may be inappropriate, and I have heard how difficult it is to analyze plans and compare premiums, co-payments, deductibles and formularies.

Let us make it easier. Seniors, and those who counsel them, have told me that they need tools to cut through the chaos to pick the best plan. Today we will hear from one of these front-line advisors who help seniors choosing plans every day.

The implementation of the program has also been rocky. For example, I have been closely monitoring the problem that the Social Security and Medicare administrators are having withholding drug plan premiums from Social Security checks. This option was meant to simplify the program. The option was intended to make it so seniors would not have to worry about paying their premiums every month.

Instead, it has proven to be an administrative mess and, worse, it is causing real confusion and hardship for many seniors. Many have been incorrectly told that their coverage was canceled, others have had too much money withheld.

And beneficiaries are not the only ones encountering challenges. Pharmacists are on the front lines in delivering prescription drugs to our seniors. When the benefit was rolled out last year, pharmacists made sure that seniors got the drugs that they needed, despite all the system's glitches. For that, we owe them a debt of gratitude.

It is troubling to me that many pharmacies are still having difficulty in getting fair and timely compensation from drug plans. I am particularly concerned about smaller pharmacies in rural areas. If these pharmacies are forced to close, it will limit access for many seniors. I am glad we have witnesses today who can tell us about these programs as well.

The Finance Committee will be overseeing the Medicare drug benefit throughout the 110th Congress. Working together with Senator Grassley, we have set an aggressive agenda. We are going to spend a lot of time watching over the new benefit as it develops.

I thank our witnesses for joining us today for this check-up of our program. We have raised the program through its infancy. Let us see what we can do to make it even better as the program heads into its terrible twos. [Laughter.]

Senator Grassley?

**OPENING STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM IOWA**

Senator GRASSLEY. Thank you, Chairman Baucus.

Anyone who knows me well knows that I take program oversight very seriously. Some people probably wish that I didn't, but I do.

So I am pleased that the committee is holding today's hearing, and I'm looking forward to next week's hearing as well.

The Medicare Prescription Drug Benefit has proven to be a success on many fronts. We have strong enrollment, lower premiums, lower drug costs, lower costs to taxpayers, and beneficiaries are highly satisfied with their plans.

But that said, we know that the drug benefit, as with any new program of its magnitude, has had some glitches. CMS has taken a number of administrative actions to address problems as quickly as possible.

They implemented the transition fill policy, which gave new enrollees 90 days of coverage for any prescription regardless of the plan's formulary. And CMS implemented the special election period for beneficiaries eligible for additional financial assistance.

They established a dedicated call center for pharmacists, and they prohibited co-branding by the prescription drug plans with specific pharmacies because this was leading to confusion. And they took other actions to smooth implementation and reduce confusion.

Although CMS has day-to-day responsibility for administering the drug benefit, this committee is ultimately accountable for overseeing the program. And I know that the Chairman will continue this committee's longstanding commitment to conducting sound and robust oversight work.

Last year, this committee heard about some of the start-up issues in a hearing and in member meetings. The committee explored issues related to the enrollment process, the Social Security premium withhold, and drug makers' patient assistance programs. We also heard that some plans' practices have made it difficult for pharmacists to truly gauge the terms and conditions of their contracts.

The oversight work we did last year provides us with a baseline for comparing where things stand today.

Two of today's witnesses, Mr. Schule and Ms. Gross, have previously testified before the committee. They'll be able to give us an idea of what has improved, what hasn't, and what new issues may have arisen. Mr. Schule and Ms. Gross are on the frontlines, so to speak. Their insights will be particularly helpful in getting a better sense of beneficiaries' everyday experiences with the benefit.

Our other witnesses, Mr. Tucker and Ms. Gottlich, will offer more global perspectives on trends and issues that their organizations have spotted over the past year and a half.

Now, one area that remains of particular concern to me is the Social Security withhold option.

This option was supposed to be a convenient way for beneficiaries to pay their monthly premium. For many beneficiaries, that's been exactly the case. The withhold has worked like clockwork.

Unfortunately, for far too many beneficiaries, it hasn't. Just in the past few weeks, I've heard from beneficiaries in Iowa who haven't had anything withheld or have yet to receive a refund of premiums withheld in error.

Those who owe money are anxious because they're concerned they'll be dropped from their drug plans. Those who are owed money, well, they want it back, and I don't blame them.

Beneficiaries have contacted my office because they've gotten a large bill from their plans or because they see amounts withheld from their check, but it doesn't seem to be reaching their plan.

None of the beneficiaries is trying to get out of paying what they owe. Time and time again, beneficiaries say, "I know I owe this money, and I want to pay it, but I can't pay it back all at once," or they say, "just tell me who to pay!"

From what I've heard, no one seems to want to take responsibility for this problem. A beneficiary who calls a plan is told to call Medicare. When the beneficiary calls Medicare, they're told to call Social Security.

That's simply not acceptable.

I know that CMS and SSA have worked to resolve these problems, and they've made progress on the cases they have. But the bottom line is, they need to make more progress and they need to do so quickly. They need to prevent these problems from happening in the first place.

It's my understanding that Ms. Gross and volunteers at the Iowa SHIP have been helping beneficiaries with these types of problems, and I look forward to hearing more from her on this matter.

I'm also very interested, as are many members of the committee, in looking at pharmacy issues.

Last year, Chairman Baucus and I initiated letters to the Office of the Inspector General and CMS on matters including networks, reimbursements, and contracting practices. These are important issues. When we wrote the Medicare law, we wanted to make sure that beneficiaries could go to their local pharmacy.

We've been hearing that some pharmacies have had a challenging time under Part D, and I'm hopeful that Mr. Schule and Mr. Tucker can shed some more light on those issues.

Mr. Chairman, I've said it before and I'll say it again: the Medicare drug benefit is not perfect. And I am pleased that this committee is at a point this year when it can finally direct energy to taking steps to improve the benefit. Today's hearing, along with next week's hearing, will be crucial to that work.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Now I would like to welcome our panel. First, we will hear from Ms. Kris Gross, the director of the Iowa Senior Health Insurance Information Program. Ms. Gross has testified before our committee previously, and we welcome her back.

Senator, you may want to say a few more words about Kris.

Senator GRASSLEY. Yes, I do. But mostly I want to recognize her and compliment her, not for appearing before this committee, but because she has spent so many days traveling around Iowa, both before and after the implementation of this program, with me on

public meetings to help explain to seniors what was very confusing to them, and help us get this off the ground in the State of Iowa.

I want to thank you and look forward to your testimony to make sure that we are still on the track we should be on.

The CHAIRMAN. Good. Thank you.

The second witness is Vicki Gottlich from the Center for Medicare Advocacy. Third, Tobey Schule from Sykes Pharmacy in Kalispell, MT. Tobey testified at one of our hearings last year. Welcome back, Tobey. I might say to my colleagues that Tobey has been a pharmacist in our State for over 30 years. Carrying on the tradition of pharmacy services in the family is son Travis. This is a generational family enterprise.

He is very well-respected. He was named Montana's Pharmacist of the Year in 2006. If you have been to Sykes Pharmacy, you will know why. I mean, it is a great place just to be. You see Tobey's working there, you see all the people coming in. It is just a great traditional, typical family local enterprise. Tobey, we are just very proud of what you do.

In addition, we have Timothy Tucker, president-elect of the American Pharmacists Association. Thanks very much, Timothy, for coming to join us as well.

I would remind our witnesses, please limit your comments, if you can, to 5 minutes. It kind of helps things get going around here, helps with questions and so forth. But your whole statement will be included in the record.

Ms. Gross?

STATEMENT OF KRIS GROSS, DIRECTOR, SENIOR HEALTH INSURANCE INFORMATION PROGRAM, IOWA INSURANCE DIVISION, DES MOINES, IA

Ms. GROSS. I want to thank you, Chairman Baucus, Ranking Member Grassley, and members of the committee, for the opportunity to share testimony about the Medicare prescription drug benefit.

I am here today representing not only my State, but the other 54 State Health Insurance Programs across the country.

SHIPs are funded, in part, by the Centers for Medicare and Medicaid Services, and we are charged with helping Medicare beneficiaries with questions and problems related to Medicare and health insurance, including the Medicare drug benefit.

Over the past 2 years, SHIPs have educated and assisted hundreds of thousands of Medicare beneficiaries with Part D, and I would like to share the positives we have seen, but also share the ongoing issues which Iowans and others across the Nation have encountered.

For the first time, millions of Medicare beneficiaries have been provided drug coverage, thanks to Part D. The importance of this cannot be overstated. We have a SHIP client who is going to be saving \$14,000 this year, thanks to his enrollment in a Part D plan. He did not have prescription drugs before. Others are saving a few hundred dollars a year.

But wherever beneficiaries fall in the savings spectrum, the benefit has helped assure that they receive the prescriptions they need to stay healthy and better manage on a fixed income.

The extra help offered with drug costs by the low-income subsidy has also been critical. Many beneficiaries who are not eligible to receive drug assistance through State Medicaid programs have qualified for the Part D low-income subsidy, allowing them to get prescriptions at low cost.

The Medicare drug benefit was initiated and implemented in a very short period of time, considering the complexity of the program. The benefits, as I have mentioned, are extremely significant, but there are also opportunities for improvement which I would like to share.

One of the options offered to beneficiaries for paying for their Part D premiums is to have monthly premiums automatically withheld from their Social Security checks. Over the past year, this is one of the areas which has caused the greatest number of client problems.

For some of our clients, the premium was not withheld as requested; for others, a change in their plan choice was not accurately processed and reflected. The premium errors have resulted in beneficiaries being disenrolled from plans, excess premiums being withheld, and premium refunds not reimbursed.

One Iowan was enrolled in a stand-alone drug plan effective January 1, 2006. In February, she found out she was eligible for the low-income subsidy so she should no longer have paid a monthly premium, but the premium for her first plan continued to be withheld from her monthly income.

We have been working with our regional CMS office on this case, but to date she has not received her \$442 refund. This is a significant amount for someone with limited income and resources.

Another area of concern to SHIPs is the marketing practices of some stand-alone drug plans and Medicare Advantage plans with drug coverage. Door-to-door marketing has occurred, even though prohibited by Part D marketing guidance.

Beneficiaries are approached to enroll in Medicare Advantage plans with drug coverage, and sales representatives often do not explain clearly to beneficiaries that they are changing how they will receive their Medicare Part A and B benefits. Beneficiaries believe they are just changing drug plans.

One of our clients enrolled in a Medicare Advantage plan with drug coverage, thinking she was changing to a different stand-alone drug plan. She used the drug benefit in the plan, but did not realize her Medicare benefits had been shifted to a Medicare Advantage plan until a medical claim was denied by Medicare.

In addition, she continued to pay her Medicare supplement premiums for 6 months, even though the policy would not pay anything while she was enrolled in a Medicare Advantage plan. She had no idea she had enrolled in something other than a stand-alone drug plan.

It is important that the Centers for Medicare and Medicaid Services and State insurance departments work closely together to monitor and sanction questionable, or even illegal, marketing practices.

Many of the beneficiaries who are eligible for the low-income subsidy qualify for a continuous Part D special enrollment period which allows them to change plans monthly.

This freedom to choose and enroll in plans throughout the year means that low-income beneficiaries are one of the few groups who can be enrolled in Medicare Advantage drug plans after March 31. Consequently, they become a major audience for the marketing of these plans, even when the plans may be of little value to them, or even be detrimental.

Another concern with the Medicare prescription drug plan is the time it takes for data to be shared between CMS, Social Security, State Medicaid agencies, and the plans. It can take several weeks or more for information to show up correctly in all systems.

This problem occurs across the board, but the implications are most significant for low-income beneficiaries who cannot afford standard cost-sharing amounts. These individuals are the least capable of paying out of pocket for their medically necessary drugs.

We have a client we have been working with since January of this year, and we have made over 40 calls on her behalf in an effort to get her low-income subsidy eligibility to show correctly on her records.

There are bound to be problems in the early years of a program of this magnitude. My concern, and the concern of the SHIP staff and volunteers across the country, is the effect of these problems on beneficiaries. Part D has also changed our work.

Comparing plans takes less than an hour, but problem resolution is taking many more hours over a long period of time, and it has stressed our programs and the work of other advocates.

I want to thank the Senate Finance Committee for holding this hearing and for inviting my testimony. The stories I have shared are representative of many real people with real problems, and I hope the experiences I have shared verbally and in my written testimony will contribute to the success of this important benefit. Thank you.

The CHAIRMAN. Thank you, Ms. Gross.

[The prepared statement of Ms. Gross appears in the appendix.]

The CHAIRMAN. Ms. Gottlich?

STATEMENT OF VICKI GOTTLICH, J.D., LL.M., SENIOR POLICY ATTORNEY, CENTER FOR MEDICARE ADVOCACY, INC., WASHINGTON, DC

Ms. GOTTLICH. Chairman Baucus, Senator Grassley, members of the committee, thank you for the opportunity to testify today on behalf of Medicare beneficiaries concerning implementation of Medicare Part D.

When the Center for Medicare Advocacy issued our 6-month and year-end reports on Medicare Part D, we recommended that Congress hold oversight hearings on implementation of the new program. We thank you for acting on our recommendation.

We also want to thank the many members of the committee for introducing legislation to make the prescription drug program more affordable and accessible for many beneficiaries, including those with the lowest incomes and the greatest need for assistance with prescription drug coverage.

The Center hears repeatedly from the thousands of beneficiaries and their helpers we assist across the country about beneficiaries having insufficient information to make sound decisions about

which plan to choose, about the unreliability of information they do receive, and about the actions of unscrupulous marketing agents so that beneficiaries find themselves in drug and other health plans in which they did not intend to enroll.

Beneficiaries also report difficulty in obtaining exceptions for drugs not on a plan's formulary, for drugs with quantity limits, and for the off-label use of certain drugs. We hear complaints that exceptions processes are complicated and that drug plans do not comply with the regulatory requirements.

Beneficiaries who are dually eligible for Medicare and Medicaid are too often unable to obtain their medications, due in large part to data sharing problems among States, CMS, SSA, and drug plans. Data sharing problems also cause beneficiaries to have premiums withheld inappropriately from their Social Security checks.

The Center has discerned three common themes in the issues we are called upon to redress. When problems occur, they often are not resolvable, since no entity wants to take responsibility for them.

There are some Part D plans that take a variety of actions to sidestep compliance with Part D regulations, and CMS has failed to use its enforcement authority to make sure the Medicare prescription drug plan works for the people who need it.

The problems of dual eligibles and the problems of individuals who experienced improper Part D premium withholding exemplify what happens when no entity takes charge to make the complicated Part D system work.

Beneficiaries go for months without drugs they need, but cannot afford, because of the lag time in transmitting information about their Medicaid, and hence their low-income subsidy, status among States, CMS, and plans.

Beneficiaries who have premiums withheld inappropriately are shunted from their plans to CMS, to SSA, to their plans again, to other agencies without any resolution, and, if withholding stops, it can take months, even years, to get refunds.

Beneficiaries are denied access to medically necessary drugs, often drugs they have been stabilized on for years, because plans imposed abusive prior authorization requirements, lose requests for exceptions and appeals, and blatantly fail to comply with regulatory time frames for making decisions, even in the face of medical emergencies.

When we complain to CMS about systemic problems with Part D, CMS uses one of two tactics to avoid taking enforcement action: they want specifics—the names of the pharmacies that are not providing beneficiaries the generic notice to contact their plan to request a coverage determination; names of beneficiaries with income subsidy problems or who cannot get an exception, or who were bumped up to a higher-priced plan. We have already begun working to resolve the issues for the particular beneficiary. We approach CMS to look at system-wide or plan-wide problems.

The other tactic CMS takes is to tell us to work directly with the plan. Many beneficiary organizations have contacts with their Part D plans and work with them regularly, but working a problem through for a beneficiary is no substitute for enforcement against bad actors.

After I relayed, at a meeting with CMS, concerns from New England advocates about a particular drug plan which was routinely flouting appeals process requirements, CMS had a plan representative call me. The New England advocates who talked with the plan representative report that problems persist, and, in fact, some of the problems in my written testimony come from that plan.

Our written testimony includes recommendations to address the problems we encounter on a daily basis. We look forward to working with the committee on ways to resolve these problems and to make the Medicare prescription drug program work better for beneficiaries. Thank you for the opportunity to share with you the experiences of our clients and of Medicare beneficiaries and their advocates across the country.

The CHAIRMAN. Thank you, Ms. Gottlich, very much.

[The prepared statement of Ms. Gottlich appears in the appendix.]

The CHAIRMAN. Mr. Schule?

**STATEMENT OF TOBEY T. SCHULE, R.Ph.,
SYKES PHARMACY, KALISPELL, MT**

Mr. SCHULE. Chairman Baucus, Senator Grassley, members of the committee, I appreciate the privilege and opportunity to speak to you again about Medicare Part D and how it is affecting my patients and pharmacy.

I am a co-owner of an independent pharmacy in Kalispell, MT. Our pharmacy employs three pharmacists and two technicians. There are five senior apartment buildings within three blocks of our pharmacy. In addition, we provide services to three assisted living facilities and the mental health center in our community.

Medicare Part D has now been in place for about 16 months. During this time we have seen many changes. When I testified before you in February of 2006, pharmacies and patients were facing many obstacles. I have seen many positive changes, though: dual eligibles are more accurately identified; new identification cards have complete information and no co-branding; patients are more readily identifiable in the E-1 system; the patient's medications have been changed to meet their formularies so fewer changes are required; and reimbursement is more timely.

Medicare Part D has been a salvation for many seniors. My pharmacy serves a very limited-income community. These patients' budgets were so tight that even an antibiotic prescription forced them to cut somewhere else. With Part D, these patients can afford their medication.

With all the improvement, issues remain to be addressed. I continue to believe choosing a plan is too confusing. Last year, Montana had over 40 plans, and this year we have over 50. I still believe there needs to be a less complicated way of choosing a plan.

My pharmacy provides medication to our mental health facility. We are still having issues with changing their medications. As I testified last year, these patients should not have to change medications to meet a formulary, because even a minor change can result in a hospitalization.

We have seen several of our mental health patients require a hospitalization, or at the very least have to go into a mental health

safe house, because of a change to meet a formulary. I am very concerned when my patients reach the donut hole because they cannot afford their drugs and are forced to go without their medication. I saw patients hospitalized because of this. I even contacted physicians to see if we could get them on a cheaper drug.

From my perspective, pharmacies are bearing the brunt of Medicare Part D. When Part D was initiated, pharmacists were confronted with an ethical dilemma: do they care for the patient or do they worry about their finances? It was fortunate that the majority chose to care for the patient.

The first payments my pharmacy received took 75 days, with a majority of the insurance companies paying in 90 or more days. I had to pay my wholesaler every 15 days; I was forced to borrow money to meet my obligations.

If it were not for the pharmacists taking care of their patients last year, Medicare Part D would have failed. Pharmacies are required to accept the reimbursements that are dictated by the insurance companies. When I look at our reimbursements, I cannot help but think that the insurance companies make more money on prescriptions than the pharmacy.

Reimbursements are not adequate, and particularly with the shortages of pharmacists and pharmacy technicians, and are causing salaries to increase.

My pharmacy, where 90 percent of the patients are Part D, suffered a very large financial burden because of Medicare Part D. My pharmacy showed a profit of \$81,000 in 2005, with gross sales of about \$2.2 million. The profits for 2006 were \$13,000, with gross sales of \$2.4 million. Our prescription volume actually increased from the previous year, which should have shown an increase in profits.

Community pharmacies are the core of community practice. If this trend continues, there will not be community pharmacy practice. Medication therapy management is also in the full control of the insurance companies, and full review of the patient's medications and discussions with the patients need to be face to face.

Due to fraud against the elderly, we educate our patients not to accept unsolicited phone calls or give information to people they do not know. It is confusing and scary for them to receive the calls from the insurance companies.

Patients do not like to discuss personal issues with people they do not know or trust. In the 16 months that have passed with Medicare Part D in place, many things have improved for the patients, community pharmacies, and pharmacists. For this, I am pleased and hopeful.

More improvements still need to be made. Hopefully we will see improvements in choosing a plan, with patient care remaining first and foremost in the reimbursement policies to pharmacies.

Thank you again for inviting me here today. I will be happy to answer any questions.

The CHAIRMAN. Thank you, Mr. Schule.

[The prepared statement of Mr. Schule appears in the appendix.]

The CHAIRMAN. Mr. Tucker?

STATEMENT OF TIMOTHY L. TUCKER, Pharm.D. PRESIDENT-ELECT, AMERICAN PHARMACISTS ASSOCIATION, WASHINGTON, DC

Mr. TUCKER. Good morning, Chairman Baucus, Senator Grassley, members of the committee. I am Tim Tucker, a pharmacist and owner of City Drug Company, a community pharmacy in Huntington, TN. I am here today representing the profession of pharmacy as president-elect of the American Pharmacists Association.

APhA is the first established and largest professional organization, with over 60,000 members, who provide care in all practice settings. We appreciate the committee's commitment to providing oversight of this important benefit.

My written testimony provides a comprehensive overview of what has happened to date with Medicare Part D. While it focuses on remaining challenges, it is important to note that we believe that Part D has been a success because it is finally providing Medicare beneficiaries access to necessary medications.

This weekend, in preparation for this hearing, we sent a survey to a subset of our members to capture their latest thoughts on Part D. Copies of the survey results were distributed to your offices yesterday. While my oral testimony only touches upon these survey results, I am happy to address any questions you may have related to them. At this time I would like to ask the Chairman that these more recent results be added to the record.

The CHAIRMAN. Without objection.

[The survey results appear in the appendix on page 87.]

Mr. TUCKER. Thank you very much.

Medicare Part D has had a dramatic impact on the business of pharmacy. Pharmacists have not been provided the opportunities to negotiate contracts to meet their individual pharmacies' needs.

Instead, they are often offered take-it-or-leave-it contracts that force them to accept contract terms, or are offered contracts that are tied with other contracts. In these cases, if a pharmacy declines the Part D contract, then the pharmacy also loses its contracts for the other non-Medicare Part D populations.

Pharmacies have also been forced into contracts that do not cover their costs for acquiring and dispensing of medication. And while we have seen some improvements, some pharmacies continue to endure lengthy payment delays as well. The respondents to this weekend's survey indicated that fewer than 10 percent are paid within 21 days, while 33 percent are forced to wait at least a month to be paid.

Furthermore, we appreciate the efforts of the Chairman, Ranking Member, and committee members to facilitate electronic transfers of funds and to address delayed processing metric updates.

We agreed to electronically submitted claims to be paid through electronic payments to pharmacies. Unfortunately, pharmacies continue to encounter issues with this method of payment. Furthermore, our members continue to report that plans are delaying updates to the average wholesale prices, or AWP, which are the metrics used to calculate pharmacy reimbursement.

To address these situations, we recommend establishing a prompt payment standard, requiring electronic payments of electronic claims, and acquiring pricing metric updates the same day

that the plan receives an AWP change. Absent these changes, pharmacies will continue to face the possibility of dispensing Part D drugs at a financial loss.

Although formularies are common and can work when well designed, formulary management issues remain the number-one Part D administrative challenge for pharmacists. Managing each Part D plan's formulary is burdensome because each formulary is different in what it requires and how it works.

While plans could help pharmacists and prescribers by sharing information on what is required to facilitate a formulary request, that information is rarely provided.

In last weekend's survey, 78 percent of the respondents reported that less than half of the messages that they received from plans include the information they need to get the patient their medication. Because pharmacists are often the first step in implementing a formulary request, it is essential that pharmacists receive actual information in a standard format that is not unduly burdensome.

Another challenge with Part D formularies is the lack of physician participation. Frustrated by the uncompensated and burdensome work required to facilitate formulary requests, some prescribers are not fulfilling formulary requests.

We share our colleagues' frustration with the numerous and complex plan requirements which are compounded by the fact that plans do not provide the information pharmacists and physicians need to facilitate a formulary request, but, absent prescriber action, the pharmacists are unable to help their patients obtain their medications.

In addition to increasing prescriber participation and generally improving plan formulary processes, in recognition of the hours pharmacists spend each day working on these issues, we also recommend compensating pharmacists for their formulary compliance efforts.

While these operational issues are important, I would like to draw your attention to a missed opportunity in Part D. Understandably, CMS has focused its implementation efforts on getting medications to patients. However, it is time to look at how to improve the Nation's investment in Part D by ensuring that patients make the best use of their medications.

Described as a cornerstone of Part D, the required Medication and Therapy Management programs, or MTM, have fallen short of the mark. An APhA survey on plans' Part D MTM programs for 2006 found that the majority of plans' MTM programs involved mail information and telephone call centers rather than face-to-face visits between patient and clinician that have proven so successful.

Medicare could learn from the private sector, where a robust MTM continues to grow, such as the APhA Foundation's Patient Self-Management Program. In this model, the pharmacist serves as a coach and provides counseling and education about the patient's disease, medication and therapy, and lifestyle choices. These interventions have led to remarkable results.

After the initial year in the well-known Asheville Project, savings for each diabetic patient were, on average, \$1,600 to \$3,200 each year. Remarkably, diabetic patients who are in this program are

now less costly to the health care system than patients without diabetes.

Testament to this model's success is the fact that more than 40 employers have replicated it for their own employees through the APhA Foundation's most recent initiative, the Diabetes Ten City Challenge.

Most recently, the National Business Coalition on Health announced their partnership with the APhA Foundation to implement a similar patient self-management program. Unfortunately, the incentives in Part D are not aligned to facilitate replicating these private sector successes. APhA is working diligently to make MTM a reality for Medicare patients.

In addition to creating various products to prepare pharmacists and pharmacies, APhA is also working with our colleague national pharmacy organizations to establish policies to advance MTM.

Thank you for your consideration of the views of the Nation's pharmacists. Pharmacists' ultimate goal is improving patient care. While we have seen many improvements in the benefit, APhA looks forward to working with the committee to further improve the program by making it a more effective system that does not unduly burden patients or pharmacists. Improving the operations of the program and changing the focus to improving medication use will move us closer to the benefit that we all envision.

The CHAIRMAN. Thank you, Mr. Tucker, very much.

[The prepared statement of Mr. Tucker appears in the appendix.]

The CHAIRMAN. Ms. Gottlich, I would like you just to name one, two, or three enforcement actions you think that CMS should take.

Ms. GOTTLICH. Well, one of the things that we would like to see CMS do is take action against plans that routinely do not comply with the appeals process. So, for example, there are several plans that are routinely not issuing decisions within the time frame. There are regulatory actions that can be taken, short of actually terminating the contract. There are some plans, quite frankly, that have been such bad actors, that it might be worthwhile for CMS to consider whether or not their contracts should be terminated.

We know that CMS, in fact, has terminated the contract of a private fee-for-service plan, for example. There are other issues that CMS could do. It could be earlier. It could be looking at formularies more closely and looking at marketing materials more closely.

Some of the formularies that we have seen, the plan will say "we have a huge formulary," and then you go and you discover that there are all these utilization management requirements on the plan, so it means that people do not have access to the drugs.

The CHAIRMAN. And you think CMS has the authority currently?

Ms. GOTTLICH. I think CMS does have the authority, yes.

The CHAIRMAN. All right.

Ms. GROSS, what about that? Why is CMS not doing what Ms. Gottlich recommends?

Ms. GROSS. Well, I am not sure I have an answer for that. I am not as familiar, maybe, with all of the marketing guidance as she is. But there are a couple of things that—

The CHAIRMAN. No. But are requests for enforcement brought to you, to your agency, to CMS?

Ms. GROSS. Do we?

The CHAIRMAN. Do you hear requests?

Ms. GROSS. That we send to CMS?

The CHAIRMAN. Yes. Right.

Ms. GROSS. Some of them, we have. Some of them we have reported and shared with our regional office to send on, and some of those we have heard from. One of the things that happens, in one case that we sent in, is that the beneficiaries really do not want to get anyone in trouble, so we send it on to CMS and they investigate, but then the beneficiaries—

The CHAIRMAN. But why does CMS not do more, in your judgment? Why does CMS not do some of the things that Ms. Gottlich is recommending?

Ms. GROSS. I am not sure.

The CHAIRMAN. What is your best guess?

Ms. GROSS. I do not know, to be honest.

The CHAIRMAN. I am just curious. As an advocate, you have probably thought about some of this a little bit. I am just curious what you are thinking.

Ms. GROSS. Well, I am in an insurance department. My program is based in a State insurance department.

The CHAIRMAN. Yes. Right.

Ms. GROSS. And so some of the things that go on in my State, I take directly to the insurance department because it is agent action. That is one part of the program, that State insurance departments do have some authority to deal with. So, we often deal with it through our State insurance department, and I do not always send it directly to CMS.

The CHAIRMAN. All right.

Tobey, what is the answer to the clear problems that pharmacists face? That is, paid too little, too slowly? I mean, it is wrong. I agree with your main point that, here on the front line, you are providing service.

And I also agree with your main point—one of your points—that pharmacists are facing a dilemma between helping people, beneficiaries, and helping the bottom line, and choose to basically help people and eat it. So, you have thought about this a little. What can we do? What can CMS do? What needs to be done?

Mr. SCHULE. Well, I think that CMS really needs to take a look at these insurance companies. I think we need some transparency in these insurance companies so we can see what they are actually doing, where they are making their money, and why we are not. We do not always know if our information is accurate.

We hear that the insurance companies get the money from CMS, and then they are sitting on it and we are not getting our cut. So as far as the financial, it is very difficult.

The CHAIRMAN. It sounds like a float. They just want to keep the money—

Mr. SCHULE. Yes. I think they are probably making interest on the money that actually belongs to us.

The CHAIRMAN. Yes, I am sure.

Mr. SCHULE. And I think the other thing that comes across is that the pay rate, the dispensing fees to our pharmacies are lower. We will have a company that we supply or we process claims for for a patient that, say, is a working class person—their work insur-

ance is under a plan—and that same company offers a Part D plan. Their reimbursement or dispensing fees are different between the two, which I do not understand.

Why, for that company, if I dispense for someone that is at work I get a \$6 dispensing fee, for example, but when it is CMS I get \$1.25? I do not understand. My process to fill the prescription is the same whether I do it for someone working or someone who is on Part D.

The CHAIRMAN. Right. All right. Thank you.

Senator GRASSLEY?

Senator GRASSLEY. Thank you very much.

I am going to start with Ms. Gross, to talk about this problem of Social Security checks and the withholding not working the way it should, to get a sense of the magnitude of the problem. Could you tell me the percentage of all SHIP case work issues that are related to Social Security withholding?

Ms. GROSS. Well, from an Iowa perspective—

Senator GRASSLEY. Yes.

Ms. GROSS [continuing]. The case work that comes in to our State office, not counting what our volunteers deal with directly, about 40 percent of our open cases right now are related to premium withholding issues.

Senator GRASSLEY. All right.

How many of the cases have been resolved, and how long does it usually take to get them resolved?

Ms. GROSS. The time varies. We have some that we have had open since last May that are not resolved yet, so there is no average that I can say. As far as how many or what percent have been resolved—

Senator GRASSLEY. It is difficult to say.

Ms. GROSS. I have not gone back through all the cases we have had since last January to figure that out. But like I said, we have about 70 cases open right now that are premium withholding issues.

Senator GRASSLEY. Well, if it is not too much work, you might submit that as an answer in writing, or telephone it in to my staff or something.

Ms. GROSS. Sure.

Senator GRASSLEY. Have you noticed any decrease in the number of cases, or is there still a steady stream of them?

Ms. GROSS. It is still pretty steady. Now we are starting to get cases coming in from people who changed plans in 2007 and an incorrect premium is still being withheld for their 2006 plan. So, we are getting those new types of premium withholding cases.

Senator GRASSLEY. Yes.

How many on your staff do you have working on this?

Ms. GROSS. I have hired, in the last year, two part-time staff to work on case work like this, and other types of problems.

Senator GRASSLEY. All right.

On another issue, you mentioned that some plans have undertaken questionable marketing practices, and as a result some beneficiaries have been enrolled in Medicare Advantage rather than in a stand-alone prescription drug plan.

Has the Iowa beneficiary counseling program, your agency, SHIP, reported any potential violations to CMS? If so, do you receive information on how CMS would resolve them?

Ms. GROSS. We have reported some of them to our regional office and they have worked on those cases, as I mentioned to Senator Baucus. At times, beneficiaries, when they are approached by CMS, want to drop it because they do not want to get anyone in trouble. That is one of the issues that we deal with. But some of them we have heard back on; some we have not.

Senator GRASSLEY. Ms. Gottlich, as a follow-up, you also expressed concern about marketing abuses. Has the Center made any reports to CMS? If so, did it receive any information about CMS's work to address the complaints?

Ms. GOTTLICH. We do make reports continuously. We know that some of the individuals whom we have assisted have been disenrolled from the inappropriate plans and put back into the plan that they wanted to be in, but we have not seen any action taken against the plans that are continuously doing this.

Senator GRASSLEY. All right.

Mr. Tucker, your association's testimony recommends that CMS conduct greater oversight of the plan's contracting process. Could you be more specific about what steps you think the agency should take?

Mr. TUCKER. I think there is a misunderstanding with contracting. Most of our pharmacies in America do not have any kind of negotiation with a contract. We are sent a contract and it is not negotiable. It is, here it is, take it or leave it.

We would like for CMS to give more guidance to the plans of what is expected in the contract. I think there is some standardization that CMS can require of the plans, because each plan has its own way of doing everything at the present time.

Senator GRASSLEY. All right.

Mr. Schule, I have a question about the enrollment process for beneficiaries whom we call dual eligibles. I am one of those who thought we ought to keep dual eligibles, the Medicaid people, separate, but we lost that in conference, so here we are, trying to work out problems that we have with people who are eligible for Medicaid as well.

Today, CMS selects a plan for dual eligibles who did not choose one for themselves, auto assignment, we call it. What has been your customers' experience with that process? Have you found that beneficiaries usually get assigned to a plan that covers the drugs that they need?

Mr. SCHULE. That has been a real tough situation with, especially, our mental health patients. They are being enrolled in plans that are not covering them as they need. They were certainly much better.

I would have liked to have seen at least the mental health patients kept in the Medicaid system or have a requirement that the Part D company that is going to be their carrier at least stay with the formularies that these patients have been stabilized on. Some of these patients had been in the State hospital. We had set their medications off of Medicaid.

So when they came out and they were just automatically enrolled in a plan, we as pharmacists—maybe it was not our job but the type of pharmacy that we run—contacted several people, got those patients switched so that they could get medications.

I think that either we maybe pick a couple of the plans and say this is the formulary that we need for these patients, or make a standard where they all have to accept that sort of thing because they have been probably the most difficult to deal with with their medications.

Senator GRASSLEY. All right. Thank you. I am done.

If we can find the letters that I sent to CMS several months ago, I want to put them in the record.

The CHAIRMAN. We will find them, and we will put them in.

[The letters appear in the appendix on page 49.]

Senator GRASSLEY. All right. Addressing the pharmacists, we have asked CMS to consider mandatory electronic funds transfer. I guess we do have the letter here. Requiring electronic funds transfer so it would mitigate the situation that we have of some contracts saying 30 days. Most people want to be paid in 14 days.

The bottom line of it is, even at 30 days, there are some checks that are being cut that are not being mailed, so that local pharmacists are being a banker for the people in between.

The CHAIRMAN. Thank you, Senator.

Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman, very much. Thank you to each of you for your comments.

Just to follow up on what Senator Grassley was talking about, in Michigan we have heard a lot of concerns about nursing home residents who are dual eligible and the auto enrollment, and the complexity of being nursing home residents, first of all, and being able to choose a plan, as well as the auto enrollment.

Back when we debated the Medicare prescription drug benefit, I believed—and still believe—that the one choice that we did not put in, in the way of choices, was to simply go to Part D and sign up for prescription drug coverage, and that as a part of the choices is something that we should have done so that those individuals who were not able or were not interested in going through a number of private choices could just sign up for prescription drug coverage. I think it would have provided a different kind of competition that is needed.

But I wanted to ask a question of our two pharmacists. And thank you. I think what you do is so important. I am a huge supporter of maintaining community pharmacies, because, Mr. Schule, as you said, you went that extra step to help people be able to get into the plan that worked for them. That is an important part of what pharmacists do.

I am very concerned that you are not getting the right—if any—dispensing fees and so on, that your costs are not being reimbursed. I am particularly concerned when I look at the fact that we have a study that has been done now from Families USA looking at the prices reported to CMS by insurers, and actually, unfortunately, prices for the top 15 prescription drugs being used, anyway, the prices have not gone down. On average, they have gone up 9.2 percent.

So the prices are going up. I know that with those who contacted me who are now in the gap or what has been called the donut hole, they are actually seeing higher prices than before Medicare Part D came into being. So, prices are going up, but you are just not getting reimbursed, certainly, and I would argue people are paying higher prices.

My question for you, though, relates to the formularies and the problem that has happened when someone signs up for a plan, has a formulary, they choose the one that meets their needs and their medicines, but then the formulary gets changed in the middle of the year and, as you spoke about, suddenly they are not covered any more.

CMS issued guidance to the plans that they should grandfather those drugs that people signed up for during the plan's life, at least through the end of the year. Is that working? Do you see where that is working?

Mr. SCHULE. We really did not see that. We saw them maybe accepted for about 3 months. We had some that did not even make it 3 months.

Senator STABENOW. Really?

Mr. SCHULE. We had some where they gave us the initial fill, and then said, this is our formulary drug, you need to get the patient changed, which, at the very beginning of this program, to put it bluntly, it was just a nightmare. We had patients who—well, for example, for me, I saw patients who signed up for a plan.

I knew right away that they were going to be in the donut hole just based on the medications they were on and the way it was set. Then with the different tier levels, the people were signed up into wrong plans and it was difficult to try to get them shifted.

We worked with our local senior's council to help get some of these patients changed. We did get some; some we were not able to do. But the problem comes up, and we are still seeing it. They will sign people up and they will say, this is the formulary, so the patients are looking at the medications and they go, all right, it is on here, I am covered, I am all right.

Or another issue that happens a lot is, some of their drugs are on a formulary and some are not, so then they have to decide, well, can you afford these and not these? Which formulary do you pick? Then there are some where we can contact their physician and get things changed to meet a formulary.

Then we do that and then, about 3 months later, they change the formulary on these patients, and then they are right back to where they were. When you are dealing with elderly patients, these medication changes are not the thing to be doing. If you have someone stable, you should be able to leave them there, especially with the dual-eligible patients.

In Montana, we had formularies fairly well set with the Medicaid system. We got people stabilized on their medications with that. I just do not understand why, with the dual eligibles, that they did not have to just go with the formulary that they had already been established with. It was a very costly program, to me, the changes.

It would have been interesting to actually have a way to figure the costs, because the physicians were billing for bringing patients in to look at a medication change, we had some of the patients that

ended up going to the hospital, we had just different situations like that. But there was no way to figure cost. So, gosh, it might have been cheaper to pay for the more expensive medication, and we would have saved money in the long run.

Senator STABENOW. Thank you.

Mr. Chairman, I know my time is up. This is one area that I hope we would look at in terms of the formulary.

The CHAIRMAN. Senator, if you want to ask more questions, go ahead, if you wish.

Senator STABENOW. Oh. Thank you.

On the point there with the formulary, it just seems to me, in fairness, if somebody goes through—in Michigan, it can be 40 or 50 different plans—picks one that works for them, and then the plan is changed in the middle of the year but the beneficiary cannot change the plan for a year, it does not seem fair. I would hope that we could work on that together.

I do have one other question. This is for Vicki Gottlich. According to the Social Security Administration, 57 percent of the individuals found ineligible for the low-income program actually met the income requirements for enrollment, but were denied because of their financial assets.

I am wondering, what would happen if Congress eliminated the assets test? Would this actually improve the benefit? I think a good parallel is Medicaid. For example, a report by the Commonwealth Fund found that several States that removed the Medicaid assets test actually saved money through lower administrative costs and the ability to use electronic forms.

Ms. GOTTLICH. Yes. The Center for Medicare Advocacy thinks that one of the best things that could happen would be the elimination of the asset test. It would help beneficiaries because it would make more people eligible.

If you look at the statistics, the people who have too many assets, they are not very, very wealthy people. It is a very small percentage over the asset limit. The low-income subsidy is probably the best part of this program. We know that a lot of people who have not enrolled in Part D are people who are eligible for the low-income subsidy.

We also note that there are a lot of people who do not apply because they are scared of the asset test, and quite frankly they do not want to tell you what the value of their farm is, or how much their bank account has, or they cannot decide or do not know what the life insurance value is.

We also know that it is a savings in administrative costs for the State programs where they have eliminated the asset test, so it would be a really good way to protect beneficiaries.

Senator STABENOW. Thank you.

The CHAIRMAN. Thank you, Senator.

I would like us all to kind of step back a little bit and give some guidance as to the general theory of Medicare Part D and the degree to which, if any, we should start changing it.

Namely, this is a market-based plan, the theory being that the plans will market their various alternatives to seniors and the seniors have choice, and the seniors can then choose which of the var-

ious plans, with their co-pays and formularies, et cetera, make the best sense for them.

Now, clearly there have to be some consumer protections along with all that, but is that a model that we should maintain or not? That is, maintain the theory behind it, but maybe shore up consumer protections using that model?

Or on the other hand, should we start making some changes, perhaps along the lines that Senator Stabenow was suggesting, where it just goes straight and Medicare manages it directly with beneficiaries, as, say under Part A and Part B? Your thoughts about all that? It is a very fundamental question, and it would clearly be very difficult to make significant changes.

But irrespective of the difficulty, I would just like your advice as to the propriety of sticking with the basic outline and making it work better, or changing. Whoever wants to take that, take a shot at that.

Mr. SCHULE. I will jump on it.

The CHAIRMAN. Yes.

Mr. SCHULE. I would like to see the plans cut way back. It is just a nightmare for our patients. You start trying to match up formularies, and we are comparing apples and oranges all the time. The biggest issue, too, is we do not have any standards set by CMS or anybody as far as formulary. What happens is, it just appears—I guess I have to be very careful on this.

The CHAIRMAN. No, no. Be straight. Just tell us what you think. That is why you are here.

Mr. SCHULE. Whichever drug company is giving that particular insurance company the best cut, that is the drug they put on the formulary. That is the only thing I can see, because there are times when I look at some of the formularies and there are better, cleaner drugs to be using than what they are using. We will see them change within the class, and it strictly has to be a rebate coming back to the insurance company. There is no other reason that they would change.

The CHAIRMAN. All right. When you say there are too many plans, some of us are suggesting a very significant curtailment in the number of plans, somewhat along the lines this Congress took in Medigap.

That is, years ago there were so many different Medigap plans that caused so much confusion for seniors, that the Congress said, all right, we are going to set—I think there are 10 now—10 standard Medigap plans, and I have not heard a big hue and cry from the insurance industry over that one.

Should we do something similar here, say, all right, you can have 10 only? I suppose there will be lots of different variations with the formularies and co-pays and so forth. But you say there are too many plans. What is the best way to address too many plans?

Mr. SCHULE. Well, what I would like to see, I guess, is, if we have all these players, that CMS come up with a standard, and, if each company is going to offer four or five plans within their company, patients should be able to sit down, take a look at what is being offered, and they should match up with a similar base.

The CHAIRMAN. But does that mean seniors would pick from four or five different choices, or each company could have four or five,

so seniors are back where they are today? You say in Montana, there are 50 different plans.

Mr. SCHULE. Right. I guess what I would like to see is for CMS to set the standard as far as, if you are going to offer this program, you can offer up to four or five plans and they can charge different amounts, or whatever.

But each of the plans, you should be able to look at company A and company B and be able to say, yes, I am going to get this coverage. But the way it is, there are so many variables in there that there is just no way to sit down and look at them and make a change.

What is the most difficult thing for a lot of our seniors is, they will see three or four drugs on one plan, but they are on seven medications and the other four are not covered. They go, what do I do now? How do I pick off of this?

Then you start looking through them and you do not find all of them on any one plan, so then you take whichever ones are going to take the most expensive drugs off the shelf for them and cover those, and hopefully they can pick up the generic out of their own pocket.

The CHAIRMAN. Who also might have some thoughts on the solution of too many plans? Or maybe, does somebody disagree that there are too many plans?

Ms. GOTTLICH. Of course, the Center for Medicare Advocacy is on record as saying we would have liked the benefit in Medicare itself. Aside from offering a benefit as part of the Medicare program, there are options that could be done.

You could both limit the number of plans that each insurance company offers, so in the new call letter companies can offer two plans, or they can offer four if they have different models for filling in the gap. If you have 10 companies offering plans in Montana, offering four plans, that is 40 plans. That is very hard.

The CHAIRMAN. So what would you do about that?

Ms. GOTTLICH. I would cut back on the number of plans that each sponsoring organization could offer. I would also look very closely at the companies that want to be in the Part D program. CMS now has evidence of quality. It has evidence of complaints. They could really take a closer look and say to some of the companies, we do not think you have been doing as good a job as we would like, so we are not going to let you contract with us any more.

We also have been on record as supporting the idea of the Medigap concept, of allowing NAIC to develop some standard plan so you would know Plan A is the standard plan, Plan B does not have a deductible, Plan C has gap coverage, so then, as Mr. Schule said, you can look at two Plan Cs and compare to see which one is going to be more effective for you.

The CHAIRMAN. But would you want a situation where seniors still had to choose among 40 different choices?

Ms. GOTTLICH. No, we definitely do not.

The CHAIRMAN. So what is a reasonable number of choices seniors should have to make?

Ms. GOTTLICH. That is a hard one.

The CHAIRMAN. That is why I asked it. [Laughter.] What do you think? Just ballpark.

Ms. GOTTLICH. Well, there are some studies that talk about the number of choices. I think maybe 5 of 10 is probably what works.

The CHAIRMAN. Now, say we are there.

Ms. GOTTLICH. Yes.

The CHAIRMAN. Then how do you address Mr. Schule's point about, some plans' formularies include some drugs, but not other drugs, and it really puts seniors in a tough spot?

Ms. GOTTLICH. It does. I am really sort of interested in Mr. Schule's conversation because there is no discussion of using the exceptions process to get a drug covered if it is not on the formulary. So if, in November, you are seeing, I am taking seven drugs, four are on this formulary, you should have the opportunity to ask for an exception for the other three, and we are not seeing people doing that.

The CHAIRMAN. Mr. Schule, could you shed some light on the exception process, how well that works or does not work?

Mr. SCHULE. We have not had a very successful go with that. We have tried to get coverage for patients and have not been very successful. What has been happening lately is, at the beginning of this, in 2006, when we had prior authorization or where we were trying to get someone's medications covered, we were able to call in, go through the steps, and so forth.

Now what we are seeing with the insurance companies is, we try to call in on the prior authorization and they say, no, it has to be the physician's office calling. So it has taken a 180-degree turn here. So what we were kind of used to at the beginning of this plan, we are now seeing that it does not work that way now. I am not really sure why this is happening.

Generally, if we call the physician, the physician will ask us, what will they cover then? Let us start it from that point. What drug would you like me to see this patient on if we have to make this choice?

The CHAIRMAN. Right.

Mr. SCHULE. Because we are very fortunate to work closely with our physicians. But we do not have their formularies—we ask them and we just do not get, here is what we will pay and here is what we will not. It would be a simple thing, I would think, that if we put a drug in that they say they are not going to cover, that we should get a rejection and say, this is not formulary, but we will formulary this drug or this drug. It would give us a starting point.

The other thing is, if there was a perfect drug where one fits all, we would not have all these choices to go with anyway. What happens is, Mrs. Jones may not handle this drug very well, but that is the drug the insurance company says she has to have or she is just out of luck.

So we have tried two or three other drugs, and they were not effective. She either had side effects or it did not do what it was supposed to do, but yet we are still being forced to try to put Mrs. Jones back.

The thing that is probably the most frustrating is, some of the patients, previous to Part D, we have already gone that route. We have already tried drugs A and B, and now we are on drug C, and

the insurance company is saying, well, we really do not care what happened prior, we want to see a failure on A and B before we go to C.

The CHAIRMAN. Frankly, I find this quite disturbing, that essentially the plans, insurance companies, are preventing seniors from having the drug that best suits that person, at least with respect to whether it is on the formulary or compensated or not. How often does that occur?

Mr. SCHULE. More frequently than I would like to have to say. I think we probably deal with that at least weekly or every 2 weeks, we have a patient who falls into that.

The CHAIRMAN. Now, these drugs, are they necessarily very expensive or not necessarily very expensive?

Mr. SCHULE. Some of them are and some of them really are not that expensive. I guess what is frustrating to me, I mean, I realize drug costs are extremely high. I wish, as a pharmacist, I could say, gosh, it is our fault, but it is not. I mean, in over 30 years of practicing, I just cannot believe how little we are paid today compared to over the years.

So I know that the drug costs are coming from some other angle. But the problem is, we are not looking at true costs of this. The drug cost might be, say, \$100 a month, so you put that into a year. But if we have to start paying doctors, hospitals, lab tests, and all these things to make a change on a drug, those costs are never added in, so maybe we would be cheaper using that than the \$40 drug that they want us to go with.

I guess the most frustrating thing for me with this whole program is, patient care is not even in the picture. I mean, it just seems non-existent once that patient is out of our hands.

The CHAIRMAN. So how do you address patient care? Some have ideas about providing better patient care. What are your thoughts on how to begin to work with seniors and the drugs they use and do not use, et cetera? I assume you do a lot of that anyway.

Mr. SCHULE. Well, yes, we do. Patient care is something that we have done for years, not just me or my pharmacy, it is done across the country. Pharmacists are always the first health care provider people see. It seems like if someone is having a problem, they come in, they talk to us. They say, what do you think? That is when you kind of go, well, boy, you probably ought to go see the doctor again, or I will give the doctor a call.

There are a lot of things. And sometimes little Mrs. Jones just needs her hand held, too, because she is not taking her medication. But this whole program, I think partly because it is so big, is no longer patient care involvement. The insurance companies, to me, really do not care about patient care.

Never once do I see anything, literature from them, that talks about patient care. I get "Patient Lives" and "Insured," and that sort of thing, but they forget about the grandmas and grandpas. It is just a very frustrating thing for me.

When we are dealing with the elderly, it is a whole different ball game than if I am dealing with 65-year-old new retiree. It is a whole different game when you start getting into the older people. They cannot make the choices. Some of these patients do not have their children there to help them pick this stuff.

The insurance companies, when we try to call them and say, gosh, we have already been this route, we know this from 2 years ago, Mrs. Jones cannot take this, they really do not care. We do not have it on our records that it has ever been tried, so you need to try that before we will accept it.

The CHAIRMAN. Is there any difference among insurance companies, or is the attitude pretty much the same with them all?

Mr. SCHULE. I think it is the same. I think, for Montana, maybe it is a little different. We have a lot of players over there now that we never had, and they live in Montana. We do have some of our companies that have been in Montana and they seem to be doing a better job than the companies that have come into the plan and they are here now.

This whole program, to me, has missed the boat on our patients and patient care. Somehow, when you have these programs that say we need mail order, we need to do this or do that, it needs to go. And not just trying to fulfill my independent pharmacy, but it is not right. Pharmacy is a face-to-face thing.

The CHAIRMAN. Right.

Mr. SCHULE. I mean, it has to be.

The CHAIRMAN. Does anybody have any thoughts on this subject? Anybody want to chime in?

Mr. TUCKER. I do.

The CHAIRMAN. Mr. Tucker?

Mr. TUCKER. I think the number-one point is, we must relieve some of the administrative burden to the pharmacists so that patient care can be better. I think all of the pharmacists in America want to take care of their patients.

Medicare Part D has been a great plan, and some of my patients who were not able to take their medications before now can actually afford to get their medicine. But because of the number of plans that each of us works with on a daily basis, we have to simplify or standardize the administrative process because the burden now is so great.

Another way is, we must require better medication therapy management. As Mr. Schule said, pharmacists have relationships with the patients. We need to take care of those patients, and that is not over the telephone.

The CHAIRMAN. May I ask all of you, is there any possible justification for the provision now, the custom or practice now, where a senior chooses his or her plan and has to stick with it, but yet a plan can change the formulary midstream?

Is there any possible, conceivable justification for that kind of arrangement where seniors cannot change, but insurance companies can? I am just asking. I am just trying to be objective about this to see if there is a good reason, a good public policy reason, behind that.

Mr. SCHULE. We would not do it in our daily lives. If one of my suppliers all of a sudden said, I am not going to do whatever, I am going to change, I may look at the other suppliers. And I can make that change at that point. I think they need that same option.

I just cannot understand how they were able to set up such a program for themselves, the insurance companies, and the patient is left out on the step. If they make a change at that same time

when their formulary changed, I think that the patient should be allowed to make a switch at the same point.

The CHAIRMAN. Does anybody else agree or disagree with that?

Ms. GROSS. Well, I think you have been talking about the plans changing their formularies, but the other thing that happens is, beneficiaries start taking different drugs. Mid-year, they might develop an illness or something that requires a different drug that is not on the formulary either.

There is the exceptions process there for people, but that is a very burdensome process, especially for someone who is not feeling well or has other issues going on, as many Medicare beneficiaries do. So the protection may be there, but it is a burdensome process for them to go through that.

The CHAIRMAN. What about premium withholding? That is pretty burdensome. It is kind of complex, kind of confusing, a lot of hoops and hurdles and so forth. Your thoughts on how to make that work a lot better. Who wants to take a crack at that one? The goal here is to make this work better.

Ms. GROSS. I think that it is working well for people—some people. We hear from the people where it is not working. I will just take my parents, for example. They have Social Security withholding, and it is working perfectly. But for those where it is not working, there has to be something in the system.

I am not sure where in the system it is breaking down. I do not think it is that that system is not a good option, it is just, somewhere, for some people, it is breaking down, and that is where the analysis needs to be done of where that is happening. I do not have the answer.

I ask people at our regional office, why isn't this getting fixed, and they cannot necessarily tell me why it is not getting fixed quicker either. So, somewhere in the process of the withholding and the data sharing, something is not going right for some people.

The CHAIRMAN. Yes, Ms. Gottlich?

Ms. GOTTLICH. One of the things that we would like to see is there be one place where people can go, so if they have premium withholding issues they can note that, if they call SSA, SSA will say, "call this number," if they call CMS, CMS says "call this same number."

The CHAIRMAN. Right. Right.

Ms. GOTTLICH. So there is one entity and they are not shunted all over the place. That would be really helpful for people. It takes a lot of work to make all the phone calls, the 40 phone calls that people have to do sometimes.

The CHAIRMAN. I think that is right. No doubt about that.

I wonder if maybe you, Mr. Schule, Mr. Tucker, could again address the insufficient payment and the low payment. What do we do about that? I mean, is that something Congress should legislate in, or not? Could CMS do something about that if a fire were lit under CMS?

Mr. SCHULE. On that, I am almost at a point where I think we need to address it almost like we do the Medicare or Medicaid systems. We have worked under that where Medicaid pays a set dispensing fee and that is established.

I think maybe then we need to look at CMS to say you need to pay this amount on the dispensing fee, irregardless. I mean, that is how it is set up with our Medicaid systems.

If they did that, then that would also—I mean, if the insurance companies then can make more money by getting a better deal on a drug or whatever, then they can make their cut on that deal, but at least we are getting the same fee. We run into that with our Medicaid, but we get our set fee on those patients. I think if it were standardized like that, if you are going to offer a Part D plan, you are going to pay X amount for a dispensing fee.

The CHAIRMAN. What about the 5 million seniors who are not enrolled? What is going on there? Why are they not enrolled? Is there a legitimate reason or not, or just insufficient outreach? Do the seniors know about the plan, or know and reject? Why are 5 million not enrolled?

Ms. GROSS. People we have counseled over the years, when they come in and talk to us about it, they do not feel it is worth—I am not saying all 5 million. But those who are turning down signing up for a plan are saying, I am not taking that many drugs, it is not worth it to me, or I am not taking any drugs, why should I sign up for it, and that seems to be the main reason.

I am sure there are people whom we have not reached, especially with the low-income subsidy, who might be eligible. But that is the main reason that we hear, they do not feel they are going to gain anything from it.

The CHAIRMAN. And on the low-income subsidy, it just seems to me there are an awful lot of hurdles and hoops to go through that make it difficult for that to be available. Do you agree, Ms. Gottlich, or not?

Ms. GOTTLICH. I do agree with it. It is kind of funny, because the low-income subsidy has improvements over some of the other assistance programs. Though we complain about the application, it is a little easier. You do not have to bring in all your reams and bags of paper. You can attest to your income and your assets.

I think that there are a whole bunch of populations that are really very hard to reach, so it would be really useful if SSA and CMS could provide specific data by zip code to the SHIPs and to the partners of the Access to Benefits Coalition and the other organizations that are going out there doing outreach.

We know, from all public benefit programs, that other than Medicare, the take-up rates are not as high as we would like them to be, and there are populations that we are always not going to reach. But I think that there are additional ways we could reach them.

The CHAIRMAN. Should we have an asset test or not?

Ms. GOTTLICH. We should not.

The CHAIRMAN. Would the program not be abused if there were none?

Ms. GOTTLICH. I do not think that there would be abuse. I think that there is pretty ample evidence from a number of States that have eliminated the asset test for some of their programs, like the Medicare savings program, that there is not abuse when there is no asset test.

If you look at the incomes that you need to have to be eligible for these programs, these people are not going to have a lot in resources.

The CHAIRMAN. Anyone else's thoughts on that point, whether there should or should not be an asset test? Tobey?

Mr. SCHULE. Well, I do not believe, really, that an asset test should be necessary on those patients, the same thing she is saying. When I look at our patients, Sykes is kind of an entity of its own, as you know.

The CHAIRMAN. Yes, it is. It is, very much so.

Mr. SCHULE. Those people, if they are going to qualify for that as far as income, you know they haven't got anything else they are hiding anyway. It seems like another place.

The CHAIRMAN. Well, that is Skyes. But what about other parts of the country?

Mr. SCHULE. I think it is probably the same wherever you go. And I know the patients that I have that have not signed up for Part D are pretty simple, straight up. One, they are not taking enough medications, so they do not think it is worth doing. They are on generic medications, so their costs are less than what the monthly premium would be. The others, I have had some say, you know, this thing is still so darned confusing, I am not doing it.

The CHAIRMAN. That is one of the questions I was going to ask. I mean, to what degree is lack of 100-percent enrollment due to complexity of the benefit, so some seniors just think, this is too complicated for me, I am not going to do anything, just forget it? Does that sometimes happen or not?

Ms. GROSS. Yes, it does happen. The people who get to us are people who turn to us for help because they cannot do it themselves.

The CHAIRMAN. Right.

Ms. GROSS. And the Medicare website is a wonderful tool. In fact, my volunteers say you cannot really rightfully help a person enroll in a plan without doing a comparison on the website, but many beneficiaries do not have access to that themselves.

So if they do not turn to someone as an advocate or a family member who can help them do that comparison, they either just sign up for something, which may not be the best for them, or they just do not deal with it because it is too complicated.

The CHAIRMAN. Right.

Well, this has been very helpful. You have been very, very helpful, all four of you.

Before we adjourn, does anybody have anything to say? Has somebody said something that should be addressed, or something else that was not covered that should be addressed?

Ms. GROSS. I would like to go back to your question about the marketing and what CMS can do.

The CHAIRMAN. Yes. Sure.

Ms. GROSS. One of the things I have seen, and why SHIPs are very effective, is because we are in every State. We are there, we are local, like the local pharmacies and so on.

The CHAIRMAN. And I find that to be very effective, too, in Montana. It helped a lot in getting people signed up.

Ms. GROSS. And I think one of the challenges for CMS is that they are not local. They are not in every State. So I put it in my written comments, and I think I mentioned it today, but I think it is really important that CMS and the State insurance departments work together, because insurance departments are in every State. They are there locally to help deal with some of these issues, so I think, to the extent that that relationship can be enhanced, it would help with some of the marketing issues.

The CHAIRMAN. That is true. But some insurance commissioners said they would not allow some of these practices in their own States.

Ms. GROSS. But right now, because of the CMS regulations, there are limitations to what insurance departments can do related to Part D and Medicare Advantage plans.

The CHAIRMAN. I am sorry. I missed that last point.

Ms. GROSS. Because of the regulations right now, there are limits to what insurance departments can do related to Medicare Part D and Medicare Advantage plans.

The CHAIRMAN. Right. Right. But I understand, but for that limitation, some insurance departments would not put up with some of these practices. Is that true or not true, do you know?

Ms. GROSS. We certainly would investigate it in our State.

The CHAIRMAN. All right.

Ms. GOTTLICH. Actually, I was in Maine 2 weeks ago, and somebody from the Maine insurance department said that they passed through their legislature some State laws so they can go after some of the marketing practices as violations of State law, because they were looking at ways that they could act and to get around some of the Medicare prohibitions. So, I think that they would take action if they could.

The CHAIRMAN. All right. Thank you all very much. I just want to say, we take our oversight responsibilities in this committee very seriously. This has been very helpful. There will be other oversight hearings.

In fact, I think we have one scheduled next week, if I am not mistaken. I supported this program. I voted for it and worked to help make it work several years ago. It has worked pretty well, I think, for an awful lot of seniors, but clearly there are a lot of problems.

I think you all have done a pretty good job of identifying what basically most of those problems are, and now it is up to us, working together either legislatively or working with CMS or whatnot, to try to begin to get some solutions here. This is ongoing.

I strongly urge you to keep working with us, calling us, working with the committee, with new ideas so that we can hopefully do the best job possible. But thank you very, very much for taking the time. I appreciate it.

The hearing is adjourned.

[Whereupon, at 11:34 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

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United States Senate Committee on Finance

**Medicare Prescription Drug Benefit Program:
Monitoring Early Experiences**

May 2, 2007

**Testimony of Vicki Gottlich, Esq.
Center for Medicare Advocacy, Inc.**

Chairman Baucus, Senator Grassley, members of the Committee, thank you for the opportunity to testify today on behalf of Medicare beneficiaries concerning implementation of Medicare Part D. I am Vicki Gottlich, a Senior Policy Attorney with the Center for Medicare Advocacy, a national, non-profit, non-partisan organization that works to ensure fair access to Medicare and quality health care.

Overall, the Center has assisted thousands of Medicare beneficiaries and their helpers across the country to understand and utilize the Part D system, plan options, and rules. In our conversations with Medicare beneficiaries, their advocates, and policy-makers, we hear repeatedly about beneficiaries having insufficient information to make sound decisions about which plan to choose, to understand what should be covered, and to know how they will fare during Part D's various coverage gaps. In addition to having insufficient information, some beneficiaries are given incorrect information by plan marketing agents, and find themselves in drug or other health plan in which they did not intend to enroll.

Beneficiaries also report difficulty obtaining exceptions for drugs not on a plan's formulary, for drugs with quantity limits, and for the off-label use of certain drugs. Similarly, we hear many complaints that the exceptions process is both complicated and vague. Beneficiaries who are dually eligible for Medicare and Medicaid are too often unable to obtain their medications due in large part to data-sharing problems among states, the Centers for Medicare & Medicaid Services (CMS), the Social Security Administration (SSA) and Part D plans.

CMS, the agency that administers Medicare, continues to tout Part D as a resounding success, while characterizing what are persistent and systemic issues as small glitches in the system. Our experience over the past year and half continues to show otherwise. Some of the most glaring and continuing problems are:

- As currently designed, the Part D program is immensely complicated. The program's complexities affect the ability of beneficiaries to understand the program, choose plans, pay premiums, benefit appropriately from the low-income subsidy, and utilize the exceptions and appeals process.
- The complexity of the Part D program also makes the program ripe for marketing abuses; beneficiaries who do not understand the nuanced differences among plans and plan types easily fall prey to unscrupulous sales agents.
- CMS's administration of the Low-Income Subsidy (LIS) lacks clarity and uniformity so that the subsidy too often fails to reach eligible beneficiaries.
- CMS, SSA, and Part D plans still have not developed a quick, efficient, and accurate system for transferring information about enrollment and premium payments. As a result, beneficiaries continue to have premiums withheld inappropriately from their Social Security checks, continue to be owed money for premiums inappropriately paid or withheld, and sometimes are threatened with involuntary disenrollment from their drug plan for failure to pay premiums they believed were paid.

- The Part D exceptions and appeals process is too complex and too varied from plan to plan to be adequately accessible to Medicare beneficiaries. Further, the standards for appeals are too vague and do not give adequate credence to the opinion of beneficiaries' attending physician.

The Senate Finance Committee has taken an important step to ensure that people with Medicare have access to medically necessary prescriptions simply by holding oversight hearings on Medicare Part D. We thank you for that step. We also thank Senators Bingaman and Smith for introduction of bills S. 1102 and S. 1108, to improve access to the low-income subsidy that assists with Part D premiums and cost-sharing; S. 1103, to provide additional assistance for beneficiaries in the coverage gap or donut hole; and S. 1107, to reduce cost-sharing for certain dually eligible beneficiaries who receive skilled nursing care while living in the community. We thank Chairman Baucus for your leadership on S. 4, concerning negotiation of prescription drug prices.

Our testimony today addresses in more detail several other issues not already the subject of legislation.

PART D IS IMMENSELY COMPLICATED. THIS COMPLEXITY MAKES CHOOSING A PART D DRUG PLAN DIFFICULT.

The Part D prescription drug program is premised on providing Medicare beneficiaries with choices about their drug coverage. The complexity of Part D, however, impedes the ability of many Medicare beneficiaries to choose a drug plan that is right for them. According to the Kaiser Family Foundation, the number of prescription drug plans (PDPs) offered in 2007 increased by 30% over the number in 2006. Only residents of Alaska and Hawaii, with 45 and 46 options, respectively, have fewer than 50 PDPs from which to choose. Of these options, only about 10% offer the standard statutory benefit.¹ That means that the other 90% vary in their premiums, deductibles, cost-sharing, and coverage in the "donut hole" or coverage gap. All drug plans vary in their formulary, drug tier placement, and utilization management tools. The number of plans and the number of variables make choice virtually impossible.

Secretary of Health and Human Services Leavitt applauded the increased number of drug plans in 2007 in a press release issued in September 2006. Health policy analysts, however, have long questioned the value of increased health care choices to older people and people with disabilities. They particularly question the value of health care choices when, as with Part D, the variety in plan benefit structures makes comparison more difficult. Some analysts have concluded that having to choose among many options creates a burden on beneficiaries and increases their difficulty in making an informed and meaningful decision.²

¹ J. Hoadly, et al, *Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings* (Kaiser Family Foundation, Nov.2006), <http://www.kff.org/medicare/upload/7589.pdf>.

² See, e.g., Biles, Dallek, and Nicholas, *Medicare Advantage: Déjà vu All Over Again?* Health Affairs web-exclusive (December 15, 2004); Hibbard, Slovic, Peters, Finucane, Tusler, *Is The Informed-Choice Policy Approach Appropriate For Medicare Beneficiaries?* 20 Health Affairs 199 (May/June 2001); Schwartz, *The Paradox of Choice: Why More Is Less* (Ecco/HarpurCollins Publishers 2004).

Our experience bears out the conclusion of the health policy analysts. Many drug plans made numerous changes in their benefit design and cost-sharing in 2007. They increased premiums, increased costs for some drugs while reducing costs for others, moved some drugs to a higher cost-sharing tier, and changed utilization management tools such as step therapy, quantity limits, and prior authorization.³ Despite these changes, most beneficiaries did not re-evaluate the plan in which they were enrolled to determine whether a different plan would serve them better. CMS reported in a January 30, 2007 press release that only 7% of beneficiaries who were not eligible for the low-income subsidy changed plans.⁴ Beneficiaries and their helpers told the Center staff that they had found the process of choosing a plan for 2006 to be too complicated, and they could not face going through the process again.

Unfortunately, starting in January 2007, we also heard from beneficiaries who either did not understand the need to review their plan choice or who were not able to review the information as provided to them. The individuals were adversely impacted by changes to their plan's formulary and were "locked in" to that plan for all of 2007. For example a Rhode Island beneficiary whose native language is Portuguese and who has limited ability to read English enrolled in a high-cost plan in 2006 because it covered brand name drugs in the "donut hole" or coverage gap. He did not understand until April 2007 that the plan's coverage had changed and that he would have to pay for the drugs he needed while in the gap. The 40-page plan booklet he received for 2007 was in English, which he could not read, and did not highlight the formulary change.⁵ Had he known of the reduction in gap coverage, the beneficiary would have enrolled in a drug plan with a lower premium.

THE COMPLEXITY OF THE PART D PROGRAM FOSTERS MARKETING ABUSES.

Marketing scams for PDPs and Medicare Advantage plans (MAs), including MA plans with prescription drug coverage (MA-PDs), were not new to the 2006 annual enrollment period. For over a year advocates have complained about such scams as sales agents going door-to-door at senior housing facilities to solicit enrollment in MA plans; enrollment of beneficiaries with diminished capacity or limited English proficiency; targeting dual eligible beneficiaries who might not benefit from enrollment in a more costly plan; enrolling beneficiaries in a more costly PDP than the one they wanted to enroll in; or enrolling beneficiaries in an MA-PD when they wanted to enroll in a PDP.

One frequent scam during the 2006 Annual Enrollment Period involved Part D sponsors telling beneficiaries across the country that they must have a home visit to enroll in one of their PDPs. The agents who made the home visit then engaged in a hard sell to enroll the beneficiary in one of the sponsor's Medicare Advantage plans, often a private fee-for-service plan, rather than in the PDP the beneficiary wanted. A State Health Insurance Assistance Program (SHIP) counselor from Virginia who attended a sales meetings said that the salesman was so persuasive she would have enrolled in

³ *Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings, supra.*
⁴ <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2079&intNumPerPage=10&checkDate=&checkKey=&srchType=&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&choOrder=date>
⁵ See, National Senior Citizens Law Center, *Medicare Prescription Drug Plans Fail Limited English Proficient Beneficiaries* (February 2007), http://www.nslc.org/areas/medicare-part-d/article.2007-02-27.2718724527/at_download/attachment.

the PFFS plan, rather than the PDP, if she did not have the knowledge she has as a counselor.

Beneficiaries often do not learn of the marketing error until they cannot get the health care they need or they begin to receive unexpected bills. For example, a 94-year old woman from Oxford, Mississippi discovered that she was enrolled in an MA-PD when she began getting medical bills from her doctors. Her attorney said that, although the woman cannot read, she is competent and would never intentionally enroll in a program her doctors did not accept. The woman told her attorney that she does not know how she got enrolled into the plan. She said that two men came by her house, she told them she was not interested, and asked them to leave. The attorney had to go through extensive advocacy to get her retroactively disenrolled from the MA-PD and into a PDP.

When enrollment errors are discovered, advocates report that it may take months before CMS returns beneficiaries to the traditional Medicare program and the PDP they thought they had chosen. If action is required by Part D sponsors to return a beneficiary to a less costly plan, not all Part D sponsors are willing to take that action. An advocate from Maine filed a formal complaint with CMS in April 2007 against a drug plan sponsor for “bumping up” a beneficiary dually eligible for Medicare and Medicaid from a benchmark plan into a more costly plan for which she had to pay a portion of the premium, and then refusing to take corrective action. Despite initially telling the advocate that her client would be retroactively enrolled into its basic plan, the sponsor then sent a letter saying that the client could not change plans because she was outside the annual enrollment period. The statement is incorrect, since Congress protected “dual eligibles” by allowing them to change drug plans at any time. The plan sponsor continued to bill the client for premiums while raising other arguments against retroactive disenrollment. The sponsor finally agreed to help the client, but said it would not change any other enrollments.

THE COMPLEXITY OF PART D CAUSES SPECIAL PROBLEMS FOR LOW-INCOME BENEFICIARIES.

One of the major changes made by Part D is the requirement that beneficiaries who are eligible for both Medicare and Medicaid (dually eligible beneficiaries) get their prescription drugs through Medicare Part D. On January 1, 2006, these people lost their eligibility for prescription drug coverage under Medicaid. Further, Medicaid beneficiaries who become newly eligible for Medicare lose their Medicaid drug coverage when their Medicare eligibility begins, even if they are not enrolled in a Medicare prescription drug plan. Such beneficiaries may experience drug coverage gaps when they are first eligible for Medicare due to time lags in the transmission of information about their new dual status, which must flow from the state to CMS. This change in drug coverage for low-income beneficiaries was the source of some of the most serious and significant problems when Part D began in 2006. Problems with Part D drug coverage for dually eligible people persist.

Although CMS automatically enrolls dually eligible beneficiaries into plans, effective the first day of the month in which they become dually eligible for both Medicare and Medicaid if they have not chosen a plan themselves, the enrollment may not, in fact, have been effectuated by the time they lose Medicaid coverage. They are entitled to reimbursement for out-of-pocket costs above the level of their subsidized co-payments; however, their low income status may make it impossible for them to actually pay out-of-pocket. Those beneficiaries who choose a plan, rather than accept auto-

enrollment, must affirmatively request through their plan that their enrollment be retroactive to the date they became dually eligible. The plan must submit the request to CMS.

CMS has a point of service (POS) system that allows a new dually eligible beneficiary for whom plan enrollment information is not available to receive drug coverage at the pharmacy (the “point of service”) upon a showing of proof of Medicare and Medicaid enrollment. However, this system is not available to other dually eligible persons who experience difficulties at the pharmacy, including those for whom CMS’s records show enrollment in a specific plan. Moreover, many pharmacists remain unfamiliar with the POS system and, even if they know about the system, they are not obligated to use it. If pharmacists use the POS system in error, the pharmacy is liable for the difference between the billed amount and the full cost-sharing due. Ironically, when new duals are already enrolled in a plan that did not acknowledge their enrollment, the POS option does not work for them and they are worse off than if they had not been enrolled in a Part D plan at all.

As I stated earlier, dually eligible persons are entitled by law to change plans at any time. They do so at their peril, however. Considerable confusion often occurs when plan changes are made and it may be difficult to understand which plan is responsible to pay for a drug during a plan-change transition.

Additionally, Medicare beneficiaries becoming newly eligible for Medicaid experience delays in getting access to their low-income subsidy. Data are transmitted by the states monthly; a beneficiary whose dual status is determined the day after the monthly transmission will not appear as a dual-eligible until the following month. For example, a new dually eligible beneficiary from Florida has been unable to get his Hepatitis C medicine because he cannot afford the \$514.87 co-pay charged by his Part D plan. He became eligible for Medicaid, and therefore should have been automatically deemed eligible for the low-income subsidy (LIS), on March 1, 2007. However, the state failed to transmit his files to CMS with its March submission, so CMS had no record of his LIS eligibility. As of April 25, 2007, CMS has either not received, or not coded and uploaded, the April submission from the state, so his LIS –eligible status was still not recorded in CMS systems. The POS system has not been effective for the beneficiary. He reported that when he went to his pharmacy in early April, the pharmacy was not aware of the procedure for billing the point of service system. The beneficiary is experiencing adverse health consequences as a result of not having his medicine.

The Florida beneficiary’s story illustrates the complexities of the data-sharing that is required to ensure that dual-eligible beneficiaries do not experience coverage gaps or gaps in their entitlement to lower cost-sharing when they become dually eligible. It also illustrates the complexity of resolving such problems, because so many entities (the state, CMS, the pharmacy, the drug plan, and sometimes SSA) are involved and each may be required to take some action that depends on the prior actions of another entity.

RE-DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDY ARE MADE THROUGH MULTIPLE MECHANISMS, LEADING TO CONFUSION AND ERRORS.

Low-income beneficiaries must re-qualify for the Part D low-income subsidy (LIS) each year. Since several paths exist for re-qualification, the process is confusing, especially for those whose

circumstances fluctuate over the course of a year. Medicare beneficiaries who are also enrolled in Medicaid, a Medicare Savings Program,⁶ or SSI are “deemed eligible” for LIS and do not have to apply. If individuals were on the rolls in one of these programs in July of 2006, they were to be “re-deemed” eligible for the subsidy for 2007. However, plans do not always have correct information about beneficiaries’ subsidy-eligibility status, and, sometimes, neither does CMS. For example, on January 2, 2007, a dually eligible resident of Virginia who should have been deemed eligible for the low-income subsidy was told by her pharmacy that she needed to meet the Part D \$265 deductible, although people entitled to the LIS do not have a deductible. The woman had no changes in her income, assets, or program eligibility for SSI, Medicaid, or Medicare. Her Medicaid eligibility worker called her drug plan and was told, incorrectly, the woman had lost her low-income subsidy eligibility.

Anticipating such problems, CMS sent a memorandum to Part D plans in December 2006 to explain that they must use the best available data to reconcile status when a beneficiary believes he or she is still eligible for the subsidy. The beneficiary may present proof of eligibility, such as a Medicaid card, at the pharmacy and the plan should follow up to collect the evidence. In the case of the Virginia beneficiary, and in other similar situations, Part D plans have failed to follow the CMS memorandum and to inform pharmacists and beneficiaries about presenting evidence of LIS eligibility.

When a Medicaid beneficiary loses eligibility for Medicaid benefits, states have an obligation under Medicaid law to determine if that person is eligible under another category of the state’s program. For example, someone losing Medicaid eligibility might, nonetheless, still be eligible for a Medicare Savings Program, since these income and resource limits are higher than Medicaid in most states. If states routinely undertook these new determinations of eligibility for other Medicaid benefits before terminating people from the program, fewer LIS recipients would find themselves in the limbo of not knowing about their LIS status. Similarly, even for those individuals no longer eligible for any benefits under the state Medicaid program, the state or SSA could undertake independently to determine their eligibility for the LIS, which has income and resource limits that are higher than those of most states’ Medicaid programs.

BENEFICIARIES CANNOT BE GUARANTEED THAT PROBLEMS WITH THE PREMIUMS WITHHELD FROM THEIR SOCIAL SECURITY CHECKS WILL BE RESOLVED – EVER.

Paying premiums for the Part D plans they have chosen is a challenge for many beneficiaries. Many beneficiaries chose to have Part D premiums withheld from their Social Security checks and paid directly to their plans, as they are accustomed to doing with Part B premiums. For some, Social Security withholding was never implemented. For others, Social Security withholding was implemented incorrectly. Some beneficiaries received refunds of their withheld premiums that they were not owed, while others wait months to receive the premium refund that is owed them.

⁶ The Medicare Savings Programs pay the Part B premium and, for those eligible for the Qualified Medicare Beneficiary (QMB) program, Medicare cost-sharing.

Beneficiaries who experience premium problems have no place to turn; no entity is willing to take responsibility to resolve the problems. CMS tells beneficiaries to call their drug plan, drug plans tell beneficiaries to call SSA, and SSA tells beneficiaries to call CMS. I have been called by several Medicare beneficiaries who were given my name and telephone number by SSA and told to call me, even though I have no authority to stop withholding and order a refund. Advocates across the country report that regional CMS offices have told them that their clients will be put on “the list” maintained by the regional CMS office, and that the problem may not be resolved for as much as a year.

The impact on beneficiaries of paying multiple premiums and/or of awaiting refunds of premiums inappropriately paid can be severe. Some beneficiaries whose drug plans claim that they have not received premiums withheld from the beneficiaries’ Social Security checks have received dunning letters and are worried about their credit rating. As one beneficiary told me, the money she is owed may not seem like a large amount to the government or to her drug plan, but it is a large amount of money to her.

The problems of a couple from Oklahoma are typical of the time and effort that beneficiaries and their helpers must undergo in order to try to resolve problems. Although their Part D premiums were being withheld from their Social Security checks, the couple received a premium – due notice from their drug plan in September 2006. Calls and visits to SSA did not resolve the issue, and they received another premium-due notice in October. They contacted their drug plan, SSA, which said to call Medicare, and Medicare, which did not solve the problem. Despite changing to a different drug plan for 2007, for which they pay directly, premiums for a plan offered by the original plan sponsor continue to be withheld. The couple also received collection notices in March for the 2006 premiums which had already been paid. Calls to SSA lead to a referral to the state insurance commissioner, which lead to a referral to CMS, which lead back to the drug plan. The drug plan claimed not to have a record of the October request to stop premium withholding. The couple again requested the plan to stop withholding premiums for the plan in which they no longer are enrolled. On April 20, the plan told the couple that CMS acknowledged the stop-withhold request, the request would be effective May 31, 2007, and CMS estimated they would get their refund in about six months. The plan representative would not provide written confirmation of these assertions.

Despite multiple efforts, the Oklahoma couple cannot be assured that the improper withholding of premiums will be stopped. Nor do they know if and when they will receive a refund of the money due them. And, when they receive the refund, they will not receive any interest on the improperly held amounts.

THE PROCESS FOR GETTING COVERAGE OF DRUGS THAT ARE NOT ON A DRUG PLAN’S FORMULARY IS CONFUSING, COMPLICATED, AND OFTEN NOT UNDERSTOOD BY BENEFICIARIES AND THEIR HELPERS.

In promoting Part D, CMS assured beneficiaries that they would have access to all of their medically necessary prescription drugs. What CMS failed to explain to beneficiaries is that they might have to file for a “coverage determination” and pursue an appeal if the drug they need is not on their plan’s formulary or is subject to certain restrictions, such as a limitation on the number of dispensable pills (“quantity limits”) or the need to request the plan’s permission before the drug is prescribed and paid for (“prior authorization”). The process for requesting a coverage determination and then an appeal is complicated, and most beneficiaries do not even understand this process, or the fact that they have the right to seek coverage for a drug not on their plan’s formulary.

A. Beneficiaries Are Not Adequately Informed Of Their Right To Request A Coverage Determination And File An Appeal

Under Medicare regulations, the Part D appeals process cannot begin unless and until a beneficiary who is denied coverage for a drug at the pharmacy affirmatively requests a formal “coverage determination” from his or her Part D drug plan. A coverage determination can only be issued by the drug plan itself; the denial at the pharmacy counter has no legal effect. The formal coverage determination from the plan should explain why the plan will not pay for the drug and how to start the appeals process.

Most beneficiaries who are denied coverage for their prescribed medications need to request a special type of coverage determination known as an “Exception.” An Exception may include a request to cover a drug that is not on the formulary, a request to reduce the cost-sharing for a drug, a request to provide a larger dose of a drug than the formulary limit, or a request to receive the prescribed drug without first trying a less expensive drug (“step therapy”). An Exception may also include a request to provide a drug without first getting prior authorization from the drug plan.

Unfortunately, beneficiaries are not adequately informed of the need to request a coverage determination. As a consequence, they never contact their drug plan for a coverage determination and they never enter the appeals process. Advocates continue to report that pharmacies are not complying with the regulatory requirement to either post or hand to beneficiaries the CMS-approved notice, *“Medicare Prescription Drugs and Your Rights,”* which explains in general the right to contact one’s plan to request an Exception or other coverage determination. Even if the notice is posted, posting provides very little protection. The notice is often placed where it is difficult to read.

Beneficiaries who use a mail-order pharmacy may receive no information at all. For example, if a Maryland beneficiary had not called her mail-order pharmacy to inquire about the status of her refill request, she never would have been told that she needed to request prior authorization from the drug plan before it would cover her drug. Even after she called, the mail-order pharmacy never sent her the notice explaining her rights. Thus, she did not know that she had a right to request an Exception to the prior authorization requirement.

Neither CMS nor the plans take responsibility when advocates complain that beneficiaries are not being informed of their rights to ask for an Exception and then to appeal. CMS says the plans are required to ensure distribution of the generic notice; plans claim they have done their job in educating pharmacies.

Advocates also complain that beneficiaries are not being informed of their appeal rights at later stages in the appeals process. A drug plan is required to provide both the beneficiary and the prescribing doctor who filed the Coverage Determination request with a standard Coverage Determination notice developed by CMS. Despite the requirement to use the standard form, which provides reasons for the denial and an explanation of appeal rights, some plans fail to provide

enrollees with the information they need to request an appeal. For example, instead of sending the beneficiary the standard Coverage Determination, an Arizona drug plan sent the prescribing physician a letter that made no mention of the reasons for denial or of appeal rights. The letter simply stated that the request for prior authorization was denied, and that the physician should consider the alternative drugs on the plan's formulary.

Similarly, a beneficiary who requests a plan Redetermination of an unfavorable Coverage Determination is entitled to receive written notification of an unfavorable decision. The written notice must include the reasons for the adverse decision and the right to request a Reconsideration, the next step in the appeals process. Nevertheless, advocates report their clients have received unfavorable Redetermination letters that tell the beneficiary to contact his/her physician for alternative medicines, and to check the plan's formulary for covered medications. No mention is made in these notices of appeal rights.

B. Part D Plans Use A Number of Tactics to Undermine the Exceptions and Appeals Processes

Even if the pharmacy tells a beneficiary that prior authorization from the plan is required before a drug will be covered, or that another drug must be tried first before the prescribed drug will be approved, or that the drug is not on the plan's formulary, the beneficiary still does not have all the information he or she needs in order to take action to get his or her medication. Drug plans do not make available on their web site or through their customer service centers information about the utilization management tools that apply to particular formulary drugs and/or the criteria they use to evaluate a prior authorization request. Thus, beneficiaries, their doctors, and their advocates do not have the information they need to support a request for prior authorization or a request for an Exception. Worse, some plans use the prior authorization and Exceptions processes as a way to delay providing and paying for prescribed medications.

The following examples are typical of the difficulties beneficiaries encounter when trying to use the prior authorization and Exception processes.

1. A dually eligible beneficiary from Massachusetts cannot obtain coverage for a drug that she had successfully taken for eight years. Her drug plan requires her to go through "step therapy" and to try other drugs on the plan's formulary. She has tried, seriatim, each of the alternatives; each time her doctor has requested and been denied prior approval. Her doctor is currently appealing denial of prior approval after the beneficiary unsuccessfully tried every suggested alternative. The beneficiary is having difficulty breathing, is not sleeping, is nauseous, miserable and, her advocate says, "in tears."

2. On April 7, 2007, a Connecticut beneficiary with multiple health problems was prescribed a broad spectrum antibiotic to be taken for seven consecutive days. Her pharmacy told her that the drug plan would not cover the medication without providing further explanation or explanation of appeal rights. Because the beneficiary is a former registered nurse, she knew to call her drug plan to inquire about the prescription. Although the Evidence of Coverage provided by the drug plan says the drug is on its formulary and does not describe any limitations to coverage, the drug plan call center representative said the drug is subject to

prior authorization. The representative became exasperated at the beneficiary's insistence that the drug should not be subject to prior authorization and told her no one was available to do prior authorization during the weekend. When she asked what people who need prior authorization over the weekend should do, he told her she needed to get prior authorization Monday – Friday, said he would not talk to her anymore, and hung up.

The beneficiary called the plan on Monday, April 10, and spoke with a different representative who did not fax a form for her doctor to complete until the next day. The doctor returned the form that same day, received a request from the drug plan for additional information, and returned the information immediately. Because of the delay in the start of the prescribed medicine, the seriousness of the beneficiary's illness, and the beneficiary's compromised health history, the doctor gave the beneficiary a sample pack of the medicine.

CMS regulations and guidance require drug plans to respond to coverage determination requests as expeditiously as the beneficiary's condition requires, but no later than within 72 hours or 24 hours if expedited consideration is warranted. The beneficiary received a coverage determination on April 16 denying coverage. The letter, dated April 12 and postmarked April 13, said she was required to try other medicines first, even though the Evidence of Coverage and the Plan Finder on the Medicare website do not indicate that step therapy is required. The client received a second letter on April 20, also dated April 12 but postmarked April 14, that said coverage was granted. The letter said the pharmacy was informed of the approval but the pharmacy says they received nothing. Although regulations require the drug plan to contact the beneficiary, the drug plan told her she should have called her doctor or her pharmacy to find out if the exception was approved.

3. A beneficiary from New York City needed a particular medication for chronic reflux to minimize post-operative complications from a thyroidectomy. He had tried six other medications, but none was effective. The day before the surgery his Part D plan still had not provided the beneficiary or his doctor with written notice of denial of the prior authorization request and appeal rights, although the request had been made well in advance of the surgery.

In addition to requiring doctors to provide more and more information, plans continue to claim they never got a Coverage Determination or Redetermination request, so they never issue a decision. For example, a doctor in Maine faxed the blood test results requested by a drug plan three times, but the drug plan kept saying it had not received them. Advocates also report faxing exception and redetermination requests only to discover that those requests do not get forwarded to the appropriate person or office, or they get forwarded several days after they are faxed. Such tactics discourage doctors from seeking Exceptions and Coverage Determinations.

3. The Part D Appeals Process Includes Conflicting Directives Concerning The Effect Of The Attending Physician's Opinion On An Exception Request And Appeal

A beneficiary must have the support of the prescribing physician in order to succeed with an exceptions request. Indeed, the Medicare statute makes the opinion of the attending physician concerning his or her patient's need for a non-preferred drug the controlling factor in determining

coverage. However, the Part D regulation specifically downgrades the effect of the physician's opinion to such an extent that it is not clear whether any deference is given. Thus, while beneficiaries must obtain a supporting document from their physician even to enter the appeals process, Part D plans are not required to respect the physician's opinion.

For example, a drug plan denied a coverage determination request for a non-preferred formulary drug filed by a doctor on behalf of a beneficiary from Maine. Although the doctor listed the generic version of the plan's formulary alternative as one of the many medications the beneficiary had tried for her chronic condition, the plan stated that its claims history did not show that she had tried the drug. Because the drug plan does not have to respect the physician's opinion, the drug plan ignored the medical records created and supplied by the doctor to show that the beneficiary had already tried, unsuccessfully, the formulary drug.

4. Difficulties in establishing proof of safe and effective off-label drug use

The use of drugs "off-label" is legal in the United States and is governed by strict rules for marketing. In many situations, physicians and their patients have determined over time that certain drugs approved by the FDA for one purpose also help with a different medical problem. Yet Part D plans do not defer to the opinion of the treating physician, even when the off-label use is supported by scientific literature, proven safe and effective over a substantial amount of time, and covered by the beneficiary's state Medicaid program.

The Medicare statute allows for coverage of certain off-label drug uses if they are included in one of three enumerated compendia. Unfortunately, beneficiaries, their families and their advocates who are not medical professionals do not have access to these compendia, making appeals of these cases very difficult. Some advocates have turned to state resources, including state-funded hotlines, for assistance, but these resources are limited, inefficient and incomplete. Without direct access beneficiaries and advocates cannot determine whether they have found all the entries in which a drug is mentioned, or whether the entries they have been faxed are the most up-to-date and complete. In essence, Congress and CMS have established a standard of proof which the average beneficiary cannot meet because of lack of access to the required information source.

PART D COMPLAINT MECHANISMS ARE NOT PROMPT OR RELIABLE, AND CMS IS UNWILLING TO TAKE ENFORCMENT ACTION.

CMS has established a number of mechanisms through which beneficiaries may seek redress of problems with their drug plan. Most of them do not work well. Beneficiaries who are not happy with their drug plan are urged to file a complaint by calling the Medicare hotline, 1-800-Medicare. As you are aware, the General Accountability Office has issued a number of reports detailing problems with the Medicare hotline in terms of response time and accuracy of information.⁷

⁷ See, e.g., GAO, *Communications to Beneficiaries on the Prescription Drug Benefit Could be Improved* (GAO 06-664, May 2006), <http://www.gao.gov/new.items/d06654.pdf>; GAO, *Accuracy of Responses from the Medicare 1-800-Medicare Help Line Should Be Improved* (GAO 05-130, December 2004).

Despite assurances from CMS that its hotline is responsive, advocates continue to find otherwise. For example, a Massachusetts attorney who tried to call 1-800-Medicare late in the afternoon of Monday, April 23, 2007 got a recording that due to high call volume she could leave a message and someone would call her back. She hung up, called again, and got the same recording. She proceeded to leave a call-back number and was told a representative would call back in a few days. She could only leave a telephone number and whether she wanted to be called back in the morning or evening. When she had not received a phone call by 3:00 pm on Friday, April 27, she tried again, only to hear a recording that she would have to wait on hold for 25 minutes. The attorney hung up, called again, and was told to leave her call-back information. If she had been a beneficiary with an emergency drug problem she would have been left without any assistance.

An advocate from California reported receiving the same message when she called 1-800-Medicare on behalf of a client who is deaf. The advocate pointed out that if her client, who uses a video relay system rather than TTY, had been the one who got the recording, the client would have had no way to leave both the video relay number and her home number. The advocate realized the problem when she was not even allowed to leave her own extension number.

Some advocates have developed relationships with their regional CMS offices and can call their regional office contacts when egregious problems occur. At times, however, regional office staff have been so swamped with complaints that they have told advocates not to call them, but to go through the 1-800-Medicare system.

For many beneficiaries and advocates, filing a complaint with 1-800-Medicare, or even with the regional office, is like filing a complaint into a black hole. We do not know what, if any, corrective action has been taken by CMS about such complaints as marketing abuses, failure to comply with exceptions and appeals time lines and notice forms, changes in plan formularies without the required notice, and inconsistencies between plan information and the CMS web-based plan finder tool.

When national advocacy organizations raise systemic issues with the CMS central office, we are always asked for specifics: the specific pharmacy that does not post or hand out the information to call a drug plan; the specific beneficiary whose appeal was not acted on in a timely manner or who received incorrect notice; the specific beneficiary who was enrolled in a more costly drug plan than the drug plan she wanted. We raise these issues with CMS central office not because we want redress for the individual beneficiaries involved. Often we have already talked with the regional office on behalf of the beneficiary or moved to the next step in the appeals process. We alert CMS because we want them to address the problem on a system-wide basis or take corrective action against the drug plan in question. They have been unwilling to do so.

Another common response from CMS is that we should work the problem out with the drug plan. We and other advocates do, in fact, have contacts with some of the drug plans, but those contacts are no substitute for enforcement by CMS. After I raised concerns at a meeting with CMS about a particular plan that consistently failed to comply with appeals time frames and other requirements, I received a phone call from a representative of the plan. The advocates whose complaints I voiced talked with the representative. Nevertheless, the same plan continues to ignore CMS regulations and guidance about Part D appeals. Some of the examples in my testimony are from that plan.

RECOMMENDATIONS FOR CONGRESS

Based on our work on behalf of Medicare beneficiaries, the Center for Medicare Advocacy has concluded that many of the implementation problems with Part D are inevitable given the design of the program. The combination of private and public entities adds too many complications, as is well shown, for example, by the problems created in withholding premiums from Social Security checks. When two government agencies and their contractors plus thousands of private plans are involved, the number of problems increases exponentially, and the lines of responsibility for solving the problems remain muddled.

Therefore, the primary recommendation of the Center for Medicare Advocacy to Congress is to redesign Medicare Part D to create a benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.

Short of redesigning Part D, Congress could take a number of steps, in addition to those already contemplated in the bills mentioned at the beginning of this testimony, to improve the Part D program. They include:

1. Improve the ability of beneficiaries to make a reasoned and informed choice about drug coverage.
 - Limit the number of Part D plans, both PDPs and MA-PDs, offered in each region.
 - Expand oversight to ensure that information provided to beneficiaries about their plan choices is accurate and understandable
 - Strengthen requirements to ensure that information is made available in the language and/or alternative formats beneficiaries require.
 - Authorize the National Association of Insurance Commissioners (NAIC) to develop standardized Part D benefit structures, similar to the standardized Medicare supplemental insurance (Medigap) plans, so beneficiaries can compare plans more easily.
2. Protect beneficiaries who did not understand changes in their drug plan.
 - Extend to Part D plans the open enrollment period for Medicare Advantage plans that runs from January 1-March 31 each year.
 - Allow Part D plan enrollees the opportunity to change plans as frequently as CMS allows plans to change their formularies.
3. Improve the Part D exceptions and appeals process.
 - Require notice of an adverse coverage determination to be provided electronically at the pharmacy counter. The notice should include reasons for the denial, information sufficient to request an exception, and information about exception and appeal rights.
 - Require Part D plans to give deference to the opinion of the beneficiary's attending physician when making coverage decisions.

4. Authorize Part D coverage for off-label uses of drugs that are supported by peer-reviewed studies, are proven safe and effective over a substantial period of time, are covered by the beneficiary's state Medicaid program, or are listed in one of the three compendia currently included in the Medicare Act, and require that access to the compendia be made available, free of charge, to beneficiaries pursuing an appeal.
5. Require CMS to establish expeditiously a full system of real time data-sharing among all entities involved in Part D, including CMS, SSA, drug plans, and other contractors. Congress should require CMS to report on its strategies to resolve these problems effectively and within a specific time period, and should require periodic status reports from CMS. The data-sharing system should include mandatory fail-safe systems to ensure that persons who are dually eligible for Medicare and Medicaid do not experience gaps in either their drug coverage or their low-income subsidy.
6. Continue oversight of CMS to ensure that CMS exercises its enforcement authority to take actions against Part D plans that fail to comply with Part D statutory, regulatory, and contractual requirements.

We again thank the Senate Finance Committee for holding this oversight hearing on Medicare Part D implementation. We appreciate the opportunity to share with you the experiences of our clients and of Medicare beneficiaries and their advocates across the country. We look forward to working with the members of this Committee on matters related to Medicare prescription drug coverage.

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May 31, 2007

Chairman Baucus
Senator Grassley
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Dear Chairman Baucus and Senator Grassley:

Please accept these answers to your questions to be submitted for the record of the hearing, "The Medicare Prescription Drug Benefit: Review and Oversight," that was held on May 2, 2007.

Question 1: There are insufficient consumer protections in place for Medicare beneficiaries to make informed decisions about Part D plans.

The most comprehensive information about Part D plans is found on the Internet. While Internet use among older people is growing, the overwhelming majority of older people are not Internet users. The Kaiser Family Foundation reported in 2005 that less than one-third of older people had ever gone on-line, and that Internet use by older people decreased as income and education decrease. Kaiser Family Foundation: *E-Health and the Elderly: How Seniors Use the Internet for Health Information* (Jan. 2005), <http://www.kff.org/entmedia/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=50287>.

Thus, most older people have to rely on other sources, including the 1-800-Medicare help line, to get their information about prescription drug plans. The *Medicare & You Handbook* contains some information about Part D plans, but not enough information to determine whether the drugs a beneficiary takes are on the formulary and how much they will cost. In order to get all of the information needed a beneficiary would have to contact every PDP and MA-PD available. Beneficiaries who rely on the *Handbook* may also be lead to believe that the most important comparative factor is the premium, although some beneficiaries could save money on their drug costs by enrolling in a plan with a higher premium. Additionally, the *Medicare & You Handbook*

promotes Medicare Advantage plans, when, in fact, many beneficiaries are better served by remaining in traditional Medicare and choosing a PDP.

Those who use the Internet may find the www.medicare.gov web site difficult to navigate. Important information, such as drug pricing and whether a drug is subject to utilization management tools, is hard to find. The plan finder tool indicates whether a plan provides coverage in the gap, but the information is insufficient or sometimes misleading. For example, some plans that were listed as providing coverage for preferred brand name drugs in the gap in 2007 covered only a handful of drugs.

Beneficiaries who call 1-800-Medicare or a plan's customer service line often are not given complete information. Customer service representatives (CSRs) on 1-800-Medicare generally do not provide information about every PDP or MA-PD available to a beneficiary. They and the plan CSRs will tell a caller that a drug is on a plan's formulary without explaining that the plan requires prior authorization or the use of another drug before the drug will be covered. Plan CSRs generally are unwilling to share drug cost information.

Last year the General Accountability Office issued a report documenting problems with 1-800-Medicare and the Medicare plan finder tool on the Medicare web site. GAO, *Medicare: Communications to Beneficiaries on the Prescription Drug Benefit Could Be Improved*, (GAO-06-653 May 2006), <http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPAddress=162.140.64.21&filename=d06654.pdf&directory=/diskb/wais/data/gao>. CMS has made some improvements to the Internet, but problems remain. The failures of the 1-800-Medicare help line to provide complete and accurate information are on-going.

The Center continues to hear from beneficiaries and their advocates across the country about marketing abuses. At this point the abuses generally involve fraudulent practices by Medicare Advantage plans. PDP-specific abuses include enrolling a beneficiary in a higher-cost plan than requested or enrolling a beneficiary in an MA-PD rather than a PDP. When a beneficiary contacts us we work with CMS to make sure that beneficiaries are enrolled in the plans of their choice. Although the Center's practice is to complain to CMS when we hear about plan-specific abuses, we never learn from CMS what, if any, corrective action they take.

Question 2: The Center and the beneficiary advocacy groups with which we work are concerned that the Part D appeals process is not working to protect Medicare beneficiaries' access to prescribed medications. Beneficiaries are not given information at the pharmacy about why their plan is not paying for the drug. In most cases they are not given direct information to call their drug plan with questions. Thus, most beneficiaries pay for the drug and do not take further action, or they walk away without their drug. We continue to believe that all beneficiaries should be handed an electronic notice that explains why the drug is not covered and the need to contact the drug plan.

Plans do not make public their criteria for including one drug over another for their formulary, so we cannot say how often the decision is financial rather than medical. Nor do they make public

their criteria for granting a prior authorization request or an exception for a non-formulary drug. Without access to this information physicians and advocates do not know what medical information they need to submit to the plan to establish the beneficiary's need for the prescribed medicine. The lack of transparency hampers their appeal efforts.

Advocates generally report greater success at the independent review entity (reconsideration) and administrative law judge levels of review than at the plan level. Delays at the plan level are causing some advocates to routinely seek reconsideration by the independent review entity without a redetermination decision by the plan. Beneficiaries who are not represented by advocates knowledgeable about the Part D appeals process rules may not be availing themselves of this protection. We also note that some advocates who represent people dually eligible for Medicare and Medicaid find it easier to enroll their clients in a different drug plan that covers their medications rather than to go through the appeals process.

We are concerned that CMS does not have specific enough data to determine if there are certain categories and classes of drugs for which plans are more likely to impose utilization management requirements or more likely to deny claims. The Center is part of a working group on Part D appeals issues convened by the American Medical Association, and we continue to meet with CMS to share problems and experiences, including our concerns about insufficient data.

Question 3: The Center advises beneficiaries and their families to look first at a drug plan's formulary, including tier placement and utilization management requirements, when trying to determine which drug plan to choose. As stated earlier, a lower- premium plan may turn out to be more costly if a beneficiary's drugs are not covered. We also remind beneficiaries that the formulary may change during the course of the year, that the formulary can change from year to year, and that the beneficiary's drug utilization may change. Given those variables, a decision based on formulary is really only valid as of the date the decision and enrollment are made.

If a drug is withdrawn from the formulary, the plan's negotiated price for the drug is no longer available. A beneficiary may have to pay more for the drug if the negotiated price was less than the price the pharmacy otherwise charges.

We have encountered beneficiaries who had to change drugs because of changes in a plan's formulary. Most beneficiaries who are required to change to the generic equivalent of their brand name drug experience no adverse consequences. Other beneficiaries were told by the plan that the drug was covered only to discover that the plan does not or no longer covers the drug. Many doctors who oppose the change to a formulary drug assist their patients through the exceptions process. In some instances, however, beneficiaries who rely on formulary drugs while an appeal to continue covering their old drug is pending suffer relapses or declines in their conditions.

The Center for Medicare Advocacy has stated publicly that we oppose "lock-in" for both Part D and Medicare Advantage plans and that beneficiaries should be allowed to change plans during the course of the year. Even if a drug plan's formulary does not change, a beneficiary may be prescribed different drugs for an existing condition or drugs for a new condition. A different

drug plan may provide better protection in those circumstances. At a minimum, a beneficiary should be allowed to change drug plans if the beneficiary is adversely affected by a change in his or her plan's formulary.

We also believe that plans should not be allowed to remove drugs from their formularies, impose new utilization management requirements, or change cost-sharing during the course of the contract year, except where safety so requires. As the program currently works, beneficiaries, in essence, enter into a contract of adhesion with their drug plans. They choose a plan based on its contract terms, the formulary, but the plan can change the formulary every 60 days. Additionally, bids to participate in Part D are based on the original formulary, so by changing the formulary the plans also are changing their contract with CMS.

Question 5: The Center supports the additional oversight activities CMS intends to impose on the marketing of private fee-for-service plans. We and other advocacy organizations have had conversations with CMS about beginning those activities now and not waiting until the next contract year. We also believe the activities should be expanded to include all Medicare Advantage plans.

Although the current focus has been on marketing efforts by PFFS plans, we have encountered beneficiaries who found themselves enrolled in other kinds of Medicare Advantage plans either without their knowledge or without their complete understanding of what enrollment in a Medicare Advantage plan means. We hear frequently from beneficiaries who thought Medicare Advantage was another kind of Medigap policy that provides dental and vision care, and perhaps improved prescription drug coverage. These beneficiaries did not understand that they would be restricted to a network of providers, or that the Medicare Advantage plan did not protect against having to pay large co-payments for more costly health care.

In addition to the activities proposed by CMS to protect beneficiaries against marketing abuse, limitations should be placed on compensation to brokers and agents so that they receive the same compensation regardless of the insurance they promote, including Medigap policies. Equal compensation amounts would discourage agents from promoting health insurance plans or policies based on their own financial reward rather than on the need of the beneficiary.

We also believe that increased state oversight of agents and of marketing is important, since state insurance commissioners are often the first to hear about marketing problems. We agree with the recommendation of the National Association of Insurance Commissioners (NAIC) in its testimony before the House Ways and Means Committee on May 22, 2007, that the federal preemption standard in 42 USC 1395w-26(b) should be returned to its pre-Medicare Modernization Act language. The pre-2003 statutory language gave states greater leeway to protect their residents against unscrupulous marketing practices while ensuring uniformity of laws for Medicare Advantage plans in other areas involving benefit structure and design.

Finally, we are disappointed with a clarification to its marketing policies that CMS made in a proposed rule issued on May 25, 2007. (72 Fed Reg. 29403). CMS used the proposed rule to

clarify (meaning it is not accepting comments on the clarification) that a provider can limit the display of comparative plan information in his/her office to the plans in which the provider participates. CMS was concerned about confusion to a beneficiary if information about non-network plans was provided; the beneficiary might think the provider is part of the network. We object strenuously to allowing providers to display any information about Medicare Advantage plans and believe the practice should be prohibited. A beneficiary who sees information about a particular plan in his/her doctor's office might be induced to join that plan, without thinking about the implications of enrolling in a Medicare Advantage plan and without considering whether the beneficiary's other providers are also members of the network.

Question 6: The Center for Medicare Advocacy believes elimination of the asset test for eligibility for the low-income subsidy (LIS) would increase the number of beneficiaries who enroll in the subsidy and would make the application process easier. Short of elimination of the asset test, we support S.1102 and S. 1108, which increase the asset limit, make changes to how assets and income are defined, and increase LIS outreach.

Two of the biggest problem areas for beneficiaries in completing the current LIS application are having to report the cash-surrender value of life insurance policies and the amount of any "in-kind support and maintenance" (ISM) they may have received. Beneficiaries often do not have information and paperwork about cash surrender value readily available and they do not know how to obtain the information. Similarly, ISM is difficult to estimate because the amount of support changes from month to month. We believe that questions about cash surrender value and ISM can be removed from the LIS application since, under LIS eligibility rules, non-liquid resources are not taken into consideration in determining LIS eligibility. The provisions in S 1102 and S 1108 would help in this regard.

The current LIS application states, right before the signature line, that anyone who knowingly gives a false or misleading statement about a material fact commits a crime and may be sent to prison, may face penalties, or both. The threat of a fine or even prison time for possibly providing incorrect or mistaken information creates a barrier to applying for many older people and people with disabilities. This statement can be modified to remind people of their obligation to provide accurate information without being so legalistic and harsh. The Access to Benefits Coalition and National Council on Aging in their report, *the Next Steps: Strategies to Improve the Medicare Part D Low-Income Subsidy* (January 2007) <http://www.accesstobenefits.org/library/pdf/TheNextSteps.pdf>, give the example of the statement on the IRS 1040 form as language that could be used on the LIS application.

We thank you again for the opportunity to testify.

Sincerely,

Vicki Gottlich

United States Senate
WASHINGTON, DC 20510

July 17, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator McClellan:

Over the past several months, you and your staff have worked diligently to implement the Medicare prescription drug benefit. We appreciate the steps taken by the Agency and its commitment to ensure that beneficiaries have access to the drugs they need. By issuing additional guidance related to prior authorization and formulary changes, among other matters, the Agency has clearly demonstrated its authority to take swift action to improve the Medicare prescription drug benefit. As the Agency's work continues, we write to offer the following suggestions for additional improvements specifically related to pharmacies.

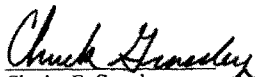
- Disclosure of Maximum Allowable Cost (MAC) List and Prices: It has come to our attention that in many instances, prescription drug plans (PDPs) do not disclose their MAC list and/or prices or any subsequent changes to pharmacists. This situation makes it difficult, if not impossible, for pharmacists to assess the payments they will receive under the contract. We are not aware of any other instance in Medicare in which providers would not be able to gauge their payments. For this reason, we strongly encourage the Agency to require PDPs to disclose this information to pharmacists.
- Daily Updating of Average Wholesale Prices (AWPs): The PDP practice of delaying updates to AWPs disadvantages pharmacists because they continue to be paid based on the outdated – usually lower – AWP until such time the PDP updates its pricing. PDPs should be required to update their pricing standards on a daily basis.
- Option for Electronic Funds Transfer (EFT): Independent pharmacies usually must pay their wholesalers for their inventory on a biweekly basis. PDPs often offer contracts that reimburse pharmacists every thirty days. As a result, many independent pharmacies have experienced cash-flow issues since the inception of the prescription drug benefit. Requiring PDPs to offer the option of electronic funds transfer would help mitigate this situation.
- Access to Extended Supplies of Part D Drugs at Retail Pharmacies: It appears that, some PDPs have taken steps that in effect, limit beneficiaries' ability to obtain extended supplies through retail pharmacies. Some PDPs have made their own mail-

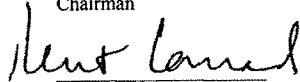
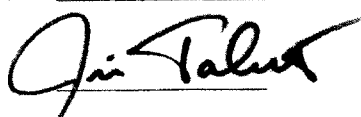

order pharmacy the only preferred pharmacy for extended supplies; others permit retail pharmacies to provide extended supplies, but require the beneficiary to pay higher cost-sharing, consistent with the guidance issued by CMS. We recognize that the situations described above may not constitute a violation of CMS rules. We are concerned, however, that these rules may undermine the spirit of the Medicare law's provisions regarding a level playing field between mail-order and retail pharmacies and the Agency's own objective of ensuring reasonable access for beneficiaries. We request that the Agency review its current policies with respect to the availability of extended supplies at retail pharmacies and to take steps to ensure that Congressional intent is met.


- Requirements Regarding Emergency Supplies Filled By Long-Term Care Pharmacies: Under CMS guidance, PDPs must have contracts with long-term care pharmacies that have the capacity to provide emergency fills. We have heard that in some situations, long-term care pharmacies have experienced difficulties in obtaining any necessary prior authorization in these circumstances, which may contravene the requirement to provide emergency fills. We urge the Agency to assess its current policies with respect to prior authorization requirements imposed by PDPs that may inhibit beneficiary access to medications in these circumstances.

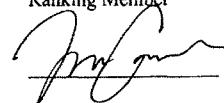
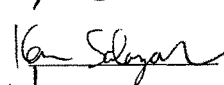
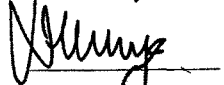

One goal of the Medicare prescription drug benefit is to ensure that beneficiaries have convenient access to their local, community pharmacies. We strongly encourage the Agency to examine PDP activities that may undermine beneficiaries' access and to consider the suggestions we offer to promote strong and continued participation of local, community pharmacies in the Medicare prescription drug program.

Sincerely,


Charles E. Grassley
Chairman


Max Baucus
Ranking Member

Blanch L. Lincoln

Rick Sutorum

Paul Ogden

Mike DeWine

Susan Collins

Craig Thomas

Conrad Burns

Rep Tom

Jay Hotz

Alvin

Tommy

Chuck Schum

Elizabeth Dole



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

SEP 27 2006

Administrator
Washington, DC 20201

The Honorable Charles E. Grassley
Chairman, Committee on Finance
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Thank you for your letter suggesting additional pharmacy-related improvements to our continuing efforts to implement the Medicare prescription drug benefit. We appreciate the Committee's bipartisan recognition of the efforts we have undertaken to date to improve the program and to ensure that Medicare beneficiaries have access to the prescription drugs they need. Just as we have throughout this year – for example, on issues related to special messaging on claims and the standardization of prior authorization materials and processes – please be assured that we will continue to work with Medicare prescription drug plans and pharmacists to facilitate good business partnerships and solutions to problems identified by both parties.

In your letter, you specifically recommend requiring plans to disclose maximum allowable costs lists and prices and to update average wholesale prices (AWP) daily. With rare exceptions, the Centers for Medicare & Medicaid Services (CMS) does not generally involve itself in dictating plan pharmacy contracting terms. Thus, for example, we generally do not opine on contracting terms and conditions associated with compensation, billing, and business practices, provided such terms and conditions are consistent with explicit Part D statutory and regulatory requirements. Nevertheless, we strongly agree that reimbursement terms in network pharmacy contracts should be as specific and clear as possible so that pharmacies can best assess the actual payments they will receive under their contracts. In addition, we have been assured that it is industry practice to regularly update AWP pricing, which typically occurs weekly.

In regards to your recommendation, we require plan sponsors to offer the option of electronic funds transfer (EFT) to mitigate cash-flow issues. We are pleased to report that America's Health Insurance Plans (AHIP) has already recognized this as an industry standard for payment terms to pharmacies. The organization, which includes many Medicare plan sponsors as their members, will work with plans and pharmaceutical benefit managers to ensure that payment for clean claims is transmitted via mail or EFT at least twice per month and no later than 30 days after the claims are first submitted by the pharmacy. In addition, AHIP has encouraged its members to move as expeditiously as possible to promote the availability and utilization of EFT payments to all pharmacies.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 does not require that access to extended day supplies of covered Part D drugs be available at all retail pharmacies, however, CMS has been very clear regarding its expectation that plans will contract with a


Page 2 – The Honorable Charles E. Grassley

sufficient number of retail pharmacies to ensure that enrollees will have reasonable access to the same extended day supply benefits at retail as are available at mail-order. We are continuing to monitor enrollee complaints regarding the availability of extended day supplies at network retail pharmacies. When we receive specific complaints, we immediately take action to investigate and resolve the issues identified in the complaint. Please be assured that we have not received a significant number of beneficiary complaints related to the availability of extended day supplies at network retail pharmacies and therefore have no reason to believe that beneficiary access to extended day supplies has been compromised in any way.

Finally, we have been very clear with plans regarding our emergency supply and prior authorization requirements and have encouraged the standardization of prior authorization processes. Given the vulnerability of our beneficiaries residing in long-term care settings, however, we remain vigilant in this area in order to ensure that plan prior authorization processes do not unduly hinder beneficiary access to medically necessary medications.

Thank you once again for bringing these important issues to my attention. We recognize the enormous value and commitment of pharmacies to the Medicare prescription drug benefit program, and our goal is to continue to work with this community, plans, Members of Congress, and other stakeholders to further streamline implementation of the program. I also will provide this response to the cosigners of your letter.

Sincerely,



Mark B. McClellan, M.D., Ph.D.

United States Senate
WASHINGTON, DC 20510

October 27, 2006

The Honorable Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Norwalk:

We are writing to continue our dialogue initiated last July with then-Administrator McClellan on pharmacy-related issues under the Medicare prescription drug program. The September 27 response that we received from Dr. McClellan prior to his departure from the Centers for Medicare and Medicaid Services (CMS) suggests that some of our recommendations included in our July 17 letter to him may not have been clear. We also want to share additional thoughts on the Agency's responses.

- Disclosure of Maximum Allowable Cost (MAC) List and Prices: In its response, the Agency stated that it "does not generally involve itself in dictating plan pharmacy contracting terms." We are somewhat puzzled by that response because we did not suggest that CMS "dictate" contract terms. We simply recommended that CMS encourage plans to disclose MAC list and price information and any subsequent changes to ensure that pharmacists can fully assess the nature of the contract. Given the Agency's response to our recommendation, we would like to learn more about other approaches it may take toward this end, especially because as stated in its response, CMS "strongly agrees that reimbursement terms in network pharmacy contracts should be as specific and clear as possible."
- Updating of Average Wholesale Prices (AWPs): Although prescription drug plan (PDP) sponsors may update AWP pricing on a "regular" basis, it is unclear whether these regular updates coincide with their receipt of changes in AWP. We want to be clear in our view that there should be no lag between a PDP sponsor's receipt of an AWP change and updates to its price list. The day on which a PDP sponsor receives an AWP change is the day on which it should update its price list.
- Option for Electronic Funds Transfer (EFT): We appreciate that CMS requires PDP sponsors to offer an EFT option. We also appreciate the effort of America's Health Insurance Plans (AHIP) to promote EFT availability and utilization. In our view, though, promoting EFT availability and utilization is a responsibility that lies with the Agency, not with a trade association whose membership does not encompass all PDP sponsors.

- Access to Extended Supplies of Part D Drugs at Retail Pharmacies: We understand that the Medicare Modernization Act of 2003 does not require that all pharmacies provide extended supplies. Our concern is that the Agency's current policies may undermine the MMA requirements to ensure (1) beneficiaries' access to their medicines through retail pharmacies and (2) level playing field between mail-order and retail pharmacies. With respect to the latter requirement, the statutory language on this matter at §1860D-4.(b)(1)(D) is not ambiguous. The MMA clearly states that sponsors "shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differentials in charge paid by such enrollees." Congressional intent behind this provision is obvious. The provision is intentionally designed as a requirement on plan sponsors to ensure that beneficiaries with prescriptions for longer term supplies can fill those prescriptions at either their local retail pharmacy or through mail order.
- Although we are pleased to know that CMS is monitoring complaints, we do not believe that this approach is sufficient to determine compliance and enforce contract requirements. In addition, this approach places the onus on the beneficiary to file a formal complaint, which is clearly not what Congress intended. We believe that the Agency should be more proactive in ensuring PDP sponsors' compliance with the law and beneficiaries' access to extended supplies in retail settings.
- Requirement Regarding Emergency Supplies Filled by Long-Term Care Pharmacies: We appreciate the Agency's vigilance in ensuring that beneficiaries in long-term care facilities have access to medically necessary prescription medicines. We want to reiterate that beneficiaries in long-term care facilities often require an emergency fill. We expect the Agency to ensure that in these circumstances, prior authorization requirements do not hinder beneficiaries' access to medications.

Thank you for your consideration of our comments.

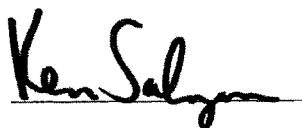
Sincerely,



Charles E. Grassley
Chairman



Max Baucus
Ranking Member




Jay R. Kypeler

Stephen L. Mason

Don Kuhl

C. J. Smith

DeP. B. B. B.

William

Kent L. L.

Mike D. White

Blanch R. Lincoln

James B.

Paul C.

Elizabeth Dole

Craig Thomas



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

FEB 14 2007

The Honorable Charles E. Grassley
Ranking Member, Committee on Finance
United States Senate
Washington, DC 20510

Dear Senator Grassley:

Thank you for your follow-up letter and the further clarification of your committee's recommendations on pharmacy related issues under the Medicare Prescription Drug Benefit.

Let me first assure the committee the Centers for Medicare & Medicaid Services (CMS) continues to believe that contracts between a Part D drug plan and network pharmacies should be as clear as possible with respect to pricing terms, updates to those terms, and methods of payment. Each of these contract terms is permissible under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA); thus, their absence and/or inclusion may be accepted and/or rejected in contract negotiations between a Part D sponsor and a pharmacy.

Given this flexibility that Plan sponsors have in negotiating contracts with pharmacies, CMS has been hesitant to assume the role of arbiter between the sponsors and their respective subcontractors. We believe that assuming this role would be unending and likely viewed as compromising the competitive marketplace conditions that Congress successfully created when crafting the MMA. The MMA, as written, shows a decided bias towards the marketplace in dictating contract terms. We believe CMS' role is to protect and encourage the best interests of Medicare beneficiaries.

Regarding the committee's view that CMS become the primary advocate of the Electronic Funds Transfer payment option, we support encouraging plans to adopt this practice. We believe our advocacy is directly responsible for moving the industry towards adopting this payment methodology, as evidenced by one of the larger trade organization's endorsement. In the future, we will continue to monitor and evaluate the progress of Part D sponsors using this option.

We note that a Part D sponsor, offering less than satisfactory or unclear contract terms, would likely find it difficult to retain enough pharmacies to meet our network requirements, and would therefore be unable to renew its Medicare Part D contract. It is important for a pharmacy provider to understand all terms of a contract before entering into an agreement with a Part D plan. In future guidance, we will continue to encourage plans to clearly disclose pricing and payment terms to ensure that pharmacy providers can fully assess the nature of the contract.

The Honorable Charles E. Grassley

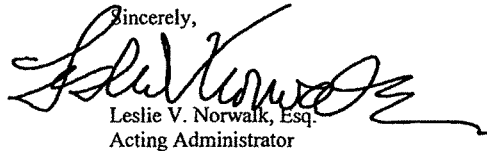
The CMS has been, and will continue to be, diligent in our pharmacy network application review process. In our communication to plans, as well as in our published policy guidance, we state that all Part D sponsors must have a sufficient number of retail pharmacies offering the same extended-day supply benefits available at mail-order pharmacies, to the extent mail order is available, and we require they attest that extended-day supplies are offered by a reasonable number of retail pharmacies in their network.

We appreciate the committee's recommendation that the Agency be more proactive in ensuring prescription drug plan sponsors' compliance with the requirements regarding access to extended-day supplies in the retail setting. We want to assure you that, as we continue to analyze complaints concerning access, we will be alert to information or trends that reveal any non-compliance with the MMA contract requirements. Given the minimal number of complaints received in this area, we believe this approach is sufficient, and that it balances the burden placed on the beneficiary to file a complaint with the resources necessary to continually monitor plan performance.

Finally, we appreciate the committee reiterating that CMS should work to ensure beneficiaries in long-term care facilities have ready access to emergency fills of their medications; specifically, that prior authorization requirements do not act as a hindrance. CMS will remain alert to any unreasonable obstruction to these beneficiaries receiving their medications. Additionally, please note that after some start-up problems earlier in the year, the prior authorization process as a whole has become increasingly more familiar and streamlined for both beneficiaries and providers. We will work to ensure this positive trend continues.

We are thankful for your clarifying your positions on these very important issues. I will also provide this response to the co-signers of your letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Leslie V. Norwalk". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Leslie V. Norwalk, Esq.
Acting Administrator

**Statement by
Kris Gross, Director
Senior Health Insurance Information Program
Iowa Insurance Division, Des Moines Iowa**

**At the Hearing on the
Medicare Prescription Drug Benefit**

**Before the Senate Committee on Finance
May 2, 2007**

I want to thank Chairman Baucus, Ranking Member Grassley, and members of the Committee for the opportunity to share testimony about the Medicare prescription drug benefit (Part D). I am Kris Gross, Director of the Senior Health Insurance Information Program (SHIIP), based in the Iowa Insurance Division, Des Moines, Iowa. I am here today representing not only my program, but also the 54 State Health Insurance Assistance Programs (SHIPs).

Since 1992 the Centers for Medicare and Medicaid Services has offered funding for SHIPs to the states. SHIPs are housed in state departments of aging, departments of insurance, and in the Medicare Quality Improvement Organization in one state. SHIPs' services are free, confidential and objective.

Our clients are all Medicare beneficiaries—aged, disabled and those with end stage renal disease. We help beneficiaries, and the people who assist them, including their caregivers, family members, and friends. We are charged with helping beneficiaries by providing information, counseling and assistance with problems and questions related to Medicare, Medicare Advantage plans, health insurance that supplements Medicare, long-term care insurance, Medicaid, claims, and in the last two years, Medicare prescription drug coverage.

The heart of SHIPs is the one-on-one, face-to-face assistance and counseling provided to our clients in their own communities. This service is offered primarily through volunteers, many of whom are peers of the people they counsel. There is variation from state to state in how programs are structured, allowing each SHIP to best meet the needs of the populations they serve.

Since 2005 our efforts to educate beneficiaries about the new Part D benefit has resulted in contact with hundreds of thousands of beneficiaries. We have educated them about the benefit, assisted with plan comparisons and enrollments, and helped them deal with problems they have encountered. I would like to share the positives we have seen, but also share the ongoing issues which Iowans and others across the nation have encountered. Once these problems are addressed, Medicare Part D will be a much more effective prescription drug benefit for Medicare beneficiaries.

Important New Benefit

Drug Coverage for the First Time

For the first time, Medicare Part D has provided drug coverage to many Medicare beneficiaries. The importance of this cannot be overstated. According to the Centers for Medicare and Medicaid Services, enrollment in stand-alone drug plans and Medicare Advantage drug plans totaled 17,631,279 as of January 16, 2007. We have a SHIIP client who is going to save \$14,000 this year thanks to his enrollment in a Part D plan. He had no prescription coverage previously and was thrilled and grateful. Others are saving a few hundred dollars a year, but wherever a beneficiary falls in the savings spectrum, the funds freed up are often critical since Medicare beneficiaries typically live on fixed incomes. The benefit has also helped assure that beneficiaries receive the prescriptions they need to stay healthy.

Extra Help with Drug Costs for Those with Limited Incomes

The extra help offered with drug costs through the low income subsidy has also been critical. Many beneficiaries who were not eligible to receive drug assistance through state Medicaid programs have qualified for the Part D low income subsidy allowing them to get prescriptions at low costs. For some, the choice to get needed prescriptions versus buying food or paying the utility bill has been eliminated.

Plan Finder Tool

As you are well aware, enrolling beneficiaries into drug plans which best suit their needs is fundamental to the success of the Medicare drug benefit. The Centers for Medicare and Medicaid Services have provided the Plan Finder Tool on the Medicare website (www.medicare.gov) which Iowa's SHIIP volunteers and staff feel is necessary to give an accurate and fair comparison of the drug plans. The tool is comprehensive and allows a beneficiary to have one-stop comparison shopping from an unbiased source. CMS has created a valuable tool and resource for anyone who has the computer skills and internet access to compare drug plans.

Opportunities for Improvement

The Medicare drug benefit was initiated and implemented in a very short period of time considering the complexity of the program. With all new programs adjustments are made and opportunities for improvement are considered. SHIPs are uniquely situated to observe the program and offer suggestions for improvement. Not only do SHIPs help beneficiaries compare and enroll in plans, but we are also the resource they return to when they encounter difficulties. Based on nearly two years of experience with Part D I'd like to offer the following opportunities for improvement.

Premium Withholding from Social Security Checks/Deposits

One of the options offered to beneficiaries for paying their Part D premiums is to have monthly premiums automatically withheld from their monthly Social Security checks. This seemed to be an efficient and effective way to pay premiums, assuring timely payments to their Part D plans. Most of our clients whom we enrolled in the Initial

Enrollment Period for Part D chose this option. Over the past year this is one of the areas of the program which has caused the greatest number of client problems. For some clients the premium was not withheld as requested, for others a change in their plan choice was not accurately processed and reflected. The premium errors have resulted in beneficiaries being disenrolled from plans, excess premiums being withheld, and premium refunds not reimbursed. Some problems have been unresolved after nearly a year of working with CMS, Social Security and the plans.

For example, one of our clients was enrolled in a stand-alone drug plan effective January 1, 2006. In February of 2006 she found out she was eligible for the low income subsidy (LIS). She finally was switched to a plan which offered a \$0 premium option on May 1, 2006. She no longer incurred a monthly premium, but the premium for her first plan- the plan in which she was no longer enrolled- continued to be withheld from her monthly income. A SHIP counselor had a conference call with Medicare, the plan and the client but nothing was resolved. We are working with our Regional CMS office, but to date she has not received a refund of the 2006 excess withholding. She is owed a refund of \$442, a significant amount for someone with limited income and resources.

These erroneous premium withhold situations are very frustrating for beneficiaries and those assisting them. Resolving the withholding and payment problems would allow beneficiaries to use this payment method as it was initially intended.

Marketing Practices

Another area of concern to SHIPs is the marketing practices of some stand-alone drug plans and Medicare Advantage plans with drug coverage. Door-to-door marketing has occurred, even though prohibited by Part D marketing guidance. Beneficiaries who are enrolled in stand-alone drug plans are approached to enroll in Medicare Advantage plans with drug coverage. Sales representatives often do not explain to these beneficiaries the differences between original Medicare and Medicare Advantage, leaving beneficiaries without a clear understanding that they are changing how they will receive their Medicare Part A and B benefits. Beneficiaries believe they are just changing drug plans.

One client enrolled in a Medicare Advantage plan with drug coverage thinking she was changing to a different stand-alone drug plan. She used the drug benefit in the plan, but did not realize her Medicare benefits had been shifted to a Medicare Advantage plan until she had a medical claim and it was denied by Medicare. In addition, she had continued to pay her Medicare supplement premiums for six months, even though the Meidgap policy would not pay anything while she was enrolled in a Medicare Advantage plan. She had no idea she had enrolled in anything more than a stand alone drug plan.

The number and types of Medicare Advantage plans have expanded tremendously in most states, making it difficult for beneficiaries to understand all available options. Iowa has 53 stand-alone drug plans and 31 Medicare Advantage plans with drug coverage. The number and variety of plans means that the process of comparing and selecting an appropriate plan is extremely challenging for consumers and those who help them. Agents selling the plans need to be sure that their clients understand what they are enrolling in before the enrollment is submitted. Some agents focus on the drug coverage

portion of a Medicare Advantage plan, and fail to provide sufficient information about the transition out of original Medicare.

There are many Medicare beneficiaries who have diminished cognitive ability due to illness or a disability, and many others who have limited income and resources. We all need to be especially vigilant that beneficiaries fully understand their options before decisions are made because plan choice can have a dramatic impact on beneficiaries' access to medications and health care providers. It is important that the Centers for Medicare and Medicaid Services and state insurance departments work closely together to monitor and sanction questionable or even illegal marketing practices.

Low Income Beneficiaries

Many of the beneficiaries who are eligible for the low income subsidy (LIS) qualify for a continuous Part D special enrollment period (SEP), which allows them to change plans monthly. This SEP provides an important protection for these individuals, allowing them to change plans as their prescription needs change. However, this flexibility has also caused concern among the SHIPs. This freedom to choose and enroll in plans throughout the year means that low income beneficiaries are one of the few groups of beneficiaries who can be enrolled in Medicare Advantage drug plans after March 31, the end of the Medicare Advantage open enrollment period end. Consequently they become a major audience for the marketing of these plans. Differences in the drug coverage portion of the Medicare Advantage plan may not be a problem for beneficiaries, but the same MA plan may require using different health care providers, a potential problem. Understanding how Medicare benefits are provided and which providers accept the Medicare Advantage plan is especially critical for beneficiaries who cannot afford to pay if a provider does not accept a plan.

This past week one of our volunteers had a client who is visually impaired. Because she is a dual eligible beneficiary she can change plans monthly. She was visited by an agent selling a Medicare Advantage plan with drug coverage after the March 31 open enrollment period ended. At the time of the agent's visit she had original Medicare, Medicaid and a stand-alone drug plan. She thought she was changing her drug plan and enrolled in the product the agent was selling. After some thought, she wondered if she had done the right thing and called a friend who contacted SHIP. It was perfectly legal for the agent to sell her a plan. However, the Medicare beneficiary did not understand she was enrolling in a Medicare Advantage plan and she did not want to change from original Medicare. This type of enrollment into MA plans, with little or unclear explanations of the differences between original Medicare and Medicare Advantage has been happening in every state in the country.

Data Sharing

Another concern with the Medicare prescription drug benefit is the time it takes for data to be shared between CMS, Social Security, state Medicaid agencies and the plans. It can take several weeks or more for information to show up correctly in all systems. This problem occurs across the board, but the implications are most significant for beneficiaries who have Medicaid or Medicare Savings Program benefits or are low income subsidy (LIS) eligible and cannot afford standard cost-sharing amounts. For

beneficiaries first becoming eligible for Medicaid and Medicare (dual eligible) the time delay may leave them without any drug coverage for a significant period of time. These individuals are the least capable of paying out-of-pocket for their medically necessary drugs.

In Iowa we have a client we've been working with since January 24 of this year. Since that date we have made 40 calls on her behalf. In an effort to get her low income subsidy eligibility to show correctly in her records, we have called her plan, CMS and Social Security. To compound this issue, the plan premium is being withheld from her Social Security payment, even though she should not be paying a premium for her prescription drug plan. Because the data in the system is not correct, she is being charged inappropriately high co-payments for her medications, in addition to paying the erroneous premium withholding from her Social Security checks.

Burden of Choice

The Medicare Modernization Act created a drug program that allows beneficiaries a choice in how they receive the benefit and who provides the benefit. However, choice becomes a burden when it is overwhelming. As I have already mentioned, we have 84 drug plan options in Iowa and many states have even more. Beneficiaries are overwhelmed by the process of comparing and evaluating these plans. The Plan Finder Tool on www.medicare.gov is an important resource in sorting through the plans, but the vast majority of beneficiaries do not use computers. In addition, plans can change benefits, formularies and premiums each year so every year beneficiaries have to make a choice. This too is a great burden, especially for those who are ill, disabled, illiterate, or facing other barriers in getting information. All of this is overwhelming, even for our SHIIP volunteers who are well-trained on Part D.

I was with SHIIP before Medicare Supplement insurance was standardized. Part D reminds me of the challenges beneficiaries had then in choosing a policy. It was impossible for consumers to adequately compare the options available to them. Once plans were standardized and the number of choices available became manageable consumers became much more confident and comfortable in making those decisions.

Conclusion

The Medicare prescription drug benefit is helping millions of beneficiaries every day. There are bound to be problems in the early years of a program of this magnitude. My concern, and the concern of the SHIP staff and volunteers across the country, is the impact of these problems on beneficiaries. The stress, confusion, and impact on their health and finances can't be ignored. In the past week I have had calls from two Iowa SHIIP counselors who have clients whose Part D problems are contributing to a deterioration of their mental health and an exacerbation of existing illnesses.

As a result of Part D issues, our volunteers and staffs are overwhelmed with clients who have problems. Part D has changed the complexion of the work SHIPs do for beneficiaries. The knowledge and skills our volunteers must possess to counsel and assist clients have expanded tremendously in the past two years. Comparing plans and

enrolling a beneficiary can be completed in an hour or two. Problem resolution is taking many more hours over a long period of time and problems we thought were resolved tend to reappear and remain unresolved a few months later. In Iowa, I have added two part-time staff to help resolve client Part D and Medicare Advantage problems when our volunteers hit roadblocks. Since January 2006 we have opened 999 cases in our state office; this figure does not include the problems resolved by our volunteers across the state. This same situation is occurring in every state throughout the SHIP network.

I want to thank the Senate Finance Committee for holding this hearing on the Medicare prescription drug benefit and for inviting my testimony. The stories I have shared are not mere anecdotes, or even the worst cases. Rather, these are representative of many real people with real problems. Some of these are very amenable to systems fixes while others could be addressed by Congress to make the lives of Medicare beneficiaries easier and to enable them to experience the maximum benefit from Part D. SHIPs, along with many other advocates for Medicare beneficiaries, want the drug benefit to have a positive impact on all beneficiaries. I hope the experiences I have shared with you will contribute to the success of this important benefit.

United States Senate Committee on Finance
Public Hearing
“The Medicare Prescription Drug Benefit: Review and Oversight”
May 2, 2007

Responses to Questions for the Record From Kris Gross

Questions for Ms. Gross and Ms. Gottlich from Senator Baucus:

1. **How important is a plan’s formulary to a senior trying to choose the best plan?** The formulary is one of the most critical factors when selecting a drug plan. If a beneficiary’s drugs are not covered by a plan, the Medicare prescription drug benefit does not exist and the plan is of no use. If a medication is not on the formulary a beneficiary will pay the full cost of the medication unless they seek an exception to the formulary. The out-of-pocket costs incurred for non-formulary drugs will never count towards the thresholds of coverage. The beneficiary will pay a premium for no benefit and will end up paying full cost for prescriptions.

There are two aspects to formulary consideration, the first is whether a drug is on the formulary for a plan and the second is whether there are any management utilization techniques (i.e. step therapy, prior authorization, or quantity limits) imposed within the formulary. While a beneficiary can seek an exception or appeal for coverage of non-formulary drugs and for removal of management utilization techniques, these are difficult processes and cannot serve as a guarantee of access to medically necessary drugs. Often the outcome is patients going without or paying out-of-pocket.

What happens to the cost of a drug for a plan’s enrollees if it’s removed from the formulary?

The Centers for Medicare and Medicaid Services (CMS) issued a memo on April 27, 2006 regarding “Formulary Changes during the Plan Year” (see attached copy of memo). This memo states that maintenance changes require a 60 day notice to the affected enrollee and others. In this case, the beneficiary would need to change drugs or bear the full cost of the drug currently prescribed if continuing to use it.

Maintenance change means replacing a brand-name with a new generic drug or modifying the formulary as a result of new information on drug safety or effectiveness. Medicare beneficiaries are often very sensitive to medications. If stabilized on something that works, changing, even to a generic, can be disruptive, requiring multiple office visits and sometimes resulting in adverse outcomes. This can be very costly.

In the case of “other formulary changes”, the memo states that “Part D plans should make such formulary changes only if enrollees currently taking the affected drugs are exempt from the formulary change for the remainder of the plan year.” The beneficiary should see no change in the cost of prescriptions in this situation. It is important that CMS monitors and enforces this policy.

The other time when a beneficiary could be affected by formulary changes is at the end of the plan year when plans can change their formularies for the following plan year. All beneficiaries need to review their current plan formulary and see if their prescriptions will be covered the next year. This annual review is a challenge for many beneficiaries who experience disability, health or memory issues. They may not be able to adequately review the notices sent prior to the Annual

Election Period and end up staying in their current plan because it takes the least action on their part and it met their needs during the past year. As a consequence, they may be in plan the next year which has changed its formulary and no longer covers their drugs. The need to review formularies (and other plan changes) annually is a great burden for beneficiaries.

It is extremely important that the message sent from CMS is not “if you’re happy, do nothing,” but rather, “take a fresh look at your plan each year.”

Have you seen patients switch medications due to changes in a formulary, and if so, was this against a doctor’s recommendation for optimal care?

We have had some reports of prescription changes related to formulary issues. Often changes in prescriptions are triggered upon discovery that the Medicare drug plan will not offer coverage for the medication as prescribed. The cause may be management utilization techniques for the prescribed drug or non-formulary prescriptions. Due to the burden on physicians to provide support for the prescription as written, the path of least resistance is changing to a formulary alternative and monitoring for any side effects. This might result in added costs for Medicare and the beneficiary in terms of extra doctor visits for monitoring, blood tests, emergency room visits for side effects, etc.

What do you think of limiting plans’ ability to change formularies mid-year?

Outside of allowing plans to expand their formularies to add new drugs or to remove drugs found to be unsafe or ineffective, I do not believe plans should be allowed to change formularies mid-year. Beneficiaries enroll in a plan based on the perception that the plan will continue to provide coverage for their drugs until the first of the next calendar year. The beneficiary is required to stay in the plan one year (with exceptions for dual eligibles, nursing residents and a few other situations) so the plan should maintain the benefits for one year also.

What about allowing beneficiaries to switch plans during the year?

The questions asked up to this point focus on changes the plan itself makes to the formulary. However, the beneficiary can also have a change in the prescriptions taken during the year. This situation is much more common than the Part D plan changing its formulary. The result is out-of-pocket expenses for the beneficiary. This issue comes up every time we do SHIP presentations on Part D. The exceptions process is in place to allow beneficiaries to request coverage of newly prescribed drugs, but this process is **very difficult** for the beneficiary and costly to medical providers who must spend time documenting and supporting the request. One SHIP director reported to me that a doctor’s office had a message on the automated answering system which stated they would not do appeals (exceptions). Allowing all beneficiaries to have the flexibility allowed dual eligibles, who can change plans monthly, would be one option. However this does not fix the entire problem because the beneficiary still needs coverage for the prescription until the plan switch is effective on the first day of the following month. A simplified exceptions process is critically important.

Questions for Ms. Gross from Senator Baucus:

2. Are SHIPs adequately funded to fulfill the needs of their communities?

Medicare Part D and the expansion of Medicare Advantage plans have placed new demands on SHIPs. Partnering with the CMS Regional Offices, Social Security and plans to resolve beneficiary problems and advocate for beneficiaries is much more time consuming and requires

additional training for volunteers and paid staff. The current funding from CMS alone is not adequate to meet the needs of beneficiaries. When a beneficiary comes to SHIP for assistance it is critical that the counselor has a comprehensive understanding of Medicare benefits and the intersections with other health care coverage. Solely knowing and counseling about Part D (as is the case with some organizations that offer limited counseling to beneficiaries) can leave many issues undiscovered or even exacerbated, thus adding complications for those in crisis. Our volunteers also need to have a sound background in Medicare Part A and B, Medicare supplement insurance, employer provided retiree health insurance, Medicare Advantage, Medicaid and Medicare Savings Programs. All of these topics need to be reviewed to assure that the beneficiary has considered all options and the impact of any decision made. SHIPs are the one organization charged (by CMS) with training our counselors in all these areas. Some states turn to state funding to assure that they can meet the needs of beneficiaries. Other states have not received state funding. In all cases, the CMS funding is not adequate in itself to meet beneficiary needs under Part D, particularly with the additional expansion of Medicare Advantage plans under the Medicare Modernization Act.

If not, what percentage increase in funding is needed? Is the distribution formula for the SHIP grants fair to rural states? If not, how should it be changed?

Some advocacy organizations have recommended that SHIP funding should be at least \$43 million so that overall SHIPs would receive \$1 per beneficiary. It is important to understand that the services SHIPs provide go beyond just Part D. We continue to provide counseling and assistance on all the topics and issues which existed prior to Part D's implementation and the expansion of Medicare Advantage plans.

I do not know the formula CMS uses for grants to rural states. I do know we receive additional funds, but I do not know how that amount is calculated. I do believe there is a minimum resource level that is needed to operate any SHIP effectively, given the grant requirements. Additional funds are needed in proportion to the number of beneficiaries, the type of beneficiaries and the geographic location of beneficiaries. Also, the type of assistance has changed since the inception of the SHIP grant. Part D and Medicare Advantage problems can require many hours of counselor time, and often staff time to resolve. Funding and access to information resources need to reflect these new responsibilities.

As part of our last SHIP grant application, we were asked to provide detailed information about our program organization and funding. This information is being consolidated into one document by the SHIP Resource Center. This would provide valuable information about the need for additional SHIP funding.

Do SHIPs need more resources or more training to provide outreach for the low-income subsidy?

SHIPs have been provided with adequate training on the low-income subsidy. It would be helpful if Social Security and CMS could specifically pinpoint who the missing LIS beneficiaries might be and share the information with SHIPs. We also need more support in developing outreach and counseling skills to deal with the new demands created by low-income beneficiaries.

Questions to Other Panelists

The following questions were not directed to me, but I would appreciate the opportunity to offer comments.

5. Do you think those activities would have a big impact on reducing the types of situations you've described and are there other things that the Center thinks CMS should be doing to oversee marketing of Medicare Advantage plans?

The activities listed are a good start. In addition, I would recommend the following:

- a. Include an appropriateness requirement for Part D sales (PDP and MAPD), including the requirement that if a reasonable person would judge that the beneficiary would benefit from having a third party present before making a decision, that an enrollment could not take place without a third party present. Agents would also have to prove that for those with the continuous enrollment, changing coverage from a PDP to a MA/MAPD would provide some advantage to the beneficiary.
- b. Individuals selling private fee-for-service (PFFS) plans with drug coverage state clearly that, while the beneficiary can use any Medicare provider, not all providers may choose to accept the payment of the PFFS plan.
- c. Currently in the Part D Eligibility and Enrollment Guidance (20.3.8.9B) there is a special enrollment period available for "Individuals who dropped a Medigap policy when they enrolled for the first time in an MA plan, and who are still in a "trial period." Because of the many beneficiaries who enrolled in MA plans thinking they were enrolling in a stand alone drug plan or did not understand the MA plan, I would suggest that this SEP should be available to anyone who enrolls in a MA plan for the first time and is in the trial period. This would require a corresponding change in the MA guidance to allow someone to disenroll from an MA plan during the 12 month trial period, not dependent on dropping a Medigap policy.

6. Despite the fact that the application for the low-income subsidy is shorter than other applications for assistance, there's a view that it's too complicated and too difficult to fill out. Do you share that view? And if so, what do you feel should be changed?

Anything that can be done to simplify eligibility for the low-income-subsidy (LIS) and enrollment in a plan for these beneficiaries is important. We have had few complaints about the LIS application, but we have had many beneficiaries experience significant delays in getting drug coverage when they are newly dual eligible. [Note: Dual eligible is used here to refer to those who have full Medicaid benefits and Medicare.] Prior to Part D, dual eligibles received assistance with their drug costs the day they received their Medicaid card. Under Part D, the state Medicaid agencies send names of the newly dual eligible to CMS once a month. CMS auto-enrolls them in a plan if they are not currently enrolled. They may wait up to two months before they show up in the Part D system as LIS eligible and enrolled in a plan. During that time they may pay full price for their prescriptions.

The Wellpoint process may be an option to receive coverage more quickly, but this is difficult for beneficiaries to understand, and at times does not work at the pharmacy. Drug coverage was a one-step process before Part D for dual eligibles, now it can take weeks to navigate a complicated process. Information between CMS and the state Medicaid agencies should be shared immediately to assure that our poorest Medicare beneficiaries have access to the prescriptions they need for their medical conditions. Part D has turned out to be much more complicated and unfriendly to dual eligibles than previous Medicaid prescription coverage. This is a very significant problem.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Beneficiary Choices
7500 Security Boulevard
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CENTER FOR BENEFICIARY CHOICES

Date: April 27, 2006
To: Part D Sponsors
From: Abby L. Block, Director
Subject: Formulary Changes During the Plan Year

Both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the benefit year. Formulary stability is extremely important so that enrollees maintain access to the benefit they chose during enrollment as represented to them by the plan.

However, prescription drug use and pricing is constantly evolving, and new drug availability, new medical knowledge, new drug pricing arrangements, and new opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur over the course of the year. These new developments may require formulary changes during the year in order to provide high-quality, low-cost prescription drug coverage.

Under Part D, no beneficiaries will be subject to a discontinuation or reduction in coverage of the drugs they are currently using, except for clear scientific and cost reasons including the availability of a new generic version of the drug or new FDA or clinical information.

All proposed formulary changes, excluding formulary expansion changes, must be submitted to CMS for review and approval. We will continue to review these requests, as we have been doing, using the principles outlined below, which include a comprehensive review of a formulary each time a change request is submitted. CMS will continue to ensure that each formulary provides a broad range of medically appropriate drugs and does not discriminate or substantially discourage enrollment of certain groups of beneficiaries.

Formulary Changes During the Plan Year

Q: What changes can Part D plans make to their formularies during the plan year?

A: Both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the plan year. We believe that formulary stability is extremely important so that enrollees maintain access to the benefit they chose during enrollment as represented to them by the plan. However, prescription drug therapies are constantly evolving, and new drug availability, new medical knowledge, and new opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur over the course of the

year. As recognized in the statute and regulations, these new developments may require formulary changes during the year in order to provide high-quality, low-cost prescription drug coverage.

We have a 4 part policy regarding formulary changes:

1. Part D plans may expand formularies by adding drugs to their formularies, reducing co-payments or coinsurance by lowering the tier of a drug, or deleting utilization management requirements any time during the year.
2. Part D plans may not change their therapeutic categories and classes in a formulary other than at the beginning of each plan year, except to account for new therapeutic uses and newly approved Part D drugs.
3. **Formulary Maintenance Changes:** After March 1, Part D plans may make maintenance changes to their formulary, such as replacing brand-name with new generic drugs or modifying formularies as a result of new information on drug safety or effectiveness. Those changes must be made in accordance with the approval procedures described below and following 60 days notice to CMS, SPAPs, prescribers, network pharmacies, pharmacists and "affected enrollees".
4. **Other Formulary Changes:** Part D plans may only remove Part D drugs from their formulary, move covered Part D drugs to a less preferred tier status, or add utilization management requirements in accordance with the approval procedures described below and following 60 days notice to CMS, SPAPs, prescribers, network pharmacies, pharmacists, and "affected enrollees". For these additional types of formulary changes approved by CMS for 2006, Part D plans should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the plan year. CMS expects that Part D plans will continue to comply with this policy in 2007 and subsequent plan years, and will include such assurances in their future bids and contracts.

Note: Part D plans are not required to obtain CMS approval or give 60 days notice when removing formulary drugs that have been withdrawn from the market by either the FDA or a product manufacturer.

Additional detail on these policies is included below.

Formulary Maintenance Changes

In order to promote best practices and protect the interests of Medicare beneficiaries, CMS will generally give positive consideration to the following types of formulary changes:

1. Removal or placement in less preferred tier of a brand drug upon the availability and addition of an A-rated generic or multi-source brand equivalent, at a lower tier or cost to the beneficiary.
2. Removal of a non-Part D drug inadvertently included on the formulary.
3. Removal of a drug based upon a new FDA "black box" warning or market withdrawal.
4. Removal or placement in a less preferred tier based upon new clinical guidelines or information recognized by CMS (e.g. CDC's recommendation against using older anti-virals for treatment and prophylaxis of the flu)

5. The addition of utilization management when necessary to effectuate other approved formulary changes (e.g. prior authorization on a brand drug when generic is now available on formulary at a lower cost), to help determine B vs. D coverage (subject to CMS guidance on least burdensome ways to make this determination), or to promote safe utilization of a Part D drug based upon new clinical guidelines or information.

Part D plans will need to provide this type of justification when submitting these formulary change requests, but may assume that change requests based upon these justifications are approved if they do not hear from CMS within 30 days of submission. Part D plans are required to send 60 days notice to CMS, SPAPs, prescribers, network pharmacies, pharmacists, and “affected enrollees” (except for FDA or manufacturer withdrawals).

Other Formulary Changes

Experience with formulary management indicates that the vast majority of formulary changes are “maintenance” changes that would generally be approved by CMS. CMS will review additional types of formulary change requests and their corresponding justification. For these additional types of formulary changes approved by CMS for 2006, Part D plans should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the plan year. CMS expects that Part D plans will continue to comply with this policy in 2007 and subsequent plan years, and will include such assurances in their future bids and contracts. These additional types of change requests include, but are not limited to:

- Changing preferred or non-preferred formulary drugs, adding utilization management, or increasing cost sharing on preferred drugs (unrelated to the reasons stated above);
- Removing dosage forms; or
- Exchanging therapeutic alternatives (either by formulary addition/removal or tier exchanges).

If CMS disapproves a formulary change request, the justification for disapproval will generally be based on one of the following:

- The reasonableness and/or necessity for the proposed change in the context of preventing any appearance of “bait and switch” in the formulary. Medicare beneficiaries select Part D plans, in part, based on the formulary that is marketed during annual open enrollment and, therefore, have a legitimate expectation that they will have continuing access to coverage of the Part D drugs they are using throughout the plan year. This beneficiary expectation will be balanced against the plan’s desire to practice good formulary management in order to provide a low-cost, high-quality prescription drug benefit that continues to effectively meet the needs of beneficiaries. Part D plans may avoid any appearance of a “bait and switch” concern by exempting enrollees who are currently using the affected drugs from the formulary change for the remainder of the plan year.
- The proposed change on its face in the context of substantially discouraging enrollment by certain beneficiary groups.
- The impact of the proposed change on the formulary as a whole to ensure the formulary continues to satisfy the minimum formulary requirements established by CMS.

Because these additional types of change requests will require more extensive review by CMS, Part D plans must not implement such changes until they receive explicit notification of approval from CMS and must not issue any beneficiary notices of such forthcoming changes prior to receiving explicit and affirmative CMS approval.

Senate Committee on Finance
The Medicare Prescription Drug Benefit: Monitoring Early Experiences
Testimony of Tobey Schule, RPh
Sykes Pharmacy, Kalispell, MT
May 2, 2007

Chairman Baucus, Senator Grassley, members of the Committee, I appreciate the privilege and opportunity to speak to you again about Medicare Part D and how it is affecting my patients and pharmacy.

I am the co-owner of an independent pharmacy in Kalispell, Montana. Our pharmacy employs three pharmacists and two technicians. There are five senior apartment buildings within three blocks of the pharmacy. In addition, we provide services to three assisted living facilities and the mental health center in our community.

Medicare Part D has now been in place for about sixteen months. During this time we have seen many changes. When I testified before you in February 2006, pharmacies and patients were facing many obstacles. The obstacles included patients not in the system, formulary changes, low and non-reimbursement to pharmacies, and pharmacies not having the ability to identify dual-eligibles. There were long wait times on the phones and too much confusion for seniors and mental health patients in choosing a plan. I have seen many positive changes though. Dual-eligibles are more accurately identified. New identification cards have complete information and no co-branding. Patients are more readily identifiable in the E-I system. The patients' medications have been changed to meet their formularies so fewer changes are required. Reimbursement is more timely.

Medicare Part D has been a salvation for many seniors. My pharmacy serves a very limited income community. These patients' budgets were so tight that even an antibiotic prescription forced a cut somewhere else. With Part D, these patients can afford their medication.

Even with all of the improvements, issues remain to be addressed. I continue to believe choosing a plan is too confusing. Last year, Montana had over 40 plans and this year we have over 50. I still believe there needs to be a less complicated way of choosing a plan.

Although we are not having as much difficulty meeting formularies established by the insurance companies, there are still problems. Insurance companies have changed their formularies, which forces the physician, pharmacist and patient to make a change in the patient medication. Many of these formulary changes appear to be made only for the benefit of the insurance company receiving a rebate from a drug manufacturer and not for the benefit of the patient. Also, the formularies were used as a criterion in choosing a plan for the beneficiaries. How can the insurance companies be allowed to change their formularies when a patient cannot make a change in plans? This is a great example of how patient care has not been addressed.

My pharmacy provides medication to our mental health facility. We are still having issues with changing their medication. As I testified last year, these patients should not have to change medication to meet a formulary because even a minor change can result in a hospitalization. We have seen several of our mental health patients require a hospitalization or at the very least go into a mental health safe house because of a change to meet a formulary.

I am still very concerned for patients who are forced to use mail order. Our senior population needs and deserves face-to-face interaction with their pharmacist. Our mental health patients deserve the same. There is more to practicing pharmacy than handing a patient a bottle of pills. I feel mail order compromises patient care.

I have encountered many patients for whom the donut hole was devastating. Prior to Medicare Part D, these patients were able to receive free or reduced cost medication supplied by the major drug companies. These medication programs ended for these patients when their Medicare Part D became active. The cost of the medications that were previously supplied by the drug manufacturer put these patients into the donut hole. These patients were able to pay for their generic medications and would not have been into their donut hole if the programs had continued.

I am very concerned when my patients reach the donut hole because they cannot afford drugs while they are in the coverage gap. Drug costs are extremely high, especially when generics are not available. Some of the formularies require a branded drug even when a generic is available, so we have to dispense the higher cost branded drug to the patient to meet the patient's formulary. The patient has to pay these high prices until they get through the donut hole. Being in the donut hole often means patients cannot afford their drugs and are forced to go without their medication. I saw patients hospitalized because of this. I even contacted physicians to see if we could get them on a cheaper drug.

We had patients who we knew from the implementation of Medicare Part D and their insurance formularies that they would definitely fall victim to the donut hole. We made requests with the physician to make changes in the patient's medication regimen early on. Again, this was not always optimum therapy, but it was better than leaving the patient without medication because they could not afford it.

I have had physicians vent their frustrations about the insurance formularies to me. They question who is practicing medicine, the physician or the insurance companies?

We had several of our mental health patients encounter severe financial burden after the Medicare Part D was initiated. These patients were rolled out of Medicaid services where their co-pays were \$1.00 up to \$5.00. The co-pays for their medication are now \$30.00 to \$60.00 because they are on tier 2 and 3 levels on their insurance formularies. I feel the same as I did at the start of Medicare Part D. These patients should not have been forced out of Medicaid and into a Medicare Part D insurance plan.

From my perspective, pharmacies are bearing the brunt of Medicare Part D. When Part D was initiated, pharmacists were confronted with an ethical dilemma. Do they care for the patient or do they worry about their finances? It was fortunate that the majority chose to care for the patient. The first payments my pharmacy received took 75 days, with the majority of insurance companies paying in 90 or more days. I had to pay my wholesaler every 15 days. I was forced to borrow money to meet my obligations. If it were not for the pharmacists taking care of patients last year, Medicare Part D would have failed. If the pharmacy had refused to provide medications for the patients because of non-confirmed payment, these patients would have been without medication. I am convinced that many patients would have been hospitalized because of their lack of ability to get medication.

Pharmacies are required to accept the reimbursements that are dictated by the insurance companies. When I look at our reimbursements, I cannot help but think that the insurance companies make more money on the prescriptions than the pharmacy. Reimbursement is not adequate, particularly when the shortages of pharmacists and pharmacy technicians are causing salaries to increase.

In the past year, we saw many pharmacies across the country close. In the same year, we saw an increase in the number of insurance companies offering Medicare Part D coverage.

My pharmacy – with 90 percent of patients on Part D – suffered a very large financial burden because of Medicare Part D. Sykes Pharmacy showed a profit of \$81,000 in 2005 with gross sales of about \$2.2 million. The profits for 2006 were \$13,000 with gross sales of about \$2.4 million. Our prescription volume actually increased from the previous year, which should have increased profits. What is very sad is that if we would have liquidated our inventory and invested the money, we would have been able to generate more profits than operating the pharmacy. Community pharmacies are the core of community practice. If this trend continues, there will not be community pharmacy practice.

I have discussed with my colleagues, the changes both positive and negative which have occurred in pharmacy since the implementation of Medicare Part D. The overall consensus is that the insurance companies have too much control and with no transparency. Patient care is not first and foremost. True patient pharmaceutical care needs to be face to face.

Medication Therapy Management is also at the full control of insurance companies. Insurers identify the eligible patients and then provide this service in-house. A full review of the patient's medications and discussions with the patient needs to be face-to-face. Due to fraud against the elderly, we educate our patients not to accept unsolicited phone calls or give information to people they don't know. It is confusing and scary for them to receive calls from the insurance companies. When a patient is counseled about their medication, it is important to read their body language to tell if they really understand what is being discussed. Patients do not like to discuss personal issues with

people they do not know or trust. In order to be effective and in the best interest of patient care, MTM needs to be done by the patient's local and trusted pharmacist.

I also question why the Medicare program does not recognize pharmacists as providers. Pharmacists spend a minimum of 6 years in school and obtain a specialized education. They should be paid for their professional services as part of the health care delivery system. Pharmacies should not have to sell potato chips and motor oil to make a profit.

In the sixteen months that have passed with Medicare Part D in place, many things have improved for patients, community pharmacies and pharmacists. For this I am pleased and hopeful. More improvements still need to be made. Hopefully we will see improvements choosing a plan, with patient care remaining first and foremost, and in reimbursement policies to pharmacies.

Thank you again, Chairman Baucus, Senator Grassley and members of the Committee, for inviting me here today. I will be happy to answer any questions.

Sykes Pharmacy
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Chairman Baucus and Senator Grassley

Question 7

Both Chairman Baucus and I have a particular interest in the medication therapy management requirement. The purpose of the requirement is to assure that Part D covered drugs are used appropriately, to optimize therapeutic outcomes and to reduce adverse events. What has been your experience in participating in these programs?

Answer

I personally have not seen the medication therapy management being successful. In 2006, my pharmacy only performed 2 cases. They were both from Community Rx.

Currently we have received 4 cases that will be done in the next week. These also are from the Community Rx. This is the only insurance company that has presented cases to us.

There needs to be a check and balance with the insurance companies. They are the ones that identify the patients for the medication therapy management and then they perform them in house. It is imperative that medication therapy management be performed by the patients own pharmacist, who they know and trust.

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**Testimony of the American Pharmacists Association
Timothy L. Tucker, PharmD, President-Elect**

**Before the Committee on Finance
United States Senate**

**Hearing on
The Medicare Prescription Drug Benefit: Monitoring Early Experiences
May 2, 2007**

Good morning. Thank you for the opportunity to appear before you today and present the views of the American Pharmacists Association. I am Tim Tucker, a pharmacist and the President-elect of APhA. I have been in practice for 19 years and currently own a community pharmacy in Huntingdon, Tennessee. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the military.

We appreciate the Committee's commitment to providing oversight of this important benefit. As we look to the program's future, it is important to take advantage of what we have learned from the first year's successes and failures to address the program's weaknesses. The Medicare Part D prescription drug benefit took the important step of providing Medicare beneficiaries access to prescription medications — one of the primary tools in health care's tool kit. As a result, pharmacists believe it is imperative that we make this benefit work and their efforts to date reflect this commitment. While largely a success — due to pharmacists' efforts, as well as the work of the Centers for Medicare and Medicaid Services (CMS) and other agencies — challenges continue to impact pharmacists and their ability to help patients make the best use of their medications. Because of pharmacists' critical role administering the benefit, it is essential to fix the problems that impede pharmacists' ability to work within the program.

Although my written testimony references survey results from several surveys that we conducted in 2006, my oral comments will reference results from a survey we conducted this week of our members.

Pharmacy Reimbursement: The Low and Slow of Part D

Medicare Part D has had a dramatic impact on the business of pharmacy. Contracting and reimbursement issues continue to plague pharmacy. These issues include unfair negotiation tactics, delayed updates of pricing metrics, low reimbursement levels, delayed payments, and a lack of pricing transparency. Some of these issues are amplified for the pharmacies serving low-income or uninsured patients.

Unfair "Negotiations"

The program architects assumed that providing pharmacies the authority to negotiate would provide pharmacies the opportunity to negotiate contracts that meet their individual pharmacy's needs. Unfortunately, pharmacies are often faced with two scenarios, neither of which represents the spirit of the law.

First, pharmacies are offered "take it or leave it contracts". Just as they sound, these contracts force pharmacies to accept contract terms without an opportunity to negotiate rates. Second, pharmacies are offered contracts that are "tied" with other contracts. In these cases, a Part D plan links the Part D contract to other contracts that the pharmacy may have with the Plan for other, non-Medicare Part D populations. If the pharmacy chooses to contract with the Plan to serve Part D beneficiaries, then the pharmacy can retain its other contracts with the Plan. But if the pharmacy declines the Part D contract, then the pharmacy also loses its contracts for the other, non-Medicare Part D populations.

The contracting situation is even worse for many of the pharmacies and healthcare entities that form the nation's safety net and provide care for the uninsured. Although Part D plans are encouraged to include safety net pharmacies in their networks, many part D plans have ignored or systematically excluded these pharmacies from their contracting activities.

Some safety-net entities are not able to meet the standard terms of a Part D contract due to formulary restrictions, or other constraints based on their Federal funding to care for the uninsured or specific patient groups. The Health Resources and Services Administration (HRSA) worked with CMS to develop a Model Safety Net Pharmacy Addendum to Pharmacy Contract for Part D. The Addendum was designed to bridge the standard contract terms that many safety net providers are not able to meet. APhA applauds these efforts by HRSA and CMS. Unfortunately, many Part D plans are avoiding safety-net providers, or offer severely reduced reimbursement rates. Consequently, these pharmacies and their already vulnerable patients are less able to reap the benefits of Part D. Until the business and financial incentives for the plans align with the public policy concerns of including safety net pharmacies, these pharmacies – and their patients – will continue to be excluded from meaningful participation in Part D.

At a minimum, greater oversight of plan contracting processes is required to ensure that community pharmacy can continue to serve Medicare Part D beneficiaries. Additionally, we recommend that Congress consider providing an anti-trust exemption to allow individual pharmacies to collectively negotiate with Part D plans. This step would go a long way in helping level the “negotiation” playing field.

Low Reimbursement

Because of the lack of opportunity for pharmacies to negotiate their contracts with Part D plans, pharmacies have been forced into contracts that do not cover their costs. To ensure that Medicare beneficiaries continue to have access to community pharmacies, additional oversight of pharmacy reimbursement must be established. This oversight would provide greater assurances that a pharmacy’s costs associated with acquiring a drug product are covered, and that Part D plans provide pharmacies a “reasonable” dispensing fee to cover the pharmacy’s costs associated with dispensing the product. The fee would cover salaries, overhead, and a reasonable profit and would be based on data from relevant “cost to dispense” studies. Reimbursement rates must include a fair return to the community pharmacy that has elected to participate in the program. Absent these assurances, pharmacies will continue to be asked by Plans to dispense Part D drugs at a financial loss.

Slow Reimbursement

Some Part D plans have also challenged the financial viability of pharmacies by unnecessarily delaying their payments. While we have seen some improvements in the program, some pharmacies continue to endure lengthy payment delays for medications dispensed to patients. Pharmacies cannot sustain long delays in payment particularly since those with whom pharmacy contracts, such as wholesalers, are enforcing penalties for any delayed payments from pharmacies.

In our December, 2006 survey, respondents (59) indicated that on average: none were reimbursed by the plans with whom they contract within 14 days; 14% were reimbursed by the plans with whom they contract within 15-21 days; 15% were reimbursed by the plans with whom they contract within 22-30 days; 12% were reimbursed by the plans with whom they contract within 31-60 days; and 7% reported that it took the plans longer than 60 days to reimburse the pharmacy. One respondent to the August, 2006 survey reported that their group purchaser showed about \$60,000 of outstanding receipts of over 90 days from about 4 or 5 Part D Plans. The December, 2006 survey revealed the various ways pharmacies have addressed these cash flow problems. Seventeen percent of survey respondents reported negotiating extensions with wholesalers; 9% reported taking out a business loan/line of credit; 7% reported taking out a personal loan/line of credit; 10% reported laying off staff; and 3% reported reducing pharmacy hours.

Likely due to pharmacy’s expressed concern regarding ongoing delays, CMS surveyed Part D plans on the frequency of their payments to pharmacies. CMS reported that their survey results indicated that of the 20 plans that responded, all reported that their contracts require them to pay pharmacies within 15 days. In a July 6, 2006 letter to the Agency, APhA disputed CMS’ survey method. APhA suggested that a mere review of contract terms does not reflect actual reimbursement practices and to truly gain insight into how frequently pharmacies are paid, CMS should survey pharmacies. The weakness of CMS’ survey is exemplified by the reports APhA received of pharmacists receiving multiple reimbursement checks in one envelope. Although the Part D plans may cut reimbursement checks every 14 days, as per the terms of the contract, they waited to mail the payments until multiple checks were cut. Clearly, more needs to be done ensure that plans are complying with the letter and the spirit of their contract terms. It is egregious to place this financial burden on the backs of pharmacy. In addition to increasing oversight in this process, we strongly recommend

establishing a "prompt payment" standard that would require plans to pay pharmacies every 14 days for electronic claims and every 30 days for paper claims.

Electronic Funds Transfer

As we have described, the business of pharmacy is heavily reliant on a timely cash flow and cannot sustain long delays in payment. The manner in which pharmacy claims are submitted to Part D plans should influence the timeliness of pharmacy payments. Ideally, electronically submitted claims would be paid through electronic payments to pharmacies – much like many of us do with our own personal banking. We appreciate the efforts of the Chairman, Ranking Member and Committee members to facilitate electronic transfers of funds. Despite these efforts and those of the American Health Insurance Plans (AHIP) to ensure that electronic funds transfer (EFT) is adopted by Part D plans as a payment standard, pharmacies continue to encounter issues with this method of payment. We strongly recommend requiring Part D plans that receive pharmacy claims electronically to send pharmacy payments electronically through a real-time EFT system.

Delayed Pricing Metric Updates

Even if a contract allowed for fair reimbursement and pharmacies were paid promptly, unless the payment metrics upon which a pharmacy's reimbursement is based are updated on a timely basis the pharmacy may face financial losses. APhA appreciates the efforts of the Chairman, Ranking Member, and other Committee members to address delayed pricing metric updates. Our members continue to report that prescription drug plans are delaying updates to their Average Wholesale Prices (AWPs). This practice disadvantages pharmacists by basing their reimbursement on the outdated AWPs, which are often lower than the current AWPs.

Without regular updates to the database used to reimburse pharmacies, pharmacies are at risk for being underpaid for the prescriptions they dispense. Because pharmacies are expected to pay current 'real time' prices to manufacturers and wholesalers from which they purchase drugs, it is only fair that plans pay pharmacies based on the current prices at which pharmacies are purchasing drugs. To ensure that pharmacies are receiving appropriate compensation that reflects the latest available data, we support your recommendation to require pricing metric updates the same day that the Plan receives an AWP change. Absent this change, pharmacies will continue to be underpaid for prescriptions.

Generic Drug Pricing Transparency

Part D contracts with pharmacies often fail to include information about payment rates for generic drugs that is essential to pharmacies' ability to anticipate and plan for business costs. APhA recommends requiring plans to disclose their reimbursement terms for generic drug products. The terms should detail how the plan will reimburse pharmacies for the generic drug products they dispense to Part D beneficiaries, to which generic drug products these reimbursement rates will apply, and how frequently these rates will change. Absent this information, pharmacies enter into contracts without the access to the elements required for them to accurately predict the reimbursement they will receive from plans for generic drug products.

"Direct Negotiation"

Current "direct negotiation" proposals lack sufficient detail for APhA to take a position on them. Absent these additional details, APhA is left to hypothesize about how direct negotiation and striking the non-interference clause would impact pharmacy reimbursement for the drug product and the dispensing-related pharmacist services that are reflected in the dispensing fee.

Some argue that pharmacy could fare better because the government would be authorized to 'interfere' in the negotiations between pharmacies and prescription drug plans and/or their PBM colleagues. However, others argue that pharmacy could fare worse because of the government's track record on pharmacy reimbursement. In the Medicaid program, the average pharmacy dispensing fee is about \$4 when it costs on average about \$10 to dispense a medication.¹ Those who oppose direct negotiation suggest this low reimbursement would be replicated in Medicare Part D. APhA will wait to take a position on current direct negotiation proposals until greater details are available about how drug products and pharmacist services would be reimbursed.

¹ National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies, Grant Thornton LLP, January 2007

Plan-to-Plan Claim Reconciliation

When a beneficiary switches plans it isn't always clear to the pharmacist dispensing the prescription which plan, or that even a new plan, should be billed. Sometimes the information on the new plan isn't presented to the pharmacist and the pharmacist inadvertently bills the wrong plan. This situation often occurs with dual-eligibles who can switch plans at any time. When an incorrect billing occurs, pharmacies are asked to re-bill the claim to the "correct" plan. To do this requires a lot of administrative work for the pharmacy, which has no responsibility for the accuracy of the Part D database used to bill pharmacy claims. We strongly encourage the Committee to direct CMS to implement a "plan to plan" reconciliation process to eliminate the need for plans to use pharmacies as billing intermediaries. Plans could directly bill other plans, removing the need to use community pharmacies as billing arbitrators.

Formulary Management

Formularies are a common pharmacy benefit management tool that when well-designed can provide patients access to medications while balancing cost and clinical effectiveness. APhA opposes formularies that unfairly limit – through administrative, financial, or other means – patient access to necessary medications. Severely limiting patient access to necessary medications would make the Part D benefit an empty promise.

Standardization

A commonly reported administrative burden for pharmacists is the time and effort required to manage each individual plan's formulary because each formulary is different in what it requires of the pharmacist, patient, and prescriber. For example, the message the plan communicates to the pharmacist and whether it provides "actionable" information, the forms that are required to process a prior-authorization or exceptions request, how and to whom the forms must be transmitted, and the required information can differ for each plan. Because pharmacists play an integral role in implementing formulary management tools for patients, it is essential that they have the information that they need to execute a plan's processes.

The results of APhA's December, 2006 survey reflected the various ways plans are responding to claims for non-formulary drugs. The following represent what the 59 survey respondents identified as plan actions: 85% reported that plans rejected claims; 44% reported that plans provided formulary alternatives; 86% reported that plans required prior authorization; and 29% reported that plans were required an exceptions request. Such a high number of rejected claims that require prior authorization or an exceptions request demands that more be done to reduce the administrative burden on pharmacists who must take the initial step of communicating the plan's required information to the patient's prescriber to facilitate a prior-authorization or exceptions request.

CMS recognized the challenges of these formulary management tools and encouraged the industry to standardize prior-authorization processes. Industry created a workgroup in which APhA participates. The workgroup has focused on creating standardized claims messaging. Two of the five messages were adopted by the National Council for Prescription Drug Programs (NCPDP), the standards development organization for transmission of pharmacy claims data. While this was an important first step, the need for the messages remains. Our December 2006 survey found that only 29% of the claims messages returned by plans provided specific, actionable information more than 50% of the time. Clearly, more needs to be done.

Prescriber Participation

Formulary management issues remain the number one complaint of APhA members regarding the administration of the Part D benefit. Some of this reflects an ongoing issue with prescriber involvement in this process. Pharmacists continue to report that a large number of physicians, frustrated by the uncompensated and burdensome work required to facilitate formulary management decisions, will not respond to formulary requests from pharmacists. This is reflected in the same APhA December 2006 survey in which 59 respondents reported on their experience with prescribers regarding prior authorization or exceptions requests: 34% reported that prescribers were very willing to complete the process; 85% reported that prescribers relied upon the pharmacist for plan and formulary alternative information; 15% reported that prescribers required patients to schedule office visits to resolve formulary issues; 63% reported that prescribers refused or delayed requests because of lack of time; and 31% reported that prescribers would not participate in the process.

Formulary Management Recommendations

Some of these issues could be resolved if plans shared their formulary information with pharmacists, prescribers and patients. Such sharing would facilitate patients making better informed plan choices, prescribers making better educated decisions about what medications to prescribe to their patients, and pharmacists better understanding their patients' options when faced with a plan rejection of a claim for a prescribed medication. Current postings are sporadic, difficult to find (nearly impossible without Internet access) and confusing.

To address remaining issues with formulary management, APhA recommends:

- Conducting outreach to the prescribing community to ensure their participation in formulary compliance.
- Requiring plans to provide "actionable" messages in formulary edits that give pharmacists the information necessary to facilitate a plan formulary decision.
- Requiring plans to standardize tier processes, to standardize electronic claims, and to use the standardized "Medicare Part D Coverage Determination Request Form".
- Requiring plans to provide easily accessible formulary information to pharmacists, preferably in a downloadable format.
- Requiring plans to share formulary-related communications with pharmacists and prescribers.
- Similar to the administrative fee CMS pays states, compensating pharmacists for their formulary compliance efforts.
- During the annual renewal process, expanding the evaluation of plans to include the plan's administration of prior authorizations and step therapy, and processing of exceptions requests.

Medication Therapy Management: Increasing Our ROI**MTM 2006: Missed Opportunities**

Understandably, CMS has focused its implementation efforts on getting medications to patients. However, it is time to look comprehensively at the program and at how to improve the nation's investment in Medicare Part D by ensuring that patients make the best use of their medications. The medication therapy management (MTM) programs that Part D plans are required to provide a subset of Medicare beneficiaries were expected to generate these outcomes. Described as a "cornerstone" of the new prescription drug benefit, MTM services are an essential component of effective patient care. Generally speaking, MTM programs compensate pharmacists for providing a range of clinical services to patients, including educating patients about their medication and the conditions for which the medications are prescribed, reviewing a patient's medication regimen, developing a medication action plan to address identified issues, monitoring a patient's medication therapy over time, screening for potential adverse effects of medication, and monitoring a patient's ability to take his/her medication correctly².

Unfortunately, most plans have fallen short of the mark. The cost of a plan's MTM program is part of the Part D plan's administrative. Because the program does not have a separate payment for MTM services, there is little to no incentive for a stand-alone prescription drug plan (PDP) to provide a robust MTM program. MTM is seen simply as a cost to be squeezed out of their administrative fee. The MA-PD programs have a greater incentive to provide a "robust" MTM program because they will capture savings in their medical benefit from healthier patients that may experience fewer physician office and emergency department visits — a result of many well designed MTM programs.

From November 2005 to April 2006, APhA conducted a telephonic and email survey of large and national health insurance plans to learn about the construct of Part D MTM programs for 2006³. The method of service delivery reported by the plans was variable and ranged from mailed information (76%) to telephone call centers (90%) to face-to-face visits (19%) between a patient and clinician (primarily pharmacists). Some plans (28%) offered a "tiered" MTM benefit in which all targeted beneficiaries were eligible for "low intensity" services such as mailed educational materials, but a subset of beneficiaries meeting specified criteria were eligible for "high intensity" face-to-face consultations with a

² The MTM Consensus Definition is located at:

<http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=4577&TEMPLATE=/CM/ContentDisplay.cfm>

³ Touchette, DR, Burns, AB, Bough, MA, Blackburn, JC. Survey of Medicare Part D Plans' Medication Therapy Management Programs. *J Am Pharm Assoc.* 2006;46:683-691.

clinician, primarily pharmacists. Patient education, adherence programs, and medication reviews were the most common types of services offered by the plans. The number of chronic conditions required to receive MTM services ranged from 2-6 and the number of medications ranged from 2-24. Twelve of the 21 MTM programs further required targeted beneficiaries to have chronic diseases from a specified list. This early data suggests that more may need to be done to align the incentives to facilitate more beneficiaries receiving more robust MTM.

MTM: The Other Half of the Story

Focusing on product cost is only half of the medication use story. As more high-tech medications are developed, more patients are being asked to self-manage their diseases. In many cases, what used to be accomplished through an invasive medical procedure is now treated with medication therapy. While a positive medical advancement, these medication regimens may be more complicated for a patient to self-manage. Outside the hospital or nursing home, patients — not physicians or pharmacists — must manage their medications. And the data supports that patients are not always given the tools necessary to effectively manage their medication therapy alone.

Each year, Americans spend more than \$75 billion on prescription and nonprescription drugs. Yet, a study published over a decade ago in the Archives of Internal Medicine⁴ noted that more than \$76 billion is spent on preventable drug-related medical problems caused by improper medication use. In a 2000 update to this study⁵, the cost of drug-related morbidity and mortality in the ambulatory setting had risen to exceed \$177 billion. Furthermore, an independent study⁶ conducted by researchers at the David Geffen School of Medicine, University of California, Los Angeles, concluded that when initiating new medications, physicians often fail (up to 65% of the time) to communicate critical elements of medication use to the patient. And, a recent report of the Institute of Medicine (IOM) report, *Preventing Medication Errors: Quality Chasm Series* identified multiple challenges consumers face when using medications that result in billions of dollars unnecessarily being spent by patients and the healthcare system. These statistics support stepping away from our current silo approach of focusing only on product cost and looking at other factors that contribute to our rising health care budget, such as ensuring that patients are receiving the full benefit of their medications.

Provided the opportunity, pharmacists, working with patients and physicians, are the best equipped and positioned to address many medication related problems and improve medication use. The Institute of Medicine (IOM) agrees. In its recent report, *Preventing Medication Errors: Quality Chasm Series*, the IOM recommends that patients be empowered for safe and effective medication self-management. It also suggests that pharmacists address these problems by becoming the managers of patients' medication health.

MTM: Results

A few examples of MTM improving health and saving health care dollars include:

- A long term assessment of the clinical, economic, and humanistic outcomes of community pharmacists providing MTM for patients with asthma found that: all subjective and objective measures of asthma improved; emergency department visits and hospitalizations decreased; and while medication costs increased, asthma-related medical claims decreased with estimated direct cost savings of \$725 per patient per year⁷
- The medication therapy management services of pharmacists in 1000 hospitals saved nearly 400 lives and \$5.1 billion in health care costs^{8,9}.
- Patient compliance with medication for high cholesterol improved from a national average of 40% to 90% with medication therapy management¹⁰.

⁴ *Archives of Internal Medicine*, Vol. 155, Oct. 9, 1995, pp. 1949-1956.

⁵ Ernst FR, Grizzle, AJ. Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model. *Journal of the American Pharmaceutical Association*. 2001; Mar-Apr; 41(2):192-199

⁶ *Archives of Internal Medicine*, Vol. 166, Sept. 25, 2006, pp. 1855-1862.

⁷ The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. *J Am Pharm Assoc*. 2006;46(2):133-47.

⁸ Bond CA, Raehl CL, Pitterle ME, Franke T. Health care professional staffing, hospital characteristics, and hospital mortality rates. *Pharmacotherapy* 1999; 19(2):130-8.

⁹ Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacy staffing, and the total cost of care in U.S. hospitals. *Pharmacotherapy* 2000 June; 20(6):609-21.

¹⁰ Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in Project ImPACT: Hyperlipidemia.

- Pharmacists providing MTM services to patients in long-term care facilities increased the number of patients receiving optimal care by 45% - resulting in an estimated \$3.7 billion in cost avoidance¹¹.
- Patients treated with blood thinners in a pharmacist-managed anticoagulation clinic had fewer emergency room visits, fewer hospitalizations, and showed a total cost savings of \$1,621 per patient¹².

The idea of providing comprehensive pharmacist services to patients to empower them to self-manage their medication health is not new to the federal government. The Department of Veterans Affairs has provided MTM services to their patients for years. Pharmacists' services at a Veterans Administration outpatient clinic reduced the number of medications taken by an average of 2.4 prescriptions per person¹³. With such improved patient outcomes and reduced health care expenditures, there is little doubt that MTM services, given a chance, could contribute considerably to the efforts to increase the Medicare program's return on investment in pharmaceuticals. Unfortunately, these opportunities have not yet been secured within the Medicare Part D benefit.

APhA Foundation: Empowering Patients

Support for providing MTM to patients continues to grow within the private sector. The APhA Foundation's Patient Self-Management Program (PSMP) uses the accessibility and skills of community pharmacists to benefit employers and their employees with chronic illnesses. The success of this model has been replicated in communities large and small throughout the country; and it could be applied to the Medicare program.

In the Foundation's model, an employer (or a coalition of employers within a community) works with the APhA Foundation to provide this voluntary benefit to its employees. Participating employees are then matched with a pharmacist from a network of providers. The pharmacist conducts one-on-one meetings with the employee and follows a process of care established by the APhA Foundation specifically for this program. The pharmacist serves as a "coach" and provides counseling and education with regards to the patient's disease, medication therapy, and lifestyle choices. This relatively simple intervention has led to remarkable results. In the well known "Asheville Project," average net savings of \$1,600-\$3,200 per person with diabetes, in the program, were realized each year from year two on.¹⁴

More than 40 employers have recognized the value added by pharmacists as evidenced by their replication of the Asheville model for their own employees through the APhA Foundation's most recent initiative, the Diabetes Ten City Challenge. The Challenge is an innovative program that employers and communities can use to fight diabetes and reduce health care costs. Employer groups in ten communities were invited to establish a voluntary health benefit for employees and dependents. Using incentives, employers encourage people to manage their diabetes with the help of pharmacist coaches, physicians, and community health resources. Current participants include the following employers: Pittsburgh Business Group on Health; Northwest Georgia Healthcare Partnership; Hawaii Business Health Council, Honolulu; City of Milwaukee; The Charleston/Spartanburg South Carolina Area; University of Southern California; Manatee County Government and Pinellas County Sheriff's Office, Tampa Bay Area; City of Colorado Springs; Midwest Business Group on Health, Chicago, IL; and Western Maryland Health System, Cumberland, MD.

This model has proven so successful that on May 1, 2007, the non-profit National Business Coalition on Health (NBCH) announced a partnership with the American Pharmacists Association Foundation to implement a patient self-management program modeled after the Asheville Project. The NBCH has a membership of nearly 70 employer-led coalitions across the United States, representing over 10,000 employers and approximately 34 million employees and their dependents.

Journal of the American Pharmaceutical Association 2000; 40(2):157-165.

¹¹ The Fleetwood Project, American Society of Consultant Pharmacists.

¹² Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care. control, patient outcome, and health care costs. *Archives of Internal Medicine* 1998; 158: 1541-7.

¹³ Galt KA. Cost avoidance acceptance, and outcomes associated with pharmacotherapy consult clinic in a Veterans Affairs medical center. *Pharmacotherapy* 1998 Sept.-Oct.; 18(5): 1103-11

¹⁴ Garrett DG, Blum BM. Patient Self-Management Program for Diabetes: First-Year Clinical, Humanistic and Economic Outcomes. *Journal of the American Pharmacists Association*; 2005 March/April; 45(2): 130-137.

The newly announced project will involve developing resources and providing technical assistance to NBCH members who wish to implement a patient self-management program for their employees.

State-based Medicaid MTM Programs

Several states, including Iowa, Minnesota, Missouri, and North Carolina are currently offering MTM services to Medicaid beneficiaries, and more states are considering adding an MTM benefit. The Iowa Medicaid Pharmaceutical Case Management (PCM) Program, implemented in 2000, targets high risk patients who take four or more regularly scheduled non-topical medications, are not nursing home residents, and who have at least one of twelve select disease states. Pharmacists perform face-to-face comprehensive medication reviews with the patient, then conduct ongoing patient monitoring to address medication problems. An evaluation of the initial phase of this program found that patients receiving PCM services had a statistically significant improvement in the Medication Appropriateness Index (MAI), and the percentage of PCM patients using high-risk medications decreased significantly.¹⁵ A similar program was initiated in Minnesota in April 2006.

Barriers to "Robust" MTM

The results of the APhA Foundation projects are remarkable and replicable. It is time to provide Medicare beneficiaries the opportunity to share in these successes. MTM will remain a missed opportunity if improvements are not made to the current Medicare MTM benefit. To further the development of and patient access to robust MTM programs, APhA recommends removing current barriers to robust MTM, which include:

- Lack of standardization in MTM service design.
- Variability in how patients are targeted.
- Lack of standardized documentation and billing requirements for MTM services.
- Inconsistent contracting processes that do not ensure patients' ability to receive MTM from their pharmacist of choice.
- Disruption in continuity of patient access to MTM services. Each year plans must re-determine which of their enrollees are eligible for MTM. This results in a lag time where patients do not receive MTM services.
- Inadequate promotion (via the Plan Finder) of MTM service benefits to patients.
- Lack of access to important health care information, such as the diagnosis and laboratory data, needed to perform comprehensive medication therapy management.
- Deficiencies in required "robust" outcomes measures for the MTM benefit. PQA, a pharmacy quality alliance, is working in collaboration with CMS to develop performance measures to measure pharmacy and pharmacist performance.
- Inappropriate plan incentives, such as requiring that MTM be part of a plan's administrative fee
- Absence of links between Part D and Parts A and B data hampers abilities to evaluate overall impact of MTM services.

APhA is working diligently to make MTM a reality for Medicare patients. In addition to various products to prepare pharmacists, APhA is also working to establish policies to advance MTM. These efforts involve collaboration with other colleague national pharmacy organizations¹⁶ to make MTM a reality for Medicare patients. This coalition is currently developing policy proposals that will advance the quality and effectiveness of MTM provided to Medicare beneficiaries.

Patient Access to Pharmacist of Choice

Ensuring Patient Access to Community Pharmacies

Under the "any willing pharmacy" provision of the Medicare Modernization Act, plans are required to allow any pharmacy that is willing to accept the plan's terms and conditions to participate in the plan's pharmacy network.

¹⁵ Chrischilles EA, Carter BL, Lund BC, et al. Evaluation of the Iowa Medicaid pharmaceutical case management program. *J Am Pharm Assoc.* 2004;44(3):337-49.

¹⁶ Academy of Managed Care Pharmacy, American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, and the College of Psychiatric and Neurologic Pharmacists

However, we received numerous reports of plans that informed pharmacies that they must join the plan's pharmacy network by a specific date or they would be locked out from the plan's pharmacy network. To address these issues, APhA recommends:

- Requiring plans to allow any pharmacy willing to accept the plan's terms and conditions to participate in the plan's pharmacy network at any time – preventing plans from establishing arbitrary deadlines to lock pharmacies out of the plan's network.
- Providing incentives to Part D plans to have safety-net pharmacies participate in the program while not permitting plans to penalize these pharmacies with reduced reimbursement rates.

90-Day "Extended" Supplies

As you know, the Medicare Part D program was designed to allow Medicare beneficiaries to access a 90-day supply of their medications at their pharmacy of choice. The intent of this provision was to "level the playing field" between retail and mail-service pharmacies and give community pharmacies the same opportunity to provide a 90-day supply of medications under the same terms and conditions as a mail-service pharmacy; any differential in charge (between the community and mail-service) is paid by the beneficiary.

We appreciate the efforts of the Chairman, Ranking member, and Committee members to ensure patient access to extended (90-day) supplies of Part D drugs at community pharmacies. Unfortunately, despite these efforts, it does not appear that this "level playing field" provision is being implemented as intended. Our members report that the reimbursement rates that are being offered to them are too low for them to accept and pharmacist attempts to negotiate with the plans are rejected. Therefore, we strongly recommend additional oversight of this provision to ensure that the practical application of the law meets Congress' intent to provide patients access to extended medication supplies at their pharmacy of choice.

Enrollment/Eligibility

An ongoing challenge with the program is the lack of a monthly enrollment deadline. Although CMS encourages beneficiaries to enroll or switch plans before the 15th of any month, nothing prevents beneficiaries from enrolling or switching plans at any time. When a data lag occurs, pharmacists are faced with angry and confused patients and insufficient information to process the claim. While some systems have been implemented to try to help pharmacists manage this situation, we strongly recommend changing the enrollment requirements to avert the data lag issue. APhA recommends:

- Setting a date certain, such as the 15th of the month, by which a beneficiary must enroll in a plan in order for their benefits to "kick in" by the first of the next month.
- Limiting dual-eligible plan switches to quarterly deadlines.
- Compensating pharmacists for their enrollment and eligibility verification efforts. Ninety percent of respondents to a December 2006 APhA survey reported that they were helping patients compare and evaluate Medicare Part D plans for the 2007 benefit.

Part B vs. Part D Payment

The addition of the Part D benefit to the Medicare program created confusion with regard to how to bill certain medications that had previously been covered by Medicare Part B. The decision of whether Part B or D pays depends on where the drug is administered or dispensed and for what condition the drug is being used. CMS has provided guidance to prescribers, pharmacists, and plans on when a medication should be billed to Medicare Part D or Medicare Part B.

Unfortunately, despite CMS' efforts to rectify this situation, this B versus D situation remains an administrative burden for pharmacists. Our members have reported that plans are unnecessarily delaying payments — and therefore, potentially, patient care — by requiring proof for these medications above and beyond what should be necessary to process the claim. While we support efforts by plans to ensure they pay only legitimate claims, these delay tactics must be stopped. Results of a September, 2006 APhA survey (77 respondents) provides some insight: 74% responded that plans were requiring a diagnosis; 16% were requiring an indication; 31% were requiring a statement from the prescriber; and 32% were requiring proof of denial from Part B.

It is very difficult and sometimes impossible to get a paper claim rejecting a Part B claim. In most cases, the Part B claim would be rejected via an electronic message, therefore obtaining a paper copy of the claims rejection forces the pharmacist to call Medicare Part B administrators. This effort delays patients receiving their medication unless they are willing to pay out-of-pocket, which is not an option for many beneficiaries particularly those taking expensive medications, such as medications for organ transplants. To address these concerns, APhA recommends:

- Providing plans additional information on what medications should be covered by Medicare Part B versus Medicare Part D.
- Monitoring plan compliance with B/D directives to ensure only minimally necessary procedures are required of pharmacists and prescribers and that coverage decisions are not unnecessarily delayed.
- Requiring prescribers to include the indication for the medication on all prescriptions.

Other Operational Issues

While we have provided details on many issues that continue to impact pharmacists and patients, a few more operational issues remain. We encourage the Committee to consider these as they work to improve the Medicare Part D prescription drug benefit:

- Provide additional oversight of plans
- Secure the current co-branding exemption, which was done through Agency guidance, in federal law and extend the co-branding exemption to all marketing materials.
- Educate beneficiaries about the gap in coverage, the "donut hole" to avoid patient confusion.

Conclusion

A medication's value cannot be measured simply by cost; it must include its effect on a patient's health. An improperly used or unused medication is, ultimately, the most expensive medication. While we seek ways to improve the return on investment in our health care system, we must look beyond medication cost and focus on improving medication use. This is where we can create the real value. Improving medication use requires that patients understand their medications and how to use them. Pharmacists are best equipped to help them accomplish this. The benefits of MTM are clear both financially and clinically. As a result, APhA strongly encourages the Committee to include in its review of Medicare Part D the prospect of expanding access to pharmacist-provided MTM to Medicare beneficiaries and to limit the administrative burdens we have outlined that impact the pharmacist's ability to provide patient care services.

Thank you for your consideration of the views of the nation's pharmacists. APhA looks forward to working with the Committee to improve the program through a more effective system of providing prescription medications to Medicare beneficiaries.



American Pharmacists Association®
Improving medication use. Advancing patient care.

**American Pharmacists Association
2007 Medicare Part D Survey
Results**

General Overview

1. What is your overall impression of the administration of the Medicare Part D program?
(n=478)

Very satisfied	2%
Somewhat satisfied	29
Neutral	17
Somewhat dissatisfied	30
Very dissatisfied.....	22

2. Compared to 2006, how has the administration changed?
(n=478)

Dramatically better	2%
Better	35
No change	47
Worsened	13
Dramatically worse.....	3

3. In general, has the Medicare Part D program improved the ability of your patients to access affordable and necessary medications?
(n=478)

Yes.....	61%
No	30
Don't know	9

Medicare Part D Challenges

4. In 2007, what challenges have you experienced in dispensing prescription medications through Medicare Part D? *(Please select all that apply.)* (n=448)
- | | |
|--|-----|
| No challenges | 3% |
| Inaccurate information from CMS | 33% |
| Inaccurate information from the plan | 47% |
| Lack of response from the plan | 47% |
| Dual-eligibles switching plans | 50% |
| Low income beneficiaries switching plans | 36% |
| Patients' inability to pay their share of costs under the plan | 50% |
| Formulary requirements (including prior authorization and step therapy programs) | 84% |
| Other (specify) | 21% |
5. How does the number of problems with Medicare Part D plans compare with the number of problems with other commercial third-party payors? (n=448)
- | | |
|--|-----|
| Medicare Part D problems are more numerous | 54% |
| About the same number of problems | 43 |
| Fewer problems | 2 |
6. How does the time it takes to resolve a Medicare Part D problem compare with the time for resolving a problem with other commercial third-party payors? (n=448)
- | | |
|---|-----|
| Medicare Part D problems take more time | 56% |
| About the same amount of time | 42 |
| Less time | 1 |

Effect on the Pharmacy

7. What effect has the implementation of Medicare Part D had on your pharmacy practice? *(Please select all that apply.)* (n=436)
- | | |
|--|-----|
| No effect on pharmacy practice | 4% |
| Less time to counsel patients | 49% |
| Provided opportunity to work with patients on choice of plan and better understand their needs | 23% |
| Negative cash flow | 53% |
| Increased overall pharmacy revenue | 6% |
| Lower profit margins | 69% |
| Hired more staff to help resolve issues | 17% |
| Increased number of prescriptions | 26% |
| Paid more overtime for staff to resolve problems | 20% |
| Severely impaired workflow | 38% |
| Increased number of patients | 20% |
| Other (specify) | 14% |

8. What cash flow problems have you had to address? *(Please select all that apply.)*
 (n=436)
- Negotiate extensions with wholesalers24%
 - Take out a business loan/line of credit.....21%
 - Take out a personal loan/line of credit13%
 - Lay off staff13%
 - Reduce pharmacy hours6%
 - No action taken26%
 - No cash flow problems experienced3%
 - Don't know30%

Formulary Management

9. How are plans responding to claims for non-formulary drugs? **Note:** This question does not relate to a plan's transition supply. *(Please select all that apply.)*

- (n=429)
- Paying the claim as submitted3%
 - Providing a temporary 30-day supply.....21%
 - Providing a 1-week or less temporary supply10%
 - Rejecting the claim.....81%
 - Providing formulary alternatives.....41%
 - Requiring prior authorization.....81%
 - Requiring an exceptions request.....30%

10. What has your experience been with prescribers in regard to prior authorization or exceptions requests? *(Please select all that apply.)*

- (n=429)
- Very willing to complete the process15%
 - Rely on pharmacist for plan and formulary alternative information78%
 - Require patient to schedule office visit.....13%
 - Require patient to pay prescriber a processing fee unrelated to an office visit9%
 - Refuse or delay because of lack of time.....68%
 - Will not participate.....34%

11. What percentage of the claims messages returned by plans provide specific, actionable information?

- (n=428)
- 0%.....1%
 - 1%–10%22
 - 11%–25%26
 - 26%–50%29
 - 51%–75%16
 - 76%–99%5
 - 100%.....1

Product Reimbursement

12. Overall, were the plans willing to work with your pharmacy to negotiate contracts and reimbursement rates?
(n=420)
- | | |
|-----------------------------------|----|
| Yes..... | 8% |
| No..... | 47 |
| Did not attempt to negotiate..... | 44 |
13. Did the Medicare Part D plans "tie" the Part D contracts with other contracts you already held with the plan?
(n=420)
- | | |
|----------|-----|
| Yes..... | 50% |
| No..... | 50 |
14. On average, how long does it take for Part D plans to reimburse you?
(n=420)
- | | |
|-----------------|------|
| Same day..... | <.5% |
| 1-7 days..... | <.5 |
| 8-14 days..... | .2 |
| 15-21 days..... | .6 |
| 22-30 days..... | 15 |
| 31-45 days..... | 22 |
| 46-60 days..... | .8 |
| 61+ days..... | .3 |
| Don't know..... | 43 |
15. What percentage of the Medicare Part D plans that you accept at your pharmacy do you bill electronically?
(n=420)
- | | |
|-----------------|------|
| 0%..... | -- |
| 1%-10%..... | -- |
| 11%-25%..... | <.5% |
| 26%-50%..... | .1 |
| 51%-75%..... | .1 |
| 76%-99%..... | .8 |
| 100%..... | .86 |
| Don't know..... | .3 |
16. What percentage of Medicare Part D plans that you bill electronically pay you electronically?
(n=406)
- | | |
|-----------------|-----|
| 0%..... | 14% |
| 1%-10%..... | 10 |
| 11%-25%..... | 4 |
| 26%-50%..... | 6 |
| 51%-75%..... | 8 |
| 76%-99%..... | 6 |
| 100%..... | 11 |
| Don't know..... | 40 |

Extended Medication Supplies

17. Have your Part D plans provided you with the opportunity to negotiate the 90-day supply rate?
 (n=416)
 Yes.....24%
 No41
 Did not attempt to negotiate.....35
18. At what rate do plans offer reimbursement for 90-day supplies? *(Please select all that apply.)*
 (n=416)
 Mail-service rate.....44%
 Alternative community pharmacy rate.....31%
 Not applicable35%

Medication Therapy Management (MTM) Services

19. Did any plans approach you about providing MTM services to their enrollees?
 (n=416)
 Yes.....43%
 No57
20. If yes, in your opinion, did the plan offer appropriate compensation for your services?
 (n=178)
 Yes.....49%
 No51
21. What type of MTM services are you currently providing to Medicare beneficiaries under a contract with a Part D plan? *(Please select all that apply.)*
 (n=178)
 "Brown bag" medication reviews 47%
 Refill reminders/Medication compliance..... 19%
 Education and training 47%
 Monitoring and evaluating patients' response to medications..... 39%
 Selecting, initiating, modifying, or administering medication therapy 31%
 Disease management 23%
 None 25%
 Other (specify) 2%

Coverage Gap

22. What have your patients done when they reach the coverage gap? *(Please select all that apply.)*
 (n=413)
 Stopped taking medicines 75%
 Continued to take medicines with no change in regimen 48%
 Switched to lower cost alternative(s) 54%
 Altered adherence to previous regimen (i.e. split pills, skipped dosage) 78%
 Other (specify) 11%

Demographics

23. In what type of setting are you currently primarily practicing? *(Please select only one.)*
(n=413)
- | | |
|--|-----|
| Chain pharmacy (4+ units)..... | 22% |
| Supermarket pharmacy..... | 9 |
| Mass merchant pharmacy..... | 3 |
| Independent pharmacy (1-3 units) | 50 |
| Hospital (inpatient) pharmacy | 3 |
| Clinic (outpatient) pharmacy | 6 |
| Mail-service pharmacy | 1 |
| Managed care pharmacy | 2 |
| Long-term care pharmacy..... | 3 |
| Other (specify) | 1 |
24. Do you practice in a rural, suburban, or urban area? *(Please select only one.)*
(n=413)
- | | |
|----------------|-----|
| Rural | 34% |
| Suburban | 39 |
| Urban..... | 27 |
25. Overall, how many prescriptions does your pharmacy dispense per day?
(n=411)
- | | |
|------------------|----|
| None | 1% |
| 1-200..... | 48 |
| 201-500..... | 42 |
| 501-1,000..... | 5 |
| 1,001-2,000..... | 2 |
| 2,001+..... | 1 |
26. What percent of the prescriptions dispensed are covered by Medicare Part D?
(n=411)
- | | |
|---------------|----|
| None | 1% |
| 1%-10% | 6 |
| 11%-25% | 37 |
| 26%-50% | 36 |
| 51%-75% | 16 |
| 76%-99% | 4 |
| 100%..... | -- |
27. How many Medicare Part D plans do you accept at your pharmacy?
(n=411)
- | | |
|------------|----|
| None | 2% |
| 1-10..... | 8 |
| 11-20..... | 24 |
| 21-30..... | 16 |
| 31-40..... | 15 |
| 41+..... | 35 |



May 31, 2007

The Honorable Max Baucus, Chairman
Committee on Finance
United States Senate
Washington, DC 20510-6200

The Honorable Charles Grassley
Committee on Finance
United States Senate
Washington, DC 20510-6200

RE: Questions for the Record Regarding the May 2, 2007 Hearing, "The Medicare Prescription Drug Benefit: Monitoring Early Experiences"

Dear Chairman Baucus and Senator Grassley:

Thank you for providing the American Pharmacists Association (APhA) the opportunity to present its views at the May 2, 2007 Finance Committee hearing on the Medicare Part D prescription drug benefit. This letter responds to the specific question directed to me in your May 10, 2007 letter and also provides insight into a few of the other questions that were directed to my fellow panelists. Again, as I mentioned in my oral statement, Medicare Part D is a great success through collaborative efforts by Congress, the Centers for Medicare and Medicaid Services, pharmacists, and other health care providers to ensure that the program continues to offer the Medicare population access to necessary medications.

Specific Request

8. Pharmacists had a lot to learn about the new benefit before it got off the ground. CMS spent a lot of time educating pharmacists about the benefit, as well they should have. But I don't think that it is solely the Agency's responsibility. What has the Association done to educate its members about the benefit and what ongoing educational activities does the Association have underway?

As soon as the law was enacted, APhA began educating its members about Medicare Part D. Those important efforts continue today. Because pharmacists play an integral role in helping patients understand and navigate the new benefit, and because they are essential to administering the benefit, pharmacist education on Medicare Part D became a critical new focus for APhA.

APhA actively pursued opportunities to educate its members about key aspects of Medicare Part D. While some resources were developed by APhA alone, as you will see from the descriptions below, other resources were developed in collaboration with our colleague national pharmacy organizations. Some of these resources provide an overview of the benefit, while others provide detailed information on specific aspects of the benefit.

Communications

The primary example of interactive, live programming were the many presentations APhA staff provided to pharmacy and pharmacist audiences. While we commonly have requests to speak throughout the year on legislative and regulatory issues, requests for presentations skyrocketed after the Medicare Part D law was enacted. These presentations were held across the country for various audiences. Since 2004, APhA staff has given over 80 presentations about the Medicare Part D prescription drug benefit.

Another important resource is the APhA Resources: Medicare website¹, which was developed soon after the law was enacted. The website continues to serve as a robust online resource for pharmacists and others seeking information on Medicare Part D, medication therapy management (MTM), Medicare Part B, and other related Medicare issues such as reimbursement for durable medical equipment. In addition to the website, APhA created a Medicare email address for APhA members to send questions to APhA staff regarding the benefit. Those questions were often used to design our educational materials.

Upon the law's passage, APhA began including information on the new prescription drug benefit in our written communications. From the beginning of 2004 through August, 2006 APhA's monthly publication, *Pharmacy Today*, with a circulation of about 139,000, included a column on specific elements of Medicare Part D. The Medicare 101 column was designed as a "how to" column for pharmacists. Topics included the challenges for dual-eligible drug coverage moving from Medicaid to Medicare, electronic prescribing, the Centers for Medicare and Medicaid Services' (CMS) marketing guidelines, the new competitive bidding program for durable medical equipment, and the point-of-service enrollment option.

Additionally, our weekly email publication *FOCUS*, which is sent to all APhA members, has included a Medicare Spotlight column since November 2005. Bi-weekly, we send all our members the most current legislative and regulatory information, including Medicare Part D updates, in our *Legislative & Regulatory Update*. Some of APhA's Part D work has also been published in the *Journal of the American Pharmacists Association* (JAPhA), a peer-reviewed journal with a circulation of about 24,000. Medicare Part D updates have also been included in APhA's bimonthly *Academy Insider* e-Newsletter to all pharmacist and scientist members, the monthly *Federal Pharmacists Update* e-Newsletter (to pharmacists working for the Veterans Administration, Department of Defense, and the Public Health Service), and the monthly *APhALINK* update to chain corporate managers. APhA also works closely with its affiliated state pharmacy associations.

Special Populations

In addition to our regularly scheduled written member communications, APhA has conducted special mailings to our student pharmacist members. Students have and continue to play a large role in helping to educate seniors about the benefit. For example, in 2005 the 92 student chapters at all of the schools and colleges of pharmacy in the United States and Puerto Rico were sent 100 copies of Medicare materials including *Facts About Medicare*, *Quick Facts About Medicare*, and *SSA-How to Get Signed up for SSA*. This information was reviewed with APhA student leaders from across the country at the APhA Summer Leadership Institute in July 2005. It was also included in the APhA student outreach visits that were conducted in the fall of 2005 at 82 universities. Additionally, APhA conducted special programming at the annual student pharmacist Midyear Regional Meetings, with over 1,500 student pharmacists attending. This programming, *The ABCs of*

¹ May 17, 2007 accessed at www.aphanet.org/Medicare

Medication Therapy Management Services, helped student pharmacists gain a better understanding of how the law and regulations affected the profession of pharmacy and their communities. The session also provided tips and ideas on how to educate their communities about the implementation of the Part D benefit. At these events, each student chapter received a *Medicare Toolkit* and other materials. Students were encouraged to use this information to educate seniors about the new benefit.

APhA, in cooperation with the HRSA Pharmacy Services Support Center (PSSC), developed an Awards Program to encourage student pharmacists to consider career options as safety net pharmacist. The program offers cash awards to students to develop and implement projects to help their patients. The program gives preference to project ideas focused on Part D education to those who are 340B-eligible or who are medically underserved. One project that was awarded from Shenandoah University reached out to nearly 400 patients in northern Virginia and West Virginia. This program educated not only student pharmacists and pharmacists, but also other health care professionals working at the 340B clinic.

Tools

A key element of APhA's education program has focused on a particular aspect of the benefit, MTM services. In 2004, APhA commissioned the Lewin Group to identify MTM standards of practice and to develop a model that payers could consider when evaluating pharmacist compensation for MTM services. Their final report, *Medication Therapy Management: A Critical Review*² serves as a resource for public and private entities designing and implementing an MTM program.

Also in 2004, APhA worked with the other national pharmacy organizations to develop a consensus definition for MTM³. To this end, APhA hosted the Pharmacy Stakeholders Conference on Medication Therapy Management Services. The conference included representatives from eleven different national pharmacy associations. Various program criteria as well as a definition of MTM services were developed at the consensus-building conference.

The consensus definition spearheaded a series of other tools for pharmacists to use as they navigate the benefit. Building upon the consensus definition, APhA & the National Association of Chain Drug Store (NACDS) Foundation collaborated to develop the *Medication Therapy Management in Community Pharmacy Practice: Core Elements of an MTM Service*⁴. This model describes the core elements of MTM services that can be provided in a community pharmacy setting. Following this work, APhA and the NACDS Foundation continued their collaboration and produced the *MTM Implementation Manual for Community Pharmacies* as well as a CD-ROM training program *MTM Training & Techniques for Providing MTM Services in Community Pharmacy*. The implementation manual is focused on helping community pharmacists and pharmacy operators implement effective MTM services in their practice settings, and the training program is an interactive tool to help pharmacists prepare for and perform MTM services in community pharmacies. Both resources are available on the APhA website at <http://www.pharmacist.com/mtm/training.cfm>.

Soon after the Core Elements was created, APhA was part of an effort led by the Academy of Managed Care Pharmacy (AMCP) that involved nine national pharmacy organizations. This effort produced the Components

² American Pharmacists Association. Medication Therapy Management Services: A Critical Review. *J Am Pharm Assoc.* 2005;45:580-587.

³ Bluml BM. Definition of medication therapy management: development of profession-wide consensus. *J Am Pharm Assoc.* 2005;45:566-72.

⁴ American Pharmacists Association and National Association of Chain Drug Stores Foundation. Medication therapy management in community pharmacy services: core elements of an MTM service, (I version 1.0) *J Am Pharm Assoc.* 2005;45:573-579.

of a Sound MTM Program⁵ consensus document, which describes features and operational aspects of quality MTM programs. Recognizing that some pharmacists may question their readiness to provide MTM, APhA also created an MTM Self-Assessment Tool. This simple survey is designed to help a pharmacist gauge how prepared they are to provide MTM and is available at <http://www.pharmacist.com/MTM>. The most recent activity around MTM is a collaborative effort by APhA and the American Society of Consultant Pharmacists (ASCP). Recognizing that some pharmacists may desire or require additional training before providing MTM, APhA and ASCP created an MTM Certificate Training Program. A pilot of the program was launched at the APhA 2007 Annual Meeting in March of 2007. The pilot was a great success and there are plans for collaboration with organizations and academic institutions to expand the delivery of this program to pharmacists throughout the country. Additional information on this program is available at <http://www.pharmacist.com/CTP/MTM.cfm>

Continuing Education

APhA developed a four-part, continuing education monograph series, "Understanding Medicare: What Pharmacists Need to Know". The following topics were covered in the series: Monograph 1 - An Overview of Pharmacy Issues; Monograph 2: Medication Therapy Management Services and Chronic Care Improvement Programs; Monograph 3: Navigating the Medicare Prescription Drug Benefit; and Monograph 4: Final Regulations for Medicare Part D. The first monograph was published in 2004, soon after the law was enacted. The final monograph was published in 2005 after the regulations were finalized by CMS. These monographs were free to APhA members and available for purchase by non-members. More than 6,800 pharmacists participated in the "Understanding Medicare: What Pharmacists Need to Know" monograph series.

Recognizing that some pharmacists would benefit from a live presentation that allowed for questions and answers, APhA and the NACDS Foundation collaborated once again in 2005 to conduct a series of ten live meetings "Medicare Part D Enrollment for Community Pharmacy Regional Conferences" across the country. Three-hour presentations were conducted over a two week period in Boston, Denver, New York, San Francisco, Philadelphia, Seattle, Atlanta, Chicago, Dallas, and Kansas City. This live programming reached 2,317 pharmacists and one of the sessions was taped to provide web access to the program. The web-cast presentation was accessed by 2,293 pharmacists.

Building on the "live" format, APhA has conducted live continuing education sessions on Medicare topics at its Annual Meetings since 2004. Covered topics included: "Medicare Drug Benefit: What You Need to Know," "Medication Therapy Management Law," "A Primer on Medication Therapy Management Services," and "Pastries and Policies: Meeting the Therapy Needs of Our Elderly Population." While specific Medicare information was provided in these sessions, APhA also shared information during the "Legislative and Regulatory Update" sessions at the Annual Meeting. Since 2004, participants at the APhA Annual Meeting have been provided the opportunity to pick up Medicare Part D information and talk to policy staff at the policy booth that exhibits at the meeting. Attendance at the APhA Annual Meeting was: 4,950 in 2004; 4,988 in 2005; 5,472 in 2006; and 5,207 attendees in 2007.

In addition to the continuing education sessions at APhA's Annual Meeting in 2005, nearly 200 pharmacists attended a Medicare Drug Benefit Training Session that helped prepare them for an Orlando Senior Outreach Event. At this event, 62 pharmacists and student pharmacists talked about the new Medicare prescription drug benefit, conducted medication reviews, demonstrated use of medication adherence tools, and measured blood pressure, cholesterol and glucose, and bone density for 160 senior citizens from the Orlando area. The outreach effort provided an opportunity for area seniors to learn how to reduce their costs for prescription medications as

⁵ Anonymous. Sound Medication Therapy Management Programs. *J Manag Care Pharm.* 2006; 12 (3 Suppl):S2-13

the Medicare Part D benefit phased in, to discover the value of health screenings, and to meet one-on-one with pharmacists for medication checks and adherence education.

Additional Follow-Up

Beyond the specific question I was asked to address, I would like to take this opportunity to provide some perspective on a few of the other questions that you asked of my fellow panelists.

Informed Choices

Medicare beneficiaries face several obstacles when trying to choose the plan that best meets their needs. While the CMS Plan Finder is a terrific tool, it requires a patient to be Internet savvy. Some pharmacists helped patients overcome this obstacle by providing Internet access at their stores while others took home the patient's medication information, researched the patient's options, and printed out the Plan Finder results for the patient to pick up at the pharmacy. Despite these efforts, CMS' marketing guidelines prevent pharmacists from enrolling patients out of fear that pharmacies will direct patients into plans that financially benefit the pharmacist rather than the patient. It is unfortunate that pharmacists are not authorized to help beneficiaries complete the enrollment process.

Furthermore, the Plan Finder has design limitations. For example, it is not clear when a drug requires step therapy or is on an elevated formulary. At a minimum, the Plan Finder should be expanded to educate the patient on further plan details, including these formulary details and information about the plan's MTM program for which the beneficiary may be eligible.

Marketing Abuses

APhA members have reported two major concerns with regards to marketing practices. First, some plans are contacting beneficiaries after enrollment to switch them to the plan's mail-service pharmacy. We support mail-service as an option, but support freedom of choice as patients should not be coerced into obtaining their medications from any particular pharmacy.

Second, we have heard of health plans marketing diabetic testing strips and using this opportunity to switch patients into their Part D plan. It is not until the patient requests a prescription refill from their local community pharmacy that they are made aware of the switch. In addition to the patient confusion this causes, major challenges follow as the pharmacist attempts to help the patient remedy this situation and obtain their needed medication.

Formularies

A plan's formulary is critical for a beneficiary to choose a plan that best meets their needs. We appreciate your concern about changes in formularies. Changing a patient's drug regimen can be very disruptive to the treatment of their medical condition, particularly mental health patients as Pharmacist Toby Schule described in his testimony. Therefore, we support efforts to limit any negative impact on a patient's medication regimen. At a minimum, we encourage oversight of the annual election period letters sent to beneficiaries to ensure that they are provided all of the specifics necessary to determine whether they should switch plans because of a plan's formulary.

While we appreciate the concept of allowing patients the freedom to change plans due to a formulary change, we caution against this approach. Allowing patients to switch plans more than annually subject them to new plan requirements that could lead to disruption in care, including any medication therapy management they may be receiving.

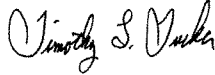
Medication Therapy Management (MTM)

As I stated in my testimony, APhA believes that MTM remains a missed opportunity within Medicare. While some plans have taken the bold step of providing a robust MTM program to their enrollees, many have not. Pharmacists have reported not being assigned patients, patients "disappearing" from a plan's MTM queue, and not being able to access plan-provided documentation systems that are critical to continuity of care. Additionally, because the MTM definition includes the cost threshold, MTM patients are rarely identified before March of the calendar year. Finally, a patient who was identified year one must wait to be re-certified as eligible in year two – resulting in a disruption of care. We encourage you to consider ways to improve baseline of current MTM programs and standardize MTM programs across plans so that patients experience limited disruptions in care.

Conclusion

APhA appreciates your oversight of this important program that has done so much to help America's Medicare population and your ongoing efforts to limit activities that may negatively impact patients' abilities to access necessary medications. We have the ability to poll our members on any or all of these issues if you would like additional information. APhA looks forward to continuing to work with you and your staff to ensure that Medicare Part D becomes the benefit that we all envisioned.

Sincerely,



Timothy L. Tucker, Pharm.D.
President-Elect

Cc: John A. Gans, PharmD, Executive Vice President
Catherine M. Polley, RPh, Chief Policy Officer, Senior Vice President, Government and Professional Affairs
Kristina A. Lunner, Senior Director, Government Affairs

COMMUNICATIONS

Statement of the American College of Clinical Pharmacy

Submitted to the Senate Committee on Finance in conjunction with its hearing on

“The Medicare Prescription Drug Benefit: Monitoring Early Experiences” May 2, 2007

Introduction

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity provided by Chairman Baucus and members of the Senate Finance Committee to submit this statement for the record concerning early experiences with implementation of the Medicare Part D prescription drug benefit.

ACCP is a national professional and scientific society representing more than 8,000 clinical pharmacist practitioners, researchers and educators. Our members have been among the profession's leaders for almost three decades in developing and providing professional services, consultation, cutting-edge clinical research, and education programs that improve the quality of medication use in the health care settings in which they practice.

ACCP has consistently advocated for inclusion of a comprehensive pharmacy services benefit within all health care programs. As medication use among Americans continues to grow and prescription medications play an increasingly central role in improving the health outcomes and quality of life in patients with both acute and chronic diseases, the importance and value of pharmacist-provided medication management services have become clear.

Improving Medication Use for Medicare Beneficiaries

In its 2006 report, *Preventing Medication Errors*, the Institute of Medicine (IOM) outlined many of the deficiencies of the current healthcare system that result in hundreds of thousands of individuals becoming ill, needing additional medical treatment or hospital admission. The report found that **between 44,000 - 98,000 Americans die each year as a result of medical errors**. The estimated cost of treating medication errors in Medicare beneficiaries is at least \$887 million a year.

Given the fact that the typical Medicare beneficiary sees three or more physicians (or other healthcare providers) each year and takes more than five medications, the need for appropriate, pharmacist-provided care is even greater among Medicare beneficiaries than for the overall population.

Medication Therapy Management (MTM) under Medicare Part D

ACCP welcomed the inclusion of “medication therapy management services” (MTMS) as a key component of the Medicare Part D prescription drug benefit. The statement in the preamble to the Part D final rule stating that MTMS should evolve to become a “cornerstone” of the Part D benefit fully reflects both ACCP members’ expectations of the program and their own commitment to quality patient care.

Effective medication management encompasses an array of professional services that optimize therapeutic outcomes for individual patients. Among the services included in a comprehensive medication management program are:

- Formulating a medication treatment plan and monitoring and evaluating the patient’s response to therapy,
- Performing a comprehensive medication review to identify, resolve and prevent medication-related problems, and
- Coordinating and integrating medication management services within the broader healthcare management services being provided to the patient.

However, under current Part D guidelines, MTM services are insufficiently comprehensive in scope and quality. Equally importantly, they are being made available to only a very small proportion of Part D beneficiaries. Data presented by CMS at the May 1, 2007, meeting of the Pharmacy Quality Alliance showed that only 7.7% of beneficiaries in stand-alone prescription drug plans (PDP’s) and 3.8% of beneficiaries in Medicare Advantage plans (MA-PD’s) participated in the plans’ MTM programs in 2006.

Under the current Part D regulations, the vast majority of Medicare beneficiaries receive essentially no professional services to help them achieve safe and appropriate outcomes from their use of medications. Given the nation’s significant investment in providing medications through the Part D benefit, failure to assure the provision of more comprehensive MTM services is a **significant missed opportunity** to improve health outcomes and reduce overall healthcare costs across the entire Medicare beneficiary population.

Expanding beneficiary access to comprehensive medication therapy management services would yield important benefits to patients and to the Medicare program, including:

- Optimized therapeutic outcomes
- More appropriate and cost-effective use of medications
- Reduced medication errors and adverse drug events
- More effective and efficient coordination of care
- Improved quality of life

Policy Changes Are Needed to Enhance Medication Management (MTM) within Medicare

ACCP is one of seven national pharmacist practitioner organizations¹ involved in a coalition effort that will shortly propose substantial policy changes and enhancements to the existing MTM provisions within the Medicare program. The organizations believe that better integration of more comprehensive MTM services provided by pharmacists is essential to achieve the best outcomes from, and maximize the value of Medicare's expenditures for, prescription medications.

ACCP and our coalition partners will be seeking opportunities to meet with members and staff of the committee in the coming weeks to discuss proposals to substantially enhance coverage for MTM services within the Medicare program. We look forward to a productive and beneficial dialogue.

For more information on clinical pharmacy and its practitioners, contact:

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¹ Academy of Managed Care Pharmacy, American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, College of Psychiatric & Neurologic Pharmacists.



**STATEMENT
Of
DAVID KYLLO
Executive Director
National Center for Assisted Living
To
Senate Finance Committee
“Monitoring Early Experiences”**

May 3, 2007

**Congress Should Waive Medicare Part D Co-Payments for Dual Eligible
Beneficiaries Receiving Long Term Care Services in Home and
Community-Based Settings,
including Assisted Living/Residential Care Facilities**

The National Center for Assisted Living (NCAL) is the assisted living voice of the American Health Care Association (AHCA). On behalf of NCAL and AHCA, I would like to thank the Committee for this opportunity to raise an issue of vital importance to America's seniors, and particularly important for frail elderly people with very low incomes. AHCA/NCAL is a non-profit federation of affiliated state health care organizations, together representing nearly 11,000 non-profit and for-profit nursing facilities, assisted living residences, sub-acute centers, and homes for persons with developmental disabilities. NCAL represents more than 2,400 assisted living facilities providing long term care services to about 108,000 residents.

With Medicare Part D now in its second year, it is clear that the program has helped millions of seniors and people with disabilities gain access to needed medications. However, Medicare Part D needs to be modified so that frailest dual eligibles are treated equally. We believe that an existing gap in Medicare Part D coverage may well have been a mistake of omission made as policymakers put together this complex legislation.

Recognizing the vulnerability and special needs of very low-income people living in long term care facilities, the *Medicare Modernization Act of 2003* exempted dual eligible beneficiaries (those covered by both Medicare and Medicaid) living in “long term care facilities” from any cost-sharing for Part D prescription drugs. Technically, under the Medicare Part D program, the Centers for Medicare & Medicaid Services (CMS) defines a long term care facility as a nursing facility, an intermediate care facility for people with mental retardation and developmental disabilities, or an inpatient psychiatric hospital.

Unfortunately, the *MMA* legislation did not extend the waiver of co-payments for prescriptions to dual eligible residents of assisted living/residential care (AL/RC) facilities and others in home and community-based settings (HCBS), despite the fact that this population may be eligible for nursing home care and has similar needs, vulnerabilities, and income limitations. Under the Part D program, dual eligible assisted living residents and others in HCBS must make co-payments of \$1.00 - \$5.35 in 2007, with the exact amount depending on a person's income and whether a medication is generic. Because of their very low income (often just a few dollars in a personal needs allowance), these co-payments can present financial hardships for dual eligible residents and can impede them from receiving necessary medications. Requiring these co-payments is also inconsistent with efforts to expand Medicaid-covered long term care options – including HCBS – for our nation's most vulnerable citizens who had historically only received care in nursing homes. Under current law, these dual eligible residents automatically receive reduced Part D benefits by choosing to live at home or in an AL/RC facility rather than in a nursing home.

AHCA/NCAL thanks Senator Gordon Smith (R-OR) and the seven co-sponsors, Senators Jeff Bingaman (D-NM), Barbara Boxer (D-CA), Hillary Clinton (D-NY), Susan Collins (R-ME), Blanche Lincoln (D-AR), Bill Nelson (D-FL), and John Kerry (D-MA), who have introduced bipartisan legislation that would provide relief to this group of frail elderly individuals. *The Home and Community-Based Services Copayment Equity Act of 2007 (S. 1107)* would eliminate Medicare Part D co-payments for more than one million low-income Americans, including dual eligible residents of AL/RC facilities and other licensed facilities such as group homes for people with developmental disabilities, psychiatric health facilities, and mental health rehabilitation centers. Dual eligible beneficiaries receiving services in a home setting under HCBS waivers also would be relieved of Part D co-payments. This legislation is supported by a growing coalition of more than 35 national organizations representing a wide range of interests—consumers, health care and long-term care providers, geriatric care professionals, pharmacists, and state officials.

Currently, approximately 15% of the nearly one million Americans in assisted living residences are dually eligible for Medicaid and Medicare coverage. Under HCBS waivers, residents placed in AL/RC facilities must be eligible for placement in nursing homes. Like nursing home residents who rely on Medicaid, more than 120,000 dual eligible residents living in AL/RC facilities have very limited financial resources, often just a few dollars a month from a personal needs allowance. These residents, like those in nursing homes, often require multiple prescription medications – about 8 – 10 prescriptions – according to recent studies. So, in some instances, the amount of their combined Medicare Part D co-pays exceeds their monthly personal needs allowances. In addition, because their Part D co-pays are indexed for inflation while their limited resources grow less rapidly, if at all, there is an even greater burden placed on these individuals.

On January 1, 2006, dual eligible beneficiaries who previously received medications under Medicaid programs were automatically enrolled in Medicare Part D drug plans. Under Part D, pharmacies and Part D Plans are not required to dispense medications if a beneficiary does not pay co-payments. Unless the law is changed, dual eligible residents of AL/RC facilities and others receiving services under Medicaid waivers who cannot afford these co-payments may be at risk for not receiving essential medications.

Another reason we support the elimination of Medicare Part D co-payments for this population is to maintain a level playing field between institutional and community-based services under Medicaid. For many years, policymakers and the public have supported expanding options for people to receive long-term care services at home and in community-based settings under the Medicaid program. AHCA/NCAL supports the principle of Medicaid providing the appropriate services in the setting that best meets each individual's needs and preferences. According to an analysis of the Medicare Part D co-payment legislation, which was conducted for AHCA/NCAL by the Lewin Group, by next year, the number of dual eligible beneficiaries in home and community based settings that would be impacted by this legislation will be larger than the number of dual eligible beneficiaries living in nursing homes and other institutions.

For a small investment in covering Medicare Part D co-pays, Congress would remove an impediment that could prevent some people from remaining at home or in an assisted living facility, thereby saving state and federal dollars as these care settings can be less expensive than the care provided in America's nursing homes. Still, the most important reason to pass this legislation is to help frail, elderly seniors afford much-needed medications.

Thank you for this opportunity to bring this important issue to the attention of the Committee.

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For more information, please contact NCAL Senior Policy Director Karl Polzer at (202)898-6320 or kpolzer@ncal.org.



Medicare Rights Center

**Statement for the Record of Robert M. Hayes
President, Medicare Rights Center**

**Hearing on “The Medicare Prescription Drug Benefit: Monitoring Early
Experiences”
Before the United States Senate Committee on Finance
May 2, 2007**

**520 Eighth Avenue, North Wing, 3rd Floor · New York, New York 10018
110 Maryland Avenue, NE, Suite 112 · Washington, D. C. 20002 · www.medicarerights.org**

Thank you for the opportunity to submit this testimony on implementation of the Medicare prescription drug benefit.

The Medicare Rights Center (MRC) is a not-for-profit consumer service organization, with offices in New York, Washington and Baltimore. It is supported by foundation grants, individual donations and contracts with both the public and private sectors. We are consumer-driven and independent, relying on a small staff and hundreds of deeply committed volunteers to carry out our mission. Our non-partisan mission is to serve the 43 million men and women with Medicare.

Through national and state telephone hotlines, casework and professional and public education programs, MRC provides direct assistance to people with Medicare from coast to coast. Each year, the Medicare Rights Center receives over 80,000 calls for assistance from people with Medicare. We provide hotline services and technical assistance to professionals across the country who assist people with Medicare. We also offer Medicare Interactive, the nation's only independent, web-based Medicare counseling tool at www.medicarerights.org/help.html.

Last year, we launched a Part D appeals program, recruiting a battery of volunteer lawyers and physicians to assist people with Medicare to obtain medications denied by their Part D plans. Drug plans place the Medicare Rights Center's toll-free phone number on notices informing their enrollees that the Part D plan is denying coverage of a prescribed medication.

Our testimony today focuses on the Part D appeals system, the process people with Medicare must navigate when they discover that they can not get their prescription filled. We also bring to your attention the particular problems of our clients who are seeking coverage of drugs that have proven effective in treating their condition, even though they were originally approved by the Food and Drug Administration for different indications. Because of a misreading of the statute by the Centers for Medicare & Medicaid Services, our clients are told that their plan is legally barred from covering this "off-label" use of the drug under Part D, even though everyone, including their doctor and their Part D plan, agrees the drug is medically necessary.

The Part D Appeals System

Under the law, Part D plans are required to provide coverage for all medically necessary drugs, with the exception of those excluded by statute. They do not.

Plans are given wide discretion to decide what drugs will be listed on their formularies and what restrictions they will place on the drugs they cover. The appeals process exists to ensure that these formulary restrictions and exclusions do not undermine the fundamental requirement to cover any drug that is medically necessary. When this system fails, people are not just out of luck. They are out of needed medicine, and the promise Congress made to people with Medicare is broken.

To work, the Part D appeals system must meet the following tests:

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- People with Medicare must be informed of their rights to appeal and given the information they need—forms, fax and telephone numbers and timelines—to launch an appeal;
- Part D plans must handle all appeals expeditiously, within mandatory timelines, and refrain from obstructing the process either through incompetence or neglect;
- Decisions on appeals must be made, both by Part D plans and in the independent review, on the basis of objective, clinical assessments and in conformity with the spirit and the letter of the law.

Sixteen months into the drug benefit, we report that the Part D appeals system fails all three tests. Common problems include misinformation, delays and plan denials that reflect ignorance of Medicare requirements and the urgent medical needs of our clients.

Many plan members do not know they can appeal the denial of drug coverage by their plan. This lack of information usually originates with plans' customer service representatives, who neglect to tell members that they have a right to appeal or else tell them they cannot appeal. When plan representatives do mention the appeals option, they do not provide appeals forms, fax numbers for requests or other information needed to begin the process.

If an individual is able to file an appeal, the process too often bogs down in delays and miscommunication. The problems begin with the first step in the appeals process, when the plan member tries to request a redetermination of the denial. At this stage, the member is only asking the plan to reconsider its decision. Plans block the process at the start by failing to respond to these requests. One plan, WellCare, failed to acknowledge four requests we faxed on behalf of a client; many plans never respond, even though the law requires a response within seven days. The following story illustrates how plans can obstruct the appeals process and turn it into a bureaucratic nightmare for people with Medicare in need of vital medicines:

In February 2007, we received a call from a Utah man whose son is a member of Sierra Health. Sierra Health denied the son's prescription for a pain medicine he used to control severe, debilitating migraines. Because of his illness, the son was unable to navigate the appeals system and his father, who didn't know what to do, sought our help. Our counselor faxed a request for a redetermination but could not reach anyone at Sierra who could answer questions about the status of the request. At one point, the counselor was disconnected. Another time, the customer representative could not obtain information because her "system was down."

Plan members have 60 days after receiving a redetermination in which to file an appeal to the next stage, to Maximus Federal Services, a federal contractor. When we filed an appeal with Maximus, as advised by a Sierra representative, Sierra's defense was that we filed too late—more than 60 days after the redetermination. Sierra said the redetermination was issued in January, though neither we nor our client received it.

After the Part D plan has issued a redetermination—routinely an affirmation of its original coverage denial, an appeal can be made for an independent review to Maximus, a contractor for Medicare.¹ With the exception of appeals for off-label uses of drugs, an area where a misreading of the statute by the Centers for Medicare & Medicaid Services (CMS) results in a ban on Part D coverage, the Medicare Rights Center generally wins its appeals to Maximus. This success should not be taken as a sign that the Part D appeals system is working. In fact, it shows the opposite: that Part D plans are failing to use the appeals process to objectively assess whether they are responsible for coverage. It illustrates how Part D plans use the appeals process to prevent, or at least delay, coverage for drugs that are medically necessary but whose expense diminishes their bottom line. The following case is illustrative:

Ms. R is a Medicare beneficiary and survivor of Hurricane Katrina who was diagnosed with acute myelogenous leukemia in March 2002. To treat this condition, she had a bone marrow transplant in March 2005. After her transplant, Ms. R's physicians prescribed Cellcept to treat the chronic graft host disease that resulted from the transplant. According to her physicians, this treatment has been instrumental in preventing rejection of the transplant. At the time of her transplant, Ms. R did not have Medicare coverage because she was in the twenty-four month period people with disabilities must wait for Medicare coverage.

Ms. R became eligible for Medicare in June 2005, and enrolled in Community Care Rx in January 2006 to access Medicare Part D prescription coverage. Until January 2007, Community Care Rx provided coverage for her Cellcept prescription. However, on January 5, 2007, she received a "Notice of Denial of Medicare Prescription Drug Coverage" stating that this medication was excluded from Part D coverage because coverage is available under Medicare Part B. Community Care Rx failed to recognize that Part B would only cover Ms. R's Cellcept prescription if her transplant was covered by Medicare. In both the determination and redetermination stage, Community Care Rx ignored evidence of the date of the transplant and the plain guidance from the Centers for Medicare & Medicaid Services mandating coverage under Part D.

Ms. R was forced to pay \$1,200 a month out-of-pocket for this prescription while in the appeals process. Ultimately, in March of 2007, over two months later, Maximus Federal Services issued a favorable decision granting coverage of her prescription. If Ms. R had not had access to help from an experienced advocate, she would likely still be without coverage.

A Part D appeals system that requires the help of an experienced advocate to navigate is a failure, especially where there is absolutely no federal support to provide advocacy services to people with

¹ Data provided by CMS shows 8,772 redeterminations issued by plans from January 1, 2006 to July 31, 2006 and 8,336 appeals decided by Maximus, the qualified independent contractor. Since every appeal for an independent review is of a negative redetermination by the plan, it follows that, during the period surveyed, plans denied coverage in 95 percent of cases. Decisions in the independent review stage overruled plans 42 percent of the time.

Medicare. Without a dogged advocate familiar with the rights afforded people with Medicare and the responsibilities of the Part D plans, there is little hope of success in this appeals system. Our advocates hound the plans to comply with deadlines, help doctors provide evidence that demonstrate the prescribed medicine is medically necessary and assemble a case to present to both the plan and Maximus. Under Part D, people with Medicare effectively need a lawyer to get the medicines they need.

Senators Baucus and Grassley, we urge this committee to use its jurisdiction to ensure CMS conducts vigorous oversight and enforcement of Part D plans' implementation of the Part D appeals process. We remain skeptical, however, that a system of private, for-profit Part D plans that have financial incentives to deny coverage of needed but expensive medicines will ever feature an appeals system that guarantees access to medically necessary drugs. Congress should give older adults and people with disabilities the option to obtain drug coverage directly through Medicare, the program they trust to provide coverage in their interest and on the basis of medical necessity instead of a responsibility to maximize profit for shareholders.

Medicare Part D Coverage of "Off-label" Prescriptions

The Medicare Rights Center is representing a number of clients in their appeals for Part D coverage of drugs used for off-label indications—to treat conditions other than those listed on the FDA label. These cases concern off-label uses of drugs that have proven effective for our clients and are backed by wider, published evidence of effectiveness. However, CMS' narrow reading of the statute holds that these off-label uses are excluded from Part D coverage, because the off-label uses are not listed in compendia cited by the statute. (Compendia list indications approved by the FDA as well as some off-label indications.) This interpretation precludes coverage of medically accepted indications for which there is evidence of effectiveness, such as in peer-reviewed literature, the standard that applies to coverage of Part B drugs. CMS should revise its statutory interpretation and require Part D plans to provide coverage for medically necessary off-label prescriptions.

Illustrative Case:

Mr. H, a Medicare beneficiary and veteran of the U.S. Navy, was severely injured in a tornado on March 29, 1997. He suffered severe craniofacial trauma for which he underwent removal of his left eye, removal of portions of the left frontal lobe of his brain, and extensive cranial facial reconstruction. At the time of the injury, he was diagnosed with organic brain disease that causes him to suffer from severe migraines. Shortly thereafter, he became eligible for Medicare on account of his disability.

Since the tornado, Mr. H has required pain medication to manage the incapacitating headaches that cause seizures when left untreated. As a result, he has developed a tolerance to pain medications, causing most pain killers to be ineffective in managing his acute migraines.

For six years, Mr. H was using Actiq, which is indicated by the FDA to treat breakthrough pain in cancer patients, to manage his migraines and reduce the risk of seizing. Before the enactment of Medicare Part D, Mr. H received coverage of his Actiq prescription under the state Medicaid program, TennCare. Initially, when Medicare Part D was enacted and Mr. H was forced to enroll in a Medicare prescription drug plan, Humana covered his Actiq prescription. In October 2006, however, Mr. H was suddenly told by his pharmacist that Humana was denying coverage. Mr. H did not receive notice that his coverage would change nor did he receive a transitional supply.

Because he could not afford to pay for his Actiq prescription out-of-pocket, Mr. H's prescribing physician, Dr. B, prescribed Fentora, which is also indicated by the FDA to treat breakthrough pain in cancer patients, as a replacement for the Actiq. Fentora has also proven to successfully ease Mr. H's pain. Initially, Humana provided coverage of Mr. H's Fentora prescription, but in January 2007, ended this coverage without prior notification or transition fill.

Because his Fentora prescription costs approximately \$1,500 a month, Mr. H cannot afford to pay for it out-of-pocket. As a result, he visits the emergency room on a biweekly basis so that he can receive the medication at the hospital and avoid suffering from a seizure caused by his extremely severe pain. Maximus Federal Services has denied his appeal for Part D coverage and MRC is representing him in his appeal for review by an Administrative Law Judge.

Legal background:

The Medicare Part D statute creates a benefit that requires drug plans to cover drugs that are reasonable and necessary for the treatment of an illness, excepting explicitly listed exclusions. Nevertheless, Medicare regulations, specifically 42 C.F.R. § 423.100, exclude coverage of drugs that are not prescribed for a “medically accepted indication” as defined by the Medicaid statute in 42 U.S.C. § 1396r-8(k)(6). This regulation violates the purpose of the statute.

“Medically accepted indication” is defined in the Medicaid statute as,

any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act of the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).” 42 U.S.C. § 1396r-8(k)(6).

The language of the Medicare Part D statute does not exclude coverage of off-label prescriptions. “Covered Part D drug” is defined in relevant part as,

a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2)...and such term **includes** a vaccine licensed under section 351 of the Public Health Service Act and

any use of a covered part D drug for a medically accepted indication (as defined in section 1927(k)(6)). 42 U.S.C. § 1395w-102(e).

Although this definition includes drugs that are prescribed for medically accepted indications, it **does not exclude** coverage for those that are prescribed for other indications, such as off-label prescriptions. Likewise, the reference to subparagraph (A) of section 1927(k)(2) specifically incorporates only subparagraph (A) and does not explicitly incorporate other paragraphs in section 1927 that limit coverage to medically accepted indications. Congress could have created a bar against coverage of off-label prescriptions, as it did by referencing the list of specific exclusions, but explicitly did not do so. *See* 42 U.S.C. § 1395w-102(e)(2).

Similarly, the structure of the Medicare Part D statutes demonstrates an intention to provide coverage for prescriptions that are medically necessary unless explicitly excluded. In developing their formularies, Part D plans are required by statute to base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature. 42 U.S.C. § 1395w-104(b)(3)(B)(i). Part D plans are also required to implement an appeals process that will allow enrollees to secure coverage of drugs that are not included in the plans formulary but are medically necessary. 42 U.S.C. § 1395w-104(h)(2). Under the statute, enrollees have the right to coverage if their prescribing physician indicates that none of the drugs on the formulary would be as effective. *Id.* Looking more broadly, Medicare Part B provides coverage of medically necessary off-label prescriptions. 42 U.S.C. § 1395x(t).

For these reasons, the purpose of the Medicare Part D statute should be honored by requiring plans to provide coverage for medically necessary off-label prescriptions.



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement on

**The Medicare Prescription Drug Benefit:
Monitoring Early Experiences**

**Wednesday, May 2nd, 2007
Committee on Finance
United States Senate**

**NACDS
413 N. Lee Street
Alexandria, VA 22314
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The Medicare Prescription Drug Benefit: Monitoring Early Experiences

Chairman Baucus, Senator Grassley and Members of the Senate Finance Committee, the National Association of Chain Drug Stores (NACDS) is pleased to submit this statement for the record for this important hearing on the early experiences of Medicare beneficiaries and pharmacies with the new Medicare Part D prescription drug benefit program. NACDS represents companies that operate more than 35,000 community retail pharmacies in the United States. We are the primary providers of pharmacy services to Medicare beneficiaries.

We want to thank you, Mr. Chairman, as well as Senator Grassley, for the leadership and concern that you have both shown for beneficiaries and pharmacies by advocating certain changes in the Medicare Part D program. These changes, such as requiring plans to provide more transparency in pharmacy contracting terms and more expeditious payments to pharmacies, would enhance beneficiary access to medications and pharmacy services. We have supported similar modifications to the Part D program, but these efforts have not yet come to fruition.

In addition, we appreciate the fact that you, Senator Baucus, introduced the "Pharmacy Access Improvement Act" (PhAIM, S. 2664) in the 109th Congress, which would address many of the important operational and financial issues that pharmacies have faced to date with Medicare Part D. We hope you will introduce another version of that bill in this Congress, and we want to work with you on moving through the legislative process many of the provisions that are included in this bill.

NACDS believes that the new Medicare Part D prescription drug benefit has helped to provide prescription drug coverage for millions of seniors who previously didn't have such coverage. We are also pleased that many of the pharmacists that work in chain-operated pharmacies have helped to make this program a success by educating beneficiaries about the program. Many pharmacies have also weathered some difficult implementation issues in the early days of the program. However, NACDS will continue to work with Congress and CMS to enhance the operation of the program for beneficiaries and pharmacists. We would like to make specific suggestions to the Committee on improvements we believe should be made to the program.

Establish "Rolling" Beneficiary Enrollment Time Frame

There is nothing more frustrating for a beneficiary or a pharmacist than being unable to provide prescription services to a Medicare beneficiary who is waiting at the pharmacy counter. Yet, a particular enrollment rule in the existing Part D program has the effect of making it difficult for pharmacists to provide prescription services in certain situations.

That is because beneficiaries are able to access their Part D benefit on the first day of the next month after they enroll, no matter how late in the previous month they join a Part D plan or switch plans. Thus, a beneficiary who enrolls in a plan during the last week of the month would expect to have his or her prescriptions filled in a pharmacy by the first day of the next month, and have those prescriptions paid for by the plan that he or she just joined.

However, it is unrealistic to expect that CMS and the chosen plan can process the beneficiary's application, confirm eligibility, and provide information to the plan and the CMS eligibility verification systems— so that it is in the pharmacy system – in such a short timeframe.

Right now, it is supposed to take approximately 10 to 14 days from the time of enrollment in a plan, until the time that the data are available to the pharmacist. Even if this timeframe is reduced, it would remain virtually impossible for important beneficiary billing information to be in pharmacy systems by the first of the month if a beneficiary enrolls in a plan in the last week of the previous month. Such expectations are unfair to the beneficiary, unfair to the pharmacist, and will undoubtedly create delays in a patient receiving his or her medication. Thus, it is essential that there be more time between the submission of an application to a Part D plan and the time that the enrollment and billing information can be obtained and active at the pharmacy.

We believe that CMS should consider making enrollments effective at the time that the plan delivers all necessary billing information to the beneficiary, particularly the standard identification card. This might require that a minimum enrollment processing window be established (such as 15 or 30 days), which would allow sufficient time for the plan to process the application, determine eligibility for any low-income subsidies, and ensure that the beneficiary receives all the enrollment information, including the identification card. If plans can deliver that information to a beneficiary more rapidly than this time enrollment processing time period, then the enrollment would become effective sooner. Plans should be required to compete on this aspect of benefit design so that beneficiaries would be able to use this as another criterion in selecting a plan.

We believe that this enrollment rule for Part D plans should apply to beneficiaries that enroll during the annual coordinated election periods, during special enrollment periods (such as the dual eligibles who can switch plans each month) and continuous enrollment periods.

Assure Beneficiaries' Access to Retail Pharmacies

The Medicare Modernization Act (MMA) requires Part D plans to allow “any pharmacy” that is willing to meet the plan's terms and conditions to participate in its network at the time that the pharmacy is willing to do so. Therefore, we do not believe that a plan can create a term or condition of participation in its contract that requires the pharmacy to join the network by a certain date or risk being “locked-out” of the network for the full plan year. Because we understand that some plans are not allowing “any willing pharmacy” to participate, and since CMS has not made a final determination on this matter, we urge Congress to clarify the intent of this provision.

We support the provision that was included in last year's PhAIM Act, which stated that “a previous refusal by a pharmacy of an offer to participate, or the expiration of such an offer, shall not be grounds to exclude a pharmacy from participation...” In terms of assuring beneficiary access to retail pharmacies, this is an important provision because there are several situations in which a retail pharmacy, which may or may not have been given the chance to participate in the establishment of the network, may want to join the plan's network.

These situations include where the pharmacy has changed ownership; the pharmacy may be new; the rates paid by the plan may have changed since the original contract was proposed, making it more feasible for the pharmacy to participate; new beneficiaries might have moved into the area which want to use the pharmacy, but the pharmacy did not choose to originally participate in the plan; the number of beneficiaries enrolled in the plan has increased because enrollment is higher than expected or other plans have left the area, increasing the number of beneficiaries that want to use the retail pharmacy. There are likely other situations.

We also believe that it was the intent of Congress to require that only preferred network retail pharmacies count toward meeting the TRICARE pharmacy access requirements, not all pharmacies under contract to the plan's network. However, CMS is allowing plans to count both preferred and non preferred retail pharmacies toward meeting the TRICARE standards.

Because of the higher cost sharing differentials that plans can establish between non preferred and preferred pharmacies, we believe that this CMS interpretation can financially disadvantage Medicare beneficiaries if the local retail pharmacy closest to them is designated as a non preferred pharmacy. For this reason, we also support a provision in the PhAIM Act that would require plans, in meeting the TRICARE standards, to only count in-network preferred pharmacies.

Assure Beneficiaries Can Obtain "Extended" Quantities of Medications at Retail Pharmacies

Given the fair choice of obtaining their prescription medications at a retail pharmacy or a mail order pharmacy, beneficiaries overwhelmingly choose their local community retail pharmacy. We find this factor especially important among older Americans, who appreciate the opportunity to talk face to face with their pharmacist about their health care and their medications.

It is for this reason that we believe Congress intended that Medicare beneficiaries should be able to obtain an extended day supply of Part D medications (such as a 90 day supply) at their local retail pharmacy if they wanted to do so. Moreover, Congress said in MMA that any difference in charge between obtaining this prescription at a retail pharmacy as compared to a mail order pharmacy would be borne by the beneficiary. It is important to note that beneficiaries do not pay more cost sharing at retail pharmacies than they do at a mail order pharmacy for a 90-day supply of medication if the retail pharmacy accepts the rate that the Part D plan pays the mail order firm for the 90-day supply. If the pharmacy cannot accept the mail order rate, but negotiates a higher rate with the plan, then the beneficiary pays the difference in charge – as required by the MMA – and that should be the beneficiary's choice.

However, this provision is not being implemented consistent with Congressional intent. CMS is not requiring plans to allow any retail pharmacy in their networks to provide an extended day supply of medication. CMS only requires plans to include a sufficient number of retail pharmacies in their networks to provide beneficiaries "reasonable" access to a 90 day supply. However, there is no public standard for what constitutes "reasonable access." CMS has said that they are monitoring "complaints" from beneficiaries regarding whether they cannot obtain an extended day's supply at a retail pharmacy.

But, this lack of an “objective” standard creates uneven access for beneficiaries among plans in terms of obtaining a 90 day supply at their retail pharmacy. Moreover, in spite of our urging them to do so, CMS has not published any data about the percentage of all network retail pharmacies in each plan that are under contract to provide an extended day supply.

Beneficiaries should be able to obtain a 90-day supply of medication from any retail pharmacy that is willing to dispense these quantities. The current CMS policy unfairly penalizes beneficiaries who want to obtain their extended day supply from their retail pharmacies.

In addition, to reduce confusion for the beneficiary and help them compare benefits among Part D plans, CMS also needs to create a standard definition of “extended day” supply of medication. Some plans define “extended” supply as any quantity of drug exceeding a 31 day supply, some define it as any quantity exceeding a 34 day supply, while other use a 90 day supply. NACDS believes that only a 90 day supply of medication or greater should be considered an “extended day” supply.

Require Prompt Payment and Electronic Funds Transfer (EFT)

Many retail pharmacies have experienced – and are still experiencing – significant financial difficulties as a result of the transformation of many of their patients to Medicare Part D plans, which generally have “lower, slower” payments for prescriptions. While we may not want Congress or the Secretary to dictate specific reimbursement rates for pharmacies, we believe there are certain steps that plans and CMS can take to help improve the cash flow for all pharmacies.

For example, we believe that plans should be required to pay retail pharmacies promptly for “clean” Part D prescription claims that are submitted to the plans (14 days for claims filed electronically and 30 days for all other claims). Moreover, plans should send payments for these claims through a real-time electronic funds transfer system (EFT).

In addition, to assure that pharmacies are being paid appropriately for prescription drugs dispensed to Medicare beneficiaries, all Part D plans should be required to update their pricing benchmarks (i.e. AWP, WAC) on a daily basis. Without these daily updates, pharmacies could be underpaid for many prescriptions, especially for brand name drugs.

Disclose Plan Generic Drug Reimbursement Terms

The contracts that Part D plans offer to retail pharmacies often omit important information about payment rates for generic drugs. Plans should more clearly specify how the plans will reimburse retail pharmacies for the generic drugs they dispense to beneficiaries, the generic drugs to which these reimbursement rates apply, and how often these rates will change. It is unfair to ask pharmacies to enter into contracts without this information, because it makes it difficult for pharmacies to accurately predict the reimbursement they will receive from plans for generic prescriptions.

We also believe that plans should continue to create incentives for beneficiaries to ask for – and for pharmacists to dispense – generic medications. The generic dispensing rate for Prescription Drug Plans (PDPs) has been increasing since the start of the program, and is reaching almost 60 percent of all prescriptions. We think this very high generic dispensing rate has been achieved because of the incentives that beneficiaries have to ask for generics, and the incentives that pharmacists have to dispense generics. Pharmacists work with patients and their physicians each and every day to find the most cost effective therapies that will meet the physician’s goals for treatment.

Establish Plan-to-Plan Rx Claim Reconciliation

Several important claims-related administrative issues need to be brought to the attention of Congress. We urge that Congress direct that CMS implement a “plan to plan” reconciliation process to obviate the need for plans to use pharmacies as billing intermediaries. In some cases, pharmacies are being forced to refund payments to one plan for claims that have been appropriately adjudicated and already paid, only to have to chase down and rebill these claims to another plan.

The need to rebill these claims to other plans occurs frequently because many beneficiaries – such as dual eligibles – can change plans frequently. In these cases, the new plan billing information may not be in the pharmacy computer system when a beneficiary is filling a prescription, and the old plan is incorrectly charged. Thus, the prescription needs to somehow be correctly charged to the beneficiary’s new Part D plan.

These “reverse and rebill” claims have become a significant administrative burden for many pharmacies. For example, it is often the case that the drug for which the claim is reversed is not covered by the other plan, or may be covered at a different cost sharing amount or payment amount. Pharmacies cannot and should not be caught in the middle of this process which primarily results from the fact that CMS and plans cannot incorporate accurate billing information into the systems fast enough. We ask that you work with us to encourage CMS to develop a process that would allow for this plan to plan reconciliation and reduce these unnecessary administrative burdens on retail pharmacies.

Move Medicare Part B Drugs to Medicare Part D

Medicare Part B continues to cover certain outpatient prescription drugs that were covered before the development of Medicare Part D. These Part B covered drugs include immunosuppressive drugs, certain oral cancer drugs, certain oral antiemetic drugs and inhalation drugs.

However, sometimes these drugs are covered under Part B if used by the physician for one medical reason, but Part D if being used for another medical reason. Part B also covers certain vaccines, such as pneumococcal and influenza vaccines. Part D will also cover vaccines that are not covered under Part B, and it is expected that many new Part D covered vaccines will be approved over the next few years.

As you might imagine, pharmacies face significant administrative hassles and complexities in determining whether to bill Medicare Part B or Part D for a drug that could be covered under either program. Appropriate billing for these drugs depends on the medical condition for which the drug is being prescribed by the physician.

Generally, the pharmacist has to call the physician each and every time one of these drugs is prescribed to obtain the reason the physician is using the drug. This can cause delays in filling prescriptions for Medicare beneficiaries. As an interim step, we have been working with Part D plans to create special electronic messages that are being sent to pharmacies to help them bill the appropriate part of the Medicare program. However, to rectify this situation in the long term, Congress should consider moving all Medicare Part B oral and inhalation drugs to Medicare Part D.

We support the provision included in last year's tax bill that pays pharmacies for the administration of Part D vaccines under Part B for 2007 and then shifts payment for administration fees to Part D for 2008. We are working with CMS on developing a workable, practical approach to assure that this provision can be implemented such that it increases Medicare beneficiaries' access to Part D covered vaccines.

Incorporate Pharmacy Quality Indicators into Part D

Without a doubt, we are disappointed that more Part D plans are not offering more robust medication therapy management (MTM) programs and that more plans are not using community-based retail pharmacies to provide these services. Unfortunately, very little data exists on current Part D MTM programs to evaluate how these programs are being implemented.

For example, Part D plans should be required to report to CMS the method by which they deliver MTM services to beneficiaries (i.e., retail pharmacies, nurses, call centers), the percentage of MTM services delivered through each method, and whether the beneficiary is given a choice of provider of MTM services. CMS should report these data to help improve the quality of MTM programs.

The plans should also report the number of retail pharmacies that are under contract with Part D plans to provide MTM services. It is important to know whether these services are being provided by community-based providers or if they are centralized through call centers. There is also no requirement that plans report the scope and nature of the MTM services that they provide. For example, are plans providing special extended counseling, refill reminders, disease-based programs or other specialized services? The plans should report the services most commonly provided, and the average number of days that these services are provided to beneficiaries.

While we have concerns with the evolution of Part D MTM programs to date, we believe that better days are ahead. NACDS is an active participant in the PQA, which is an alliance of Part D stakeholders that is in the process of designing quality measures for pharmacy providers. We commend CMS for launching the PQA last April, and we believe that the work of PQA will result in an increase in quality of care for Medicare beneficiaries.

PQA is in the process of developing and validating 35 potential measures of pharmacy quality – including in areas of patient adherence and patient safety– for such disease conditions as congestive heart failure, hypertension, diabetes, and hyperlipidemia. These quality measures could be used as the basis of evaluating the quality of care provided by pharmacies under Part D, and could ultimately lead to a “pay for performance” model for pharmacies.

We urge that CMS expeditiously conduct demonstration projects on the measures that are tested and validated, and seek to begin to incorporate these measures into the Part D program in the near future. Pharmacy recognizes that its value in the health care system is dependent on demonstrating that it can bring value and an increase in quality to the health care system and the lives of the patients that we serve.

Mr. Chairman, we thank you again for calling this hearing and look forward to working with you on making improvements to the Medicare Part D program.



Statement of the National Home Infusion Association

to the

Committee on Finance

United States Senate

May 2, 2007

Hearing on the Medicare Prescription Drug Benefit: Monitoring Early Experiences

For the Record

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The National Home Infusion Association ("NHIA") is pleased to present this written statement for the record in connection with the Senate Finance Committee's May 2, 2007 hearing on the Medicare prescription drug benefit.

NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services to patients in the home and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion provider organizations; and hospital-based infusion organizations. Generally, infusion pharmacies can be defined as pharmacy-based, decentralized patient care facilities that provide care in alternate sites to patients with either acute or chronic conditions.

As reflected in the testimony presented at the hearing, the new Part D drug benefit has been providing access to prescription drugs to seniors who had limited or no coverage prior to enrollment in Part D. Notwithstanding some initial implementation problems, *as a retail drug benefit*, Part D appears to be working fairly well.

However, beneficiaries who require infusion therapy and are capable of receiving this therapy in their homes are not being adequately served by Part D. The problem stems from the fact that the Centers for Medicare and Medicaid Services ("CMS") has interpreted and implemented the Part D benefit largely as a retail drug benefit. Unfortunately, the structure that can work well for dispensing pills and other prescriptions at the retail pharmacy level is not feasible for more complex intravenous therapies that require more extensive clinical services, care coordination, equipment, and supplies for proper administration. It is noteworthy that private sector health plans typically cover home infusion therapy as a comprehensive medical benefit rather than a pharmacy benefit.

What is Home Infusion Therapy?

Home infusion therapy involves administering medications into the patient's bloodstream. It is prescribed when the patient's condition is so severe that it cannot be treated effectively by oral medications. Infusion drugs must be:

- Compounded in a sterile environment;
- Maintained in appropriate conditions to ensure sterility and stability;
- Administered at exactly the right dose and on the right schedule;
- Administered using the appropriate vascular access device (often a long-term device) which is placed in the correct anatomical location based on the expected duration of therapy, the pH, osmolarity, and osmolality of the medication;
- Administered using an appropriate drug delivery device;
- Flushed with the proper flushing solution between doses; and
- Monitored for adverse reactions and therapeutic efficacy.

The range of variables that must be managed by the infusion pharmacy to ensure safe and appropriate administration has led commercial payers to treat home infusion therapy as a medical service, reimbursed under their medical benefit (rather than the prescription drug benefit) and paid for using a per diem for clinical services, supplies, and equipment with separate payments for nursing visits. It also has led most commercial payers to require that infusion pharmacies be accredited by nationally recognized accreditation organizations. Commercial payers have used this

model aggressively to reduce overall health care costs while achieving high levels of patient satisfaction.

Home Infusion Pharmacy Services Differ from Retail Pharmacy Services

To ensure safe and proper administration of infusion drugs as outlined above, home infusion pharmacies provide the following services:

- Comprehensive assessment that considers patient history, current physical and mental status, lab reports, cognitive and psychosocial status, family/care partner support, prescribed treatment, concurrent oral prescriptions, and over-the-counter medications;
- Maintenance of appropriate procedures for the compounding and distribution of sterile infusion products as outlined in the national standards and state and federal regulations;
- Drug interaction monitoring and identification of potential drug, dose or drug-catheter incompatibilities;
- Comprehensive admission procedures that include patient education of medical and disposable equipment use, medication storage and handling, emergency procedures, vascular access device management, recognition and reporting of adverse drug reactions;
- Comprehensive care planning that considers actual or potential drug or equipment-related problems, therapy monitoring with specific patient goals, and coordination of activities with other providers such as home health agencies and physicians;
- Ongoing patient monitoring and reassessment activities to continually assess for response to treatment, drug complications, adverse reactions, and patient compliance;
- Laboratory report reviews, as applicable, and subsequent consults with care professionals to adjust medication orders if necessary;
- Maintenance of appropriate physical facilities for storage, preparation, dispensing, and quality control of all infusion medications and equipment;
- Ongoing employee education and competence validation activities; and
- Performance improvement programs that include collection of clinical outcomes data, patient perception data, trending and analysis of these and other performance measurement data, and root cause evaluations of all sentinel events.

Home Infusion Therapy is not a Good Fit under Part D

CMS's final Part D rule limited coverage of infusion therapy to the cost of the drugs alone and a retail-like dispensing fee. The regulation expressly disallowed coverage for the professional services, supplies, or equipment necessary to safely provide home infusion therapy, which typically represent more than half the cost of caring for these patients. This fundamental coverage shortfall, as well as the general inapplicability of the retail benefit design to home infusion therapies, has adversely affected the care of Medicare beneficiaries in several ways.

Dual-eligible beneficiaries typically had full coverage of home infusion therapy under Medicaid prior to their enrollment in Part D. Once enrolled in Part D, however, many dual-eligible beneficiaries initially experienced a disruption in care due to the states' uncertainty as to their role in providing Medicaid "wrap-around" coverage to fill in the gaps left by the drug-only coverage offered by Part D. CMS has been working to

clarify the states' role and resolve these issues, which has helped to minimize disruptions in care. However, dual-eligibles continue to be adversely affected by restricted formularies, cumbersome prior authorization processes, inadequate coordination of care, and a lack of access to qualified providers in Part D home infusion networks. These issues have led to unnecessary hospital admissions and hospital discharge delays that continue to this day.

It has been our experience that Part D enrollees who are not dual-eligibles or do not have supplemental insurance have little or no access to home infusion therapies under Medicare Part D. Since the non-covered home infusion supplies, equipment, and professional services constitute most of the costs associated with home infusion therapy, these Medicare beneficiaries are effectively denied access to home infusion. Many are being forced to seek treatment in hospitals and skilled nursing facilities at a significantly higher cost to Medicare and at much greater inconvenience to the patients.

In addition, Part D coverage limitations can pose a very real threat to health and safety. There were initial reports that some non-infusion pharmacies were sending non-compounded intravenous drugs by mail to beneficiaries, without educating the patients on how to mix and administer the drug, without any clinical oversight that should be provided based on community standards of care, and without the necessary supplies and equipment that are integral to the drug's safe and proper administration. Fortunately, CMS was quick to recognize the serious safety concerns and took steps to minimize or eliminate these occurrences. While these efforts have helped to address the worst abuses observed during the early weeks of Part D, the root causes of poor quality of care remain intact: a fundamental coverage shortfall, a lack of appropriate quality standards, and an alignment of incentives that do not foster quality patient care.

Since the Part D benefit went into effect on January 1, 2006, the following issues have arisen and remain with respect to the coverage and provision of home infusion therapy under this benefit:

- The absence of coverage for the professional services, supplies and equipment has discouraged the participation of qualified home infusion pharmacies in Part D.
- A disturbing number of PDPs have omitted home infusion drugs from their formularies and have not implemented a timely exceptions process that permits infusion patients who have acute needs to access these drugs.
- Other PDPs are genuinely concerned and frustrated about Part D's incomplete coverage for home infusion therapy and are waiting for CMS or Congress to correct this situation.
- Part D does not provide quality standards applicable to home infusion therapy. Consequently, Medicare beneficiaries are at risk of receiving infusion drugs from entities that do not meet well-established standards of care.

We should note for the Committee that we are in regular communication with CMS officials on these issues, and appreciate CMS' on-going efforts to address our concerns. In light of the over-arching structure of the Part D benefit, however, as

well as its limitations described above, it is apparent that the coverage problems will only be resolved by a statutory change.

Proposed Solution

CMS has determined that it does not have the authority to cover infusion therapy services, supplies, and equipment. Yet, CMS openly acknowledges that its policies leave "gaps in coverage" for home infusion. NHIA strongly believes that home infusion therapy professional services, supplies and equipment should be covered by Medicare. Last year, legislation that would provide comprehensive Medicare coverage of home infusion therapy was introduced in the House. We are working with legislators in both houses of Congress to develop similar legislation in the 110th Congress. This legislation would continue to cover infusion drugs under Part D, but would cover home infusion services, supplies and equipment under Part B. The bill also would provide CMS with the authority to do what is necessary to ensure that this benefit, involving two Parts of the Medicare program, is practical and workable for beneficiaries. If enacted, this legislation would lower costs, produce better outcomes for beneficiaries, and implement rigorous quality standards.

For decades, the private sector has made effective use of home infusion therapy to deliver life-saving treatments to patients without the added cost and inconvenience of hospitalization. Medicare's "coverage gap" in this area actually increases costs to the Medicare program because patients are forced into more expensive treatment settings, such as hospitals or skilled nursing facilities, to receive their care. Since most beneficiaries cannot afford to pay home infusion ancillary costs out-of-pocket, the Medicare program can achieve the efficiencies, cost savings, and quality improvements employed in the private sector only if the requisite home infusion services, supplies, and equipment are covered under Part B.

Why do we believe that home infusion services, supplies, and equipment should be covered under Part B? Part B is the most logical part of the Medicare program in which to place the non-drug components of the therapy and where national Medicare quality standards for the provision of this therapy can most easily be developed. As a result, infusion therapy could be defined and covered accurately under Part B. By contrast, even if Congress were to amend Part D to require full coverage for home infusion, it would remain an awkward fit since the Part D administrative structure is designed for a drug-only benefit and is not one that can easily be adjusted to accommodate what CMS acknowledges to be a complex medical benefit.

Medicare's coverage gap also jeopardizes patient safety. Studies show that the application of stringent quality standards for home infusion therapy produces superior outcomes for patients. There is growing evidence that hospital stays significantly increase the possibility of serious infections. When beneficiaries receive infusion therapy within the home setting, they are far less likely to acquire infections. In addition, they are not inconvenienced by long distance travel to receive their treatments, and are able to recover from their illness within the comfort of their own homes.

In addition, Medicare Part D does not provide quality standards applicable to home infusion therapy. Medicare beneficiaries are at risk of receiving drugs from entities that do not meet well-established standards of care. Complex intravenous therapies that require extensive clinical services, care coordination, equipment, and supplies should be administered in adherence to stringent quality standards of care. The

proposed legislation would require the Secretary of the Department of Health and Human Services to develop appropriate quality standards to ensure the safe and effective provision of home infusion therapy.

As long as Congress allows incomplete coverage of and access to home infusion therapy in Medicare, the program will not realize the potential efficiencies, cost-savings, and quality improvements possible.

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Every day that passes without complete Medicare coverage of home infusion therapy is a missed opportunity to bring cost-effective care in the most convenient setting to beneficiaries. Medicare beneficiaries have a legitimate expectation that they now can obtain home infusion therapy through the Medicare program. We stand ready to work with Congress to fulfill this expectation for our seniors. Thank you for your interest in overseeing and improving the implementation of this important benefit.

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