HEARING ON BENEFICIARY PROTECTIONS IN MEDICARE PART D

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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HEARING ON BENEFICIARY PROTECTIONS IN MEDICARE PART D

THURSDAY, JUNE 21, 2007

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON SELECT REVENUE MEASURES,
Washington, D.C

The Subcommittee met, pursuant to notice, at 2:00 p.m., in room 1100, Longworth House Office Building, Hon. Fortney Pet Stark [Chairman of the Subcommittee] presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTHFOR IMMEDIATE RELEASE

FOR IMMEDIATE RELEASE
June 21, 2007
HL–14

CONTACT:

Stark Announces a Hearing on Beneficiary Protections in Medicare Part D

House Ways and Means Health Subcommittee Chairman Pete Stark (D–CA) announced today that the Subcommittee on Health will hold a hearing on protecting beneficiaries in Medicare Part D plans. **The hearing will take place at 2 p.m. on Thursday, June 21, 2007, in Room 1100, Longworth House Office Building.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from the invited witness only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

The Medicare Modernization Act of 2003 (P.L. 108–173) created a new Medicare Part D voluntary prescription drug program for beneficiaries. Since January 2006, beneficiaries have had the opportunity to enroll in private-sector prescription drug plans. As of March 2007, 16.9 million beneficiaries were enrolled in stand-alone prescription drug plans (PDPs) and another 7.1 million were enrolled in Medicare Advantage plans offering prescription drugs (MA–PDs). Millions more Medicare beneficiaries receive drug coverage through other sources like the Department of Veterans Affairs or a former employer.

In nearly every state, beneficiaries must choose among more than 50 different drug plan options offered by eight to 40 different plan sponsors. Each plan can offer a unique benefit structure as long as it is actuarially equivalent to the standard benefit. This forces beneficiaries to compare widely varying premium, cost-sharing, formulary, and utilization management designs. Beneficiary confusion about the number and type of plan offerings has led to calls for prescription drug plan standardization, similar to the Medigap market, or for the creation of a drug program administered by Medicare that competes with private sector plans.

Implementation of the new Part D drug program was fraught with problems. Beneficiaries had trouble navigating the multitude of drug plan choices, and even after signing up many still struggled to get their drugs at the pharmacy counter. While many of those early problems have been fixed, Congress has an obligation to make sure Part D runs smoothly and beneficiaries are adequately protected. Advocates for Medicare beneficiaries have expressed ongoing concerns with enrollment periods and practices, formulary requirements and exceptions, appeals and grievance procedures, marketing abuses and beneficiary education.

In announcing this hearing, Chairman Stark said: **"Part D has been up and running for a year and a half, and Congress has yet to look at any changes necessary to protect beneficiaries in this new program. It's time to shine the light on Part D and see if there are some simple things we can do to improve the program for beneficiaries and taxpayers."**

FOCUS OF THE HEARING:

The hearing will focus on Medicare Part D, ongoing beneficiary protection issues in the new program, and possible statutory changes necessary to improve the program for beneficiaries and taxpayers.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov,* select "110th Congress" from the menu entitled, "Committee Hearings" (*http://waysandmeans.house.gov/Hearings.asp?congress=18*). Select the hearing for which you would like to submit, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You MUST REPLY to the email and ATTACH your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business **Thursday, July 5, 2007**. Finally, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721.

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

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

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

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

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

Chairman STARK. We will begin our hearing.

We focused a lot of attention last month on the low-income subsidies for Part D, and we are going to continue today taking a look at how it is working overall for beneficiaries. We don't intend for today's hearing to be a cheerleading session, and I hope we will lay

the groundwork for improvements that we might possibly be able to achieve in this year's legislation. The program, it is new, but it doesn't mean that we can't, working together, acknowledge ways in which we could improve it.

I am going to ask unanimous consent that the rest of this magnificent statement that I have prepared, in the interest of time, because I understand in another 20 or 30 minutes we may have some votes, so for the rest of this statement appear in the record in its entirety.

[The prepared statement of Mr. Stark follows:]

Dawson, Andrew

From: Cohen, Yoni
Sent: Thursday, June 21, 2007 2:43 PM
To: Cohen, Yoni
Subject: STARK OPENING STATEMENT AT A HEARING ON BENEFICIARY PROTECTIONS IN MEDICARE PART D

NEWS
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13TH DISTRICT, CALIFORNIA
CHAIRMAN, WAYS AND MEANS HEALTH SUBCOMMITTEE

FOR IMMEDIATE RELEASE, Thursday, June 21, 2007
CONTACT: Yoni Cohen, Stark (202) 225-3202

STARK OPENING STATEMENT AT A HEARING ON BENEFICIARY PROTECTIONS IN MEDICARE PART D

WASHINGTON, D.C. -- Representative Pete Stark (D-CA), Chairman of the Ways and Means Health Subcommittee, delivered the following opening remarks at today's hearing on beneficiary protections in Medicare Part D.

"Last month, we had an opportunity to focus a lot of attention on the Part D Low Income Subsidy (LIS). Today, we continue our look at the Part D program, taking a much broader look at how Part D is working for beneficiaries. Unlike the few sessions on this in the previous Congress, today's hearing will not be a cheerleading session. Instead, I hope this hearing will lay the groundwork for improvements to Part D that may be included in the Medicare sections of forthcoming health legislation we hope to move this summer. This program may be new, but that doesn't mean we can't acknowledge its flaws and make it better.

"In a perfect world, today's hearing would focus on creating a Part D plan run by Medicare that would negotiate for lower prices and compete against the private plans. We could set up a situation similar to what happens now for medical benefits, with Medicare offering its coverage and private plans available for folks who opt to go down that road. I know that proposal isn't yet ripe, but I hope we can at least talk about standardizing Part D products so beneficiaries are better able to compare the 50 or more plans available in their communities. As we know, the standardization model has been quite successful in the Medigap market.

"One of the most basic requirements for a functional private market is an informed consumer. Reams of research show that too many options are overwhelming. The private plans are aware of this, and thus push past the acceptable limits of marketing in an effort to scoop up senior citizens and lock in their market share. Inertia is a powerful force for anyone, and especially for those who are faced with too many choices. We desperately need to bring some order to this market.

"As we all know, Part D had some serious growing pains in 2006. That is to be expected of any new program of this size. We'll hear today that some of these problems have been fixed, but we'll also hear from our witnesses that beneficiaries still have major concerns with Part D.

"Enrollment problems continue to be a huge area of concern for beneficiaries and advocates alike. There are a number of technical issues that pose real problems to real people with respect to maintaining and changing Part D status. This is of particular concern to dual-eligible beneficiaries and I look forward to GAOs testimony on that issue.

"Even when beneficiaries are properly signed up for a plan, some still have difficulty obtaining appropriate medicines. We'll hear from Dr. O'Brien that HIV/AIDS patients often struggle to get needed medications even though plans are required to cover all the antiretroviral drugs as one of the so-called "protected classes."

"Beneficiaries also face difficulties trying to appeal improper enrollment decisions or wrongful denials of necessary medications. We'll hear today that many beneficiaries never even learn about the appeals process and those that do are often unable to navigate it without professional help. Streamlining this process would make Part D work better for beneficiaries and providers.

"In sum, we have an opportunity to learn about what is working and what is not working in Part D. We even have one of Part D's largest participants here to provide their suggestions on how to make the program work better. I thank them for agreeing to join us today, and I hope to offer them some suggestions as well!

"I hope we can capitalize on this opportunity and work in a bipartisan fashion to make improvements to Part D that will improve the program for beneficiaries and taxpayers alike.

"I look forward to the testimony of all our witnesses, and I yield to Mr. Camp for any opening statement he'd like to make."

-30-

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Chairman STARK. I recognize Mr. Camp for any comments he would like to make.

Mr. CAMP. Thank you, Mr. Chairman.

I have a pretty long statement as well, which I will ask unanimous consent to be placed in the record. In the interest of time, I will shorten mine as well.

I just want to say that we have almost 28 million Medicare beneficiaries receiving help with prescription drug costs because of the Medicare Modernization Act. A total of 39 million Medicare beneficiaries have drug coverage, and that is a significant success. Seniors are saving an average of 1,200 off the cost of prescription drugs this year, and national polls show that more than 80 percent of seniors are satisfied with their benefits.

Obviously, is Part D perfect? Of course not. Can Part D be improved? I absolutely believe it can. But I think we need to tread carefully when considering fundamental changes in this important, successful and well-liked program.

I just want to make sure that, having looked at some of the testimony that we have today, there may be a few inaccuracies in some of those on the second panel; and I would like us to address at least the testimony. Two witnesses are going to say that CMS does not notify beneficiaries of their right to appeal, and in my knowledge CMS does dedicate 10 pages in the Medicare and You Handbook, which is now issued to every beneficiary.

Obviously, we hold these hearings to get a better understanding of important issues that help guide us as we try to legislate, but I do also want to make certain that the information the Committee receives is accurate. So, I look forward to hearing the testimony today and shedding light on this very important program, and I will have the rest of my statement placed in the record.

Thank you, Mr. Chairman.

Chairman STARK. Without objection.

[The prepared statement of Mr. Camp follows:]

Statement of Ranking Member Dave Camp
Subcommittee on Health
Hearing on Part D Beneficiary Protections
June 21, 2007

Thank you, Chairman Stark.

Today, 28 million Medicare beneficiaries are receiving assistance with their prescription drug costs as a result of the Medicare Modernization Act. A total of 39 million Medicare beneficiaries now have prescription drug coverage – a significant success.

The impact Part D has had on Medicare beneficiaries speaks for itself – seniors are saving an average of $1,200 off the costs of their prescription drugs this year. National polls show that more than 80% of seniors are satisfied with their new benefit.

The costs of the program are also much lower than earlier estimates. Because Medicare plans negotiated deeper discounts, cost estimates from the

Congressional Budget Office and Office of Management and Budget show the cost of drug benefit for taxpayer is nearly $200 billion less than originally anticipated.

That is not to say that start of this program was without problems. Beneficiaries had difficulties getting information about their plan choices, were confused with the enrollment process, or encountered problems with their co-payment amounts.

In response to these difficulties, Secretary Leavitt, CMS Administrators McClellan and Norwalk, their staffs and literally thousands of senior advocates, pharmacists and Medicare plan employees worked together to fix the problems and assist Medicare beneficiaries in choosing the plan that best met their needs. I applaud everyone involved for their help working through these problems.

Yet there are calls to modify or gut the Medicare drug benefit. Before we rush to adopt the "reforms" that some of our witnesses will talk about today, I hope that we will look at the actual experiences of beneficiaries who are enrolled in the program.

One example of this type of problematic reform would be the proposal to restrict beneficiaries' choices, limiting them to just a few government approved plan options. While many beneficiaries were confused by the large number of plans, less than 10% of them chose the so-called "standard benefit" designed by Congress. We should not be surprised that seniors, rather than government bureaucrats, were better able to judge which plan best fits their health care needs.

Is Part D perfect? Of course not. Can Part D be improved? Absolutely. But we need to tread carefully when considering fundamental changes to this important, successful, and well-liked program.

Mr. Chairman, before I yield back I'd just like to say one thing. I'm concerned by a few inaccuracies that are contained within the testimony of some of those on the second panel today.

Two witnesses claim that CMS does not notify beneficiaries of their right to an appeal when, to my knowledge, CMS dedicates 10 pages on these rights in the

"Medicare and You Handbook" that is mailed each year to every beneficiary. These same witnesses claim that beneficiary advocates do not have access to the three compendia that govern the approval for off-label prescription drug use. However, I'm told that these compendia are widely available in both electronic and print format. In fact, one of these compendia is posted on a free Internet site.

Our subcommittee holds these hearings to gain a better understanding of important issues to help guide our actions during the legislative process. We must be able to trust that the information being presented at these hearings is accurate. I hope that the Chairman and other members of this subcommittee share my concerns.

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

Chairman STARK. If nobody else cares to enlighten us at this point, we will turn to our first panel. It is a pleasure to have the Acting CMS Administrator, Leslie Norwalk, back with us today; and we have the privilege of being enlightened by Ms. Kathleen King from the Government Accountability Office, which I assume you know as GAO.

Thank you both for joining us; and can you tell us, starting with Ms. Norwalk, how we might improve Part D and make it work better for our beneficiaries?

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

Ms. NORWALK. I am happy to do that, Chairman Stark. Good afternoon. I will probably do a little bit of cheerleading first, but I promise to get to that in my statement.

Chairman Stark, Representative Camp and distinguished Members of the Subcommittee, I am pleased to be here to discuss the Medicare prescription drug benefit, or Part D. Today, 24 million people in Medicare are enrolled in Part D. For more than a year, surveys have consistently told us that over 80 percent of beneficiaries are satisfied with their coverage. Part D is working especially well for those needing assistance most urgently. Nearly nine out of ten new eligibles report satisfaction with the Medicare drug benefit.

As you know, the Medicare Modernization Act established a number of important beneficiary protections under Medicare Part D which help ensure that beneficiaries do, in fact, have access to the covered drugs they need and also help prevent discrimination against certain classes of beneficiaries. Seamless policies implementing these protections require plans to provide a wide range of information to enrollees regarding their rights and benefits under the plan.

All Part D plans must contract with a broad-knit range of network pharmacies throughout their service area, conform to detailed marketing guidelines, operate toll-free customer service lines with convenient hours and participate in consumer satisfaction surveys.

Plan formularies are required to be submitted annually for CMS review and approval. We follow a rigorous multi-step review process to ensure that plan formularies include a wide range of Part D-covered drugs across all therapeutic drugs and categories. We also review plan utilization management techniques, such as prior authorization or step therapy, to ensure that they are not being used to discriminate against beneficiaries, particularly those with high drug costs; and these are techniques widely used in Medicaid and the commercial market.

Utilization management techniques may be viewed appropriately as an added benefit for plan enrollees. Step therapy and prior authorization are routinely used to ensure that dosing follows the updated label or to protect against potentially lethal drug interactions.

While these utilization management techniques may sometimes cause delays or frustration, they in fact protect beneficiaries, which is our utmost priority. This is particularly the case given the num-

ber of beneficiaries with multiple doctors that may know the patient's full drug history.

Plans also must have grievance coverage determination in appeals processes that are consistent with statutory requirements and CMS policy. Beneficiaries may request an exception to gain coverage of nonformulary drugs from their plan, and once granted that exception remains in effect through the duration of the benefit year.

Our policies require that plans grant exceptions when medically necessary based on a prescribing physician's supporting statement. For example, if a physician indicates and provides supporting medical evidence that the covered Part D drug on any tier of a plan's formulary would not be as effective and/or would have an adverse effect for a planned enrollee, that plan must cover the prescribed non-formulary drug.

Plans must issue decisions on requested exemptions as quickly as an enrollee's health status requires. Plans must also have procedures to expedite these determinations and render decisions within 24 hours. As an enrollee, his or her designated representative, or the enrollee's prescribing physician, may request that a Part D plan expedite coverage determination when the enrollee or the physician believes that waiting for a decision under the standard timeframe may place the enrollee's health in serious jeopardy. If an enrollee is dissatisfied with the coverage determination, he or she can appeal.

The prescribing physician may also ask for an expedited first-level appeal or redetermination on behalf of the enrollee. Standard redeterminations must be communicated within 7 days after receiving the request. For an expedited redetermination, they must be done within 72 hours after the request.

If a plan issues an adverse redetermination, they are required to give the enrollee notice that includes information on how to do a further appeal with an independent review entity, or IRE. To help ensure these requirements are followed, CMS collects data on the number of appeals that are forwarded by the plan to the IRE for consideration and analyze that data and investigate outliers. We also receive appeal information directly from the IRE.

We have done a whole lot to make the coverage determination and appeals process more understandable and accessible for beneficiaries, as Representative Camp mentioned, including a whole host of publications and so forth. We also have given the pharmacy a standard form to give to beneficiaries when drugs are denied at the counter.

In addition to these, we have established baseline measures for tracking plan performance across a wide range of other metrics, including customer service, satisfaction surveys, complaint data, appeals data, disenrollment rates, generic dispensing and various quality measures.

As a part of our routine monitoring, CMS immediately contacts plans to resolve any identified patterns of unacceptable performance or to prevent potential problems. We will also issue report cards later this year on plan performance so beneficiaries can look at them for the upcoming enrollment season.

We also take very seriously any violation of program requirements. When warranted, we initiate compliant actions against plans not meeting the baseline measures. Actions may range from corrective action plans to civil monetary penalties or removal from the program, depending on the extent to which plans have violated the requirements.

Our efforts are continually evolving. For example, we are working to improve methods of identifying companies focused on compliance audits in order to make more effective use of available resources. We have a risk contractor assessment methodology that identifies organizations in program areas representing the greatest compliance risks to Medicare beneficiaries in the government and expect to have an enhanced, centralized, data-driven risk assessment in place for the 2008 benefit year.

With ongoing vigilance and improvements such as this, I am confident we will continue to see high levels of beneficiary satisfaction with Part D and will effectively manage plan compliance as problem areas arise.

Finally, the number one challenge CMS has encountered in implementing the benefit is the requirement that beneficiaries must be allowed to have their premiums withheld from Social Security checks. We have dedicated more staff, more resources and more time on this considerable issue than any other, and it is our first and foremost concern.

We are in the final stages of completing our review of impacted beneficiaries who have premium withhold issues. Our next step is reconciling all 2006 premiums, and we expect to complete this in a matter of months.

Unfortunately, there is no quick fix for this problem. CMS and the Social Security Administration will continue to devote significant resources to solving the numerous underlying issues that lead to inaccurate premiums and beneficiary cost sharing due to the premium withhold requirements.

Thank you, and I would be happy to answer any questions you might have. My written statement I think you should have for the record.

[The prepared statement of Ms. Norwalk:]

Statement of Leslie V. Norwalk, Acting Administrator, Centers for Medicare and Medicaid Services

Good afternoon Chairman Stark, Representative Camp and distinguished members of the Subcommittee. I am pleased to be here today to discuss the Medicare prescription drug benefit (Part D) and in particular, beneficiary protections and plan oversight. Following the enactment of Part D with the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), CMS undertook an unprecedented outreach campaign, resulting in approximately 90 percent of eligible beneficiaries having creditable coverage for prescription drugs through Part D or other sources by the end of the initial enrollment period (May 15, 2006). CMS has worked equally hard to ensure that once enrolled, people with Medicare are able to take advantage of their prescription drug coverage without difficulty.

Part D in 2007: Lower Costs and Improved Satisfaction

In many respects, Part D is the single most important benefit addition in the history of the Medicare program. Nearly 24 million beneficiaries are enrolled in a Part D Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug Plan (MA–PD). More importantly, according to recent surveys, overall satisfaction with Part D continues to be high among enrollees in the Medicare drug benefit. In September of 2006, a survey conducted for the Medicare Rx Education Network re-

ported that over 80 percent of Medicare beneficiaries are satisfied with their current coverage and drug plans, including beneficiaries eligible for both Medicare and Medicaid (dual eligibles), who receive the low income subsidy (LIS).[1] According to the follow-up survey conducted by the Network in early January 2007, overwhelming majorities of enrollees give Part D high ratings along a number of dimensions: 91 percent said the plan is convenient to use; 89 percent said they understand how the plan works; 86 percent said the plan has good customer service; 81 percent said the co-pays are affordable; 79 percent said the monthly premium is affordable; and 77 percent said the plan covers all medicines. Part D is working especially well for those who need assistance most urgently. The Medicare Rx Education Network reports that almost 9 out of 10 dual-eligible enrollees are satisfied with their coverage.

In addition to beneficiary participation and satisfaction, the program also has resulted in significant savings for beneficiaries and lower-than-projected costs for taxpayers. Beneficiaries are saving an average of 1,200 a year, with estimated average premiums in 2007 now at $22 a month, down from an average of $23 a month in 2006 and 42 percent lower than the original estimate of 37 a month.

The latest cost projections for Part D through 2015, released on April 23 with the 2007 Medicare Trustees Report, are 13 percent lower than estimated in the 2006 Trustees Report (and substantially lower than the original estimates from 2003). Plan bids for 2007 were 10 percent lower than in 2006, as a result of intense competition among plans to attract and retain enrollees and plans' expectations to further increase use of inexpensive generic drugs, rather than more costly brand-name equivalents. In addition, overall prescription drug costs have increased much more slowly during 2004–2006 than in prior years. Together with additional factors, these developments have reduced projected Part D costs significantly compared to the estimates in the 2006 Trustees Report.

What a Difference a Year Makes: Lessons Learned

When CMS last appeared before this Subcommittee to testify regarding the Part D prescription drug benefit, we reported on our efforts to resolve a number of systems and process issues that impacted some Part D enrollees' ability to access covered drugs. CMS worked hard to find and fix the problems, and took significant steps early to avoid similar issues in 2007. We worked with plans, pharmacists and States to improve data systems impacting beneficiary access. For example, we facilitated better communication between plans and pharmacies, which resulted in upgrades to pharmacy software systems that will improve messaging between pharmacies and plans for better customer service. Also, throughout the year, CMS made a series of systems and process changes and enhancements to improve our file and data exchanges with plans, SSA and the States to improve performance and accuracy in beneficiary enrollment and benefits processing.

In September of 2006, CMS published a "Readiness Checklist" for all prescription drug plans, reminding them of their obligations, key dates, and vital tasks to ensure a smooth annual enrollment season and transition to the 2007 benefit year. The Readiness Checklist included elements related to call center requirements, complaint resolution, systems testing and connectivity, data submission and file processing, enrollment procedures, beneficiary marketing and communication strategies, beneficiary and pharmacy customer service, and timely payment to pharmacies.

In early November 2006, CMS asked all plans to report on their successes and any problems encountered in accomplishing the tasks on the Readiness Checklist. The results from this exercise served two important functions: First, it reassured CMS that the vast majority of plans were fully prepared for annual enrollment and the new benefit year, and that they had successfully implemented our guidance and requirements. Second, it identified areas where some plans indeed were having problems—for example, some plans reported that they were not able to issue the Annual Notices of Change (ANOCs) within the timeframe specified by CMS. Using this information from the Readiness Checklist, CMS was able to quickly implement a strategy to ensure that beneficiaries who did not receive an ANOC in a timely manner would be granted a special election period to extend the period of time they had to make a decision about their 2007 plan choice. CMS intends to repeat the Readiness Checklist exercise again this fall, in preparation for the 2008 plan year.

In the case of dual eligibles, CMS worked vigorously to address and fix the problems that caused the transition issues in 2006 in order to ensure a smoother transition in 2007. In the fall of 2006, CMS identified a handful of plans that either would

[1] Results are based on a telephone survey of 802 seniors ages 65+ enrolled in Medicare, conducted September 1–7, 2006, by KRC Research for the Medicare Rx Education Network. Of those surveyed, 82 percent are somewhat (29 percent) or very (53 percent) satisfied with their coverage. The margin of error for the full sample is + 3.5 percentage points.

be receiving auto-enrollees and facilitated enrollees for the first time or would receive a significantly higher volume of auto-enrollees and facilitated enrollees in 2007 compared to 2006. To ensure that these beneficiaries would experience a smooth transition to receiving their prescription benefits through a Part D plan, CMS conducted auto-enrollment and facilitated enrollment readiness audits. These audits were very thorough and examined all of the systems and other processes plans needed to have in place to successfully process the enrollment records, communicate with beneficiaries, and provide service. Any plan that was not fully prepared to undertake this important task was excluded from receiving auto-enrollments and facilitated enrollments. CMS plans to administer readiness audits again in 2007, in preparation for the 2008 benefit year.

To ensure a smooth transition for the existing LIS population specifically, CMS worked with States and SSA to identify dual eligibles and other limited-income beneficiaries (QMB, SLMB, Q–1 and SSI) beneficiaries who would again automatically qualify for LIS in 2007. Such beneficiaries were "re-deemed" for the low income subsidy for all of 2007. CMS also identified those who would not be automatically eligible in 2007, and worked with SSA to contact these individuals by mail in September of 2006. The notification explained the loss of deemed status, encouraged the beneficiary to apply for LIS, and provided an application for LIS with a postage paid envelope. It was CMS's goal to ensure that each of these beneficiaries was aware of their change in status and able to take action accordingly.

Additionally, CMS provided guidance and information to State Medicaid Directors, including a list of the affected beneficiaries (at the zip code level), and sent information to plans about their affected members in early October so that they could conduct outreach (by phone or mail). Over the past several months, almost 50 percent of those who had lost their deemed status regained such status or applied for the subsidy and qualified for LIS with SSA. CMS has already provided guidance to States about our process for 2008, and we have been working with SSA to identify ways to reach out to those who lose deemed status to ensure that they apply with SSA as early as possible.

CMS also anticipated transition issues related to the requirement that plan sponsors must qualify annually for automatic assignment of dual eligible beneficiaries. Due to the nature of the annual bidding process and the requirement that dual eligible beneficiaries be assigned only to plans that submit bids below the regional low-income benchmark (LIS benchmark), a strong potential existed that many plans qualified to accept auto-assignment of dual eligible beneficiaries in 2006 might not qualify in 2007 resulting in a large-scale shift of this population in the new benefit year.

To address this issue, as well as to promote effective competition that builds on the savings achieved through beneficiaries' plan choices in 2006, CMS is conducting a demonstration for 2007 that implements a transitional approach to determining the federal contribution to the drug benefit for low-income Medicare beneficiaries in 2007. This demonstration resulted in greater stability in zero-premium plan options for LIS beneficiaries, thus minimizing the need for beneficiaries to be reassigned for 2007. In addition, as another key aspect of CMS' efforts to minimize dual eligible beneficiary movement among plans, CMS is conducting a demonstration for 2007 that permits plans with premium increases of less than 2 above the LIS benchmark to qualify to retain their current LIS beneficiaries. Where the plan's premium increased by more than that amount, the beneficiary was reassigned to another plan offered by the same sponsor with a premium below the benchmark, where possible, to minimize transition issues. If a beneficiary had independently chosen that plan for 2006, CMS honored the decision for 2007, allowing the beneficiary to remain in their 2006 plan. In these cases, plans notified individuals of their prospective premium increase in 2007 and of their right to change plans.

Thanks to these efforts, fewer than 250,000 individuals needed to be re-assigned randomly to different prescription drug plan sponsors. These individuals received a letter on color-coded (blue) paper in November indicating that their 2006 plan's premiums were increasing for 2007 and that they would be reassigned to a new plan.

Finally, CMS has made important strides to promote a seamless transition for Medicaid-eligible individuals who are about to attain Medicare eligibility. In July of 2006, we asked States to begin submitting information to us concerning these individuals in advance of their Medicare eligibility so that CMS can deem them eligible for the LIS and assign them to a Medicare Part D plan before the start of their Part D eligibility. This prospective identification and enrollment process has resulted in the seamless transition of more than 10,000 new dual eligible individuals per month into Medicare Part D coverage.

Beneficiary Protection and CMS Oversight of Part D Plans

Medicare Part D includes beneficiary rights and protections similar to those in other parts of Medicare. These rights and protections are intended to ensure beneficiaries have access to covered Part D drugs, and prevent discrimination against certain classes of beneficiaries (*e.g.*, those with high drug costs). For example, Part D plans are required to submit formularies for CMS review and approval, and to provide a wide range of information to beneficiaries on such matters as plan formularies and benefits. Plans also must have grievance, coverage determinations, and appeals processes that are consistent with CMS regulatory requirements. In addition to these protections, which are highlighted in greater detail below, all Part D plans must contract with a broad network of retail pharmacies throughout their service area; must conform to detailed marketing guidelines; must operate toll-free customer service lines with convenient hours; and must participate in consumer satisfaction surveys (among many other things).

Formulary Requirements

The MMA requires CMS to review Part D formularies to ensure that beneficiaries have access to a broad range of medically appropriate prescription drugs to treat all disease states. CMS relies on stringent formulary requirements, overseen through a comprehensive, multi-step review process, to help ensure beneficiaries have access to covered Part D drugs. Formularies and formulary management practices vary across plans, subject to CMS-published guidelines reflecting two overarching policy objectives. First, Part D plan sponsors must have robust formularies developed and approved in accordance with CMS guidance that do not substantially discourage enrollment by or discriminate against particular types of beneficiaries. Second, plan sponsors are expected to use approaches to drug benefit management that are proven and in widespread use in prescription drug benefit management outside of Medicare.

As a condition of participation in Part D, sponsors must submit their plan formularies for CMS review and approval. CMS considers covered drugs as well as utilization management techniques in reviewing plan formularies. If CMS reviewers find that a plan's formulary could substantially discourage enrollment by certain types of beneficiaries or otherwise violates Part D program requirements, that formulary will not be accepted and if unchanged, the plan is not eligible for a Part D contract.

In addition to maintaining robust formularies, Part D plans' transition processes must address situations in which a beneficiary first presents at a participating pharmacy with a prescription for a drug that is not on the formulary, unaware of what drug is covered by the plan or of the plan's exception process. Plans must have systems capabilities that allow them to provide a one-time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) in order to accommodate the immediate needs of the beneficiary. In general, during the first 90 days in a plan, Medicare drug plans must provide their enrollees with 30 days to transition to another drug on the plan's formulary or to request a formulary exception. Different rules may apply for people who reside in an institution (like a nursing home). An effective transition process ensures that new drug plan enrollees will have timely access to the drugs they need while allowing the flexibility necessary for plans to develop a benefit design that promotes beneficiary choice and affordable access to medically necessary drugs. CMS reviews attestations of plan sponsors' transition processes as part of the plan benefit design review. Plan transition processes must address such situations for new enrollees, in addition to situations where enrollees are stabilized on formulary drugs that require prior authorization or step therapy under a plan's utilization management rules.

Outside of the transition period, if a beneficiary's physician determines that it is medically necessary for the beneficiary to take a certain drug, and the beneficiary has already tried similar drugs on his/her plan's formulary and they did not work, the beneficiary or the physician can contact the plan to request a formulary exception. If the request is approved, the plan will cover the drug.

Coverage Determinations (including Exceptions) and Appeals

CMS has incorporated substantial enrollee protections in the Part D coverage determination and appeals processes, which build on the processes used for the Medicare Advantage program and reflect additional considerations for prescription drugs. As mentioned above, beneficiaries may request a formulary exception. Part D plans must grant an exception, consistent with the prescribing physician's supporting statement, when it determines that the drug is medically necessary because (1) all covered Part D drugs on any tier of a plan's formulary would not be as effective

for the enrollee as the non-formulary drug, and/or would have adverse effects; (2) the number of doses available under a dose restriction for the prescription drug has been ineffective or is likely to be ineffective or adversely affect patient compliance; or (3) the prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements has been ineffective or is likely to be ineffective or adversely affect patient compliance, or has caused or is likely to cause an adverse reaction or other harm.

Plans must issue decisions as quickly as an enrollee's health status requires. In addition, plans must have procedures to expedite these determinations and render decisions within 24 hours. An enrollee, their designated representative, or the enrollee's prescribing physician may request that a Part D plan expedite a coverage determination when the enrollee or his or her physician believes that waiting for a decision under the standard timeframe may place the enrollee's life, health, or ability to regain maximum function in serious jeopardy.

If an enrollee is dissatisfied with a coverage determination, he or she can appeal the decision (including a decision on an exception request). The prescribing physician also can ask for an expedited first-level appeal (redetermination) on behalf of the enrollee. For expedited redeterminations, a Part D plan must give the enrollee (and prescribing physician involved, as appropriate) notice of its decision as quickly as the enrollee's health status requires, but no later than 72 hours after receiving the request. Decisions on standard redeterminations must be communicated to the enrollee in writing no later than 7 days after receiving the request. If a plan issues an adverse redetermination, the enrollee will receive a notice that includes information on how to request a reconsideration by the Part D independent review entity (IRE).

Plans are required to report data to CMS related to, among other things, prior authorization, step edits, formulary exceptions, tiering exceptions, and appeals. For example, the number of appeals forwarded by a plan to the IRE for consideration due to the plan's inability to meet timeframes for coverage determinations and redeterminations are collected by CMS and outliers are investigated. CMS also receives appeals information directly from the IRE, which is then compared to information submitted by the plans for further monitoring.

CMS has taken a number of steps to make the coverage determination and appeals processes more understandable and accessible. For example, CMS has developed publications designed for beneficiaries and physicians that explain how to request a coverage determination or an appeal and model forms that can be used when requesting coverage determinations (including requests for prior authorization). CMS also developed "best practice" standards for plan websites for the dissemination of appeals information.

Oversight of Part D Plans

Building upon lessons learned and information gathered during 2006, CMS has strengthened its oversight of Part D plans. CMS continually collects and analyzes performance data submitted by Part D plans, internal systems, and beneficiaries. CMS has established baseline measures for the performance data and has been tracking results over time. Plans not meeting the baseline measures are contacted by CMS and compliance actions are initiated. Actions range from warning letters all the way through civil monetary penalties and removal from the program, depending on the extent to which plans have violated Part D program requirements. All violations are taken very seriously by CMS, with beneficiary protection the foremost concern.

Compliance audits are another key approach to Part D plan oversight. CMS is working to improve its methods for identifying companies for compliance audits, making more efficient use of the resources available for ensuring compliance. For example, we have developed a contractor risk assessment methodology that informs the audit process by identifying organizations and program areas that represent the greatest compliance risks to Medicare beneficiaries and the government. CMS can then direct audit resources to those high risk contracts. While receipt and analysis of data is central to this oversight strategy, regularly scheduled and focused/targeted program compliance and program integrity audits remain necessary to ensure program compliance and document the Agency's program oversight responsibilities. Based on enhanced knowledge of the program—what is working well and what areas need to be strengthened—CMS is revising the risk assessment methodology to better equip us to focus our oversight resources on the most problematic plans. We anticipate the revised risk assessment tool will be ready for implementation and use in January 2008.

Currently, CMS is aware that there are significant concerns about the marketing practices of some plans. We are extremely concerned about reports of marketing

schemes designed to confuse, mislead or defraud beneficiaries, and are taking vigorous action to address violations. CMS enforcement responses to marketing violations may range from issuing a warning letter to requesting a corrective action plan to imposing civil monetary penalties or ultimately terminating a plan sponsor's contract. CMS also takes steps to ensure that beneficiaries are protected. Any beneficiary who believes he or she was enrolled in a plan without his or her consent may contact the plan, 1–800–MEDICARE, or a CMS Regional Office for assistance in disenrolling from the plan and selecting another Part D plan if desired. CMS has caseworkers in all Regional Offices and in our Central Office available to assist beneficiaries in resolving such issues, and has recently updated its protocols to ensure that caseworkers understand how to handle these requests expeditiously.

Further, CMS is now working with a contractor to augment the internal agency resources available for Part D compliance audits. Among other things, the contractor is conducting "secret shopping" at marketing events across the country; such information enables CMS to learn firsthand what is happening in the sales marketplace and to identify organizations for compliance intervention that are not meeting CMS marketing and enrollment requirements.

CMS also has strengthened relationships with State regulators that oversee the market conduct of health insurers. Specifically, CMS worked cooperatively with the National Association of Insurance Commissioners (NAIC) and State Departments of Insurance to develop a model Compliance and Enforcement memorandum of Understanding (MOU). This MOU enables CMS and State Departments of Insurance to freely share compliance and enforcement information, to better oversee the operations and market conduct of companies we jointly regulate and to facilitate the sharing of specific information about marketing agent conduct.

Conclusion

CMS continues to make significant progress in overseeing and promoting quality Part D prescription drug coverage. With ongoing effort and vigilance, I am confident we will see continued high levels of plan compliance with program requirements, along with significant improvements where necessary on this critical front. Thank you again for the opportunity to speak with you today. I look forward to answering your questions.

Chairman STARK. Ms. King.

STATEMENT OF KATHLEEN M. KING, DIRECTOR, MEDICARE PAYMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. KING. Mr. Chairman, Mr. Camp and Members of the Committee, thank you for inviting me to speak with you today. I am here to talk to you about a recently issued GAO report on challenges in enrolling new dual-eligible beneficiaries into Medicare Part D. As you know, the Medicare Modernization Act switched the drug coverage of Medicare beneficiaries and dual-eligible beneficiaries into Medicare effective January 1, 2006; and we were asked to take a look at that enrollment process.

My remarks today are going to focus on two aspects of that report. The first is CMS's process for enrolling dual-eligible beneficiaries into Part D plans and CMS's implementation of the retroactive coverage policy.

The dual-eligible beneficiaries are, as you know, more vulnerable than other Medicare beneficiaries. They are poorer, they have more extensive healthcare needs than other beneficiaries, they have higher rates of cognitive impairment and disability.

There are two different groups of dual-eligible beneficiaries, and if you will bear with me on this. About one-third of them are going from Medicaid to Medicare, that is, they are becoming Medicare eligible by virtue of turning 65 or exhausting their 2-year waiting period due to disability. Two-thirds of them are going from Medicare

to Medicaid, and they are doing so because they have a loss in income and resources. So, they have Medicare first and then they become Medicaid.

I have brought you a complicated chart, which is up on your screens; and I am not going to walk you through every part of that. But I just show it to you so that you understand how complicated the enrollment process is. There are multiple partners involved in it, including SSA, the State, CMS and prescription drug plans; and data exchanges flow back and forth across them, as you can see on your chart. This enrollment process has different effects on the one-third group and the two-thirds group.

In our work, we found that it takes about a minimum of 5 weeks for the enrollment process to be completed because of its complexity. CMS had to piece together existing data systems not used to operating in real time in order to do this. So, the enrollment process initially has an effect different on the one-third group and the two-thirds group.

For the one-third who are going from Medicaid to Medicare, their eligibility deate can be anticipated because CMS and SSA knows when they are going to turn 65 or when their waiting period is up. During 2006 CMS they devised a process to do prospective enrollment for these beneficiaries so they could bypass a lot of the difficulties experienced during the 5-week waiting period.

But for the two-thirds who are going from Medicare to Medicaid it is not possible to enroll them at this point prospectively. They may be likely to encounter difficulties in getting their prescription drugs at the pharmacy counter before the enrollment process has not been completed.

I want to show you—I will just flip to this other chart—the length of time that elapses and what the processes are in completing that enrollment. That is just for purposes of illustration.

Next, I want to turn to the retroactive coverage policy that CMS implemented with regard to dual-eligibles. CMS has determined that eligibility for Part D should go back to the first day of Medicaid eligibility. So, the enrollment process takes 5 weeks, and generally the Medicaid eligibility is retroactive several months. So, there is about a 5-month period in which beneficiaries are eligible for Medicare Part D, but don't have their membership information. During this period the plans are being paid for providing these benefits.

But last year CMS did not know how many beneficiaries were claiming reimbursement for retroactive coverage and did not inform beneficiaries of their right to be reimbursed for previous drug purchases. We think it is unlikely that beneficiaries would have saved their receipts if they didn't know until later that they were eligible for Part D.

During this period retroactive coverage, CMS paid about $100 million to the plan for providing benefits; and we don't know how many people actually filed claims for reimbursements during that time.

I also wanted to point out to you that we have some other ongoing work t looking at formulary coverage determinations and appeals; the plan fraud, waste and abuse plans; and complaints about to Part D that have been filed both to CMS and to the plans them-

selves. We expect to be able to report on these issues by the end of the year.

Mr. Chairman, that concludes my prepared statement.

Chairman STARK. Filed by the end of the year you said.

Ms. KING. Yes.

That concludes my prepared statement. I would be happy to answer any questions. Thank you.

[The prepared statement of Ms. King:]

Statement of Kathleen M. King, Director, Medicare Payment, U.S. Government Accountability Office

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Health, Committee on Ways and Means, House of Representatives

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MEDICARE PART D

CMS's Process and Policy for Enrolling New Dual-Eligible Beneficiaries

Statement of Kathleen M. King
Director, Health Care

GAO-07-1022T

GAO

Highlights

Highlights of GAO-07-1002T, a testimony before the Subcommittee on Health, Committee on Ways and Means, House of Representatives

June 21, 2007

MEDICARE PART D

CMS's Process and Policy for Enrolling New Dual-Eligible Beneficiaries

Why GAO Did This Study

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), dual-eligible beneficiaries—individuals with both Medicare and Medicaid coverage—have their drug costs covered under Medicare Part D rather than under state Medicaid programs. The MMA requires the Centers for Medicare & Medicaid Services (CMS) to enroll these beneficiaries in a Medicare prescription drug plan (PDP) if they do not select a plan on their own. CMS enrolled about 5.5 million dual-eligible beneficiaries in late 2005 and about 634,000 who became dually eligible during 2006.

GAO was asked to testify on (1) CMS's process for enrolling new dual-eligible beneficiaries into PDPs and its effect on access to drugs and (2) how CMS set the effective coverage date for certain dual-eligible beneficiaries and its implementation of this policy. This testimony is based on the GAO report, *Medicare Part D: Challenges in Enrolling New Dual-Eligible Beneficiaries* (GAO-07-272).

What GAO Recommends

GAO's report contains several recommendations, including that CMS require PDPs to modify beneficiary notices and that CMS monitor the implementation of its payment policy. CMS did not agree with all of the recommendations, but it has taken steps to implement some.

www.gao.gov/cgi-bin/getrpt?GAO-07-1002T.

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

What GAO Found

CMS's process for enrolling new dual-eligible beneficiaries who have not yet signed up for a PDP involves many parties, information systems, and administrative steps, and takes a minimum of 5 weeks to complete. For about two-thirds of these individuals—generally Medicare beneficiaries who subsequently qualify for Medicaid—pharmacies may not have up-to-date PDP enrollment information needed to bill PDPs appropriately until the beneficiaries' data are completely processed. As a result, these beneficiaries may have difficulty obtaining their Part D-covered prescription drugs during this interval. CMS has created contingency measures to help individuals obtain their new Medicare benefit, but these measures have not always worked effectively. For the other one-third of new dual-eligible beneficiaries—Medicaid enrollees who become Medicare-eligible because of age or disability—CMS eliminated the impact of processing time by enrolling them in PDPs just prior to their attaining Medicare eligibility. This prospective enrollment, implemented in late 2006, offers these dual-eligible beneficiaries a seamless transition to Medicare Part D coverage.

CMS set the effective Part D coverage date for Medicare eligible beneficiaries who subsequently become eligible for Medicaid to coincide with the date their Medicaid coverage becomes effective. Under this policy, which was designed to provide drug coverage for dual-eligible beneficiaries as soon as they attain dual-eligible status, the start of the Part D coverage can extend retroactively for several months before the date beneficiaries are notified of their PDP enrollment. GAO found that CMS did not fully implement or monitor the impact of this policy. Although beneficiaries are entitled to reimbursement for covered drug costs incurred during this retroactive period, CMS did not begin informing them of this right until March 2007. Given their vulnerability, it is unlikely that these beneficiaries would have sought reimbursement or retained proof of their drug purchases if they were not informed for their right to do so. Also, CMS made monthly payments to PDPs for providing drug coverage during retroactive periods, but did not monitor PDPs' reimbursements to beneficiaries during that period. GAO estimated that in 2006, Medicare paid PDPs millions of dollars for coverage during periods for which dual-eligible beneficiaries may not have sought reimbursement for their drugs.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you discuss the Medicare Part D prescription drug benefit. Implementation of this new drug benefit has raised particular concerns for individuals eligible for both Medicare and full Medicaid benefits—known as dual-eligible beneficiaries.[1] These individuals account for about 15 percent of all Medicare beneficiaries and 15 percent of all Medicaid enrollees. As a group, they are generally poorer and tend to have more extensive health care needs than other Medicare beneficiaries. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[2] dual-eligible beneficiaries—who previously received drug benefits under Medicaid—have had their prescription drug costs paid under Medicare Part D since January 1, 2006. In addition, the MMA requires the Centers for Medicare & Medicaid Services (CMS)[3] to assist dual-eligible beneficiaries by enrolling them in a private Medicare prescription drug plan (PDP) if they do not select a plan on their own. CMS enrolled about 5.5 million dual-eligible beneficiaries in late 2005 for the initial implementation of Part D and about 634,000 beneficiaries who became dual-eligible during 2006.

My testimony today will summarize selected findings from the previously released GAO report, *Medicare Part D: Challenges in Enrolling New Dual-Eligible Beneficiaries*.[4] Specifically, my remarks today will focus on (1) CMS's process for enrolling new dual-eligible beneficiaries into PDPs and its effect on beneficiary access to drugs and (2) how CMS set the effective Part D coverage date for certain dual-eligible beneficiaries and its implementation of this policy.

[1]We use the term dual-eligible beneficiaries to refer to individuals who qualify for a state's full package of Medicaid benefits.

[2]MMA, Pub. L. No. 108-173, tit. I, § 101, et seq., 117 stat. 2066, 2071-2152 (2003) (to be codified at 42 U.S.C. § 1395w-101, et seq. and 42 U.S.C. § 1396u-5).

[3]CMS is the agency that administers the Medicare program on behalf of the Secretary of Health and Human Services.

[4]GAO, *Medicare Part D: Challenges in Enrolling New Dual-Eligible Beneficiaries*, GAO-07-272 (Washington, D.C.: May 4, 2007).

To address these issues, we conducted site visits in six states—California, Maine, Maryland, Michigan, New Jersey, and Texas—to learn about dual-eligible beneficiaries' enrollment in Part D from the perspective of state Medicaid agencies, pharmacies, and long-term care providers. We also interviewed officials from CMS and representatives of PDPs about issues that pertain to dual-eligible beneficiaries. We conducted the work for our report from March 2006 through April 2007 in accordance with generally accepted government auditing standards.

In summary, we found that CMS's process for enrolling new dual-eligible beneficiaries involves many parties, information systems, and administrative steps, and takes a minimum of 5 weeks to complete. For the majority of these individuals—generally Medicare beneficiaries not yet enrolled in Part D who subsequently qualify for Medicaid—this processing interval can create difficulties in obtaining Part D-covered drugs at their pharmacies. For other new dual-eligible beneficiaries—Medicaid enrollees who become Medicare eligible because of age or disability—CMS took steps to eliminate the impact of the processing interval by enrolling them in PDPs just prior to their attaining Medicare eligibility. In addition, for the Medicare first, Medicaid second group of new dual-eligible beneficiaries, CMS set the effective date of Part D coverage to coincide with the first date of their Medicaid eligibility. Under this policy, which was designed to provide drug coverage for dual-eligible beneficiaries as soon as they attain dual-eligible status, the start of their Part D coverage can be retroactively set to several months before the date of their actual PDP enrollment. We found that CMS did not fully implement or monitor the impact of this coverage date policy. Although beneficiaries are entitled to reimbursement for covered drug costs incurred during this retroactive period, CMS and PDPs did not begin informing them of this right until March 2007. Also, CMS did not track Medicare payments made to PDPs to provide retroactive coverage or monitor PDPs' reimbursements to beneficiaries for that period. We estimate that in 2006, Medicare paid PDPs about $100 million for coverage during periods for which dual-eligible beneficiaries may not have sought reimbursement for their drug costs. In the report, we recommend that CMS require PDPs to notify beneficiaries about their right to reimbursement, monitor implementation of its retroactive payment policy, and take other steps to improve the operational efficiency of the program.

Background

Dual-eligible beneficiaries are a particularly vulnerable population. These individuals are typically poorer, tend to have far more extensive health care needs, have higher rates of cognitive impairments, and are more likely to be disabled than other Medicare beneficiaries. About three out of four dual-eligible beneficiaries live in the community and typically obtain drugs through retail pharmacies. Other dual-eligible beneficiaries reside in long-term care facilities and obtain drugs through pharmacies that specifically serve these facilities.

In general, individuals become dual-eligible beneficiaries in two ways. One way is when Medicare-eligible individuals subsequently become Medicaid eligible. This typically occurs when income and resources of beneficiaries fall below certain levels and they enroll in the Supplemental Security Income (SSI) program,[1] or they incur medical costs that reduce their income below Medicaid eligibility thresholds. If these Medicare beneficiaries did not sign up for a Part D plan on their own, they have no drug coverage until they are enrolled in a PDP by CMS. CMS data show that this group represented about two-thirds of new dual-eligible beneficiaries the agency enrolled in PDPs in 2006. According to CMS, it is not possible for it to predict which Medicare beneficiaries will become Medicaid eligible in any given month because Medicaid eligibility determinations are a state function.

Another way individuals become dually eligible is when Medicaid beneficiaries subsequently become eligible for Medicare by reaching 65 years of age or by completing the 24-month disability waiting period.[2] Once they become dual-eligible beneficiaries, they can no longer receive coverage from state Medicaid agencies for their Part D-covered prescription drugs. In 2006, this group represented approximately one-third of the new dual-eligible beneficiaries enrolled in PDPs by CMS. CMS can generally learn from states when these individuals will become dually eligible.

[1] In most states, beneficiaries who qualify for cash assistance from SSI—a cash assistance program for aged, blind, and disabled individuals with limited income and resources—automatically qualify for full Medicaid benefits.

[2] Under Social Security Disability Insurance (DI), which assists people who worked but became disabled before their retirement age, individuals are eligible for Medicare coverage after they have received DI cash benefits for 24 months.

For dual-eligible beneficiaries, Medicare provides a low-income subsidy that covers most of their out-of-pocket costs for Part D drug coverage. This subsidy covers the full amount of the monthly premium that non-subsidy-eligible beneficiaries normally pay, up to the low-income benchmark premium.[1] The subsidy also covers most or all of a dual-eligible beneficiary's prescription copayments. In 2007, these beneficiaries are responsible for copayments that range from $1 to $5.35 per prescription, depending on their income and asset levels, with the exception of those in long-term care facilities, who pay no copayments.

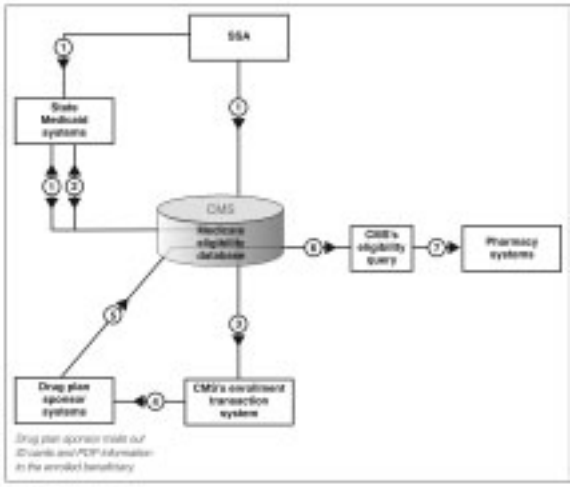
CMS's Enrollment Process Takes Time and Can Create Difficulties for Some Dual-Eligible Beneficiaries

Given the number of entities, information systems, and administrative steps involved, it takes a minimum of 5 weeks for CMS to identify and enroll a new dual-eligible beneficiary in a PDP. As a result, two out of three new dual-eligible beneficiaries—generally those who are Medicare eligible and then become Medicaid eligible—may experience difficulties obtaining their prescription drugs under Part D during this interval. For other new dual-eligible beneficiaries—those switching from Medicaid to Medicare drug coverage—CMS instituted a prospective enrollment process in late 2006 that enrolls these individuals before their date of Medicare eligibility and offers a seamless transition to Part D coverage.

Multiple parties and information systems are involved in identifying and enrolling dual-eligible beneficiaries in PDPs. As shown in figure 1, CMS, the Social Security Administration (SSA), state Medicaid agencies, and PDP sponsors play key roles in providing information needed to ensure that new dual-eligible beneficiaries are identified and enrolled properly. SSA maintains information on Medicare eligibility that is used by CMS and some states. State Medicaid agencies are responsible for forwarding to CMS lists of beneficiaries whom the state believes to be eligible for both Medicare and Medicaid. CMS is then responsible for making plan assignments and processing enrollments. PDP sponsors maintain information systems that are responsible for exchanging enrollment and billing information with CMS.

[1]The low-income benchmark is the average monthly beneficiary premium for all PDPs in a region, weighted by each plan's enrollment.

Figure 1: Overview of the Major Systems and Steps Used to Enroll Dual-Eligible Beneficiaries in PDPs

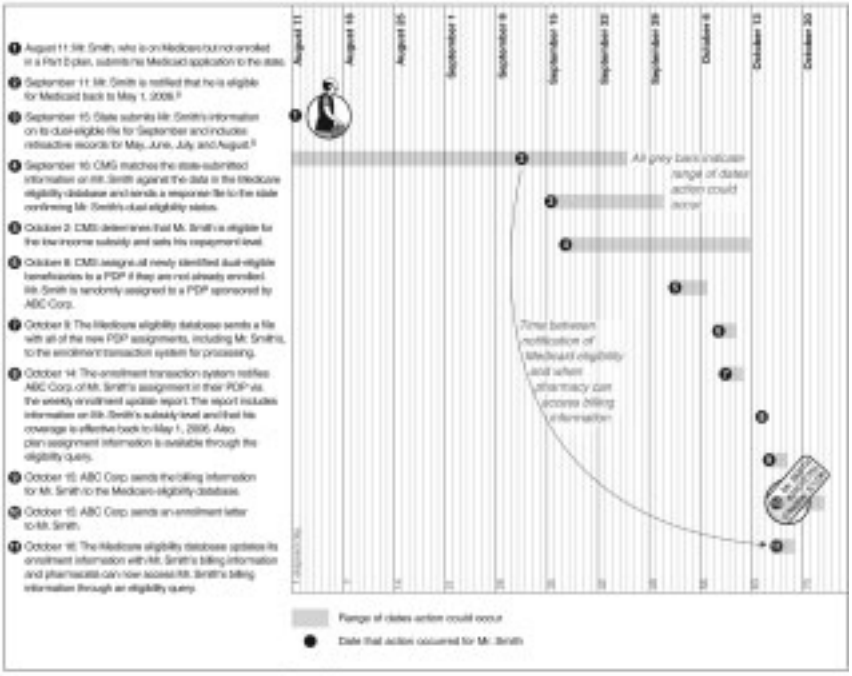


Source: GAO.

Notes: CMS adapted existing information systems used in the administration of other parts of the Medicare program to perform specific functions required under Part D. The Medicare eligibility database serves as a repository for Medicare beneficiary entitlement, eligibility, and demographic data. The database is used by CMS to provide up-to-date information to verify the status of dual-eligible beneficiaries, as well as determine subsidy status and make assignments to PDPs. The enrollment transaction system is used to enroll beneficiaries in PDPs. The eligibility query is used by pharmacies to obtain Part D enrollment information from the Medicare eligibility database.

The process of enrolling dual-eligible beneficiaries requires several steps. It begins when state Medicaid agencies identify new dual-eligible beneficiaries and ends when PDPs make billing information available to pharmacies and send enrollment information to dual-eligible beneficiaries. We estimate that it takes at least 5 weeks to complete the process under current procedures. During this interval, pharmacies may not have up-to-date PDP enrollment information on new dual-eligible individuals. This may result in beneficiaries having difficulty obtaining Part D-covered drugs at their pharmacies. To illustrate why this occurs, we present the hypothetical example of Mr. Smith, who as a Medicare beneficiary did not sign up for the Part D drug benefit and, therefore, upon becoming Medicaid eligible, was enrolled in a PDP by CMS. (Fig. 2 shows the steps in Mr. Smith's enrollment process.)

Figure 2: Mr. Smith, a Hypothetical Example of the Enrollment Process for a Newly Identified Dual-Eligible Beneficiary Who Was Medicare Eligible but without Previous Part D Coverage



Source: GAO.

Notes: The dates presented in this example of enrollment for Mr. Smith generally represent the best-case scenario. The range of dates represent the minimum and maximum length of elapsed time allowed for processing and notification, based on information provided by CMS. GAO makes no assurances that the events described would occur on the dates provided for any specific dual-eligible beneficiary.

[a]The scenario presented reflects an application to Medicaid based on a reason other than disability. State Medicaid agencies have 45 days to make eligibility determinations not based on disability and 90 days for eligibility determinations based on disability, subject to extensions in certain circumstances.

[b]If the state Medicaid agency did not determine that Mr. Smith was eligible for Medicaid before it submitted its September dual-eligible file, his information could not be submitted until October. This scenario is not presented in this figure.

From the time Mr. Smith applies for his state's Medicaid program on August 11, it takes about 1 month for him to receive notification from the state that he is eligible for Medicaid, thus beginning the enrollment process. From there, Mr. Smith's new status is submitted by his state to CMS in a monthly file transmittal. Once CMS receives the lists of dual-eligible beneficiaries from all of the states, it verifies eligibility for Medicare and sets each beneficiary's cost-sharing level. Then, around October 8, CMS assigns Mr. Smith to a PDP randomly, based on the premium level and the geographic area served by the PDP.[5] CMS next notifies the PDP sponsor, which then has to enroll him in its plan and assign the necessary billing information. This billing information, such as a member identification number, is necessary for pharmacies to correctly bill the PDP for Mr. Smith's prescriptions. The PDP also has to inform Mr. Smith of his enrollment information. By the time this process is completed, it is the middle of October.

CMS has developed some contingency measures to help individuals like Mr. Smith during the processing interval. However, we found that these measures have not always worked effectively. For instance, CMS designed an enrollment contingency option to ensure that dual-eligible beneficiaries who were not yet enrolled in a PDP could get their medications covered under Part D, while also providing assurance that the pharmacy would be reimbursed for those medications. However, representatives of pharmacy associations we spoke with reported problems with reimbursements after using this option, which has led some pharmacies to stop using it.

[5]Some states have assisted dual-eligible beneficiaries by using other methods to select a PDP for enrollment, including methods that also consider drug utilization information. For example, the State of Maine used beneficiary-specific data to reassign nearly half of the state's dual-eligible beneficiaries to PDPs that covered more of their prescriptions. After reassignment, the number of beneficiaries whose PDP covered nearly all of their prescription drugs increased significantly.

To avoid a gap in coverage for beneficiaries transitioning from Medicaid to Medicare prescription drug coverage, CMS has implemented a prospective enrollment process. Because states can predict and notify CMS which Medicaid beneficiaries will become new dual-eligible beneficiaries and when, CMS begins the enrollment process for these individuals 2 months before the their anticipated dual-eligible status is attained. By conducting the processing steps early, the prospective enrollment used for this group of new dual-eligible beneficiaries should ensure a seamless transition from Medicaid drug coverage to Medicare Part D coverage. Fully implemented in November 2006, prospective enrollment applies to about one-third of the new dual-eligible beneficiaries enrolled in PDPs by CMS.

CMS Made Drug Coverage Retroactive, but Did Not Inform Beneficiaries of Their Right to Reimbursement

For the majority of new dual-eligible beneficiaries, CMS requires PDPs to provide drug coverage retroactively, typically by several months. During 2006, Medicare paid PDPs millions of dollars to provide coverage to dual-eligible beneficiaries for drug costs that may have been incurred during the retroactive coverage period. However, we found that CMS did not fully implement or monitor the impact of this policy.

CMS made the effective date of Part D drug coverage for Medicare beneficiaries who become Medicaid eligible coincide with the effective date of their Medicaid eligibility. Under this policy, Part D coverage for these beneficiaries is effective the first day of the month that Medicaid eligibility is effective, which generally occurs 3 months prior to the date an individual's Medicaid application was submitted to the state, if the individual was eligible for Medicaid during this time. Thus, the Part D coverage period can extend retroactively back several months from when the actual PDP enrollment takes place.

Medicare makes payments to the PDPs for providing drug coverage retroactively. Specifically, PDPs are paid approximately $80 per month for the retroactive coverage period.[9] PDPs, in turn, are responsible for reimbursing their members (or another payer) for Part D drug costs incurred during the retroactive months. For instance, in the case of Mr. Smith, while he applied for Medicaid in August and learned of his PDP assignment for Part D in October, his coverage was effective May 1. If

[9]The $80 per month includes the direct subsidy Medicare pays PDPs for providing the Medicare drug benefit to any Medicare beneficiary and the low-income premium subsidy CMS pays PDPs to cover the cost of premiums dual-eligible beneficiaries would pay if they were not receiving the low-income subsidy.

Mr. Smith incurred any costs for Part D-covered prescription drugs from May—when he became eligible for Medicaid—through October, he could submit his receipts to his assigned PDP and be reimbursed by the PDP, less the copayments he would pay as a dual-eligible beneficiary.

We found that CMS's implementation of this policy in 2006 was incomplete. While dual-eligible beneficiaries were entitled to reimbursement by their PDPs in 2006, neither CMS nor PDPs notified dual-eligible beneficiaries of this right. The model letters used until March 2007 to inform dual-eligible beneficiaries of their PDP enrollment did not include any language concerning reimbursement of out-of-pocket costs incurred during retroactive coverage periods. In response to a recommendation in our report, CMS modified the model letters that the agency and PDPs use to notify dual-eligible beneficiaries about their PDP enrollment. The revised letters let beneficiaries know that they may be eligible for reimbursement of some prescription costs incurred during retroactive coverage periods.

Given the vulnerability of this population, it seems unlikely that many dual-eligible beneficiaries would have contacted their PDPs for reimbursement if they were not clearly informed of their right to do so and given information about how to file for reimbursement, neither would they likely have retained proof of their drug expenditures. Mr. Smith, for example, would need receipts for drug purchases made during a 5-month period preceding the date he was notified of his PDP enrollment—at a time when he could not foresee the need for doing so.

Further, CMS did not monitor how many months of retroactive coverage PDPs provided, nor did it monitor PDP reimbursements to beneficiaries for costs incurred during retroactive coverage periods. Based on data provided by CMS, we estimate that Medicare paid about $100 million to PDP sponsors in 2006 for retroactive coverage. CMS does not know what portion of this $100 million PDPs paid to dual-eligible beneficiaries to reimburse them for drug costs. If Mr. Smith's PDP did not reimburse Mr. Smith for any prescription drugs purchased during the retroactive coverage period, the PDP retained Medicare's payments for that period.

Conclusions

Given the time it takes to complete the enrollment process, CMS has taken action to ensure ready access to Part D for some new dual-eligible beneficiaries, but difficulties remain for others. For the one-third of new dual-eligible beneficiaries whose eligibility can be predicted, CMS's decision to implement prospective enrollment should eliminate the

coverage gap in transitioning from Medicaid to Medicare drug coverage. However, because of inherent processing lags, most new dual-eligible beneficiaries may continue to experience difficulties obtaining their drugs for at least 5 weeks after being notified of their dual-eligible status. In addition, CMS's incomplete implementation of its retroactive coverage policy in 2006 means that CMS paid PDPs millions of dollars for coverage during periods for which dual-eligible beneficiaries may not have sought reimbursement for their drug costs. Without routine monitoring of this policy, the agency remains unaware of what portion of these funds was subsequently reimbursed to beneficiaries and, therefore, cannot ensure the efficient use of program funds.

Our report contains several recommendations. We recommend that CMS require PDPs to notify beneficiaries of their right to reimbursement and monitor implementation of its retroactive payment policy. We also recommend that CMS take other steps to improve the operational efficiency of the program. Although the agency did not agree with all of them, it has already taken steps to implement some of our recommendations. As of March 2007, CMS has modified its letters to dual-eligible beneficiaries to include language informing them of their right to reimbursement for drug costs incurred during retroactive coverage periods and required PDP sponsors to do the same. In addition, CMS officials told us that they plan to analyze data to determine the magnitude of payments made to PDPs for retroactive coverage and the amounts PDPs have paid to beneficiaries. We hope that CMS will use this information to evaluate the effectiveness of its retroactive coverage policy. If, after conducting the analysis, CMS determines that it is paying PDPs substantial amounts of money and dual-eligible beneficiaries are not requesting reimbursements, the agency may want to rethink its policy in light of pursuing the most efficient use of Medicare funds.

Mr. Chairman, this concludes my prepared remarks. I would be pleased to respond to any questions that you or other members of the subcommittee may have at this time.

Contacts and Acknowledgments

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Chairman STARK. Thank you both. It is my understanding we will be having some votes in a few minutes, but let us see if we can start with some of our questions.

I am curious, Ms. Norwalk. Can you tell me how many plans have been subject to sanctions?

Ms. NORWALK. If you are talking about intermediate sanctions, including civil monetary penalties, there have been nine civil monetary penalties assessed against prescription drug plans in 2007 and 69 against Medicare Advantage Plans in 2006 and 2007. Then, of course, the seven recently announced private fee-for-service and marketing suspensions that were voluntary.

Chairman STARK. Do those suspensions that you mentioned that were voluntary, did those include the drug plans?

Ms. NORWALK. Those are just the seven private fee-for-service plans. That was the most recent action.

Chairman STARK. But for those seven I believe some of them offer Part D programs. Did they agree to suspend marketing Part D as well as their Medicare Advantage?

Ms. NORWALK. It is mainly just private fee-for-service. Of course, because that is the one plan type at the moment that is currently allowed to have open enrollment, where the other plans you would only enroll in them if you are aging in or coming into the program because of a disability. So, essentially, the other plans aren't marketing right now.

Chairman STARK. In 2007 and in 2006, there were 69. So, give or take 75 sanctions in the last year and a half.

Ms. NORWALK. Correct. Those are civil monetary penalties, as opposed to other sanctions, for example, corrective action plans and those things that we may have required of the plans.

Chairman STARK. How many more sanctions were there of other types?

Ms. NORWALK. My count is somewhere in the neighborhood of about 70 corrective action plans for different organizations for different sorts of issues. There are other things that we may have done as well, and I don't have the numbers. But warning letters we suppress, information on the drug plan or other Web sites if we don't have accurate formulary data, for example. So, those are things that we may do. It really depends on your definition of what a sanction is or that may not rise to the level of something as severe as a civil monetary penalty.

Chairman STARK. I would hardly call a sanction letting these guys cop a plea and get a voluntary stop marketing when some of them probably should have gone to jail or paid criminal fines. It hardly seems to me that we are punishing those private fee-for-service plans.

As I recall the letters that we sent outlining the egregious marketing violations—I wish our former insurance commissioner was here—but I am sure that had State insurance commissioners been able to weigh in on this they would have probably filed some criminal penalties.

Ms. NORWALK. I am not actually limiting our response to that particular voluntary agreement.

Chairman STARK. I am just suggesting that that voluntary agreement was egregious.

Ms. NORWALK. There are a number of benefits to having done it that way, if I may, Mr. Chairman. One of them is, typically, there are a number of weeks of appeal processes and the like; and given what we have been hearing, getting the plans to agree to stop their marketing immediately would allow us to delve deeper into the issues that arise so that we could resolve them. If there are further sanctions that are warranted and we have issues of fraud, we refer it to law enforcement and the like; and there may well be other activities just depending on what it is that we find. But we thought the most important thing to do would be to stop the marketing to make sure that we can protect beneficiaries.

Chairman STARK. So, they weren't just copping a plea. You just got them to hold while you investigate them further.

Ms. NORWALK. There may be some issues that do require further investigation. It is my hope that we may not have to, but I can assure you if we have instances of fraud or any other things that we will do the other appropriate actions.

But they do take longer. Civil monetary penalties, for example, need to be done through the Justice Department and the like, and the processes are longer internally. So, we thought this was a good first step.

Chairman STARK. Let me run through, if I may, a series of issues that we might be able to consider in legislation this year largely because they wouldn't cost a lot of money and therefore we might get them past the PAYGO issue. If you could just respond to the extent that CMS would favor, object or have no position on these. It would be helpful if we can get into it later, but I thought I would just run through these.

In the State oversight or Part D plans, the current law prohibits States from regulating marketing activities of the sponsors. Would you have a position on our changing the statute so that States could enforce marketing guidelines on the plan?

Ms. NORWALK. CMS would object to that. We are happy to work with the States. We, in fact, have a MOU. I think 26 States have signed the MOU. I think it is important that we work together. But to have a national benefit we need to have a single standard, and I think CMS is the appropriate enforcer of that particular standard. But appreciating that much of the marketing is actually done through agents and brokers that are in fact State regulated, and there are not only law enforcement officials that are State, there are also Federal, I think it is critical that we have all of those together.

Chairman STARK. You object. I will let Mr. Pomeroy explain to you the problems of the regulation as a State commissioner.

There are six therapeutic classes now in which you require coverage. Would you object to our codifying this in legislation?

Ms. NORWALK. Obviously, we feel those six classes are important beneficiary protections. One of the detriments of codifying it may be the further inability of plans to negotiate the prices on those drugs within those classes. So, it really depends both on what the score might be as well as how it is drafted. Obviously, we feel it is important enough that we have done it on an administrative basis.

I also think that doing it on an administrative basis allows us, as the science continues to change, it may be that all or substantially all drugs with any one of those classes may not be necessary in the future, just depending on the state of pharmaceutical improvements.

Chairman STARK. Excuse my pronunciation here, but we have had a number of requests from the mental health community that cover benzodiazepines.

Ms. NORWALK. Benzodiazepines, uh-huh?

Chairman STARK. If we eliminate their exclusion would you object? Support that? No position?

Ms. NORWALK. I am not sure I have a position. I would like to go back and talk to the experts internally.

Chairman STARK. Okay. One of the concerns that I have and that has been raised, and if you don't understand the reasons for it I will go into it further, but Part D beneficiaries can only join, as I understand it, from November 15 through December 31. However, Advantage Plans have an open enrollment through March 31. This has the effect of giving Medicare Advantage Plans an added benefit. Because if people missed the December 31, the only place they can possibly get a drug benefit is in Medicare Advantage.

Would you object to making the Medicare Advantage and the Part D open enrollment periods both run through the same period of time? I would prefer March 31.

Ms. NORWALK. I do want to clarify one thing. I am fairly certain—and I have to check the regs—but I am fairly certain that one of the things we did in implementing those regulations is that you cannot get a drug benefit if you have not signed up for one within the November 15 through December 31 timeframe. Meaning that while you can sign up for a Medicare Advantage Plan through March 31, you cannot sign up for one with a drug benefit unless you were already in one and were switching to a Medicare Advantage Plan with a drug benefit.

Chairman STARK. The question is, can you switch from one Part D to the other?

Ms. NORWALK. You could switch from a Part D plan to a Medicare plan with drug coverage, but you cannot switch from no drug plan to a plan with drug coverage. Either you have it or you don't have it in either case.

Chairman STARK. But if you could only join a Part D plan through the 31st, can you switch from one Part D plan to the other after the 31st of December?

Ms. NORWALK. No, you cannot switch from a stand-alone drug plan after December 31.

Chairman STARK. To a different stand-alone drug plan?

Ms. NORWALK. To a different stand-alone drug plan.

Chairman STARK. But you could switch after December 31 from a stand-alone drug plan to a Medicare.

Ms. NORWALK. But only one with drugs, that is correct.

Chairman STARK. Would you object to our making those so there is an advantage one way or the other?

Ms. NORWALK. I don't think so. I would like to ask the actuaries if there is an economic impact.

The second piece of that is just the administrative issues that we already have with switching plans during the plan year with the drug benefit. As I noted in my oral statement, part of the issues we have right now relate to plan switching particularly in 2006 after December 31 so that there are considerable administrative burdens. If we could clean those up administratively, I would have less of an issue.

Chairman STARK. If we could do that, too, I would share that with you. But it would also make it somewhat easier, it seems to me it, to level the marketing playingfield as well as make it somewhat simpler for the beneficiaries.

Finally, to turn to transparency, would you object to our requiring public disclosure of sanctions taken against plan sponsors so that people signing up would have some idea of the standards that these plans met?

Ms. NORWALK. We actually are going to go ahead and do that. It will be a part of our consumer report that we put out on the plans next year. We have had significant numbers of inquiries around corrective action plans generally, and we are currently working on a way to make them easily understood so that we do put at least some summary information up on our Web site so that the public can have access.

Chairman STARK. So, we are in a lock-set on that one.

Mr. Camp.

Mr. CAMP. Thank you Mr. Chairman.

I just want to clarify a little bit about what we heard about the dual-eligibles. How many total dual-eligibles are there? Or if I said that CMS enrolled about five and a half million in 2005——

Ms. NORWALK. You would be right.

Mr. CAMP. I understand, Ms. King, your testimony was about the new dual-eligibles?

Ms. KING. Yes. There are about 634,000 of them.

Mr. CAMP. Then your testimony that a third of those which were in Medicare and for usually financial reasons find themselves on Medicaid, a third of those represent a third of that 634,000?

Ms. KING. Yes.

Mr. CAMP. Your testimony then, the two-thirds, that is two-thirds of that 634,000?

Ms. KING. Yes.

Mr. CAMP. Of those, what percentage did not have a plan? Are you aware of?

Ms. KING. Let me be sure I understand your question.

Mr. CAMP. Of the new dual-eligibles, the two-thirds that you testified to in your testimony, how many of those—what percentage of total dual-eligibles did not have a plan?

Ms. KING. Prior to? I'm sorry. I don't know the answer to that.

Ms. NORWALK. Obviously, no one had a plan in 2005. In 2006, we auto-enrolled everybody. Unless there were glitches between the computer systems, we enrolled them as soon as we found them. So, I suspect that, ultimately, none.

Mr. CAMP. Ms. Norwalk, I know a lot of work has been done on improving the enrollment process, and I sort of wanted to highlight what number of folks we are talking about. But tell me, I know from your written testimony some of the details of your efforts

there to improve the enrollment process from 2006 to 2007. Can you describe how these efforts may or may not have helped and is there any data showing fewer complaints or shorter wait times, if you have any of that to share with us?

Ms. NORWALK. I think, just generally, the entire process, if you compare 2006 to 2007, was a significant improvement, not surprisingly, given the number of people that we had in the plan already and the relatively few numbers that switched between 1 year to the next. So, I think generally we did better, just because of the much easier, much more compressed timeframes; and beneficiaries had an opportunity the year before to take a look at data, et cetera.

Mr. CAMP. As a matter of fact, I think more than half of the enrollees renewed their 2006 drug coverage without it making a change on their 2007. So, it would seem to me that they made the proper choice from their standpoint.

Ms. NORWALK. Correct. Given the satisfaction ratings that we have seen, 80 percent are satisfied with their coverage. We would like to get the 20 percent satisfied, too, of course, but we are certainly moving in that direction.

We have heard very little from pharmacies this year as well. Last year, a lot of those complaints came in from pharmacies. So, I think certainly the total evidence looks very good as well, the survey result.

Mr. CAMP. How are beneficiaries protected from midyear formulary changes?

Ms. NORWALK. Formulary changes do happen on occasion.

The first point is that all of them are reviewed by CMS for approval. Midyear, the first thing we do is we grandfather anyone who is on a particular drug where a plan might have a formulary change. The first and most important thing is that if you are on that drug you can stay on that drug in the plan. The sorts of things that we might do from a formulary change that we would approve are likely to be generics coming into market, a black box warning or some other safety concern that the FDA has put out. Those types of things we would do. Most changes, in fact, we do not permit to happen midyear. So, maybe from a formulary change on the positive side we would also allow formularies to add drugs or plans to add drugs to their formularies as they go forward. Particularly as new drugs come to market, we think that is awfully important.

Mr. CAMP. Can you talk a little bit about the appeals process and what steps CMS might have in place to notify beneficiaries of their appeal rights?

Ms. NORWALK. You have raised a pretty good question.

What I did is I went to staff and asked exactly what we do. One of the things we do, we have a standard form that plans require the pharmacist to hand out or at least have available where they can see it if they don't actually have a hard copy.

Specifically, what happens at the pharmacy counter if a prescription drug isn't received and written right, they have to have an explanation and so forth. So, here's the OMB approved form, a single page that the pharmacy hands out. As you noted in your testimony, Mr. Camp, we have the Medicare appeal rights and Medicare and You Handbook.

Chairman STARK. Could you yield at that point?

Mr. CAMP. Yes, I would be happy to.

Chairman STARK. Are you talking about I think the same thing I have here?

Ms. NORWALK. Yes.

Chairman STARK. What I am finding, and you raised the question about 11 pages, I think. All I see here is it says if you have a Medicare Advantage Plan or a Medicare prescription drug plan, look at your plan materials to learn how to file an appeal or go—am I missing something?

Mr. CAMP. I think you have the 2006. The 2007 handbook has the 11 pages.

Chairman STARK. I have the 2008 handbook.

Ms. NORWALK. You are ahead of us.

Mr. CAMP. At least I know in the 2007 handbook there is no page. I haven't seen 2008 yet.

Ms. NORWALK. We do require the plans to send an evidence of coverage to every beneficiary. One of the other things that we are doing both this year and we do every year is to have a standard evidence of coverage. Plans are required to include very specific information about their appeals process. Obviously, the appeals process in the Medicare and You Handbook does need to be more general, because reaching every individual plan doesn't make sense to have in the handbook. So, they would need to refer to some of the plan guidance.

The other things that we do—we also have it on our Web site. We have tip sheets for our partners that talk exactly about how to file a complaint and so forth, also good for them to handout to beneficiaries. That is very specific about getting the drugs that they need.

So, we really have tried to reach them in every possible way, through communications that we send, communications the plans send, through what they get at the pharmacy level, et cetera. So, we do require all of these communications to occur regarding an appeal if a beneficiary can't get a particular drug.

Chairman STARK. If the gentleman from Michigan would yield?

Mr. CAMP. I would be happy to yield.

Chairman STARK. How many appeals in a year to the nearest hundred thousand or whatever?

Ms. NORWALK. All I can tell you currently—and I will see if we can get some information specifically from the plans in terms of their numbers. I do have a sense of how many numbers that appeal to the second level, that redetermination level to MAXIMUS, our independent review entity. They see about a thousand a month on average, sometimes more, sometimes less in terms of appeals. Some of them are overturned. Some of them are upheld. It just depends on the issue.

Chairman STARK. It just seems to me that I think if we had to concentrate any efforts to either simplify or unify the procedures, to say, look, once somebody is appealing, most often they could be the most sick or not have a drug they need or that their doctor thinks they need; and I would just like to join with either you, Ms. Norwalk, or Mr. Camp. Anything we could do to make that process quicker? I don't think we would lose any money.

Ms. NORWALK. We do have some of the fastest turn-around times in any insurance industry in terms of appeals. I think it is better than the self-employed benefits program, and it is better than typically what you see in the commercial market. So, we really feel that that is important.

We do have other sorts of safeguards. For example, once a drug has been prior authorized you should not have to have it prior authorized again and so forth. We have a special hotline for pharmacies to call. They can call us. The plans have special pharmacy hotlines as well. So, we really have tried with our own administrative mechanisms to do as much as we can to make it as easy as possible on the beneficiary.

Mr. CAMP. I think the language I am looking in this 2007 book is very much plain English.

If you have Medicare, you have certain guaranteed rights. One of these is the right to a fair process to appeal decisions about healthcare payments or services. No matter what kind of Medicare plan you have, you may have the right to appeal these decisions. You may appeal if—and there is bullet points. So, I hope that plain language that I see in the 2007 book isn't changed significantly for the 2008 book, and that is where we might be able to work together.

Ms. NORWALK. Absolutely. You and your staff, Mr. Camp, should have that. As you can see, Chairman Stark has a copy here. So, we have given it to the Committee for review. It is in its final stages, so we look forward to hearing your comments. It has been through one round on the Hill already.

Mr. CAMP. Thank you, Mr. Chairman.

Chairman STARK. We have a couple of minutes. Unfortunately, it is going to be a half hour process. I wonder if I could ask the witnesses, offer you a cup of coffee, if you wouldn't mind sticking around until we get back. Because I know other Members would like to inquire.

Ms. NORWALK. Of course.

Chairman STARK. Thanks so much.

We will stand in recess subject to the call of the chair.

[Recess.]

RPTS STRICKLAND

DCMN MAGMER

[3:25 p.m.]

Chairman STARK. I thank our witnesses for their patience, and I would like to see if Mr. Doggett would like to inquire.

Mr. DOGGETT. Yes, Mr. Chairman.

Thank you, for your testimony, Ms. King. Thank you for this particular report and for all of the important work that the GAO does to attempt to assure a little bit of accountability for the taxpayers' dollars.

I found your report to be very alarming. As I understand your findings, the Bush Administration paid out $100 million to insurance companies and other sponsors of these plans and does not know whether they got anything for it.

Ms. KING. That is correct.

Mr. DOGGETT. Yes. So, often here, usually at campaign time, I hear about waste, fraud and abuse of the government; and yet the ability of this Administration to throw money at problems as long as their friends catch it never ceases to appall me.

With reference to this 100 million which was your estimate of the amount of money that CMS paid out for 2006, CMS does not dispute your amount of $100 million paid out.

Ms. KING. That is correct.

Mr. DOGGETT. CMS could not give you any information to indicate that they got anything for the $100 million.

Ms. KING. We recommended to CMS that they start tracking their beneficiaries who were in retroactive coverage periods and start tracking the dollars paid out during that time, and they agreed to do that going forward.

Mr. DOGGETT. Going forward. So, forget about the first $100 million that may have been wasted, but they will at least have a modicum of accountability for the future.

As to the past $100 million that they shelled out, that $100 million was alleged to assure prescription drug coverage for some of the poorest people in this country. If I understand correctly, they did not know they were entitled to coverage at the time the $100 million went out. The beneficiaries, they had not been notified.

Ms. KING. That is a function of two things. One is the length of time of the enrollment processing period, which is about 5 weeks; and then the other part of it is the decision to make coverage retroactive to the first date of Medicaid eligibility, which is 3 months—generally, 3 months prior to their Medicaid application.

Mr. DOGGETT. Well, did you find out after paying out the $100 million—surely the Bush Administration notified these poor people to save their receipts, and if they managed to buy their prescriptions instead of buying their groceries to save that receipt and turn in so they could gets reimbursed. Did that happen?

Ms. KING. In March of 2007 CMS did send out a letter to beneficiaries——

Mr. DOGGETT. March of 2007?

Ms. KING. Yes.

Mr. DOGGETT. Was that about the future or did that tell them about a year after they may have incurred that receipt that they needed to keep their receipts and turn them in and get reimbursed?

Ms. KING. I believe that March 2007 was the first time.

Mr. DOGGETT. Again, the poor people who made these payments were not told that they had any rights to get reimbursed out of the $100 million the Bush Administration paid out.

How about the community pharmacists? Because I know many of these poor people go to a community pharmacy to get their benefits. This was occurring at the same time that there were multiple complaints from community pharmacists that they were not being properly paid by the same companies that got the $100 million, wasn't it?

Ms. KING. I am afraid I can't answer that question because the community pharmacy thing was not part of the scope of our study.

Mr. DOGGETT. I understand. Well, thank you for the study you did. It is an amazing finding. But—as part of the overall problem

of throwing money in the wrong direction and not according the protection that people have.

Ms. NORWALK. May I have an opportunity to respond, Mr. Doggett?

Mr. DOGGETT. I have a quite a few questions for you as well. If my time permits.

As you know, we have had requests outstanding since the last time you were here to determine whether CMS had any specific objections to the extra help legislation that I have introduced. We still don't have an answer. Do you have it today?

Ms. NORWALK. It depends on the specific piece of that. I know that we are working with the IRS and the Social Security Administration to get back to those specifics.

Mr. DOGGETT. Each specific piece that I have been asking for responses, responsive responses for months that I have been unable to get from you. Do you have those answers?

Ms. NORWALK. I don't have them with me, but I will be sure to get them.

Mr. DOGGETT. Do you have any updated information on how many people who are eligible for extra help have not received it?

Ms. NORWALK. We anticipate in terms of specifics just over 3 million.

Mr. DOGGETT. You don't dispute the estimate that the folks at GAO made of about $100 million paid out?

Ms. NORWALK. I actually would like to go through a little more detail——

Mr. DOGGETT. I would like to get answers to my questions first.

Ms. NORWALK. I do think the $100 million is accurate in terms of fees paid to plans.

Mr. DOGGETT. Did you track to see what, if any, benefits were paid out of that $100 million?

Ms. NORWALK. It is part of the process that we will be doing with enrollment and premium reconciliation for 2006 that is ongoing currently. So, we will be tracking that. That is correct, yes.

Mr. DOGGETT. So, when do you expect to be able to tell us what we got for the $100 million payment?

Ms. NORWALK. There are three different reconciliation processes ongoing. We should have them completed by the fall.

Mr. DOGGETT. You will be able to tell us then precisely by plan out of that $100 million you paid out precisely how much in benefits they paid out?

Ms. NORWALK. As long as we can figure out the time in which the retroactive nature occurs. Because, as Ms. King pointed out, you enroll in the benefit in August, but you are retroactive. As long as we can figure out from the State perspective—I am not sure our systems or the plan systems allow us to do that. But if they do, we would be able to have some basic information. In terms of the specifics, I am not sure.

But I will point out that we have spent a lot of time—and I would like to correct Ms. King. I actually have information we gave to beneficiaries in particular to our plan partners and the SHIPs, the State Health Insurance Programs, that specifically state please save your receipts. We did this in December, 2005; we reissued it in 2006; and we continue to do it. We do think it is important.

I am happy to report that the States and their Medicaid forms also say save your receipts, so we do encourage that——

Mr. DOGGETT. You expect that there will be some payments that were made out of that $100 million?

Ms. NORWALK. Oh, absolutely. And——

Mr. DOGGETT. When it is that you think you will have that by plan?

Ms. NORWALK. It depends on our enrollment processes and our reconciliation. I am hopeful that it will be later this fall. But it really depends on the computer processes. So, as long as they go well.

Mr. DOGGETT. Do you expect that information will show that most of that $100 million was paid out in benefits or kept by the insurance companies?

Ms. NORWALK. You will recall those are premium payments. In terms of specifics, I have no idea how much the beneficiaries will have saved their receipts. It is similar to Medicaid because in the Medicaid program with retroactive enrollment you save your receipts and submit them. I suspect it would be similar to what you see on the Medicaid side.

Mr. DOGGETT. Which would be about what?

Ms. NORWALK. I don't know, but I will see if I can find out for you.

Mr. DOGGETT. Thank you very much.

Thank you, Mr. Chairman.

Chairman STARK. Mr. Johnson would you like to inquire.

Mr. JOHNSON. Thank you, Mr. Chairman.

Ms. Norwalk, isn't it true that Medicare and the handbook which CMS annually sends to every Medicare beneficiary contains several pages of information specifically addressing beneficiaries?

Ms. NORWALK. Of course.

Mr. JOHNSON. Doesn't it also include information on how to file an appeal and phone numbers of who to call to file a complaint?

Ms. NORWALK. It does.

Mr. JOHNSON. So, what other steps do you take to notify beneficiaries to make sure they understand what their rights are?

Ms. NORWALK. I think one of the most important things is what happens at the pharmacy counter, so beneficiaries have this information at their home on a regular basis. I don't know, some may look at it—their Medicare handbook may be well-worn and others may simply collect dust. I am not sure. But it is still important when you go to the pharmacy that you would have information. So, we have required the plans to tell the pharmacies to hand this out to beneficiaries or at least make available the right so if a beneficiary is denied a prescription at the counter he or she will know how to get an appeal.

We also have lots of information that we put on the—both on our Web site and give to our partners so that they can help beneficiaries, as often they do, with an appeal. So, we have very specific information as to all the steps that they take.

In the Evidence of Coverage, which is the brochure that the plan sends to each beneficiary, they are required to have also the very specific steps at each plan that they take that are individual to that plan, the numbers that they call for the plan and likewise.

One more thing, if I might add, which I did not get to. In 2007, we do collect from the prescription drug plans their appeal rates within the plan. So, we will have some information around first quarter internal plan appeals in fairly short order. I think those plan numbers have come in, and we are taking a look and scrubbing them and making sure that they are comparing apples-to-apples.

Mr. JOHNSON. Well, I understand that more than half of the Part D enrollees renewed their drug coverage when making their 2007 plan choice. Can you talk about some of the beneficiary surveys that CMS conducted showing that seniors might be smarter than some groups give them credit for?

Ms. NORWALK. Medicare beneficiaries are incredibly smart, and I know that for a number of reasons. The first way I know is, from the beginning of the benefit, the amount of generic prescriptions that are currently prescribed for Medicare beneficiaries has risen every single quarter, depending on the plan type. Almost 62, 63 percent, in fact, Medicare Advantage plans 68 percent. They are very smart shoppers.

Likewise, we know that they use our comparison tools and work with the partners to make sure that they have been enrolled in the right plan, and the surveys that we have done, not only—not just CMS but independent surveys, including the Kaiser Family Foundation—do focus on how happy beneficiaries are with their plan coverage and what steps they have taken to enroll to be sure they have chosen the right plan. We would like everyone to be 100 percent happy, but for the second year of a program, 80 percent approval ratings, we are very pleased. Thank you.

Mr. JOHNSON. I think seniors are saving money, and more drugs are available for them, and they cost a lot less than what they thought.

Ms. NORWALK. Well, we are pleased both with the cost figures as well as the satisfaction figures; and we anticipate that they probably are related, that they are paying less than they initially anticipated that they would be paying.

Mr. JOHNSON. They are. Thank you very much.

Thank you, Mr. Chairman.

Chairman STARK. Just out of curiosity, before I recognize Mr. Thompson, do we know of the 26 million enrollees—whatever it is.

Ms. NORWALK. Twenty-four, I think.

Chairman STARK. Twenty-four million. Do we know how many of those people out of the 24 million did not file any claims at all?

Ms. NORWALK. I don't know. I suspect that is something that we could figure out when we go through the reconciliation process for 2006 as we determine——

Chairman STARK. Somebody is nodding their head behind you. Do you know? Do you have a guess?

Ms. NORWALK. We will know.

Chairman STARK. Half?

Ms. NORWALK. I would be very surprised if it is anywhere close to half. I suspect it is a much smaller percentage.

Medicare beneficiaries typically take a fairly large number of prescriptions. We should have some idea once we go through this reconciliation process in terms of how we would pay the reinsur-

ance for last year. So, we will know significantly more once that process finishes in the fall.

Chairman STARK. I am not talking about appeals.

Ms. NORWALK. No, no, I am not talking about appeals either.

Chairman STARK. Might just have the insurance and not be sick enough to need it.

Ms. NORWALK. I am not talking about appeals.

One of the things we do from a reconciliation basis in order for us to pay reinsurance for the catastrophic coverage where we pay plans 80 percent of that cost, we will have significantly more information as we go through that, but it is a process that we are currently undertaking with the plans once we finish a few other computer runs.

Chairman STARK. I apologize for intruding on your time.

Mr. Thompson, if you would like to inquire.

Mr. THOMPSON. It was on my time?

Thank you, Mr. Chairman.

Ms. Norwalk, does CMS plan to increase the level of funding provided to the SHIPs?

Ms. NORWALK. We did increase it this year 5 percent.

Mr. THOMPSON. Giving them an additional 5 percent?

Ms. Norwalk, you obviously believe they are doing a good job.

Ms. NORWALK. I think they are wonderful partners. I am grateful for their help.

Mr. THOMPSON. Is 5 percent going to be enough?

Ms. NORWALK. I am sure that all of us could use more money. The more money we have the better——

Mr. THOMPSON. In your professional opinion, is 5 percent going to be enough for them to do the counseling that they need?

Ms. NORWALK. I do think it is sufficient. I am certainly glad that we could give them an increase in their spending.

Mr. THOMPSON. If you felt they needed more, would CMS support increased appropriation for SHIP outreach?

Ms. NORWALK. I would not complain.

Mr. THOMPSON. I want to go back to something that the Chairman started his questioning with earlier today when he was talking about the intermediate sanctions and asked you about specific numbers. Are you guys taking actions against other plans if problems don't rise to the level of intermediate sanctions?

Ms. NORWALK. Absolutely.

Mr. THOMPSON. What are they? You talk about compliance actions.

Ms. NORWALK. Right, corrective action plans. If we find a particular issue with a plan through any number of mechanisms, particularly if it is a systemic issue, we will ask the plan to tell us how they will correct that. If we have issues that continue over time, then the level of sanction may continue to something more egregious. Or if the issue is more egregious, then they might have something beyond a corrective action plan like a civil monetary penalty.

Mr. THOMPSON. Who determines what is egregious? The law does not talk about compliance actions, as I recall.

Ms. NORWALK. I am not sure that the statute is very specific about that. But we have everything from issues relating to—if it

is a fraud issue, what is the beneficiary harm? How many people are impacted? There are a number of different things that we consider.

The statute does—when looking at civil monetary penalties, the statute does more globally, not specific to Part D but globally with Medicare, tell what are mitigating factors? What are aggravating factors and the like?

I think, more generally, when we look at enforcement we can take a look at those sorts of things to consider what is the appropriate issue, how much is the beneficiary harmed, and how easy is it to solve? You know it when you see it, if you will.

Mr. THOMPSON. Is that available to the Committee so we kind of get an idea of the problems that you are having and making that——

Ms. NORWALK. One of the things that I mentioned to the Chairman is that we do plan to make the corrective actions that we have put into place public. I think I would like to do it in a way that the public can understand what it means. There is a lot of jargon that we use, so we will need to go back and make sure that we can put out summary information that is useful to the Committee. If you would like to see things behind that, I am sure we can share that with you as well.

Mr. THOMPSON. When will that be, when we get that?

Ms. NORWALK. I am hopeful that we can do it in the next few weeks. In short order.

Mr. THOMPSON. Of the 600,000 beneficiaries that no longer qualify for the automatic enrollment in '07, how many much those folks are now enrolled in Part D?

Ms. NORWALK. I am not sure I have—400,000 are back in. So, two-thirds.

Mr. THOMPSON. So, 400,000 are enrolled?

Ms. NORWALK. Have requalified for LIS, I will confirm that number. I want to be sure that is right.

Mr. THOMPSON. What you are doing to contact those remaining unenrolled?

Ms. NORWALK. There are two issues, I think. There are a number of different populations that had issues with the year change. Partly some of them may have lost their dual-eligible status, so reaching out to them to see if they qualify for the LIS status—I think that is the group you are speaking of—some of them may not qualify for LIS.

Mr. THOMPSON. The LIS folks can enroll at any time.

Ms. NORWALK. Correct.

Mr. THOMPSON. Are you doing some sort of outreach to them?

Ms. NORWALK. Yes, we did specific outreach. Everything from using specific colored letters so if they took it to a plan—if they took to a partner, the partner would know how to help them and the like and so on and so forth. Social Security sent them an extra application with a postage-paid envelope. We worked with the State Medicaid programs giving them a list of who these individuals are, so on and so forth.

Mr. THOMPSON. Can we get an idea of how well we are doing enrolling those guys?

Ms. NORWALK. That should be fairly easy for me to check, so I could get back to you in a few days.

Mr. THOMPSON. Thank you.

I yield back.

Chairman STARK. Mr. Pomeroy, would you like to inquire?

Mr. POMEROY. Thank you, Mr. Chairman.

Ms. Norwalk, you testified almost a month to the day, May 22nd, on Medicare Advantage private fee-for-service plans; and at that time there were a number of questions addressed to you which you did not have information with you. We sent you a letter dated June 5th and have been informed that there is still some time required for us to get the information from CMS. I would just alert you to information that I would like, and that is the FTEs that CMS has added for purposes of reviewing these private fee-for-service plans.

Ms. NORWALK. I can tell you I don't think there have been any additional added. I suspect that we have moved around resources, and that might be a harder thing to determine.

So, typically, what we will do when we go through a process, including whether it is private fee-for-service or any other increase in Medicare Advantage plans, we will often work with our regional offices as well as our central office. So, when someone is needing to do plan review we might move the resources around. But I don't know of any additional people that were hired specifically for this purpose.

Mr. POMEROY. Earlier you indicated that you did not think the States should have a regulatory role beyond the role of agent licensure and solvency evaluation of the companies.

Ms. NORWALK. Correct.

Mr. POMEROY. But now you are telling us that ought to be a CMS function, this regulatory role; and now you are telling us that, by the way, we have hired no people to do it.

Ms. NORWALK. I think we can do it with the resources that we have.

Mr. POMEROY. When I was the insurance commissioner just for the State of North Dakota, I had 40 people involved in consumer protection. Obviously, not all of them dedicated to the senior market, although some of them were. How many personnel do you have devoted to making certain that the consumer safeguards are met in the State of North Dakota?

Ms. NORWALK. I can't answer specifically for North Dakota, but there are a number of things that we do separate and apart from FTEs. One of the things we have done recently is credit with a group of three different companies called medics, and these medics will specifically look at both the prescription drug plans as well as the Medicare Advantage Plans going forward to look at waste, fraud and abuse and so forth. So, we have funded——

Mr. POMEROY. Waste, fraud and abuse? I don't understand. How would waste, fraud and abuse be an issue on the insurance sale?

Ms. NORWALK. It may well be. Some of the issues, as I am sure you are aware, relate to brokers who have forged signatures. That is a fraud issue. Anytime there is misrepresentation, one of the groups that may look into that, and these are a new one, including $14 million in additional funding this year.

Mr. POMEROY. I absolutely do not understand why you have got so much more comfort contracting out at taxpayer dollars to private entities with no regulatory background and you don't want to expand the working relationship with State insurance departments, the professionals in consumer regulation, consumer protection when it comes to insurance.

Ms. NORWALK. I absolutely do want to continue to expand the relationships we have with insurance departments, which is why we have worked——

Mr. POMEROY. How do you see those relationships? In other words, if I am your State partner, I have got to have stuff to do, and stuff to do has got to get beyond licensing agents and looking at company solvency.

Ms. NORWALK. I agree, and the medics are one piece of that.

Let me go through the different pieces. One of the things we have done we have signed a memorandum of understanding that we developed with the National Association of Insurance Commissioners. We have signed that with 27 States, including the District of Columbia and Puerto Rico. One of the things it does is it allows the States who signed the MOU to have password access to see CMS compliance and enforcement actions. We would like to have consistent sharing of information between the States, CMS, our contractors and——

Mr. POMEROY. I see that my time is about to expire.

I will introduce into the record a letter received June 19th, 2007, by the Chairman and Ranking Member of this Committee. It is signed by the President of the National Association of Insurance Commissioners and other officials with that association of State officials.

They indicate in this letter: We urge you to restore State insurance regulatory authority over Medicare Advantage and Medicare prescription drug plans so that States can fulfill their traditional role of consumer protection in this area.

It appears to me that your State partners do not feel like they are being partnered with.

Ms. NORWALK. I am more than happy—I disagree with the premise of the letter, that the States need to have the ability to sanction the plans. They already have the ability to sanction agents and brokers. I think we need to work together not only in those two regards but also generally with law enforcement to be sure that we can share information, and the MOU allows——

Mr. POMEROY. You know, there is an awful lot of company activity that ultimately drives market activities. I have been stunned to see protections that we put in place in the late eighties, protections I was intimately involved in drafting and putting into place now shunted aside by marketing practices of companies, that they are basically given this loophole, a complete pass on State regulatory authority that has long been in place protecting the senior market. I think it is a growing problem.

I see my time has expired, Mr. Chairman. I do want to add this for the record, however.

Chairman STARK. Without objection. It will appear in the record.

[The information follows:]

NAIC
assisting progress . . . together
NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS

June 19, 2007

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

The Honorable Joe Barton, Ranking Member
Committee on House Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Chairman Dingell and Ranking Member Barton:

Thank you for your Committee's interest in widespread abuses in the marketing and sales of Medicare Advantage and Medicare prescription drug plans. As you hold hearings and consider the possibility of legislative solutions, we urge you to restore state insurance regulatory authority over the plans participating in these programs, and that you consider the current regulation of Medicare Supplement (Medigap) insurance as a potential regulatory model.

The National Association of Insurance Commissioners (NAIC) represents the chief insurance regulators from the 50 states, the District of Columbia, and five U.S. territories, whose primary objective is to protect consumers and promote healthy insurance markets. Insurance Commissioners have extensive institutional and personal experience in the regulation of private health insurance, including insurance products for senior citizens and, therefore we write to offer our suggestions and assistance.

As you know, deplorable practices have been reported in the marketing and sales of some Medicare Advantage and Medicare Part D prescription drug plans. State insurance departments and the State Health Insurance Assistance Program (SHIP) offices within our departments have reported patterns of overly aggressive and deceptive or abusive marketing and sales practices. We have received troublesome reports of tactics leading beneficiaries to enroll in a Medicare Advantage plan without full knowledge or understanding of the consequences of their decision. In many instances, unscrupulous agents and marketers misled beneficiaries into believing they were signing up for a stand-alone prescription drug plan or a Medigap plan, rather than a Medicare Advantage plan. Frequently, the beneficiaries did not know they were giving up traditional Medicare, potentially restricting or altering their access to providers, or were not fully aware of the new plan's benefits or cost-sharing. Some were even told that traditional Medicare was being eliminated, or that they were talking to a representative of the Medicare program.

As state insurance regulators, we are also concerned that the current federal marketing guidelines permit high-pressure sales tactics that states consider inappropriate for senior citizens, such as cold calls and cross-selling.[1] Insurance agents have used Medicare Part D as a pre-text to enter the home of a senior, and once inside sell the senior an unrelated and sometimes unsuitable insurance product -- including Medicare Advantage plans, annuities, life insurance policies, funeral policies, and other types of products, which often pay higher commissions. In addition, state regulators have also reported that companies are working with unlicensed agents and brokers in violation of federal marketing guidelines and high rates of other abusive practices, including outright fraud.

Under other circumstances, these practices would be prohibited by state law, monitored and questioned by watchful state insurance regulators, and controlled by the state-based insurance regulatory structure. However, since these cases involve Medicare Advantage or Medicare Part D, the hands of state insurance regulators are often tied, as states are largely pre-empted from regulating these plans. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 rolled back and pre-empted state insurance regulation of Medicare Advantage plans, except for licensing and solvency.[2] The MMA also established the same limited boundaries of state insurance regulation for Medicare Part D prescription drug plans.[3]

Unlike Medigap insurance or other types of state-regulated health insurance, the state insurance commissioner has very limited authority over the insurance company, and cannot ensure that marketing strategies or practices are appropriate for this vulnerable population. State insurance regulators are restricted in their ability to monitor companies in the marketplace. We are hindered in our authority to take corrective action against a company for misconduct or to have problems rectified in a timely manner. Often, consumers must wait months for a resolution, if one is provided at all.

State insurance regulators do have authority over insurance agents and brokers. However, without any real authority over the plans themselves, a wide regulatory gap exists that allows abusive marketing and sales practices to flourish. Without authority over the plans, state insurance regulators cannot prevent the abusive marketing and sales practices. Instead state insurance regulators simply receive the extraordinarily high number of complaints that result from these abuses. In addition, state insurance regulators' already limited ability to hold companies responsible for the acts of their agents has been eroded even further by CMS' interpretation that state insurance agent appointment laws, which help create an agency relationship between plans and their agents/brokers, are pre-empted and unenforceable.[4]

We urge you to restore state insurance regulatory authority over the Medicare Advantage and Medicare prescription drug plans so that states can fulfill their traditional role of consumer

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[1] CMS Medicare Marketing Guidelines, pages 112-113.
[2] Social Security Act, Sec. 1856(b)(3) states "The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part."
[3] Social Security Act, Sec. 1860D-12(g) states " The provisions of ...1856(b)(3) shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C."
[4] Medicare Marketing Guidelines, page 130, states "Because CMS...explicitly addresses the use of marketing representatives, state marketing agent appointment laws will not apply to organizations".

protection in this area. In doing so, we encourage you to consider Medigap insurance as a good regulatory model. As you know, standardization of Medigap insurance came about with the passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA-90) in response to rampant abuses targeting seniors in the Medigap insurance marketplace that bear a striking similarity to the problems we are seeing today with Medicare Advantage and Medicare Part D prescription drug plans.

The regulation of Medigap insurance provides a good model for enforcement, as states have the ability to take action against both the agents and the companies themselves. However, states should not simply be enforcing unworkable guidelines set by CMS. OBRA-90 included a unique delegation of regulation development authority to the NAIC for Medigap insurance, providing the NAIC with a specified period of time to develop and establish the federal minimum standards.[1] In developing these standards, the legislation also prescribed that the NAIC consult a balanced working group composed of industry representatives, Medicare beneficiaries, and other qualified interested individuals, thus ensuring that the final proposal is balanced and enforceable.[2] These NAIC-established standards were then adopted by the federal government as the federal minimum, and are enforced by the states. We believe a similar process could be utilized to establish marketing guidelines for Medicare Advantage and Medicare prescription drug plans, as well as to allow effective state regulation of these plans.

We look forward to continuing to work with you as you endeavor to protect consumers in Medicare Advantage and Medicare prescription drug plans. We offer the services of this organization as a resource for you as you consider these issues.

Sincerely,

NAIC President
Commissioner of Insurance
State of Alabama

Catherine J. Weatherford
Executive VP and CEO

Joel Ario, Chair
Health Insurance and Managed
Care (B) Committee
Administrator of Insurance
State of Oregon

Sean Dilweg, Chair
Senior Issues (B) Task Force
Commissioner of Insurance
State of Wisconsin

[1] Social Security Act, Section 1882 (p)(1)(A).
[2] Social Security Act, Sec. 1882(p)(1)(D) states "In promulgating standards under this paragraph, the Association or Secretary shall consult with a working group composed of representatives of issuers of medicare supplemental policies, consumer groups, medicare beneficiaries, and other qualified individuals. Such representatives shall be selected in a manner so as to assure balanced representation among the interested groups."

Chairman STARK. Mr. Kind, would you like to inquire?

Mr. KIND. Thank you, Mr. Chairman.

I would like to thank the witnesses, especially you, Ms. Norwalk, for your patience today. I know it has been a long afternoon so far.

I want to echo what Mr. Pomeroy was alluding to and that is the greater role that we should be allowing State insurance commissioners to play. They have expertise, they have got capacity, they have been doing this already.

Frankly, I see a lot of shortcomings with CMS's oversight with these Part D plans right now. It is my understanding that CMS mainly is focused on the plan bid and contracting process in regards to oversight capability, and that seems to be falling short in a lot of areas. Allowing State insurance commissioners expanded authority to get in and start hearing appeals of consistent complaints could go a long way to alleviate the concerns that our offices are receiving almost on a daily basis.

Let me highlight a few of the concerns which are consistent in what I am hearing from my constituents back home. The appeals process, how difficult it is to access and especially for some things such as formulary exception requests, enrollment decisions, billing issues. Especially on the billing issues, if there is a wrong billing issue that pops up with a senior on a fixed income and having a lengthy, drawn-out appeals process, this is very traumatic for many of these seniors to have to wait and try to get this resolved ultimately.

I know you are eager to jump in, but let me also explain a couple of the other things that I am hearing so you have a feel of what is going on in western Wisconsin at least.

But the open enrollment period and whether CMS could keep an open mind about establishing at least a special enrollment period for mistakes that were made. Whether someone was wrongfully enrolled in a plan or wrongfully disenrolled in a plan or some type of mistreatment along those lines.

Finally, ultimately, the marketing practices. I know Mr. Fleming is going to be on the next panel from Humana, and I know it is going to be to get uncomfortable. Because we have a specific case in Wisconsin that just burned my britches, and it was the fact that they contracted out with a private collection agency to go out and hound and harass a 100-year-old senior who was wrongfully being charged premiums under Part D when she was Medicaid qualified. After the State aging specialist sent them verification that she was Medicaid qualified—and I am saying this now to give Mr. Fleming a chance to respond so I don't just spring this on him. After that State specialist contacted the collection agency and Humana five separate times, 4 months later, she was still notified, my constituent, that she was being disenrolled and that this private collection agency was hounding her for past premiums that she did not pay because she wasn't supposed to pay.

Then the appeals process was so difficult, and it led to my office contacting Humana's office here in D.C. specifically asking them to look into this matter and what is being done to this 100-year-old wasn't right, only to get the response from the person at other line that they will try to issue a decision shortly. It will be the final decision with no further conversation. When we brought it to their at-

tention that what they are doing now is against the law, she said that is going to be the ending of the conversation because it is getting too hostile.

What we wanted was the right result in this. If that is what is going on out there with some of these people, it is just not right and it needs to be fixed. I think there are some proposals here that we are serious in addressing that maybe with your help and guidance we could try to get right at the end of the day.

Ms. NORWALK. In terms of your initial comments in terms of only looking at the bids and so forth, I want to be clear we oversee a whole host of things; and I will get to your specific situation. I think it is important.

In terms of marketing practices, without question, we look at those; and we do already have a special election period for individuals who have been told misleading information.

So, inasmuch as you have an instance where that has happened and you know of it, please work with our Congressional Liaison Office. We are more than happy to do that change. We do that across the board whether or not there is a congressional sponsor. That is something else that you should know. We have a standard operating procedure in place to be sure beneficiaries get reconsideration and can change plans if that is necessary.

The formulary exception process is something that we also pay very close attention to and ensure that there are many good reasons to have things—prior approvals or other utilization management techniques to help the beneficiary, particularly when many beneficiaries have numerous doctors and there may be contraindication or this same medication being prescribed more often than that.

In terms of appeals and access, something else that we oversee, we do collect the appeals even at the plan level. We started to do this this year with drug plans. We will have more first quarter information shortly once we have taken a close look at the numbers and done some scrubbing.

As to the enrollment, we have been working closely with the plans to make sure that we can fix those enrollment issues, not to mention the billing issues.

To be clear, many of those may not be the fault of the plans. I would like to raise my hand and tell you that much of this is between CMS and Social Security and our computer problems. We have moved a long way to fixing them. We are not done. It is a horrible, intractable problem. I merely point that out. Blame rests squarely on my shoulders, and I can assure you we are doing all we can to fix it as soon as possible.

Some of the issues may be plan related. I don't know about the particular situation there, but I don't want to pass the blame when, frankly, it may be mine.

Mr. KIND. Thank you.

I see my time has expired, Mr. Chairman. Thank you.

Chairman STARK. Mr. Becerra, would you like to inquire?

Mr. BECERRA. Yes, thank you, Mr. Chairman. Thank you.

Ms. Norwalk, thank you for your patience; and, hopefully, we will let you be on your way pretty soon.

I do want to mention—it is not the subject of this hearing, but I want to thank you for your diligence in trying to stay in touch with the County of Los Angeles with its ongoing issues with Martin Luther King Hospital. I am not sure where this is going to go, but I hope we work toward something that will continue to provide service to all the individuals who live in and around the area of the MLK Hospital, so hopefully some of those folks don't suffer by bad conduct by some of the folks at the hospital.

A question with regard to your response to a letter I sent to you in April. I thank you for your prompt response in May to a concern that Chairman Stark and I raised to you with regard to services being provided to all Medicare beneficiaries, especially those with limited English proficiency. Could you give me more detail?

It has only been a month and a half since you sent the response, so you may not have a lot more information to share with me. But I am concerned that—I am not sure if you have yet had a chance to really get on top of the plans to make sure that they are beginning to respond accordingly, as they are required to, to provide services to all individuals who are Medicare eligible for Part D. Do you have anything you can report on what is going on with the plans?

Ms. NORWALK. I do not have any updates from the correspondents so—but will be back on Tuesday. So, if I have any then I would be more than happy to give it to you.

One of the things I do know is that we had our conference with the State Health Insurance Assistance Program, the SHIP directors, a couple of weeks ago; and we focused on a number of things including those who may have difficulty understanding language. We have asked them to focus maybe 5 percent of their budget on those, not with those who have limited English proficiency but who have other mental issues in terms of not being able to understand what materials there are there.

So, we have asked them to focus on that and are hopeful that it will make a difference as we move forward. That is one of the things we are concerned about. I will get you more specifics if we have an update to that. I am not sure if any new information is available on that.

Mr. BECERRA. I look forward to hearing from you on Tuesday about that. I would ask between now and Tuesday that, if nothing has been done, that you try to tell us by Tuesday that something is being done.

Every day that we go forward without doing something there are Medicare beneficiaries who are not receiving the benefits that they are entitled to. This has been going on for well over a year and a half how. So, I hope that CMS will perk up and take some of the compliance actions that you have outlined in your letter. Because I think it is outrageous that the plans knowingly are not moving forward when it is required of them to do so, and they are getting the benefits of providing services to these individuals, yet they are not providing all of those services. I hope by Tuesday you can give us some pretty specific information on what CMS is doing to enforce compliance by the plans on that particular item.

Ms. NORWALK. Sure.

Mr. BECERRA. I, Ms. King, have some concerns with regard as well to the $100 million that we are not yet clear how it was spent, where it went and what we got for it. I am wondering if you can tell us if you got enough cooperation from the folks at CMS in trying to discern answers about that 100 million that is still up in the air.

Ms. KING. We did. They provided us information that enabled us to calculate the money that was actually paid out to the plan. So, they did cooperate with us fully on that.

Mr. BECERRA. Did they cooperate fully and try to tell you what we received for those payments?

Ms. KING. They don't know yet. I mean, they were—you know, they told us that they had not tracked that yet, and we recommended that they track it, and they agreed to do so.

Mr. BECERRA. This is my difficulty. If I talk to somebody in my family, a constituent in my district, and ask them did you go to the store? Yes. Did you spend some money? Yes. How much did you spend? $100. Do you know what you got? No.

It sounds kind of strange. We paid $100 million for something. Yet we can't be told what we got. I am not sure if you are telling me that you are satisfied with that answer, that, yes, the taxpayers gave the government 100 million which we did spend, the government spent, but we can't yet know from the government how we spent it.

Ms. KING. We would like to know.

Mr. BECERRA. I am glad you would like to know. I am wondering in the report why is it that we don't know.

Ms. KING. I think, at the same time, we understand the genesis of the problem, the length of the enrollment process and the retroactivity that gave rise to it. I think we would like to know. We made recommendations to the agency that they do a better job of tracking the people and the months of eligibility and the amounts actually paid out.

Mr. BECERRA. One last question, Mr. Chairman.

Are you planning to follow up on this? Continue to track this?

Ms. KING. We do as a matter of course follow up on all recommendations that we make to agencies.

Mr. BECERRA. So, one of the issues that you will follow up on is how that money was spent?

Ms. KING. Yes.

Mr. BECERRA. Thank you.

Thank you, Mr. Chairman.

Chairman STARK. Mrs. Tubbs-Jones, would you like to inquire?

Mrs. JONES. Good afternoon. I don't want to repeat questions that others have already asked, but has anybody discussed with you the issue of retroactivity and the fact that persons who are eligible for Medicare—that has been discussed already?

Ms. NORWALK. I am happy to give you a quick response.

Mrs. JONES. One minute.

Ms. NORWALK. Absolutely. Yes, we have discussed it here. Basically, what we have done is we have let the State Medicaid agencies let beneficiaries know—I looked at Texas today—they said, do you have drugs for past receipts? Save them. We tell our partners to save them.

Now, thanks to GAO's good recommendation, we sent a letter to beneficiaries when they qualify to say please save your receipts and send them in and the like.

Mrs. JONES. Are you able to determine how many people received dollars through retroactivity and is there a statute of limitations for which you can apply for retroactivity?

Ms. NORWALK. Typically, retroactivity goes—well, it would be January 1st of '06. That would have been last year. The States have that 3 months back from the date of application, but it probably depends on State law. In terms of filing with the plans those receipts, we have asked the plans to be generous; and it typically would include both the 3 months back and however many months——

Mrs. JONES. You have asked them to be generous?

Ms. NORWALK. We told them to be generous. Because they are getting premiums for those payments.

Mrs. JONES. Let me switch course for a moment. Can you tell me—we have been in this program a year and a half now. How many people have reached the donut hole? What are you doing to help people through the donut hole? For the record, just in case people don't know what I am talking about, it is the point where they spent $2,500 and they have to reach $5,000 in order to get part of the plan and they continue to pay the premium.

Ms. NORWALK. That is the second deductible.

A couple of things. The first point is that last year we estimate somewhere between 3 and 4 million reached the coverage gap last year, the donut hole.

Mrs. JONES. That is what percentage of those who are covered?

Ms. NORWALK. There are 24 million who have the prescription drug benefit through the Medicare Program. That is not the retiree drug subsidy. So, one-sixth.

Mrs. JONES. Keep going.

Ms. NORWALK. The second piece in terms of helping them, one of the things we have done is worked very closely with States. States often have assistance programs. But also with the pharmaceutical manufacturers who have programs. So, that beneficiaries who are either in a coverage gap but may have difficulty in paying for the prescriptions—we have 47 different programs. We have all of them available on our Web site. Obviously, there is no way for us to provide Federal funds under the statute there, but one of the things we do is give as much information as possible to help them. If they find themselves in a situation where they are in trouble financially, that we can help them through there.

The other piece is the negotiated price for those prescriptions are offered in that donut hole, in that coverage gap, so that Medicare beneficiaries are not paying the full price that they might if they had no coverage at all.

Mrs. JONES. It was speculated that in the process of implementing this program that much more than one-eighth of the recipients or persons participating in there program would have reached the donut hole. Is that not true?

Ms. NORWALK. I don't remember the initial estimates. I could track them down.

Mrs. JONES. I would appreciate you sending to me and my Committee Members this piece on only 3 to 4 million. What about the people who jumped the donut hole and are at the $5,000? How many people is that and what is the percentage?

Ms. NORWALK. I will have that information. It is part of the process, much like those numbers that you were concerned about in terms of retroactive enrollment for dual eligibles, and we are going through a process for paying the plans from last year in 2006. We are reconciling our books to make sure that we have the right amounts, and we will know exactly what we are paying in terms of catastrophic coverage for beneficiaries both to the plans as well as the numbers. We will have those numbers. It will probably be a few more months before our reconciliation process is finished, but we will have that and be able to give you those specifics.

Mrs. JONES. You have to get to the plans to get that answer, not to the individuals?

Ms. NORWALK. Yes, that information will come from the plans. Because the plans cover the benefit once the beneficiary has gone through the donut hole. The plans will pay the claims, and we will reimburse the plan 80 percent. The plan pays 15, and the beneficiary pays 5.

Mrs. JONES. I am particularly interested in that information. Oftentimes, we have these hearings, and we ask for information, and we don't get it. I want this information.

Ms. NORWALK. Absolutely. I promise you will get it as soon as we finish the reconciliation process.

Mrs. JONES. What are we talking about? A year from now?

Ms. NORWALK. Fall. 2007, maybe a year from now; 2006 will be this fall.

Mrs. JONES. Thank you, Mr. Chairman.

Chairman STARK. Thank you.

Ms. Norwalk, you are working with a contractor, as you state, to augment your resources for compliance audits. Who is that contractor?

Ms. NORWALK. We have three contractors for the medics.

Chairman STARK. Is that the same as the medics?

Ms. NORWALK. Yes. Delmarva Foundation is one, the SAIC is one, and EDS is the third.

Chairman STARK. SAIC and EDS. That is our Texas friends? Okay.

Ms. NORWALK. Yes.

Chairman STARK. Do you receive periodic reports from them?

Ms. NORWALK. We do.

Chairman STARK. Monthly, quarterly?

Ms. NORWALK. Probably monthly, but I will have to confirm that. They have addressed 3,844 complaints, conducted 859 investigations, referred 20 cases to law enforcement and sent 11 immediate advisements to law enforcement.

Chairman STARK. Would we be able to review those?

Ms. NORWALK. I suspect that you could review most of them. The ones that are referred to law enforcement, it depends on where they are in law enforcement.

Chairman STARK. I don't mean to make this the topic of the hearing, but if we sent our staff over they would be able to——

Ms. NORWALK. As long as it is not confidential because law enforcement is going after someone. I believe they would be happy to share that with you.

Chairman STARK. Thank you. Thank you.

I have one other question. I think last year there were three plans operating on waivers which meant that they were not licensed by any State. How many plans are operating on waivers now?

Ms. NORWALK. I don't know that off the top of my head. It may be that they all have been licensed at least in one State, but I will have to check that. I know we worked with the plans before and asked them to get licensed. I don't know—I personally don't know, but I am sure it is knowable, so I will get back to you.

Chairman STARK. It is my understanding that many of these plans operate on waivers even if they are not applying for licensure in a State; is that correct?

Ms. NORWALK. No, we did require that they be licensed. I think it is three years. We required them to be licensed within a certain amount of time. I think that time is three years. But that is just off the top of my head. So, that they would have to at least go and apply.

Of course, every State, in terms of licensing, can take a different amount time; and we wanted to be sure they were not held up by that in terms of operating their plans. But we do require them to be licensed ultimately.

Chairman STARK. So, if they are not licensed by a State, we have no—and this is the point of my concern—we really have no independent assessment of the integrity of their assets?

Ms. NORWALK. Well, we at CMS would do a review of their financials and ensure that they have the appropriate——

Chairman STARK. Who would do that at CMS?

Ms. NORWALK. I presume it is going to be one of the plan groups that does the oversight. The Center for Beneficiary Choices within there would do that review. Unless it is something that is actuarial.

Chairman STARK. You have people who are capable of analyzing the integrity of an insurance company and their ability to pay for long-term liabilities?

Ms. NORWALK. I suspect that we do.

One of the things that happened with the Balanced Budget Act was the provider sponsored organization legislation that allowed CMS to do or HCFA to do just that where we had the oversight. So, it is a continuation of that. I believe that we work with the NAIC to determine what would be appropriate in terms of bonding to provide appropriate financial protection for beneficiaries.

By the way, we work with the States whether or not a plan is licensed; and if we are concerned about the financial wherewithal of a plan, we will look to close them down.

Chairman STARK. Thank you. That is a concern.

As I say, we have run into that in private pension plans and a host of private union plans where they haven't had the resources; and I am mostly concerned where a plan gets stuck with some kind of long-tail liability that they just don't have the resources to absorb that.

Ms. NORWALK. I frankly think that is a concern whether or not they are State licensed.

Chairman STARK. If you are paying attention to it, then we will assume that responsibility is the government's.

Any other Members? Mr. Doggett?

Mr. DOGGETT. Are you familiar with, Ms. Norwalk, with the complaints or concerns that some pharmaceutical benefit managers and Medicare Advantage Plans earn interest off of the float between when they are paid and when they pay the pharmacies that actually provide the benefits to these beneficiaries?

Ms. NORWALK. I haven't heard that specific complaint.

Last year, to be fair, we heard a lot about pharmacies being concerned about the timeliness of payments. So, we did a review of how long it took to make payments, and I am happy to report that the billing cycle is typical to what you would see in the commercial market on a 30-day cycle, and there are—in fact, all the top 20 plans all of them pay between 30 days.

Mr. DOGGETT. Is it fair to say, if I understand your answer right, you have never heard the complaint before about the middleman benefits from the float or benefiting from the float and you are satisfied with the survey you have that there is prompt payment to pharmacies?

Ms. NORWALK. I am satisfied with the survey that certainly the top 20 plans, which are a significant 90-some percent of the enrollment of beneficiaries, do pay plans within 30 days. Not only that, they often—plans may pay pharmacies twice within those 30 days, and we do have the specifics in terms of the billing cycles.

Mr. DOGGETT. If you would leave those with us, that would be helpful.

In your formulary guidance documents, as I understand it, if a plan is not providing six therapeutic classes they would be in breach of contract?

Ms. NORWALK. They do need to provide all the drugs within those six classes that we have enumerated. That is correct. If they are not, they would not be compliant. We would not approve their formulary until they did include them all; and if we did not approve their formulary, they couldn't bid.

Mr. DOGGETT. Have you ever denied a contract application because of a discriminatory formulary?

Ms. NORWALK. Typically, we would work with a plan to have them remove whatever the discriminating feature is; and we do include discrimination check on all formularies prior to them being approved and before they would be allowed to bid. So, rather than saying you cannot bid at all, we would work with them to say these are the specific aspects of your formulary we find discriminatory. You will need to change them.

Mr. DOGGETT. Has that been done previously?

Ms. NORWALK. I am quite sure it has. I do recall personally getting involved with a plan.

Mr. DOGGETT. Can you provide information concerning determination that formularies were discriminatory?

Ms. NORWALK. I would actually expect it is less likely to happen in 2007—not to mention the plan year 2008. It may have been

more of an issue early on in the process. I will see if we have that information.

Mr. DOGGETT. I was a bit confused by your responses to Chairman Stark on the question of why we should not codify those six therapeutic classes. I believe you indicated that science could change and perhaps we wouldn't need six classes. Is that one of your concerns?

Ms. NORWALK. That that might be one thing. For example, if you have a black box warning or if you found out that some of those drugs were not safe. It also gives you more flexibility particularly around how is that particularly defined?

One of the things I am concerned about, as I know the Members of the Committee are, is the cost of the prescription drug program. One of the things that happens when you mandate that a class be covered——

Mr. DOGGETT. You do mandate it now through your contract documents?

Ms. NORWALK. That is correct, and I am getting to that point in a second. But, by doing so, I assure you that one of the things we did was made it much harder for plans to negotiate a price around the drugs in those six classes.

Mr. DOGGETT. Your contract makes it more difficult to negotiate?

Ms. NORWALK. Requiring those six classes be covered. So, yes, our contract with the plans requiring them to cover six classes means that they have very little negotiating ability with the pharmaceutical manufacturers who make those drugs in those classes. Believe me, we heard from the plans complaining about it. Because they want to be able to provide the best coverage at the lowest price. But we felt it was so important that these classes be covered, at least with what we know now to put them there. If you put it in the statute, you take away some of that—the ability to ensure that you are balancing the safety and efficacy on the one hand, the economics on the other hand and, thirdly, the ability of the plans to negotiate while at the same time making sure that Medicare beneficiaries have the drugs they need, particularly in these classes that are very sensitive.

Mr. DOGGETT. So, with time about to expire, yes or no, do you support codifying your current policy?

Ms. NORWALK. No, I don't think it needs to be codified.

Mr. DOGGETT. Thank you.

Chairman STARK. Mr. Camp.

Mr. CAMP. Thank you, Mr. Chairman.

Ms. Norwalk, we are going to be receiving testimony that one patient has had to stop seeing their regular community provider because they were unable to dedicate the resources needed to get the frequent authorizations required by drug plans. Now isn't it true that beneficiaries need just one prior authorization decision for the entire year for the prescription they are seeking to fill?

Ms. NORWALK. Yes, that is true. There may be an instance—for example, one of the things that the Medicare statute requires is that if it is covered under the Part B program—B as in boy—then the prescription drug plan cannot cover it. There may be an instance, somebody has moved from one setting to another, a sec-

ond prior authorization may make sense. But generally, yes, once a drug is prior authorized it should not be required to be done again.

Mr. CAMP. With regard to AIDS drugs and other drugs in the six protected classes, do beneficiaries need to receive prior authorization?

Ms. NORWALK. With AIDS drugs, no. There is one AIDS drug that would be prior auth. If they are new AIDS drugs that come to market, they do typically—if they are added to the formulary later in the process, they may be prior authorized. A couple of exceptions, but generally, no, AIDS drugs are not.

With chemotherapy drugs, immunosuppressive, also, in the six protected classes they may be prior authorized, particularly because of that B versus D issue that I mentioned; and that is a lot of the complaints that we hear from people. But, generally, those drugs are not prior authorized.

We see prior authorization in some instances as very important, when in particular Medicare beneficiaries, statistically, 23 percent of them see a dozen doctors a year because they have five or more chronic conditions, they have 50 prescriptions. If you can imagine a dozen doctors writing scripts for 50 prescriptions, you may have duplicates.

I think there are very good reasons and safety checks to ensure that prior auth be used in many instances, but certainly in the AIDS category we are very concerned about that. If we hear of specifics we are more than happy to go back to the plans and ensure that beneficiaries are getting the drugs we intend them to get.

Mr. CAMP. I just wanted to touch on the GAO report and the comments about the 100 million that Medicare has paid to different prescription drug plans. The purpose of this is to cover what we call retroactive coverage; is that right?

Ms. NORWALK. Correct.

Mr. CAMP. That is coverage where individuals become eligible, and this backdates to a former time.

Ms. NORWALK. Correct.

Mr. CAMP. From what I understand from the testimony, there is going to be a reconciliation of this $100 million that will get into plan-specific information which in terms of the numbers of beneficiaries and the amounts these beneficiaries have received that we can expect some time in the fall?

Ms. NORWALK. We should know more. If I am wrong about that I will get back to you, but we should know more about that once we go through the reconciliation process and get more specifics.

I would like to point out in the GAO report they did not object to our linking the effective coverage date to Medicaid's retroactive eligibility date. The interesting thing is, once you are dual-eligible, the statute requires you to be covered by Medicare for your drug benefit. But for other benefits, even for retroactive eligibility in Medicaid, of course you can bring your receipts in to the State and the State will reimburse you. Conceptually, it works the same way; and we want very much for it to work on a go-forward basis.

I am grateful for Ms. King's report, which is one of the reasons why in March we said we will tell the beneficiaries specifically in a letter about retroactive enrollment in this. We had always pro-

vided information to beneficiaries and partners about, hey, save your receipts, send them in, the plans will reimburse you for them.

I, too, will be very interested to know how this has been working with the plans and look forward to sharing with the Committee more details as to how many plans have been reimbursing beneficiaries for this retroactive bit. But these are premium payments, and you are getting paid for coverage, and that is really the point.

Mr. CAMP. Thank you very much.

Thank you, Mr. Chairman.

Mrs. JONES. Quickly—thank you, Mr. Chairman—how much money was allocated to educate recipients about retroactivity?

Ms. NORWALK. I don't know if there is anything specifically about retroactivity.

Mrs. JONES. Maybe not retroactivity. Excuse me, reimbursement.

Ms. NORWALK. Reimbursement generally? I can tell you about all the publications. I don't know how much we paid to print them and so on and so forth.

I can tell you more generally, in terms of working with our partners, tens of millions of dollars. But it is very hard to know—when you are working with someone you may have a number of things that come up——

Mrs. JONES. You are not telling me that tens of millions of dollars were spent on educating our seniors receiving Medicare prescription drug benefit that they were eligible for reimbursement——

Ms. NORWALK. No, no, no——

Mrs. JONES. That is my question. How much money was allocated to discuss with seniors reimbursement?

Ms. NORWALK. I suspect—it would be hard for me to know. I don't know that it is a number that is knowable, because it is a part of many things that we work with our partners, including the SHIPS.

Mrs. JONES. I want that answered. It is not something that is knowable? What is "knowable?" What does the word "knowable" mean?

Ms. NORWALK. I don't know. Meaning I don't think it is possible for me to go back and ask anyone at CMS, gee, how much do we spend toward this line item specifically?

I do think, more globally, it is a package of information that we provide to beneficiaries for which we spend a significant amount money educating them. It is a piece of what we educate them on, but there has not been anything specifically in terms of you must spend X number of dollars on this particular component. It has been more global in terms of education.

Mrs. JONES. Let me say this to you. When we put in program in plan there were lots of seniors that were totally confused and overwhelmed about how to sign up for the program. If they are overwhelmed about that, clearly they were probably overwhelmed about reimbursement. I am suggesting to you that even if you can't delineate the specific amount of money that was allocated to talk to them about reimbursement, it would do you well on behalf of all the seniors out here who are pinching pennies to find out whether you did a good job at it and figure out what dollars you could ex-

pend to do that. In your report to me about those other things I asked you about, even if you can't delineate a number for me, I would like to know.

Ms. NORWALK. We can certainly show you all the things we have done in terms of outreach materials——

Mrs. JONES. I don't want to see that. I have seen that, and I have been part of the outreach in my congressional district. I am specifically asking you about reimbursement.

Ms. NORWALK. We may know more once we do the reconciliation process so we can figure out specifically where we had issues. Which is to your point, has it worked or hasn't it worked. Well, we will know once we finish——

Mrs. JONES. That wasn't my question. That is something you want to answer. The question is about reimbursement for the seniors who was out here. Ma'am, you don't have to keep giving me your on and on answer. Just get the answer I want. Okay? Thank you.

Ms. NORWALK. Okay.

Chairman STARK. I, too, Ms. Norwalk, have another issue that has come up. I think you mentioned that beneficiary premiums decreased. But we were advised by Consumers Union who said they looked into 60 plans in a particular ZIP Code in Texas, and they found that 32 plans had increased their price, 20 stayed the same and eight decreased. They also found that in another New York ZIP Code, 61 plans offered coverage in February of this year and, by June, 35 of those plans had increased, 17 stayed the same and nine decreased.

So, that basically sounds like there is a little bit of bait and switch. Because the beneficiaries can't change. They shop around for the lowest price. Then these shylocks go and raise the price on them during the year. Why should we allow that?

Ms. NORWALK. Actually, you raised two different issues. The first issue in terms of the premiums between 2006 and 2007, this is a calculation that our actuaries make.

Chairman STARK. Why should we allow the plan——

Ms. NORWALK. Let me explain why there is a difference.

Chairman STARK. Stop a minute. Just, in a sense, why should we allow the plans—in one case, a plan had a 26 percent increase during the year. I mean, these guys are supposed to be insurance pros. Unless you allow the beneficiary to change—but if you lock the beneficiary in, why isn't it fair to say that the plans ought to hold their premium and their formulary steady for the year?

Ms. NORWALK. Well, the premiums do stay stable for the year. I suspect Consumers Union is complaining about cost-sharing or coinsurance of the price of the prescription.

Chairman STARK. That is an increase in cost.

Ms. NORWALK. But it is different from the premium, just to be clear. But the reason it's important is because 93 percent of beneficiaries chose plans with copayments, and those copayments in fact do not change throughout the year. If you are in a deductible period, the price of a prescription may go up or go down, but the copayments do not change if you are in a benefit period. I think it is important to know that most beneficiaries chose plans and

have that option of taking a copayment, rather than coinsurance, where they are protected from price changes. In terms of——

Chairman STARK. I guess my question is why we should allow it. In this ZIP Code there were 61 plans, Zip Code 00501. You are quite correct it was increase in costs—35 increased their costs, 17 stayed equal, and nine—bless them—decreased. But——

Ms. NORWALK. It depends on the prescription.

Chairman STARK. But the increase was 178 bucks.

Ms. NORWALK. It would depend on the vast prescriptions that you review.

Chairman STARK. Why should we let them change it?

Ms. NORWALK. It is a basic nature of how the prescription drug market works in the commercial sector as well as in Medicare. So, even under the Federal Employee Health Benefit Program, you may pay different amounts for the same drug.

Chairman STARK. Just slow down a bit. I don't care which way you want to go on this, but it doesn't seem fair to me if I sign up for a plan, pay my premium and I have shopped, so I am in the free market, which we like to protect, that then I got to stay in that plan for a year. But if a plan changes the cost, which is important to me, I can't change. Why is that fair?

Ms. NORWALK. It actually may not be that the plan is changing the cost per se. Let me explain.

Chairman STARK. Why is that fair that there should be any change?

Ms. NORWALK. Because beneficiaries could choose plans that wouldn't have a change because they are getting copayments, and 93 percent of them did choose that. But the issue is not so much the plan change in the cost; it is how the plan reimburses the pharmacy for the prescription. It is typically on the basis of something, as you know, called a wholesale price.

Chairman STARK. This isn't costing the beneficiary. All I am saying is that if the plan changes the cost to the beneficiary, but the beneficiary can't change plans, why is that fair? Why shouldn't the plan be locked in to say, look, you are going to tell me what my cost is when I sign up so we have a contract, I guess, as we lawyers would call it? Now, why should they be able to wiggle out of it by changing the cost and I can't change plans?

Ms. NORWALK. We do. I think it is important to let beneficiaries know up front that some of their costs may change, particularly if they choose plans that have co-insurance and not copayments.

Chairman STARK. Then why don't we let them change plans?

Ms. NORWALK. Partly it is a matter of the administrative burden. That would be why.

Chairman STARK. It depends on these poor plans that aren't making any money, huh? Okay. Well, I am just glad to see which side you come on.

Mr. Camp.

Mr. CAMP. I was just going to suggest, if the questions are completed, maybe we could go to the second panel. We have all had a couple of chances here.

Chairman STARK. I have a couple more on this issue, Mr. Doggett.

Mr. DOGGETT. Do you believe it is desirable for consumers to know which plans offer the most possibility and which offer the most bate and switch.

Ms. NORWALK. I do think it is important for beneficiaries to know. In fact, that is why we have included it in our consumer reports that they will have available for the 2008 plan year.

Mr. DOGGETT. So, in the 2008 plan year, somebody will be able to go back and see how much the plan changed.

Ms. NORWALK. They will have some idea relative to the other plans; that is correct.

Mr. DOGGETT. What form will it take?

Ms. NORWALK. I will have to get back to you on the specifics. I think it is stars. We want to make it as easy as possible; one, two, three or four, or whatever. I think it is one to three stars, depending how stable your request is.

Mr. DOGGETT. Do you have any objection to legislation to require plans to tell consumers what the price change has been during the prior year on the package of, say, the hundred most commonly prescribed drugs.

Ms. NORWALK. I think consumer information is fine. I don't know that you need to require it in a statute. But if that is the suggestion, that is sort of what we are trying to get to with price stability, is that same type of information, something they can understand.

Mr. DOGGETT. Apparently the Texas plans that were surveyed by Consumers Union all have stars. You are saying this is a prospected development, this is something you will do in the future that you have not done in the past? Is that correct?

Ms. NORWALK. No. I think the issue is, what is the—this is actually currently on our plan finder now; the stars are. But we provide, it is a level of data that is underneath that that I think is important on a go forward basis, just to make sure that, if beneficiaries are choosing plans, compared with the others, have their prices moved more or less relative to other plans that are available in the area? Or might they want to choose a plan with a copayment like most beneficiaries have chosen to insulate themselves from those price changes?

Mr. DOGGETT. I am glad you don't object to legislation to address this problem. I just want to be sure that I understand where you are on this. As I understand it the plans, consumers' union survey, all had a star so that, the Texas plan, so that if someone were looking at it, they would assume they are all fine. I believe what you are saying——

Ms. NORWALK. I think the point is a comparative tool. So, what we wanted is to be able to say, are they the same or better or worse than the plan next door?

Mr. DOGGETT. That is all very reasonable, but are you going to have a separate column or category where a single or disabled person looking at that column would be able to evaluate the plans on the sole basis, separately, of whether they had price stability or whether they did a lot of bate and switch?

Ms. NORWALK. Well, the price stability is in fact one of the many things that we give a rating for. The information that is un-

derneath that I think is what you are asking for. I will check and see.

Mr. DOGGETT. You are giving an overall rating, and I am asking whether you would specifically be able to compare plans based on price stability.

Ms. NORWALK. I think, yes, that is something we will be making, if we don't already, that we will be making available on a number of features, not all specific, not just a single plan that is one, two or three star, but also the features below that.

Mr. CAMP. If the gentleman would yield, I don't think we have Medicare evaluating the physicians or hospitals at this point.

Ms. NORWALK. We are getting there.

Mr. CAMP. So, there is a huge field here talking about evaluation of providers.

Mr. DOGGETT. This is on effectiveness, this is just solely on whether they bate and switch. As I understand it, you agree it is good to provide that information and you hope to provide it.

Ms. NORWALK. Correct.

Mr. DOGGETT. Thank you.

Chairman STARK. Thank you both of you for your patience and letting us to try your patience.

Thank you, Ms. King.

Thank you, Ms. Norwalk.

We are on panel two: Dr. Steve O'Brien, an HIV/AIDS specialist from my neck of the woods, Oakland, California. Thank you, Dr. O'Brien, for coming out here and taking good care of our constituents in Alta Bates.

Dr. William Fleming, a doctor of pharmacy, who runs Humana's Part D product line. It will be interesting to have the plan perspective when we talk about changes to improve the beneficiaries benefits.

Mr. Paul Precht from the Medicare Rights Center will discuss enrollment issues.

Mr. Tom Maher with Medicare Today will talk about beneficiary education.

Finally, Ms. Vicki Gottlich, who is joining us from the Center of Medicare Advocacy, will talk about beneficiary grievances and appeals.

Dr. O'Brien, we have all of your written testimony, and without objection, it will appear in the record in its entirety. Would you care to enlighten us in about 5 minutes, an overview of information, we would appreciate it. Please lead off. I have to add that my oldest two daughters were both born in Alta Bates; how do you like that?

STATEMENT OF STEPHEN O'BRIEN, M.D., MEDICAL DIRECTOR, ALTA BATES SUMMIT EAST BAY AIDS CENTER, OAKLAND, CALIFORNIA.

Dr. O'BRIEN. Thank you, Mr. Chairman.

Alta Bates is the third busiest delivery hospital in the United States, so we see a lot of babies there.

Chairman STARK. This is before you had an emergency room or any more than one building. I don't want to tell you how long ago it was.

Dr. O'BRIEN. Good afternoon, Mr. Chairman, and distinguished Members of the Committee. My name is Steve O'Brien, and I am the medical director of the East Bay AIDS Center affiliated with Alta Bates Summit Medical Center in Oakland, California. The East Bay AIDS Center was the first community-hospital-based HIV program in the country, and we are currently the largest community-hospital-based HIV program in the United States. We provide primary and secondary specialty medical care to more than 1,300 people living with HIV/AIDS, most of whom are indigent people of color; a third of our patients are women; and we have the largest youth-specific HIV clinic in California.

I am an HIV specialist, and I serve on the Public Policy Committee of the American Academy of HIV Medicine, a nonprofit organization of HIV specialists. The academy is a part of a broader coalition of advocates known as the HIV Medicare and Medicaid Working Group which is focused on improving the lives of those living with HIV disease who are on Medicare and Medicaid.

The great news is that, in the United States, AIDS is not the disease that it used to be. Thanks largely to effective antiretroviral therapy prescribed by HIV expert providers, mortality from AIDS have fallen 80 percent. However, suppression of the HIV virus demands strict adherence to individualized complex daily regiments. Drugs that work for patient A may not work for patient B and vice versa. Because these drugs are not interchangeable with one another, HIV patients need unhindered and uninterrupted access to all of the FDA-approved medications available to treat the disease.

Since the advent of Part D, Medicare now offers drug coverage to about 100,000 beneficiaries with HIV, which is about 20 percent of all people living with HIV in care in the United States. While the addition of the Medicare drug coverage to those without prior drug coverage is clearly beneficial, the majority of my 450 HIV Medicare patients are worse off now than they were before the passage of Medicare Part D.

Most of my patients had good drug coverage before Part D, and the new program has been challenging, often disruptive and more costly to them. Patients have had trouble accessing drugs and have gone without medications they can't afford or they can't get. Enrollment problems and/or changes in plans have also caused disruption in patient access. We are a tertiary referral center, and we receive many patients who have had to transfer from community providers that were previously seen for many years because those community providers lack the resources to deal with the frequent authorization processes required by a Part D medication.

There are many plans that require monthly authorizations for crucial medicines such as fluconazole for cryptococcal meningitis. Many patients also left their community pharmacy and transferred to less convenient HIV-specialty pharmacies because those pharmacies have the expertise available for handling all the paper work required for Medicare Part D.

This didn't happen when these patients were receiving the same drugs through Medicaid or through the AIDS Drug Assistance Program or ADAP. Some plans have placed some HIV drugs in higher tiers, making them more expensive and difficult to access. Tiering the drugs in this way can effectively drive patients away and rid

many plans of their expensive AIDS patients. Patients with excessive cost-sharing burdens are choosing not to take some drugs or to reduce dosing in order to save money. One of my patients has chosen to return to an old seizure medication which has more side effects, but it is cheaper for her than the less toxic and more effective alternative. Many.

Patients with prohibitive cost-sharing for their visits and equipment are coming into the clinic less frequently and refusing to see subspecialists in order to minimize their out-of-pocket costs. These cost-sharing expenses used to be covered by ADAP when their drug coverage was provided by Medicaid and ADAP in California. But now, with Part D covering these medications, these patients are facing new expenses for their medical care they were not previously experiencing and are rationing their care. One patient I saw on Monday, for example, cut her visits now to twice a year, and she is reluctant to see her neurosurgeon and follow up for her brain tumor because she feels she can't afford these high expenses because she is caring for her elderly patients.

The academy and the HIV Medicine Association recently conducted a joint survey of their members on how Medicare Part D has affected HIV care. A particular concern is the high percentage of providers like me who reported that the dually eligible patients are now worse off under Medicare Part D. Many of the problems appear to stem from complex, often inappropriate, prior authorization processes and incorrect assignment of low-income subsidies for beneficiaries. These problems occur despite the protections for antiretrovirals and the five other drug classes included in the CMS formulary guidance.

In order to improve the Part D law, I have five brief specific recommendations: Number one, provide codified protection for the six protected classes. CMS has included antiretrovirals as one of the six protected classes so its Part D plans are required to cover all or substantially all drugs and prohibits plans from applying utilization management, such as prior authorization, to HIV medication. Despite the guidance language, the committed staff at CMS led by Dr. Jeffrey Coleman is working hard, but not all plans are complying. Just this last week, Dr. Wong in Massachusetts reported a patient receiving a very common HIV antiretroviral medication was denied because there was no prior authorization. Providers are often too frustrated, too busy with the delivery of patient care or just too overwhelmed with the burden of paper work generated by Part D to plead their cases to CMS. The protection for these six classes is essential but is currently only offered as guidance by CMS and must be renewed annually.

My colleagues and I urge Congress to write into law the protections for these six classes, including HIV medications. In addition, drug plans who consistently violate those provisions should be sanctioned and evaluated for their continued participation in the Part D program. We are united in this goal with a wide range of national organizations representing those with mental health challenges, cancer and epilepsy.

Number two, coverage for new antiretrovirals must be provided within 30 days of FDA approval. New approved antiretroviral drugs of protected classes are subject to expedited review within 90

days. But that is too long to wait, because these new drugs are really for people with very, very advanced disease, and they are the only option they have. Waiting 90 days for a new drug when you have no immune system is really no option when it can mean life or death. Newly approved medications in the six classes should be added to all formularies within 30 days of FDA approval, and this would save lives.

Number three, cost-sharing should be capped for low-income patients. People living with HIV/AIDS generally receive a dozen or more prescriptions per month. The sickest patients have the most medications, and cost-sharing disproportionately burdens people who are the sickest and poorest and who survive in the Bay Area on incomes of $600 to $1,200 a month. For the poorest of patients, even copayments as low as $3 to $5 per prescription can add up, forcing them to choose between food, shelter and life-saving healthcare and treatment. Many of my patients with co-pays will pick up only a portion of their medication or they will skip months at a time when they feel money is tight, and they can't afford that. That threatens their health. Congress should consider passing a beneficiary's monthly cost-sharing burden, particularly for the lower income patients who cannot afford multiple copayments every month.

Number four, coverage during enrollment changes and transitions in coverage needs to be guaranteed. Proper enrollment into a drug plan has been difficult. During times of transition between plans, patients and their providers are often confused. Many patients often don't even know their plan has changed. Many of my patients claim they never get the letter, although I am sure it has been mailed. This requires reauthorization for their drugs and often a delay in getting them their medication.

There is also some bad actors amongst the plans. Earlier this spring, one company, Sierra RX, abruptly disenrolled hundreds of HIV patients from coverage in their enhanced plan. The disenrollments were unjustified, and after a time-consuming case-by-case investigation by CMS, which found no cause for the abrupt dismissal, CMS mandated reenrollment, but not before a patient's health had been endangered. Enrollment and disenrollment protection should be enacted.

Finally, number five, ADAP payments should count toward true out-of-pocket expenditures. Many patients with HIV rely on Ryan White's AIDS Drug Assistance Program for coverage prior to Part D. But now, ADAPs require all these patients to enroll in the Medicare Part D benefit. However, since HHS is interpreted to be MMA, such that ADAP expenditures do not count toward the true out-of-pocket expenditures or TrOOP, beneficiaries receiving support from ADAP will never come to their doughnut hole and ADAP will continuously be used to pay for these expenses. This further strains the very limited ADAP programs. Federal law should support efforts to maximize Medicare coverage and allow expenditures made by AIDS Drug Assistance Programs to count toward TrOOP.

In conclusion, Medicare Part D, has been helpful to a few of my patients. But to many of my patients, it has been confusing, stressful and disruptive for their care. For the HIV clinicians, it has been challenging on the best of days, and frustrating and overwhelming

on the worse. We spend hours on the phone at our desk filling out authorization requests for different plans. But the different requests for different plans is confusing. My nurses and pharmacists tell me they are now spending at least twice as much time per patient getting the same drugs now that they are on Medicare Part D as they did prior to that. The hours spent on patient advocacy are robbed from our limited time with patient care.

So, Congress has an opportunity to help by providing safeguards for the six protected classes by mandating access to new antiretrovirals within 30 days, by capping out-of-pocket cost-sharing for low-income patients, by guaranteeing coverage during plan transition, increasing surveillance and sanctioning by bad actors, by guaranteeing at least one enhanced plan that offers coverage through the doughnut hole and by allowing ADAP expenditures to count toward true out-of-pocket expenditures. We appreciate the hard work of this Committee, particularly the Chairman and Members. I appreciate the opportunity to share my story and happy to answer any questions you might have.

[The prepared statement of Dr. O'Brien follows:]

Statement of Steve O'Brien, M.D., Medical Director, Alta Bates Summit East Bay AIDS Center, Oakland, California

Good afternoon. My name is Stephen O'Brien and I am the Medical Director of the Alta Bates Summit East Bay AIDS Center in Oakland, California, which provides primary and specialty medical care to more than 1,300 HIV-infected people, most of who are indigent people of color living in the Oakland area and surrounding counties. I am an HIV specialist in internal medicine, and I serve on the Public Policy Committee of the American Academy of HIV Medicine, a non-profit member organization of HIV specialists throughout the United States.

The American Academy of HIV Medicine is a member of a broader coalition of committed advocates through the nation known as the HIV Medicare & Medicaid Working Group, which is focused on improving the lives of those individuals living with HIV disease and receiving care and treatment from either or both of the Medicare and Medicaid programs.

I. Overview:

By now most Americans are familiar with the dramatic improvements in the treatment of HIV infection that have reduced mortality due to the disease by nearly 80 percent. Once almost always considered a fatal diagnosis, HIV disease can now be managed with consistent and reliable access to a combination of medications known as highly-active antiretroviral therapy (HAART).

These medications are critical to the health and well-being of patients infected with HIV/AIDS; however, successful viral suppression demands *strict adherence* to a complex drug regimen that requires *multiple doses of three or more highly expensive medications* daily. In addition, antiretroviral medications are simply not interchangeable with one another due to individual physiologic factors and differences in toxicity, efficacy, drug interactions, and drug-sensitivity of the patient's virus. As a result, it is critical that people with HIV/AIDS maintain unhindered access to all of the FDA-approved medications available to treat the disease and its complications. Beyond viral suppression, people with HIV disease often must contend with opportunistic complications and serious co-occurring conditions such as hepatitis C and mental illness, as well as complications such as diabetes, elevated cholesterols, and heart conditions resulting from the HAART medications themselves.

Through the passage of the Medicare Modernization Act of 2003, Medicare now offers prescription drug coverage to approximately 100,000 Medicare-eligible beneficiaries with HIV/AIDS, roughly 20% of those in care. Medicare is the second largest source of federal funding for HIV care and treatment after Medicaid.

While the addition of Medicare drug coverage to those without prior drug coverage is clearly beneficial, for the majority of my 450 California Medicare patients, many of whom had good drug coverage before Medicare Part D, the program has been challenging, often disruptive and more costly. Patients have had trouble accessing antiretrovirals and treatment for opportunistic infections. Patients have gone without medications they can't afford or can't access through their new plans. Changes

in plans have caused disruption in patient's access to long term medications. Some patient's have had to transfer to new medical providers and pharmacies that specialize in the complex authorization processes required by various insurers.

Most antiretrovirals are readily available through most plans. However, some plans have placed some antiretrovirals in higher tiers, thereby making them more expensive or more difficult to access. Most patients, who are not "locked into" plans, have changed plans, those who are locked in have changed during open enrollment; therefore, tiering effectively rids many plans of their expensive AIDS patients.

It is not just the antiretrovirals, however, that patients are having difficulty accessing. For example, we have had many patients have difficulty receiving the antifungal fluconazole to treat cryptococcal meningitis. Fluconazole is the treatment of choice for this common opportunistic infection but many plans delay authorizing this drug or require monthly reauthorizations. This has led to prolonged hospitalizations and gaps in treatment.

Patients with excessive cost sharing burdens for their drugs are sometimes choosing not to take some drugs or to take reduced dosing in order to save money. One patient has chosen to return to a cheaper anti-seizure medication (Dilantin) with more side effects because it is cheaper than the less toxic alternative (Keppra) we had her taking. Many patients with prohibitive cost-sharing for their medical visits and medical equipment are coming to clinic less often and refusing to see subspecialists in order to minimize their out of pocket expenditures. One patient I saw on June 18 has cut her visits to twice per year and is reluctant to see her neurosurgeon for follow up on her brain tumor because she feels she can't afford her high share of the cost of care.

As a tertiary referral center, we have received several patients in transfer who had to stop seeing their regular community provider because they were unable to dedicate the resources needed to get the frequent authorizations required by Medicare Part D plans. For the same reason, many patients have left their more convenient community pharmacy and transferred to less convenient HIV specialty pharmacies that have the expertise to file the appropriate paper work to get the drugs the patient needs. This didn't happen when these patient's were receiving the same drugs through Medicaid or the AIDS Drug Assistance Program (ADAP).

But compare my individual experience with a broader picture of the nation's HIV patients. The American Academy of HIV Medicine (AAHIVM) and the HIV Medicine Association (HIVMA) recently conducted a joint survey of their HIV medical provider members to obtain information on how Medicare Part D has affected HIV care today.

HIV medical providers reported challenges obtaining antiretroviral and non-antiretroviral medications for their Medicare patients with HIV/AIDS. Many of the problems appear to stem from complex and in some cases inappropriate prior authorization processes; high prescription drug co-payments; inadequate formulary coverage of both antiretroviral and non-antiretroviral medications—such as cholesterol medications, pain medications, medications for HIV-related opportunistic infections and hypertensive medications. Moreover, there have been data system problems at the Centers for Medicaid and Medicare Services (CMS) and at the Medicare prescription drug plans, including incorrect assignment of Low Income Subsidy for beneficiaries. These problems occurred despite the protections for antiretrovirals and the five other drug classes included in the Centers for Medicare and Medicaid (CMS) 2006 and 2007 formulary guidance.

Of particular concern is the high percentage of HIV medical providers who reported that their patients who are dually eligible for Medicare and Medicaid are *worse off under Medicare Part D*. With Medicaid drug coverage, this population had access to an open drug formulary and in many states were not subject to cost-sharing. (If they were subject to cost sharing, Medicaid law ensures that beneficiaries are not denied access to drugs or other services due to an inability to meet cost-sharing obligations.) Low income people with HIV/AIDS can face significant cost sharing obligations under Medicare Part D, forcing them to forgo necessary medications in lieu of food or rent. The Medicare Modernization Act of 2003 called for CMS to conduct a study of how dual eligibles with HIV/AIDS would fare under Medicare Part D that to this date has not been released publicly. Better monitoring of the dual eligible population is needed along with stronger protections to ensure that they maintain reliable access to lifesaving drug therapies.

What follows are key findings from the joint AAHIVM and HIVMA survey of HIV medical providers.

Medicare Part D Drug Plans are not meeting the needs of beneficiaries with HIV/AIDS.

- 83% of respondents reported that their patients had experienced problems getting their prescriptions since joining a Medicare drug plan. Of those reporting problems for their patients with HIV/AIDS:
- 80% reported one or more of a patient's drugs were subject to prior authorization.
- 76% reported one or more of a patient's drugs were not covered by their plan's formulary.
- 73% reported that patients could not afford the co-payments/cost-sharing.
- 44% reported that a patient's drugs were subject to quantity limits.

People with HIV/AIDS experience lapses in medications due to Part D problems.

- Of those reporting problems with Part D, 75% reported that patients with HIV/AIDS went without medications due to Part D problems. Of those who reported specific medication lapses:
- Sixty-five percent reported patients with HIV/AIDS going without antiretrovirals as well as other medications.
- Eleven percent reported patients with HIV/AIDS going without only antiretrovirals
- Twenty-four percent respondents reported patients with HIV/AIDS going without only non-antiretroviral medications.

Problems with Part D coverage led to unscheduled medical visits and other adverse health consequences for some patients.

- Sixty percent of respondents who reported problems indicated that patients with HIV/AIDS came in for unscheduled or extra medical visits due to Part D problems.
- Twenty-eight percent of respondents who reported problems indicated that patients with HIV/AIDS experienced other adverse health consequences due to Part D problems.
- For those who reported problems, the percentage of respondents reporting that patients with HIV/AIDS had trouble accessing medications included: antiretroviral medications (54%); mental health medications (55%); cholesterol medications (55%); pain medications (46%); medications for HIV-related opportunistic infections (36%); hypertensive medications (35%) and hepatitis medications (22%).

II. Protections for HIV Antiretrovirals and other drugs under the Six Protected Classes

CMS has included antiretrovirals as one of six protected drug classes for which Part D plans are required to cover "all or substantially all drugs" available. The formulary guidance prohibits plans from applying utilization management techniques such as prior authorization to HIV antiretrovirals with the exception of one drug, enfuvirtide. Prior authorization is allowed with enfuvirtide only when the patient is new to the drug. Despite the guidance, not all beneficiaries are guaranteed access to these drugs as evidenced by the AAHIVM/HIVMA survey findings and reports from HIV medical providers. Just this past week, Dr. Michael Wong in Massachusetts reported a patient who was denied stavudine, a common antiretroviral, at the pharmacy subject to a prior authorization. The patient has been on this medication for years, and Dr. Wong reported that this has never been an issue before. The patient has end stage renal disease, is on dialysis, and has been on his current ARV regimen for at least a year without problems. Cindy Zoellner, PharmD and HIV Clinical Pharmacy Specialist in Dallas, Texas reported a similar problem with coverage of darunavir in her clinic. The plan faxed her the prior authorization form, which required 13 pages of documentation, including office notes, labs, and genotype test results. Both health plans were in clear violation of the guidance. My colleagues and I have seen other surprises as well, such as the denial of fixed-dose combination drugs such as Truvada (combination of tenofovir and emtricitabine), Combivir (zidovudine and lamivudine), and Epzicom (abacavir and lamivudine) to name a few. The individual component agents are approved, but these combinations that are designed to improve the ease of administration and minimize pill burden are not consistently included in many Part D plans.

In spite of needed improvements, the protection for these six classes is essential for Medicare beneficiaries but is currently only offered as guidance issued by CMS and must be renewed annually. My colleagues and I, the American Academy of HIV Medicine, and the whole of the HIV Medicare & Medicaid Work Group, **urge Con-**

gress to write into law the protections for the six classes including HIV antiretrovirals that are currently offered in guidance. In seeking codification of these protections, we are united with a wide range of national organizations working to secure access to medications essential in the treatment of serious diseases. These groups include the AIDS Institute, the American Academy of Neurology, the American Psychiatric Association, the Cancer Leadership Council, the Epilepsy Foundation, the HIV Medicine Association, Mental Health America, the National Alliance of State and Territorial AIDS Directors, the National Alliance on Mental Illness, Project Inform, and the TEN Project. In addition, drug plans that consistently violate this provision should be viewed as unfit to participate in the Medicare Part D program. These classes of drugs all represent treatment for very serious conditions and in the case of HIV—life-threatening illnesses. This protection is critical to patients.

III. Coverage for New HIV Antiretrovirals

Newly approved antiretrovirals (as well as drugs in the other protected classes) are subject to an expedited 90-day review process to be added to patient formularies but for a patient who has exhausted all currently available medication options, 90 days is too long to wait. By virtue of qualifying for Medicare, a majority of Medicare beneficiaries with HIV/AIDS are in advanced stages of disease progression and, therefore, more treatment experienced than persons with HIV/AIDS who do not qualify for Medicare. They are more likely to be resistant to available antiretroviral therapies, which mean that available drugs are no longer effective at suppressing HIV. Antiretroviral agents newly approved by the Food and Drug Administration (FDA) may be essential for many Medicare beneficiaries to maintain an effective anti-HIV treatment protocol.

Newly approved medications in the six protected classes, including anitiretrovirals, should be added to all drug plans formularies within 30 days of FDA approval to ensure Medicare beneficiaries have access to new HIV therapies that could literally save their lives

IV. Cost sharing

People living with HIV/AIDS generally depend on access to 8 to 14 prescriptions a month to suppress HIV, manage treatment side effects and manage co-occurring conditions. Co-payments and other forms of cost sharing, disproportionately burden people who are the sickest, the most in need of drugs and struggling to live on very low monthly incomes that range from $600 to $1,200. For the poorest of patients, even co-payments as low as $3.10 to $5.35 per prescription can add up to $50 to $60 a month that they just do not have, forcing them to make difficult choices between food, shelter and lifesaving health care and treatment.

For patients with income just above the eligibility requirement for the low-income subsidy, the cost-sharing required for their HIV drugs can impede access to vital medications. As an example of the co-payments borne by those who do not qualify for the low income subsidy, let me outline drug costs for a typical, and relatively simple, HIV regimen under the Humana Standard Plan (which is comparable to the other plan options) available in California. The cost sharing before the patient has met the deductible and again during the donut hole would be around $819.60 per month (353.19 for Combivir and 466.41 for efavirenz); after the patient meets the deductible and before he reaches the donut hole the cost would be $204.90 per month (88.30 for Combivir and 116.60 for efavirenz). Finally, when the patient's drug costs reach the out of pocket limit of 3,850, the patient's co-payments drop to $40.98 ($17.66 for combivir and 23.32 for efavirenz). These costs are in addition to the premiums charged by the plan. Our patients in California and about half of the states often can get help through their AIDS Drug Assistance Program (ADAP) with these costs, if they qualify for the program. This assistance, however, is not readily available in every state, or for every person that might apply.

Congress should consider capping the beneficiary's mothnly cost sharing burden, particularly for those low-income patients who cannot afford co-payments for multiple medications.

V. Enrollment issues: Proper LIS assignment

Enrollment into a prescription drug plan has been difficult for many populations of individuals, but we also have stories to report from within the HIV population—not just enrollment, but dis-enrollment as well. Earlier this spring, one company, Sierra Rx, abruptly dis-enrolled hundreds of HIV patients from coverage their enhanced plan (a plan offering coverage on brand and generic drugs through the coverage gap or donut hole in exchange for a higher monthly premium. The plan made this "mistake" ironically after it was widely reported that the enhanced plan, an attractive option for patients with HIV, who routinely hit the hole in March or April

every year, had severe losses during the first three months of operation. The dis-enrollments were unjustified and after time-consuming case-by-case investigations by CMS which found no cause for the abrupt dismissal, CMS mandated re-enrollment for virtually all of the clients that had been dis-enrolled. In several states the ADAPs stepped in and provided medications while CMS was reviewing cases, but the process and was extremely time-consuming and frustrating for clients and case managers. If ADAPs had not been able to intervene to ensure coverage of essential drugs during this period of disruption the patients could have faced drug resistance problems, increased disease morbidity, and other severe problems associated with loss of access to HIV medications.

In California where I am from and in some other states as well, many Medicare beneficiaries with AIDS are eligible for Medicaid through their state Medicaid "medically needy" or "spend down" program. These programs allow people to qualify for Medicaid coverage because their medical expenses are so high that when deducted from their income they meet the Medicaid income eligibility criteria. Under current policy, CMS only automatically enrolls people into the low-income subsidy program who have met the Medicaid spend down requirement during specific "snapshot" months of the calendar year. This policy results in denying access to many who are truly "medically needy" but have lower countable expenses in a CMS "snapshot" month. **Fairness and efficiency support enactment of a federal policy that grants access to the low-income subsidy to any person whom a state Medicaid program has certified as a Medicaid-eligible.** With such a policy, those who are truly unable to meet the cost sharing required under Medicare Part D will have access to a low income-subsidy and the life-saving prescription drug coverage they need.

VI. ADAP and TrOOP

Many Medicare beneficiaries with HIV/AIDS relied on the Ryan White CARE Act's AIDS Drug Assistance Program (ADAP) for drug coverage prior to Medicare Part D. Beginning in January 2006, ADAPs were required to enroll all eligible ADAP beneficiaries into Medicare Part D. The U.S. Department of Health and Human Services determined that ADAP expenditures could not count toward the true out of pocket cost limit known as "TrOOP". Meeting or paying "TrOOP" expenses is the trigger that moves a beneficiary from the coverage gap into a meaningful level of drug coverage, known as catastrophic coverage. Therefore, beneficiaries receiving support from ADAPs will never reach a meaningful level of drug coverage if the ADAP supplements their coverage during the donut hole. ADAP dollars that must be used to supplement Medicare are dollars that cannot be allocated to other needy individuals who do not have Medicare coverage. Federal policy should support efforts to maximize Medicare coverage to meet the needs of Medicare beneficiaries with HIV/AIDS. **Our organizations urge Congress to clarify the law to allow expenditures made by AIDS Drug Assistance Programs (ADAPs) to count toward the True-Out-of-Pocket (TrOOP) limit.**

VII. Conclusion:

Medicare Part D has been helpful to a few of my patients, yet for many, if not most others, it has been confusing, stressful, and disruptive to their care. From the HIV medical provider perspective, it has been challenging on the best of days, outrageous on the worst. We spend hours on the phone or at our desks on a daily basis, filling out prior authorization request for many different plan and for numerous medications. We often act as the only advocate for patients who otherwise haven't been heard or cannot navigate the very difficult system. It is not clear how many patients fall through the cracks in this system, but we fear that for every one we hear about, there is at least one other who we don't. The hours spent on patient advocacy are robbed from our limited time for delivering care, and it is this complicated and time consuming bureaucracy that is inadvertently perpetuating the healthcare disparities that plague this very vulnerable population.

Congress has an opportunity to help, by codifying the six protected classes, increasing surveillance and sanctioning of bad actors, capping monthly cost-sharing, guaranteeing at least one enhanced plan that offers coverage of both brand name and generic drugs through the doughnut hole, and by allowing ADAP expenditures to count towards TrOOP.

I appreciate the opportunity to share my story and the stories of my colleagues and I remain eager to assist this body in the design of possible solutions.

Thank you.

Chairman STARK. Thank you.
r. Fleming.

STATEMENT OF WILLIAM FLEMING, PHARMD, VICE PRESIDENT, PHARMACY AND CLINICAL INTEGRATION, HUMANA, INC.

Mr. FLEMING. Mr. Chairman, Representative Camp and Committee Members, thank you for asking me to testify about Part D program protections for beneficiaries. I am William Fleming, a pharmacist and vice president of pharmacy for Humana. Humana offers three uniform stand-alone PDPs in all 50 States, here in D.C. and one in Puerto Rico. We have over 4.6 million Medicare members, including over 1.1 million subsidized members. Our members have access to an open formulary of all Medicare covered drugs through over 60,000 pharmacies and our own mail order. In 2007, we expect to pay for nearly 200 million prescriptions or nearly $11 billion of drug costs. Let me highlight a few beneficiary protections.

First, we provide local pharmacy access. In 2006, we added 5,400 independent pharmacies to our network, bringing the number of independents to one-third of the total. We pay for pharmacist consultations and have electronic funds transfers to ensure prompt payment.

Second, we help members better understand and use their plan. We design tools to educate beneficiaries on how to pick the plan that is right for them, compare drug costs, learn about their drugs, consult with their physicians on alternatives that can save money and help them improve their health. We send members messages about when they receive their ID cards, when they are nearing the coverage gap and whether there are clinically effective cost-saving generic alternatives to the brand drugs prescribed. We made over 750,000 calls to notify members about generic alternatives. We work with physicians, pharmacies, care givers, consumer groups and government agencies to maximize resources to improve health outcomes.

Regarding SmartSummaryRx, which is in your packet, to help members maximize their coverage and have confidence to talk with their doctors, we designed SmartSummaryRx. Members who receive this monthly statement, it tracks their drug usage and costs, the doctors who prescribe the drugs, members who are compliant on their medications, whether savings are available and provides personalized wellness information. This helps them become more informed consumers. We also provide a record of the drugs they use. Smart Summary acts as a portable personal health record and assists doctors in coordinating medications for our members.

Regarding formulary, all Medicare covered drugs are on our formulary. We negotiate directly with drug manufacturers and retailers. We have four drug coverage tiers. We require prior authorization, safety and quantity limits and step therapy in a small number of drugs to guide to equally effective less-costly therapies. We encourage the use of generics, mail order and 90-day at retail purchasing.

Regarding exceptions and appeals, during 2006, we processed appeals for less than 1 percent of claims, mostly for directly marketed, brand name drugs or to determine coverage under part B or Part D.

Regarding outcomes, we are working to improve quality outcomes through the medication therapy management programs working with 32 quality improvement organizations and supporting efforts to promote research. Medication therapy is required for all beneficiaries with high drug cost and multiple chronic conditions that use multi-chronic medications. One million Humana members qualify for this program and receive general mailings, telephone and face-to-face counseling with a pharmacist on potential adverse reactions, drug interaction issues or compliance with a doctor's orders. We intend to make it available to other members in the future.

Regarding areas for consideration, there are some areas where the program should be improved. Number one, Medicare part B versus Part D drug coverage: Certain categories of drugs may be covered under part B or Part D, depending on the setting and/or the clinical situation. MEDPAC just made three recommendations. We agree with all of them.

Number two, coverage of Part D excluded drugs: Two types of drugs, the benzodiazepines and the barbiturates are covered by Medicaid. Part D low-income beneficiaries have access to these drugs. We believe that all beneficiaries should have access to keep costs down and provide other treatment options for diseases like epilepsy.

Number three, Social Security Administration deductions: Thousands of beneficiaries will still have issues with incorrect Social Security premium deductions. This issue must be resolved between CMS and Social Security. We provide hardship waivers to low-income members who continue to experience problems.

In conclusion, most beneficiaries now have some form of prescription drug coverage, the majority of whom are satisfied in saving money. But improvements can be made. At Humana, we support strong beneficiary protections to educate, improve health options and resolve beneficiary concerns. I look forward to responding to your questions.

I would like at this time to briefly respond to a question Congressman Kind raised regarding a Humana beneficiary. We deeply regret that this situation occurred. Our procedures do not turn cases like this over to collection agencies, not for 100-year olds or for 65-year olds. That was wrong. I know that your office called us and that the issue was resolved. We have talked to the member. We are not perfect and constantly work to improve our training to prevent these types of cases from occurring again. Thank you.

[The prepared statement of Mr. Fleming:]

Statement of William Fleming, PharmD, Vice President, Pharmacy and Clinical Integration, Humana, Louisville, Kentucky

Testimony on

Protecting Beneficiaries in Medicare Part D Plans

By

William Fleming, PharmD
Vice President, Pharmacy and Clinical Integration
Humana Inc.

Before the
United States House of Representatives
Ways and Means Committee
Health Subcommittee

June 21, 2007

Mr. Chairman, Representative Camp and other members of the Committee, thank you for permitting me to testify about one of the most important benefits Medicare beneficiaries now receive – an outpatient prescription drug benefit. I am William Fleming, a pharmacist and Vice President of Pharmacy and Clinical Integration for Humana Inc. Humana is headquartered in Louisville, Kentucky. For more than twenty years, Humana has been serving Medicare beneficiaries through health plans that offer affordable, comprehensive health care coverage. We currently offer three stand-alone prescription drug plans (PDPs) in 50 states, the District of Columbia (and one plan in Puerto Rico); private fee-for-service plans in 50 states; regional preferred provider plans in 23 states; local preferred provider plans in 17 states; and HMOs in 8 states and Puerto Rico. We also offer a Medicare Supplement product in 36 states. In addition, Humana offers private health plan options through the Department of Defense's TRICARE program to military families and plans to government employees through the Federal Employees Health Benefits Program. We offer Medicaid plans in Florida and a Medicaid-type plan in Puerto Rico. Finally, we offer health insurance coverage and related services to employer groups and individuals. In total, we provide medical insurance to over 11 million members.

Today, I will speak about the importance of the prescription drug program for Medicare beneficiaries, our experiences in implementing this program, mechanisms in place to protect beneficiaries, lessons learned from first year experiences and some recommendations.

Humana Part D Plans

Humana currently offers three, uniform stand-alone Medicare PDP products in every state, the District of Columbia and one plan in Puerto Rico. (Please see **Attachment #1** for an outline of these products.) We currently offer one product that reflects the statutory benefit design with a deductible, coinsurance and no coverage in the coverage gap; one product with no deductible, copayments and no coverage in the coverage gap; and a third product with no deductible and copayments, including copayments through the coverage gap for generic drugs only (a few specialty generics are also excluded).

In 2006, Humana similarly offered three, uniform, stand-alone Part D products in 46 states (all but Alaska, Hawaii, New Hampshire and Maine). The benefit design for these products was the same except that the most comprehensive of our products provided brand coverage through the gap.

We have a four-tier, open formulary. All FDA, Medicare-approved medications covered under Part D are on our drug list. While we contract with a pharmacy benefit manager (PBM), Argus Health Systems, we only use them to process claims. Unlike many other sponsors, we directly negotiate our own contracts with retail pharmacies, long term care pharmacies, and drug manufacturers.

Valued Benefit for Beneficiaries

Today, over 4.6 million Medicare beneficiaries belong to a Humana plan offering prescription drugs, including over 1.5 million dually-eligible beneficiaries. Over 1.5 million of our members enrolled through the Center for Medicare and Medicaid Services (CMS) website or our Humana website. On average, our non-subsidized or voluntary members saved over $1,600 each last year.

Our members have wide access to pharmacies. Humana has contracted with nearly 60,000 chain and independent pharmacies, including all major chains, thousands of independent pharmacies and long-term care pharmacies. Our plans offer mail order, along with low premiums, broad formulary, comprehensive health education programs and Medication Therapy Management Programs (MTMP) for beneficiaries with high prescription drug costs and chronic conditions.

In 2006, we paid for more than 140 million prescriptions, representing nearly $9 billion of drug expense. We mailed approximately 26,700,000 SmartSummaryRx℠ statements (monthly, personalized statement of expenses, savings opportunities, prescription drugs taken and customized health information. **Please see Attachment #2**).

In 2007, for a full year of benefits, we expect to pay for nearly 200 million prescription drugs representing nearly $11 billion of drug costs; fill more than 3 million prescriptions through our own pharmacies; mail more than 40 million SmartSummaryRx℠ statements; communicate with nearly 1 out of every 5 members about cost-savings opportunities; and, strive to work with 1 out of every 7 members through our MTMP. Our members average 40 prescriptions per year.

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additional monies, such as using generics where possible (upon consultation with their physician) or using mail order. We provide guidance to members using brands in the coverage gap informing them of manufacturers' pharmacy assistance plans that offered discounts on certain single source drugs.

For most beneficiaries and their families or caregivers, including low-income seniors, those with chronic diseases and those who are nursing home residents, this new prescription drug benefit provides savings and coverage relief.

Program Start-Up Issues

The Part D start-up and operational implementation issues are well-known and mostly related to the lack of interoperability among health information systems among all stakeholders including CMS, Social Security Administration (SSA), state Medicaid agencies, drug sponsors, and pharmacies (among others) and to the accuracy of the data exchanged. This situation affected enrollment eligibility, accounting for true-out-of-pocket-expenses, prescription drug events, premium deductions, web site drug price calculators and many others. The timing of CMS' installation of a new information system at the time of the 2006 enrollment season did not allow for end-to-end processing tests. As well, we and most other parties underestimated the numbers of beneficiaries who would seek coverage and the resources needed to address their issues. CMS has worked to resolve system issues and continues to meet regularly with plan sponsors on remaining systems-related issues. To date, we are in the last phases of reconciling 2006 enrollment and payment. Issues still remain with Social Security deductions, but we anticipate the major issues should be resolved within the next 2 months. Given these

system issues, Humana's policy has been to issue hardship waivers for those beneficiaries with limited incomes who have experienced SSA deduction issues and who cannot afford to pay the remaining premium amounts due to the delay in accurately processing their deductions.

Important Protections for Beneficiaries

Humana and other Part D plans began in earnest preparing for implementation with the promulgation of the Medicare Modernization Act regulations. In our case, planning and staffing were based on historical data we acquired during more than 20 years of government program contracting. Our data proved almost irrelevant given the overwhelming acceptance of the Part D benefit by beneficiaries and the aforementioned system issues. In evaluating the credible data we now have and the beneficiary impact of the program, there are some lessons learned that have added value to the program for beneficiaries or resulted in strengthened beneficiary protections. Let me highlight a few.

1) **Pharmacy Access:** Humana's network includes all national chains, 21,710 independent pharmacies and 6,786 long term care (LTC) pharmacies. During 2006, we added over 5,400 independent pharmacies to enhance beneficiary access to local community pharmacies. We learned early on the importance of communicating regularly with these pharmacies to improve beneficiary experience at the pharmacy counter. We arranged ongoing contact with the National Association of Chain Drug Stores (NACDS), the National Community Pharmacists Association (NCPA), state pharmacy associations and those

pharmacies filling large numbers of our prescriptions. We continue to email, fax and use national and state association websites to distribute our regular pharmacy bulletins. We participate in call-ins hosted by the associations and have "hot links" on some of the national and state web sites.

During 2006, independent pharmacies expressed deep concern about the amount of and delay in reimbursement. Humana reimburses pharmacies every 10 days (which equals three times monthly). We also designed our payment formula for our MTMP in such a way as to encourage participation by independent pharmacists. We pay a set dollar amount per minute for consultations by in-store pharmacists. We have had a large number of independent pharmacies participate in this program—proportionately larger than retail chain participation.

We have also worked closely with long term care pharmacies and their trade group to ensure access and prevent operational problems for institutionalized members. We have hired an expert in long-term care to help guide our strategies and day-to-day relationships with LTC pharmacies. LTC pharmacies represent a significant source of our pharmacy expense for our stand-alone prescription drug plans. Working collaboratively with the major LTC pharmacy chains, group purchasing organizations and the facility groups these entities service, we are identifying opportunities to improve operational issues and achieve greater efficiencies in the delivery of pharmaceutical care in the institutional setting. Through enhanced communication of our formulary structure and a close clinical

partnership with our MTMP, we anticipate that LTC pharmacies will be able to deliver new savings to the Medicare program and improved clinical outcomes.

To further ensure that beneficiaries do not encounter issues at the prescription counter, through our trade group, America's Health Insurance Plans (AHIP), and member plans, we have participated in a work group with NACDS and NCPA to recommend new messaging and new codes to facilitate the electronic exchange of pharmacy data from sponsors to pharmacies. The group also promoted the use of electronic funds transfer to expedite sponsor payments. We continue to participate in this work group to continually improve beneficiary and pharmacy satisfaction and outcomes.

Finally, in January 2006, Humana opened our own mail order facility, RightSource, in Phoenix, Arizona. This facility is expected to fill more than 2 million prescriptions for our Medicare members in 2007.

2) Transition Period: CMS requires a 30-day transition period for beneficiaries who are on a prescription drug that is not on their Part D plan formulary to work with their doctors to change to a drug that is on the formulary. Given Part D start-up issues and the newness of this benefit, during the first enrollment period in 2006, Humana's transition plan was **90** days for those whose enrollment was effective January 1, 2006 and **60**-days from initial enrollment for all others. (CMS required plans to grant 90 days for those enrolled January 1, 2006; 60 days

for those enrolled as of February 1, 2006 and 30 days for those with March 1 effective dates.) Today, Humana's enrollment transition period is 30 days as required by regulation; *in addition*, Humana extends the transition period to all beneficiaries at the beginning of the plan year, rather than just the new enrollees to our plan.

There is an unintended, positive consequence for beneficiaries and for the government from the transition period policy. At the end of March 2006, as a significant number of our members were about to have to change one of their medications or pay more for it, we approached various manufacturers who produced the drug. We shared the number of beneficiaries affected and the formulary placement for their drug. Several of the manufacturers lowered their prices, leaving the drug in a more favorable cost-sharing position for the beneficiary. The beneficiaries saved money, had continuity of care and the program saved money.

3) Formulary, including generic usage and bulk purchasing: As previously mentioned, all Medicare-approved drugs are on our formulary, and the formulary is uniform across all our drug plans. The only excluded drugs are those that are statutorily excluded from Medicare coverage, like benzodiazepines. We negotiate with drug manufacturers and retailers to receive the best price for covered prescription drugs. Besides making it simple for beneficiaries, physicians and pharmacists, we have early indications that our single formulary strategy may

result in additional program efficiencies. At the same time, when a generic product is approved by the Food and Drug Administration (FDA), we make that product available to our beneficiaries. To ensure appropriate utilization, we have adopted four primary tiers for coverage of drugs. We require prior authorization on a small number of high-cost specialty medications, have safety/quantity limits on certain drugs to promote appropriate dosing consistent with FDA-approved labeling and require step therapy on a small number of drugs to guide beneficiaries and prescribers to equally-effective drugs in a more favorable cost-sharing tier. Less than 2% of our members were affected by changes in prior authorization, safety/quantity limits and step therapy protocols from 2006 to 2007. Our transition policy ensured that affected beneficiaries received a temporary supply of their medication while they pursued an exception or coverage determination.

A number of studies demonstrate that these strategies are highly effective in making prescription drugs more affordable for consumers. For example:

- A 2003 Lewin Group study[1] for the Center for Health Care Strategies found that Medicaid managed care plans reduced prescription drug costs by 15 percent below the level states would otherwise have experienced under Medicaid fee-for-service.

[1] Center for Health Care Strategies, January 2003, Comparison of Medicaid Pharmacy Costs and Usage Between the Fee-for-Service and Capitated Setting.

- In addition, the Government Accountability Office (GAO) has reported[2] that pharmacy benefit management techniques used by health plans in the Federal Employees Health Benefits Program (FEHBP) resulted in savings of 18 percent for brand-name drugs and 47 percent for generic drugs, compared to the average cash price customers would pay at retail pharmacies.

These findings clearly demonstrate that the private sector has a strong track record in using its experience and capabilities to deliver affordable prescription drug benefits. Our experience indicates that beneficiaries are more willing to (a) use generics than our commercial populations and (b) purchase in bulk (i.e. 90-day supplies). At the end of 2006, our generic dispensing rate averaged 60% and at the end of 2007, the rate is expected to exceed 63%.

Bulk purchasing is also positive. Beneficiaries using mail order save ½ of a copayment for those plans that have copayments (for those that don't, mail order generally saves about 10% of the cost of the medication). Through outbound calls and notifications in members' monthly statements, we encourage members currently taking brand name drugs for which there are effective generic alternatives, to speak with their physicians. Through these processes, we have averaged 15-20% conversions to alternative drugs. Our data shows that members are more willing to change their cholesterol medications than those taking

[2] Government Accountability Office, January 2003, Federal Employees' Health Benefits: Effects of Using Pharmacy Benefits Managers on Health Plans, Enrollees, and Pharmacies (GAO-03-196).

stomach medications. For those members who are switching to alternatives, they are saving on average $250-300 per year per drug.

We also seek to protect members from formulary changes. While the statute and regulations allow for mid-year formulary changes with adequate notice to the beneficiary, Humana minimizes these types of changes. We believe the beneficiary's best interest is served by making any changes with the new plan year effective January 1. During the plan year, Humana only removes drugs from our formulary in cases where the FDA issues a safety warning or re-classifies a drug, for example, from a Part D-covered drug to one where it is not covered, like a DESI drug. [Certain drugs reviewed by the FDA's Drug Efficacy Study Implementation (DESI) program are determined to lack substantial evidence of effectiveness for all of its labeled indications and are termed Less-than-Effective or Identical, Related and Similar. They are excluded under the Part D benefit.]

Generic drugs are vitally important to the affordability of Part D for the beneficiary and the government. As a result, Humana is working with some Part D plans, employers, pharmacy benefit managers and others through the Coalition for a Competitive Prescription Drug Market to advocate for the creation of an FDA pathway for the approval of follow-on biologics.

4) Exceptions and Appeals: During 2006, we received and processed more than 1 million exceptions and appeals. We have more than 150 associates working on

exceptions and appeals, including more than 10 clinicians. Average turn-around time for exception/appeal requests currently is well within the 72 hours required. The most frequently requested exceptions are for Januvia (diabetes), Celebrex (arthritis), Coreg CR (high blood pressure), Protonix and Nexium (stomach ulcers), Byetta (diabetes) and Lunesta (sleep). All of these actively marketed, brand name drugs are included on our formulary; however, many have alternative options in a more preferred formulary tier with a lower cost share for the beneficiary.

Two of the most frequently requested coverage determinations are for methotrexate and oral immunosuppressants, both of which may be covered either under the Part B or Part D programs. I will address the inherent difficulties with making these types of coverage determinations later in my testimony.

Early in the program, physicians expressed concern about access to exception and appeals forms and also held concerns about the variability in content of these forms. Through AHIP, Humana worked with other plans and the American Medical Association to develop one uniform "Coverage Determination Request Form" designed to simplify the exception and appeals processes. These forms are visibly highlighted on our website. We have also made a web tool available for physicians to request authorizations 24/7.

5) Medication Therapy Management Program (MTMP): The MMA requires sponsors to offer an MTMP for those members with expected prescription drug expenses over $4,000, who have multiple chronic conditions and who use multiple chronic medications. Today, Humana has over 1 million beneficiaries eligible for this program. We have more than 6,000 pharmacies participating in our MTMP and continue to reach out to all pharmacies to participate. We anticipate 10,000 pharmacies will be in the program by the beginning of 2008. Our program has 3 levels of interventions: general mailings, telephonic, and face-to-face with a pharmacist. Generally, the health of the beneficiary will determine the intervention method that is employed. All beneficiaries who are eligible for MTMP will receive an invitation in their monthly SmartSummaryRx^{sm} statement inviting them to call us for further discussion. To supplement these invitations, we conduct telephonic outreach to these MTMP-eligible beneficiaries to proactively engage them in this opportunity. Once a beneficiary goes through a telephonic MTMP consultation, he/she will be referred for a face-to-face pharmacist consultation with a retail pharmacy if it is believed that the beneficiary needs further guidance. We have more than 80 associates (nurses, pharmacists, customer service representatives) working in this program. To date, we have messaged MTMP more than 5 million times through our SmartSummaryRx^{sm}. We have made more than 750,000 outbound phone call attempts to MTMP-eligible beneficiaries and more than 26,000 of them have received a one-on-one MTM consultation (telephonically or face-to-face) with a nurse or pharmacist.

Let me share a story to illustrate the impact of this program:

- A North Carolina PDP member received an outbound call from our clinical call center. We realized that this member needed a face-to-face intervention. The member was referred to a local, participating MTMP pharmacy. The pharmacist identified a potential clinical issue related to the member's chief complaint about pain in her lower extremities. In examining her prescription drug record, the pharmacist recognized that this could be a case of a painful muscle condition called rhabdomyolysis. This condition is associated with statin or cholesterol drugs. The pharmacist contacted the member's doctor; the doctor agreed with the pharmacist and the statin drug was discontinued. The member went to see the doctor for further review and analysis. The physician prescribed another type of cholesterol medication for the member. Our follow-up with the member indicates that all is well at this point. This intervention avoided a bad case of rhabdomyolysis which would have resulted in a hospitalization and an extra cost to the system of more than $20,000.

Results of the MTMP are still being evaluated, but early indications show medical and pharmacy savings are achieved with the consultations. We expect to expand our MTMP work this year beyond that required under the MMA, such that we contact all members with high drug costs who would benefit from this program.

6) SmartSummaryRx℠: Each month that a Humana member fills a prescription, the member receives a personalized statement containing his/her prescription drug activity during the previous month, including what stage the member is in, a list of the drugs he/she is taking (including a color picture of the drug, the common type of drug it is, the physician who prescribed it and when the member filled it), the retail and plan cost of those drugs as well as what the plan and member paid. The Statement also includes health and wellness information about the member's conditions based on drugs taken and other demographics, and information Medicare wants the member to have. Several times throughout the year, a beneficiary receives a wallet-sized listing of the drugs the member is taking so he/she can carry it with them. The Statement also uses symbols to send members messages about certain drugs, e.g. that savings are possible by substituting a generic for a brand name drug and that the member should discuss that with his/her doctor. The Statement is designed to provide members with a personal health record with a transparent look into their prescription drug usage and provides doctors with that the doctor may be unaware of such as possible drug/drug interactions or drug (non-)compliance.

7) Quality Outcomes: There are a number of ways in which Humana is working to improve outcomes in the provision of prescription drug coverage in many ways: first, through our SmartSummaryRx℠ statement as described above; second, through our MTMP. Humana has developed relationships with 32 Quality Improvement Organizations (QIOs) to look at opportunities to understand

whether various programs (like MTMPs) are improving quality of pharmaceutical care for the beneficiary. Third, Humana is participating in all the workgroups and subcommittees of the Pharmacy Quality Alliance (PQA) whose goal is to develop the standards and metrics for measuring pharmacy quality. The PQA has already established a starter-set of quality metrics and is now in the process of validating those measures. At the same time, the PQA is working quickly to develop model templates for reporting those same measures to pharmacists/pharmacies and the general public.

8) Beneficiary Outreach and Education: Humana has a fundamental belief that we will engage the beneficiary in our "pharmacy literacy" campaigns. We have a robust outreach campaign that we call "Maximize Your Benefits." This is our "high-touch, low cost" direct-to-consumer campaign whose goal is to create an informed beneficiary who will be armed with the right information to talk with his/her doctor about his/her prescription drug needs. These campaigns generally revolve around 3 fundamental opportunities for the beneficiary: (1) generic drugs, (2) bulk purchasing, and (3) invitations for MTMPs. Any Medicare beneficiary who receives a higher cost drug (to them) for which they have a potential lower cost alternative will receive a message (email, phone call, letter) to let them know about the opportunity and what they should consider talking with their physician about their needs. Generally, we see about a 15-20% change rate with these campaigns (meaning that nearly 20% of the beneficiaries who receive the message contact their physician and ultimately receive a different medication).

On the other hand, LTC beneficiaries and beneficiaries who do not have the confidence to ask their physician questions about their pharmacy regimen need more of a "concierge" service. On the LTC side, we have hired a LTC expert to work with the LTC facilities throughout the country to ensure we have the same level of rigor in examining generic drug opportunities as we are seeing in the outpatient setting.

For the beneficiary who lacks confidence, we have launched "concierge" programs in 2007 to help them. While early, these concierge programs are intended to work on behalf of the beneficiary to help the beneficiary contact his/her physician to make adjustments to his/her medication regimens (as appropriate and as approved by his/her physician).

9) Beneficiary Group Concerns: During the first year of implementation, there were many concerns raised by beneficiary groups, senior advocates and the State Health Insurance Assistance Programs (SHIPs). Humana continues to participate in a work group organized by AHIP that includes its Beneficiary Advisory Council. Through that group, many issues have been addressed, such as the need for CMS to allow authorized representatives to be able to enroll and disenroll beneficiaries. The group cited the need for more educational materials and AHIP worked with SHIP representatives, NACDS, NCPA and others to produce a workbook for beneficiaries to use when considering a Part D plan. The workbook has been published and is being updated for use during the next annual enrollment period. The group also expressed concern about broker and agent training which

led to a collaborative effort on the part of AHIP, the National Association of Health Underwriters and the Association of Health Insurance Advisors to produce a standard training program. Currently, the program is being revised and will be submitted to CMS to review for accuracy, content and applicability for ongoing use.

One of the lessons learned from the first year's implementation was the need to reach out to more stakeholders prior to the start of the enrollment season. Last fall, prior to the 2007 open enrollment season, Humana communicated with all state Departments of Insurance, SHIPs, affected Medicaid agencies and others to share information about the upcoming enrollment period, benefits and to answer any questions those entities had. We continue to work with them throughout the year to ensure that they can expeditiously respond to beneficiaries who contact their agencies about Part D issues.

Areas for Consideration

1) **Medicare Part B versus Part D drug coverage:** The Academy of Managed Care Pharmacy (AMCP) produced a white paper regarding Part B versus Part D coverage. I serve on the Legislative Committee for AMCP and fully support the position of this white paper from both a Humana and an industry perspective. The follow-on comments are highlights of that white paper (which can be found at www.amcp.org). Certain categories of drugs may continue to be covered under Part B or Part D in a variety of settings, under

a variety of payment methodologies and varying clinical situations. These categories include:

- Drugs requiring the use of durable medical equipment (DME)
- Drugs furnished "incident to" a physician service
- Immunosuppressant drugs
- Oral anti-cancer drugs
- Oral anti-emetic drugs
- Erythropoietin (EPO)
- Prophylactic vaccines
- Parenteral nutrition

In many cases, drugs in these categories could be covered under Part B or Part D depending on a beneficiary's diagnosis, the site of service, and the medical use of the drugs.

Even with sophisticated automated processing of some Part B vs. Part D drug claims, it is difficult for beneficiaries to understand why some drugs are covered under their Part D benefit in varying circumstances. For example:

- Immunosuppressant medications are covered under Part B for a beneficiary who receives a transplant from a Medicare-approved facility, and who is entitled to Medicare Part A benefits at the time of transplant. If these conditions are not met, or if a drug is used for purposes other than immunosuppression, the drug must be covered under Part D.

- There are different rules for different vaccines: Influenza, pneumococcal and hepatitis B are always covered under Part B. However, all other vaccines are covered under Part D, unless they are administered directly related to the treatment of an injury or direct exposure to a disease, in which case they are covered under Part B.
- Oral anti-emetic medications are covered under Part B when given within 48 hours of chemotherapy and under Part D in all other situations. This requires the Part D plan to precisely determine at what time chemotherapy took place.
- Oral anti-cancer drugs are covered by Part B for the treatment of cancer. However, one of these drugs, methotrexate, is also used for the treatment of rheumatoid arthritis. If a patient has received a prescription for methotrexate, a Part D plan must determine if the patient is being treated for rheumatoid arthritis before it can be reimbursed under the Part D benefit.

<u>These Part B versus Part D issues create challenges for the beneficiary, including:</u>

- *Risks for Beneficiaries*

  -can create situations where beneficiaries cannot obtain needed medications in a timely fashion.
- *Imposing Artificial Requirements for Prior Authorization*

  -dispensing is delayed, care is disrupted and plan and pharmacy costs increase.
    - *Drug-Specific Definition versus Method of Delivery Determination*

A clear definition of these categories, with each drug being covered by only one method, would significantly improve operational efficiencies.

- *Site Determination*

Several of the medications caught in the Part B/Part D overlap are medications for which the overhead cost associated with processing a prior authorization greatly exceeds the cost of the drug itself. For example, the widely used medication prednisone costs less than a dollar. When used as an immunosuppressant, it is covered under Part B; but for the vast majority of prescriptions it is covered under Part D. However, hours may be spent by Part D plans, pharmacies, prescribers and beneficiaries trying to establish appropriate coverage for an individual patient.

- *Diagnosis As a Part B/Part D Determinant*

The process necessary to obtain this required information adds time, expense and delay.

- *Unintended Consequences: Changes in Behavior Based on Part B/Part D Complexity*

If a pharmacy and/or a Part D plan must explore all options before being able to expediently resolve authorization issues for a medication, beneficiaries will eventually learn to obtain medication in a dosage form or from a location that does not require authorization. This may include receiving medications in a physician's office or receiving an infused rather than an oral version of a medication. Besides creating hassles for beneficiaries, this leads to more expensive claims under Medicare Part B. On the other hand, some

beneficiaries may forego medications altogether to avoid the administrative barriers, putting their health in jeopardy.

In this month's MedPAC report, the commissioners recommended that Congress change the law to allow CMS to identify selected overlap drugs that are covered under Part D most of the time and are low-cost drugs, and direct plans to cover them under Part D. ***We agree with this recommendation.*** Second, for drugs that continue to be covered by Part B and Part D, it recommends that Congress authorize prescription drug plans to approve transition supplies while coverage is being determined. ***We agree with this recommendation as a short-term measure.*** Third, it recommends that Congress should permit coverage for appropriate preventive vaccines under Part B instead of Part D. ***We agree with this recommendation.***

2) Social Security Administration Deduction Issues: Thousands of beneficiaries still have issues with the amount of their SSA deductions. We recommend that SSA and CMS work together to improve the current exchange of data to ensure that deductions are timely and accurate.

3) Coverage of Part D Excluded Drugs (Benzodiazepine coverage):

The MMA specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid. The excluded drugs or classes of drugs included:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(K) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

Although Medicare Part D does not cover barbiturates and benzodiazepines, most State Medicaid programs do provide this wrap benefit coverage to fill

this clinical need in dual eligible population. Non-dual eligible Medicare Part D beneficiaries have no coverage and are forced to pay out of pocket for access to these important and clinically necessary drug therapies. For the commercial population, with the exception of barbiturates and benzodiazepines, excluded drugs (as described above) are generally not covered in the commercial population. We believe that the same policy should apply in Medicare.

CONCLUSION

Thank you again for giving me the opportunity to testify about this important benefit for Medicare. We urge you to ensure consistency and stabilization, while recognizing the tremendous value it is providing to millions of Medicare beneficiaries across the nation.

Attachment #1 - Outline of Humana's Prescription Drug Products

Attachment #2 – SmartSummaryRx℠ Statement

Details of Humana's 2007 Medicare Part D Prescription Drug Plans

COSTS AND BENEFITS OF EACH PLAN		STANDARD PLAN* $10.20 - $18.20 range of monthly plan premium	ENHANCED PLAN $17.10 - $29.60 range of monthly plan premium	COMPLETE PLAN $69.50 - $88.40 range of monthly plan premium
STAGE 1	YOU PAY	$265 deductible	NO deductible Copayments until total drug costs reach $2,400: ■ Preferred generics....$5 ■ Preferred brand.....$30 ■ Non-preferred.....$60 ■ Specialty.....25% coinsurance	NO deductible Copayments until total drug costs reach $2,400: ■ Preferred generics.....$5 ■ Preferred brand.....$30 ■ Non-preferred.....$60 ■ Specialty.....25% coinsurance
	HUMANA PAYS	$0		
STAGE 2	YOU PAY	25% of next $2,135 of total drug costs (= $533.75)		
	HUMANA PAYS	75% of cost toward the $2,400 limit	Balance of costs	Balance of costs
STAGE 3	YOU PAY	100% until your total out-of-pocket costs reach $3,850 *This is the coverage gap*	100% until your total out-of-pocket costs reach $3,850 *This is the coverage gap*	$5 copayment for preferred generic drugs until your total out-of-pocket costs reach $3,850
	HUMANA PAYS	$0	$0	Balance of costs for generic drugs
STAGE 4	YOU PAY	Minimum of $2.15 for generic drugs and $5.35 for other prescription drugs or a maximum of 5% coinsurance.	Minimum of $2.15 for generic drugs and $5.35 for other prescription drugs or a maximum of 5% coinsurance.	Minimum of $2.15 for generic drugs and $5.35 for other prescription drugs or a maximum of 5% coinsurance.
	HUMANA PAYS	95% of total drug costs for the rest of the year	95% of total drug costs for the rest of the year	95% of total drug costs for the rest of the year

The plans shown above are available in all service areas and regions, except Puerto Rico.
*Humana Standard Plan matches the Federal Government basic Part D plan.

10/06

HUMANA.

SmartSummary Rx™

Your personal prescription benefits statement

Member name: John Doe
Member ID: H12345678
Plan name: Humana Prescription Drug Plan Standard S5884-075

Where you are in your plan (as of May 31, 2006)

Stage 1	You pay 100% of costs	
Stage 2	You pay 25%	Plan pays 75%
Stage 3	You pay 100% of costs	
Stage 4	You pay 5%	Plan pays 95%

You are here. You have $1,029 left to pay before you reach the next stage.

Numbers to watch

	This month	This year
Total prescription costs with plan	$688.49	$4,070.94
What you paid with the plan	$688.49	$2,570.96
What you would have paid without the plan (Average retail prices)	$958.58	$5,117.05

Information in this statement is current as of May 31, 2006. Premiums are not included in these calculations.

JOHN DOE
500 WEST MAIN ST
LOUISVILLE KY 40202-3363

What's inside

Look for these markers throughout your statement

- Savings alert
- Health alerts
- Prescription coverage changes
- Online resources
- Phone resources
- How your plan works

Contact us

Benefit questions
visit www.humana.com
or call 1-866-255-7451

Hours of operation
Monday to Sunday, 8 am to 8 pm

Alternate format
TTY 1-800-833-3301
(speech and hearing impaired)

SmartSummaryRx™ HUMANA

Your personal prescription benefits statement

John Doe
page 2 of 16

How your plan works for you

This information is current as of May 31, 2006. For more detailed information about your prescription drug coverage, please review your Evidence of Coverage or your benefits summary you received during enrollment.

Stage 1 Annual deductible - Up to $250 in total prescription costs with plan

You pay:	100%
The plan pays:	0%

Average retail prices this stage $582.20

What you paid	$444.75
What plan paid	$0.00
Plan discounts	$137.46

Value this stage: you paid 76% of retail prices in this stage, a savings of $137.46.

Stage 2 Initial coverage - $250 to $2,250 in total prescription costs with plan

You pay:	25%
The plan pays:	75%

Average retail prices this stage $2,819.86

What you paid	$305.27
What plan paid	$1,499.98
Plan discounts	$569.87

Value this stage: you paid 11% of retail prices in this stage, a savings of $2,069.85.

Stage 3 Coverage gap - Until what you pay reaches $3,600

You pay:	100%
The plan pays:	0%

Average retail prices this stage $1,714.99

What you paid	$1,820.94
What plan paid	$0.00
Plan discounts	$338.78

You are here. You'll move to Stage 4 when the total you've paid reaches $3600.
To date you've paid $2,570.96, leaving $1,029.04 more in costs this stage.

Stage 4 Catastrophic coverage - No limit

You pay:	5% or
For generic drugs	$2 minimum
For all other drugs	$5 minimum
The plan and Medicare pay:	95%

Likelihood of reaching this stage:
If your current use of medications continues unchanged throughout the year, it is likely that you will enter this stage before the end of this plan year. Your average prescription costs to date are $1,017.74.

SmartSummary Rx

HUMANA

Your personal prescription benefits statement

Your prescription claims (for May 1 to May 31, 2006)

Humana negotiates a reduced price with the pharmacy for its members, which is reflected in "Prescription cost with plan" column. The prescription cost can vary by pharmacy, location, quantity, strength and dosage of the medication. Adjusted claims may not be reflected in the table below; or if displayed, the amount paid may not be accurately reflected due to the amount of the adjustment.

Drug name	Average retail price	Prescription cost with plan	What you paid	What the plan paid
May 3, 2006, WALGREEN DRUG STORE **LANTUS 100 UNITS/ML VIAL** Drug category: Preferred brand	$78.99	$67.52	$67.52	$0.00
May 9, 2006, WALGREEN DRUG STORE **NOVOFINE 30 NEEDLES** Drug category: Generic	$110.97	$84.39	$84.39	$0.00
May 10, 2006, WALGREEN DRUG STORE **NOVOLOG FLEXPEN SYRINGE** Drug category: Preferred brand	$319.99	$275.39	$275.39	$0.00
May 20, 2006, WALGREEN DRUG STORE **LEVOTHYROXINE 100 MCG TABLET** Drug category: Generic	$15.29	$6.09	$6.09	$0.00
May 28, 2006, WALGREEN DRUG STORE **LANTUS 100 UNITS/ML VIAL** Drug category: Preferred brand	$78.99	$67.52	$67.52	$0.00
May 31, 2006, WALGREEN DRUG STORE **DIGITEK 250 MCG TABLET** Drug category: Generic	$14.09	$8.33	$8.33	$0.00
May 31, 2006, WALGREEN DRUG STORE **MICARDIS 40 MG TABLET** Drug category: Non-Preferred brand	$179.89	$138.63	$138.63	$0.00
May 31, 2006, WALGREEN DRUG STORE **HYDROCODONE/APAP 5/500 TAB** Drug category: Generic	$16.79	$2.45	$2.45	$0.00
May 31, 2006, WALGREEN DRUG STORE **ENALAPRIL MALEATE 20 MG TAB** Drug category: Generic	$127.59	$22.18	$22.18	$0.00
May 31, 2006, WALGREEN DRUG STORE **INSULIN 1/2 ML SYRINGE** Drug category: Generic	$15.99	$15.99	$15.99	$0.00
Total this month	**$958.58**	**$688.49**	**$688.49**	**$0.00**

SmartSummary Rx

HUMANA

Your personal prescription benefits statement

Your prescription claims continued (for May 1 to May 31, 2006)

Drug name	Average retail price	Prescription cost with plan	What you paid	What the plan paid
Total this year	**$5,117.05**	**$4,070.94**	**$2,570.96**	**$1,499.98**

Did you know you may save time and money by having your prescriptions delivered to your home? Your plan allows you to receive 3 months of medications delivered right to your home. Log on to MyHumana through www.humana.com, or call 1-800-379-0092 (TTY 1-800-833-3301) to register to use this mail order benefit.

As a Humana member, you are eligible to sign up for the Humana Active Outlook program which provides you with information to:

- Live well - participate in cooking classes, attend health seminars, and get healthy recipes.
- Interact - understand health conditions and team up with members who have similar concerns.
- Explore - get travel tips, master your digital camera, and find out how to protect yourself from fraud.
- Advocate - learn about Medicare topics important to people with Medicare and find out how you can get involved.

Sign up for Humana Active Outlook now at no additional cost by visiting www.humana-medicare.com.

You're saving money! By taking generics drugs, you are using your plan benefits to save you money.

What's new in health care

Articles are taken from a news service that focuses on health care. Where possible, we have tried to select topics that may be particularly interesting to you, based on information in our records from your insurance claims or other information you may have provided us.

Taking generic drugs boosts adherence

Patients who take generic prescription drugs are more likely to adhere to their doctor's prescribed therapy plan than patients who take brand-name drugs.

The findings of the study in the *Archives of Internal Medicine* are another reason why "generic drugs should be prescribed for patients beginning chronic therapy, as long as there are no specific clinical reasons why a branded drug may be more appropriate," said researcher Dr. William Shrank, of Brigham and Women's Hospital and Harvard Medical School in Boston.

Shrank's group looked at how well 6,755 patients enrolled in a pharmacy benefit plan stuck to their drug regimens. Under their benefit plan, the patients had to pay the highest co-payment for non-preferred brand-name drugs, smaller co-payments for preferred brand-name drugs, and the smallest or no co-payment for generics. The group received a total of 7,532 new prescriptions during the study period.

There were six classes of drugs included in the study: cholesterol-lowering statins; oral contraceptives; inhaled corticosteroids for asthma; and three antihypertensives (calcium-channel blockers, angiotensin receptor blockers and angiotensin-converting enzyme inhibitors).

Patients who took generic drugs showed a 12.6 percent increase in therapy adherence, compared to patients who took brand-name drugs with the highest co-payments. Patients who took drugs with smaller co-payments had an 8 percent increase in adherence compared to those who used the most expensive drugs.

Other findings:

- Patients who took a generic drug had a 62 percent better chance of achieving adequate adherence and those who took a brand-name second-tier drug had a 30 percent better chance than those who took third-tier drugs.
- Patients who were initially prescribed the most expensive drugs were 2.1 times more likely to switch to a drug in a cheaper group than patients initially prescribed generic drugs.
- Patients who switched from their initial prescription were 2.8 times more likely to switch to a less-expensive, lower-tier brand-name or generic than to a higher-tier drug.
- Patients who initially received generic drugs switched at less than half the rate of those who received the most expensive drugs.

SOURCE: Brigham and Women's Hospital, news release, Feb. 13, 2006

Medicare wants you to know

Content in this section of the document is required by Medicare. Keep this notice for your records. This is not a bill.

Medicare wants you to know continued...

Drug Expenses
We offer additional coverage on some prescription drugs not normally covered in a Medicare Prescription Drug Plan. The amount paid for these drugs is not included in any of the amounts listed below.

Annual deductible (Stage 1)

You have met $444.74 of your $250 deductible for 2006.

Amount paid for prescriptions
You and/or others who have paid for your prescriptions have spent $4,070.94 in co-payments and/or co-insurance this year. This amount may also include payments made by your current or former employer/union, other insurance plan or policy.This amount counts towards your initial coverage limit.

Humana has paid $1,499.98. These payments count towards your initial coverage limit.

Together, $4,070.94 has been paid by Humana, you and/or others. This is the total that counts towards your initial coverage limit of $2,250.

Out-of-pocket payments after you reach the initial coverage limit (Stage 2)
You have spent $2,570.96 since reaching your initial coverage limit. You still have $1,029.04 to spend before you qualify for catastrophic coverage.

Total out-of-pocket expenditures that count towards the catastrophic coverage threshold
You and/or others on your behalf have spent a total of $2,570.96 on prescription drugs covered by Humana for 2006. This total includes the amounts spent for your deductible, co-payments and co-insurance, and coverage gap payments. This amount does not include payments made by your current or former employer/union, another insurance plan or policy, or other excluded parties.

Total amount paid for your drugs this year
$4,070.94. This is the total amount that has been spent on your drugs this year. It includes the amount paid by you and/or others on your behalf towards the initial coverage limit, coverage gap payments and catastrophic coverage. It also includes the amount Humana paid for drugs during your initial coverage limit and catastrophic coverage.

Upcoming changes to Humana's formulary
Humana may add or remove drugs from our formulary during the year. If we remove drugs from our formulary, add prior authorization, quantity limits, step therapy restrictions on a drug, or move a drug to a higher cost-sharing tier, we will notify you of the change at least 60 days before the date the change becomes effective. However, if the Food and Drug Administration deems a drug on our formulary to be unsafe or the drug's manufacturer removes the drug from the market we will immediately remove the drug from our formulary.

The table below outlines upcoming changes to our formulary that will impact you:

SmartSummaryRx

HUMANA

Your personal prescription benefits statement

Medicare wants you to know continued...

Name of affected drug	Description of change	Reason for change	Alternative drug*	Alternative drug copayment/coinsurance

There are no formulary changes this month

* Alternative drugs are drugs in the same therapeutic category/class or cost-sharing tier as the affected drug. Only your physician can determine if the alternate listed here is appropriate for you given the individualized nature of drug therapy. Please consult with your physician as to whether this is an appropriate drug for you.

For your information and protection

Your privacy

Your privacy is important to us. At Humana, we consider your personal, health and financial information to be confidential. Humana protects your information and only uses or discloses your information in accordance with federal and state privacy laws and Humana's privacy policy. For additional information on Humana's privacy policy, please access Humana's Notice of Privacy Practices on the Web at www.humana.com.

Your rights

If your plan ever denies coverage for your prescription drugs, we will explain our decision to you. You always have the right to appeal and ask us to review the claim that was denied. In addition, if your physician prescribes a drug that is not on our formulary, is not a preferred drug or is subject to additional utilization requirements you may ask us to make a coverage exception.

Your questions

If you have questions about your statement, contact Humana toll free at 1-866-255-7451 (TTY 1-800-833-3301), Monday to Sunday, 8 am to 8 pm. If you suspect fraud, please contact Humana or 1-800-MEDICARE (1-800-633-4227) 24 hours a day and 7 days a week. TTY users should call 1-877-486-2048.

If you would like to receive your SmartSummaryRx (PDP EOB) in Spanish, please call 1-866-255-7451 and select option "For all other questions", or log on to *My*Humana to change your language preferences.

Si quisiera recibir su SmartSummaryRx (PDP EOB) en español, por favor llame 1-866-255-7451 y seleccione la opción de 6, acceda *My*Humana para cambiar su preferencias de idioma.

Your Rx Record

HUMANA

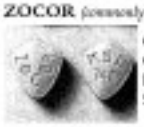
May 1, 2006 to May 31, 2006 — John Doe

Your Rx Record is provided as a courtesy to help you manage taking and refilling your medications, and to communicate with your doctor or pharmacist about the medications you are taking. You may want to have this with you on your next visit with your doctor or pharmacy.

The pictures displayed below should match the drugs you are currently taking. However, in some instances, your actual drug may look different. Contact your doctor or pharmacist for more information or if you have questions about the information displayed below.

YOUR REGULAR PRESCRIPTIONS

ZOCOR *(commonly used for: Cholesterol)*



Category: Non-Preferred brand
Quantity: 30 TABS
Days supply: 30
Strength: 20MG

Pharmacy: Walgreen Drug Store
Doctor: Rotenberg

Refill dates — *Please fill in your next refill date*

Feb '06	Jan '06										
8th	7th										

Your notes (include instructions, interactions and side effects):

FUROSEMIDE *(commonly used for: Heart)*

Category: Generic
Quantity: 180 TABS
Days supply: 90
Strength: 40MG

Pharmacy: Walgreen Drug Store
Doctor: Rotenberg

Refill dates — *Please fill in your next refill date*

Mar '06											
7th											

Your notes (include instructions, interactions and side effects):

Your Rx Record

HUMANA.

May 1, 2006 to May 31, 2006 — John Doe

GLIPIZIDE *(commonly used for: Diabetes)*

Category: Generic
Quantity: 60 TABS
Days supply: 30
Strength: 10MG

Pharmacy: Walgreen Drug Store
Doctor: Rotenberg

Refill dates — *Please fill in your next refill date*

Mar '06	Feb '06	Jan '06									
7th	8th	7th									

Your notes (include instructions, interactions and side effects):

TOPROL XL *(commonly used for: Heart)*

Category: Preferred brand
Quantity: 60 TB24
Days supply: 30
Strength: 100MG

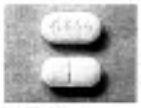
Pharmacy: Walgreen Drug Store
Doctor: Rotenberg

Refill dates — *Please fill in your next refill date*

Mar '06	Feb '06	Jan '06									
7th	8th	7th									

Your notes (include instructions, interactions and side effects):

DOXAZOSIN MESYLATE *(commonly used for: Heart)*



Category: Generic
Quantity: 31 TABS
Days supply: 31
Strength: 4MG

Pharmacy: Walgreen Drug Store
Doctor: Alavi

Refill dates — *Please fill in your next refill date*

Mar '06											
17th											

Your notes (include instructions, interactions and side effects):

Your Rx Record

HUMANA.

May 1, 2006 to May 31, 2006 — John Doe

PLAVIX *(commonly used for: BLOOD AGENTS)*

Category: Preferred brand
Quantity: 90 TABS
Days supply: 90
Strength: 75MG

Pharmacy: Walgreen Drug Store
Doctor: Rotenberg

Refill dates — *Please fill in your next refill date*

Apr '06	Jan '06										
15th	21st										

Your notes (include instructions, interactions and side effects):

NORVASC *(commonly used for: Heart)*

Category: Preferred brand
Quantity: 90 TABS
Days supply: 90
Strength: 10MG

Pharmacy: Walgreen Drug Store
Doctor: Rotenberg

Refill dates — *Please fill in your next refill date*

Apr '06	Jan '06										
10th	21st										

Your notes (include instructions, interactions and side effects):

NOVOFINE 30 *(commonly used for: Products / Supplies)*

Category: Generic
Quantity: 300 MISC
Days supply: 30
Strength: 30GX0.8"

Pharmacy: Walgreen Drug Store
Doctor: Alavi

Refill dates — *Please fill in your next refill date*

May '06	Mar '06	Mar '06									
9th	16th	1st									

Your notes (include instructions, interactions and side effects):

Your Rx Record

HUMANA.

May 1, 2006 to May 31, 2006 — John Doe

NOVOLOG *(commonly used for: Diabetes)*

Category: Preferred brand
Quantity: 30 SOLN
Days supply: 30
Strength: 100 U/ML

Pharmacy: Walgreen Drug Store
Doctor: Alavi

Refill dates — *Please fill in your next refill date*

May '06	Mar '06	Feb '06									
10th	26th	8th									

Your notes (include instructions, interactions and side effects):

LEVOTHYROXINE SODIUM *(commonly used for: Thyroid)*

Category: Generic
Quantity: 31 TABS
Days supply: 31
Strength: 100MCG

Pharmacy: Walgreen Drug Store
Doctor: Alavi

Refill dates — *Please fill in your next refill date*

May '06											
20th											

Your notes (include instructions, interactions and side effects):

LANTUS *(commonly used for: Diabetes)*

Category: Preferred brand
Quantity: 10 SOLN
Days supply: 20
Strength: 100 U/ML

Pharmacy: Walgreen Drug Store
Doctor: Alavi

Refill dates — *Please fill in your next refill date*

May '06	May '06	Apr '06	Mar '06	Mar '06	Feb '06	Jan '06	Jan '06				
28th	3rd	15th	20th	7th	9th	25th	7th				

Your notes (include instructions, interactions and side effects):

Your Rx Record

HUMANA.

May 1, 2006 to May 31, 2006 — John Doe

DIGITEK *(commonly used for: Heart)*

Category: Generic
Quantity: 30 TABS
Days supply: 30
Strength: 250MCG

Pharmacy: Walgreen Drug Store
Doctor: Rotenberg

Refill dates — *Please fill in your next refill date*

May '06	Mar '06	Feb '06	Jan '06								
31st	7th	8th	7th								

Your notes (include instructions, interactions and side effects):

ENALAPRIL MALEATE *(commonly used for: Heart)*

Category: Generic
Quantity: 60 TABS
Days supply: 30
Strength: 20MG

Pharmacy: Walgreen Drug Store
Doctor: Rotenberg

Refill dates — *Please fill in your next refill date*

May '06	Mar '06	Feb '06	Jan '06								
31st	7th	8th	7th								

Your notes (include instructions, interactions and side effects):

INSULIN SYRINGE *(commonly used for: Products / Supplies)*

No Image Available

Category: Generic
Quantity: 100 MISC
Days supply: 30
Strength: 29 GAUGE

Pharmacy: Walgreen Drug Store
Doctor: Alavi

Refill dates — *Please fill in your next refill date*

May '06	Mar '06	Feb '06									
31st	10th	28th									

Your notes (include instructions, interactions and side effects):

Your Rx Record

HUMANA.

May 1, 2006 to May 31, 2006 — John Doe

MICARDIS *(commonly used for: Heart)*

Category: Non-Preferred brand
Quantity: 30 TABS
Days supply: 30
Strength: 40MG

Pharmacy: Walgreen Drug Store
Doctor: Rosenberg

Refill dates — *Please fill in your next refill date*

May '06	Mar '06	Feb '06	Jan '06								
31st	7th	9th	7th								

Your notes (include instructions, interactions and side effects):

OTHER PRESCRIPTIONS

CEPHALEXIN *(commonly used for: Antibiotic)*

Category: Generic
Quantity: 40 CAPS
Days supply: 10
Strength: 500MG

Pharmacy: Walgreen Drug Store
Doctor: Visotsky
Date filled: Apr 29 '06

HYDROCODONE W/ACETAMINOPHEN *(commonly used for: Pain Management - Narcotic)*

Category: Generic
Quantity: 25 TABS
Days supply: 4
Strength: 5-500MG

Pharmacy: Walgreen Drug Store
Doctor: Hann
Date filled: May 31 '06

A list of your regular prescriptions at your fingertips!

HUMANA.

Humana Rx Record On-the-Go

At Humana, we want you to have the personal prescription information you need, when you need it. That's why we're sending you a personalized Humana Rx Record On-the-Go—a pocket-sized record of the prescriptions drugs you're taking. Carry your record with you, so you can show it to your doctor or pharmacist or have it handy in case of an emergency.

Just cut out the Rx Record On-the-Go inserts below and fold as indicated. Two copies are attached—one for your pocket or purse, and one for a family member or for your personal files.

Front of Card 1

Humana Rx Record On-the-Go

A record of your regular prescriptions as of May 31/06

Name John Doe

Member ID H123456789

HUMANA

Your Rx Record On-the-Go is provided as a courtesy to help you manage your medications, and to communicate with your doctor or pharmacist. Humana makes this information available for the sole purpose of providing educational information on health-related issues. It is not intended to be a substitute for professional medical advice. This card does not imply evidence of coverage with Humana.

Emergency contact

Name _____

Phone _____

My pharmacy and doctor

Name _____

Phone _____

Name _____

Phone _____

Name _____

Phone _____

Back of Card 2

Regular prescriptions	Qty	Dosage
ZOCOR	30	20MG
FUROSEMIDE	180	40MG
GLIPIZIDE	60	10MG
TOPROL XL	60	100MG
DORAZOSIN MESYLATE	31	4MG
PLAVIX	90	75MG
NORVASC	90	10MG
NOVOHME 30	300	30G30.8"
NOVOLOG	30	100 U/ML
LEVOTHYROXINE SODIUM	31	100MCG
LANTUS	10	100 U/ML
DIGITEK	30	250MCG
ENALAPRIL MALEATE	60	20MG
INSULIN SYRINGE	100	29 GxUG
MICARDIS	30	40MG

Other drugs I take

_____

_____

_____

Reactions or allergies

_____

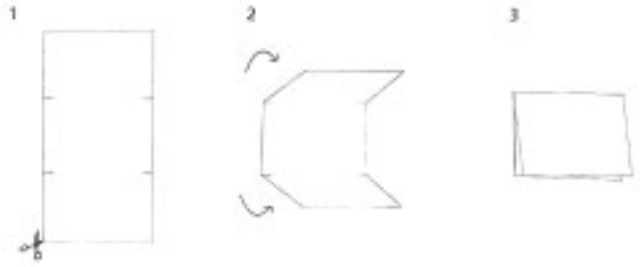
_____

_____

CUT CARDS ALONG DOTTED LINES AND FOLD AS INDICATED

GH19584RR - A04/06

Medicare approved HMO, PPO, PDP and PFFS plans.



Front of Card 2

Humana Rx Record On-the-Go

A record of your regular prescriptions as of May 31/06

Name John Doe

Member ID H12345678

HUMANA

Your Rx Record On-the-Go is provided as a courtesy to help you manage your medications, and to communicate with your doctor or pharmacist. Humana makes this information available for the sole purpose of providing educational information on health-related issues. It is not intended to be a substitute for professional medical advice. This card does not imply evidence of coverage with Humana.

Emergency contacts

Name:

Phone:

My pharmacy and doctor

Name:

Phone:

Name:

Phone:

Name:

Phone:

Back of Card 2

Regular prescriptions	Qty	Dosage
ZOCOR	30	20MG
FUROSEMIDE	180	40MG
SLIPSIDE	60	10MG
TOPROL XL	60	100MG
DOXAZOSIN MESYLATE	31	4MG
PLAVIX	90	75MG
NORVASC	90	10MG
NOVODRINE 30	300	30GR8.8"
NOVOLOG	30	100 U/ML
LEVOTHYROXINE SODIUM	31	100MCG
LANTUS	10	100 U/ML
ORGITEK	30	250MCG
ENALAPRIL MALEATE	60	20MG
INSULIN SYRINGE	100	29 GAUGE
MICARDIS	30	40MG

Other drugs I take

Reactions or allergies

CUT CARDS ALONG DOTTED LINES AND FOLD AS INDICATED

Chairman STARK. Thank you.
Mr. Precht.

STATEMENT OF PAUL PRECHT, POLICY DIRECTOR, MEDICARE RIGHTS CENTER

Mr. PRECHT. I am Paul Precht, deputy policy director for the Medicare Rights Center. Thank you for this opportunity to testify on the protections for people with Medicare under the Part D prescription drug benefit.

The written testimony we have submitted describes where these protections fall short and makes specific recommendations for actions that Congress can take to strengthen them. All these recommendations are drawn from the experiences of the caseworkers at the Medicare Rights Center. Our case workers have been helping people with part D problems over the last year and a half, whether it is appealing a plan's coverage denial so they can receive the drugs they need or securing enrollment in a plan that best meets their needs. These cases are by their very nature what social scientists call anecdotal, although the people we help, people who are very sick and desperate to receive the medical care they need, certainly would not describe their ordeals as anecdotes.

In preparation for this testimony, however, I wanted to ensure that the enrollment problems our clients are experiencing are not just isolated incidents. So, I reviewed a report by the Oklahoma Insurance Department that systematically examines the market conduct of a company that is one of the largest purveyors of both Part D and Medicare advantage plans. What I read exactly mirrors the experience of the people we help.

The most common story is this. Someone seeking to enroll in a stand-alone drug plan is signed up by a sales agent for an HMO or other Medicare advantage product. When they discover the change to their coverage, usually when they receive a medical bill, they call 1–800–MEDICARE to disenroll. Medicare tells them to call the plan, but the plan tells them that they can't disenroll, that they are locked in for the year. This is exactly what the Oklahoma Insurance Commissioner found. When the company was presented with evidence of these bate-and-switch-tactics, instead of taking action to disenroll the victim and put them back in original Medicare, it dismissed the complaint as frivolous as an attempt to avoid lock-in.

Companies should not have the say-so over whether someone can obtain a special enrollment period, which all victims of marketing abuse are entitled to under CMS guidance. But people with Medicare have no due process protections, no rights to appeal for an independent review of Part D and Part C enrollment decisions that are made either by plans or by CMS. Even when the victims of fraudulent marketing get help from the Medicare Rights Center or another trained counselor to obtain a retroactive reinstatement in original Medicare, a process necessary to get medical bills properly covered, it can take months for CMS to process.

We are encouraged that the agency is working to expedite this process. We remain convinced that fair and efficient resolution of enrollment problems must be available to all people with Medicare, not those lucky enough to have a counselor with contacts at CMS

regional offices who is advocating on their behalf. The surest way for Congress to accomplish that is to lift the lock-in that prevents people from changing their Part D or Medicare advantage plan during the course of the year. We receive numerous calls from Part D enrollees who are dismayed to discover in January, after they were locked in for the year, that the premiums, drug coverage or copayment of the plan they chose the previous year had changed.

The annual notices have changed. Even if they are received in time, they are so complex as to be indecipherable. We have recommended that CMS require plans to personalize these annual notices of change. Plans have the capability, and all you have to do is to look at Humana's documents that they send out every month to know that they can in fact get personalized information. The reality is that most people learn about premium increases when they get their bill and about coverage changes when their prescription is rejected at the pharmacy counter. Lifting lock-in or at least extending open enrollment for the first 3 months of the calendar year when changes to Part C coverage are still allowed would allow people with Medicare to choose their drug plan once they know what the real deal is.

People with Medicare and Medicaid and other recipients of the low-income subsidy do have the right to change plans during the course of the year, but these individuals are more likely to have cognitive or mental impairments, low health literacy levels and to live alone, isolated from anyone who can help with plan selection. As a result, most do not exercise their option to change plans and remain in the one they were assigned by CMS, an assignment that was made at random without regard to matching drug regiments and formulary coverage. Next year, experts project between one and two million of these low-income people with Medicare will be randomly reshuffled among the Part D plans that qualify for a full premium subsidy. After changing their drug regiments to comply with their current plan's formulary restrictions, these individuals will again have to change the drugs they take to accommodate the new plan's formulary. We can avoid such disruptions to the medical care of this vulnerable population.

A number of States have matched the drug regiments of the members of their pharmaceutical assistance programs when selecting the Part D plans for these residents. Researchers with the Medicare payment advisory commission have concluded that this is a viable option for the annual reassignment of dual eligibles and other low-income Part D enrollees. It requires a statutory change, however, since random plan assignment is written into the law.

Thank you, again, for this opportunity to testify. We believe the experience over the first year and a half of the Medicare drug benefit point to some concrete practical ways to improve the consumer protections under Part D, and we stand ready to work with Committee Members of both parties on enacting such improvements.

[The prepared statement of Mr. Precht:]

Statement of Paul Precht, Policy Director, Medicare Rights Center

Thank you Chairman Stark, Ranking Member Camp, distinguished members of the House Ways and Means Health Subcommittee, for holding this hearing on the consumer protections for people with Medicare under the Part D prescription drug benefit.

Unlike the hospital and outpatient medical benefits available under Medicare Parts A and B, prescription drug coverage is available only through private companies. There is no option to receive prescription drug coverage directly through Medicare. Instead of providing this option and using the purchasing power of 43 million people with Medicare to lower prescription drug prices, Congress established a system of private Part D plans which are at risk for the drug spending of their enrollees, a powerful incentive to hold down usage.

When enacting Part D in 2003, Congress recognized the financial incentives Part D plans have to restrict access to expensive medications and to discourage enrollment by people with Medicare who have high prescription drug costs. Congress therefore established a number of consumer protections under Part D that provide the right of appeal when Part D plan denies coverage for a prescription drug, that prohibit plans from designing formularies that discriminate against people who need high-cost drugs, and that ensure all people with Medicare, especially low-income older adults and people with disabilities, have access to coverage under a Part D plan. These and other statutory protections are vital to ensure Part D guarantees access to the prescription drugs people with Medicare need to stay alive and healthy. The experience over the first 18 months of the Part D benefit, however, shows that these consumer protections fall short. Legislation is needed to ensure both the Part D plans and the Centers for Medicare & Medicaid Services (CMS) fulfill Congress' intent to provide meaningful consumer protections that guarantee access to quality, affordable drug coverage for people with Medicare.

Founded in 1989, the Medicare Rights Center is the largest independent source of information and assistance for people with Medicare. Since January 1, 2006, our case workers and volunteers have worked overtime helping people with Medicare deal with problems with the Part D prescription drug benefit. The problems fall into three broad categories:

- Problems securing and maintaining enrollment in the Part D plan that best suits their needs;
- Problems accessing affordable medicines under the low income subsidy, or Extra Help, program;
- Problems obtaining coverage for the medicines they need once they are enrolled in a Part D plan.

Enrollment

One of the most persistent and frustrating problems is the continuing inability of the computer systems used by CMS, the Social Security Administration (SSA) and the Part D plans to consistently and accurately transmit information on enrollment, premium and low-income status to each other. This information sharing is critical to ensure the correct premium for the right Part D plan is deducted from an individual's Social Security check and enrollment in the low income subsidy is reflected in the premium and cost sharing charged by the Part D plan.

Recently, we have been working to prevent people with Medicare from being dropped by their Part D plan for nonpayment of premiums. These individuals are having Part D premium deducted from their Social Security checks, but because of these systems problems, premiums are not finding their way to the Part D plans. We have been told repeatedly by CMS that these systems problems will be resolved "soon" but the resolution date has repeatedly slipped. Many of our clients are on low, fixed incomes. They cannot afford to have a premium deducted each month from their Social Security check, sometimes for a more expensive Part D plan that they quit last December, and also write a monthly check to their new Part D plan.

They should not have to. In fact, CMS told plans in March that they cannot disenroll individuals for nonpayment of premiums if the fault lies in these systems problems that fail to transmit funds deducted from Social Security checks to the correct plan. Despite this guidance from CMS, plans are still threatening to disenroll these individuals. This is one of the many areas where stronger oversight and enforcement by CMS of plan behavior is necessary.

Here is the story one person submitted to the Medicare Rights Center:

I am writing on behalf of my 91-year-old mother, a California resident. Funds are being withdrawn in error out of her monthly social security check since January 2007. After 5 months of repeated phone calls, we still can't get anyone to accept responsibility and it still remains unresolved. Below is a brief summary of the steps we have taken.

In December, 2006, Medicare was notified that Mom dropped Humana Part D Drug Coverage and switched to SierraRx due to Humana raising their rates from $50.90 to $80.90.

Since January 2007, $80.90 has been erroneously deducted each month from Mom's Social Security check through May 2007. In addition, Mom is paying her own SierraRx monthly fees by check.

I spoke to Social Security Security and they said there is nothing they can do. We were told by Humana in April that Social Security had updated its files, but $80.90 was again withdrawn for May's check. This has caused much emotional and financial stress.

Our caseworkers also handle a number of enrollment cases that are the fallout of aggressive and deceptive marketing, generally of Medicare Advantage plans that include the prescription drug benefit. The victims of such marketing abuses often need to retroactively disenroll from their MA plan in order to get Original Medicare to pay for medical care that the plan refuses to cover. They also have to return to the Part D plan they had previously through a Special Enrollment Period that is allowed for victims of marketing abuse. Even our experienced caseworkers can experience difficulty getting CMS regional offices to process these enrollment transactions. Although some CMS staff members are responsive, in other instances, MRC caseworkers must hound the regional office to process the enrollment and disenrollment while our clients wait months to get their Part D and Medicare coverage rectified.

The situation is even worse for the vast majority of people with Medicare that do not receive assistance from an MRC caseworker, a counselor with a State Health Information and Assistance Program or from the constituent services staff of their congressional representative. Our clients report being told by operators at 1–800–Medicare to "call your plan" when they seek to disenroll after being duped into a Medicare Advantage plan. When they call the plan, however, they are told that they cannot disenroll, that they are locked in, even though individuals who are the victims of marketing abuse are entitled to a special enrollment period.

There is a common thread underlying all these enrollment problems. There are no due process protections for enrollment decisions under Part D or under the Medicare Advantage program. An individual dropped from their Part D plan for nonpayment of premiums who can show the premiums were deducted from her Social Security check has no guarantee of an independent review that could reinstate coverage. Someone seeking reinstatement in a Part D plan and disenrollment from a Medicare Advantage plan has no recourse if CMS officials do not believe she was victimized by fraudulent or deceptive marketing. Congress should enact due process protections that govern enrollment decisions made by CMS and Part D plans. It's common sense, basic fairness and a requirement of constitutional law.

We also recommend that Congress lift lock-in for the Part D and the Medicare Advantage programs, a broader solution that would help resolve these and other Part D consumer problems. Last winter, a number of clients reported that they had not received notice from their Part D plans about premium increases, formulary changes or curtailments to the coverage in the doughnut hole. These complaints focused on a far wider array of plans than the single company CMS identified publicly as failing to send out its annual notice of change in time. By the time consumers discovered the changes to their coverage, it was too late. They were barred by the statutory lock-in provision from changing their Part D plan.

Because of the way enrollment periods are structured, however, these clients did have the ability to change their Part D coverage, but only if they traded a stand-alone drug plan for a drug plan that came with a Medicare Advantage plan, a so-called MA–PD. Congress should align the enrollment periods, extending the ability to change Part D plans into the first three months of the calendar year. This will provide people an opportunity to change plans once they have become aware, at the pharmacy counter and through the bills they receive, of how coverage in their Part D plan has changed. There is no reason why someone can change Part D coverage only when one of the parties to the transaction is a Medicare Advantage plan, but not when the change is between stand-alone Part D plans. This extended enrollment period will also provide make it easier for the data exchange systems to accommodate enrollment decisions made just days before the December 31 deadline.

Any steps Congress takes to add flexibility to the Part D enrollment process will help people with Medicare who find it difficult to select among multiple plans, each with different formularies, cost sharing, premiums and drug prices. Both drug prices and formularies can change at any time during the year, as of course can the medical condition and the need for specific medicines, of a Part D enrollee. Lock-in removes the ability of most consumers to respond to those changes after January 1.

Many people with Medicare, especially, but not exclusively, individuals with cognitive impairment or low levels of literacy, are unable to conduct the formulary review and on-line price comparison necessary to make an informed selection of a Part D plan. Congress recognized this reality when it provided for automatic Part D en-

rollment for individuals transitioning from Medicaid to Part D drug coverage. CMS extended that process by "facilitating" enrollment of all individuals receiving the low income subsidy who have not made an independent plan selection.

Assignment of plans under automatic enrollment, however, is completely random, with no regard given to whether the assigned Part D plan covers the drugs of its new enrollee. Many of the coverage problems that people experienced at the start of Part D in 2006 are attributable to this random assignment. Matching drug regimens with plan formularies is a more sensible approach, but random assignment of dual eligibles is written into the Medicare statute. A number of states use formulary criteria in assigning plans for members of their state pharmaceutical assistance commissions and through these efforts were able to match individuals with plans that covered their drugs, the same process that informed consumers use in their plan selection.

Random reassignment of people with Medicare receiving the low income subsidy is slated to occur on an annual basis, as plans that received auto enrollments in one year find their Part D premium is above the regional low income benchmark, which is based on average Part D premiums charged by Part D and MA plans in the area. CMS minimized the number of low income people subject to random reassignment by using its demonstration authority to change how the low income benchmark was calculated in 2007. As CMS phases-in the benchmark setting formula set by statute, millions of low income subsidy recipients are likely to be randomly reassigned to new plans, with different formularies, on an annual basis. Congress should amend the law to require CMS to match drug regimens and formularies in effecting these reassignments.

Low Income Subsidy

Changing Part D plans, either on a voluntary basis or by random reassignment, often interrupts access to affordable medicines for low income individuals because systems problems prevent the record of enrollment in the low income subsidy from traveling with the individual when they change plans. This means that the individual may face a $265 deductible or a high copayment instead of the copayments of 5 or less that are set by statute. For individuals living on low, fixed incomes this can put vital medicines for treating hypertension or controlling seizures out of reach.

Although this problem is rooted in the systems problems it is compounded by a persistent failure of Part D plans to comply with CMS guidance requiring plans to accept "best available evidence" of enrollment in the low income subsidy. What this policy should mean is that an individual can present her Medicaid card or LIS award letter from SSA at the pharmacy, the pharmacist will inform the Part D plan customer service center of the customer's LIS status, and the plan customer representative will fix it so the electronic billing transaction between plan and pharmacy charges the appropriate copayment for an LIS recipient. However, our clients often experience a flat out refusal by plan customer service representatives to charge the appropriate copayment, even when a pharmacist or MRC case worker explains the requirements laid out in CMS guidance. Improved oversight and enforcement by CMS are needed in this area as well.

Part D Appeals

Part D plans are given wide latitude to decide what drugs they will cover and what restrictions they will place on the drugs they do cover. To protect access to medically necessary drugs, Congress established an appeals process. Since the start of the Part D benefit, the Medicare Rights Center has helped hundreds of individuals navigate the appeals system and obtain coverage for the medicines they need. In our experience, the Part D appeals system is cumbersome, unfair and vulnerable to obstructionist tactics by Part D plans.

The appeals process usually breaks down before it starts, when the consumer obtains a rejection at the pharmacy counter. Many consumers are never notified of their appeal rights because CMS has failed to articulate and enforce regulations that would ensure people with Medicare are notified of their rights. We recommend that Congress direct CMS to require that Part D plans and their pharmacies provide a written explanation at the pharmacy of why coverage of why their prescription has been denied, an explanation of their appeals rights and the necessary contact information to begin the appeals process. Without such notice, the Part D appeals process will remain little more than a fiction.

After having a prescription rejected at the pharmacy counter, a consumer must then call the Part D plan to obtain an exception, also known as a coverage determination. At that point, the consumer must convince her doctor to write to the plan to explain why the prescribed drug is medically necessary. Not only are doctors not

paid for this task, they often must deal with plans that refuse to explain the criteria used for obtaining coverage. In fact, only last week did CMS clarify that Part D plans must provide this information to doctors.

If the plan affirms its initial denial of coverage, consumers must ask the plan a second time for coverage "redetermination," often after they have already engaged in a back-and-forth between their doctor and the plan for more information. CMS statistics show that plans deny 95 percent of redeterminations but that a majority of these redeterminations are overturned through independent review. We recommend that Congress simplify the appeals process by requiring the initial rejection at the pharmacy to count as the first coverage determination. Consumers would ask their plans one time for a coverage "redetermination," before proceeding to an independent review. Congress can also help secure the participation of doctors in the appeals process by allowing them to represent their patients at the redetermination and independent review stages without securing an appointment to represent their clients.

The Medicare Rights Center wins most of the cases once we obtain an independent review of the plans' coverage denial, with the exception of appeals for coverage of drugs prescribed for off-label indications, indications other than those approved by the Food and Drug Administration. CMS' interpretation of the statute defines a medically accepted indication only as one that is specified on the label or an off-label use that is referenced in one of three medical compendia. If the prescription is off-label but not included in the specific compendia, Medicare Part D will not provide coverage, even if the usage has been shown effective in peer-reviewed clinical literature, the standard that applies for Part B drugs. We urge Congress to clarify the Part D statute so that the definition of medically accepted indication is consistent with Part B and our clients can obtain coverage for drugs that have proven effective in treating their condition. The story of one of our current clients shows why Congressional action is necessary.

Mr. H, a U.S. Air Force veteran, was severely injured in a tornado in 1997. As a result, he had to undergo removal of his left eye, removal of portions of the left frontal lobe of his brain, and extensive cranial facial reconstruction.

Mr. H has worked to manage his pain with his prescribing physician, a board-certified pain management specialist. For six years, under the supervision of his physician, Mr. H successfully used Actiq, a medicine approved by the FDA for treatment of breakthrough pain for cancer patients, to manage his migraines and reduce his risk of seizing. Before the enactment of Medicare Part D, Mr. H received coverage for Actiq under his state's Medicaid program, TennCare. Initially, his Part D plan covered Actiq, but in October 2006 Mr. H was suddenly told by his pharmacist that the drug would no longer be covered. Because Actiq was being prescribed for an off-label indication, it was not considered a medically accepted indication under Part D.

Mr. H's doctor prescribed Fentora, also approved for treating cancer-related pain, as a replacement. Recently published peer-reviewed literature has demonstrated that Fentora is a safe and effective method of treating neuropathic pain and the drug has proven successful at easing Mr. H's pain. Initially, Mr. H's Part D plan covered Mr. H's Fentora prescription, but in January 2007, the plan ended this coverage without prior notification to Mr. H or a transition fill.

Since Humana stopped covering his Fentora prescription, Mr. H has been forced to go without treatment because he cannot afford to pay out-of-pocket. When Mr. H had access to his Fentora prescription, he experienced only one seizure per month; without this prescription, he now experiences approximately four seizures every week. As a result, Mr. H must now make frequent trips to the emergency room. This pain hampers every aspect of his life, including his ability to interact with his family and complete daily tasks.

Because Medicare Part D regulations do not allow for consideration of peer-reviewed medical literature, Mr. H's appeals to for coverage to both his plan and the independent review entity were unsuccessful. On Mr. H's behalf, MRC has submitted a request for review of this decision by an Administrative Law Judge, and we are currently waiting for a hearing to be scheduled.

We believe the experience of people with Medicare over the first year-and-a-half of the Part D benefit should guide Congress' efforts to improve consumer protections. We recommend that Congress take action to streamline the Part D appeals process and ensure access to medically necessary drugs, including for off-label uses that have proven to be clinically effective. Enrollment protections for people with Medicare, including the removal of lock-in for Part D and the Medicare Advantage program, should also be enacted. Finally, Congress should direct CMS to exercise its oversight and enforcement responsibilities so that the protections afforded people with Medicare on paper are in fact provided by the Part D plans. The Medicare

Rights Center stands ready to work with members of both parties on making stronger Part D consumer protections a reality.

Chairman STARK. Thank you, Mr. Precht.
Mr. Maher.

STATEMENT OF TOM MAHER, REGIONAL DIRECTOR, HEALTHCARE LEADERSHIP COUNCIL AND MEDICARE TODAY

Mr. MAHER. Chairman Stark, Ranking Member Camp and Members of the Subcommittee, thank you for the invitation to join you today to discuss the Medicare Part D prescription drug benefit and, specifically, the lessons we have learned about outreach to beneficiaries about Part D enrollment. My name is Tom Maher, and I am representing the Medicare Today partnership, an alliance of 400 organizations representing seniors, patients, healthcare providers, employers, care givers and many others. The members of Medicare Today work with Medicare beneficiaries in all 50 States providing information and enrollment assistance to literally millions of individuals. As a regional director for the initiative, I personally have been involved in numerous education and enrollment events in several States in the midwest and the northeast.

To give you an example of the work that we have done in one of my States, New Hampshire, we conducted hundreds of outreach and counseling events in an effort to reach the roughly 188,000 Medicare beneficiaries in the State. By January of 2007, 135,500 had prescription drug coverage ?in the State of New Hampshire.?

This hearing is intended to help policy makers learn more about outreach strategies that were most effective in helping beneficiaries to make informed Part D enrollment decisions. I hope I can shed some light on that issue.

Before Medicare Today counseled any seniors, we engaged in polling and control reaction simulations conducted by the Atlanta based Shapiro Public Opinion Research firm. The results were illuminating. We learned that, while mass communication tools like television advertising and direct mail had their uses, there is no substitute for direct one-on-one communication between beneficiaries and someone who understands and can answer questions about the Part D program. Town hall meetings, forums are effective; individual counseling is very effective.

The information gleaned from this study was borne out in the field. Even though individuals have received information in the mail from Medicare about Part D, this was still a brandnew program, and seniors were skeptical as consumers. This skepticism is heightened by media stories saying the program wouldn't work, it was too complicated and wouldn't save seniors any money. A lot of those stories were out there before seniors even signed up for Medicare Part D.

To cut through the skepticism, we worked with community institutions, local hospitals, churches, senior centers and pharmacies, places where local residents feel comfortable attending an educational forum. At these events, we offered the opportunity for one-on-one counseling to address concerns, answer questions and to give people information they sought and needed. It is important to

note that none of our Medicare Today volunteers, nor to the best of my knowledge, any other individuals or organizations that we partnered with were there to persuade seniors to enroll in plans. We were there simply to provide information on how to enroll, how the program would work or works and the coverage and potential savings they might see if they signed up. For the vast majority of beneficiaries, that is all they needed. We met personally with thousands of people who needed to see in black and white that their particular drugs would be covered and that they would be able to reduce their out-of-pocket pharmaceutical costs. Even in the case of people taking a few medications, they were able to see they could get protection for the future with low monthly premiums. Throughout this process, we worked very closely with CMS and the Social Security Administration.

Mr. Chairman, during those early stages of the Part D program, there were bumps in the road when it came to the implementation. For a new program of this magnitude, it would have been incredibly surprising if everything had run perfectly. What needs to be said about the Federal officials involved in this program is their responsiveness has been exemplary, especially the folks I worked with in the Boston CMS office. Whenever we pointed out problems with the enrollment process or with the plan finder tool, CMS listened to us and took us seriously and acted upon our comments and suggestions.

Our work is continuing in New Hampshire. We assist newly eligible beneficiaries as well as those who have not been enrolled and may still have questions about the program. I believe we still need intensive outreach to low-income seniors who qualify for additional financial assistance. Nationally, 90 percent of Medicare beneficiaries now have prescription drug coverage, and I believe we are on the right track. But we should continue to educate and assist low-income seniors. We have learned a great deal over the past couple of years. We have learned that community partnerships can be effective in conducting public program outreach. We have learned that mass communication regarding these programs needs to be complimented with individual one-on-one counseling.

The Medicare Today partnership commissioned the American Viewpoint Public Opinion Research firm to do a survey of a thousand seniors regarding the Part D enrollment process. Asked whether enrollment was easy or difficult, 72 percent said very or relatively easy, and 89 percent of those who self-enrolled said they experienced no problems with the process. We are proud of that success rate.

Mr. Chairman, thank you again for the opportunity, and I am happy to answer any questions you may have.

[The prepared statement of Mr. Maher:]

Statement of Tom Maher, Regional Director, Medicare Today, Concord, New Hampshire

Chairman Stark, Ranking Member Camp and the members of the subcommittee. Thank you for the invitation to join you today to discuss the Medicare Part D prescription drug benefit and, specifically, the lessons we've learned about outreach to beneficiaries about Part D enrollment.

My name is Tom Maher, and I am representing the *Medicare Today* partnership, an alliance of over 400 organizations representing seniors, patients, health care providers, employers, caregivers and many others. The members of *Medicare Today*

worked with Medicare beneficiaries in all 50 states, providing information and enrollment assistance to literally millions of individuals. As a regional director for the initiative, I have personally been involved in numerous education and enrollment events in several states in the Midwest and northeast.

To give you an example of the work we've done, in one of my states, New Hampshire, we conducted 100s of outreach and counseling events in an effort to reach the roughly 188,000 Medicare beneficiaries in the state. By January of 2007, 135,500 had prescription drug coverage.

This hearing is intended to help policymakers learn more about the outreach strategies that were most effective in helping beneficiaries make an informed Part D enrollment decision. I hope I can shed some light on that issue.

Before *Medicare Today* counseled seniors, we engaged in polling and controlled reaction simulations conducted by the Atlanta-based Shapiro Group public opinion research firm. The results were illuminating. We learned that, while mass communications tools like television advertising and direct mail have their uses, there is no substitute for direct one-on-one communication between beneficiaries and someone who understands and can answer questions about the Part D program. Town meetings and forums are effective. Individual counseling is effective.

The information gleaned from this study was borne out in the field. Even though individuals had received information in the mail about Medicare Part D, this was still a brand new program and seniors tend to be skeptical consumers. This skepticism was heightened by media stories saying the program wouldn't work, it was too complicated, and it wouldn't save seniors any money.

To cut through the skepticism, we worked with community institutions—local hospitals, churches, senior centers, pharmacies—places where local residents feel comfortable attending an educational forum. At these events, we offered the opportunity for one-on-one counseling—to address concerns, to answer questions, to give people the information they sought and needed.

It's important to note that none of our *Medicare Today* volunteers nor, to the best of my knowledge, other individuals and organizations involved in outreach tried to persuade beneficiaries to enroll in a Part D plan. Our approach was simply to provide objective information on how to enroll, how the program works, and the coverage and potential savings involved.

For the vast majority of beneficiaries, that was all they needed. We met personally with thousands of people who needed to see, in black and white, that their particular drugs would be covered and that they would be able to reduce their out-of-pocket pharmaceutical costs. Even in the case of people taking a few medications, they were able to see that they could get protection for the future for low monthly premiums.

Throughout this process, we worked very closely with the Centers for Medicare and Medicaid Services and the Social Security Administration. Mr. Chairman, during the early stages of the Part D program, there were bumps in the road when it came to implementation. For a new program of this magnitude, it would have been incredibly surprising if everything had run perfectly. What needs to be said about the federal officials involved with this program is that their responsiveness has been exemplary. Whenever we pointed out problems with the enrollment process or with the PlanFinder tool, CMS listened to us, took us seriously, and acted upon our comments and suggestions.

This work is continuing, as we assist newly-eligible beneficiaries as well as those who have not enrolled and may still have questions about the program. I believe we still need intensive outreach to low-income seniors, who quality for additional financial assistance. Nationally, more than 90 percent of Medicare beneficiaries now have prescription drug coverage, I believe we're on the right track, but we should continue to educate and assist low income seniors.

We've learned a great deal over the past couple of years. We've learned that community partnerships can be effective in conducting public program outreach. We've learned that mass communication regarding these programs needs to be complimented with individual, one-on-one counseling. The *Medicare Today* partnership commissioned the American Viewpoint public opinion research firm to do a survey of 1,000 seniors regarding the Part D enrollment process. Asked whether enrolling was easy or difficult, 72 percent said "very or relatively" easy, and 89 percent of those who self-enrolled said they experienced no problems with the process. We're proud of that success rate.

Mr. Chairman, thank you again for this opportunity and I will be happy to answer your questions.

Chairman STARK. Thank you.
Ms. Gottlich.

STATEMENT OF VICKI GOTTLICH, ESQ., SENIOR POLICY ATTORNEY, CENTER FOR MEDICARE ADVOCACY, INC.

Ms. GOTTLICH. Chairman Stark, Congressman Camp, Members of the Committee, thank you for the opportunity to testify today about beneficiary protections and Medicare Part D.

I am Vicky Gottlich of the Center for Medicare Advocacy. The center is a national nonprofit organization headquartered in Connecticut. We represent beneficiaries in the State of Connecticut. We also advocate and assist and educate beneficiaries and their advocates across the country. My written testimony discusses the complexity of Part D benefits and includes recommendations for simplifying the appeal system as a way to improve beneficiary protections. My oral comments will provide examples of the issues I describe in my written testimony. Some of these examples came to the center's attention just this week.

CMS educational efforts and the "Medicare and You" handbook and planned materials don't do an adequate job of explaining the technicalities of Part D or of alerting beneficiaries to benefit changes. For example, a beneficiary from Florida e-mailed us this week to complain that she had reached the coverage gap but that her Humana complete plan no longer covered brand name drugs in the gap. She is paying a higher premium for gap coverage that does not benefit her and she cannot change to a lower-cost plan. This very articulate beneficiary did not understand that private insurance companies that offer Part D can change the plan benefit structure each year for their own reasons and regardless of reimbursement rates. She received an annual notice of change last year, but the annual notice of change was very difficult to read and, for many beneficiaries, is too complicated. Unfortunately, we are in the process of reviewing the draft model, and we will notice a change for next year, and quite frankly, it is worse. State health insurance assistance programs, like Choices in Connecticut and HICAP in California, do a good job in education and counseling, but they don't have adequate funding to assist all beneficiaries.

As an aside, I would like to point out that the CMS promotes gap coverage. We already know that the one plan providing limited brand name gap coverage in 2007 will not do so in 2008, leaving beneficiaries who must use brand name drugs without assistance in the gap. Congressman Camp, I would like to clarify our comments about the notice of the lack of appeal rights. We agree with you that the "Medicare and You" handbook does include information about appeal rights. As a partner with CMS, I get to comment on the draft of that handbook every year, and every year, I have commented that the descriptions are inadequate. CMS rarely takes any of my comments and makes improvements.

But it is not enough for us to say, that information is in the handbook. In 1996, the OIG did two reports on HMO enrollees and their knowledge of appeal rights. The OIG found that enrollees knew about appeal rights in general, but what they didn't understand is how those appeal rights would apply to specific situations. As Ms. Norwalk said today, the most important thing is what hap-

pens at the pharmacy counter. It is the required notices that Ms. Norwalk described that are not being handed out, that are not being displayed so that beneficiaries don't even know how to start the process. They don't know that the information about appeal rights in the "Medicare and You" handbook applies to them at that situation. But it is not only beneficiaries who don't have this information; it is actually the trade press and doctors who don't know about this protection. BNA yesterday reported on a new study about Part D formularies printed today in the Journal of the American Medical Association. The study said that when a beneficiary learns at the pharmacy that a drug is not covered, the pharmacist or patient must seek a new prescription from the doctor or the beneficiary must pay higher cost-sharing for the prescribed medication. There was no mention in the BNA article that the beneficiary or the physician could seek an exception to cover nonformulary drugs or to lower the cost sharing. It will not be sufficient to get data from CMS or from plans about appeals because this data will not capture the number of people who walked away from the pharmacy without getting the drug or paying for the drug out-of-pocket and not understanding that they could have sought protection through the appeals process.

We also recommend in our written testimony simplifying the appeals process by eliminating distinctions between exceptions, coverage determinations and prior authorizations and by requiring plans to make prior authorizations and utilization management requirements widely available. The Maine Legal Services for the Elderly program contacted me on Tuesday about drug plans that impose more than a prior authorization or utilization management requirement on drugs so that a beneficiary or a physician must have to request an exception more than once. For example, one plan that listed both prior authorization and quantity limits for Lipitor told Maine Legal Services that the prior authorization really just meant the quantity limit distinction. The physician therefore requested an exception based on quantity limits which was denied because he had not shown that the patient had tried other drugs and failed. The plan did not describe the step therapy requirement anywhere and had not told the advocates about the requirement when they inquired.

I would like to clarify a point that Ms. Norwalk made. She said that if somebody gets prior authorization, they get prior authorization for the entire plan year. That is actually not true. If you get an exception, it lasts for the entire plan year. But if you get prior authorization, plans sometimes will require the physician to request prior authorization on a monthly basis. That is very burdensome, especially since doctors are not compensated for this work. Even if a beneficiary gets an exception from one plan, however, she has to go through the process again, sometimes with a different outcome if she changes plans.

So, again, this week, we heard from Michigan SHpp describing a beneficiary whose doctor faxed twice to her new plan an exception request based on the beneficiary's need for both a higher dose of a formulary drug and a drug in a format that was not on the formulary. This was a duplication for this beneficiary because the beneficiary had been in a previous plan in which she had gotten

the exception. Although beneficiary protections exist in Part D, they are inadequate and not being applied properly to help beneficiaries in the program themselves.

One further area where we see problems is in the off-label drug use. Individuals who require drugs that are off-label can request an exception. They have to establish that the drug is approved by one of three compendia listed in Medicare regulations. Unfortunately, those compendia are not accessible to the general public. Advocates and doctors must pay in order to get evidence they need in order to present their appeal. An advocate from Minnesota complained that she was able to get free access at the good will of the med school library to some of the information in the compendia, except they didn't give her all of the information she needed; so she didn't have all of the information, and she lost her appeal.

We are recommending one of two things: either that plans be required to provide access to the compendia if they are denying a drug based on off-label use, or that the standard be changed to a provision that is similar to the requirement that Medicare contractors provide access to drugs under the part B standard of review. In sum, there are too many drug plans; there are too many varied benefit packages. People don't have enough information to make adequate choices. As indicated, people are not filing appeals. They are either not getting their drugs, or they are paying for them by themselves. If they try to use the appeals process, it is too difficult.

We would like to recommend that the best protection would be to include a drug benefit as part of Medicare and to give the Secretary the authority to negotiate drug prices on behalf of beneficiaries. Additionally, we would like to see the number of plans available limited and the benefit structure standardized so that beneficiaries have a better chance of understanding what is being offered and getting access to the drugs they need. Thank you.

[The prepared statement of Ms. Gottlich:]

Statement of Vicki Gottlich, Senior Policy Attorney, Center for Medicare Advocacy

Chairman Stark, Ranking Member Camp, distinguished Members of the Subcommittee, thank you for the opportunity to testify today on behalf of Medicare beneficiaries concerning beneficiary protections under 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 Part D. We hear repeatedly from them about problems that arise from the complexity of the program. There are too many plans with varying benefit structures and formularies, making meaningful comparisons impossible. Beneficiaries have insufficient information to make sound choices and to understand formularies and coverage gaps. Some beneficiaries are given incorrect information by plan marketing agents and find themselves in drug or other health plans in which they did not intend to enroll. Beneficiaries are not enrolled in the correct plan or are charged incorrect cost-sharing because of bottlenecks in transferring information about enrollment, premium payments, and cost-sharing among Part D plans, the Centers for Medicare & Medicaid Services (CMS), and the Social Security Administration (SSA). The Part D exceptions and appeals process is so convoluted that it is not adequately accessible to Medicare beneficiaries.

We thank Chairman Stark for your leadership in holding hearings on Part D and in introducing legislation to add important consumer protections to the program. We also thank Congressman Doggett for your legislation to improve the low-income subsidy, and Congressman Becerra for your legislation to improve the Medicare Savings

Programs. Both the Doggett and Becerra bills will provide needed assistance to people with limited income and resources. We thank Congressmen Murphy and Courtney, from the Center's home state of Connecticut, for their Part D legislation as well.

The Center for Medicare Advocacy believes that the best consumer protection for Medicare beneficiaries would be to add a drug benefit to the traditional Medicare program and to stop the privatization of Medicare. For over 20 years, the Center has watched what happens to Medicare beneficiaries when private health insurance companies decide to change their benefit packages, shift more costs onto beneficiaries, or leave Medicare entirely, all for business reasons that may have nothing to do with Medicare funding and that definitely have nothing to do with the well-being of older people and people with disabilities. For example, the June 15, 2007 *Drug Benefits News* reported that more plans will go to a four-tiered benefit design in 2008 to avoid adverse selection by beneficiaries with greater drug care needs. Plans keep premiums lower by requiring "the relatively-resource intensive beneficiary to pay more." We will leave that conversation for a different hearing, however, and focus instead today on the Part D exceptions and appeals processes.

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 they might 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 very detailed. 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.

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. We have heard from beneficiaries who use a mail-order pharmacy and who received no medication, no information as to why they did not receive their drug, and no notice explaining their rights.

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 informed of their appeal rights at later stages in the appeals process. Some plans are not using the standard Coverage Determination notice developed by CMS, and therefore not providing beneficiaries and their doctors with information needed to appeal. Other plans are not telling beneficiaries of further appeal opportunities if their first level of appeal is also denied.

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 needed to take action to get the medication. Drug plans do not make available on their websites 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. We appreciate that CMS issued guidance on June 14, 2007, on making prior authorization requirements available. The guidance still puts the burden on the beneficiary or doctor to ask for the information, however, and, since the CMS document is only guidance and not regulatory, it is unclear the extent to which plans will comply.

Some plans use the prior authorization and Exceptions processes as a way to delay providing and paying for prescribed medications. They may require doctors to provide more and more information, or they may claim they never got a Coverage Determination or Redetermination request. In both situations, they can avoid issuing a decision and avoid or delay further appeals.

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 under an Exceptions request. The Part D regulations, however, specifically downgrade 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 exceptions process, Part D plans are not required to respect the physician's opinion. Plans ignore or discount medical records submitted by doctors. Some are not satisfied that a formulary drug is ineffective for a beneficiary, for example, unless their own claims history for the beneficiary, and not the doctor's medical records for that individual, show ineffectiveness.

Problems are exacerbated when the appeal involves an "off-label" drug. 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 specified 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 in finding the compendia, but these resources are limited, inefficient, and incomplete. Without direct access to the compendia, 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.

CMS has established a number of mechanisms through which beneficiaries may seek redress of problems, including problems with drug plan appeal processes. 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, yet the problems identified by the Government Accountability Office in its reports detailing problems with the Medicare hotline have not abated.[1] 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 hotline.

For many beneficiaries and advocates, filing a complaint with 1–800–MEDICARE, or even with the regional office, is like filing a complaint in 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 timelines 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 the Center and other 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 bene-

[1] See, e.g., GAO, *Communications to Beneficiaries on the Prescription Drug Benefit Could be Improved* (GAO 06–654, May 2006), http://www.gao.gov/new.items/d06654.pdf; GAO, *Accuracy of Responses from the 1–800–MEDICARE Help Line Should Be Improved* (GAO 05–130, December 2004), http://www.gao.gov/new. items/d05130.pdf.

ficiary 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, however, not simply 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 are generally 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 many of the major drug plans, but those contacts are no substitute for enforcement by CMS.

The Center for Medicare Advocacy, in collaboration with the Medicare Rights Center and the National Council on Aging, developed recommendations to establish one process through which beneficiaries and their prescribing physicians may more easily ask plans for decisions, to be known as initial determinations, about drug coverage. Our recommendations would simplify and streamline the processes:

- The distinction between exceptions and other coverage determinations should be eliminated. Appeals for coverage of non-formulary drugs, requests concerning utilization management tools, and requests for prior authorization should all be treated the same. The various names and processes under the current system create confusion for beneficiaries, doctors, advocates, and Part D plans.
- The initial determination notice should be issued automatically at the pharmacy whenever a plan rule prevented the pharmacy from filling the prescription. The notice should clearly explain, using standard language developed by CMS, the plan's basis and rationale for the denial of coverage and should contain a clear statement that the beneficiary or the doctor may appeal by requesting a redetermination of the decision by the plan. Mail-order pharmacies should be required to contact a beneficiary by telephone when orders cannot be filled as prescribed due to formulary restrictions and then to send a written notice.
- Plans should defer to the statement of the physician unless they can demonstrate objective, verifiable medical evidence that contravenes the treating physician's judgment.
- Physicians should be reimbursed for time spent asking for exceptions and other coverage determinations and appeals.
- The Medicare statute should be modified to incorporate policy that requires plans to continue supplying a drug to beneficiaries stabilized on that drug on the same basis throughout the year even after a mid-year plan formulary adjustment that removes the drug from the formulary, places the drug on a higher tier, or subjects the drug to new utilization management requirements.
- Plans should be required to provide beneficiaries a 72-hour supply of a drug they are currently taking after being told that the drug is not covered by their formulary, pending the outcome of a redetermination. This Medicaid-based provision would afford beneficiaries minimal protection against abrupt withdrawal from drugs which sustain health and, in some cases, life. If the FDA removes a drug from the market for reasons of safety or efficacy, Part D enrollees should have immediate access to a temporary supply of an alternative therapy.
- Drug plans should be required to specify in their notices that an adverse initial coverage determination is based upon an off-label usage of a medication. As stated earlier, advocates and members of the general public must pay large sums of money to access the drug compendia, referenced in the statute, for coverage of off-label use of Part D drugs. Reference to the compendia, therefore, should be replaced with a statutory standard that is consistent with the Part B standard that an off-label drug is prescribed for a medically necessary indication. Alternatively, Part D plans should be required to provide, as part of their notice, direct access to the drug compendia they relied upon to deny coverage. Such a provision is similar to the requirement that Medicare contractors provide access to the local coverage policies upon which they rely for Part A and Part B claims.
- The Medicare statute should be modified to incorporate current CMS policy requiring plans to cover substantially all drugs in six protected classes: anti-retroviral drugs, anti-depressant drugs, anti-convulsant drugs, anti-psychotic drugs, immunosuppressant drugs, and anti-cancer drugs.
- The current statutory section, 42 U.S.C. 1395w-104(h), which states that only a Part D-eligible individual can bring an appeal, should be amended to permit a physician to request an appeal.
- Beneficiaries should have access to the information submitted by the plan in opposition to their appeal in order to ensure a more complete and objective review

by the Independent Review Entity that considers all perspectives on the matter in dispute.

- A formal, standardized appeals process for enrollment and disenrollment disputes, as well as a related special enrollment period, should be created and enforced. Data collection requirements should include data points on the
  - Effectiveness of plan transitions, appeals, and exceptions processes in providing uninterrupted access to prescribed medicines;
  - Effect of plan formulary restrictions and appeals processes on access to key drug classes, including the six protected classes and specialty tier drugs;
  - Impact of plan formulary restrictions and appeals processes on access to prescribed medications by vulnerable beneficiaries, such as LIS recipients and dual eligibles; and
  - Plan access policies and practices to enable dispensing of specific medicines most subject to appeal and most likely to be covered upon independent review.

The Part D prescription drug program is not working for many beneficiaries. Improving the appeals process will provide additional protection for beneficiaries who cannot get access to prescribed medications. Other consumer improvements could address marketing problems, enrollment and disenrollment problems, the lack of adequate information, and standardization of plan structures. While the real answer to problems encountered by beneficiaries is to provide a Medicare prescription drug benefit in the traditional Medicare program, the protections mentioned above are needed if the Part D program is to continue in its current form.

The Center for Medicare Advocacy looks forward to working with this Subcommittee to ensure that all Medicare beneficiaries get the prescriptions they require.

Chairman STARK. Thank you.

Dr. O'Brien, in your testimony, you suggested about 100,000 Medicare eligible beneficiaries with HIV/AIDS, and if that is 20 percent, with my shoes and socks on, I assume you are saying there is a half a million people in this country currently receiving some kind of care for HIV/AIDS.

Dr. O'BRIEN. Yes.

Chairman STARK. I would suppose, Dr. Fleming, that they are very expensive. Insurance companies without the kind consideration that Humana has would just as soon avoid them if they could, because they are very expensive patients.

Mr. FLEMING. HIV patients certainly are very expensive patients.

Chairman STARK. So, insurance companies would, if they could, avoid—and I don't say that in a pejorative sense—but are not out running ads and media exchanges saying, if you come see us, we would like to insure you.

Mr. FLEMING. It comes with the territory.

Chairman STARK. No, I understand that. Because you were, months ago, you may not know it, in our letter from Consumers Union, as being in zip code 00501, it is my understanding that you were the plan that increased a plan 603 bucks some time between February of this year and June of this year. That is 50 bucks a month for folks. For whatever reason, it could be very a good business reason. If we decided to do something somehow to protect the beneficiaries from changes that could affect them in a way they couldn't predict when they were making the choice at the beginning, wouldn't it be simpler for the insurance companies to let us just say that if someone has some problem, either they lose coverage or the price increases, the cost increases, that they be al-

lowed to change rather than try and draw a whole lot of rules about what you could do as a plan in terms of holding your costs constant? I don't know how many people there are that this would affect, but it sounds to me it would be a lot simpler for, unless you suspect that that would just be adverse selection on all your colleagues in the business.

Mr. FLEMING. I assume you are talking about lock-in and removing the lock-in.

Chairman STARK. Yes, or restricting a plan from making changes during the year. Those would be the two alternatives that I see.

Mr. FLEMING. May I address both of them? In general, we don't support the lock-in. We believe the lock-in issue is a complex issue because of the variation between PDPs and MA–PDs. We believe that the previous rules for changing plans worked well, which result in peace of mind, I think, for the beneficiary and, frankly, for the advocacy groups.

Chairman STARK. This is a huge bureaucratic problem for you guys if that happens?

Mr. FLEMING. As far as the member changing plans? The only thing that I would recommend that you think about is you think about what needs to follow the member from plan A to plan B as far as TrOOP and all the financial stuff. So, there needs to be a mechanism, I believe, that would allow for that transfer of information from plan A to plan B.

Chairman STARK. Well, I am inclined to agree with you that it just would seem, from our standpoint, simpler to say, do away with the lock-in or adjust it, than try to figure out how to understand your complications and regulate them. I think I would be more comfortable with that.

If any of the other witnesses have any feelings about that, I would be glad to hear from them, but it seems a simpler way for us to approach it.

You suggest, Ms. Gottlich, that, currently, only an individual can bring an appeal, and you would like to permit a physician to request an appeal. I think that makes a whole lot of sense to me in that if, in fact, I was going to go to Dr. Fleming and explain why I need my Zocor and not that other thing that I can't pronounce that is the equivalent, I don't know why, but if my doctor wrote you the note, he or she could probably spell the words that explain the reasons and frame the appeal. First of all, the doctor would have to tell me what to say, and then I would have to rewrite it and tell you why. Then you would have to answer me, and I would have to go to a doctor and say, this is what Dr. Fleming said. The doctor did it more quickly and in a manner that would be easier for you to determine whether it was a reasonable request and probably save everybody a lot of time. I can't believe that doctors would do this capriciously because their time is pretty valuable. Would you have any feeling about her suggestion that we let docs file on behalf of their patient?

Mr. FLEMING. Conceptually, no. I think the issue that we need to think about is, by the time it gets to an appeal, that means the beneficiary and the beneficiary's physician has called in and has made the request and there is a reason why the request cannot be

approved. So, it is likely that the appeal would not have any further information that would say, here is the reason why this drug should be approved that I have not already disclosed to you.

Now the cases where there is new information that has come forward, let us say a drug gets a new labeling between when it was requested and when the appeal comes through, that is new information that could in theory come out on appeal in that case. In that scenario, I could see that making some sense.

Chairman STARK. But as I said, I thought it made some sense.

Ms. GOTTLICH. Let me just describe the scenario as it currently works now. The doctor will request the exception. It will be denied. The next step is redetermination. The doctor will have to file that as well. There will be a delay because the plan will ask the doctor to go get an appointment of representation form. In the meantime, the beneficiary is not getting the medicine. Even if it is denied again, the doctor still cannot appeal to the independent review entity without getting the appointment of representative form adding an additional delay. So it really lengthens the whole process when you really need something quick and the regulations have very short timeframes.

Chairman STARK. Dr. Fleming, how are you going on your Chinese adoption?

Mr. FLEMING. Sir, if you could help me out with that, I would appreciate it. A year ago, I was saying six to 9 months, and I am still saying six to 9 months.

Chairman STARK. What I have got to tell you, anticipating your success, let me ask you to Google up Concordia Language Villages as an experience for perhaps your older children, and perhaps you, Mr. Fleming, at some point, if you are interested in Chinese culture and Chinese language, and I hope you will be. Our children have gone there, and it is an amazing series of camps in Minnesota, and I just wanted to add that.

Mr. FLEMING. Thank you for that advice.

Chairman STARK. Do you have any advice, Mr. Camp?

Mr. CAMP. I want to thank everyone for their testimony today. I do think it is important to remember that, despite the information we are getting, 80 percent of the seniors are satisfied with their drug coverage and would recommend Part D to a friend.

I do, Ms. Gottlich, want to say that if you have any—I have looked at this 2007 "Medicare and You" report, and I think that the appeal information is in very plain language. Circle the form is sort of the level it is at now. If you have specifics—now, the 2008 report is simply a draft report, and I realize that is a work in progress. We have an opportunity to impact that draft report. If you could get to me in writing the specifics of the exact language that you think is a problem in the 2007 report, I would be happy to look at that. If I think it is appropriate, I will pass it along. Maybe we can help make a better booklet because I think this right to appeal section is fairly straightforward.

But I also would like to say, Dr. O'Brien, you describe I think that Medicaid and ADAP are beneficial programs. But I would just want to point out to you that at least three States have waiting lists for patients to enroll in ADAP. Two States are restricting access to certain AIDS drugs. Three States have further restricted

eligibility to ADAP. Four more States are expected to adopt similar cost-containment measures. Also many State Medicaid programs limit the number of prescriptions people can receive each month. I will just say, Medicare does not cap enrollment. So, one of the big global benefits, you may not see in your clinic, but at least from a nationwide standpoint, Medicare doesn't cap enrollment. In the drug benefit, they don't reduce program eligibility. They don't implement limits on the number of drugs a senior can take each month. So I would contrast that program with ADAP and just say that I think the new Medicare drug benefit in terms of eligibility and to not cap enrollment is superior to the programs you mention.

Dr. O'BRIEN. Would you——

Mr. CAMP. I don't really need a comment. My time is very limited, but briefly if you have something new.

Mr. FLEMING. You are absolutely right, sir. In certain States, there are waiting lists. That is why we want to add ADAP to the TrOOP, so we are not further depleting ADAP. We also don't want to punish people in States where ADAP and Medicaid have been generous, more generous than the current Medicare plan.

Mr. CAMP. So, we have a nationwide plan. Really, in terms of if you are Medicaid eligible, you can change each month. I wanted to ask a question, Dr. Fleming, about that. If plans or individuals were able to change the plans, how are you envisioning the details of that? Would they be able to change biannually, quarterly, and how do you see that impacting the cost of the program?

Mr. FLEMING. I don't know that I put enough thought into the mechanisms for the change, but certainly when you go back pre-MMA, the way it worked there, a beneficiary could change from a month-to-month basis. In the world of Part D and the complexities of TrOOP and all the TrOOP calculations and the funding mechanisms around it, I think it is going to be something that needs to be thought through to see how those dollars flow through the system, because, to your point, I don't think we want an unintended consequence of raising costs necessarily because of the change.

On the other hand, we see the value and the peace of mind from the beneficiary and from the advocacy groups. We understand that. If a beneficiary is not happy with a plan, we fully support the notion that they should be able to change.

Mr. CAMP. We see more than half of the beneficiaries did not change from 2006 to 2007, so many people made, in their opinion, the right choice.

Mr. FLEMING. Well, the majority of people did not change. As well, I think someone mentioned earlier, that the auto enrollees certainly had the ability to change month to month. We see very little change there. So, I believe by offering that as an opportunity, you are going to see very little change at the end of the day from plan to plan.

Mr. CAMP. The question is, what cost effect that might have to a program, because obviously we don't want the program to fall under its own rate, because there are a lot of people getting a significant benefit. I know, for example, patients that enrolled in the Part D plan that Dr. O'Brien mentioned are saving more than $7,000 on AIDS drug medicine. That is a fairly significant savings.

Mr. FLEMING. That is a lot of money. If it is permissible to you, I would like to take that back as a to-do and provide our thoughts back for the formal record.

Mr. CAMP. I would be interested because I do think there is some other point Mr. Stark made that if the plans can change, and I realize many people are on a set co-pay so their co-pay doesn't change, but if the plans can change, why not the individuals? I think we need to explore that and see if there is something we can do there. Thank you very much. Thank you all for your testimony.

Chairman STARK. Ms. Tubbs Jones.

Mrs. JONES. Thank you very much. I would like for the record to say that we cannot presume because a senior does not change their prescription drug benefit plan that they are satisfied. Some of them are just so downtrodden with the responsibilities that they have, they say, the hell with it, I am just going to just keep what I have, at least I know what I have got. It is just like saying 80 percent of them are satisfied with the prescription drug benefit; 80 percent of those polled were satisfied. We don't know what the group that was polled said. That is just like, if you want to believe 4 percent unemployment in the United States of America. I don't know what United States people are living in, but there is greater than a 4 percent unemployment in the United States of America. So, we have to be careful throwing these numbers around.

My question to you, Ms. Gottlich, is, how long does the appeal process take.

Ms. GOTTLICH. Well, if it goes by the regulations——

Mrs. JONES. You know how often that is. That is like a speedy trial, right.

Ms. GOTTLICH. Exactly. It can be very quick. It can be 10 days to get through the independent review entity. But what we are finding often is that there are delays at the plan level. So, doctors will not get notices. You have to go through and get the appointment.

Mrs. JONES. So, the appeal process may take 10 days, but to get to the appeal process, we don't know how long that will take.

Ms. GOTTLICH. When it works right, it can be very fast, and the exception from Michigan that I described that we heard about this week got resolved this week. But there are situations where plans keep asking for more and more and more information. So, we had cases that dragged on for months.

Mrs. JONES. So, Dr. O'Brien, what do you do for a patient who is denied coverage? What impact does that have on your ability to treat that patient? Do you have drugs to give them, or what happens?

Dr. O'BRIEN. There have been cases we have had to hospitalize patients. For example, I use the example in my written testimony of fluconazole for cryptococcal meningitis. For some people, fluconazole has been very, very difficult. We have plans that make us authorize for that on a monthly basis. Cryptococcal meningitis in an AIDS patient is a lifetime disease. So, we have ended up having to put people in the hospital or put them on IB amphotericin, a relatively toxic antiretroviral fungal medication. Mrs. Jones. I am a trial lawyer, so accuse me of being highly litigious.

Who is liable for that situation of that patient not receiving the type of prescription that they should be receiving once it is prescribed by the doctor?

Dr. O'BRIEN. I am not a trial lawyer, so I could not offer an opinion on that.

Mrs. JONES. No one has been sued that you know of yet with regard to that? I just wanted to throw it out there.

I think, and nobody has asked me, but I think that the patient should be able to change prescription drug programs as often as the programs are able to change formulary. If they could change formulary, the people ought to be able to switch and go to the type of prescription that they have.

I thought I was going to use up all my time, Mr. Chairman. I didn't. I am so proud of myself. I yield back the balance of my time.

Chairman STARK. Thank you, ma'am.

Mr. JOHNSON.

Mr. JOHNSON. Thank you, Mr. Chairman. I am not a trial lawyer.

Chairman STARK. Oh, you would be a good one, though.

Mr. JOHNSON. You bet.

According to a survey conducted by Medicare Education Network in January of this year, overwhelming majorities of enrollees gave Part D high ratings. We have been quoting a lot of percentages, but they said 91 percent said the plan is convenient to use, 89 percent said they understand how the plan works, 86 percent said the plan had good customer service, 81 percent said copays are affordable, 79 percent said the monthly premium is affordable, and 77 percent said the plan covers all medicines. Those results contradict some of the testimony.

If the beneficiaries are satisfied with their Part D benefit in competition successfully keeping prices affordable for our seniors, I wonder, Mr. Precht and Ms. Gottlich, what you think, why you think choice and competition are bad for America or America's seniors?

Mr. PRECHT. I don't.

Mr. JOHNSON. Well, good.

Mr. PRECHT. We think that the choice should be expanded to include an option directly under Medicare so that people can get drug coverage directly through the Medicare Program. That is how it works with Parts A and B. They can get their Medicare directly from the original Medicare Program or they can choose the Medicare Advantage Plan.

I just want to say one other thing. If 77 percent of the folks say that Part D is covering all of their drugs, when we are talking about consumer protection, we are talking about the other 33 percent, the folks that are running into problems getting coverage. What we are asking for is making that appeals process work a little better, getting the plans to give the benefit of the doubt to the doctor when he says that this is the drug that is working for my patient. That is essentially what we are saying.

Ms. GOTTLICH. The other two points are that if you look at studies, and actually my favorite is the book Blink, the best selling book, there are some times when their choices are too broad, so there is no choice at all.

That is what I think is going on with the Part D plans. There are too many plans so people just choose a plan based on the name or something their friend says. They don't really analyze to see if it is the best plan for them, because there are way too many plans to take a look at everything. Yeah, it is fine to have a choice plan. We would like to see the number reduced, we would like to include a plan in Medicare.

The other thing to look at in the statistics, as Mrs. Tubbs Jones said, is what do the statistics tell us. If you look at the Kaiser satisfaction survey, they said 80 percent of the people were satisfied. But the people who weren't satisfied were the people who were poor, the people who used the most drugs. These are the people who we are trying to protect. It would be nice to work to 100 percent satisfaction.

Mr. JOHNSON. You don't know that for sure, you are just presuming that.

Ms. GOTTLICH. No, no, no. That is what Kaiser said in their beneficiary survey earlier in the year.

Mr. JOHNSON. Dr. Fleming, you know, I like your smart summary. I think that is a good document and a great service to your customers. I wonder why you decided to provide that resource to your beneficiaries and if you can tell us what the costs are above and beyond the traditional benefit.

Mr. FLEMING. Sure. The smart summary was our response to the requirement in the regulation that said that we needed to provide a monthly summary of the medications used by the beneficiary. So, we decided to work with seniors and we had seniors help us develop this tool.

Frankly, I am not sure we are smart enough to develop something like this. We worked with them in focus groups to help develop this tool to give them pictures, charts and graphs around where you are within the coverage parameter, the donut hole. We gave a lot of good information——

Mr. JOHNSON. Is that computed into your cost.

Mr. FLEMING. It is computed into our premium and cost. One of the things we are very proud of is this Humana Rx Record On-The-Go, which is really a tool that whenever you go to the doctor's office or ER, whenever you get that question, what drugs you are taking, if they can pull this little tool, it is something you fold up in your billfold, pull it out, hand it to the doctor in the ER, it gives them a list of the entire medications they have used over the last 6 months.

What we intended to do with this was to really derive peace of mind with that beneficiary, give them confidence about their ability to make decisions.

I think you talked earlier about how seniors are smart. We do think they are smart because they have helped us a lot in thinking about how we take a requirement regulation and really make it a usable document, a relationship vehicle frankly with them.

Mr. JOHNSON. Thank you. Thank you, Mr. Chairman.

Chairman STARK. Dr. O'Brien, how much does it cost, can you tell me on average, to treat an AIDS/HIV patient, the whole hospital, the physician services, the pharmaceuticals on average in a year? Do you have any idea?

Dr. O'BRIEN. I don't have those numbers at my fingertips, it depends a lot on what stage of the illness the person is in. Antiretroviral drugs themselves can cost $20,000 a year for a course of antiretroviral therapy, again depending on which drugs, and how many drugs the person is on. That is probably the largest expenditure for a person that is not being hospitalized.

Chairman STARK. Any idea, Dr. Fleming? Do you have any idea what Humana's out-of-pocket if you have to provide benefits to an AIDS——

Mr. FLEMING. I don't know the specific for that. I am certainly not an expert in HIV, but I can tell you for most HIV members, if they have the elefined standard plan, they are likely going to go through the donut hole and into the catastrophic coverage at some point through the year, because these are $400 per month therapies and if you are on two or three of them, they are very expensive.

Chairman STARK. Do you have any——

Dr. O'BRIEN. My colleague helped inform me that 11 to $13,000 per year for drugs for somebody not hospitalized; somebody with advanced disease requiring hospitalization, on average $100,000 per year.

Chairman STARK. $100,000?

Dr. O'BRIEN. Yes.

Chairman STARK. One of the things I might suggest, I guess if we have got a half million people and that we—a simple solution here, I am sure the insurance companies would join me in this, but would there be any real reason most of them—there would be less and less disabled, but many of them would qualify as disabled, that we wouldn't treat them as we do end stage renal? Why do we have to fuss around with this? With the prescription drugs changing, with the level of treatment changing, I am not sure we would save—we might save some money, but it is a kind of—maybe it isn't that unique, maybe I just opened the door to 100 other diseases of this nature that would require that I—in spite of Michael Moore, I would lose, but I don't know. I don't know whether there is any similarity there. It would certainly go ahead.

Dr. O'BRIEN. We certainly strongly support the idea of that. HIV is beyond just the disease is a major killer of young African Americans, over 50 percent of new HIV and AIDS cases in African Americans. It is also a communicable disease; treating somebody is prevention. Treating somebody with HIV is not only treating that person and their family, it is preventing other people from becoming infected. So, there is a community interest in treating people. We strongly support the idea of universal coverage for people with HIV/AIDS.

Chairman STARK. I sense that if we did this that the number would suddenly jump, the number under treatment from 500—the people who would come in, so perhaps we would have an increase. It is just an idea.

As I say, we spend about 58,000 on average on dialysis patients, and my guess is we have about 200 or 250,000 of those. So, your numbers are perhaps—you have a higher number but perhaps a smaller cost. We haven't had huge increases much to the dismay

of some of the major dialysis companies, but we haven't had a huge increase in payment in that program. Just an idea.

I want to thank all of you for your patience for waiting, accommodating our kind of fractured voting schedule here. I thank my colleagues for their patience with the Chairman's long-winded inquiries.

Mrs. JONES. Mr. Chairman, I want to ask that if you all have any other guidance you would like to give us around this area as we move through, we would be deeply appreciative.

Chairman STARK. I would second that.

If there are no further inquiries, the hearing is adjourned.

[Whereupon, at 5:39 p.m., the hearing was adjourned.]

[Submissions for the record to follow:]

Statement of American Association of Retired People

Chairman Stark, Ranking Member Camp, distinguished Subcommittee members, on behalf of AARP's 39 million members, we thank you for holding this hearing on the need to strengthen beneficiary protections in the Medicare Part D prescription drug program.

Among the most important protections in Part D is the extra help provided by the low-income subsidy to those least able to afford their drug costs. LIS provides greatly reduced costs and no gap in coverage (no "doughnut hole") for beneficiaries with incomes below 150 percent of the federal poverty level ($15,315 for individuals, $20,535 for couples).

We are pleased that the LIS is providing essential help with premiums and copays to millions who otherwise might go without lifesaving medicines because of cost. We commend the Center for Medicare and Medicaid Services (CMS) for providing auto—and facilitated enrollment in LIS for people enrolled in Medicaid, a Medicare Savings Program (MSP), or receiving Supplemental Security Income and deemed eligible for LIS. We also applaud CMS for waiving the late enrollment penalty for anyone found eligible for LIS. We similarly appreciate steps the Social Security Administration (SSA) has taken to minimize the burden of annual LIS eligibility redeterminations.

We have worked diligently with CMS, SSA, the Access to Benefits Coalition, State Health Insurance Assistance Programs, and many other partners on the daunting task of finding and enrolling low-income beneficiaries who are not deemed eligible. Reaching beneficiaries with limited incomes has always been a challenge, but LIS outreach and enrollment is especially difficult because the LIS program has a serious flaw—an asset test.

AARP believes that addressing the asset test should be a top priority for Congress this year, along with efforts to create a level playing field between Medicare Advantage and traditional fee-for-service Medicare. A portion of any savings generated by creating such a level playing field should be reinvested first in Medicare, particularly to address the Part D asset test limits.

LIS Protection Out of Reach for Many Low-Income Beneficiaries

Millions of people who need the extra help LIS provides are not getting it, largely because of the asset test. To be eligible for LIS, beneficiaries can have no more than $11,710 in savings, or $23,410 for a couple, no matter how low their income or how high their other living expenses.

These amounts are hardly enough to get people through retirement, and AARP has consistently opposed the asset test. However, the LIS is currently denied to anyone who has saved even one dollar over these limits.

The asset test directly contradicts efforts to encourage people to save by penalizing even those with modest savings. We should encourage people to save for retirement, not penalize those who do.

The Kaiser Family Foundation has estimated that more than 2.3 million beneficiaries who meet LIS income criteria do not meet the asset test. Almost half exceed the asset limit by $25,000 or less. In fact, the asset test is the leading reason why people who apply for the subsidy are rejected.

Daunting Application Imposes Barrier

The asset test is also proving to be a serious barrier to enrollment even for those who meet its unreasonable limits. CMS projected in its final regulation on Part D

that 14.4 million beneficiaries would be eligible for the LIS[1] wever, to date, only slightly more than 9 million are enrolled. That means up to 5 million eligible individuals are not getting the Medicare help they need. CMS has estimated that as many as 3 million of these people have no drug coverage at all.

Because of the asset test, the LIS application form is eight pages of daunting and invasive questions that are difficult for many people to answer. For example, it:

- requires people to report not just savings but such obscure details as the current cash value of any life insurance policies—information people simply do not have on hand;
- asks people whether they expect to use savings for funeral or burial expenses, but does not explain that individuals can have up to $1,500 (3,000 for couples) in savings above the asset limits for such expenses;
- asks invasive questions, such as whether applicants get help with meals or other household expenses from family members or charities which can be difficult to estimate and embarrassing to some; and
- threatens applicants with prison terms if information they provide is incorrect.

Applying for the LIS thus can seem overwhelming and require many hours, extra help from family members or insurance counselors, and often repeated efforts to find all of the required information.

This asset test and the paperwork barrier it creates is a key reason why between 3 and 5 million people who should qualify for the LIS are not getting it.

Inadequate Coordiantion with Medicare Savings Programs

Similar problems plague the Medicare Savings Programs (MSPs) that help pay other Medicare cost sharing requirements. As with LIS, millions of Medicare beneficiaries living on very limited incomes are not getting the help they need from these vital programs. In addition, there is only limited coordination between LIS and MSP, even though they serve primarily the same populations.

MSPs are state-administered programs and include:

- the Qualified Medicare Beneficiary (QMB) program which pays Medicare Part B premiums and cost sharing for those living at or below the poverty line,
- the Specified Low-Income Medicare Beneficiary (SLMB) program which pays Part B Premiums for those between 100 and 120 percent of poverty, and
- the Qualified Individual (QI) program which gives states capped allotments—subject to periodic reauthorization by Congress—to pay Part B premiums for those between 120 and 135 percent of poverty.

Beneficiaries enrolled in MSP programs are automatically eligible for and enrolled in the LIS. However, SSA does not screen LIS applicants to see if they are also eligible for MSP. This is a serious missed opportunity, as MSP eligibility criteria in several states is less restrictive than LIS criteria, and some states have effectively eliminated the asset test altogether. Thus, many individuals who are eligible for the LIS under their state's MSP rules are being improperly rejected because SSA only reviews applicants against LIS criteria.

The same kind of barrier to enrollment seen with the LIS exists in the majority of states that still impose an asset test on their MSP programs. The result, not surprisingly, is that the vast majority of MSP-eligible individuals are not enrolled. Urban Institute researchers estimate that two thirds of beneficiaries eligible for QMB, and fully 87 percent who are eligible for SLMB, are not enrolled.[2]

AARP also believes that there should be full coordination between the LIS and MSP programs. Applicants for either the LIS or MSP should be screened for both programs. Eligibility criteria should be simplified, standardized and harmonized to reduce confusion and unnecessary barriers created by varying state rules.

In addition, the QI program should be made permanent by folding it into the SLMB program so it is no longer subject to annual allotment caps and all eligible individuals can be assured of needed assistance.

First Steps

AARP is firmly committed to eliminating the asset test. Until the asset test is fully eliminated, AARP believes there are interim steps Congress can and should take that can significantly reduce the barrier it creates to the LIS and MSP.

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[1] CMS–4068–P, Medicare Program: Medicare Prescription Drug Benefit, 69 Fed. Reg. 46632: August 3, 2004

[2] Dorn, S. and Kenny, G.M., *Automatically Enrolling Eligible Children and Families into Medicaid and SCHIP: Opportunities, Obstacles, and Options for Federal Policymakers* (New York, NY: The Commonwealth Fund, June 2006).

AARP is proud to support the Prescription Coverage Now Act of 2007 (H.R. 1536), introduced by Representative Lloyd Doggett of Texas. This legislation takes solid first steps toward our goals of eliminating the asset test, increasing enrollment, and improving coordination between the LIS and MSP. We have worked closely with Rep. Doggett's office on this legislation, and greatly appreciate his strong leadership.

Raising the Limits: *Most importantly, this legislation would increase the asset test limits to 27,500 for individuals and $55,000 for couples. This will provide relief to millions of beneficiaries who truly need the help the LIS can provide. Even those who did not oppose an asset test in Medicare's drug plan agree that current limits—$11,710 for individuals, $23,410 for couples—are far too low.*

Streamlining the Application: *In addition to raising the asset limits, Rep. Doggett's legislation would streamline the LIS application in two very important ways. First, it would eliminate the question about the cash value of life insurance. Asking for the cash value of life insurance makes the application process unduly difficult—this is information that people—regardless of income—simply do not have on hand. Asking for this data needlessly lengthens the application form and requires individuals to calculate the cash value figure. This unnecessary and harmful red-tape barrier to the LIS application needs to be removed.*

The legislation would further streamline the LIS application by deleting the confusing and embarrassing question about whether someone gets occasional help from family or charities with living expenses like groceries. Many low income people get assistance from family, churches, and food banks on a highly irregular, as-needed basis and in very limited amounts. This question, however, requires applicants to enter a specific average monthly amount. Given the often irregular nature of such assistance, this is a figure that many people are unlikely to know with any degree of accuracy. And those who rely on such assistance are the same individuals who are most in need of the LIS.

Efficiently Targeting Outreach: The Prescription Coverage Now Act would also help SSA target its LIS outreach efforts to beneficiaries who meet the LIS income criteria. The bill would allow Social Security officials to use IRS data—data they already have to determine income-related Part B premiums—to also determine who meets LIS income criteria. SSA could then much more efficiently and effectively target LIS outreach efforts to just these individuals. Currently, the IRS verifies income data submitted by people who apply for the LIS, but SSA does not have authority to use the IRS data it already has to determine which Medicare beneficiaries have incomes that meet LIS eligibility criteria for outreach purposes. The HHS Inspector General has said that legislation authorizing this limited use of income data would help to more effectively and efficiently target LIS outreach efforts.[3]

Coordinating the LIS and MSP: Rep. Doggett's legislation takes an additional important step of requiring SSA to screen LIS applicants for MSP eligibility. Full coordination between the LIS and MSP would mean that many more low-income beneficiaries would get needed help with both Part D and traditional Medicare premiums and cost-sharing obligations. Additional important provisions in the Prescription Coverage Now Act would:

- keep the LIS cost sharing affordable by indexing it to the general inflation rate, rather then the increase in overall Part D costs as under current law;
- exclude the value of LIS benefits from counting against eligibility for other low-income assistance programs; and
- permanently waive the late enrollment penalty for people enrolled in the LIS.

AARP is committed to working diligently to ensure this important legislation is enacted into law this year.

Additional Steps

While the Prescription Coverage Now Act is a critical first step, there are additional legislative steps that can and should be taken to help low-income Medicare beneficiaries. For example, people who are not eligible for the LIS or MSP may be eligible for a state pharmacy assistance program (SPAP). These state-funded programs often help people with income and asset levels above the LIS and MSP eligibility cut-offs. A system to coordinate enrollment applications between LIS/MSP and these programs also could prove to be very useful. Action also is needed to make MSP eligibility criteria consistent across the states and make the QI program a permanent and reliable source of assistance. We know that members of this Committee

[3] Identifying Beneficiaries Eligible for the Medicare Part D Low-Income Subsidy, Daniel R. Levinson, Inspector General, November 17, 2006, http://oig.hhs.gov/oei/reports/oei-03–06–00120.pdf

are working to develop legislation to address this concern and we look forward to working with you.

In addition, AARP supports legislative efforts to improve the Part D benefit by:

- eliminating co-pays for Medicaid beneficiaries who get long term care services in Home and Community Based Service (HCBS) programs, as is done now for beneficiaries receiving these services in nursing homes;
- counting payments by federally qualified health clinics, AIDS drug assistance programs, the Indian Health Service and drug company Patient Assistance Programs (PAP) toward the Part D "doughnut hole" coverage gap; and
- increasing funding for State Health Insurance Programs, which provide the one-on-one counseling that is most helpful to beneficiaries applying for the LIS.

Conclusion

The Medicare prescription drug benefit represents the most significant change to Medicare since the program began in 1965. The extra financial help provided to people who most need it through the LIS is a key component of this achievement, but its success is far from complete.

It is critical that we eliminate the asset test that is penalizing people who save for retirement and imposing a barrier to enrollment in the LIS. The Prescription Coverage Now Act is an important first step to eliminating the asset test and ensuring that more people who need the assistance the LIS provides can get it. We are committed to seeing its enactment this year, and we look forward to working with members of Congress from both sides of the aisle to improve the new Medicare prescription drug benefit and to ensure that all older Americans have access to affordable prescription drugs.

Statement of American College of Physicians

The 123,000 internal medicine physicians and medical student members of the American College of Physicians congratulate Chairman Stark and the members of the House Ways and Means Subcommittee on Health for convening today's hearing on "on protecting beneficiaries in Medicare Part D plans." The College believes that while the addition of a prescription drug benefit to Medicare through the Medicare Modernization Act of 2003 significantly contributes to improved health and quality of life for our seniors and disabled Americans, there are ways to improve this program to enhance its effectiveness. The College appreciates this opportunity to share with the Committee our observations and related recommendations to achieve this goal.

The College has long supported the addition of prescription drug coverage under Medicare. Prescription drugs are an essential tool for treating and preventing many acute and chronic conditions. In 1965, when Medicare was first established, pharmaceutical therapies were not as commonly available as they are now, and outpatient prescription drugs were not nearly as important a component of health care. Today, however, they are a primary form of medical care and often substitute for more costly therapies. The growing importance and increased use of prescription drugs have had a disproportionate impact on the elderly, who use prescription drugs more extensively than the general population because of high rates of chronic illness.

Recent survey data reflects that most Medicare beneficiaries are satisfied with their Part D plan and believe it is saving them money.[1] A review of the literature and the observations of our members reflect areas that need to be improved to ensure that access to these important medications is available to all beneficiaries and that the most effective medication is received in a timely manner. The College requests that the Committee consider the following:

- **Congress should pass legislation to facilitate increased enrollment for the Part D low income subsidy (LIS).** The current Part D benefit provides a low income subsidy (LIS) to beneficiaries with incomes below 150 % of the federal poverty level. This subsidy significantly reduces or eliminates premium payments and provides for substantially reduced copayments for medications. Without the LIS, many of these low-income individuals are unable to obtain the

[1] Kaiser Family Foundation/Harvard School of Public Health. Seniors and the Medicare prescription drug benefit. December 2006. Accessed at http://www.kff.org/kaiserpolls/upload/7604.pdf on 19 June 2007

medication they require. Recent data [2] indicates that over 3 million beneficiaries who meet the income requirement for the LIS are not receiving the subsidy and are not enrolled in a Part D program. The non-partisan Commonwealth Fund recently outlined a series of recommendations to address this problem that include removing or modifying of the overly restrictive asset requirement, simplifying of the enrollment process and providing improved means for beneficiaries to navigate the process.[3] The College recommends that Congress consider implementation of these recommendations.

- **Congress should pass legislation to make the Part D benefit less complex and provide both beneficiaries and their physicians with more essential information to make plan choices and treatment decisions.**
- Survey data indicates that 73 % of seniors, 91 % of pharmacists and 92 % of physicians agree that the current Part D benefit is overly complex.[4] The typical beneficiary has a choice of anywhere from 45–60 drug plans to choose from in their local area; each with a different premium, deductible, co-payment structure and formulary. In addition, important formulary information regarding the plans use of prior authorization and utilization management procedures (e.g. tiering, step-therapy) is often not readily accessible. These problems make it difficult for beneficiaries, often in consultation with their personal physicians, to choose the plan that best needs their medication needs. The College recommends that;
- **Congress should consider legislation to reduce the number of plan choices available to beneficiaries.** One possible option is to use an approach similar to how Medigap plans are currently offered—drug plans would be able to offer only a limited number of standard benefit designs which are defined by Congress.
- Congress should provide the Centers for Medicare and Medicaid Services (CMS) with increased authority (including facilitating its ability to enact financial penalties) to ensure that all Part D plans make essential formulary information, including prior authorization and utilization management information, easily accessible at least through placement on their web site and through contact with a designated plan representative.
- **Congress should provide increased funding to the State Health Insurance Assistance Programs (SHIPs) in each state.** These programs, often provided through the local Office on Aging, offer the one-on-one counseling to Medicare beneficiaries that is often needed to help navigate the current complex process of choosing the most beneficial drug plan. It is reported that these programs are currently overwhelmed and require increased funding to adequately provide these services.
- **Congress should pass legislation to improve the Part D benefit's exception and appeals process.**

Our members continue to report multiple occasions when the medication they prescribe for a beneficiary cannot be fulfilled at the pharmacy due to it not being in the plan's formulary, or due to various prior authorization or utilization management requirements. As noted above, having information about these formulary limitations for each plan easily available to the prescribing physician would significantly reduce the frequency of these events. Nonetheless, there are occasion when the patient must have the specifically prescribed medication, and the patient and his or her physician must request an exception to the formulary limitation. The current exceptions and appeals process is overly complex and evidences several problems that interfere in the beneficiary obtaining their required medication in a timely manner. The College believes that the current exceptions and appeals process can be improved by the following recommendations:

- **Congress should pass legislation to simplify and make more uniform the exceptions and appeals process.** Currently, while CMS has encouraged each plan to accept a standardized exception and appeals request form developed by the American Medical Association Part D Workgroup, each plan continues to devise its own processes, standards of medical necessity, and criteria

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[2] The Commonwealth Fund. Improving the Medicare Part D program for the most vulnerable beneficiaries. May 2007. Accessed at http://www.commonwealthfund.org/usr_doc/Summer_improvingMedicarepartD_1031.pdf?section=4039 on 19 June 2007

[3] The Commonwealth Fund. Improving the Medicare Part D program for the most vulnerable beneficiaries. May 2007. Accessed at http://www.commonwealthfund.org/usr_doc/Summer_improvingMedicarepartD—1031.pdf?section=4039 on 19 June 2007

[4] Kaiser Family Foundation/Harvard School of Public Health. Seniors and the Medicare prescription drug benefit. December 2006. Accessed at http://www.kff.org/kaiserpolls/upload/7604.pdf on 19 June 2007

for reviewing requests for exceptions and other coverage determinations. This complexity confuses the beneficiary and adds excessive burden to the physician practice attempting to assist the beneficiary in obtaining the needed medications. Legislation to require increased standardization of the process and criteria plans use for exceptions and appeals would significantly improve the situation.

- **Congress should provide CMS with increased authority to ensure that beneficiaries receive essential information in a timely manner to challenge a plan's coverage decision.** Pharmacies are currently required by regulation to either post or hand to beneficiaries a generic notice explaining their rights to request an exception to a coverage decision when a prescription is denied. It has been the experience of our members and beneficiary advocates that this information is often not provided by the local or mail order pharmacy, leaving the beneficiary to either have to pay for the drug without any coverage or go without the drug. The College recommends that Congress provide CMS with increased authority (including facilitating its ability to enact financial penalties) to ensure that this information is routinely provided in a timely manner.
- **Congress should pass legislation that requires plans to give deference to the supporting statement of the medical expert.** Current language in the Medicare statute indicates that physician statements are appropriate support for formulary exceptions and CMS guidance to plans indicates that these statements should be given significant consideration. Unfortunately, these statements are not supported within the Part D appeal regulations that instruct that physician's opinions do not control determinations about requests for exceptions. This opens the door for too many decisions on care to be made for financial reasons, as opposed to medical considerations. It is recommended that the Part D language be changed to give deference to the statement of the medical expert—the physician. The treating physician's clinical judgment should be over-ruled only by reference to objective, verifiable medical evidence.
- **Congress should pass legislation that provides Part D covered beneficiaries with increased access to "off-label" use medications.** Physicians frequently prescribe medications for indications not expressly approved by the Federal Drug Administration for inclusion on the drug's label and patient insert information. Off-label medications are often used in the treatment of many chronic and progressive medical conditions (e.g. cancer, multiple sclerosis.) The current Medicare Part D statute allows plans to deny coverage for off-label indications that are not expressly recognized in a limited number of specified drug compendia. This restriction is much more limited than prescribed under Medicare Part B policy[5] and more restrictive than standards employed by most private sector health plans. The College recommends that the language be changed to be consistent with the less restrictive language found within the Medicare Part B regulations, which takes into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.
- **Congress should direct CMS to identify selected Part B and Part D overlap drugs and direct plans to always cover them under Part D.** There are a significant number of medications that can be covered under either Medicare Part B or Part D. The decision depends upon such factors as patient diagnosis, timing of treatment, use of durable medical equipment and the location of dispensing the medication. Often, Part D plans will delay approval of these "overlap" medication under a prior authorization restriction until additional information is obtained. This delays the beneficiary from receiving the medication in a timely manner, and provides substantial unnecessary burden on both the pharmacist and the prescribing physician. Recently, MedPAC[6] has recommended that Congress direct CMS to identify selected Part B and Part D overlap drugs and direct plans to always cover them under Part D. Furthermore, MedPAC indicated that the identified drugs should be low cost and covered under Part D most of the time. The College supports this recommendation.
- **Congress should pass legislation to permit coverage for appropriate preventive vaccines under Medicare Part B instead of Part D and not include the cost of these vaccines within the Medicare sustainable growth rate (SGR) calculation.** The Medicare Modernization Act specified

[5] Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual. Chapter 15, Section 50.4.2. Accessed at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf on 19 June 2007

[6] MedPAC. Issues in Medicare coverage of drugs. Report to Congress: Promoting Greater Efficiency in Medicare (June 2007). Accessed at http://medpac.gov/chapters/Jun07—Ch07.pdf on 19 June 2007

that all new preventive vaccines be covered under Medicare Part D. This legislation did not affect the three preventive vaccines that were already covered under Medicare Part B, i.e. hepatitis B, pnuemoccocal and influenza vaccine. Physicians, medications suppliers and beneficiaries are all familiar with the well established methods of paying for the vaccines and its administration under Medicare Part B. While various approaches have been suggested (delivery through a specialty pharmacy, use of a web portal), there is no proven effective method to pay providers for the cost of the vaccine and its administration through the Part D plans. This problem has recently been highlighted by the introduction of a herpes-zoster vaccine into the market place. In most cases, beneficiaries who currently want this vaccine are required to pay their physician the full cost of the vaccine (approximately $200) and then attempt to be reimbursed for this cost by the Part D plan. This is clearly not an efficient method, and places the beneficiary at substantial risk of not receiving adequate reimbursement from the plan. Furthermore, our members have reported on beneficiary reluctance to follow their advice to take this preventive vaccine due to the high, up-front and at risk expense. In response to this problem, MedPAC has recently recommended that Congress should permit coverage for appropriate preventive vaccines under Medicare Part B instead of Part D.[7] The College supports this recommendation that will increase access to these newly approved preventive vaccines with the additional stipulation that the costs of these medications are not included as part of the Medicare sustainable grow rate (SGR) calculation used to determine rates under the Medicare Physician Fee Schedule. These costs should not contribute to the unrealistic more than 40 % cut in physician fees already projected from the faulty and ineffective SGR methodology over the next decade.

In summary, the addition of prescription drug coverage to the Medicare benefit significantly contributes to improved health and quality of life for our senior and disabled Americans. The College believes that the implementation of the following recommendations will further ensure that access to these important medications is available to all beneficiaries and that the most effective medication is received in a timely manner. These recommendations are:

- **Congress should pass legislation to facilitate increased enrollment for the Part D low income subsidy (LIS).**
- **Congress should pass legislation to make the Part D benefit less complex and provide both beneficiaries and their physicians with more essential information to make plan choice and treatment decisions. More specifically, it is recommended that:**
- **Congress should consider legislation to reduce the number of plan choices available to beneficiaries.**
- **Congress should provide the Centers for Medicare and Medicaid Services (CMS) with the authority (including the ability to enact financial penalties) to ensure that all Part D plans make all essential formulary information, including prior authorization and utilization management information, easily accessible at least through placement on their web site and through contact with a designated plan representative.**
- **Congress should provide increased funding to the State Health Insurance Assistance Programs (SHIPs) in each state. Congress should pass legislation to improve the Part D benefit's exception and appeals process. More specifically, it is recommended that:**
- **Congress should pass legislation to simplify and make more uniform the exceptions and appeals process.**
- **Congress should provide CMS with the authority to ensure that beneficiaries receive essential information in a timely manner to challenge a plan's coverage decision.**
- **Congress should pass legislation that requires plans to give deference to the supporting statement of the medical expert.**
- **Congress should pass legislation that provides Part D covered beneficiaries with increased access to "off-label" use medications.**
- **Congress should direct CMS to identify selected Part B and Part D overlap drugs and direct plans to always cover them under Part D.**
- **Congress should pass legislation to permit coverage for appropriate preventive vaccines under Medicare Part B instead of Part D and not**

[7] MedPAC. Issues in Medicare coverage of drugs. Report to Congress: Promoting Greater Efficiency in Medicare (June 2007). Accessed at http://medpac.gov/chapters/Jun07—Ch07.pdf on 19 June 2007

include the cost of these vaccines within the Medicare sustainable growth rate (SGR) calculation.

Statement of Assisted Living Federation of America

Mr. Chairman and members of the Subcommittee, thank you for allowing me to submit this written testimony.

In 2003, Congress enacted one of the most substantive changes to Medicare in recent memory, the Medicare Modernization Act (MMA). The prescription drug benefit (Part D) contained within the MMA has been well documented in providing access and affordability of prescription medicines to America's seniors. However, while Part D has brought control over their own health care into many seniors' own hands, Part D needs one significant change that will benefit over 100,000 seniors.

Recognizing the vulnerability of very low-income people living in long-term care settings such as nursing homes, The U.S. Congress exempted "dual eligibles" (people eligible for both Medicare and Medicaid) living in nursing homes from any co-payment for Part D prescription drugs.

Unfortunately, the MMA did not eliminate co-payments for dual eligible residents of *assisted living*, even though the residents of assisted living communities are usually "nursing-home eligible' by definition and have similar needs for medications. That is, while the individual living in a nursing home is exempt from co-payments for Part D prescription drugs, the individual living in an assisted living community is forced to pay the same co-payments for the same Part D prescription drugs.

Like nursing home residents on Medicaid, the over 100,000 assisted living residents (dual eligible) have very limited financial resources. Their personal needs allowances average $60 a month. For many of these assisted living residents, the amount of their Part D co-payments exceeds their monthly personal needs allowances.

Residents in nursing homes and assisted living use a similar number of prescriptions—approximately 8–10, according to recent studies. Even Part D co-payments of $1-$5 per prescription can present financial hardships for dual eligible assisted living residents, and, as we have heard from communities across the country, could impede people from receiving needed medications.

More and more, seniors are looking to assisted living as their preferred senior housing option. Time and again, we hear from seniors who are concerned about being forced to receive their long term care in an institutional setting such as a nursing home. As it stands, the MMA is effectively punishing those dual eligible seniors who have chosen assisted living—a community based alternative to nursing homes.

Congressional staff from both sides of the aisle have indicated to us that the inconsistency in the MMA described above occurred for no other reason than simple oversight on the part of proponents of this meaningful legislation.

The stated focus of this hearing was to focus on Medicare Part D, ongoing beneficiary protection issues in the new program, and possible statutory changes necessary to improve the program for beneficiaries and taxpayers.

Mr. Chairman and members of the Subcommittee: It is not often that we have an opportunity to go back and correct a mistake. You have, however, an opportunity to do just that. Over 100,000 dual eligible seniors in assisted living would be grateful for your swift action to provide this relief with a simple statutory change that corrects this oversight.

Thank you again for this opportunity.

Statement of Consumers Union

Thank you for holding today's hearing on Beneficiary Protections in Medicare Part D.

Consumers Union supports a number of improvements in the operation of the program that will help consumers deal with the confusing array of choices and administrative complexities in the current law.

But there is one key consumer protection that simply has not received enough attention—the apparent 'bait and switch' occurring for some beneficiaries when it comes to plan prices. Our research the past 19 months has found that even though

an individual may shop for a plan to find the best coverage for the drugs they take, the plan they select may dramatically increase its prices the following year, and the beneficiary is helpless because they are locked into that plan.

Consumers Union has been monitoring the price of five randomly selected drugs[1] in a zip code in five of the most populous states since December, 2005, and we continually see dramatic swings in the price of that package of drugs to consumers.

We looked at 60 plans in Texas zip 75135 that offered coverage in February 2007 and what the estimated annual cost to an enrollee was for those same drugs this June. Thirty-two (32) plans increased in cost, 20 stayed the same, and 8 decreased. The average increase was $195, with the range of changes varying between $3 and $480. A 480 increase is equivalent to a 19.8% increase in just one third of a year. While most of the plans increased in cost, a few decreased. Of the eight plans that decreased in cost, most only had minor changes, although there were two high-priced plans that decreased by about 25%.

In New York zip 00501, there were 61 plans offering coverage in February 2007 and we followed these plans until June. Thirty-five (35) plans increased in cost, 17 stayed the same, and 9 decreased. The average increase was $178, with the range of changes varying between $2 and $603. For the plan that increased $603, this is equivalent to a 26% increase. As in the case with Texas, most of the plans increased in cost, and only a few decreased. The majority of the plans that decreased in cost had minor price changes, the largest being 7.7%.

The good news is that some plans do not increase prices. Consumers need to know which plans offer the most price stability. We believe CMS needs to do a better job in monitoring, disciplining and not renewing those plans that offer a low price in the fall open enrollment season, yet raise the price on a package of commonly prescribed drugs in the following months at a rate higher than medical inflation.

We urge you to consider legislation to require plans to tell consumers what the price change has been during the year on a package of the 100 most commonly prescribed generics and 100 most commonly prescribed brands.[1] Plans which increase costs on this broad package of drugs more than a certain percentage—such as the medical economic index—should not be permitted to renew in the following plan year. Another option is to allow people who enroll in a plan which has large price increases to leave at any time and join another plan with more price stability.

These measures would greatly enhance consumers' ability to make cost-effective choices in selecting a Medicare Part D plan. And they also would hold plans accountable for controlling spiraling drug costs. Thank you for your consideration of these views.

Sincerely,

William Vaughan
Senior Policy Analyst

With an exceptions process, of course, for unavoidable plant closures and supply disruptions due to accident, disasters, etc.

Statement of Long Term Care Pharmacy Alliance

INTRODUCTION

Chairman Stark, Ranking Member Camp, and Distinguished Members of the Subcommittee, the Long Term Care Pharmacy Alliance (LTCPA)[1] mmends your leadership in holding this important hearing to address issues related to beneficiary protections in Medicare Part D plans. LTCPA appreciates the opportunity to share the experiences and perspectives of its member pharmacies as the Committee considers ways to strengthen the Part D program for beneficiaries.

More than 1.6 million Medicare beneficiaries reside in long-term care (LTC) facilities nationwide. These patients, who can no longer care for themselves, are among the most vulnerable individuals served by the new Medicare drug benefit program. They are typically older, may suffer multiple chronic conditions, and are frequently cognitively impaired.

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[1] Lipitor 10mg; Altace 10 mg; Celebrex 200 mg; nifedipine ER 30 mg; Zoloft 100 mg.

[1] *The Long Term Care Pharmacy Alliance (LTCPA) represents the nation's major long-term care pharmacy providers. Together, LTCPA's members serve more than 1.5 million people—including more than two-thirds of all nursing facility residents—through networks of nearly 500 pharmacies nationwide.*

LTCPA's member pharmacies dispense medications and provide specialized services tailored to the needs of patients in nursing homes, assisted living facilities, hospice programs, and similar institutional sites of care. Since passage of the 2003 Medicare Modernization Act (MMA), LTC pharmacies have been working with health care professionals, patient advocates, private plans and the Centers for Medicare and Medicaid Services (CMS) to make the new Medicare drug benefit responsive to the needs of this frail elderly population.

Congress largely tasked CMS with defining the details of this benefit for the LTC segment of the Medicare population. The Agency has made considerable strides, operating within its understanding of its existing authorities, to make the Medicare Part D program "work" for beneficiaries residing in LTC facilities. However, LTC residents continue to face significant challenges in obtaining full access to medically necessary drugs under Part D.

To strengthen the Medicare drug benefit in the LTC setting, LTCPA respectfully submits the following recommendations for consideration. We look forward to working closely with members of the Ways and Means Committee in improving protections for Medicare beneficiaries under Part D.

RECOMMENDATIONS

I. *LTC Standards For Part D Plans*

In implementing the new drug benefit, CMS has relied heavily on subregulatory guidance to encourage plans to comply with its stated policies. In March 2005, the Agency released two guidance documents designed to make Part D more responsive to the particular needs of enrollees residing in LTC settings:

- *Long-Term Care Guidance*—Established ten core service and performance criteria for LTC pharmacies participating in plans' networks, and encouraged plans to incorporate these criteria into their contracts with LTC pharmacies.
- *Transition Guidance*—Established appropriate procedures for plans to ensure patients have access to needed medications upon entering a LTC facility.

These guidance documents include important protections for patients; however, they do not have the force of regulation or law. Plans' compliance may lessen as the program matures and Part D payments change or the guidance becomes "lost to history" over time.

Recommendation: **LTCPA urges the Subcommittee to codify CMS guidance documents as enforceable standards for Part D plans serving LTC residents.**

II. *Assistance For LTC Residents*

More than 70 percent of LTC residents are dually eligible for Medicare and Medicaid. These dual eligible beneficiaries were randomly auto-enrolled into Part D benchmark plans if they did not select a plan on their own.

However, Part D benchmark plans in each region vary widely in their coverage of drugs commonly dispensed to nursing home residents. In every region, there are benchmark plans that either do not have several common drugs on formulary or that subject them to drug utilization management controls, including prior authorization.

While LTC residents are eligible for a special enrollment period (SEP) to change plans, most do not know about this provision. Many also lack the cognitive ability or knowledge to evaluate complex plan offerings, but do not have a guardian or family member nearby to help.

Unfortunately, CMS Marketing Guidelines currently bar health care professionals (including physicians, nurses and pharmacists) from providing advice to nursing home residents in selecting a specific Part D plan. Further, CMS defines nursing homes as "non-benefit providing third parties" and prohibits nursing home administrators and staff from discussing specific plans with their residents.

This rule simply defies common sense. Nursing home staff and patients' physicians are most likely to know which Part D plans in a given region offer appropriate coverage for residents of LTC facilities. Absent an effective "gag order" from CMS, professional caregivers in nursing homes are well equipped to provide objective information about coverage options to residents who enter the facility, become eligible for Medicare, or desire to change plans.

Recommendation: **LTCPA urges the Subcommittee to authorize nursing facility caregivers and staff and residents' physicians to assist LTC residents in Part D plan selection and enrollment.**

III. ***Immediate Enrollment for LTC Residents***

Current CMS regulations treat LTC residents identically to other beneficiaries for enrollment purposes under Part D. That is, if a beneficiary enrolls in a new Part D plan, the new enrollment is effective the first of the following month. Prior to the Part D program, however, Medicaid drug coverage for dual eligibles residing in nursing facilities took effect on the date of application.

The CMS rule is highly problematic for LTC residents, because medication needs significantly change between the ambulatory and nursing home setting. A beneficiary will frequently change plans in that situation, forcing both the LTC facility and the LTC pharmacy to deal with a variety of different formularies and different drug utilization management procedures during the course of a single month.

These administrative hurdles put nursing facilities at risk for citations for failure to provide all necessary medications. LTC pharmacies also are at risk for failing to undertake their contractual obligations to provide prescription medications to residents in a timely fashion.

Recommendation: **LTCPA urges the Subcommittee to establish a process for Medicare Part D coverage to begin immediately upon plan enrollment for beneficiaries entering a LTC facility and for LTC residents who change their plan enrollment.**

IV. ***Protections For Assisted Living Residents***

In its regulations implementing Part D, CMS incorporated a preexisting definition of "long-term care facility." This definition did not include assisted living facilities, and citing a lack of statutory authority, the Agency did not expand its scope.

As a result, assisted living residents lack the same protections extended to nursing home residents under Part D. Yet dual eligible residents of assisted living facilities are also low-income and lack the resources to make co-payments under Part D. While they may be able to function in a less restrictive care setting, many assisted living residents nonetheless require specialized pharmacy services to meet their complex medication needs.

CMS has correctly recognized that many residents of assisted living facilities require the same core service and performance standards reflected in its Long-Term Care Guidance. Likewise, the Agency and federal policy-makers have actively promoted home and community-based services as an alternative to care in nursing facilities.

Recommendation: **LTCPA urges the Subcommittee to extend Part D's exemption from co-payments to include Medicare beneficiaries residing in assisted living.**

V. ***LTC Pharmacy Access***

Part D plans are not currently required to demonstrate that they have an adequate LTC pharmacy network with the experience, capacity, and contractual access to beneficiaries to fully serve all LTC residents in a given region. While CMS used the TriCare standards to establish network adequacy criteria for retail pharmacies serving ambulatory beneficiaries, the Agency did not set mandatory, quantifiable standards for plans' LTC pharmacy networks.

Instead, CMS simply asks that the plans "attest" they have sufficient numbers of pharmacies in their network that could meet certain performance and service criteria. Moreover, the current LTC pharmacy access standard fails to include the Agency's own definition of a LTC pharmacy as "a pharmacy owned by or under contract with a LTC facility to provide prescription drugs to the facility's residents" in its regulations.

CMS cannot currently confirm whether the pharmacies in a plan's LTC network can adequately serve the number of LTC pharmacy beds in the region, or whether those pharmacies have any actual experience providing services to residents of LTC facilities.

Recommendation: **LTCPA urges the Subcommittee to establish a LTC network adequacy standard to ensure all Part D plans have the capacity to serve at least 90 percent of their enrollees who reside in LTC facilities.**

VI. ***Protecting LTC Beneficiaries From Improper Cost-sharing***

Under Part D, dual eligible beneficiaries residing in LTC facilities are exempt from paying co-payments for their prescription drugs. However, since the launch of Part D, and continuing today, CMS has failed to accurately identify large numbers of dual eligible LTC residents and provide complete and accurate data to Part D plans. Some pharmacies report that CMS and Part D plan databases continue to fail to identify as many as 20 percent of dual eligible beneficiaries in some nursing homes, and there is little evidence that progress is being made to reduce that failure rate.

As a result, most Part D plans have improperly assessed co-payments for prescription drugs provided to large numbers of dual eligible LTC residents. Those co-payments have been—and continue to be—withheld from payments owed by Part D plans to LTC pharmacies. To date, tens of millions of dollars have been wrongly withheld. LTC pharmacies have sought to collect the unpaid amounts directly from Part D plans, recognizing that dual eligible LTC residents are not liable for co-payments. Given the enormous financial strain of carrying this debt, however, the situation has become untenable for LTC pharmacies and must be resolved.

CMS has advised plans that they can accept a LTC pharmacy's "best available evidence" that a beneficiary is a dual eligible LTC resident in order to resolve co-payment claims. Such evidence could include a Part D enrollee's Medicaid and Medicare numbers, the date the beneficiary entered the LTC facility and an attestation from the LTC pharmacy that it did not collect a co-payment.

Unfortunately, CMS has failed to develop and enforce clear procedures for using "best available evidence" to resolve past claims and to prevent wrongly assessed co-payments in the future. As a result, most Part D plans have not acted on the Agency's guidance, and LTC pharmacies have had very limited success in recovering improperly withheld co-payments from Part D plans.

Recommendation: **LTCPA urges the Subcommittee to direct CMS to develop and implement procedures to identify dual eligible LTC residents who are exempt from cost-sharing and to protect those beneficiaries from improperly assessed co-payments.**

VII. ***LTC Plan Quality***

CMS collects data from Part D plans on a number of variables (*e.g.*, aggregate counts of the number of exceptions requests, grievances, etc.). The Agency relies on the data to report to Congress on various aspects of the ongoing implementation and operation of the Part D program.

However, the MMA did not require any separate reporting by CMS or the plans regarding Part D services to LTC residents. Neither CMS nor the plans currently report the number of enrollments and disenrollments, the number of LTC residents' exceptions requests that were approved or disapproved, or the number of appeals and grievances filed in the LTC setting.

Recommendation: **LTCPA urges the Subcommittee to direct CMS to collect data and report annually to Congress on the quality of Part D plans' drug coverage for LTC residents.**

CONCLUSION

LTCPA makes the following recommendations to strengthen Part D in the LTC setting:

- Codify CMS guidance documents as enforceable standards for Part D plans serving LTC residents;
- Authorize nursing facility administrators and staff and patients' physicians to assist LTC residents in Part D plan selection and enrollment;
- Establish a process for Medicare Part D coverage to begin immediately upon plan enrollment for beneficiaries entering a LTC facility and for LTC residents who change their plan enrollment;
- Extend Part D's exemption from co-payments to include Medicare beneficiaries residing in assisted living facilities;
- Establish a LTC network adequacy standard to ensure all Part D plans have the capacity to serve at least 90 percent of their enrollees who reside in LTC facilities;

- Direct CMS to develop and implement procedures to identify dual eligible LTC residents who are exempt from cost-sharing and to protect those beneficiaries from improperly assessed co-payments; and
- Direct CMS to collect data and report annually to Congress on the quality of Part D plans' drug coverage for LTC residents.

The nation's LTC pharmacies are committed to ensuring the safe and timely delivery of necessary medications and specialized pharmacy services to their patients. To that end, LTCPA welcomes the opportunity to work with members of the Ways and Means Committee to improve Medicare prescription drug coverage for beneficiaries residing in LTC facilities.

Submitted by:

Darrell McKigney
Acting Executive Director
Long Term Care Pharmacy Alliance

Statement of Mental Health America

Mental Health America is dedicated to helping all people live mentally healthier lives. Our network of over 320 state and local affiliates nationwide includes advocates, consumers of mental health services, family members of consumers, providers of mental health care, and other concerned citizens—all dedicated to improving mental health care and promoting mental wellness. Last November, we changed our name from the National Mental Health Association to Mental Health America in order to better communicate how fundamental mental health is to overall health and well-being.

Many Medicare beneficiaries struggle with mental illnesses, often alone and without medications that have proven widely effective and that would likely ease their symptoms and lead to recovery. Some 20 percent of older Americans experience mental disorders, such as anxiety disorders, mood disorders (including depression and bipolar disorder), and schizophrenia.[1] However, two-thirds of older adults living in the community who need psychiatric services do not receive them.[2] Furthermore, individuals receiving Medicare because of a disability also frequently experience mental illness. According to a survey by the Kaiser Family Foundation, psychiatric disorders, such as schizophrenia, bipolar disorder, and depression, were the second most commonly reported conditions among beneficiaries with disabilities,[3] and over two-thirds of Medicare beneficiaries with disabilities say they often feel depressed.[4]

Strengthen Protection for Six Drug Classes of Clinical Concern

We strongly support the policy established in sub-regulatory guidance by the Centers for Medicare and Medicaid Services (CMS) directing Medicare Part D prescription drug plans to cover all or substantially all medications in six key categories, including anti-depressants, anti-psychotics, and anti-convulsants. However, not all beneficiaries in need of these medications have benefited from this policy presumably due to a failure by certain plans to abide by this sub-regulatory guidance. Failure of this policy to function as intended has had a particularly harmful impact on dual eligible beneficiaries. A recent survey by the American Psychiatric Institute for Research and Education (APIRE) of psychiatrists treating dual eligibles found that in 2006 over half of the dual eligible psychiatric patients studied had at least one problem accessing their medications and 69 percent of patients with access problems experienced a significant adverse clinical event, such as an emergency room visit, hospitalization, homelessness, or incarceration in jail or prison (compared to 40 percent among patients with not access problems).[5]

Clearly, this policy requiring coverage of the six key classes must be strengthened to improve plan compliance. Moreover, because this policy has been established through sub-regulatory guidance it must be renewed every year which gives the

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[1] Administration on Aging, U.S. Department of Health and Human Services, *Older Adults and Mental Health: Issues and Opportunities*, 2001, p. 9.

[2] Medicare Rights Center, *Medicare Facts and Faces*, October 2001.

[3] The Henry J. Kaiser Family Foundation, *Understanding the Health-care Needs and Experiences of People with Disabilities: Findings from a 2003 Survey*, December 2003, p. 4.

[4] Ibid.

[5] American Psychiatric Institute for Research and Education, *The Impact of Medicare Part D on Medication Access and Continuity: Preliminary Findings from a National Study of Dual Eligible Psychiatric Patients*.

Part D plans the opportunity to exert substantial pressure on CMS each year to revoke this critical protection. We urge the Committee to develop and work toward enactment of legislation codifying the protections CMS has established for the key drug classes of clinical concern.

Comprehensive coverage of medications in these categories is crucial because of the often idiosyncratic responses to different medications within these classes, which are based on a wide range of individual factors. The effect of these drugs can vary based on the age of the individual consumer, their genetic and cultural background, whether the consumer has any co-occurring illnesses, and even variations in metabolic rate. These medications can have distinctive effects on cognitive functioning that vary among individuals and cause idiopathic side-effects that greatly influence medication tolerability in individual consumers. As a result, these drugs are not generally interchangeable and not suitable for common utilization management techniques that focus solely on cost.

Thus, we are concerned by several of the exceptions CMS has made to the policy regarding the six key classes. We are concerned, in particular, by the exception to allow plans to exclude medications when another medication with the same active ingredient is included on the plan's formulary. Medications that share the same active ingredients often have differing side effects, profoundly affecting whether a consumer continues treatment. We also oppose the exception to allow plans to exclude extended release versions of these protected classes of medications. Extended release versions of psychotropic medications can greatly facilitate adherence to treatment regimens by reducing the frequency or severity of the side effects associated with some of these medications—side effects that can themselves be disabling.

In addition, we have urged CMS to prohibit or severely limit the application of dosage or quantity limits to medications in the protected classes. Quantity limits on mental health medications can have particularly harmful effects on consumers. Even a small decline in the use of mental health medications can cause deterioration of an individual's health and increased emergency room visits.

Finally, we strongly support the CMS policy that plans must not apply prior authorization or step therapy requirements to beneficiaries already taking these protected medications, and that plans are to assume an enrollee is already taking a medication if it cannot be determined at the point of sale whether they are requesting a refill or a new fill of a prescription. Adherence to this policy by Part D plans is vitally important to prevent beneficiaries from being forced to switch mental health medications which can have serious adverse effects. However, the APIRE survey found that approximately 28 percent of the dual eligible psychiatric patients studied were previously stabilized on a medication but had to switch to a different medication than was clinically desirable. Thus, we urge the Committee to include in legislation codifying the protections for the six key drug classes, restrictions on the use of prior authorization and step therapy requirements with these medications.

Repeal Exclusion of Benzodiazepines and Barbiturates from Part D

Although anti-depressants, anti-psychotics, and anti-convulsants are essential categories of medications for treating mental illnesses, there are other psychotropic medications that are also commonly used to treat mental disorders, including benzodiazepines and barbiturates. Unfortunately, the Medicare Modernization Act excluded coverage of these medications from the Part D benefit. Benzodiazepines are highly effective treatments for acute anxiety in the elderly, for panic disorders, and for short term treatment of insomnia. Abrupt discontinuation of these medications can result in severe withdrawal symptoms. The APIRE survey found that 28 percent of patients studied had problems accessing benzodiazepines and 38 percent of these patients were hospitalized. Thus, we urge the Committee to act on legislation repealing the exclusion of benzodiazepines and barbiturates from the Part D benefit.

Although most states cover benzodiazepines and barbiturates through their Medicaid programs for duals eligibles, requiring these very low-income, vulnerable beneficiaries to use a different program just to access these particular medications is very confusing and many will not be aware of this special provision for these medications. In addition, this approach creates additional administrative barriers to accessing these medications. And, finally, although most states do cover benzodiazepines and barbiturates for some Medicaid beneficiaries, many limit this coverage only to those who are categorically eligible and thus exclude the medically needy population who spend down their incomes on medical expenses to become eligible for Medicaid. In addition, some states do not cover all benzodiazepines and barbiturates.

We commend Chairman Stark and other members of the Committee for your leadership in introducing legislation to address the shortcomings in mental health care

under Medicare and urge you to build on those efforts by codifying into law the CMS policy requiring Part D plan coverage of all medications in the six drug classes of clinical concern and by repealing the exclusion of benzodiazepines and barbiturates from Part D.

Statement of National Association of Drug Chain Stores, Alexandria, Virginia

Beneficiary Protections in Medicare Part D

Chairman Stark, Ranking Member Camp, and members of the House Ways and Means Subcommittee on Health, the National Association of Chain Drug Stores (NACDS) is pleased to submit this statement for this important hearing on current beneficiary protections in the

Medicare Part D prescription drug 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.

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 believe 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 a plan's network. 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 believe that CMS has developed a workable, practical approach to implementing this provision with the result that it will increase 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 National Center for Assisted Living

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, particularly 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 dually eligible beneficiaries (those covered by both Medicare and Medicaid) 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 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 thank Senator Gordon Smith (R–OR) and the nine co-sponsors—Senators Jeff Bingaman (D–NM), Barbara Boxer (D–CA), Sherrod Brown (D–OH), Maria Cantwell (D–WA), 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 (see attached letter to Senator Smith from these organizations dated June 11, 2007). We ask that the House immediately introduce companion legislation.

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.

For more information, please contact NCAL Senior Policy Director Karl Polzer

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June 11, 2007
The Honorable Gordon H. Smith
United States Senate
Washington, DC 20510

Dear Senator Smith,

The organizations listed below strongly support legislation that would eliminate Medicare Part D co-payments for low-income residents of assisted living and residential care facilities and others receiving home and community-based services under Medicaid. We commend you and your co-sponsors for introducing *The Home and Community Services Copayment Equity Act of 2007 (S. 1107)* and urge passage of this legislation.

Recognizing the vulnerability of very low-income people living in long term care facilities such as nursing homes, Congress exempted dual eligibles (people eligible for both Medicare and Medicaid) living in these facilities from any cost-sharing for Part D prescription drugs. Unfortunately, the original Part D legislation did not eliminate co-payments for dual eligible residents of assisted living and residential care, even though this population is usually "nursing-home eligible" by definition and has similar needs, incomes and vulnerabilities. Like nursing home residents on Medicaid, the 121,000 dual eligibles in assisted living and residential care have very limited financial resources, often just a few dollars a month from a personal needs allowance. For many of these residents, the amount of their Part D co-payments exceeds their monthly personal needs allowances.

Residents in nursing homes and assisted living and residential care use a similar number of prescriptions—approximately 8–10, according to recent studies. Even

Part D co-payments of $1—$5.35 per prescription can present financial hardships for dually eligible assisted living residents, and, as we have heard from facilities across the country, could impede people from receiving needed medications.

Passage of *S. 1107* would eliminate Part D co-payments for about 1 million dual eligible beneficiaries, including residents of assisted living and residential care as well as other licensed facilities such as group homes for people with mental retardation and developmental disabilities, psychiatric health facilities and mental health rehabilitation centers. Dual eligibles receiving services under home and community-based waivers in a home setting would also be relieved of Part D co-payments under the bill.

We would like to thank you and your colleagues for introducing this legislation and look forward to working with you to ensure its passage.

Letter to Senator Smith

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Sincerely,

Alliance for Holistic Aging
Alzheimer's Association
American Academy of Home Care Physicians
American Association of Homes and Services for the Aging
American Geriatrics Society
American Health Care Association
American Medical Directors Association
American Network of Community Options and Resources
American Seniors Housing Association
American Society of Consultant Pharmacists
Assisted Living Federation of America
Benjamin Rose Institute
Center for Medicare Advocacy
Consumer Consortium on Assisted Living
Developmental Disabilities Nurses Association
Epilepsy Foundation
Families USA
Long Term Care Pharmacy Alliance
Medicare Rights Center
National Adult Family Care Organization
National Alliance on Mental Illness
National Association of Boards of Examiners of Long Term Care Administrators
National Association for Home Care & Hospice
National Association of Local Long Term Care Ombudsmen
National Association of Professional Geriatric Care Managers
National Association of Social Workers
National Association of State Directors of Developmental Disabilities Services
National Association of State Ombudsman Programs
National Association of State Units on Aging
National Center for Assisted Living
National Community Pharmacists Association
National Multiple Sclerosis Society
NCCNHR: The National Consumer Voice for Quality Long-Term Care
The Arc of the United States
United Cerebral Palsy
United Jewish Communities
Washington State Long Term Care Ombudsman Program

Statement of National Home Infusion Association

The National Home Infusion Association ("NHIA") is pleased to present this written statement for the record in connection with the Ways and Means Health Subcommittee's June 21, 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.

It is now clear that 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. As explained below, Part D does not cover the infusion-related professional services, supplies and equipment necessary for the safe and effective provision of home infusion therapy. 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, as do some state Medicaid programs.

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. Specific home infusion therapies provided include anti-infectives, chemotherapy, pain management, inotropic therapy, hydration therapy, immunotherapy, steroid therapy, tocolytic therapy and others. Medical conditions treated with home infusion therapy include:

- Infections of all kinds, including respiratory, urinary tract, soft-tissue, post-operative infections, and pneumonia;
- Cancer and cancer-related pain;
- AIDS-related conditions such as anemia, malnutrition, and severe pain;
- Congestive heart failure;
- Immune deficiencies;
- Multiple sclerosis;
- Hemophilia

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 important 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, and since most beneficiaries cannot afford to pay home infusion ancillary costs out-of-pocket, 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 risk to the patients' health and their well being.

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:

- As described above, 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 Subcommittee that we are in regular communication with CMS officials on these issues and appreciate CMS' on-going efforts to address our concerns. However, in light of the over-arching structure of the Part D benefit, as well as its limitations described above, it is apparent that the coverage problems can only be resolved by a statutory change.

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.

Proposed Solution

On June 7, Representatives Eliot Engel and Kay Granger introduced the "Medicare Home Infusion Therapy Coverage Act" (H.R. 2567), which would provide comprehensive Medicare coverage of home infusion therapy. This legislation would continue to cover infusion drugs under Part D, but would cover home infusion therapy professional services, supplies and equipment under Medicare 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.

Because complex intravenous therapies that require extensive clinical services, care coordination, equipment, and supplies should be administered in adherence to stringent quality standards of care, H.R. 2567 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.

If enacted, this legislation would lower costs, produce better outcomes for beneficiaries, and implement rigorous quality standards. 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.

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.

For further information, please contact Russell Bodoff, Executive Director of NHIA

Statement of National Senior Citizens Law Center, Oakland, California

The National Senior Citizens Law Center (NSCLC) is please to submit this written statement to the House Ways and Means Committee's Subcommittee on Health on the topic of protecting beneficiaries of Medicare Part D. These comments are submitted by the Oakland, California office of NSCLC, which has particular responsibility in the organization for Medicare Part D advocacy and litigation.

NSCLC advocates nationally on behalf of the low-income elderly and persons with disabilities. We have been working with hundreds of legal services attorneys, State Health Insurance Assistance Programs (SHIP) counselors, and other lawyers and non-lawyer advocates for the elderly and disabled on Medicare Part D issues since the inception of the program. These contacts with advocates across the country have given us the opportunity to monitor closely the challenges that low income beneficiaries have faced in accessing benefits under Part D.

Medicare Part D, after a year and a half of implementation, fails to deliver consistent, guaranteed access to medically necessary drugs for all beneficiaries. The most vulnerable members of the Medicare population—dual eligibles (those who receive both Medicare and Medicaid) and other recipients of the Low Income Subsidy (LIS)—are in great need of increased protection. In this testimony, NSCLC urges Congress to act in four critically important areas: (1) access to the LIS for those determined or deemed eligible; (2) procedural protections for LIS recipients; (3) procedures allowing Medicare beneficiaries to obtain medically necessary drugs through exceptions and appeals; and (4) oversight, monitoring and complaint resolution for individuals, especially dual eligibles, who have problems getting drugs or the LIS.

I. *System Design Flaws Limit Access to Low Income Subsidy Benefits*

With the Medicare Modernization Act of 2003, Congress intended that the poorest, most vulnerable enrollees would receive the maximum level of protection. To this end, Congress mandated that dual eligible beneficiaries should be automatically enrolled in private drug plans, to ensure a seamless transition from Medicaid to Medicare drug coverage. In addition, dual eligibles receive the LIS without needing to apply. The LIS was designed also to assist other low-income beneficiaries who could not afford the high out-of-pocket costs associated with Part D.

For dual eligibles and others automatically entitled to the LIS, the process has not been seamless. Systemic delays and errors in the Medicare Part D system mean that the proper LIS subsidy often is not available at the pharmacy counter. According to the recent GAO report, the data management system established by CMS takes a minimum of five weeks to make LIS information accessible at the pharmacy for new dual eligibles. CMS admits that the process may result in delays of more than two months. In addition, advocates report that beneficiaries often experience a variety of glitches that cause them to get the wrong subsidy level or to lose the LIS entirely. These delays and errors are not mere inconveniences. Lack of subsidy can lead to full-blown medical crises for LIS beneficiaries who have no other means of accessing necessary medications.

Delays associated with the LIS also greatly undermine another beneficiary protection Congress created in the MMA: the continuous enrollment period that allows dual eligibles to change prescription drug plans at any time, effective the first day of the following month.[1] This important procedural protection means that if a dual eligible needs a drug not covered by the current plan's formulary, he or she can switch to a different plan that does cover the drug for the next month. Yet with the current flawed CMS system, requests to change plans frequently do not take effect in a timely manner, and LIS information may be further delayed or lost. When dual eligibles and other LIS individuals are not promptly transferred along with their subsidy, they cannot receive the full intended benefit of a continuous enrollment period.

If Medicare Part D is to provide full protection for LIS beneficiaries, an infrastructure for transferring data in real time is indispensable. The many Part D actors include private drug plans, the States, the SSA, pharmacies, and a multitude of government contractors. Without strong federal leadership, the current complex system will continue to breed widespread inefficiency, delays, confusion, and errors for beneficiaries.

To this end, Congress should establish a deadline for CMS conversion to a real-time data transfer system. With a single, central data system that all relevant parties could access in real time, LIS errors would be reduced and beneficiaries would receive fewer confusing mixed messages. Pharmacists

[1] CMS guidance now extends this enrollment period to all LIS recipients.

would receive reliable information about their customers' plan enrollment and subsidy status.

Most immediately, dual eligibles and other low-income beneficiaries desperately need an effective safety net for the times when the current system fails to deliver accurate LIS information. The current pharmacy-level safety net for dual eligibles, the Point of Sale (POS) mechanism, covers only one type of problem encountered by dual eligibles (delayed auto-enrollment).[2] Dual eligibles and others who encounter problems with the LIS or with plan membership are not permitted to access the POS mechanism for a temporary supply of medication.

Congress should requie CMS to expand the scope of this safety net to cover all LIS problems.

II. *CMS Drops LIS Recipients Without Adequate Due Process*

In late 2006, more than 630,000 low-income Medicare beneficiaries—eight percent of all LIS recipients—were dropped off of the LIS for 2007 because of a change in their Medicaid status. These individuals lost their subsidy effective January 1, 2007, unless they took some further action. Appropriately, given the administration's abandonment of this group's needs, this population was known as the "un-redeemed."

CMS failed to take appropriate procedural steps to ensure that this vulnerable population would continue to receive access to necessary medications. CMS did not review "un-redeemed" cases to determine whether their income and resources were low enough to remain eligible for the LIS or whether they could qualify for the LIS on some other basis. The agency simply terminated the benefit outright. While CMS asserted that the agency sent a notice to these individuals in September, many beneficiaries report never receiving it. Those who did receive the notice were told that they must apply with SSA to re-qualify.

"Un-redeemed" beneficiaries had no opportunity to appeal. As a result, individuals who were victims of a CMS mistake (i.e. who were in fact still receiving Medicaid) found themselves bounced back from drug plans to CMS to SSA and to State agencies. No governmental entity took ownership of this problem. To make matters more confusing, SSA implemented an entirely separate process for "redetermining" LIS eligibility for those who qualified for the LIS through an application with SSA.

Congress should require CMS to*:*

- **Establish sufficient procedural protections to ensure that no beneficiary drops off the LIS rolls because of loss of automatic eligibility without first being screened for all possible categories of LIS eligibility.**
- **Institute appropriate notice and appeal rights.**
- **Streamline and standardize CMS and SSA processes for reviewing LIS eligibility in order to minimize confusion.**

III. *The Exceptions and Appeals Process Needs Overhaul*.

The MMA gives all Medicare Part D beneficiaries a statutory right to appeal a drug plan's decision to deny coverage of a prescription drug. In practice, however, the procedures authorized by CMS are so complicated and contain so many major gaps that beneficiaries' ability to exercise that right is severely constrained.

Typically, a beneficiary learns that his or her prescription will not be covered by the plan at the pharmacy. The pharmacist receives a computer message of non-coverage. The beneficiary is then faced with the choice of paying full price for the drug (an impossibility for most dual eligibles and other LIS recipients) or going without needed medication.

Beneficiaries are given no specific information or assistance in requesting an exception to the formulary or otherwise appealing the denial of coverage. CMS does not even mandate that pharmacists share the specific reasons for the denial with the beneficiary, although specific denial codes are generally available. The beneficiary usually receives no specific notice of appeal rights. Instead, a generic notice is posted somewhere on a pharmacy wall, without plan-specific contact information. Most importantly, the beneficiary has no right to an emergency supply of drugs, even in circumstances of extreme hardship.[3]

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[2] The POS mechanism also suffers from other major flaws. For instance, pharmacists who contract with Part D plans are not required to use it. As one advocate explains, "I frequently hear from clients that pharmacists either don't understand POS billing or simply don't want to spend the time going through the steps to bill POS." Contact NSCLC for more information about flaws with the POS and how to fix them.

[3] Plans are required to have transition policies for medications on which a beneficiary is already stabilized, but beneficiaries to not enjoy these protections for new prescriptions.

If a beneficiary manages to find information about the appeals procedure, he or she will learn that the initial denial at the pharmacy cannot be immediately appealed; instead, the beneficiary must take the additional step of asking for a "coverage determination," a request that often must be supported by a doctor's statement. Each plan may have a different process for handling coverage determinations.

Once a beneficiary obtains a coverage determination, appeal rights finally begin. There are five different levels of appeals, beginning with reconsideration by the plan itself and ending with federal court review. Those without skilled advocates or patient doctors stand little or no chance of navigating this labyrinth of appeals. Moreover, advocates and beneficiaries report that plans often fail to adhere to the required timeframes; CMS does not appear to be monitoring this activity.

Congress could require simplification and streamlining of the appeals process. NSCLC recommends the follow steps, which could be accomplished by CMS regulation, guidance and enforcement.

- **Require plans to treat the denial at the pharmacy as a coverage determination, triggering notice requirements and appeal rights.**
- **Provide particularized notices stating the reason for denial and explaining procedures for contesting a determination.**
- **Require provision of temporary emergency drug supplies.**
- **Establish uniform procedures and criteria for all Part D drug plans.**

Another serious impediment to access to necessary and often life saving drugs, is the statutory limit on Part D coverage of off-label uses. Currently, the MMA permits Part D coverage of off-label uses only if those uses appear in one of three commercially prepared compendia, leading to significantly more restrictive coverage than is provided by many non-Medicare insurance plans, which cover off-label uses if support by peer-reviewed literature, and by Medicaid, which gives states appropriate flexibility in off-label coverage.

NSCLC recommends that Congress amend the MMA to provide Part D coverage of recognized off-label uses of medication when supported by a showing of medical necessary.

IV. *Oversight, Monitoring and Complaint Resolution Are Inadequate.*

The current CMS system for tracking and resolving complaints involving Medicare Part D is faulty. CMS relies too much on the private Part D plans to receive and respond to beneficiary complaints. This failure has two serious consequences: (1) dual eligibles and others do not get the help they need solving problems; and (2) CMS is not able efficiently to identify systemic problems and come up with effective, system-wide solutions.

When problems arise like those involving the Low Income Subsidy (described in Section I above), beneficiaries are not able to get the help that they need to resolve the problem, but are often bounced between plans and CMS. If a beneficiary contacts 1–800–MEDICARE, the customer service representative tells him or her to first contact the Part D plans, even though plan representatives are often unable or unwilling to untangle LIS data errors. Beneficiaries end up being sent from plan to agency and back again without resolution. As one experienced advocate told us, "My clients are not able to resolve these types of problems [with the Low Income Subsidy] on their own and they do not know who to contact for assistance. By the time they reach me, they are confused and exhausted by their fruitless efforts."

CMS has no way to track such frustrating experiences. CMS directs 1–800–MEDICARE customer services representatives (CSRs) not to keep a detailed record of the problems of callers who are referred to plans. CSRs have no capability to enter complaints about the Medicare Part D system itself (e.g., that CMS has not promptly transferred LIS information) into the CMS complaint tracking system. When callers do manage to file complaints successfully, the overwhelming majority of those are, once again, forwarded on to plans for resolution. CMS does little to determine the effectiveness of plans' complaint resolution. For all of these reasons, CMS' current monitoring system fails to capture the beneficiary experience. Relying only on aggregate complaint data and limited polling, CMS officials are often unaware of systemic problems faced by the most vulnerable Part D participants.

Increased Congressional oversight of CMS can help solve this problem.

Congress should:

- **Require CMS to establish a special ombudsman or other trouble-shooting office to get LIS and enrollment problems fixed quickly;**
- **Increase funding for State Health Insurance Assistance Programs (SHIPs), and community based organizations which provide the one-on-**

one counseling that is necessary in light of the complexities of Medicare Part D; and

- **Mandate continued, in-depth investigation of problems faced by dual eligibles and other low-income Medicare Part D beneficiaries.**

Thank you for the opportunity to submit this testimony. The National Senior Citizens Law Center would be pleased to work with the Congress to address the problems we have identified; please feel free to contact any of us.

Anna Rich, Liman Fellow
Katharine Hsiao, Co-Directing Attorney
Georgia Burke, Co-Directing Attorney
Kevin Prindiville, Staff Attorney

Statement of Alliance of Claims Assistance Professionals

Medicare Part D needs to streamline procedures for snowbirds. My clients are experiencing great difficulty because of address change forms and involuntary disenrollment due to relocation. Plan D members receive a flurry of forms they do not understand, and anxiety levels are high. If there were one government Medicare D plan, this would not be a problem. Privatization is costing more than it is worth. In Ohio, 59 private plans all have customer service with extended hours. How much is this costing taxpayers?

Recently, I called 1–800–medicare for a client under 65 who needs a D plan. The "benefit specialist" immediately launched into a hard sell on the Humana Advantage plan with pdp. She knew all the benefits of this plan down to the fine print. I reached her at a government agency—are taxpayers now paying to advertise products of a private insurance company?

Kathleen Hogue

MEDIFORM Inc.

Lisa,

What I have found is that patients were taken advantage of in that they thought they were enrolling for Part D and somebody signed them up for an Advantage plan. When they realized that their Physicians would not take that plan, they have a very difficult time re-enrolling in traditional Medicare.

Robin

I am in complete agreement.

What I heard from my congressman is that choices are good and probably the next generation of seniors will want the choices.....

In Connecticut we have 54 plans available this year. I am for choices, but I would not want to have that many choices. They are confusing to seniors and did not add any value to the program.

From the first year to the second year the overall quality of coverage decreased. If this trend continues we will be dwindling down to nothing.

Katalin

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