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EXAMINING THE FEDERAL GOVERNMENT'S PARTNERSHIP WITH AMERICA'S PHARMACISTS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

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EXAMINING THE FEDERAL GOVERNMENT'S PARTNERSHIP WITH AMERICA'S PHARMACISTS

TUESDAY, MAY 23, 2006

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

The subcommittee met, pursuant to notice, at 11:04 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Nathan Deal (chairman) presiding.

Members present: Representatives Upton, Norwood, Shadegg, Ferguson, Burgess, Barton (ex officio), Brown, Waxman, Pallone, Eshoo, Allen, Baldwin, and Dingell (ex officio).

Staff present: David Rosenfeld, Chief Health Counsel; Melissa Bartlett, Counsel; Bill O'Brien, Legislative Analyst; Brandon Clark, Policy Coordinator; Chad Grant, Legislative Clerk; John Ford, Minority Counsel; Jessica McNiece, Minority Research Assistant; and Jonathan Brater, Minority Staff Assistant.

MR. DEAL. Subcommittee will come to order. The Chair will recognize himself for an opening statement.

Today, we are holding a hearing entitled "Examining the Federal Government's Partnership with America's Pharmacists." As we all know, pharmacists are an integral and irreplaceable component of our healthcare delivery system, and we are here this morning to explore the prominent issues facing these healthcare professionals. To assist us in this task, I am proud to say that we have two expert panels of witnesses appearing before us, and I would like to sincerely thank each of them for taking the time out of their schedules to be with us.

Since the focus of this hearing is on the major issues facing pharmacists, we felt that it was important to include all the major players in the pharmacy delivery system in order to gain a full perspective of the issues. To this end, we have representatives from the Centers for Medicare and Medicaid Services, community pharmacists, chain drug store pharmacists, long-term care pharmacists, prescription drug plan distributors, and pharmacy benefit managers. It is important to note that the Minority has requested a witness from a beneficiary advocacy organization, but instead of expanding the focus of an already robust

hearing, we have confirmed our intent to hold another pharmacy hearing where the beneficiary input will be of focus. Of course, we have had beneficiary input in the past in previous hearings. We appreciate the Minority's willingness to work with us to put together this multi-faceted hearing here today.

There is no doubt that one of the major topics of discussion at today's hearing will be the provisions within the Medicare Modernization Act and the impact of the new Medicare prescription drug benefit. As my colleagues are aware, on January 1 of this year, prescription drug coverage for our seniors became more than just something we talked about in Congress. It became a reality for every single person eligible for Medicare. This legislation accomplished a very important thing. It helped tens of millions of senior citizens save thousands of dollars on their prescription drugs. For years before enactment of this new benefit, we heard the horror stories of seniors having to choose between buying groceries or their medicines, and pharmacists having to advise patients which drugs on their lists were the most important because the patient simply could not afford to buy all of their prescribed medications. Now, all the beneficiaries have the option to have good drug coverage and to have the quality of life that we want for our American seniors. In fact, more than 38 million people with Medicare now have good secure prescription drug coverage and enrollment in Medicare Part D related coverage accounts for over 32 million of these beneficiaries. These truly are astounding numbers that have exceeded almost everyone's expectations, and the unparalleled effort to get this brand new change to Medicare up and running and to get people enrolled has been incredible in itself.

Of course, the success of the new Medicare prescription drug benefit would not have been possible without the many people represented in this room today, and no group was more important than our pharmacists who truly were the heroes of the implementation of this new benefit.

Again, I want to thank our witnesses for taking the time to testify before us today, and I look forward to hearing from each of you.

At this time, I would like to ask unanimous consent that all committee members may have their statements and questions for the record submitted. Without objection, so ordered.

[The prepared statement of Hon. Nathan Deal follows:]

PREPARED STATEMENT OF THE HON. NATHAN DEAL, CHAIRMAN, SUBCOMMITTEE ON HEALTH

- The Committee will come to order, and the Chair recognizes himself for an opening statement.

- As we all know, pharmacists are an integral and irreplaceable component of our healthcare delivery system, and we are here this morning to explore the prominent issues facing these healthcare professionals.
- To assist us in this task, I am proud to say that we have two expert panels of witnesses appearing before us today, and I would like to sincerely thank each one of them for taking time out of their busy schedules to join us.
- Since the focus of this hearing is on the major issues facing pharmacists, we felt that it was important to include all of the major players in the pharmacy-delivery system in order to gain a full perspective of the issues.
- To this end, we have representatives from
    - the Centers for Medicare and Medicaid Services
    - Community pharmacists
    - Chain drug store pharmacists
    - Long-term care pharmacists
    - Prescription drug plans
    - Distributors
    - Pharmacy benefit managers
- It is important to note that the Minority had requested a witness from a beneficiary-advocacy organization, but instead of expanding the focus of an already robust hearing, we have confirmed our intent to hold another pharmacy hearing where beneficiary input will be a focus.
- And we appreciate the minority's willingness to work with us as we put together this multifaceted hearing.
- There is no doubt that one of the major topics of discussion at today's hearing will be the provisions within the Medicare Modernization Act and the impact of the new Medicare Prescription Drug Benefit.
- As my colleagues are aware, on January 1, 2006, prescription drug coverage for our seniors became more than just something we talked about in Congress – it became a reality for every single person eligible for Medicare.
- This legislation accomplished a very important thing – it helped tens of millions of senior citizens save thousands of dollars on their prescription drugs.
- For years before enactment of this new benefit we heard the horror stories of our seniors having to choose between buying groceries or their medicines and pharmacists having to advise patients which drugs on their list were the most important because the patients could not afford to buy all of their prescribed medication.
- Well, now all beneficiaries have the option to have good drug coverage and have the quality of life that we wish for all of America's seniors.
- In fact, more than 38 million people with Medicare now have good, secure prescription drug coverage, and enrollment in Medicare-Part D-related coverage accounts for over 32 million of these beneficiaries.
- These truly are astounding numbers that have exceeded almost everyone's expectations, and the unparalleled effort to get this brand new change to Medicare up and running and get people enrolled has been incredible.
- Of course, the success of the new Medicare Prescription Drug Benefit would not have been possible without the many people represented in this room, and no group was more important than our pharmacists who truly were the heroes of the implementation of this new benefit.
- Again, I want to thank our witnesses for taking the time to testify before us today. I look forward to hearing from each of you.
- At this time, I would also like to ask for Unanimous Consent that all Committee Members be able to submit statements and questions for the record.

- I now recognize the Ranking Member of the Subcommittee, Mr. Brown from Ohio, for five minutes for his opening statement.

MR. DEAL. I am now pleased to recognize our Ranking Member of the subcommittee, Mr. Brown, for his opening statement.

MR. BROWN. Thank you, Mr. Chairman. I would like to thank the witnesses for joining us. I want to extend a special welcome to the three witnesses from my home State, Charles Hallberg from Cleveland, and Dr. Larry Galluzzo and Timothy Hopkins, both from Mason, Ohio, Warren County. Thank you for being here.

Unfortunately, as you pointed out, Mr. Chairman, there is one key witness missing. There is no beneficiary here. I am perplexed by that. My guess is that the Majority and the Minority are aligned when it comes to the issues of what we do to help pharmacists, even though as this bill went and made its way through Congress previously many of us raised alarms about how pharmacists were not as major a part of this bill, as important a part of this new law, as they should be. We can agree today that pharmacists should be paid fairly and paid properly. We can agree today that benefit cards should not be used as billboards. We can agree today the use of cost-saving generic drugs should, in fact, be promoted. We can agree today that medication therapy services should be encouraged, and we can agree that nursing home residents should be able to secure the coverage they need from the pharmacies best equipped to serve them. But again, I am concerned the majority feels justified in denying any beneficiary their right to come before this panel. I appreciate the fact, Mr. Chairman, that you invited witnesses from my home State, but the witness list was chosen by the Majority, and again, excluded beneficiaries. At any hearing that we have about Medicare Part D, beneficiaries obviously should--at least one beneficiary should be included to enter in this discussion with pharmacists and with others.

The supply chain and the coverage chain are well represented, but the customer chain isn't represented at all. Medicare obviously begins and ends with the beneficiaries. When pharmacies are underpaid, they can't promptly serve Medicare beneficiaries. When benefit cards turn into advertisements, Medicare beneficiaries become just a marketing statistic. When generic drugs aren't dispensed, Medicare beneficiaries pay more out of pocket. When medication therapy is given short shift, Medicare beneficiaries lose ground against chronic conditions. And when the unique circumstances of nursing home residents are dismissed as insignificant, Medicare beneficiaries get a firsthand look at why a program like Medicare fee-for-service, which is comprehensive and flexible enough to probably carry the moniker "one size does, indeed, fit all," why a program like Medicare fee-for-service makes a lot more sense

than doing it the way we are doing it through Medicare Part D, which tells seniors to find the least imperfect fit and keep your fingers crossed.

Pharmacy issues are beneficiary issues. Members of this subcommittee are expected to work for Medicare beneficiaries, not around them. In his written testimony, Dr. Galluzzo raised some important issues that have bearing on access to medicine for nursing home residents. His concerns inevitably lead to serious beneficiary concerns. If residents must choose a plan that covers their long-term care pharmacy, how do they also choose a plan that covers all of their medicines? How often do those two variables collide, and how often do they coincide? It would useful to hear from a beneficiary representative who could actually address this concern.

This hearing is important. I am glad we are holding it. I am a proud cosponsor of H.R. 5182, bipartisan legislation introduced by Walter Jones and Marion Barry that addresses important issues raised by pharmacists and by those representing the pharmacy community, including prompt pay rules, co-branding medication therapy, and generic dispensing fees. I am glad we are discussing the serious issues raised by Dr. Galluzzo, specific to long-term care pharmacy. I am confident that all of our witnesses will provide valuable input. But this hearing is about access and cost and quality. It has everything to do with the beneficiary. It is a sad statement that everyone but Medicare beneficiaries will have their say today.

Thank you, Mr. Chairman.

MR. DEAL. I recognize Dr. Burgess for an opening statement.

MR. BURGESS. Thank you, Mr. Chairman.

For once in this committee, I find myself in agreement with the Ranking Member. This is an important hearing and I am glad we are having it today. Now, my understanding is we are going to have a similar hearing that will be devoted purely to beneficiaries forthcoming in the near future. I know the gentleman from Ohio was retiring, but maybe we will get that done before he leaves.

Timely reimbursement for healthcare providers is an essential component to maintain the health of the healthcare delivery system. When payment levels are negatively impacted or payment timelines are altered, it can adversely impact the delivery of healthcare, the health of the provider, and ultimately the health of the patient. With the implementation of the Medicare Part D prescription drug program, the Government became a major payer of senior's medications, and the plans that have been contracted to do so must meet minimum requirements.

At the outset of the program, I heard from pharmacists in my area about the difficulties that they were having with the program, many of which impacted their bottom line. I am thankful that CMS and HHS

worked to resolve many of these problems. Some we took on as just simply constituent cases and were able to get a satisfactory resolution in every time we asked. I urge the Department to remain diligent and ensure that this program doesn't become a burden for frontline pharmacists who are small business owners.

For years, prompt payment was a major issue pitting physicians against health insurers in the State of Texas. I hope that the health plans will have learned important lessons from that example, as well as numerous other prompt pay battles around the country. I, for one, never understood why it was necessary to have a law that required people to pay their bills on time. I was always required to pay my bills on time when I ran a medical practice.

Mr. Chairman, I do thank you for holding the hearing today. I look forward to the witnesses' testimony, and I will yield back.

MR. DEAL. I thank the gentleman.

Mr. Waxman is recognized for an opening statement.

MR. WAXMAN. Thank you, Mr. Chairman. I am pleased that the subcommittee is holding a hearing today to examine the issues that have been faced by America's pharmacists since the implementation of Medicare Part D benefit and the enactment of the Deficit Reduction Act. Certainly, the initial months of implementation of the Medicare drug benefit have put many pressures and tasks on our pharmacists. They have been close to the front lines in dealing with the complications and difficulties in that program. It is indeed critical that we examine these issues and take steps to remedy some of the obvious problems, but the fact is that the pharmacists have faced many of these problems because they were on the front line trying to help the beneficiaries deal with the complications and frustrations of this program.

So to get a more complete picture of what has gone wrong and what needs to be changed, we should be hearing today from both pharmacists and beneficiaries. Both of them have important stories to tell. I know we have been promised an opportunity to hear from beneficiaries. This is not the first time we have been promised that. In fact, the Minority, the Democrats, have submitted a petition which requires another hearing on this subject, and that is supposed to come about under the rules we have been promised. It is inexplicable that we don't have time to hear from the beneficiaries, as well as all the others that we are going to hear from today. Beneficiaries are the ones who want to be able to access the program through their own pharmacists. They are the ones who suffer if the pharmacists can't afford to spend the time to wait hours on the phone to see if someone is covered, who have to seek their pharmacist's help to deal with prior authorization and set therapy requirements, and who need their pharmacist to work with their physician to be sure the proper

approvals are received so their drug can be covered. And it is going to be the beneficiaries and the pharmacists who will be dealing with the confusion and the anger and frustration that will inevitably occur when people start hitting the so-called donut hole in coverage where they must pay the full bill out-of-pocket. The pharmacists have indeed been in the middle of these problems. They have been made worse by the fact that some plans make them wait months for payment, putting tremendous cash flow problems on them. Some plans don't pay adequately for the cost of providing drugs, particularly low-cost generic drugs whose use we want to encourage. We know that the pharmacists may have to spend more time explaining why the generic is appropriate, yet their reimbursement is sometimes miniscule for these drugs. We know pharmacists will be on the front line trying to deal with the differing requirements among the plans for prior authorization. This can be time-consuming for them and frustrating for them and the beneficiaries they are trying to serve.

Finally, we know that some plans engage in the practice of putting a specific pharmacy chain logo on their cards, causing beneficiaries to think that is where they must go to get their drugs. This surely disadvantages the community pharmacy. We hope that what we hear today will be used to form an appropriate legislative response.

MR. DEAL. I thank the gentleman.

As you can tell by the bells, we have votes that have started. Mr. Upton, I am going to try to get your opening statement in, and then we will recess for the votes.

MR. UPTON. The thing is, Mr. Chairman, I won't take my full allotment of three minutes.

I want to thank you for having this hearing. I do look forward to having the hearing with the beneficiaries later on. I also want to thank my pharmacists in southwest Michigan, those both large organizations, the Walgreen's, et cetera, as well as the small mom and pop shops as well. I know that I spent much of my recess time in March and throughout the weekends stopping at a number of pharmacies throughout my district, checking in on them, finding out how things were going. I was very pleased with the response that I got. I know that for many seniors signing up for Part D, it was a confusing process. We had in Michigan some 42 different plans that beneficiaries were able to pick and choose from, and I have to say that as I went through my different communities, whether it be my hometown of St. Joe or Kalamazoo, a much larger city, our pharmacists were on the front line and they did a wonderful job in terms of trying to find the right program, the right fit for those seniors that wanted to participate in the plan. I know that in our district we had about 70-some percent of eligible seniors sign up. I think

that the satisfaction rate was pretty good. We did a lot of outreach to help with our pharmacists, as well as our beneficiaries, to make sure that they had the right plan, trying to ease that transition, and I again thank them for the work that they do and that they did. I know that this plan isn't perfect. We need to look at a number of different things where we can help facilitate it even better, which is one of the reasons why I have endorsed and signed on as a cosponsor of Nancy Johnson's legislation to ease the penalty, to take away the penalty for those that did not sign up for the Part D plan by the May 15 date, and I would like to think that this House, in a bipartisan basis, will be able to push that legislation through the House floor in the coming weeks.

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

MR. DEAL. I thank the gentleman.

I am going to make an exception to what I just said. The Ranking Member of the Committee, Mr. Dingell, is here, and he is a little bit incapacitated. We don't want to have him to have to move around too much on his crutches. I am going to recognize him for his opening statement, and then we will recess.

MR. DINGELL. Mr. Chairman, thank you for your courtesy, and I am grateful to you.

Mr. Chairman, Medicare Part D and the changes to payments for prescription drugs under Medicaid have significantly affected pharmacies and the beneficiaries they serve. For some, these changes have created such severe ramifications that some pharmacists are uncertain if they can continue to serve the patients in their communities. Therefore, I am pleased that we will hear today about the impact of the Part D program and the Medicaid changes on pharmacies.

I am, Mr. Chairman, much disappointed that the Majority refused to allow the committee to hear from any witnesses who would give beneficiary perspective on pharmacy issues. We will hear various perspectives from the business community and the Administration, but not one word from the people who these programs are designed to help and whom the pharmacists serve. We will also hear from the Administration, for the second time this year, on Part D, and its efforts to work out all the problems that this program has caused, but we will again not hear from the seniors and the persons with disabilities most affected by them. We will hear from WellPoint, for the second time this year, about their work as the backup contractors in Medicare Part D, but we will not hear from the beneficiary's perspective about how well that has worked. We will hear from the wholesalers, who have no direct link either to Part D or Medicaid, as they do not get reimbursement from these programs, but again, we will not hear from the beneficiaries. We will hear a pharmacist's perspective on helping beneficiaries to

determine whether their drugs are covered by the prescription plan they have chosen, or how to file an appeal if they aren't, but again, we will not hear from the beneficiary's perspective on that interaction. We will hear about the burdensome plan restrictions that have caused problems for pharmacies in delivering medicines to patients in the long-term care setting, but we will again not hear from those who are at the receiving end of the restrictions, the patients.

The fact is that the Minority requested only one witness at this hearing. We asked only one witness, compared to the seven categories from which the Majority chose their witnesses. It is indeed a shame that the Majority is not interested in the concerns of the beneficiaries to the point of excluding them from this hearing. Our goal in this hearing was to hear all perspectives, so that we can find out what is working and what is not, and why.

I also note that the Minority has not been afforded the opportunity to have its hearing on Medicare Part D which we requested under the House Rules in March, when a balanced and complete hearing on this program was also denied by the Chairman. Beneficiaries come with many different needs and circumstances. Congress has an obligation to hear from as many as possible to better understand how this program affects the people who deserve the help, and how it is working, not just how it is going to serve the interests of the insurance companies and providers. When the Chairman provides the minority hearing as required under the House Rules, I hope the beneficiaries will be heard and we will at last have a clear, comprehensive, and decent picture of the situation before us.

Thank you, Mr. Chairman.

MR. DEAL. We are going to stand in recess. There are three votes on the floor and we will resume as soon as those votes are concluded.

[Recess.]

MR. DEAL. I recognize Mr. Allen for his opening statement.

MR. ALLEN. Mr. Chairman, thank you for calling this important hearing to examine the vital role of pharmacists in our healthcare system.

Over the past 7 months, pharmacists have worked tirelessly to help Medicare beneficiaries navigate the Part D labyrinth. While it is appropriate to focus on the pharmacist's perspective in today's hearing, I am disappointed that the Majority would not allow us to invite a Medicare beneficiary to testify. I have heard from hundreds of seniors and people with disabilities in Maine about their experiences with the new Medicare Part D plan. Some found the process fairly easy to navigate and say they are paying less for their prescriptions than they did before, but the vast majority describe their problems choosing and signing up for a plan or dealing with the complicated appeals process if a

drug is not in their plans formulary. One area of agreement is the tremendous assistance that beneficiaries have received from their local pharmacists. Pharmacists in Maine did not allow beneficiaries to leave the store without their prescriptions, even if payment was to be delayed or not received at all. Pharmacists in Maine tell me that Medicare D is running more smoothly than earlier this year, but about 25 percent of prescription drug claims still need special attention. This can entail additional calls to CMS or the PBM that is running the plan, which can take 30 minutes to an hour. Pharmacists are not reimbursed for their time dealing with problems like these, and they are not paid for the true costs of dispensing care in either the Medicare or Medicaid programs.

Maine pharmacies are struggling right now with cash flow. They are waiting for 30 to 45 days to get paid, compared to 7 to 10 days when the State was paying for medications under Medicaid. It is estimated that 25 percent of an average Maine pharmacy's cash flow is tied up in this process. Maine has lost 17 community pharmacies in just the past 2 years. These pharmacies closed not because of competition or poor management, but rather due to reimbursement cuts at both the State and Federal level.

I look forward to hearing from our distinguished panelists today. I hope their testimony will highlight the unique role pharmacists play in meeting the healthcare needs of Americans, as well as the challenges that they face, both financial and administrative.

With that, Mr. Chairman, I yield back.

MR. DEAL. I am pleased to recognize the Chairman of the Full Committee, Mr. Barton, for an opening statement.

CHAIRMAN BARTON. Thank you, Mr. Chairman. Thank you for holding this hearing. I apologize to our witnesses for the interruptions. We have got votes on the floor and all this kind of stuff, and we do apologize for having to suspend the hearing.

I look forward to hearing our witnesses' perspectives today on the issues that are facing America's pharmacists. Pharmacists have been on the front line, providing the new Medicare prescription drug benefit to our seniors. There have been some problems. That is to be expected, unfortunately, with any large new government program. I am told that things are improving now, but we must remain vigilant to ensure the program continues to be a success.

The witnesses today are going to provide their insight regarding payment concerns expressed in recent months by some pharmacists. For example, back in January and February, many members of this committee heard stories about how pharmacists experienced delay in payments by Medicare drug plans. I have been told repeatedly by the Administration that this issue is being addressed, that the cash flow

crunch experienced by pharmacists at the beginning is getting better. I look forward to hearing from CMS and other witnesses today on this issue.

I want to echo the remarks of Chairman Deal regarding our commitment to holding an additional hearing where beneficiaries will be provided a separate forum to discuss any overall concerns regarding the underlying benefit program itself. As technical problems arise, this committee will remain committed to making sure that they are addressed quickly if a legislative solution is needed. Some may exploit minor problems that have surfaced during the initial implementation of the new benefit program in an attempt to discredit the overall program. We should not lose sight, however, that more than 38 million people now have a prescription drug benefit program under Medicare. This is due in large part to the efforts of the witnesses appearing here today: CMS, the pharmacists, plan providers, and other payers, all who have helped to make this benefit accessible to any beneficiary who wants it. Please keep up the good work as we work together to address the outstanding startup glitches that still remain. I am committed to making the program work.

Again, I want to thank Chairman Deal for calling the hearing, and thank the witnesses for being here today. We look forward to hearing their testimony.

With that, Mr. Chairman, I yield back.

[The prepared statement of Hon. Joe Barton follows:]

PREPARED STATEMENT OF THE HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Good morning. I would like to welcome all of our witnesses here today. I look forward to hearing your perspectives on Medicare prescription drug coverage payment issues for America's pharmacists.

Pharmacists have been on the front lines of providing the new Medicare prescription drug benefit to our seniors. There have been some growing pains, but they were hardly unexpected. Every new, large program has them. Things seem to be improving, but I also believe that success will depend on us keeping a close eye on the program's progress.

The witnesses today will help us better understand payment concerns expressed in recent months by many pharmacists. Back in January and February, we all heard stories about how the mechanism to pay pharmacists was stalled. I have been told that CMS is untangling that knot, and pharmacists are beginning to get the money they are owed. I look forward to hearing from CMS and the other witnesses today on this issue and echo the remarks of Chairman Deal regarding our commitment to hold an additional hearing where beneficiaries will be provided a forum to discuss their experiences.

As challenges arise in Medicare Part D, this Committee will deal with them. Now, it's also true that a handful of people prefer to celebrate the glitches. To some of us, it almost looks like they want political benefits in the next election more than prescription drug benefits for Medicare patients. Yet the public doesn't seem to have much taste for politics. More than 38 million people now have prescription drug coverage, and they

give it increasingly high marks on satisfaction surveys. This is due, in large part, to the efforts of the witnesses appearing here today – thanks to CMS, pharmacists, plans and other payers, and to everyone who has helped make this benefit accessible to all Medicare beneficiaries.

I want to thank Chairman Deal for calling this hearing, and reiterate my thanks to all the witnesses for coming today. I look forward to their testimony.

MR. DEAL. I thank the Chairman.

Mr. Pallone is recognized for an opening statement.

MR. PALLONE. Thank you, Mr. Chairman. I don't want to beat a dead horse, but I do want to mention that I was disappointed that we didn't have a beneficiary representative here today, and I did hear you in the beginning acknowledge the role of the beneficiaries and say that a hearing would be held separately with their testimony. But I do want to stress that I really think that not only in this case, dealing with pharmacists, but in any case where we are dealing with Medicare Part D, whenever we do have a hearing, I really think that beneficiaries should be included in each of those hearings because of the impact on them. You know, obviously there is a lot of controversy over Part D and Democrats, including myself, feel that it is very confusing and that it is not being implemented in a fashion that is helpful to beneficiaries. So I do think it is always important whenever we have a hearing on Part D to include the beneficiaries, and I would just make that request once again. I know you are going to have the separate hearing, but I think we need to include them in every hearing.

I wanted to say with regard to the subject matter of the hearing today, whether it is revisions to Medicaid payment policies to the rollout of Medicare Part D, whatever the issue is, I can't remember a time when pharmacists were so directly impacted by changes in Federal health policy. I have been hearing from them constantly, and as these policies are implemented, it is important that members of the committee hear from pharmacists about how they are being affected. For most of us, this will not be the first time we hear from our pharmacists about Part D. Since the beginning of January, I have received numerous calls, mostly from community pharmacists, about the challenges that they faced under the new program, and I have heard all the horror stories about those pharmacists who were on the phone for hours with private drug companies or CMS, desperately seeking to fill the prescriptions that their customers needed. These problems are not just startup problems, as many of my Republican friends contend. They are systematic problems, from late payments to unfair marketing practices. I think that the pharmacists have been uniquely disadvantaged by Medicare Part D.

Now, I have introduced a bill that attempts to provide relief on the payment issue that would require prompt payment for the medications,

and secondly, that would prohibit the practice of co-branding, which levels the playing field between the large chain drug stores and independently owned pharmacies. In New Jersey, under Medicaid the rule was that you get paid electronically within 15 days and 30 days with written. Most pharmacists have testified here, many before this committee, that they are waiting 60 to 90 days, and the co-branding issue is just outrageous. I mean, the Medicare recipients and seniors are now getting cards that have major chain stores on the cards, and they think that they can't go to their independent pharmacists. So these problems need to be addressed, and that is why I introduced that bill.

Thank you, Mr. Chairman.

MR. DEAL. I thank the gentleman.

Mr. Ferguson is recognized for an opening statement.

MR. FERGUSON. Thank you, Mr. Chairman. Thank you for holding this hearing and giving us an opportunity to hear the concerns of pharmacists about the implementation of Medicare Part D.

We are now almost five full months into have a prescription drug benefit in Medicare, and as a result, there are 39 million people who are Medicare beneficiaries. That is representing more than 90 percent of Medicare beneficiaries now have coverage for prescription drugs. That is extraordinary. Almost 40 million people in this country are now paying less for their live-saving, life-enhancing drugs than they were before. I think that when you talk to them, and certainly when I hear from beneficiaries in my district who have worked through many of these implementation issues and problems that we have seen, they are absolutely delighted with the cost savings that they are seeing. I have heard a number that the average beneficiary is saving $1,100 a year on their medication, which is fabulous.

But I think anybody involved in this implementation would say that this has been a long and difficult process in implementing this benefit, and our pharmacists have literally been on the front lines of that effort. I have spoken with many of the pharmacists in my district. I met with some this morning, and I have seen that these dedicated professionals are working as hard as they can. I have heard one instance of a pharmacist who didn't pay himself for the first two months of this year because of problems in payment issues that they have seen. These are folks who are working as hard as they can to make this benefit work, and they should be commended for that. The pharmacists that I have met with also have a lot to say about how to make the program better, how to address these problems. These are folks who are vital to the healthcare needs of our seniors. These are folks who are trusted by their customers, by our seniors.

I look forward to hearing from our panelists today. They represent the breadth of participants in the drug delivery system for Medicare Part D, and I look forward to working with our pharmacists in order to make sure that this program continues to get better and continues to serve the needs of those who need these medications the most.

Thank you so much. I yield back.

MR. DEAL. I thank the gentleman.

Ms. Baldwin is recognized for an opening statement.

MS. BALDWIN. Thank you, Mr. Chairman. I thank the witnesses for joining us today.

Pharmacists play a unique role in our healthcare system. For many people, and I think this is especially true for our seniors, pharmacists are their main point of contact with our healthcare system. It is a pharmacist who knows what drugs they are taking and who will take a little time to ask how things are going with a new prescription medication. Pharmacists certainly have had to hear a lot and bear a lot of the burden in dealing with the problems with Part D. So I am happy that we are going to have the chance here today to hear more about the pharmacists' perspective on Part D and the changes that were made as part of the Medicaid cuts passed into law last year.

I do have to join with my colleagues in noting it is a loss to our subcommittee that there are no witnesses on either of the panels today who are here to represent the beneficiary perspective, and certainly if we are talking about pharmacy issues, beneficiaries have a lot to say. For so many beneficiaries, all they know of Part D is their experience at the pharmacy. They don't have any direct interaction with CMS or with PBM, but they do know what has happened when they have gone to their pharmacy to get a prescription filled. Not having that perspective as part of this discussion is unfortunate, and I regret that it hasn't been included.

I hope that our friends from pharmacy will do their best to give us an idea of what their clients' experiences have been, as well as what their own experiences have been, especially as they relate to Part D. Just yesterday, a pharmacist from Stouten, Wisconsin, came to my office and told me about all of the issues he has encountered with Part D, and there have been a lot. Slow reimbursement, confusion over prior authorization, and constant formulary changes have made Part D a real challenge for pharmacists. I am afraid that that challenge will only grow as time passes and seniors find themselves falling into the donut hole where they have no prescription drug coverage and the pharmacists are the ones who get to bear that bad news and explain that to confused senior citizens.

But to sum up, I would like to tell you what this pharmacist from Stouten, Wisconsin, told me of his opinion on Part D. He said that Part

D was such a convoluted program, it was like, and I quote, "using your attorney to hire the neighbor's kid to mow the lawn." It is convoluted, and the rollout has been fraught with issues, and as I suspect we will hear today, pharmacists have been on the front lines.

I look forward to hearing about their experiences, and I thank you, Mr. Chairman, for the time.

MR. DEAL. Ms. Eshoo is recognized for an opening statement.

MS. ESHOO. Mr. Chairman, I will submit my opening statement for the record.

I would just like to ask a question of you. Why isn't there someone representing the beneficiary community? I understand that there were requests that were made, and I know that you are very respectful of hearings.

MR. DEAL. I appreciate the question.

MS. ESHOO. Many of the hearings that I come to, there are very few here. Of course, you are here because you are the Chairman, but they are important, and we learn from those that come in and offer their views. It seems to me that it creates a hole in the panel. I mean, I don't think that that speaks well for any of us.

MR. DEAL. May I respond?

MS. ESHOO. Can you maybe enlighten us? Certainly.

MR. DEAL. Thank you for asking the question.

I think it is a criticism without merit. As you may recall, on March the 1st we had a hearing on Medicare Part D. We had two beneficiaries and a beneficiary advocate that testified. The purpose of this hearing is to examine the distribution chain of pharmaceuticals. We invited your side to ask for PBM directors, representatives of the pharmacy community, et cetera, et cetera, but no one was invited by your side to do that. We are going to have another hearing where beneficiaries will be heard from, but I think there are enough concerns about the issues in this very complex contractual relationship of how drugs get from the manufacturer to the pharmacist, and quite frankly, that is the purpose of the hearing.

I think it is a legitimate purpose. I seriously doubt that any beneficiary, other than the one I will introduce in a few minutes, really knows anything about those issues. So it was intended to be restricted to the pharmaceutical distribution chain.

MS. ESHOO. Well, Mr. Chairman, I appreciate what you just said, but I think that we need to keep in mind that the hearing that you referenced, the chain drugs were there, independent pharmacists were there, plants were there, Administration was there, WellPoint was there, and so I don't think it would have hurt. But you know, I will go with

what you said, and I think maybe part company with the explanation, but I respect you and I appreciate your addressing it--

MR. DEAL. Thank you.

MS. ESHOO. --as best you could.

MR. DEAL. I believe we have exhausted our members who are here to make opening statements, so we will proceed to the first panel. I am very pleased to be able to introduce our first panel which is made up of Ms. Leslie Norwalk, who is the Deputy Administrator of the Centers for Medicare and Medicaid Services. We appreciate you being here. For all witnesses, I will say to you that your written testimony is being made a part of the record. We would ask you during the 5 minutes to summarize your general testimony and we are pleased to have you here. We will recognize you at this time.

STATEMENT OF LESLIE NORWALK, DEPUTY ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

MS. NORWALK. Thank you, Chairman Deal, members of the committee. It is good to be with you here this afternoon to discuss how wonderful, frankly, we all agree that pharmacists have been in implementing the new prescription drug benefit. That is, without a doubt, nice that we can agree on something, certainly.

They have been instrumental in our success in being able to ensure that over 38 million beneficiaries have prescription drug coverage in the Medicare program, over 90 percent of beneficiaries with coverage; certainly, not where we were a year ago, and it is a remarkable accomplishment, something that the pharmacists have played an important role in.

Do you realize that we are actually filling three million prescriptions a day? Without the pharmacy and the pharmacists, we certainly wouldn't be here. Pharmacists were there in January when we had systems break down. They made sure that our most vulnerable beneficiaries got the drugs they needed. We have come a long way since January, and most of these problems are behind us, but let us face it. We could not have done it without the pharmacies. They ensure that beneficiaries get scripts that are safe and effective for them. They promote lower costs and higher quality.

I have personally been around the country and met with a significant number of pharmacists throughout town hall meetings and so forth and visited with them and appreciate that they have experienced real challenges in this implementation. We have worked very closely with them to solve their problems. We have made significant progress in

resolving data handoff issues between the States, the prescription drug plans, and CMS so that pharmacists could get accurate information on beneficiaries at the pharmacy counter without having to call us at 1-800-Medicare or the plans, and then would be able to build a correct plan with the correct co-payment, even when the beneficiary forgets his or her drug card.

We have engaged in extensive and varied outreach. The Secretary, the Administrator, and I, along with numerous CMS pharmacists and regional office staff, we visited pharmacies firsthand to see the problems that they have had. We have provided online resources in particular for pharmacies. We have worked closely with the pharmacy associations on both systemic issues and individual complaints. We have held open door calls so that individual pharmacists have an opportunity to let us know their concerns directly. We have also facilitated the interaction between plans and pharmacists to simplify a number of important business issues, business processes, and to minimize pharmacy administrative costs and burden, including standardized coding and messaging, and providing an E-1 query system, a dedicated pharmacy line at 1-800-Medicare. We have expanded the billing window to 180 days so that pharmacists could get claims payment when there was coordination of benefits issues, and we have extended the transition period for beneficiaries.

Finally, we will be announcing, hopefully later on today, that all plans for 2007 cannot provide co-branding material on their prescription drug cards, and they will need to provide those cards to beneficiaries brand new in 2007 with no co-branding of pharmacy. Now, we did that initially so that AARP, employers, and the PACE program in Pennsylvania so that co-branding could be on the cards. That can continue, but no pharmacy information can be on that card so that beneficiaries aren't confused about their options that are available to them, and again, new cards will be sent out in '07.

The next complaint that we heard about from independent pharmacies in particular is that they are not being paid quickly enough, particularly because the pharmacists often will pay their wholesalers on a weekly basis, and they do that in order to receive payment concessions, such as discounts, from the wholesaler. The time lag between payment from the plans and their payments to the wholesalers was causing a cash flow problem. However, I point out that under the Medicare Modernization Act, CMS is prohibited from interfering with the negotiations between the prescription drug plans and the pharmacies, and due to this, we cannot require that payment be made within a particular timeframe. But we are concerned about reports, and I think one was mentioned earlier here this morning, that payment is often maybe taking longer than it is in the standard contracts between these plans, and

whenever we have received specific information about a plan not paying a pharmacy in accordance to its contract, we have investigated them. We haven't found all that many problems. Our research has found that delays in payments generally resulted from typical startup issues, such as miscommunication around billing addresses, for example, or if there is a group purchasing organization or other intermediary often getting the check, it is unclear to the pharmacy which plan has made the payments for what. Our own survey found that 18 of the top 20 prescription drug plans paid pharmacy claims on a 15-day payment cycle or less, which lines up well with private industry norms with which the pharmacy is accustomed. The MMA, however, does include some protections for pharmacies, including access standards and any willing provider provisions.

Competition for the Medicare business has helped keep those costs down. The estimates are $8 billion cheaper in 2006 alone, and $58 billion cheaper over 10 years when compared to last year's--the baseline last year to this year's President's budget. So we are pleased the taxpayers and beneficiaries alike can share in these savings.

But pharmacists are healthcare professionals. They provide incredibly valuable services to our beneficiaries and to patients of all kinds. Often, they are paid for these services indirectly through the purchasing and selling price of their prescription drugs. But these days, purchasers are looking to separate the acquisition costs of prescriptions from other services that are provided, as is evidenced in the DRA changes to Medicaid payments. As this change occurs, it is critically important for us to consider how to value the quality of services that pharmacists as healthcare professionals provide, and to that end, we have been working with the Pharmacy Quality Alliance, which includes pharmacists and insurers to work together to develop and evaluate quality measures. Pharmacists need to be a part of this discussion of how to value their services, because we all know that they do much more than simply sell prescription drugs. With value-based purchasing, pharmacists will have an opportunity to be rewarded for providing quality care.

In closing, I would like to reiterate my sincere appreciation for pharmacists across the country, and look forward to continuing to work with them and the public to help them understand the nature and real value of the services they provide. I look forward to answering any questions you or the committee may have.

[The prepared statement of Leslie Norwalk follows:]

PREPARED STATEMENT OF LESLIE NORWALK, DEPUTY ADMINISTRATOR, CENTERS FOR MEDICARE & MEDICAID SERVICES

Chairman Deal, Representative Brown, I thank you for inviting me here this morning to talk about how the Centers for Medicare & Medicaid Services (CMS) has worked with pharmacists to implement the Medicare prescription drug benefit. CMS has fully engaged with the pharmacy community in this effort and they have been key partners in the success of this benefit so far. We greatly appreciate their efforts and appreciate receiving their feedback and input on how to improve our operations. We look forward to continuing to work with them in meeting the needs of people with Medicare.

The Secretary, the Administrator and I have all traveled the country and listened to the concerns that pharmacists have about the Medicare prescription drug program. To this point, among other things, CMS has improved its data systems, provided extensive education and outreach, hired pharmacists and worked with the prescription drug plans to simplify business processes between them and the pharmacists who actually serve our Medicare beneficiaries. Before the benefit began, we worked with pharmacy associations to inform their members about what was coming, and we established electronic systems to assist them in verifying eligibility of enrolled beneficiaries. Since the benefit became available in January, we have issued multiple guidance letters to Medicare prescription drug plans on topics ranging from the need to improve their customer service to pharmacists, to allowing the pharmacists to submit bills for a longer than typical period, many of which have been aimed at streamlining plan/pharmacist/beneficiary interactions – so that pharmacists can continue with the outstanding job they have been doing. We are continuing to work closely with pharmacists to address further issues as they arise.

Pre-Implementation Work with Pharmacists

We knew early on that pharmacists would be key players to the success of the Medicare Prescription Drug benefit. As front-line providers, pharmacists are the health care professionals to whom many patients turn to for advice and counseling on a broad range of issues, from minor aches and ailments, to medication therapy management, to decisions on what drug plans may be best for them. Interaction and a strong partnership with the pharmacists and the pharmacy community has been a top priority for CMS.

In preparing for implementation of the Medicare Drug benefit, CMS made a point of hiring pharmacists. We hired at least one pharmacist in each of our ten regional offices. And we added ten more pharmacists in our central office, including pharmacists in senior leadership positions inside the Center for Beneficiary Choices and a pharmacy expert within the immediate office of the Administrator. They effectively brought the pharmacy perspectives to bear throughout CMS during our preparation and implementation phases. We also contracted with 125 additional pharmacists to review plan formularies for the 2006 benefit year, and to ensure that plans continued compliance with our regulations and formulary guidance after the drug benefit went into effect.

From the beginning of our implementation efforts, we have engaged in rigorous outreach to the pharmacy community. This included an effort beginning in May of 2005 when we partnered with chain and independent pharmacies in an education and outreach program for beneficiaries likely to qualify for the low income subsidy. The effort reached over 30,000 stores. Those communications between CMS and pharmacies marked the beginning of an extensive and lasting effort to exchange information with the pharmacy community. We continued our regular communications with pharmacies through the Medicare Rx Update. Since last May, we have sent 42 updates to pharmacists and pharmacy associations. With over 2,700 subscribers and its known multiplying effect (state and national organizations distribute it as well) these updates have gone a long way toward informing the pharmacy community about the procedures

surrounding Part D. Indeed, we have provided outreach through national, state and local pharmacy organizations and their newsletters and email lists, as well as their standards-setting organization and technical societies.

CMS' regional office pharmacists traveled the country and presented to tens of thousands of pharmacists in 2005 – and they remain in constant contact with pharmacists all over the nation. One part of these outreach efforts involved hundreds of town hall and state pharmacy association meetings around the country – including our participation in 27 National Community Pharmacists Association (NCPA) Part D town hall events, with attendance approaching 7,000 independent pharmacists. We have held numerous national conference calls and posted extensive information on a page of the CMS web site dedicated to pharmacists.

All of our efforts are in addition to the tremendous work that pharmacy associations and individual pharmacies have done with our support. These efforts have resulted in over 50,000 pharmacists and pharmacy technicians receiving continuing education related to Part D, several Part D centered websites with millions of hits, numerous conferences, and in-store efforts that have educated thousands of pharmacists and engaged millions of people. These efforts to provide outreach to pharmacists continue through the present day, and we are grateful to the pharmacy community for doing so much to make a difference for Medicare beneficiaries.

Recognizing some of the difficulties that pharmacists have in administering private third party programs, CMS collaborated with pharmacists starting in 2004 to create a system that would help them identify beneficiary plan information through their existing pharmacy systems. This collaboration has yielded an electronic eligibility and enrollment query system that has now become part of most pharmacies' work flow. If a Medicare enrollee does not have a card or proof of enrollment in a prescription drug plan, pharmacists can use this eligibility system (the E1 system) to obtain information needed to determine the beneficiary's Part D plan and fill the prescription. Retail pharmacists now generally have the ability to perform real-time eligibility determinations for Medicare beneficiaries on their existing computer systems, which has resulted in new efficiencies at the pharmacy counter.

To assist pharmacists in learning to use this tool, CMS produced a CD-ROM that was distributed to national associations and placed on our Pharmacy website. We also held special training events conducted by CMS pharmacists from our ten regions in connection with that tool.

The E1 system is working as designed, providing rapid responses to pharmacists' queries. Response times since January 2 have consistently been less than one second. In addition, the number of queries is decreasing, because more people with Medicare are enrolling early in the month and have accurate billing information with them when they go to the pharmacy. Pharmacies have also been able to obtain that information from the individual's plan, in most cases. As a result, inquiries to the system have declined markedly from the opening days of the benefit. For example, on January 4, the E1 system received nearly 1.5 million inquiries. On January 31st, it dropped to around 300,000 and then to just over 120,000 on May 1st. While the need for the E1 system has been reduced remarkably, it nevertheless has provided many pharmacies with critical information to ensure that beneficiaries received drug coverage from the appropriate plan. Since January 1, using the E1 system, pharmacists have been able to identify plan information for beneficiaries more than 14 million times.

Post-Implementation Work with Pharmacists

CMS has taken many steps in order to ensure that accurate enrollment and payment information was available when people with Medicare prescription drug coverage went to the pharmacy to obtain their medications. However, during the first weeks of January, it became apparent that certain beneficiaries, particularly some dual-eligible beneficiaries

who switched or joined plans late in the month, had difficulty accessing their coverage when they went to the pharmacy. Working with an independent experts and the drug plans and states, CMS refined data quality and availability to enhance system performance. For example, CMS has made available twice-monthly summaries on eligibility and copay status for all enrollees in the limited income subsidy in each plan, and is monitoring plan use of these data to assure their coverage records are up to date. As a result of these steps, more complete, accurate, and timely information has been available to pharmacists when they fill prescriptions for people with Medicare drug coverage.

In addition to refining data systems related to coverage, we also provided expanded, direct customer support to pharmacists by modifying our call centers to include dedicated lines for pharmacists. We provided a toll-free number exclusively for pharmacists and worked to ensure that answer times were well under a minute. Pharmacists could call that line to obtain beneficiary enrollment information if they were unable to access it through the E1 system. We also increased funding for customer service representatives (CSR) to assist our beneficiaries and the professionals who serve them.

In addition to this significant strengthening of our 1-800-MEDICARE capabilities, we have issued guidance to the plans, instructing them to increase the numbers of CSRs in their own call centers, expand call center hours, and take other necessary steps to provide timely and effective responses to inquiries from enrollees and health professionals, including pharmacists. Plans have responded and as a result, call handling and wait times have improved significantly.

In addition to bolstering customer service efforts on our own part and through the plans, on February 2, we issued guidance calling on plans to extend the length of time during which they supplied a transitional supply of off-formulary medications from 30 days, to 90 days to ensure that pharmacists were able to readily help beneficiaries access their medically necessary prescription drugs during the initial transition period. We then encouraged plans to aggressively work to identify their enrollees who needed assistance to transition to on-formulary medications, or obtain an exception with the help of their provider. These steps made it possible for pharmacists to more easily fill prescriptions during the initial startup of the benefit and helped ease the burden of the transition on beneficiaries and pharmacists. Additionally, we issued guidance to plans on formulary changes, specifying that patients who had been stabilized on a medication that was covered by a plan when they enrolled could continue to be covered for that medication, even if the plan took their drug off of the formulary, unless the change was made because of a new generic coming on the market, an FDA safety warning, or new clinical guidelines becoming available. This move reduced concerns and confusion for both patients and pharmacists.

We also asked the Part D plans to work with pharmacists to resolve claims for medications dispensed when the pharmacist could not obtain adequate information on coverage for an enrolled beneficiary. Many pharmacists did provide medications to their patients, even when they could not verify coverage through a plan, and we are grateful to them for being willing to support their patients in this difficult position. We expect plans to appropriately compensate pharmacists for medications the pharmacists properly dispensed to plan enrollees, but due to systems issues were not initially covered by the plan.

Because implementation challenges delayed payment of claims or verification of beneficiary eligibility for a percentage of Medicare enrollees, CMS has instructed plans that their typical window for submission of claims by pharmacies must be expanded. Ordinarily plans have a time period of between 30 and 90 days during which a pharmacy can submit claims. We have required plans to expand that to 180 days for claims incurred during the first half of the year in recognition of the fact that pharmacies may

not have been able to obtain appropriate or adequate billing information even though they have dispensed medications to meet their patients' needs.

For beneficiaries who were for any time covered by two different plans, CMS is facilitating plan-to-plan reconciliation of claims paid, so that pharmacists will not have to resubmit claims or sort out issues of coverage once the beneficiary's coverage status is resolved. CMS has also developed a process for state-to-plan reconciliation for claims incurred by States and State Pharmaceutical Assistance Programs between January 1 and March 31, 2006 which provided coverage to dual eligible and other low-income subsidy eligible individuals through state payment systems – again providing an alternative process for recouping costs that avoids pharmacies having to reverse and re-bill claims.

To ensure that quality service by plans to their network pharmacists is a continuing part of the Medicare prescription drug program, in addition to the various pieces of guidance we have issued during 2006, we have indicated to plans that their customer service to pharmacies will be used as a measure of their effectiveness and compliance with contractual requirements.

In its 2006 marketing guidelines, CMS permitted Part D plans to co-brand. Many plans took advantage of this opportunity and have co-branded with a number of organizations, including state pharmaceutical assistance programs and the AARP. Some plans co-branded with pharmacies, and placed the name or logo of the pharmacy on the prescription drug insurance card. CMS and the plans are providing complete information on participating pharmacies. This is available through plan pharmacy network directories provided to plan enrollees, through our respective websites, and also by calling plan phone numbers. Nonetheless, to assure that beneficiaries do not conclude that they could only get their prescriptions covered at co-branded pharmacies, for 2007 and beyond CMS will prohibit plans from placing pharmacy logos on beneficiary cards. Doing so should alleviate any potential for beneficiary confusion over which pharmacies they can use, and better ensure that they know they are able to access all pharmacies that participate in their plan's pharmacy network.

Working with Long Term Care Pharmacies

Early in preparations for implementation of the prescription drug benefit,CMS identified long-term care residents as a particularly vulnerable population, and created a long-term care "campaign within a campaign" to address their special needs. In the LTC population, 70 percent are full-benefit dual eligibles, beneficiaries that are entitled to Medicare Part A and/or Part B, and are also eligible for Medicaid benefits. The Medicare Modernization Act required that all dual eligible beneficiaries receive prescription drug coverage from Medicare, rather than Medicaid. CMS needed to ensure that nearly six million dual eligibles would continue to be covered under the new program.

Adding to the challenge of switching coverage for so many beneficiaries, many nursing home residents have cognitive and/or other impairments which make communication a challenge. To address this issue, CMS worked with the nursing home industry and related advocacy associations to get information to their members and caregivers. We communicated directly to the staffs of the more than 16,800 nursing homes throughout the nation. Further, since January 2006, CMS has kept nursing homes up-to-date on policy clarifications and recommendations that directly impact nursing home patient care and participation in Part D. These include:

- Continuation of a dedicated fax/express mail program that allowed nursing homes to obtain residents' Part D enrollment data from Medicare, with more than 500,000 records processed, to ensure continuity of care;
- Continuation of Part D auto-enrollment of full-benefit dual eligibles in nursing homes;

- Weekly calls with industry representatives to help troubleshoot individual Part D cases, fine-tune our procedures, address anticipated questions and concerns, and receive feedback;
- Identification of CMS Regional Office long-term care leads to troubleshoot Part D nursing home cases in their respective regions;
- Providing industry groups with Part D plan contacts for the exceptions and appeals processes;
- Issuing written guidance for differentiating Part B and Part D drugs in the LTC setting, thereby eliminating confusion, speeding prescription fulfillment and reducing physician call backs on transitions, exceptions and appeals;
- Distribution of a model Part D Exception & Prior Authorization trigger form to assist with exceptions requests;
- Distribution of mid-year Part D formulary request information;
- Issuing guidance to plans charging them with using best available information to adjust subsidy levels in the event that data received from CMS does not yet reflect full dual eligible institutionalized status and the corresponding $0 co-payments for beneficiaries in this population. This guidance also advised plans to reimburse LTC pharmacies directly for underpaid cost sharing subsidies when those pharmacies have refrained from billing their residents.
- Clarifying that $0 co-payments for full benefit dual eligibles are effective the first day of the first month that the individual is expected to remain in a LTC facility for the entire calendar month; and
- Allowing those entering a nursing home as a resident after May 15 to enroll in a prescription drug plan without having to wait until the next open enrollment in November 2006.

Standardizing Business Procedures and Practices

Efforts to reduce administrative burdens associated with health insurance coverage and payments have the potential to reduce pharmacists' costs by shortening the amounts of time they have to spend in resolving problems at the pharmacy counter. CMS has strongly supported collaborative efforts undertaken by the plans and pharmacists to reduce the day-to-day costs of working with different health insurance plans. This is one of many examples of how various parties are working together not only to improve the Medicare drug benefit for pharmacists, but also to use this opportunity to reduce administrative costs more generally for pharmacists.

In January we heard concerns from pharmacists about different claims processing and administrative systems and protocols used by the various Medicare prescription drug plans. While pharmacists have long had to deal with multiple health insurance plans, the new drug benefit provided an opportunity to streamline administrative procedures across insurance plans. We have made plans aware of the challenges posed by their varying requirements, and supported external industry discussions involving both plan and pharmacy representatives. As a result, in early April, a group of pharmacy and plan organizations, including America's Health Insurance Plans (AHIP), the NCPA, and the National Association of Chain Drug Stores (NACDS), announced an unprecedented joint effort to simplify and standardize the steps that most affect service for Medicare beneficiaries filling prescriptions at pharmacies.

NACDS, NCPA, and AHIP worked together, along with the American Pharmacists Association (APhA) and the Pharmaceutical Care Management Association (PCMA) and others, to simplify and standardize the electronic claims processing messages going from Medicare Part D drug plans to pharmacies. The initial step in this effort was to provide pharmacists electronic message clarity regarding the coverage status of certain drugs.

Coverage denials can be grouped into many categories: drugs that are denied because they are excluded from Part D coverage as mandated by the Medicare Modernization Act, and drugs that are denied because they are covered under Medicare Part B, the drug is not on a plan formulary, or requires some prior authorization. Pharmacists need clarity about why a particular drug is not covered, and they need it in a format that is recognized and consistent between plans. This information will help the pharmacist guide the beneficiary to the appropriate next step, whether that is contacting his or her physician for an alternative prescription, billing Medicare Part B, or paying out of pocket.

To alleviate some of this concern, AHIP, NACDS, and NCPA developed and presented joint recommendations to a Work Group of the National Council for Prescription Drug Programs (NCPDP), the organization that creates and promotes standards for transferring data to and from pharmacies. NCPDP then approved a process for using standardized coding and electronic messages notifying pharmacists of claims rejections when the prescription is excluded from Medicare, or may be covered under Medicare Part B.

AHIP, NACDS, and NCPA have transmitted to CMS and NCPDP a second set of recommendations to further improve service to Medicare beneficiaries filling prescriptions at community pharmacies. That proposal for additional standardized electronic claims processing messages to pharmacists addresses prior authorization requirements, daily dose limitations, quantities that may be dispensed for a given prescription, and age and gender contraindications.

On February 7, CMS posted to its website a model form for beneficiaries to use in requesting a coverage determination. The form was developed with input from the American Medical Association (AMA), AHIP and others and is accompanied by instructions. Cooperation between the plans and physician organizations led to a form that will receive wider adoption and use and will help reduce confusion for providers, plans and our beneficiaries.

CMS has also posted contact information on our web site for every drug plan for those wishing to pursue an appeal. To facilitate communications between pharmacists and physicians, we recently posted a form for pharmacists to use to inform physicians that their patient's plan is requiring use of another drug, step therapy, or prior authorization. To ensure access to these forms and other important exceptions and appeals information, we required plans to create exceptions and appeals web pages with this information. We have also encouraged plans to accept prior approval requests by fax, rather than requiring phone calls from physicians, since that is less time consuming for the physicians.

CMS also sent information to plans which will expedite their processes for making sure they are not inappropriately paying for drugs that should be covered under Medicare Part B, and we have worked with Epocrates, an electronic prescribing software company, to ensure that their product provides accurate and easy access to plan formularies. We've also held weekly prescribers' conference calls and bi-weekly meetings with the AMA and other organizations to find out what prescribers are experiencing, to supply them with information on our activities and answer their specific questions.

Current Conditions

Many pharmacists expressed concerns that they are not being paid in a timely fashion. Interruptions in cash flow occurred as pharmacies switched from the system used by their respective state Medicaid payment systems to those of the Medicare prescription drug plans. However, a clear majority of PDPs are paying pharmacies well within the industry standard of 30 days from the time a clean electronic claim is submitted to the time a pharmacy receives payment. A recent CMS survey found that up to 18 out of the top 20 PDPs pay pharmacy claims on a twice-a-month billing cycle of 15

days or less. A 15-day billing cycle generally provides pharmacies with payment within 21-25 days. These top plans account for more than 90 percent of the drug coverage for Medicare beneficiaries.

Because resolving specific pharmacy complaints is a top priority for CMS, we have investigated a number of complaints from pharmacists that they have not been paid in a timely manner. The result of the vast majority of these investigations has been that the plan has paid the pharmacy in accordance with the terms of its contract. In some cases, a plan sent a check to the wrong address or to the pharmacy's claims payment representative (e.g., a pharmacy buying group or Group Purchasing Organization (GPO), etc.). Additionally, we discovered situations where plans may have printed checks that were held several days before mailing. In these cases, the plans quickly remedied any problems to ensure pharmacies are paid as expeditiously as possible.

The Medicare prescription drug benefit represents a new line of business for the pharmacies, but it does not differ substantially from the private commercial market with which they are already familiar. Thus, the contract terms require that claims for medications dispensed to people with coverage under the Medicare prescription drug benefit are being paid in a timeframe with which pharmacies are accustomed and within which they know how to operate.

In addition to expressing concerns about prompt payment and cash flow issues, smaller pharmacies have complained to CMS that low Medicare payment rates may threaten access to a robust pharmacy network for Medicare beneficiaries. We are very sympathetic to the concerns of small pharmacies. In particular, the MMA creates a competitive environment that provides constraints on how aggressive plans can be in negotiating pharmacy rates. CMS will not approve a plan for participation in the Medicare program unless it can demonstrate that it can meet the TriCare access standards for pharmacy network participation. This provides small independent pharmacies, particularly those in underserved areas, with bargaining power that they can use to negotiate favorable rates with the plans. Plans are also required to accept into their network any pharmacy that is willing to participate and hence, cannot selectively exclude specific pharmacies.

Congress specifically included these provisions to assure beneficiary access to pharmacies in the Medicare program. However, a corollary benefit to pharmacies is that these standards assure that pharmacy payment rates remain acceptable to pharmacies. For example, if a plan is overly aggressive in its contracting, and enough pharmacies independently decide not to accept the network rate, the plan will not be able to participate in the program because it does not meet the TriCare Access standards. On the other hand, if a plan can meet the TriCare Access standard because a sufficient number of pharmacies accept the plan's network contract rate, this is a strong indication that pharmacy network rates are acceptable to most pharmacies and that competition is working to keep premiums and prices low for beneficiaries while preserving access to an adequate number of pharmacies for the beneficiary. Aggressive contracting by plans, while meeting the TriCare Access requirements, has contributed to more affordable prescription drug costs for Medicare beneficiaries and taxpayers while preserving convenient access to pharmacies.

Supporting Quality in the Pharmacy Environment

While the new drug benefit has led to greater access to needed prescription medicines for our beneficiaries, CMS believes that further steps can be taken to support high-quality pharmacy care, that may result in better health and lower overall health care costs. In line with CMS' extensive efforts to improve and promote quality across the health care settings we serve, in April we announced the formation of the Pharmacy Quality Alliance (PQA). The goal of the PQA will be to agree on a strategy for measuring and reporting data that will help consumers make informed choices and

appropriate healthcare decisions. The founding members of the PQA include leading pharmacy organizations, health plans, consumer and employer groups.

CMS has implemented quality measurement programs in other payment systems within Medicare, and now it is time for a similar consensus effort to support pharmacy services in order to promote higher quality care and lower overall costs. We would like to like to place more emphasis on providing better support for high quality innovative healthcare. The PQA is the vehicle that can help us do this. We cannot do it by ourselves at CMS, but we will assuredly support and promote a collaborative effort across the healthcare system.

While the primary goal of the PQA is to develop strategies for defining and measuring pharmacy performance, CMS expects that this will lead to greater interest in plans that promote high-quality pharmacy services and potentially new pharmacy payment models to help improve patient outcomes at a lower cost. We are very interested in supporting the testing and development of those payment models. Private sector expertise, working in collaboration with the other key stakeholders in our program, is absolutely essential for making this happen soon.

Thanks to the Ambulatory Care Quality Alliance and to the leadership and hard work of the health plans and many physician organizations involved in ambulatory care, we have made substantial progress in creating consensus around meaningful measures of quality of physician care. We are now in the process of implementing physician payment demonstration programs that tests whether we can obtain higher quality care at a lower overall cost to our healthcare system.

We believe that through the PQA we can make a similar kind of progress in the development of pharmacy-care quality measures and the development of better support for high quality pharmacy care. Encouraging higher quality and less costly care is a critical priority for us at CMS, just as providing high quality care and avoiding preventable complications is a top priority for our nation's health professionals.

Pharmacists and other health professionals want to do everything in their power to provide the best care for their patients. When we provide consumers with better information about quality and when our payment systems encourage better quality, we enable health professionals to focus on what they do best.

This is part of a fundamental strategy in Medicare and Medicaid today. For 40 years, our programs have focused on paying the bills without really taking into account as much as we should, whether what we are buying really improves beneficiary outcomes, at the lowest possible cost.

Pharmacists and pharmacies have already demonstrated the tremendous value they provide in their work through the implementation of the Medicare drug benefit. They have shown that they can add much more as well, including helping people find lower cost drugs like generic medicine.

They can help people who have multiple illnesses understand how to use their medication thus improving patient compliance with treatment plans and preventing complications. All of these things can improve quality and reduce overall healthcare costs, to achieve a healthcare system that provides the right care for each patient every time.

A recent CMS analysis indicated that a beneficiary with common chronic conditions who enrolls in a Medicare prescription drug plan can save, on average, more than 55 percent compared to what they would pay without drug coverage. If they switch to lower-cost generic medications, which have exactly the same active ingredients as the brand-name medicines they had been taking, they could achieve savings of up to 70 percent over what they would pay without drug coverage.

Even larger savings are possible on a very broad range of drug plans for beneficiaries who also switch to lower-cost "therapeutically equivalent" drugs – drugs in the same drug class that have very similar effects. Those who switch to less expensive

brand-name therapeutic equivalents can save even more— with savings of up to 83 percent for the plan with the lowest cost.

Pharmacists can provide a valuable service through coordination of care with respect to prescription medications. This could help reduce adverse drug interactions and the accompanying expenses and risks to beneficiaries. Their participation in medication therapy management programs has the potential to help patients better understand how their medications work and what to expect. Promoting continuity and coordination of care and medication therapy management may lead to appropriate utilization of prescription drugs and better health for Medicare beneficiaries at a lower cost.

Deficit Reduction Act of 2005 (DRA)

In conjunction with concerns about payment rates in the Medicare drug benefit, pharmacists have also raised concerns about reimbursement rates in state Medicaid and other programs. Specifically, they cite recent changes in the Deficit Reduction Act (DRA) that will affect the way the Medicaid program calculates the Federal Upper Limit (FUL), which is used by many states to determine the maximum level of reimbursement at which a state will reimburse a pharmacy for multiple source drugs, including generic drugs. The goal of these DRA provisions is to capture the most accurate pricing data possible to assure that the Federal government and State Medicaid programs are not overpaying pharmacies for generic drugs.

While the DRA represents an opportunity for state and the federal governments to save money on generic product costs, actual savings will be dependent upon the actions that states take in implementing the new FUL. For example, if states do not maintain the right incentives for encouraging generic utilization, potential savings on generic reimbursement will be lost to higher and more expensive brand name utilization. For this reason, CMS has consistently encouraged states to align incentives for optimizing generic utilization and consider paying pharmacists more in dispensing fees if they can assist the state in saving money through greater generic utilization.

In its "Road Map to Medicaid Reform", CMS also encourages states to "Re-align Medicaid prices on prescriptions drugs with other purchasers and protect community pharmacists." Specifically, CMS said:

> *… States retain the overall authority for pharmacy reimbursement and may target reimbursement to providers, for example, through higher dispensing fees for independent pharmacies, pharmacies serving a large share of low-income beneficiaries, or pharmacies in rural areas to assure access. States can also adjust payments to provide more financial support to pharmacists that improve quality and reduce costs of drug coverage and chronic disease management…*

Private and public payers, including Medicaid, do not want to pay more for products and supplies than is reasonable or necessary. They are, however, willing to pay for a high level of service that promotes quality and the very best health outcomes. We believe that the states should have the tools and options to promote a value-based approach to the delivery of health care, and specifically the delivery of prescription drug benefits, and CMS intends to continue to support the implementation of such steps in pharmacy care.

Conclusion

CMS worked hard to resolve the early challenges of implementing the Medicare prescription drug benefit. We greatly appreciate the way in which the pharmacy community has stepped up to the challenge and how they have worked with us and the plans to identify and resolve these issues. Plans are now paying for millions of prescriptions every day, and pharmacies are receiving those payments in a timely fashion. Competition among plans has resulted in prices for beneficiaries and the government that

are substantially lower than originally expected, and we have already seen important improvements in the delivery of the drug benefit to reduce costs for pharmacists and to promote more effective use of prescription drugs. We look forward to continuing to work closely with the pharmacy community to ensure that our beneficiaries receive the highest quality of care at the lowest cost, and that pharmacies are able to operate freely in a market setting, running their businesses as they see fit, without the necessity of complying with a cumbersome regulatory structure.

I thank the Committee for its time and look forward to answering any questions you may have.

MR. DEAL. Thank you very much.

First of all, let me pass on some thank you's from my congressional office and I think probably from many other congressional offices where we have asked for your assistance in assisting our local pharmacists. We found that your organization has been very willing to do so and we appreciate that.

I think probably without exception, most who are in the supply chain would say that CMS has done an excellent job of putting on the number of people necessary to respond to the calls. It was a dramatic increase in personnel, I know, on your part to be able to do that, and I think some of the criticism would be that maybe the insurance companies haven't done a like job of being able to respond to inquiries and questions and calls.

Let me talk about a few things that I think all of us are mutually concerned about. One of the issues is the so-called enrollment lag. That appears to be where some of the confusion at the outset and will continue, I suppose, to be a problem as we have people enrolling every day and as we have renewals of those taking place. Would you address that issue, and is there a good solution for somebody who enrolls on the next to the last day of the month with a new plan and then the first day of the next month comes in and expects their prescription to be filled under that plan?

MS. NORWALK. Right. We have done a number of things. The Medicare Modernization Act tells us that when someone enrolls on the last day of the month, that their enrollment is effective the next day, if that is the beginning of the month. That has, in fact, caused some difficulty for us, and what we have done is a couple of things.

The first thing is we implemented something called the E-1 system, or the E-1 query, and as soon as the computer programs can talk to each other between the plans and CMS, the pharmacy will have access to computer information so they don't have to make a phone call to determine what plan the beneficiary is in, as soon as that enrollment can be processed. Now, enrollment processing can take a week or so, depending on how it comes in. If it is done through an agent or a broker, if it is done online, the timing may change a little bit. What we have done, given that there is a time lag in information flow, is we have tried

to let the beneficiary know to bring to the pharmacy whatever information he or she may have so the pharmacist can determine what plan is the appropriate plan to bill and what co-payments and so forth are associated with that plan. We have had some limited success with that, but given the Medicare Modernization Act dictates that what we have done thus far is really tried to educate beneficiaries. It was a significant problem when 20 million people joined the system on one day. It is a problem that we have seen significantly less of, but since a quarter of a million people are eligible for the Medicare benefit every month, it will continue to be an issue if people sign up late. So we encourage people to sign up early and bring with them whatever information they have to the pharmacy to minimize the issues once they get there.

MR. DEAL. All right.

One of the issues that we are going to hear talked about by the panel that follows you is the loophole. We will have the opportunity to discuss with the industry itself, but your statistics were rather revealing. The majority appears that the major plans are on a 15-day cycle. Is that right?

MS. NORWALK. Yeah, that is what our own research has found.

MR. DEAL. All right. Let me go to another one. The co-branding issue has been a big one, and you have said that you are not going to allow co-branding next year?

MS. NORWALK. Right.

MR. DEAL. They can't just carry those same cards with the branding on it. Will they have to issue new cards?

MS. NORWALK. That is correct.

MR. DEAL. Okay. I think that goes a long way toward taking care of that.

Let me ask you about medication management therapy. Where is that issue in the overall scheme of things, and what is CMS contemplating there?

MS. NORWALK. Well, for 2006, medication therapy management is something new for us, at least, obviously the whole thing is new. What we wanted to do was allow plans to develop their own best practices to figure out what we could do on a go forward basis, as opposed to requiring and mandating something in particular. It is one of the things that the Pharmacy Quality Alliance will be looking at to help determine what makes sense for plans and the pharmacists alike to ensure that beneficiaries receive the most value for the services, particularly for those beneficiaries who have chronic drug needs and are taking many, many prescriptions and spend thousands of dollars on drugs a year. In order to ensure that those beneficiaries are well taken care of and have the appropriate medication therapy management, we would like to see

what can develop in a number of the plans and then develop a best practice approach. I believe on your next panel you have someone testifying from Georgia, who, in fact, they are working on that issue in Georgia to also develop best practices, and that is the sort of thing that we would like to continue to encourage, whether it is through our QIO program, our Quality Improvement Organizations, or the Pharmacy Quality Alliance, we think there are lots of ways that this may be successful. We didn't want to stifle those ways in going forward, but want to encourage best practices as we learn more about those programs.

MR. DEAL. Real quickly, formulary changes. Dr. McClellan on March the 1st I believe said that there had been no requests for formulary changes. Has that status changed?

MS. NORWALK. That is not accurate. There are 450,000 formulary drugs in the Medicare program, if you look at all the formularies. We have had a request for under one percent of them. The last number that I saw, we had approved--of the 450,000 drugs, we had approved changes in 3,000 of them. Two-thirds of those changes, roughly 2,000, were because generics became available on the market. The other third were because either the drug was withdrawn from the market or there were other safety concerns, or there was an issue with the prescription possibly being covered by Medicare Part B. The physician benefit and the statute require that that be paid under the physician benefit, continue to be paid there, and that they may have had some prior authorization. So that is the majority of the things that we approved. After that--during that or shortly thereafter that hearing, we required that any changes in formulary that are made for 2006, and frankly, beyond, would have to grandfather the beneficiary in. We are very concerned about the bait and switch. So beneficiaries who relied on a particular formulary when they signed up for that plan and take a particular prescription on that formulary must be allowed to continue to take that prescription for the rest of the year, and then when they change plans the next year that formulary would be able to change.

MR. DEAL. Thank you.

MS. NORWALK. Thank you.

MR. DEAL. Mr. Allen is recognized for questions.

MR. ALLEN. Thank you very much, Ms. Norwalk, for being here.

I want to ask you some questions about the low-income subsidy. As of April 28, which is the last data that we have, anyway, the Families USA study shows that about one-quarter of the 7.2 million people, low-income seniors that qualify for the low-income subsidy are actually receiving the subsidies. The number may have changed since April 28, but that was their number. In Maine, the estimate was 45,000 are estimated to eligible for the low-income assistance, but as of April 28,

only 16 percent had received it. My understanding is some hadn't signed up, some had not been approved by CMS, and some had been approved but the system hadn't recognized that they qualified. If we can get those people into the system and get the extra help they need, I am sure you understand that would be better for them and better for the pharmacists and everyone.

So several questions. I wondered if you could provide a final tally on the number of beneficiaries who have signed up for extra help as of May 15, compared to how many are eligible, and I don't know if you might have that now, but the second part of that question is break that down for the number of people with disabilities. So the overall group, and then the number of disabilities. How many have signed up as compared to how many are eligible?

MS. NORWALK. From the best numbers that we have thus far, there are about 4.5, 4.2 million beneficiaries as of today. We continue to get enrollments coming in, so that is sort of where we are now. There are about 4.5 million that have not signed up for the benefit. While I am not sure that we have the same numbers that Families USA does, I am not sure that we use the same baseline. We estimate about 3 million of the 4.5 million are LIS beneficiaries, so a significant portion of those beneficiaries are LIS. I don't have a breakdown as to disabled versus aged beneficiaries, I am sorry. I don't know that I have ever actually seen those numbers. I can see if we can run them for you.

MR. ALLEN. That would be helpful.

MS. NORWALK. We will take a look at that.

If your point is, we need to reach out to these beneficiaries and get them enrolled in this plan in 2006, I could hardly agree with you more. There are a couple of things that we are doing and we have been doing since the beginning. Certainly, one is to reach out the community health centers; 90 percent of the community health center population tends to be the limited income subsidy individual, and reaching out through the community health centers to make sure that they know and understand what is available to them, even after this enrollment deadline has passed, because we have allowed a special election period for those who have LIS who qualify after May 15 who will be able to enroll in the plan for the rest of this year without a late enrollment penalty. So reaching out to them now is really our number one concern from an outreach perspective and beneficiaries.

In addition, we have issued a grant to the National Council on Aging to do more specific and targeted outreach and determine what methods work the best to find these people and to let them know about the benefit. They are, without a doubt, the hardest group to reach that we have, and we are looking forward to as many ways to get them as possible to at

least give them the option, help them with their Social Security paperwork, and allow them to join a prescription drug plan.

MR. ALLEN. Have you thought about working through hospital emergency rooms, for example?

MS. NORWALK. Also a terrific idea, and I will go back and see if that is another way that we have approached it, and if we haven't, I think it is something that we can at least get the hospitals and work with them to put information in their waiting rooms and the like. It is an excellent idea.

MR. ALLEN. Okay.

MS. NORWALK. I don't know if that is a part of our plan or not.

MR. ALLEN. I am told that the disabled tend to not use the same sources of information as others, and I think--don't you have to reach out in somewhat different ways to find the disabled population?

MS. NORWALK. Absolutely. We have--

MR. ALLEN. There are, I guess, some who might show up at community health centers, but--

MS. NORWALK. Right.

MR. ALLEN. --they might not.

MS. NORWALK. Right. From an LIS perspective, that is one of our targets, but one of the things that we have done generally with outreach is really done an unprecedented campaign to find people, as we say, where they live, work, play, and pray. We have worked with church organizations, religious organizations generally. We have done all different types of media advertisements. I am sure you have heard about the bus that toured around the country. I know it spent some time in Maine.

MR. ALLEN. It did.

MS. NORWALK. So we have done a lot of things. We have tens of thousands of partners who have been fantastic and instrumental in helping us find the 32 million people who have coverage through Medicare, separate and apart from the six million with other coverage, in order to make sure that people didn't miss the May 15 opportunity. We wanted to be sure that they knew about it and they were able to make a choice by May 15.

MR. ALLEN. It would be very helpful--I thank you for all the work you are doing, and will do. It would be very helpful if you could give us as much data as possible on who signed up, who may still be out there among those who are eligible for the low-income subsidy, because I think that is the way that we can all work together to address the problem most effectively. So I would appreciate following this hearing--

MS. NORWALK. Sure.

MR. ALLEN. --that data as soon as you have it available.

MS. NORWALK. No problem.

MR. ALLEN. Thank you.

MR. DEAL. Dr. Norwood.

MR. NORWOOD. Thank you very much, Mr. Chairman.

Ms. Norwalk, welcome. We are thankful and glad that you are here. Over the last 12 years, I don't suppose I know many people that have been more critical of CMS than I have been, but I have got to tell you, I think you folks have handled this Part D prescription drug part rather admirably. I have watched carefully, waiting and watching, and you have not made too many mistakes. I appreciate that fact.

Tell me this about your authority. CMS generally has a lot of authority, and I wonder about your authority to pace these Part D plans and their payment practices. How much leeway do you have in that?

MS. NORWALK. Well, we do have a significant amount of authority, particularly to ensure that the plans can implement the benefit as written and follow our guidelines, so we have authority to ensure that, obviously, the plan is not either prescribing the prescription or dispensing it, but that is actually done through a pharmacy, and if that part fails, then we have great problems. So we do--and the plans have been very helpful in working with us, so if we come up with a problem, they are willing to take a look and try to resolve that issue without question, because they, too, appreciate that this, in order to be successful, that the pharmacists need to play an important role. You certainly have a number of plans on the next panel that you can ask about that specifically, but we have found them to be, as a general rule, helpful.

But inasmuch as they are not abiding by their own contracts, and beneficiaries don't have access to prescriptions, which at the end of the day, even though you don't have a beneficiary representative, it is what I care most about. Can beneficiaries have access to their prescriptions at a price that is affordable for both the beneficiary and the taxpayer?

MR. NORWOOD. Well, we all care about that part of it. I also happen to care about particularly the community pharmacists, too, that have spread all over Georgia. I am curious at a remark you made in your opening statement where you said that you didn't have much authority over payment being made in a particular timeframe. I am not seeing you all have any trouble having authority at making rules. It seems to me it is pretty important that these plans pay the pharmacists in a timely manner.

The reason I bring that up is that may be going on today, because all this is new, but history would tell us that that did not happen very well over the years with health insurance. Plans just typically would run rough shod over people, particularly at the end of the month, making sure they didn't get paid, et cetera, et cetera. I think maybe you know the story. I want to know why you couldn't use your authority to say--and I

am not trying to term up a time, but let us just say 30 days. Why couldn't you insist that if you want to participate in this program, you must pay your bills in 30 days?

MS. NORWALK. Well, I think that generally you are correct. Medicare has a significant amount of authority to do any number of things. However, in this particular instance, the statute is clear that we are not permitted to interfere with the negotiations between plans and pharmacies, or plans and manufacturers, for that matter. One of the most critical things are payment terms within those negotiations, and payment terms both include the rate of payment as well as the timing of payment.

Now, you did ask an important question, and I think it is somewhat of a distinction. We do need to ensure that plans pay pharmacies and they pay so in a timely manner. How timely is defined is a matter of negotiation between the pharmacist and the plan. It is nice to know that 18 of the top 20 plans do pay within a 15-day cycle. That is helpful.

MR. NORWOOD. What if they don't? What can you do?

MS. NORWALK. It is a matter of contract between the pharmacy and the plan. So if the pharmacy determines that that is not sufficient amount of time, the pharmacy has the option of not--during renegotiation.

MR. NORWOOD. Probably I don't have that option if I am in Watley, Georgia. You know, the single pharmacist out there doesn't have many options. The big plan has all the options, and if they may agree in their contract to pay in 15 days, there is no reason on earth to believe that will continue. What can you do at CMS to kick them out if they don't do that?

MS. NORWALK. Well, other than requiring them to pay according to their contract terms between the two, which is something that we have offered to do. Typically, it is an issue between the two private parties, but if you know of pharmacists who are not being paid in accordance with their terms of the plans, we would appreciate it if you would let us know so that we can investigate and ensure that those plans meet the obligations of their contracts.

MR. NORWOOD. I would in a minute, but I am more concerned because I don't hear you saying this is automatically something we at CMS are aware of. We know this can happen. As more or smaller plans drop out, there are going to be fewer plans. They are going to consolidate. I mean, I can just sort of see it 5 years from now, and I am really trying to make sure you have the authority to do something about it.

MS. NORWALK. One thing the Medicare Modernization Act does do is it requires that the plans adhere to the Tricare Access Standards for pharmacies, which means that 90 percent of beneficiaries have to have access to a pharmacy within two miles if they live in an urban area, 90

percent of beneficiaries have to have access within five miles in a suburban area, and 70 percent of beneficiaries in the plan have to have access to rural pharmacies within 15 miles.

I do know that in certain instances, pharmacies have used that to their advantage in negotiating, although I hear the same complaints that you do, is that independent pharmacies, particularly smaller ones, have a difficult time negotiating with the plans and feel that they have little negotiating leverage. So I don't want to diminish that--

MR. NORWOOD. No, don't.

MS. NORWALK. --but the Medicare Modernization Act, other than the Tricare Access Standards, does not have any additional protections that help the pharmacy in that particular way.

MR. NORWOOD. Mr. Chairman, I see my time is up. I hope we will be able to submit in writing the many questions. I have a long list I would like to get answered.

MR. DEAL. Yes, that has already been agreed to by unanimous consent, so you may do so.

Ms. Baldwin, you are recognized for questions.

MS. BALDWIN. Thank you, Mr. Chairman.

On March 1, our subcommittee had a hearing entitled "Medicare Part D: Implementation of the New Drug Benefit." At that subcommittee hearing, Dr. McClellan appeared and Ranking Member Dingell had a series of questions that he presented on prior authorization and appeals procedures under Part D plans. And we were, in offering those questions, interested to know how many beneficiaries had not been able to fill needed prescriptions or have had to go through complicated administrative hoops.

So first, Ranking Member Dingell asked for data on the number of appeals filed to date, the types of appeals filed, whether it was resolved in favor of the beneficiary or in favor of the plan, and the most commonly appealed drugs. I am wondering whether you have the data that was requested here with you today.

MS. NORWALK. I don't, but I am happy to get it for you.

MS. BALDWIN. Okay.

A second area of inquiry was a request for a listing of the different medicines across plans that are subject to restrictions, what sort of cost sharing is charged for those medications that are restricted. And I don't know if you have any of that data with you today--

MS. NORWALK. It is available on our website, Medicare.gov, so if you have someone in the office, I am happy to print it off for you, but it is one of those things that you can look at by plan and actually with each of the plans--there is another way, as well, but let me finish the Medicare.gov. It is important for beneficiaries or anyone who is looking

at which prescription plan to choose, for example, what requirements there would be. Is there step therapy, prior authorization, other utilization management techniques that help keep the cost down? And if they exist, they are actually on our website by drug with an asterisk so that you can find out--if you are interested in a particular--drug, you can find out what plans in your area, in Wisconsin, for example, have varying requirements. Not all the plans do, but many do.

MS. BALDWIN. Well, we are certainly interested in aggregate data, and I--

MS. NORWALK. I will see if we have--

MS. BALDWIN. In terms of--

MS. NORWALK. I don't know that we have aggregate, but I will check.

MS. BALDWIN. In terms of propriety, I certainly hope that the Ranking Member Dingell's specific questions will be responded to before they are posted on the web. I mean, there was a series of questions, the last area, by the way, being on plan performance with respect to appeals, which plans in each State were the best and worst with respect to meeting CMS-required appeals time frames, and which plans did beneficiaries have to appeal the most, et cetera.

MS. NORWALK. My understanding is the plans have to submit the specific data to us by the end of this month. We haven't seen that data yet. We do have some preliminary data from the appeals that went to the Center for Health Dispute Resolution, our contractor who looks at the second level.

MS. BALDWIN. But my understanding is that CMS requires reporting on a quarterly basis, and the end of the quarter would have been March 31--

MS. NORWALK. We certainly hope that we can promptly get--because of our transition policy, we expect to have very few appeals because we required plans to cover those drugs for the first 90 days. I wouldn't expect a whole lot for the first quarter. The second quarter is really going to be important.

MS. BALDWIN. We certainly hope that in a timely fashion these questions that were posed on March 1 by Ranking Member Dingell can be reported to us on the committee.

I wanted to just move to a different topic briefly, and that is the donut hole. You know, when Congress was debating this legislation, I certainly was very concerned about this particular policy, and I know many of my colleagues are. Just to remind everyone, the donut hole is the point at which the beneficiaries reach $2,251 in drug spending and once they reach this point, there is no drug coverage at all for them until they surpass $5,100 in spending. I guess one of my concerns is how we

are going to educate beneficiaries and pharmacists about this. Many of our constituents will be affected. I think many will walk into their pharmacies one day to have their prescription filled and suddenly discover that their prescription is no longer covered because they have fallen into the donut hole. I know I am trying to get the word out so that people are fully educated, but I would like to hear what CMS is doing to work with pharmacists and beneficiaries to prepare everyone for this.

MS. NORWALK. Well, there are a number of different things. In terms of some statistics, you might find it interesting that of the beneficiaries, of the 38 million beneficiaries with prescription drug coverage, 75 percent, for whatever reason, don't have a donut hole at all. Either they have employer coverage, they have chosen a plan that doesn't have a donut hole, because it was an option for beneficiaries to choose a plan without one. Twenty percent of beneficiaries who chose plans chose a plan with coverage in the gap, either brand or generic, or generic only. So many beneficiaries won't have that, because that is the choice they made before May 15. Of the remaining 25 percent, we anticipate now probably between 10 to 15 percent of them would actually reach a gap in coverage. Beneficiaries are required by CMS policy to ensure that beneficiaries know where they are from an EOB perspective so they know how much they have spent in prescription drugs, how much they have, and so forth.

So really, it is up to the plan to ensure that the beneficiary knows where they are on that coverage and the plans are required to let them know what they have spent thus far in terms of prescriptions and have that available to them, say, if they were to call their 1-800 number at the plan, how much is left before I reach the coverage gap, for example. So there are lots of different ways. I appreciate that this is going to be a very important point for beneficiaries who don't understand what this means, that it is a second deductible and what happens if they were to get there.

One of the other things that we have been doing is working very closely with patient assistance programs, and we appreciate that many beneficiaries who didn't have coverage often look to these patient assistance programs to get help. The Senate Finance Committee had a hearing not too long ago, and many of the companies pledged to work with CMS and the Federal government to continue those programs, even when beneficiaries do have prescription drug coverage under Medicare. So we are hopeful to work with a number of different ways to ensure that those beneficiaries at least understand that they do get discounts once they reach the coverage gap, something they may not have had before if they didn't have coverage, or that they can have access to other help through pharmaceutical manufacturers' assistance programs.

MR. DEAL. The Gentlelady's time has expired.

Mr. Shadegg is recognized for questions.

MR. SHADEGG. Thank you, Mr. Chairman. I apologize that I could not get here earlier. I commend you for holding this hearing.

Ms. Norwalk, I think CMS is performing a very important role here, and I am encouraged that your study has found progress in this area. I am, however, concerned. I come to this kind of from the earlier debates over patients' rights and the issue of prompt pay. I am concerned, and I would like to know whether when you looked at billing errors as the reasons for delay in payment, when I hear from doctors back home, I hear doctors in the billing context with doctors tell me well, the errors were minute. The errors were not really the kind of thing that prevented the insurance company from paying the bill, or the information they claimed they needed was new and added on.

One question I would like you to briefly address is in your study when you found, in fact, that it wasn't part billing errors or lack of information which caused the pharmaceutical industry perhaps to delay in paying the pharmacies, were they legitimate absences of information supplied by the pharmacists, or did you look at the character of the missing information?

MS. NORWALK. I don't know that we studied in particular whether or not something was a clean claim, which was the vernacular, of course, for what information is missing, although I understand anecdotally that it is pretty consistent with what is seen in the commercial market. You might want to ask the second panel their impression about this, but that has been my understanding. I don't know that we did a systematic study of why claims were denied as opposed to paid late. We looked more specifically at claims that were paid beyond the billing cycle that the plan had contracted for.

MR. SHADEGG. Although I understand that part of the reason for them being delayed late is that there were errors or lack of communication?

MS. NORWALK. Right.

MR. SHADEGG. One of the problems is that in this situation, late payment means more money in the pocket of one party and less money in the pocket of the other party, because of time value of money.

My second question is when I negotiate with my credit card company, and quite frankly, I don't do much negotiating, they tell me that there is a very stern late fee, and if I pay my bill with the credit card company late, they don't discuss with me whether or not there was some dispute, they just impose the fee. You mentioned earlier that you are prohibited from injecting yourself in the negotiation between the pharmacist and the plan. I guess one of my questions would be do you

know why? And is it, I suppose, a lack of bargaining power, the pharmacies do not insert automatic late penalties, late fees, for late payment of fees as a contractual matter?

MS. NORWALK. And I don't know. I haven't looked at enough contracts to say definitively whether or not--some may, in fact, have a late fee. Some may not. I really can't speak to that. It wasn't a part of what we look through, but again, maybe some of the next panel may have some idea whether that is included. It certainly is up to the pharmacy and the plan to negotiate that, and it could be incorporated in the contractual requirement if they wanted.

MR. SHADEGG. I appreciate all your planning and the report you did.

I would yield the balance of my time to my colleague from Georgia, Mr. Norwood.

MR. NORWOOD. Thank you, Mr. Shadegg. I appreciate that.

Ms. Norwalk, just a quick follow-up on preauthorization. Explain to us exactly--when I walk in with a prescription and I have got a temperature of 105 and I am ready to get that prescription filled and I hand it to the pharmacist, and he says, hey, I have got to get this preauthorized. Take us from there.

MS. NORWALK. Well, it depends. One of the things that we have been working on is to allow the pharmacy to have information at the pharmacy counter through the NCPDP standards so they can get a standard message as to what the problem is with a particular prescription. Does it require prior authorization and do you need to call the plan? Is a generic available? With prior authorization, one of the issues that we found, for the most part, was that if the Medicare Part B program, the physician benefit was intended to pay for this drug, in many instances under Part B, sometimes it did not pay for it under Part D and so on.

MR. NORWOOD. Well, how long does that--excuse me, the time is running out. How long does that take, and how many plans require preauthorization on prescription drugs?

MS. NORWALK. I don't have the exact number. A significant number of plans do it, particularly for B versus D. Sometimes they do it for safety reasons. In terms of how long it takes will probably depend on the issue for prior authorization, whether it is Part B versus Part D, whether it is a safety issue, whether it is gee, don't they want to take the generic question, and if they can call the plan and so forth.

So a lot of that can be adjudicated online, which means little time, sometimes over the phone.

MR. NORWOOD. Does the pharmacist or the physician have to get the preauthorization?

MS. NORWALK. Well, typically the pharmacist will need to get it in order to bill, but in certain instances they may need to call the physician,

which is why we have allowed physicians to write a diagnosis on the script to shortcut that step.

MR. NORWOOD. But is this out of hand? Is it going too far? That is the last question.

MS. NORWALK. We haven't heard so many complaints thus far to lead me to believe it has gone out of hand. We do pay attention to this sort of complaint, so I don't think so. I do think we could make it more smooth, which is something that we are working on, and it is one of the things that the Pharmacy Quality Alliance is working on. I don't think that it is out of hand. We do allow an emergency exception, of course, so that beneficiaries can get an emergency fill if necessary, even without prior authorization.

MR. NORWOOD. Thank you, Mr. Shadegg, thank you, Mr. Chairman.

MR. DEAL. Thank you.

Ms. Eshoo is recognized for questions.

MS. ESHOO. Thank you, Mr. Chairman. Ms. Norwalk, welcome.

I would like to examine the area of those that change over from one plan to another. Since the benefit has been available to America's seniors, can you give us an outline of approximately how many changes there are every month in switching from one plan to another?

MS. NORWALK. We do have the numbers; I don't think I have them with me, but we do have the numbers of those who are dually eligible who switch from one plan to another. Sometimes they switch--

MS. ESHOO. Those as well.

MS. NORWALK. Yes, there are others. I will have to see if we actually--I have seen the numbers on duals. I will have to see if we can find the others. Of course, after May 15, while the duals can continue to switch month after month, other beneficiaries will need to wait until the November 15 open enrollment period--

MS. ESHOO. I understand, but dual eligibles are not the only ones that--

MS. NORWALK. No, that is true.

MS. ESHOO. --that have changed.

MS. NORWALK. I will see if we have got them.

MS. ESHOO. The title of the hearing is "Examining the Federal Government's Partnership with America's Pharmacists," and so my question goes to that partnership. If, in fact, and it is fact that individual insurers put out their plans and then have a relationship with those that they insure, it seems to me that the Federal government needs to understand very well and know the movement of those plans and where some of the glitches might be. So I would very much appreciate getting a number on not only the dual eligibles, but on everyone.

I want to continue in this vein. Whatever that number is, say someone changes, walks into a pharmacy on the 27th and they are changing, that becomes a burden for the pharmacist in order to be able to track, to know what they have moved to, what is included, what is excluded. And that is the real point of my question, but we need to examine what the changes are and then take a look at what we might be able to do about it. Going into my local pharmacy--and I have a mix of chains and small pharmacies in my district--this is a real issue for them. They have to be kind of the--not kind of, you know, the doctor, the pharmacist, the social worker, the good neighbor, and the business person at the counter all at once.

MS. NORWALK. Absolutely.

MS. ESHOO. So it does present a problem. We are going to say we have examining the Federal government's partnership with them, we are all extolling pharmacists. They are the trenches. So this is an area I think we need to not only know what the numbers are, but then how smoothly it can go.

I mean, what I am struck with is I can go into any department store and I like to use just one credit card, but they always want to have you open an account at their store. They are going to give you an additional 15 percent off, so open an account with us. They can issue a store credit card. Now, has CMS looked at being able to help pharmacists and seniors with faster data transactions?

MS. NORWALK. We have, actually. One of the things that I mentioned earlier was something called the E-1 system, and this system was designed specifically for the problem that you mentioned, to address that problem so that a pharmacy--

MS. ESHOO. Is it in place?

MS. NORWALK. It is in place.

MS. ESHOO. And where is it?

MS. NORWALK. It is in place at every pharmacy counter across the country. Almost all pharmacies do use this transaction. It has been used over 14 million times thus far to figure out what plan is the beneficiary in, even if they switched.

Now, as I was talking with you--

MS. ESHOO. And the data, I mean, the system functions within what period of time? Is it--

MS. NORWALK. Split seconds.

MS. ESHOO. Split second?

MS. NORWALK. If all the data--

MS. ESHOO. Why are my pharmacists complaining, then?

MS. NORWALK. Well, it may well be--

MS. ESHOO. They don't know about it, or--

MS. NORWALK. --they may not know about it. We have done a significant amount of outreach, but we are more than happy to work with your office to make sure that they do know about it and do know what sorts of questions to use to query the system, whether it is the Social Security number of the beneficiary, whether it is their birthday, their last name, and so forth. We have tried to make it as easy as possible just by putting in a few patient identifiers that the system will tell them exactly what plan that beneficiary is in instantaneously.

We have also been working diligently with the plans to ensure that they submit that information to us as quickly as possible so that we can put it into the system.

MS. ESHOO. But that is where it originates.

MS. NORWALK. There--we have--

MS. ESHOO. Wait a minute. How much time is there between a requirement for them to report the change so that it can go into this system?

MS. NORWALK. It typically happens within days of the enrollment.

MS. ESHOO. Well, but that is my very point. I mean, if Mrs. Smith goes to the pharmacy, she has changed who she is insured by, and you are saying that it is split second information for the pharmacist but it is not entered, how is it split second?

MS. NORWALK. Well, as soon as it is entered it is split second. That is one of the--

MS. ESHOO. Wait a minute, that is a little misleading, though. Wait a second here, all right. I mean, the system has to be able to record it in order for the pharmacist to get split second information. So it is not split second information first, it has to be processed. That is really the heart of my question, and I mean, I am not fabricating this. This is an area of great discomfort, and the pharmacists are the ones that are caught in this glitch. So tell me what you propose to do about it and by when, or what we can look forward to, or what I say back to them?

MS. NORWALK. As Chairman Deal pointed out earlier, in fact, his first question looked at the enrollment lag and what does that mean. If you sign up for the benefit on, let us say, April 30 and it is in effect May 1, there will be a time lag before that information is actually input into the system. It typically is about a week for that lag to occur. What we suggest and what we tell beneficiaries is to bring in information so that the pharmacist knows what plan that beneficiary has either changed to, what is the name, and we have required the plans in sending letters to beneficiaries to ensure that it has something called a bin PCN number so the pharmacist knows exactly what to input and what plan to use.

So we have done an effort--

MS. ESHOO. I appreciate your response. I have to tell you that I think that people look for answers that are a bit more nimble than that, but this is really a function of such a complex system that, you know, it renders these problems.

So thank you. I didn't make an opening statement, Mr. Chairman, but I think I am still being held to having made one. Thank you.

MR. DEAL. Dr. Burgess is recognized for questions.

MR. BURGESS. Thank you, Mr. Chairman.

Ms. Norwalk, if we could just stay on that for just a second, the enrollment lag. Is the Part D system any more or less nimble than other insurance products that are already out there?

MS. NORWALK. It depends on the date in which they can enroll versus the date in which the enrollment is effective. The statute tells us that you can enroll--they specifically define a time period and also tell us when the enrollment is effective, so it is a matter of when the beneficiary signs up. I would suspect in most employer plans, they have an opportunity to choose between two or three plans and are often given--even, I think, under FEHB I would be willing to bet--I can't remember when our open enrollment period ends. So FEHB ended December 9 this year, so there was a three-week lag between the time in which you chose a plan and the time in which the beneficiaries--or, you know, the Federal employees had that enrollment effective. So I suspect that is pretty standard that Medicare is unusual.

MR. BURGESS. Medicare is unusual?

MS. NORWALK. Yes.

MR. BURGESS. How long is your enrollment lag? If FEHB is three weeks--

MS. NORWALK. Zero. Which is to say if you would sign up at April 30 at 11:59 p.m., at 12:01 a.m., two minutes later, your enrollment is effective in the plan you chose.

MR. BURGESS. But there is still a lag until somebody inputs the data, correct?

MS. NORWALK. But in terms of--that is the coverage begins then, which is to say, let us say you have got a prescription and you went to the pharmacy after midnight on the first day of the month. You could submit your claim and get reimbursement, so you do have coverage. I think the point being made was that may be difficult for the pharmacy to determine well, what plan are you in if you don't remember.

MR. BURGESS. But is that degree of difficulty any more or less than people encounter when they change insurances and jobs?

MS. NORWALK. No.

MR. BURGESS. January seems to me to be a time when a lot of that happens, and people encounter that every day in other insurance products. This is not unique to Part D.

MS. NORWALK. I would even argue the opposite, that because of the E-1 query system that we do have, we make it significantly easier for pharmacists because we provide for almost all of our beneficiaries split second information for them to determine what plan a beneficiary is in.

MR. BURGESS. Okay. Now, we heard from one of the pharmacists when we had this hearing earlier in the year, one of the complaints was that when they would get a coverage denial, there would be no explanation that came along with that, which left them then having to phone back to the physician's office and try to figure out what the appropriate next steps would be. Are we working on that?

MS. NORWALK. Absolutely. It is one of the top priorities of the Pharmacy Quality Alliance, which is a combination of plans, pharmacists, and CMS, as well as ARC so that we can ensure that the pharmacist knows why something is denied. Is it an excluded drug, is it a barbiturate or benzodiazepine? Is it something that requires prior authorization? Is it a drug that is not on the formulary because there is a generic available? Standardized messaging is one of the most common complaints and burdens that I heard from pharmacists, particularly early on, and it is something that the PQA has already begun to address so that through the same type of system, this E-1 query, similar type of HIPAA standard, standard messages can be passed from plans to the pharmacist in order to reduce the burden at the pharmacy and provide instantaneous messaging, the same for each plan.

MR. BURGESS. But I would also offer that that is not a whole lot for those who haven't been in the business of writing prescriptions and holding on 800 numbers from PBMs. That is not unusual in the real world, even before Medicare Part D came along.

MS. NORWALK. Right.

MR. BURGESS. Dr. Norwood was asking some questions about the authority you have to police Part D plans and their payment practices. Have you got a big enough stick to police the plans?

MS. NORWALK. We do have pretty significant authority. At the end of the day, of course, if we don't think the plans are meeting up to our expectations, we won't renew their contracts for the following year. Typically, if you look at the past, most of the problems we have had with our Medicare Advantage plans have been in the marketing arena, and we would not permit new enrollment, for example. We also have, under certain circumstances, civil monetary penalties that we can do.

MR. BURGESS. You do?

MS. NORWALK. We do. It depends on the violation.

MR. BURGESS. Now, the coverage gap was also brought up, and I do feel obligated to mention that there are a number of plans, at least in my State, where if, in particular, is willing to select a generic product, there is no coverage gap, and I think I would like to encourage more people to look at that when they sign up. In fact, there is one plan in my State that has branded and generics in the gap. I hope that product is still available next year. I don't see how it is possible, but presumably they have a business model they think will work.

In the coverage gap, though, some of the large pharmaceutical companies have made their patient assistance plans available, but there was concern from the Office of Inspector General that this may be regarded as an illegal inducement for them to continue doing that. Have we got that squared away?

MS. NORWALK. Well, the OIG has put out something called an advisory opinion for a company. I think it is widely known to be Schering-Plough, that allows Schering-Plough to provide coverage for beneficiaries without regard to the fact that they are in the prescription drug program. So there is a way to go about that. I understand that other companies have submitted to the OIG advisory opinion requests. So some ways are problematic, other ways are not, and I know that the companies are working with the OIG to ensure that if they do have a patient assistance program, they are not getting Federal reimbursement for the drugs that are provided under that program, and that is really the key to ensure it is not a kickback.

MR. BURGESS. Finally, are there any areas of the country where you have identified that people have trouble obtaining a prescription, whether it be through mail order, mom and pop, or a large name pharmacy?

MS. NORWALK. Not that I am aware of. I don't think that we have heard complaints about people being able to obtain prescriptions anywhere. We were very serious when we went through the Tricare Access Standards to ensure that plans would not be approved unless they had met those standards that pharmacies were available for beneficiaries, and not just mail order, but also retail.

MR. BURGESS. Okay. Mr. Chairman, thank you. You have been very helpful. I will yield back.

MR. DEAL. Well, thank you, Ms. Norwalk. We appreciate your presence here today, and I am sure there will be some follow-up that you will have on written questions. Thank you very much.

MS. NORWALK. Thank you.

MR. DEAL. May I ask panel two if they would take their seats at the table? I thank the gentlemen for being here today, and I will introduce the second panel.

First of all, Mr. Mark Merritt, President and CEO of Pharmaceutical Care Management Association; Mr. Timothy Hopkins, Vice President of Retail Mail Service Operation for Pharmacy Management of WellPoint; Mr. Kenneth Couch, President of Smith Drug Company in Spartanburg, South Carolina; Dr. Buddy Harden, Executive Vice President and CEO of the Georgia Pharmacy Association, and my token beneficiary on the panel; Mr. Gary Wirth, the Director of Professional Services of Ahold, USA, and on behalf of the National Association of Chain Drug Stores; Dr. Larry Galluzzo, am I pronouncing that close enough? That is correct, all right.

MR. GALLUZO. I am a little bit embarrassed by being called a doctor. There is a doctorate program for the college of pharmacy. I have not taken that, so I am not a physician. I am not a Doctor of Pharmacy, I am Mr. Larry Galluzzo.

MR. DEAL. Well, Mr. Galluzzo, we are pleased to have you here. He is the President of Skilled Care Pharmacy in Mason, Ohio. And Mr. Charles Hallberg, President of MemberHealth, Inc. of Cleveland, Ohio.

Gentlemen, we are pleased to have you here. As I said at the outset of the first hearing, your written testimony has already been made a part of the record. We would ask you in the 5 minutes allotted if you would summarize that.

Mr. Merritt, we will begin with you.

STATEMENTS OF MARK MERRITT, PRESIDENT AND CEO, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION; TIMOTHY HOPKINS, VICE PRESIDENT, RETAIL MAIL SERVICE OPERATION FOR PHARMACY MANAGEMENT, WELLPOINT, INC.; KENNETH COUCH, PRESIDENT, SMITH DRUG COMPANY; DR. BUDDY HARDEN, EXECUTIVE VICE PRESIDENT AND CEO, GEORGIA PHARMACY ASSOCIATION; GARY WIRTH, DIRECTOR OF PROFESSIONAL SERVICES, AHOLD USA, ON BEHALF OF NATIONAL ASSOCIATION OF CHAIN DRUG STORES; LARRY GALLUZZO, PRESIDENT, SKILLED CARE PHARMACY; AND CHARLES E. HALLBERG, PRESIDENT, MEMBERHEALTH, INC.

MR. MERRITT. Thank you, Chairman Deal, and other distinguished members. We appreciate this opportunity to testify before you today. My name is Mark Merritt. I am President of the Pharmaceutical Care Management Association. I am pleased to be here to discuss how pharmacy benefit managers and Part D plans are working with

pharmacists to deliver safe and affordable prescription drugs to America's seniors.

Over the past two decades, private and public purchasers have turned to PBMs to help them manage drug spending and ensure that enrollees have access to the medicines that they need. Typically, we save clients 25 percent of what they would otherwise spend without our help. PBMs are now helping to administer the Part D benefit. So far, the results are promising. Part D premiums are coming in 30 percent lower than originally projected and discounts on drugs being almost twice as deep as originally projected. In this regard, we are exceeding expectations set by Congress and continuing to move forward. Recent surveys show that seniors like the program as well, once they actually begin to use it.

Retail pharmacists play a crucial role in the success of Part D. PBMs understand this and contract with over 50,000 pharmacies across the country. Our member companies directly employ well over 4,000 pharmacists in our own industry. We realize that the business environment for retail pharmacies has changed in recent years. The advent of large chains like Wal-Mart and Walgreen's, the increase in third party coverage of drugs, the decrease in the number of cash-paying uninsured customers and reduced Medicaid payments are all forces at work here. We understand that. To their credit, in spite of these challenges, pharmacies continue to grow. Just this Sunday, NCPA, the group representing the community pharmacists, said that of their 25,000 independent pharmacies across America, that while 12 had closed their doors since the beginning of the year, 200 new independent pharmacies have opened in the past year. Another recent article quoted a pharmacist repeating what many have said today, in that the early startup problems have largely been resolved. There is always more to be done. We understand that, but we think that we are moving ahead in the right direction.

Nonetheless, to address the concerns expressed by the pharmacies and others, PCMA member companies recently pledged to pay pharmacy claims within 30 days. This is the same standard used for doctors and hospitals in Medicare's Part A and B. It is used by most of the commercial market, not just healthcare, but business generally in America, along with individual payments, and it is also the standard used by the community pharmacies own Medicare PDP, the CCRX.

PCMA member companies process tens of millions of claims a month, and make payments to over 50,000 different pharmacies. With such large volume, a 30-day standard helps improve quality, ensure accurate payments, reduce fraud and abuse, all of which cost the system billions of dollars each year.

It is not clear that the legislative proposals to address pharmacists' concerns about prompt pay and medication therapy management would add value to seniors. We do know that they cost a lot more money. Recently, PCMA commissioned a cost estimate of one proposal S. 2263, and found that the bill would increase costs by $9.4 billion over 10 years. Of that amount, $7.7 billion would be new costs to the Federal government, while $1.7 billion would come from increased beneficiary premiums. Other proposals go even further. H.R. 5182 includes many of the same provisions as the Senate bill, but would also mandate sharply increased dispensing fees. PCMA believes that these measures would increase costs even more than $9 billion mentioned by the study of the other bill, the Senate bill. The payment and design of clinical services we believe should be left to the private sector, not micromanaged by the Government. Micromanagement would increase costs to the Medicare program, to beneficiaries, and taxpayers with no corresponding benefit to consumers.

PCMA member plans are proud of our achievements of the first few months of this new program. We have faced hurdles along the way, but have worked collaboratively with pharmacists and others to address them. The services we provide and the results we are seeking show the high standards that we place on quality and affordability. In short, we believe that we are doing the job that Congress and America's seniors have asked us to do, although, of course, we can always do more and are willing to do so.

I appreciate the opportunity to testify today, and I am happy to answer any questions you might have.

[The prepared statement of Mark Merritt follows:]

PREPARED STATEMENT OF MARK MERRITT, PRESIDENT AND CEO, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Good Morning Chairman Deal, Ranking Member Brown and all the Members of the Health Subcommittee. I am Mark Merritt, President and CEO of the Pharmaceutical Care Management Association (PCMA). I'm pleased to be here today to discuss how pharmacy benefit management (PBMs) companies and Medicare Part D plan sponsors are working together with pharmacies across America to deliver safe and affordable drugs to patients.

PCMA is the national association representing America's PBMs and Medicare Prescription Drug Plans (PDPs.) PCMA represents both independent, stand-alone PBMs and health plans' subsidiaries. Together, PCMA member companies administer prescription drug plans that provide access to safe, effective, and affordable prescription drugs for more than 200 million Americans in private and public health care programs, including five of the ten national Medicare Part D PDPs.

MARKET CHANGE AND CONSUMER DEMAND

By way of background, I want to share with you some information about what plans and PBMs do, and why we exist in today's marketplace.

As Members of this committee know, the pharmaceutical marketplace has changed significantly in the last 20 years with an unprecedented number of new drugs coming to market, many with "blockbuster" sales potential. A significant growth in utilization of prescription drugs began in the mid-1980s as a result of the availability of new medicines. As more and more people demanded access to these medicines, employers and the government expanded insurance coverage to include prescription drugs. In 1990, 31 percent of payments for prescriptions came from third-party payers and Medicaid; by 1999, that figure grew to almost 70 percent.[1] Health care payers soon realized that prescription drug cost growth was outpacing other areas of health benefits and began looking for solutions. The PBM industry as we know it today was born out of this need.

PBMs' track record for delivering quality prescription drug benefits with generous savings for consumers and employers is a good one and one in which we are proud. PBMs do this by using cost containment, clinical and utilization management tools designed to balance the payers' need for affordability with the beneficiary's need for choice and access. Such tools include:

- Pharmacy and therapeutic (P&T) committee formulary development and review;
- pharmacy network management;
- negotiation and administration of product discounts, including manufacturer rebates;
- mail-service pharmacy;
- drug utilization review (DUR);
- generic substitution;
- clinical prior authorization and step therapy;
- consumer and physician education;
- disease management; and
- consumer compliance programs.

The results cannot be denied. A recent study published in *Health Affairs* by CMS actuaries revealed that prescription drug spending in 2004 slowed to its lowest growth rate in the past 10 years, rising 8.2 percent. Overall, health spending grew in 2004 at a 7.9 percent clip, down from 8.2 percent in 2003.[2] The study's authors cited four key reasons for the slowdown in prescription drug spending:

- Rapid growth in the use of lower-price generic drugs;
- Increased use of over-the-counter medications;
- A shift toward greater mail-order dispensing; and
- Reduced consumption of certain drugs over safety concerns.

MEDICARE PART D: NEW CHALLENGES AND OPPORTUNITY

Now plans and PBMs are bringing to Medicare the knowledge and experience developed through managing drug benefits in the commercial marketplace. The new Part D benefit approved by Congress in the Medicare Modernization Act of 2003 presents new opportunities and unique challenges for our industry.

The opportunities lie in the ability to extend the cost-saving and clinical management tools used so successfully in private plans to millions of seniors and the

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[1] U.S. Department of Health and Human Services, *Report to the President: Prescription Drug Coverage, Spending, and Prices* (Washington: DHHS, April 2000).

[2] Smith, Cowan, Heffler, et al, CMS National Health Accounts Team, National Health Spending in 2004: Recent Slow-Down Led By Prescription Drug Spending, *Health Affairs*, 25, no. 1 (2006: 186 – 196.

disabled in Medicare. In this regard, I believe we have met and are exceeding expectations set by Congress and Medicare beneficiaries.

Cost Savings

In a recent analysis of prescription drug spending trends, CMS actuaries found that program-wide Medicare prescription drug plans (PDPs) are achieving deeper-than-expected discounts of 27 percent – up markedly from the 15 percent discount projection they made a year earlier. In turn, these discounts are driving overall estimates of prescription-drug trend lower. According to the report, total prescription drug expenditure growth for 2006 is revised downward from 8.1 percent to 7.7 percent to reflect actual Part D discounts available.[3]

PCMA conducted its own survey of five member plans discounts on the top 100 drugs used by seniors. Our own data shows that PCMA member PDPs are saving beneficiaries an average of 35 percent on medications purchased at retail pharmacies and 46 percent for drugs dispensed through mail-service pharmacies when compared to pharmacy usual and customary prices.[4]

And seniors like the program. A recent *Washington Post/ABC News Poll* reported that 63 percent of seniors said they were saving money with the new program and 74 percent said they had an easy time enrolling in the program.[5] Another recent poll performed by AARP found that 78 percent of those enrolled in a Medicare drug plan are satisfied with their plan.[6]

As we are all well aware, these results have not come without some effort. Implementing a program of this scale is a massive undertaking. I give Dr. Mark McClellan, Leslie Norwalk and all those at CMS great credit for the hard work they've done. Even with all the hard work, however, it would be unrealistic not to expect some challenges in the beginning.

Challenges

We were faced with data problems from the onset of enrollment. Some Medicare beneficiaries, particularly the low-income and dual-eligibles, were inadvertently enrolled in two different plans at the same time; due to late enrollment or incomplete files, some seniors did not get their enrollment information on time for the January 1 start date. These issues alone, as pharmacists and Members of this Committee are aware, created a lot of problems when beneficiaries showed up at the pharmacy counter without their drug card or with the wrong drug card. This, in turn, created long waits on telephone lines to clear up eligibility issues and link the right benefit with the right person.

Most of these start up problems have been resolved and operations are moving much more efficiently now. Part D plans have had to maintain significant flexibility in

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[3] Borger, Smith, Truffer, et al, CMS National Health Accounts Team, "Health Spending Projections Through 2015: Changes on the Horizon," *Health Affairs*, 25, no. 2 (2006): w61-w73.

[4] See "PCMA Analysis Finds Medicare Prescription Drug Discounts 'Real & Holding Steady' in First 30 Days" at http://www.pcmanet.org/newsroom/2006/pr_1_06/pr_2_06/pr_20706.htm. NOTE: PCMA's study compared only PCMA Member plan PDPs prices for the top 100 drugs used by seniors to average retail usual and customary drug prices found on the New York Attorney General's prescription Drug website at: http://www.nyagrx.org/. This study is not meant to be a comprehensive actuarial analysis of Medicare savings but a snap shot of possible savings available to beneficiaries compared to cash-paying customers.

[5] "Most Seniors Enrolled Say Drug Benefit Saves Money," Jeffrey Birnbaum, Claudia Deene, The Washingoton Post, April 12, 2006 at http://www.washingtonpost.com/wp-dyn/content/article/2006/04/11/AR2006041101685.html

[6] "New Medicare Drug Benefit is Meeting or Exceeding Expectations," AARP News Release, April 12, 2006 at http://www.aarp.org/research/press-center/presscurrentnews/medicare_drug_benefit.html

partnering with the government to resolve these issues and adjust to changing rules. For example, plans were initially asked to provide 30-days of transitional medicines to new enrollees; we ultimately provided 90-days of transitional medications. Plans waived co-pays or automatically placed individuals in low-copay tiers when information on eligibility and formulary status was missing. PCMA member Part D plans hired hundreds of additional staff to answer pharmacist and customer call lines that were beyond the scope of our initial contract requirements. All these activities added un-reimbursed costs to our plans. Throughout it all, our industry has worked collaboratively with CMS and has adapted to this changing environment. As a result, we have seen significant improvement in data file accuracy and ease of enrollment.

Aside from the practical details of signing up beneficiaries and getting their prescriptions filled, Part D represents a significant departure for PBMs from normal business practices. In our commercial business, we typically contract directly with employers or health plans to provide services to their employees and members. In Part D, we are selling our services directly to the consumer. What's more, we are making all our drug prices and formulary information available to consumers to help them make informed choices. This is the first time this type of information has ever been available on such a massive scale and it speaks to our member company's commitment to engage the consumer directly and incentive to ensure people are happy with the coverage they choose.

PLANS AND PBMs WORKING WITH PHARMACY

The increase in third-party coverage of prescription drugs, including the new Medicare Part D benefit, coupled with increasing competition from large retail chain pharmacies and recent Congressional action to reduce Medicaid payments for prescription drugs has challenged many pharmacists. As such, it is not possible to tie the financial woes some pharmacists are experiencing to any one source. Nor is it accurate to assume that the more competitive reimbursement that has accompanied these marketplace changes and government actions has had a universally negative impact on pharmacists.

PBMs have great respect for America's pharmacists. In fact, collectively, PCMA member companies employ over 4,000 pharmacists nationwide. We need pharmacists to help reach the consumers we serve. We believe pharmacists benefit in return. For example, today plans and PBMs contract with about 95 percent of the 55,000 pharmacies nationwide, meaning that virtually all pharmacies are in plan and PBM networks. By increasing access to drug coverage, we have also increased volume of prescription sales in pharmacies. Our electronic claims processing systems have ensured that claims can be paperless and receive fast and efficient adjudication. Finally, we provide vital information to pharmacies that they may not have about individual patients and the drugs they take, such as possible drug-to-drug interactions and drug recall notices.

It is important to note all the elements of payment to pharmacies for filling prescription orders. Pharmacists are reimbursed for the ingredient cost of the drug, a dispensing fee for filling the order, and the patient co-pay (this is retained by the pharmacy.) PBM and plan contracts with pharmacists include all these components which make up pharmacy reimbursement and therefore it is important to view compensation as a whole as opposed to its individual elements.

Working with pharmacists, we believe we have brought value to payers and consumers and improved the efficiency of pharmacy transactions. But pharmacy today is about more than individual prescription fills at the drug counter; it is about coordinated patient care management that provides:

- Integrated data systems that allow for an understanding of a patient's complete drug history;
- Flexibility to design and tailor different clinical services to specific disease states and patient needs; and

- Accountability for both the cost of care and quality of patient outcomes.

Prompt Pay

Much has already been said regarding prompt payment of Medicare Part D claims to pharmacists. In light of the expressed concerns that pharmacists were not being paid in a timely manner under Part D, PCMA member companies recently publicly pledged to pay pharmacies submitting clean electronic Part D claims within 30 days.[7]

For some perspective on the issue, it helps to understand what is considered standard payment cycles in other health and pharmacy benefit programs. The industry standard for payment of clean claims filed electronically for doctors, hospitals, and other providers in Medicare Parts A & B is 30 days. A 30-day timeframe is the pharmacy-claims standard in 43 states and is the standard applied to the Federal Employee Health Benefit Plan (FEHBP), Members of Congress' own health plan. The 30-day standard is applied to medical providers in the commercial marketplace and for business transactions and payments associated with credit cards and utilities. A 30-day standard helps improve quality, ensure accurate payments, and prevent fraud and abuse, which costs the health care system billions of dollars annually and increases costs for consumers and purchasers.

It also helps to understand how payment systems work. Because we are processing literally millions of claims per day for over 55,000 pharmacies, it is extremely inefficient to pay on a per-claim basis. Consistent with how other health providers are paid, Part D plans batch process claims in order to write one check per payment cycle to pharmacies. This is a system pharmacy is very familiar with as it is how payment works in the private sector today.

Finally, it helps to understand the activities plans and PBMs engage in to adjudicate claims. Claims adjudicating involves more than simple verification of plan eligibility and formulary status. Plans and PBMs review individual claims not only to ensure they are "clean" from an auditing standpoint, but also for clinical management purposes. This typically involves large system audits that match claims against certain criteria to identify outliers that may indicate possible fraud or other abuses. Audit criteria include claims that have a high cost, involve excessive quantities, and/or may have incorrect dosages or days of supply. Claims that raise red flags require an auditor to contact the pharmacy to resolve. If there are recurrent red flags in auditing for a particular pharmacy, further more intensive reviews are needed that may include involving the prescribing physician. Such programs are important tools to ensure plans and PBMs are accountable to health payers.

Medication Therapy Management and Quality Improvement

Part D plans and PBMs support the inclusion of Medication Therapy Management (MTM) programs in the Part D benefit. All PDPs included MTM programs in their bids that were approved by CMS. In fact, we believe that many of the services PBMs helped pioneer, such as drug utilization review, disease and therapeutic management and drug compliance programs, meet many of the goals of this program. However, we are concerned about efforts to establish rigid rules for MTM participation and services that would create a one-size-fits-all standard for this program.

MTM requires a coordinated effort between payer, providers and beneficiary to truly be of value. With the average senior taking five or more medications and visiting two or more different doctors and multiple pharmacies per year, a complete drug history is critical to an effective MTM program. Individual pharmacists often do not have this history, but the drug plan does and therefore can ensure patients are not taking drugs that conflict with one another or that may have deadly interactions.

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[7] See "PCMA Member Companies Pledge to Pay Medicare Pharmacy Claims Within 30 Days," at http://www.pcmanet.org/newsroom/2006/Pr_5_06/pr_05_05.htm

MTM requires flexibility in design as no single model meets the needs of different patients and disease states. Models may include working directly with a retail pharmacist or utilizing the pharmacist or health care professionals in a plan or PBM. Many clinical programs offered by plans and PBMs today have produced impressive results because they are able to refine and improve programs with experience and innovate around services that work and rid the program of those that don't. CMS intentionally allowed for flexibility and discretion in MTM services in Part D for this reason.

FLEXIBITY REMAINS KEY TO THE SUCCESS OF PART D

As businesses that negotiate many contracts with employers and pharmacists, we believe matters of payment and design of clinical services should be left to contractual agreements between plans and pharmacies, not micromanaged by the government. Doing so will only add additional costs to the Medicare program, its beneficiaries and taxpayers.

PCMA commissioned a cost-estimate of S. 2563 a bill recently introduced by Senator Thad Cochran (R-MS). This legislation would establish a prompt payment rule for Part D that would require pharmacy payment within 14 days for clean claims filed electronically and 30 days for clean claims filed on paper. Penalties would be assessed for claims not paid in that time frame. In addition, this legislation would place new requirements on the Part D MTM program, such as: mandating (as opposed to allowing flexibility, as current law does) what services MTM programs must provide; mandating the setting these services must be provided in (i.e., "face-to-face"); adding new network adequacy standards on health plans to ensure community-based pharmacies provide MTM services; and adding new requirement regarding fees paid to pharmacists.

This legislation is estimated to cost a total of $9.4 billion over ten years. Of that amount, $7.7 billion would be new federal Medicare outlays while $1.7 billion would come from increased beneficiary premiums.

While the Cochran bill would add substantial costs to the Medicare program, PCMA requested an examination of this proposal because it appears to be less onerous than other, more expansive measures pending in Congress that would, among other things, mandate dispensing fees that must be paid to pharmacists. PCMA believes strongly that theses measures would increase costs even more than the Cochran bill and that $9 billion is the minimum price tag of the various pharmacy proposals.

We believe this is an unacceptable and unneeded new cost burden on both taxpayers and Medicare beneficiaries and would urge Members to carefully consider this as they evaluate legislative proposals before them.

CONCLUSION

PCMA and its member plans are proud of our achievements in the first five months of this historic new program. We've faced hurdles along the way, but have worked collaboratively with consumers, pharmacists, doctors, CMS and others to address them and put many of them behind us. We believe the services we provide and the results we are seeing speak to the high standards we place on quality and affordability. In short, we believe we are doing the job Congress and America's seniors have asked us to do.

I appreciate the opportunity to testify and am happy to answer any questions Members may have.

MR. DEAL. Thank you. Mr. Hopkins.

MR. HOPKINS. Chairman Deal, Representative Brown, and distinguished members of the subcommittee, thank you for the opportunity to discuss WellPoint's perspective regarding the Federal Government's partnership with America's pharmacists in the Part D program. I am Tim Hopkins, Vice President in charge of Retail and Mail

Service Operation for the Pharmaceutical Benefits Management Division of WellPoint, Inc.

WellPoint is the largest publicly traded commercial health benefits company in terms of membership in the United States. I am a licensed pharmacist in the State of Ohio, and prior to joining WellPoint, served as a pharmacist with a national pharmacy chain. My background in pharmacy practice is diverse, with 15 years experience in pharmacy benefits administration, retail chain pharmacy practice, independent community pharmacy practice, and hospital pharmacy services. I played an integral role in developing the pharmacy provider network utilized by WellPoint for Part D beneficiaries.

WellPoint is proud to include in its network Anthem Blue Cross and Blue Shield of Georgia, which employs 2,700 Georgians and serves 2.4 million members in the State, including 155,000 who live in your district, Mr. Chairman. WellPoint is also proudly represented by Anthem Blue Cross and Blue Shield of Ohio, with 4,000 employees serving 2.2 million members, 81,000 who live in your district, Congressman Brown. For other members of the committee, WellPoint serves members in California, Colorado, Illinois, Indiana, Maine, New Hampshire, Texas, and Wisconsin.

WellPoint currently offers the prescription drug benefits through our Medicare Advantage prescription drug plans in many parts of the country, including the newly available regional preferred provider organization in three regions, as well as stand-alone prescription drug plans in 34 regions encompassing the 50 States and the District of Columbia. WellPoint also administers the facilitated enrollment program for CMS. Over 238,000 individuals have been served through this program, including 24,000 dual eligibles missed or in the auto enrollment program process. Our pharmacy network encompasses 56,437 pharmacies nationwide, representing 98 percent of available retail pharmacies. To date, we have dispensed over 18.5 million prescriptions for 1.4 million Part D enrolled members.

WellPoint is committed to supporting the effective implementation of Part D. WellPoint's primary goal is to ensure that beneficiaries receive all the benefits of their health coverage, including access to prescription drugs in a timely and beneficiary-friendly manner, and that pharmacists are paid promptly for the prescriptions they fill.

WellPoint realizes that Part D program success requires extensive communication between plans and pharmacies. To this effort, we have taken the following steps: adopted an inclusive network development strategy to contract a range of pharmacies, including independent and rural pharmacies; enhanced outreach programs through constant communication with pharmacies through Faxblast, conference calls with

independent pharmacy associations, and chain drug stores; engaged in active trading through our PBM for pharmacists when they call in; and provided direct technical assistance to pharmacies and their vendors as needed to address software issues. WellPoint has agreed to the standardization efforts of AHIP, NACDS, and NCPA to address issues involving pharmacy claims transactions.

We recognize that pharmacies are concerned about prompt reimbursement. In response to these concerns, we have made a strong commitment to promptly pay all Part D pharmacy claims. Although legacy Anthem and legacy WellPoint are currently paying on two separate claims systems, legacy Anthem uses a weekly cycle and legacy WellPoint uses a bimonthly cycle. Payment is received by the pharmacies within seven to ten days of the cutoff date; thus, if a pharmacy files a clean claim, the longest time that elapses between claims submission and payment receipt is 17 days for legacy Anthem and 25 days for legacy WellPoint. The claims submission and payment process for Part D program is virtually identical to that used by pharmacies for commercial business. We make electronic payment available to all pharmacies, which enables pharmacies to receive payment more quickly. However, many independent pharmacies do not take advantage of this option.

WellPoint's payment policy is consistent with or better than the industry standard. The industry standard is a 30-day cycle. Plans generally pay on a two-week cycle, and depending on when a claim is processed in that cycle, it is paid between 15 and 30 days from the date of submission. This standard is consistent with the commercial sector, Medicare fee-for-service, mandates in 43 States, the Federal Employees' Health Plan, and the Community Pharmacy Association's own Part D plan. Plans typically batch payments to pharmacies, resulting in greater efficiency and cost savings that are passed through to the Federal government and the beneficiaries in lower premiums.

In conclusion, Congress entrusted the private sector to administer the Part D benefit in the same manner in which it has successfully administered drug benefits in the commercial sector, driving down costs, improving efficiency, and enhancing care and safety for beneficiaries. We recommend Congress stay consistent with this policy.

The January 1 effective date for the launch of the Medicare Part D program brought with it a surge of business operations activity. WellPoint did extensive advanced implementation planning and outreach with pharmacists as well as other stakeholders. Our hope was that we anticipated and addressed the major barriers that might arise as seniors navigated the enrollment system and pharmacists attempted to fill prescriptions and receive payment. While it was not possible to foresee

all the challenges that this enormous undertaking would pose, WellPoint is committed to being part of the solution.

Thank you for your time today. I would be happy to answer any questions that you have.

[The prepared statement of Timothy Hopkins follows:]

PREPARED STATEMENT OF TIMOTHY HOPKINS, VICE PRESIDENT, RETAIL MAIL SERVICE OPERATION FOR PHARMACY MANAGEMENT, WELLPOINT, INC.

Introduction

Chairman Deal, Representative Brown, and distinguished members of the Subcommittee, thank you for allowing me the opportunity to discuss WellPoint's perspective regarding the federal government's partnership with America's pharmacists and the Part D program.

I am Tim Hopkins, Vice President in charge of Retail and Mail Service Operations for the Pharmaceutical Benefits Management division of WellPoint, Inc. WellPoint is the largest publicly traded commercial health benefits company in terms of membership in the United States. WellPoint was formed on November 30, 2004 from the merger of Anthem Inc. and WellPoint Health Networks. WellPoint is an independent licensee of the Blue Cross Blue Shield Association and serves its members through Blue Cross and Blue Shield plans in fourteen states. WellPoint's UniCare brand serves members in all 50 states.

I am a licensed pharmacist and, prior to joining WellPoint, served as a practicing pharmacist with a national pharmacy chain. My background in pharmacy practice is diverse, with fifteen years experience in pharmacy benefits administration, retail chain pharmacy practice, independent community pharmacy practice, and hospital pharmacy services. At WellPoint, I am building on my experience by developing pharmacy products, programs and services that meet the needs of our beneficiaries. A key focus of mine over the last year has been the planning and application processes associated with the participation of WellPoint companies in the new Medicare Part D program. I played an integral role in developing the pharmacy provider network utilized by WellPoint Part D beneficiaries.

WellPoint Participation in Part D Prescription Drug Benefit Program

WellPoint has a long history of providing services to Medicare beneficiaries, including offering Medicare supplemental insurance and Medicare Advantage programs. We serve over 1.2 million beneficiaries in these programs across the country. Prior to the launch of Part D, we offered the interim prescription drug card. WellPoint currently offers the prescription drug benefit through our Medicare Advantage-Prescription Drug Plans (MA-PDs) in many parts of the country, including the newly available Regional Preferred Provider Organization (PPO) in three regions, as well as stand-alone Prescription Drug Plans (PDPs) in all 34 regions, encompassing the 50 states and the District of Columbia. WellPoint also administers the Facilitated Enrollment Program for CMS. To date, over 238,000 individuals have been served through this program, including 24,000 dual eligibles missed during the auto-enrollment process.

Our pharmacy network includes 56,437 pharmacies nationwide, representing 98% of available retail pharmacies. To date, we have dispensed over 18.5 million prescriptions for 1.4 million Part D enrolled members.

WellPoint Commitment to Part D Success

WellPoint is committed to supporting the effective implementation of Part D. WellPoint's primary goal is to ensure that beneficiaries receive all the benefits of their

health coverage, including access to prescription drugs, in a timely and beneficiary-friendly manner, and that pharmacies are paid promptly for the prescriptions they fill.

As all stakeholders work to continually improve the implementation of this program, we must all keep in mind the tremendous value of adding a comprehensive prescription drug benefit to the Medicare program. Millions of seniors will not only see cost savings, but true improvements in their quality of life. The mindset at WellPoint is to focus on enabling seniors and disabled beneficiaries to receive their prescriptions. The recent report that nearly 38 million now have prescription drug coverage is great news, but it is also a reminder that we must keep our full attention on resolving barriers to service. As Part D members begin using their new prescription drug coverage, the confusion in the marketplace is abating and a solid foundation for the Part D program is taking hold.

Part D Success Requires Collaboration and Communication

The level of collaboration required between CMS, plans, pharmacies, and other stakeholders to make the Medicare Part D program operate successfully is unprecedented. Continuing to improve on the progress we've made requires maintaining this collective effort. A shared approach to problem solving is the essential ingredient for making this new program work for all beneficiaries. Stakeholders are stepping up to the plate and accepting mutual accountability for meeting the challenges and ensuring the success of the Part D program. When all parties are bound by a common interest in putting the beneficiary first, an environment is created that allows for constructive criticism and open dialogue, the result being timelier implementation of the steps needed to achieve a smooth transition, faster identification of new issues, and smarter problem resolution.

WellPoint realizes that Part D program success requires extensive communication between plans and pharmacies. To this effort, we have:

- Adopted an inclusive network development strategy to contract with a range of pharmacies, including independent and rural pharmacies, to increase pharmacy access to network advantages and to enhance beneficiary access to affordable prescription drugs.
- Enhanced outreach through constant communication with pharmacies through fax blasts, conference calls with independent pharmacy associations (e.g. National Association for Independent Pharmacies and other independent chain groups) and chain drug stores (e.g. National Association of Chain Drug Stores and smaller work groups formed from major chains).
- Engaged in active training through our PBM for pharmacists when they call in.
- Provided direct technical assistance to pharmacies and their vendors as necessary to address software issues.
- Agreed to the standardization efforts of AHIP, NACDS, and NCPA to address issues involving pharmacy claims transactions.

WellPoint Pharmacy Payment Policies

WellPoint has made a strong commitment to promptly pay all Part D pharmacy claims and has a payment system that exceeds the industry standard. Although legacy Anthem and legacy WellPoint are currently paying on two separate claims systems, legacy Anthem uses a weekly cutoff cycle and legacy WellPoint uses a biweekly cutoff cycle. Payment is received by the pharmacy within 7 to 10 days of the cutoff date. This means that if a pharmacy files a clean claim, the longest time that elapses between claim submission and payment receipt is 17 days for legacy Anthem and 25 days for legacy WellPoint. The claims submission and payment process is, in fact, little different for the Part D program than that used by pharmacies for commercial business. We make electronic payment and 835 claims reconciliation detail available to all pharmacies, which, in turn, enables them to receive payment and claims detail information more quickly. However, many independent pharmacies do not take advantage of this option.

We stand ready to provide assistance to independent pharmacies interested in converting to an electronic payment system.

The Importance of the Standard Payment Cycle

The industry standard is a 30-day cycle. Plans generally pay on a two-week cycle, and, depending on when a claim is processed in that cycle, it is paid between 15 and 30 days from the date of submission. This standard is consistent with the commercial sector, Medicare Parts A & B, mandates in 43 states, the federal employees' health plan, and the Community Pharmacy Association's own Part D plan. Along with the rest of the members of the Pharmaceutical Care Management Association (PCMA), WellPoint recently pledged to pay pharmacists for Medicare Part D pharmacy claims within 30 days of receipt of clean claims. This pledge signals WellPoint's continued commitment to fair and timely claims payments to America's pharmacists, who have provided tremendous assistance to seniors since the start of the Part D program.

Plans using standard pay cycles typically "batch" payments to pharmacies resulting in greater efficiency and cost savings that are then passed along to both the federal government and the beneficiary in the form of lower premiums. Arbitrary payment requirements, such as those proposed in legislation currently before Congress, will increase the likelihood of fraud by decreasing the breadth and depth of claims audits. These audits control costs and improve safety by flagging claims that have incorrect dosage, days supply, or higher than usual quantities. Reducing the 30-day cycle will ultimately result in higher costs for the federal government and beneficiaries.

Congress Intended for Part D Program to Operate Like Commercial Sector

Congress entrusted the private sector to administer the Part D benefit in the same manner in which it has successfully administered drug benefits in the commercial sector: driving down costs, improving efficiency, and enhancing care and safety for beneficiaries. We recommend Congress stay consistent with this policy.

Conclusion

The January 1st effective date for the launch of the Medicare Part D program brought with it a surge of business operations activity and customer service requests. Knowing that the program was complex, WellPoint did extensive advanced implementation planning and outreach with pharmacists as well as other stakeholders. Our hope was that we had anticipated and addressed the major barriers that might arise as seniors navigated the enrollment system and pharmacists attempted to fill prescriptions and receive payment. While it was not possible to foresee all the challenges that this enormous undertaking would pose, WellPoint is committed to being a part of the solution. We will continue to strive to get past the hurdles because the Medicare Part D prescription drug program is worth it.

Thank you for your time. I would be happy to answer any questions you may have.

MR. DEAL. Thank you. Mr. Couch, you are recognized.

MR. COUCH. Thank you, Mr. Chairman and members of the subcommittee, for inviting me to testify today on behalf of the Healthcare Distribution Management Association, HDMA.

My name is Ken Couch. I am President of Smith Drug Company located in Spartanburg, South Carolina, with a second distribution center in Paragould, Arkansas. I am a former chairman of HDMA, and currently serve on the Association's Board of Directors.

HDMA represents the Nation's primary full-service healthcare distributors. These 40 distributor members include large and regional companies, some of which are family owned and employee owned. Smith Drug Company is a distributor of pharmaceuticals and other healthcare sundry products that you would find in a community pharmacy. Our customers are overwhelmingly community professional pharmacy practitioners that own or work for family-owned businesses. They are the corner drug stores of rural areas, towns, cities, and inner cities of the Southeast. Most people taking medications give some thought to the pharmaceutical company that made the product or to the pharmacy or pharmacist that dispensed that product, but few patients understand how that product moves through the system, starting with the manufacturer and ending with the patient. A typical distribution center will store 24,000 products purchased from 800 manufacturers and distribute to 900 pharmacies on a daily basis. On an average day, a single distribution center will ship out 60,000 products. Industry-wide, we deliver nine million products to the Nation's 142,000 pharmacy settings every day. By providing daily delivery with extremely high service levels and business efficiencies in this intricate supply chain, distributors save the healthcare system $10.5 billion per year, and we do it with razor thin margins, as evidenced by our industry net profit margin of 0.75 percent.

While distributors are not reimbursed by Medicare and therefore not directly impacted by the Medicare Modernization Act, the impact it has on our pharmacy customers is directly felt by our distributors. It is important for you to understand that some distributors, like Smith Drug, community pharmacies constitute in excess of 90 percent of our customer base. Our industry sought to help prepare community pharmacists through education and awareness so that they would be more knowledgeable and comfortable in answering the Medicare beneficiaries' questions. Distributors provided thousands of pharmacists with a variety of learning and outreach tools. HDMA members, for example, developed and sponsored continuing education programs, focusing on the benefit, drafted fact sheets, provided calendars with key implementation dates and milestones, sponsored brochures and advertisements reminding beneficiaries that their pharmacists are a valuable information resource and some established well-based resource centers.

However, since implementation, a recurring problem for many of our pharmacy customers has revolved around cash flow issues, and again, my industry has stepped up. On a case-by-case basis, distributors have worked individually with their pharmacy customers to reach mutually acceptable agreements on payment plans. In some cases, credit may

have been extended, in other cases, payment terms may have been adjusted. Let me cite my company as an example. By background, Smith Drug submits weekly manufacturer purchase orders for the upcoming forecasted need of our pharmacy customers. We usually receive that product within a few days, or up to several weeks. It is our job to balance that inventory. Our pharmacy customer places an electronic order daily, usually at the close of their business. We deliver their requested products the next morning. Even though Smith Drug has better than a 99 percent service level on pharmaceuticals, to break even, we must have better than 13 inventory turns per year. In other words, we must sell and pay for the value of our warehouse and inventory in less than one month. Out of my customer base, approximately 60 percent of them have payment terms that require them to pay us twice a month. About 20 percent pay us weekly, 15 percent pay us daily, and the remainder have some variation.

To help those customers who are facing significant cash flow challenges due to Part D implementation, our company has been working with our community pharmacy customers by providing payment concessions to help them through these hard times. Most of these are at no interest or with no fees charged; however, there is a cost to Smith Drug Company. We went to our bank and asked for an extended line of credit to ride us through our customers' cash flow shortfall. We explained that we needed to prepare for a 15-day setback in cash flow, and that number that that bank would have to give us for our small company is $100 million.

As the members of this committee know, community pharmacists are an essential component of our Nation's healthcare system. Their viability is important to ensure that all patients are able not only to receive their medicines, but for the counseling and medication therapy management services that pharmacists can provide. The challenge now is to ensure that community pharmacies be continued to keep their doors open to serve the millions of Americans who depend upon them for their prescription medications.

Thank you very much for your attention. I will be glad to answer any questions.

[The prepared statement of Kenneth Couch follows:]

PREPARED STATEMENT OF KENNETH COUCH, PRESIDENT, SMITH DRUG COMPANY

Introduction

Thank you, Mr. Chairman and members of the subcommittee for inviting me to testify today on behalf of the Healthcare Distribution Management Association (HDMA). My name is Ken Couch, and I am President of the Smith Drug Company, located in Spartanburg, South Carolina with a second distribution center in Paragould, Arkansas. I

am a former chairman of HDMA and currently serve on the association's Board of Directors.

HDMA represents the nation's primary, full-service healthcare distributors. These 40 distributor members include large and regional companies, some of which are family-owned. HDMA member distributors work to secure a safe, efficient and reliable healthcare supply chain that is able to provide life-saving health products and services. These distributors are responsible for ensuring that billions of units of medication are safely delivered to tens of thousands of community retail pharmacies, hospitals, nursing homes, clinics and other provider sites in all 50 states in the safest and most efficient manner possible.

Smith Drug Company is a distributor of pharmaceuticals and other health and sundry products that you find in a community pharmacy. Smith Drug Company distributes products to 14 states and services more than 1,200 pharmacies. Our customers are overwhelmingly community professional pharmacy practitioners that own or work for family-owned businesses. They are the corner drug stores of rural areas, towns, cities, and inner cities of the Southeast.

Most people taking medicines give some thought to the pharmaceutical company that made the product, or to the pharmacy and pharmacist that dispensed that product. But few patients understand how that product moves through the system - starting with manufacturer and ending with the patient.

A typical distribution center will store 24,000 products purchased from 800 manufacturers and distribute to 900 pharmacy customers on a daily basis. On an average day, a single distribution center will ship out 60,000 products per day; industry-wide, we deliver 9 million products to the nation's 142,000 pharmacy settings every day. By providing daily delivery with extremely high service levels and business efficiencies in an intricate supply chain, distributors save the healthcare system $10.5 billion per year.

Preparing for Medicare Part D Implementation

While distributors are not reimbursed by Medicare and are therefore not directly impacted by the Medicare Prescription Drug Improvement and Modernization Act of 2003, the impact it has on our pharmacy customers is directly felt by their distributors. That is why last year the distribution industry worked very hard to help prepare the nation's pharmacists for the establishment of the Medicare drug benefit.

It is important to understand that for some distributors, like Smith Drug, community pharmacies may constitute in excess of 80 or 90 percent of their customer base. Their problems are our problems. They are more than just customers, they are partners. I am proud that my company and my industry have proven to be such a reliable partner working together to address the challenges that now confront community pharmacy as a result of the implementation of the Medicare drug benefit.

Our industry sought to help prepare community pharmacists through education and awareness so that they would be more knowledgeable and comfortable in answering the Medicare beneficiary's questions. Distributors provided thousands of pharmacists with a variety of learning and outreach tools. HDMA members, for example, developed and sponsored continuing education programs focusing on the benefit; drafted fact sheets and FAQs; provided calendars with key implementation dates and milestones; sponsored brochures and advertisements reminding beneficiaries that their pharmacists are valuable information resources; and establishing web-based resource centers.

Post Implementation Cash Flow Issues

As could be expected with such a massive undertaking, there were some significant "start-up" problems. It is my sense that many of these problems have been addressed or have decreased significantly. I and HDMA commend all those involved – CMS,

pharmacy, prescription drug plans, states and all the other stakeholders – for working together in an effort to do what is best for the patient.

However, a recurring problem for many of our pharmacy customers has revolved around cash-flow issues. Again, my industry has stepped up. On a case-by-case basis, distributors have worked individually with their pharmacy customers to reach mutually acceptable agreements on payment plans. In some cases, credit may have been extended, in other cases, payment terms have been adjusted. For anti-trust reasons, our trade association has not surveyed the membership as to what they specifically have done in this area. However, I can share what my company has done.

By way of background, Smith Drug submits weekly manufacturer purchase orders for the upcoming, forecasted need of our pharmacy customers. We usually receive that product within a few days but sometimes it can take weeks. Our pharmacy customer places an electronic order daily, usually at the close of business, and we deliver the requested products the next morning. Even though Smith Drug has a better than 99 percent service level, to break even we must have better than 13 inventory turns per year. In other words, we must sell and pay for the value of our warehouse inventory in less than a month. Our margins are razor thin, as evidenced by our industry net profit margin of 0.75 percent.

Of my customer base, approximately 60 percent of them have payment terms that require them to pay us twice a month, about 20 percent pay us weekly, 15 percent daily and the remainder have some variation. This twice a month payment terms needs some explanation. In our industry it is generally called semi-monthly pay terms. Payment for pharmaceuticals purchased by the pharmacy from the 1st through the 15th of the month are due in full on the 25th. The payment must be "in hand" or electronically transmitted. Products purchased from the 16th through the last day of the month must be paid in full by the 10th of the following month. Therefore, a prescription submitted on the 30th of the month would contain product that must be paid to the pharmacy's distributor by the 10th of the following month. If the payer just changed his payment position to 30 days, the pharmacy would most likely have missed two pay periods to his distributor.

To ease this burden, our company has been working with our community pharmacy customers by providing payment concessions to help them through these hard times. Most of these are at no interest or with no fees charged. However, there is a cost to Smith Drug. We went to our bank and asked for an extended line of credit to ride us through our customer's short fall of cash flow. We explained that we needed to prepare for a 15-day setback in cash flow. We were asked how much would that be, and we replied $100 million dollars.

Conclusion

As the members of this committee know, community pharmacists are an essential component of our nation's healthcare system. Their viability is important to ensure that all patients are able to not only receive their medicines, but for the counseling and medication therapy management services pharmacists can provide.

As noted, to help our pharmacy customers prepare for Medicare Part D, HDMA distributor members proactively worked to provide educational programs and tools. The amount of preplanning on pharmacy's part was heroic. I believe that had pharmacists not prepared themselves for this major paradigm shift for their patients, the program would have experienced even more severe problems in the first two weeks. The challenge now is to ensure that community pharmacy will continue to be able to keep their doors open to serve the millions of Americans who depend on them for their prescription medications.

I thank you for your attention and will be glad to answer any questions.

MR. DEAL. Thank you. Dr. Harden.

DR. HARDEN. Mr. Chairman and members of the committee, my name is Buddy Harden. I am a pharmacist from Georgia. Thank you for allowing me the opportunity to tell you some of the positive things that happened with Medicare Part D, but also maybe to mention some things that could be done to improve it. I would like to talk this morning about some of the provisions of the House bill that have been introduced by Mr. Brown and Mr. Allen, I believe, that do correct some of the problems that we see.

I have been privileged to practice pharmacy in a variety of settings, including community, chain, and independent, hospital, long-term care, and military. For 26 years, I owned and operated two independent pharmacies in Albany, Georgia, and Sylvester, Georgia. Currently, I serve as CEO of the Georgia Pharmacy Association.

I have a personal interest in Part D in that we do have a beneficiary on the panel this morning, because I brought my card, and quite frankly, I applied for this card because I have helped dozens of my constituents and family and friends to apply for cards. I wanted to apply for one that I felt like would have the billboard of pharmacies on it that were confusing a lot of my patients and friends. I am glad to see that CMS has taken some action in that arena. I just wish that it would be immediate action rather than waiting until next year.

I have a confession, because I have practiced pharmacy for close to 40 years and I know some of the problems that have been a part of this situation. I was interested in hearing that Ms. Norwalk mentioned that there were negotiated contracts between PBMs and pharmacies. There are no negotiations. They are take it or leave it. I have, myself, on many occasions changed contracts to reflect terms that were more friendly to me and my business operation, sent them back to a PBM, and to have them returned that there are no changes to the contract. You can be a part of our network if you will take it or not, if you leave it. So those, I think, are some things that enter into this that may not be adequately understood, but there are no negotiations on contracts.

Basically another thing that had been mentioned that I think that is interesting is that pharmacists receive discounts for paying their wholesalers on a two-week basis. I think that Mr. Couch has mentioned that their business model is set up to be paid on a two-week basis. If the pharmacist doesn't pay in that two weeks, then he is in violation of the terms of that contract. So there is no way that we can merge the 30 days and the 14 days.

Another problem that I would mention on prompt payment, and I think is addressed in the bill H.R. 5182, is that we find that yes, a check is cut, possibly, at the end of 14 days, or maybe takes 4 or 5 days to process, the check is cut on that date to basically come within the terms

of the payment cycle. However, that check may not be mailed for another six or eight days, and it may take another five or six days to get to the pharmacy. This was the main problem I feel in the beginning with what we were experiencing on prompt pay. It is just the processing of payment is sometimes slow. My pharmacists tell me that even when they get the payment, they don't get the remittance advice at the same time. It is very hard to reconcile payment against remittance advices.

One thing that I do want to make sure I have time to talk about this morning is quality assurance. You know, I am part of a Georgia technical adult education group with the people in the State of Georgia, and health literacy is a big issue. One of their slogans is give a man a fish and you feed him for the day. Teach a man to fish, and you feed him for a lifetime. And I think the medication therapy management part of what the H.R. 5182 proposes is exactly that. Quite frankly, medication therapy management would be difficult for the PDPs to institute because basically, they can't take the risk management of instituting true medication therapy management. In this program, we have done a good job of getting to a cheap price on drugs. Quite frankly, in some cases, a price that not even pharmacists can obtain those drugs at. But we have not proposed cost-effective use of drugs. I included in my written statement a study by Lyle Buchman in Arizona that proves that for every dollar we spend on drugs, we spend another dollar in correcting the problems of that drug as far as adverse drug events.

We in Georgia have participated in quality assurance programs with local industries, and have proven that we can save up to 40 percent of total healthcare costs, but it must allow the pharmacist to do some medication therapy management, and in doing so, reduce overall healthcare costs. This may increase the cost of pharmacy programs.

With that being said, I would be glad to answer any of the questions that any of the committee members may have on our recognition of the need for medication therapy management and how that should be performed. I do, again, highly recommend that this committee look very closely at Mr. Brown and Mr. Allen's bill, because it corrects, I believe, the problems we have seen develop. CMS has done an outstanding job of implementing a very difficult program, and as we have heard today, sometimes they don't have the authority to correct the problems that are needed. I think this legislation gives them that authority.

And Mr. Chairman, with that, I will end. My written testimony is in and I am glad to answer any questions, either from a beneficiary standpoint, a pharmacist's standpoint, or a personal standpoint.

Thank you.

[The prepared statement of Dr. Buddy Harden follows:]

PREPARED STATEMENT OF DR. BUDDY HARDEN, EXECUTIVE VICE PRESIDENT AND CEO, GEORGIA PHARMACY ASSOCIATION

Good Morning,

Chairman Deal and members of the Committee, my name is Oren Harden and I am a pharmacist from Georgia. Thank you for allowing me the opportunity to relate some of the positive impact of the Medicare Modernization Act of 2003 (MMA) Part D and to voice some of the concerns that patients and pharmacists have expressed to me.

I have been privileged to practice pharmacy in a variety of settings including community chain and independent, hospital, long term care and military. For twenty six years I owned and operated two independent pharmacies in Albany, Georgia and Sylvester, Georgia. Currently I serve as the CEO of the Georgia Pharmacy Association.

I have a personal interest in Part D in that I am currently a beneficiary of Medicare Part A and D. I have a patient interest in that I have worked with dozens of family, friends and neighbors to enroll in Part D. I have a professional interest in that I represent some 2500 Georgia pharmacists who have made heroic efforts and personal and business sacrifices to see that Medicare Part D accomplishes its purpose in the healthcare of beneficiaries, their patients.

I believe that Part D of the MMA has had a positive impact on the healthcare of Medicare beneficiaries. People who were unable to afford medications prior to the passage of the MMA Part D can now afford those medications. I also believe that the Centers for Medicare and Medicaid Services (CMS) has done an outstanding job of implementing a very difficult program to manage. With changes that some House members are currently proposing MMA Part D can become significantly more effective both in quality of healthcare and cost effectiveness.

That being said, I would like to share with you some concerns of pharmacists and patients about the current structure of Part D and make suggestions that I feel would improve the program for the patient, the pharmacist and CMS management.

For the patient the number of plans should be reduced. There are far too many plans that are too similar in benefit design and that only serves to confuse the patient. There are 43 different Prescription Drug Plans (PDPs) available in Georgia in addition to the Medicare Advantage Plans (MAPDs). The web based tools available from CMS are very good but most Medicare beneficiaries are unable to properly utilize those tools. They are forced in most cases to consult with insurance agents or other non-healthcare professionals who are not aware of the specific therapeutic needs of the patient and how to best create a medication management plan in one of the PDPs. I believe the pharmacist whom the patient trusts and who is most knowledgeable of the patient's formulary needs should be given the authority to work with the patient to navigate the plethora of plans and advise the patient on how to make a choice based on the patients medication needs and choice of provider. Issues such as formularies, tiering, utilization management, differential co-pays, varying deductibles, co-insurance, "donut holes" and differences in grievances and appeals are simply too complex to be made understandable to the layperson and therefore limit the help available from friends and family.

It would be very beneficial in that respect if CMS were given the authority to offer and administer a single dependable, defined benefit plan which could combine the purchasing power of over 40 million Medicare beneficiaries with that of the VA. This would provide greatly reduced product cost allowing CMS to more effectively utilize funds for pharmacist management of medication therapy. Why is pharmacist management of medication therapy plans so important? Validated studies have been published that illustrate we spend as much of our healthcare dollar in correcting "medication misadventures" or drug reactions and interactions as we do on drugs themselves. To provide proper outcomes patients must have access to the pharmacist's clinical expertise. Under the current commercial plans there is no such provision at this

time. A pharmacy benefit is not a drug product alone at the cheapest price as most PDPs or PBMs would have you think. Without the clinical knowledge and guidance of the pharmacist the drug product can do more harm than good to patient care while dramatically increasing the cost of healthcare.

Although the MMA provides for medication therapy management (MTM) in Part D, there is a disincentive to PDPs to offer proper management. The disincentive being that the major indicator of PDP performance is measured in the reduced cost of drug product not quality of outcomes. Many PDPs will opt to offer MTM via telephonic or electronic means using individuals other than the drug expert, the pharmacist. This is far less effective for quality outcomes improvement than face to face interaction between the patient and the pharmacist in constructing and managing a medication therapy plan. Medication Therapy Management should be defined by CMS, patients identified by the pharmacist and management performed by the pharmacist. Currently MTM is defined by each PDP differently and may be performed by "others" as stated in the MMA.

The Georgia Pharmacy Foundation (GPhF) working with the American Pharmacists Association and major pharmaceutical manufacturers has implemented a medication therapy management patient education model with several industries in our state to prove the increased quality of patient outcomes and the cost effectiveness of pharmacist directed MTM. One such project with a three year track record has data that illustrates that over the first two years of the MTM program, the overall annual healthcare cost for diabetic patients was lowered by 41% over the projected cost for those two years. The 41% per patient savings was in current hard dollar costs. Clinical indicators illustrate that future savings will be even more significant by virtue of the prevention of the complications of diabetes. In addition the absenteeism for the managed diabetic was reduced to almost zero and the workers compensation claims were reduced to absolute zero. The quality of life of these patients was so improved that production also increased. To accomplish improvement in quality of outcomes and reduction in overall healthcare expenditures the cost of physician's visits, pharmacist's medication therapy management and the expenditure on pharmaceuticals may increase in order to produce a savings in an individuals total healthcare costs. This local industry was so impressed by the significant improvement in the quality of life of their employees and the healthcare cost savings that GPhF is beginning implementation this week of the same type of pharmacist directed MTM with hypertensive patients at that plant. GPhF is four months into this type of program with five other employers. The structure of MMA Part D, while authorizing MTM, has the disincentive I mentioned to the utilization of this approach to medication therapy management.

Currently the Georgia Pharmacy Foundation (GPhF) and the Georgia Medical Care Foundation (GMCF), Georgia's Quality Improvement Organization (QIO) are structuring a pharmacy quality improvement pilot project in Georgia in partnership with CMS. The purpose of this pilot is to document the healthcare quality improvement and cost effectiveness of the previously mentioned method of MTM in the Medicare population. We are certain that this pilot will illustrate the benefits to be gained in funding intensive MTM performed by a pharmacist not only to dramatically improve quality of care and augment positive outcomes but also to produce significant savings in healthcare expenditures.

Far too many plans did not at implementation and still do not have the support services to efficiently serve the patient and/or the pharmacist. Many are more interested in selling than in servicing. I am aware of and have reported to CMS plans that are contacting physicians without the patient's knowledge to gain access to protected health information in order to send medications by mail order. CMS has been very responsive to take corrective action when abuses are reported. Another marketing issue that has confused many patients is co-branding. My Part D ID card has the names of only six major chains on the card itself. Many patients have assumed that they must use only

those pharmacies printed on the card thereby increasing the patient's confusion and decreasing their choice.

Form letters sent to patients who have applied for Part D can also be confusing. I received a form letter from the company with whom I applied that informed me of a potential for delay in obtaining confirmation of my enrollment. The letter stated "Information we have received indicates one of the following conditions may apply to your application which would make you ineligible". The two situations listed were that (1) you are not enrolled in Medicare Part B and/or you are not entitled to Medicare under Part A and (2) you have End State Renal Disease (ERSD) or you have had a kidney transplant and still require a regular course of dialysis. First of all if I was not very familiar with Medicare and Part A, B and D, I would be very concerned that I was not eligible for Part D on statement number one. Secondly, if I was not a healthcare professional, I would be terrified that I might have End State Renal Disease (ERSD, whatever that was). Of course I would surely know that I had not had a kidney transplant and did not require dialysis. I called the 800 customer number during the 8 am to 6 pm time frame twice and the first time after navigating an extensive menu of options received a recording that due to the popularity of their plan and high call volume no customer service representatives (CSRs) are available at this time. Upon eventually reaching customer service representative Jason on May 18th, I requested information as to why the delay. I was told that if I did not have both Part A and B I was not eligible for Part D. The most interesting part of this scenario is that I received my card the same day as I received the letter concerning the "problem" and was told by Jason ten days later when I reached customer service that I was enrolled. This on the same call in which he informed me that I was not eligible for Part D unless I had both Part A and Part B. In addition to not having sufficient CSRs this plan does not have adequately trained CSRs. This plan has one of the highest enrollments nationwide.

From the pharmacist's perspective, the main issues in implementation were inadequate provider service and customer service from PDPs, too little compensation for services and long delays in the payment for medications. Many of the pharmacists that I represent borrowed substantial sums to be able to continue to provide service for their patients. In rural Georgia, had they not been willing to shoulder the financial burden, access for the patient would have been severely restricted. In order to make Part D successful, pharmacists devoted the extra time, worked through cash flow problems and met patient's needs when there was no guarantee that they would be compensated. Their efforts were recognized by HHS Secretary Leavitt and I quote "The efforts of pharmacists over the last month have been nothing short of heroic. I've visited with and heard from pharmacists all over the country. They have been selfless, compassionate and committed to service".

Bi-Partisan Legislation has been authored in both the House and Senate at this time that addresses many of the issues important to both the patient and pharmacist. The House Bill H.R. 5182 allows for prompt payment of pharmacy claims. In regards to MTM, H.R. 5182 requires HHS/CMS to define a minimum package of services a plan must provide, allows healthcare providers to identify patients who should receive MTM and requires plans to pay pharmacists and other providers based on the time and intensity of services. Other provisions on MTM assure access to services and establish a Best Practices Commission that would ensure a model that would allow for quality outcomes. H.R. 5182 also provides access to all pharmacists by eliminating branding on Medicare ID cards. This is a giant step toward solving the issues that I have discussed and improving the Part D program for patients and for pharmacists and for Medicare. I applaud the members of the House for this insightful approach to correcting issues that were detrimental to Medicare Part D. At the time of this writing H.R. 5182 has 38 Republican and 24 Democratic co-sponsors. I would like to thank Representatives

Sherrod Brown and Tom Allen of this Committee for their co-sponsorship of this legislation. The Senate Bill addressing these issues is S. 2664.

I would like to add a final comment on a related issue before Congress at this time. If the concerns that are being addressed in Medicare Part D are also addressed prior to the implementation of the drug cost provisions affecting Medicaid in the Deficit Reduction Act of 2005, then quality of care and cost effectiveness will result immediately upon implementation of that legislation. A pharmacy benefit cannot be viewed as a drug product alone but must also include provision of the pharmacist's clinical services to ensure the proper utilization of a drug product to avoid costly complications associated with drug therapy and to provide for positive outcomes.

Thank you for the opportunity to share my thoughts how to make Medicare Part D more patient friendly, more cost effective and most importantly more focused on positive patient outcomes and quality of care.

MR. DEAL. Thank you. Mr. Wirth, you are recognized.

MR. WIRTH. Good afternoon, Chairman Deal, Ranking Member Brown, and members of the subcommittee. My name is Gary Wirth. I am the Director of Professional Services at Ahold, USA. Many of you might not know that that includes Stop and Shop Supermarkets, Giant Supermarkets, and Topps Markets on the Eastern seaboard. Together, we operate over 1,100 supermarkets with more than 600 pharmacies and employ over 100,000 associates in our stores. My office is at nearby Giant's headquarters in Landover, Maryland.

We thank you for your attention to the importance of community pharmacies to both the Federal government and neighborhoods throughout the United States. I appreciate this opportunity to speak, and I am very happy to see that the committee seems to understand many of these issues already.

Recently, some of your representatives visited one of our stores and also saw firsthand how we support the Medicare beneficiaries. I would also like to applaud CMS for their hard work in making the Medicare program successful. In our view, it is working well for beneficiaries. They have solved a lot of problems. They have had regular conference calls with pharmacies to help us to understand the program and to hear our feedback. We also have worked very hard. At our pharmacies, every pharmacy associate, that is 4,000 people, had to go through two hours of Medicare Part D training. We provided written materials for pharmacists and beneficiaries. We beefed up our own help desks and expanded hours of operation and number of people available to answer questions. We think that played a large role in our pharmacists being able to help beneficiaries to understand the program to enroll properly. We also added a link to the CMS Formulary Fnder program directly to the pharmacy computers, so when a beneficiary came in and wanted to know what plans would be good for them, our pharmacists could click a button and get that information for them.

Day in and day out, our pharmacy teams are working for the Medicare beneficiaries; however, there are still some problems. We have heard a lot today about the enrollment lag. I would like to do a flip side of that of the actual dis-enrollment lag. When a beneficiary is able to dis-enroll on the last day of the month and be eligible in a new plan on the first day of the month, that dis-enrollment information does not get transmitted either as well as the re-enrollment information. So we can process a claim on the first of the month to the old plan, receive a paid response, go ahead and dispense the medication. Two weeks, four weeks later, we get the rejection, the back end, and are being asked to then correct the billing, two to four weeks after the fact. That is a severe problem for us to do, and we urge policy makers to address this issue by establishing an enrollment deadline prior to the end of the month.

We are also concerned about the lack of a level playing field in the marketplace. The pharmacy benefit managers are controlling the everyday implementation of the Part D program. Many of them have their own mail order facilities and have an incentive to have prescriptions filled at those facilities. This continues today in the Part D benefit. It has gone on in the open market as well.

We are surprised that given all the work that the community pharmacies have done to make this program successful that CMS continues to allow steering of prescriptions to mail order pharmacies at the expense of the community pharmacy. The community pharmacists were there to help with the enrollments, to educate the beneficiaries, and we think we should have equal access to fill those prescriptions, so eliminate the co-pay steering, eliminate some of the other contractual things that are going on. For instance, a mail order rate could apply to every maintenance drug, even though it is not dispensed in a maintenance quantity. So why should I have to be paid the mail order pricing for a 35-day supply when in fact, it should only apply to a 90-day supply of drugs?

You have already heard a little bit about the formulary issues and the standardized messaging. It is very confusing at the pharmacy to get a rejected claim message and not know is it because it is non-formulary, because it is an excluded product, or if it is because the patient is not eligible? There are serious coordination benefit issues that if the pharmacist knows, they can take care of. Some plans will, rather than reject such a claim, will process that claim at a 100 percent co-pay so it looks like a payable claim. We don't find that out until the patient comes in to pick up the medication when they question why did I pay so much for that medication? Again, we applaud CMS for working on it. We hope they work a little harder to get standardized messaging back to the pharmacists so we know what to do with these patients.

The last thing I would like to point out is that again, we worked very hard, and I am surprised that in thanks for our hard work, we receive a deficit reduction act with a $10 billion withdrawal from pharmacy reimbursement to start next year. We appreciate that CMS has chosen not to publish the AMP data this summer, but we urge policy makers to tell State Medicaid directors and Governors that they need to provide a corresponding increase in the dispensing fee to keep pharmacies whole, otherwise, we have no incentive to dispense generic drugs at a loss. That will hurt the program and hurt the pharmacies as well. Ultimately, it becomes an access issue.

Finally, I would just like to mention that Medicare Part D does not work in a vacuum. When we have trouble servicing Medicare Part D patients, there is a ripple effect to all the other patients who are waiting for their medication. Solving these problems helps everyone. In addition, when the Federal government makes a stand and says we are going to pay pharmacists acquisition costs plus a dispensing fee based on AMP, the rest of the industry is going to follow. I am certain the PBMs are looking at AMP and trying to determine how can we also follow the Federal standard that has been put in place. Therefore, again, we urge you to push the States to increase the dispensing fee for their pharmacies.

Thank you, and I apologize for going over my time.

[The prepared statement of Gary Wirth follows:]

PREPARED STATEMENT OF GARY WIRTH, DIRECTOR OF PROFESSIONAL SERVICES, AHOLD USA, ON BEHALF OF NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Good afternoon Chairman Deal, Ranking Member Brown, and Members of the Energy & Commerce Health Subcommittee. I am Gary Wirth, Director of Professional Services at Ahold USA. I am pleased and honored to be here today to participate in this important hearing.

Ahold USA, owned by Ahold of the Netherlands, currently operates four prominent supermarket companies along the eastern seaboard including The Stop & Shop Supermarket Company, headquartered in Boston, MA; Giant Food LLC, based in Landover, MD; Giant Food Stores LLC, based in Carlisle, PA and Tops Markets LLC, with headquarters in Buffalo, NY. Jointly they operate over 1,100 supermarkets with 670 pharmacies, and employ over 122,000 associates. Ahold (NYSE: AHO) is a leading food provider in the United States and elsewhere in the world with 2004 consolidated net sales of approximately USD 50 billion.

Ahold USA commends you on holding this hearing to examine the federal government's partnership with America's pharmacists. Indeed, this is a critical time for pharmacists and community pharmacy. We face greater demand for our services as a result of factors such as the aging of the population and increased prescription drug volume. Simultaneously, our industry is challenged by increasing competition within community pharmacy as well as from both legitimate mail order facilities and illegal prescription drug importation and Internet pharmacies. Furthermore, there is continued pressure from both public and private payers to lower reimbursement.

As the community pharmacy industry continues to evolve in response to these changing market forces, we also recognize our relationship with the federal government

is paramount. In addition to its role as our largest payer, the federal government is also the architect of public programs and policy changes that dramatically effect community pharmacy. I'd like to spend the majority of my time before you today discussing the current status of one of these bold policy initiatives, the Medicare Part D prescription drug benefit.

Ahold USA is proud to have played a key role in assuring that millions of additional seniors now have access to prescription drug coverage as a result of the Part D benefit. As we all know, there were significant problems in the early days of the program, most of which stemmed from technological and data integrity failures. Fortunately, while there are ongoing challenges, many of these issues from the early days of implementation have stabilized.

There was a striking consistency in many of the reports about the early difficulties of the Part D benefit – the unique role of pharmacists and their efforts to serve Medicare beneficiaries. The Part D rollout was a strong reminder of community pharmacists' unique position as one of the most accessible and trusted health care providers, and the importance of a strong and vital retail community pharmacy infrastructure to our nation.

As I mentioned, many of the early issues with the Part D benefit have been resolved. However, there are ongoing issues that we think can be corrected to continue to ease the administrative burdens placed on pharmacists and to facilitate beneficiary access to their medications. Ahold USA has several suggestions on how some of the ongoing implementation issues can be addressed:

Fix Enrollment Lag: Individuals become eligible for Medicare every day, and dual eligibles have the option of changing plans every month. As a result, there is a systematic issue, commonly referred to as the "enrollment lag," that is problematic for pharmacies and beneficiaries.

Currently, a Medicare beneficiary can enroll in a Part D plan at any time and expect their enrollment to be effective the first day of the following month. If a beneficiary applies for the Part D benefit in the last few days of the month, it is simply not possible for CMS and health plans to process the beneficiary's application, confirm eligibility with CMS, and provide the necessary billing information so that it is available to pharmacists in time for the beneficiary to receive their prescriptions the first day of the next month.

Unless policymakers address this "enrollment lag" issue, late-month enrollment or plan switches may continue to be the single most challenging issue that beneficiaries and pharmacists face with Part D. If pharmacists don't have the necessary data, they cannot fill a prescription. This takes pharmacists away from serving their patients, and forces a series of calls to CMS and health plans to obtain billing and enrollment information. Pharmacists and other pharmacy staff find this experience very frustrating, but even more importantly, so do Medicare beneficiaries, who are forced to wait for extended periods of time at the pharmacy or return at a later date to obtain their prescriptions.

A variety of options exist to address this issue, and Ahold USA and the chain drug industry are committed to working with CMS and health plans to find the best solution. CMS is trying to address this issue by educating beneficiaries that enrolling late in the month will result in delays in activation of prescription drug coverage. This is a step in the right direction. Optimally, there should be an enrollment deadline established each month so there is sufficient time to process applications and enter the billing information in the system. We urge policymakers to address this issue.

Improve and Reward Quality: Ahold USA welcomes the recent announcement by CMS Administrator Mark McClellan on the formation of the Pharmacy Quality Alliance (PQA), a collaborative effort among the pharmacy community, health plans, employers, government payers, and others to improve health care quality. We believe initiatives like PQA are an ideal way to further strengthen the partnership between the federal

government and pharmacists. Identifying tools that result in better health outcomes and reduce health care costs for payers benefit pharmacists, the government, and patients.

In addition to developing strategies to define and measure pharmacy performance, CMS has indicated that PQA could also lead to new pharmacy payment models based on optimizing patient outcomes. Ahold USA supports efforts that focus on controlling costs by paying for better care and improved outcomes, and not by reducing payment rates to providers.

Level Playing Field: Community pharmacy is a highly efficient, competitive industry, operating on an average profit margin of 2 percent. Traditional chain pharmacies, supermarkets and mass merchants with pharmacies, and independent pharmacies use service, convenience, pricing, and other factors to compete aggressively. In recent years, mail order pharmacies have also become an increasing source of competition for community pharmacy. Confident of our patients' preference for their local pharmacy and the service it provides, we are certain of our ability to compete with mail order. Our request to policymakers when considering the use of mail order in public programs such as Medicare has always been to ensure a level playing field with community pharmacy.

In private sector contracts, pharmacy benefit managers (PBMs) often restrict the use of retail pharmacies in order to drive beneficiaries to use their mail order facilities. For example, typical contracts prohibit retail pharmacies from dispensing extended days supply (i.e. 90-day supplies) of medication, and require these maintenance supplies of drugs to be obtained via the PBMs' mail order pharmacy.

Recognizing the importance of patient choice and the value of the community pharmacist, the Medicare Modernization Act (MMA) attempted to limit this steering. Largely as a result of the efforts of many Members of this Subcommittee and broad congressional support, MMA was very clear that retail pharmacies could fill extended day supplies of prescription drugs as long as they agreed to the same level of payment as a mail order pharmacy. This provision, while not ideal for local pharmacies, at least offered them the opportunity to continue to dispense these prescriptions.

Unfortunately, CMS' current interpretation of this provision, as well as tactics being used by Part D plans, are inconsistent with congressional intent. Seniors are being denied the choice of obtaining these prescriptions at community retail pharmacies.

For example, some plans are telling pharmacies that they can only provide extended days supply under Medicare Part D if they accept this mail order rate for the plan's non-Medicare commercial business. Other PDPs will only allow a retail pharmacy to offer an extended days supply if the pharmacy agrees to accept the mail order reimbursement rate for all claims that are submitted, for both short term prescription quantities and extended days supply quantities.

Schemes such as these make it more difficult for retail pharmacies to offer an extended days supply, and deny the beneficiary the choice between retail and mail. We also believe that they are inconsistent with the intent of Congress.

Formulary Issues: There have been some difficulties for both beneficiaries and pharmacists with understanding Part D drug formularies and how they work. Many beneficiaries that come into our pharmacies are concerned that in the future a plan could remove the drugs they are taking from the Part D plan's formulary. Our pharmacists are also concerned about the quality of care impact of switching beneficiaries from a medication they have been taking for a long time to a different medication. There are also concerns about whether beneficiaries – especially low income dual eligibles – will be able to navigate the exceptions and appeals process. That is why we think that CMS' recent decision to allow a beneficiary to continue taking a formulary medication – even if the plan changes the formulary – is good for quality health care and will reduce the administrative burdens on beneficiaries, physicians and pharmacists to switch medications for Medicare beneficiaries.

Coverage Gaps: We are rapidly approaching the middle of the year when many seniors may fall into the "donut hole" or coverage gap. We are concerned that many Medicare beneficiaries do not fully understand the issues relating to the "donut hole" and how it will affect their Medicare coverage. Many of our pharmacists are concerned they will bear the brunt of beneficiary frustrations when they find out they are still paying premiums while in the "donut hole," but not receiving any coverage for their prescription medications.

We believe another public-private sector collaboration to develop assistance programs for beneficiaries when they hit the coverage gap would go a long way toward improvement of the program. Community pharmacy is held to charging the beneficiary no more than their discounted contract rate and therefore contributes directly to assisting beneficiaries in the coverage gap. However, many beneficiaries will undoubtedly need additional assistance to assure their access to needed medications, so we believe other parts of the system should step forward and do their part as well.

While the focus of my testimony has been on Medicare, I would like to address another critical component of the federal government's partnership with pharmacists – the Medicaid program.

While Ahold USA and other pharmacies across the country are still making adjustments as a result of Part D, we will again be asked to shoulder an incredible burden only one year later when drastic changes to the Medicaid program are implemented. We are very concerned with the changes to the Medicaid program as part of the Deficit Reduction Act (DRA), which will dramatically impact community pharmacy's ability to serve Medicaid patients.

Community pharmacy worked closely with this Subcommittee on the Medicaid provisions of the DRA. We were supportive of the Subcommittee's goal to pay pharmacies fairly and accurately for both the prescription drug product, and the professional services associated with dispensing. Recognizing these two, discrete components of pharmacy reimbursement, the House version of the Deficit Reduction Act included a minimum dispensing fee of $8 for generic drug prescriptions. This provision recognized the importance of reimbursing pharmacy for the costs associated with dispensing prescription drugs, and also attempted to maintain an incentive for dispensing generic medications. Unfortunately, the minimum dispensing fee for generic drugs was not included in the conference report. The loss of this important provision makes the DRA's dramatic reductions to product reimbursement event more devastating for community pharmacy.

The DRA reduces payments to pharmacies for generic medications by about $6.3 billion over the next four years. Beginning January 1, 2007, federal upper limits (FUL) for generic drugs will be based on Average Manufacturers Price (AMP), rather than Average Wholesale Price (AWP). We believe that the reduction in payment will be so severe that it will take away much of the incentive for pharmacists to dispense generic medications. This is counterproductive, given that less than 25 percent of the average state's Medicaid pharmacy payments are for generics, even though generics account for more than 50 percent of prescription volume. Public and private payers should be doing everything they can to increase, not decrease, the dispensing of generic drugs, since generic drug utilization is one of the most effective ways to control prescription drug costs.

The Deficit Reduction Act also requires CMS to make Average Manufacturers Price data available to states and the public soon. In theory, AMP is supposed to reflect the average prices paid to manufacturers by wholesalers for drugs distributed to the retail class of trade, which include retail pharmacies. However, we are very concerned that since there are no guidelines as to how manufacturers should calculate AMP, the AMP data released by CMS will be inaccurate and will not reflect the actual prices that retail pharmacy pays for brand and generic medications. As a result, states, Medicare plans,

and consumers could receive a misleading picture about the true acquisition costs of retail pharmacies. Medicare plans and other payers could conceivably change their pharmacy reimbursement based on faulty AMP data.

This data will be publicly available before CMS is required to issue a rule instructing drug manufacturers on how to calculate AMP. Because of its potential damaging impact to community pharmacy, we believe that this data should not be made public or shared with the states until AMP is accurately and consistently defined.

Reductions of this magnitude in Medicaid, coupled with the current economic impact of the Medicare Part D program, will unquestionably reduce access to pharmacies. We do not believe that policymakers have taken into account the cumulative economic impact that changes to Medicare and Medicaid will have on retail pharmacies and the communities they serve. We hope that you will continue to partner with America's pharmacists and pharmacies in developing public policy that benefits patients, payers, and pharmacies.

Thank you again for this opportunity to share Ahold USA's perspective. We look forward to continuing to work with Congress and the Administration on these issues. I would be happy to answer any questions. Thank you.

MR. DEAL. Mr. Galluzzo.

MR. GALLUZO. Chairman Deal, Ranking Member Brown, fellow Buckeye, and other distinguished committee members, which today right now is Mr. Burgess from Texas. I want to thank you for giving me this opportunity to testify in front of this committee and representing the long-term care pharmacy community. My name is Larry Galluzzo. I am a pharmacist and I own a long-term care pharmacy in Mason, Ohio. I have owned the company for 25 years, and I have 230 employees, and I serve the residents in Ohio, Kentucky, and Indiana.

The first thing I wanted to say before I actually get started with most of my talk is that I want to thank CMS, and I want to thank them for being able to listen and learn about long-term care pharmacy and the problems that we have with the new Medicare drug bill. Most of those problems have been worked out, but there are three major concerns that the long-term care pharmacy community have that I am going to address today.

It has been quite clear through this whole implementation process that long-term care pharmacy and retail pharmacy are totally different types of pharmacies. A resident in a long-term care facility does not go to the pharmacy, the pharmacy goes to that resident, and when we go to that resident, we bring them specialized packaging, drug reviews, monthly medical records, e-boxes, stat orders, continuing education for the nurses, and other specialized services that you just don't get from the retail pharmacy. Some of them may provide some of those services, but normally, you don't get those from a retail pharmacy.

From my experience, I will tell you that when you have a resident in a nursing facility, the first thing they expect when they are admitted is to get their medicines on time. Now, imagine your mother or your father

being admitted to a nursing facility and not being on the correct plan and denied necessary medications that they want. And to go one step further, let us suppose that they change the plan that they are on to a new plan that is going to give them access to their drugs. Well, guess what? That plan doesn't kick in until the first of the next month. So you can go one day or you can go 30 days without having access to the medications that you need. That has got to be fixed. The one thing that has to be fixed is there is no reason why when you start a new plan in the middle of the month, there is no reason why it shouldn't take effect immediately. I mean, we are in the 21st century. The technology is there. As Ms. Norwalk said, sometimes it takes a split second to see what that plan is, so why can't we start that plan in the middle of the month instead of having to wait until the end of the month?

Now, the second thing about this whole thing is if your mom and dad are in the facility, how do you know what plan to be on? You may not know, but you need to be educated. I can understand where CMS wants to protect the beneficiaries against unethical and overzealous marketing practices. It may be a conflict of interest. But the problem I have is that they have lost the opportunity to have one of the most trusted professionals in the United States of America to guide them, to educate them on the new prescription drug plans. And who is that? It is the pharmacist. If you looked at the Gallup Poll over the last 5 years, who was always in the top three? Unfortunately, it is not attorneys, and I don't mean to be disrespectful, but it is the pharmacists. The elderly, whether they go to a retail pharmacy or they are in a nursing home and their drugs are supplied by a long-term care pharmacy, they depend on us. And for us not to be able to advise them, counsel them, with them of course having the free choice to use whatever plan they want, but to take that away from us is really a sad thing. I don't think there is anyone on this committee that will disagree with me.

So the two things that really have to happen, and I think we can do this without much hardship to anybody, is to enact the plan as soon as they change that plan, and also give the pharmacists a chance to educate and counsel the residents and their families. I think that is just extremely important.

I know when I go out and do drug and resident reviews, I don't just sit at a nursing station. We go into the resident's rooms. We may take a pulse, we may check blood pressures, we may check for edema. We will ask them how their new medications are working out. But they are going to ask me, Larry, what do you think I should do about Medicare Part D? Well, right now, my hands are tied. I can't say anything to them. In fact, in the State of Ohio, State surveyors are going into our facilities, our nursing homes, and asking the question, are the pharmacies steering

people to different drug plans? Well, we are not steering anybody, but what we would like to do is be able to educate them. That is really pure and simple.

The last thing that I want to talk about, because I did say there were three, and that is co-pays. Dual eligibles in nursing facilities don't have co-pays, but unfortunately there has been a miscommunication from CMS to the prescription drug plans, and some of those are harshed with co-pays. Now obviously, they are not going to pay them, they are dual eligibles. So we are trying desperately to get the right information to the prescription drug plans so that we can be paid properly.

You heard today that 90 percent of the claims are paid within 15 to 20 days. In my pharmacy, that is not true. We used to be paid every 21 days by the State Medicaid program. Now, the time lag is an average of 45 days. When it comes to mis-billings, it used to be about $175,000 a month. Now, it is up to $380,000 a month. So there is a critical shortage in cash flow that could be fixed immediately if they just get the communication right between CMS and the prescription drug plans so they don't have co-pays on the dual eligibles, which they are not supposed to have.

That is all I have to say right now. I want to thank you for your time. If you have any questions for me later, I will be more than happy to answer them. Thank you.

[The prepared statement of Dr. Larry Galluzzo follows:]

PREPARED STATEMENT OF DR. LARRY GALLUZZO, PRESIDENT, SKILLED CARE PHARMACY

Chairman Deal, Ranking Member Brown and distinguished Committee Members:

Thank you for the opportunity to testify today as a representative of the long term care pharmacy community. I am a pharmacist by training and the president of a specialized pharmacy company that serves residents of long term care facilities in Ohio and Kentucky. Our company's pharmacists are experts in the field of pharmaceutical care for the frail elderly and have been working on the "front lines" to assist in implementing the new Medicare prescription drug benefit.

The long term care pharmacy community strongly supported the goals of the 2003 Medicare Modernization Act (MMA) to expand access to prescription drug coverage for all Medicare beneficiaries. While many of the MMA's provisions focused on beneficiaries who reside outside institutional settings, the Act also included important protections for vulnerable residents of nursing facilities.

Long term care pharmacies have worked in close partnership with the Centers for Medicare and Medicaid Services (CMS) to identify and solve the inevitable problems associated with the introduction of a major new benefit under the Medicare program. Like other pharmacy providers, long term care pharmacies have been severely impacted by extended delays in payments from prescription drug plans, as well as a multitude of burdensome documentation requirements that vary widely among plans.

CMS has issued important guidance to implement appropriate protections and ensure long term care residents' access to necessary medications. We commend the Agency for its attention to these issues, however, a number of significant concerns

remain unresolved. We look forward to working with this Committee and the Agency to address those challenges.

Overview

The typical nursing home resident is 84 years of age, female, has seven distinct diagnoses, and takes approximately eight different drugs at any given time. The patients we serve are among the oldest and sickest Medicare beneficiaries, and until January 2006, a majority received their drug coverage through State Medicaid programs. On average, 70 percent of nursing home residents received drug coverage under Medicaid, another 15 percent received coverage under Medicare Part A, and the remaining 20 percent either were private pay patients or covered by a third-party plan.

This situation changed dramatically on January 1, 2006, when dual eligible beneficiaries were auto-enrolled randomly in plans with premiums at or below the benchmark amount. The 70 percent of nursing home residents who are dually eligible for Medicaid and Medicare may now be enrolled in as few as six or as many as 16 different prescription drug plans. As a result, long term care pharmacists face a daunting task in attempting to manage these patients' drug regimens across a wide variety of plans' formularies.

As implementation of Medicare Part D continues, several "course corrections" are needed to ensure that residents of long term care facilities continue to receive the specialized pharmacy benefits anticipated under the program.

Network Access

Unlike beneficiaries residing outside institutional settings, long term care residents do not go to the pharmacy – the pharmacy comes to them. For that reason, a "retail" standard of access is inappropriate for long term care patients. To ensure access nursing home residents' access to necessary medications, the MMA authorized CMS to establish long term care pharmacy network standards for prescription drug plans.

However, CMS has not developed an objective standard to evaluate the adequacy of a plan's long term care pharmacy network. As late as November 2005, CMS continued to encourage plans to contract with long term care pharmacies to ensure convenient access to necessary services.

Under guidance issued by CMS in March 2005, plans were required to provide a list of enumerated services to residents of long term care facilities[1]. CMS expected plans to contract with pharmacies that could certify their ability to provide these services. In theory, each of the participants in these negotiations had equal incentive to compromise: the pharmacies needed access to provide services to nursing home residents, and the plans needed in-network pharmacies to fulfill their obligations for convenient access.

As the negotiations progressed, however, it soon became clear that the pharmacies had much less bargaining power than the plans. If a nursing home resident was enrolled in a plan that did not include the facility's long term care pharmacy in network, the pharmacy was forced to agree to the plan's standard agreement in order to provide services to the beneficiary. Even if the beneficiary changed to a plan that included the pharmacy in network, the new assignment would not take effect until the first day of the following month. As a result, many pharmacies were forced to accept plans' default provider agreements to avoid a lapse in coverage for beneficiaries in long term care facilities, particularly those in rural areas.

To remedy this problem, CMS should allow changes in beneficiaries' coverage to take effect immediately upon enrollment in a new plan. This approach would ensure beneficiaries' continued access to necessary pharmacy services without imposing undue hardship on plans.

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[1] Centers for Medicare and Medicaid Services: *Long Term Care Guidance* (March 16, 2005).

CMS Marketing Guidelines

In implementing Part D, CMS has gone to significant lengths to protect beneficiaries from unethical and overly aggressive marketing techniques that raise the potential for conflicts of interest. Long term care pharmacies strongly support this objective. At the same time, beneficiaries must have access to useful information necessary to select the best plan to meet their needs. Unfortunately, efforts by CMS to protect beneficiaries have made it almost impossible to help nursing home residents choose an appropriate plan.

CMS issued its guidance on marketing activities last summer.[2] This guidance is extremely prescriptive and effectively prevents long term care residents from receiving specific advice in selecting their drug plans. The simple act of suggesting to a beneficiary that certain drug plans are more responsive to the needs of long term care residents is, by CMS standards, considered a violation of the marketing guidelines.

CMS officials have expressed repeated concern that health care providers will recommend plans based on their own financial interest rather than on the interest of the beneficiary. Yet beneficiaries face a multitude of plan choices, and a recent analysis by the Kaiser Family Foundation[3] highlighted significant differences among plan formularies. Clearly, some plans are more appropriate for residents of long term care facilities. Professional caregivers should be able to communicate this information to beneficiaries, while emphasizing that they are free to choose the plan they prefer.

Compounding this problem, CMS recently issued a letter to state nursing home surveyors[4] outlining their responsibility to inspect nursing homes for evidence of steering, coaching, or requesting residents to select or change plans for any reason. This document has served to raise the stakes among nursing home operators for any well-intended effort to help residents choose an appropriate Part D plan.

Given the frail medical condition and high level of cognitive impairment among residents of long term care facilities, CMS should allow professional caregivers to provide recommendations on plan selection to Medicare beneficiaries, while assuring them of their right to choose whatever plan they prefer. This simple change would enable them to provide effective counseling without undermining residents' freedom to choose any available Part D plan.

Cost Sharing

Under the MMA's provisions, dual eligible beneficiaries residing in long term care facilities are not required to pay cost sharing for Part D covered drugs. Due to data exchange problems between the states and CMS, however, many dual eligibles were erroneously assigned co-payments under their Part D plans.

In these cases, plans have reimbursed pharmacies at a lower amount after wrongly deducting the cost sharing amounts. To avoid delay in providing needed medicines, long term care pharmacies have typically dispensed the drugs and attempted to resolve the problem later.

CMS continues to work with the states to improve the accuracy of data on dual eligible beneficiaries. In addition, CMS has provided guidance to plans that they may reimburse long term care pharmacies for inappropriately assigned co-payments. This guidance should help resolve historic claims from pharmacies owed reimbursement for

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[2] Centers for Medicare and Medicaid Services: *Medicare Marketing Guidelines for: Medicare Advantage Plans (MA); Medicare Advantage Prescription Drug Plans (MA-PD); Prescription Drug Plans (PDP); 1876 Cost Plans* (August 15, 2005).

[3] Hoadley, et al.: *An In-depth Analysis of Formularies and Other Features of Medicare Drug Plans*; Kaiser Family Foundation (April 2006).

[4] Centers for Medicare and Medicaid Services: *Memorandum from Director, Survey and Certification Group to State Survey Agency Directors* (May 11, 2006).

uncollected cost sharing, but not all plans are cooperating with efforts to clear up this backlog.

This problem persists, and long term care pharmacies are now owed millions of dollars in improperly-assigned co-payments. While the Agency's efforts to date are commendable, CMS must require plans to act promptly to resolve the significant backlog of uncollected, and improperly assigned, co-payments for dual eligible beneficiaries residing in long term care.

Conclusion

Acknowledging the challenges inherent in implementation of a major new Medicare benefit, the long term care pharmacy community recognizes the importance of the Part D program. We are committed to its success and determined to ensuring that the nation's frail elderly continue to receive the medications they need. Again, thank you for the opportunity to testify today, and I would be glad to answer any questions you may have.

MR. DEAL. Thank you. Mr. Hallberg.

MR. HALLBERG. Good afternoon, Chairman Deal, Ranking Member Brown, Congressman Burgess, nice to see you again, and other members of the committee. I am happy to testify today on the partnership with pharmacists and the implementation of Medicare Part D. My name is Chuck Hallberg. I am President and the founder of MemberHealth, Inc., sponsor of the Community Care RX program, the fourth largest standalone Part D program in the country, with about one million enrollees.

MR. DEAL. Could you pull your microphone a little closer?

MR. HALLBERG. I am sorry, is that better?

I founded MemberHealth in 1998 as a PBM. We operate now as a prescription insurance company and other programs with a national network of over 60,000 pharmacies. Prior to the start of Part D, we supported a successful Medicare discount card with approximately 450,000 enrollees.

As we approach the MMA, we thought this was a tremendous opportunity to align the business, providing prescription drugs to ensure that the beneficiaries, pharmacies, physicians, and plans and the Government all faced consistent incentives. To help us achieve this goal, we did collaborate with the National Community Pharmacists Association to build a program that leverages the pharmacist's skill to provide the best clinical outcome and the most financial value for the Medicare beneficiary. In designing our program, we focused on the idea that meeting the beneficiaries' needs is paramount. If we do that, everything else will follow.

We believe that it is in the beneficiariy's best interest to have the most appropriate care at the least cost, so we have implemented a program to help our pharmacists ensure that our enrollees take advantage of the savings available to them for generic drugs. Our generic incentive

program provides higher dispensing rates to pharmacies that meet generic dispensing goals. This payment increase provides an incentive for pharmacies to spend extra time helping our enrollees save money, and has proven very effective. The CCRX generic dispensing rate is about 60 percent and consistently comes in that percentage every day. This is well above the industry commercial standards, and we believe it is well above the Part D plan averages as well. In addition to saving money for our enrollees, the high generic dispensing rate will save Medicare money, because as we control costs better, Medicare will save through lower bids and reduced risk quarter costs.

We believe it is in the beneficiary's best interest to have a strong relationship with their pharmacist, so we designed our medication therapy management program to support this relationship. While other Part D plans may have chosen to implement MTM programs via remote methods, phone calls, and other avenues, our program pays the pharmacist to work directly with our enrollees. Once our system identifies enrollees who meet the MTM requirements, we send the information to the enrollee's pharmacy to schedule a session where the pharmacist reviews the enrollee's drugs to look for clinical problems or savings opportunities. We believe that this close interaction will help our enrollees better manage their diseases, their costs, and taps into the pharmacist's expertise. We believe that it is in the beneficiary's best interest to have an opportunity to review their drug use and ways to comply with our formulary with a pharmacist is part of their transition into the Community Care RX plan.

As a result of that, we are currently implementing a change to our transition plan under which we will pay pharmacies to perform this review for all new enrollees starting June 1. We developed this initiative because one of the lessons that we learned during the first months of Part D is the importance of ensuring a smooth transition for all new enrollees. Many of them do have questions, many of them don't understand how to transition if there is a drug on non-formulary, and many of them simply don't know how to take advantage of the best cost savings. We are paying the pharmacists as part of this transition policy to help the beneficiary reduce that confusion, answer those questions, and transition into the Medicare program. It is our welcome to Medicare medication review.

While our focus has always been on serving the beneficiary, we recognize that our network pharmacies are businesses, and we work hard to ensure that we are the best business partners that we can be. As noted above, we provided incentives for generic dispensing so that we pay for performance. We pay our pharmacists to perform the MTM and transition reviews, recognizing that the pharmacists need to make a

commitment to providing these services and must be compensated appropriately.

We also make timely payment to our pharmacies a priority. We pay our pharmacies twice a month, on the 1st and the 15th. These payments do correspond to two payment cycles per month. Weekly payments are the standard for many of the State Medicaid programs. The first cycle that we pay occurs from the 1st to the 15th, and of course, the second is from the 15th to the 31st. To further improve the timeliness of our payments, we have also implemented EFT, electronic funds transfer, for pharmacies electing that option, starting March 31. We currently pay about 35 percent of our claims electronically at the very day that the payment is due, and we look forward to getting all of our pharmacies on to this program in the coming months.

Before I close, I would be remiss if I didn't mention the outstanding effort of our network pharmacies in dealing with Part D program's startup troubles. I hope my testimony demonstrates that we at MemberHealth have sought consistently to support our pharmacies in delivering the best care to our enrollees, but the pharmacists in the community went way above and beyond the call of duty, and we will be eternally grateful for those efforts.

In closing, let me reiterate my thanks for the invitation to address the committee, and say that we believe our focus on meeting the beneficiary's prescription drugs needs through strong patient/pharmacist relationships will provide tremendous value to the beneficiaries, the pharmacies, and the Medicare program for years to come.

Thank you. I would be pleased to answer any questions.

[The prepared statement of Charles E. Hallberg follows:]

PREPARED STATEMENT OF CHARLES E. HALLBERG, PRESIDENT, MEMBERHEALTH, INC.

Good morning Chairman Deal and members of the Committee. I am happy to be here today to testify on the partnership with pharmacists to implement Medicare Part D.

I am the founder and President of MemberHealth, the sponsor of the Community Care Rx program, the fourth-largest stand-alone Part D plans in the country with about one million enrollees. I founded MemberHealth in 1998 as a pharmacy benefit management company, and we operate prescription insurance and discount programs through our national network of over sixty thousand network pharmacies. Prior to the start of Part D, we supported a successful Medicare Drug Discount Card, with 450,000 enrollees.

As we approached the MMA, we thought this was a tremendous opportunity to re-align the business of providing prescription drugs to ensure that beneficiaries, pharmacies, physicians, plans, and the government all faced consistent incentives. To help us achieve this goal, we collaborated with the National Community Pharmacists' Association (NCPA) to build a program that leverages the pharmacists' skills to provide the best clinical outcomes and most financial value for the Medicare beneficiary.

In designing the CCRx program, we focused on the idea that meeting the beneficiary's needs is paramount – if we do that everything else will work itself out.

We believe it is in the beneficiary's best interest to have the most appropriate care at least cost, so we've implemented a program with the help of our pharmacists to ensure that our enrollees take advantage of the savings available to them from generic drugs. Our generic incentive program provides higher dispensing rates to pharmacies that meet generic dispensing rate goals. This payment increase, provides an incentive for pharmacists to spend extra time helping our enrollees save money and has proven very effective. The CCRx generic dispensing rate is about sixty percent, well above industry averages and we believe well above Part D plan averages. In addition to saving money for our enrollees, this high generic dispensing rate will save Medicare money because as we control costs better, Medicare will save through lowered bids and reduced risk corridor costs.

We believe it is in the beneficiary's best interest to have a strong relationship with their pharmacist, so we designed our Medication Therapy Management (MTM) program to support this relationship. While other Part D plans have chosen to implement MTM programs via remote methods – phone calls or other avenues – our MTM program pays pharmacists to work directly with our enrollees. Once our system identifies enrollees who meet the MTM requirements, we send the information to the enrollee's pharmacy to schedule an MTM session, where the pharmacist reviews the enrollee's drugs to look for any clinical problems or savings opportunities. We believe that this close interaction will help our enrollees better manage their diseases and their costs by tapping into our pharmacists' expertise.

We believe it is in the beneficiary's best interest to have an opportunity to review their drug use and ways to comply with our formulary with a pharmacist as part of their transition to CCRx. We are now implementing a process to pay our pharmacists to perform this review for all new enrollees to CCRx starting next month. We developed this initiative because one of the lessons we learned in the first months of Part D is the importance of ensuring as smooth a transition as possible for new enrollees, and we're enlisting our pharmacists to look for clinical red flags in our new enrollees' drug use as well as opportunities to move to formulary drugs or generics or to begin formulary exception processes early if need be.

While our focus will always be on serving the beneficiary, we recognize that our network pharmacies are businesses and we work hard to ensure that we're the best business partner we can be. As noted above, we've provided incentives for generic dispensing so that we pay for performance, and we pay our pharmacists to perform MTM and transition reviews, recognizing that the pharmacists need to make a commitment to providing these services and must be compensated appropriately.

We also make timely payment to our pharmacies a priority. We pay our pharmacies twice per month – on the 1st and 15th of each month. These payments correspond to two claims cycles per month. Two cycles per month is the industry standard for the commercial marketplace. Weekly payments are the standard for many State Medicaid programs. The first cycle covers claims incurred from the 1st through the 15th of the month, while the second cycle covers the 16th through the end of the month. Payments for each claims cycle are issued 15 days following the end of a cycle. As an example, claims incurred from March 1st through March 15th are paid to the pharmacies on April 1st. We have also issued a payment calendar so that our pharmacies can monitor their payments for the remainder of 2006.

To further improve the timeliness of our payments, we recently began processing electronic fund transfers (EFTs), for those pharmacies electing that option for the claims cycle ending March 31st. We currently pay electronically for about 35% of our claims, and we are working to have the majority, if not all, of pharmacies on our EFT program, because this will cut at least five days off of the payment cycle and allow for better controls to ensure that the pharmacies are paid the right amount at the right time.

Before I close, I would be remiss if I didn't mention the outstanding efforts of our network pharmacies in dealing with the Part D program's start up troubles. I hope my testimony demonstrates that we at MemberHealth have sought consistently to support our pharmacies in delivering the best care to our enrollees, but the pharmacists in the community went above and beyond the call of duty and we will be eternally grateful for those efforts.

In closing, let me reiterate my thanks for the invitation to address the Committee and say that we believe our focus on meeting the beneficiaries' prescription drug needs through strong patient-pharmacists relationships will provide tremendous value to the beneficiaries, the pharmacies, and the Medicare program for years to come.

MR. DEAL. Well, thank you. That was interesting testimony. We got you all here at one time, now we are going to try to sort some things out.

Mr. Hallberg just mentioned electronic transfers that he is starting. I think you said about 30 percent of your people are now using it. Mr. Merritt, what percent of your payments are by electronic transfer?

MR. MERRITT. You know, I don't have that number. I can get it for you. We do know, again, we deal with about 55,000 different pharmacies, many of which are not equipped for EFT. We definitely see it as something that is coming down the road as something in the future, but for right now I don't have those particular numbers on the percentages.

MR. DEAL. But if a pharmacist is equipped to do it on his end, you are prepared on your end?

MR. MERRITT. Yeah, we are prepared on our end to do that, and it is one of the options that we offer.

We are a little concerned about mandating it right now, although we might be able to work with that. Depending on the context, as well, because there are some startup costs to be involved, especially with a lot of the independent pharmacies who are not equipped for this and maybe aren't as interested in having it. But certainly, it is something that we see coming down the road.

MR. DEAL. But it seems to me in this day and age that most everything else is done electronically, and we are talking about trying to eliminate the delay of getting the money in the hands of the person who has already had the drugs. The quicker we do it, the better, and it seems to me that that would be an inexcusable delay time between the time the claim is submitted and having to wait on a check in the mail. I think we can all do better than that. I would just simply encourage everybody to move in that direction.

Let me talk about some suggestions Mr. Wirth had, and we are talking about this enrollment lag issue. Mr. Galluzzo would say we ought to be able to do that instantaneously too. I would like to think that we at some point can, but we apparently are not there yet. It takes

everybody at this table to cooperate in doing that and achieving that goal, but in the meantime, would it be feasible, as Mr. Wirth suggests, that we pick a date that if you make your transfer from this company A to B? If you do it before the 15th of the month that your changeover would be effective the 1st of the next month, but if you do it in that last half of the month, that you are going to have to wait maybe until the following month? I mean, I know we would like to do it quicker than that, but what is a realistic solution to this? It seems to me that the first question I asked was on this issue, because I don't see this one going away. Everybody that enrolls new every day, this problem is going to multiply. What is a realistic proposal on enrollment lag? Anybody that wants to comment, not all at once.

MR. WIRTH. Chairman Deal, I would applaud a 15-day time period. That certainly works for us as a community pharmacy, but we are not the ones who have to implement the changes. There is also a significant issue of beneficiary education that they understand. CMS has worked hard to try to explain that to beneficiaries to enroll early, but that just isn't enough.

MR. DEAL. What about Mr. Hopkins?

MR. HOPKINS. One of the things that we have learned through facilitating enrollment and working collaboratively with the chains and the independent associations, and it has been recommended to CMS, is that modified E-1 transaction where you look at Part A, B, and D, and generally, when you are doing that, you can determine that if they are with WellPoint or Aetna for this service then they are probably with them for the drug component. That is currently under discussion, but I think that would help the pharmacies determine where the claim is supposed to go.

In response to your question on the lag time, I think that 15 days is the time frame that I have heard to resolve the enrollment issue.

MR. DEAL. What is it going to take for us to get there? Can the industry do it on its own, or is it going to take somebody telling you to have to do it?

MR. HALLBERG. Chairman Deal, currently I believe under the statute, if someone signs up at 11:59 the last day of the month, we are obligated to scramble if we can.

MR. DEAL. So we may have to change that if we are going to dictate some of the time frame. All right.

MR. GALLUZO. Chairman Deal, may I make a comment?

MR. DEAL. Sure.

MR. GALLUZO. There is approximately four percent of the beneficiaries that live in long-term care. Those four percent take, depending on what analysis is made, anywhere from 25 to 50 percent of

the drugs that Medicare pays for. That is a lot. So our main concern is access to those drugs, and even if they can't get the pay type right immediately, there is no reason why they can't retroactively pay the pharmacy for those prescriptions that the resident needs. The doctor is not going to be willingly changing the regimen of those elderly, so the pharmacist is going to send that medication out regardless. We just want to make sure that the resident has the access, which they will, because we will send them out, but we just want to make sure that we are going to be paid for those. That has probably been a problem in the past for us, because we are not going to deny anybody any medications. We just want a proper payment schedule and know that we are going to be paid for them.

MR. DEAL. Mr. Brown, you are recognized.

MR. BROWN. Thank you, Mr. Chairman.

Mr. Galluzzo, I caught your comment about we are not in the top three. You assume we are all attorneys. We are not all attorneys, but I assume probably Congressmen aren't in the top three, either, so that would be a better statement to make.

Let me start with you, and then I would like to ask a question sort of from everybody, Mr. Hallberg down to Mr. Hopkins, Mr. Merritt, but start with a question for you, Mr. Galluzzo. I have talked to pharmacists in darn near every part of Ohio, Norton and Troy and Cincinnati and Toledo, and one issue that always comes up is the whole issue with dual eligibles and the automatic enrollment and putting them in a plan that they didn't necessarily choose, assigned by random. This study in Connecticut found that out of pocket costs for a dual eligible could vary by thousands of dollars a year, depending on their illness, depending on a lot of factors. A study by Department of Health and Human Services, the Inspector General found that in California, Nevada, and Arizona, 50 percent of the dual eligibles were auto-enrolled, were random automatically enrolled in the plans that covered less than 85 percent of the drugs that were prescribed for them.

Comment, if you would, from a long-term care perspective, what has happened? Comment, if you would, what it means to long-term care pharmacies, and comment, if you would, on what advice you would give CMS for how to deal with dual eligibles who will continually hit the system and continually be assigned to various plans randomly.

MR. GALLUZO. That is an interesting question. I understand why they are randomly assigned, but the point of the matter is that there are some prescription drug plans out there that just aren't conducive to long-term care. If you run into those plans, and I have to admit that all the dust hasn't settled yet, but if you run into some of those plans, then it is

best that that resident is switched to a better plan. I will tell you why some plans aren't so good.

Some of them aren't so good because they have a narrow formulary, although the first 90 days, 120 days is supposed to cover just about everything. Some haven't taken the time to understand long-term care and some of the prior authorization that we have to go through is very cumbersome, and the residents aren't going to get their medication timely, or they will get it and then there won't be proper reimbursement. There are some PDPs that you can actually stay on the line for up to an hour waiting to get a question answered, and you don't dare hang up because when you call back, it is going to take another hour. So in my billing department, we have had to hire four new people just to handle the new process. The other problem I have with some PDPs is they just haven't cared to learn about long-term care and how we operate.

So my advice to CMS is give the pharmacist an opportunity to sit down with not only the resident, because these are the sickest of all of them, and some of those you can't talk to, so what you are going to end up talking to is the family. But sit down with the family and discuss the drug regimen review, discuss formularies that they are on, because we are experts in drug formularies. Then come up with a suggestion that is going to help them have better access to their medication.

The other thing is if you can start a plan on the last day of the month and you can start it on the next day, why can't you have a new plan on the 16th and start it on the 17th? If you can do it on the 31st to the 1st, why not the 16th to the 17th? That I don't understand.

MR. BROWN. Nor do I.

MR. GALLUZO. All right.

MR. BROWN. Thank you for that.

Mr. Hallberg, and if everybody would just go down the line, my understanding, and I have heard it from some of you, too, there is no requirement either in the statute or CMS rules to ensure that plans pay pharmacies promptly. I know that some plans have tried. Do we stick with voluntary efforts on the part of plans to pay, or should Congress change the statute or CMS order some regiment that plans be paid within a specific time frame? Just go up and down, give a short answer, if you would.

MR. HALLBERG. It is an excellent question, and it is a question of policy. There are different business solutions out there, as I indicated in my testimony. Although the commercial world is typically paid on a twice a month basis, many of the States for their Medicaid business have historically paid on a weekly basis. As you have heard from some of the other folks here, particularly Mr. Couch and from the wholesalers, many

of the business plans for the pharmacies across the country are well-developed to work around the existing methodologies.

The policy question is really whether or not all of those businesses should change to conform to a single commercial environment, or whether it is appropriate for Congress to enact legislation that essentially says okay, all you PBMs that were in the commercial world, you are now playing as a government contractor. When in Rome, do as the Romans do. If you are going to be in a government contract environment, and that historically has had a weekly type of time period for payment, then perhaps it is appropriate that the people who are the contractors adopt practices that are consistent with the existing policies that various governments across the country have been utilizing.

So as you mentioned, it is purely an absolutely appropriate policy for this committee and Congress to consider.

MR. BROWN. Mr. Galluzzo, should it be required or left voluntary?

MR. GALLUZO. Well, are you asking me that question?

MR. BROWN. I am asking everybody.

MR. GALLUZO. I believe in competition, and I would hope that it could be voluntary, but I am not so sure that is going to get done.

MR. BROWN. Okay. Mr. Wirth? You are the guy that talks about lawyers too, so--

MR. GALLUZO. Some of my best friends are attorneys.

MR. BROWN. Mr. Wirth.

MR. WIRTH. I would like to see Congress and policymakers define what the payment cycle means based upon the day of receipt of a clean claim. To say I am going to pay claims once a month does not mean the claims are paid in 30 days. To say I pay on the 15th and 30th of the month does not mean I pay claims in 15 days. So I prefer to see the standard be set by Congress and CMS that the payment cycle is based upon the date of receipt of that clean claim. Thank you.

MR. BROWN. Thank you. Dr. Harden?

DR. HARDEN. Mr. Brown, just a quick example. Georgia Medicaid has for several years now paid all claims EFT. Any claim submitted prior to Thursday of the week before was paid on Tuesday of the following week. Therefore, I would challenge that particularly Georgia pharmacies are not equipped to accept EFT payments. They have been doing so under Medicaid for several years, and the contract that the State had with that particular PBM required that it be done in that manner. No other plan that I am aware of has offered to step forward and make that kind of access to payment to stop this, so I would think from that particular event that probably unless it is required, it will not happen.

MR. COUCH. Congressman Brown, I am technically a distributor, and that part of the issue. I don't receive payments.

Congressman Brown, I don't think it is appropriate for me to be in that position, but I will tell you this. The whole system that we have, the business model that is producing unbelievably efficient, effective ways of getting drugs to patients at a very cost-effective number is based on quick turnaround and quick usage of rotating product and getting paid for it. As a distributor, I need to be paid promptly. My customers need to be paid promptly if I am going to be paid promptly.

I will speak to electronic payments. Our company has been using electronic payments both ways for years and years, and I would bet that well over 80 percent in 14 States use electronic payments, so electronic payment is not a problem.

MR. BROWN. Thank you. Mr. Hopkins.

MR. HOPKINS. WellPoint agrees that pharmacists should be paid promptly and accurately. WellPoint has the processes in place to ensure that this happens. I was the architect of legacy Anthem's payment process, how the payment process was set up. The electronic fund transfers, the electronic reconciliation, and our chain partners, 80 to 90 percent of them use this process. We have this process in place for our high volume independent pharmacies. I think the independents could be more effective if more chose to use this process with WellPoint. So I think this process or changing the payment rules should be left voluntary.

MR. BROWN. Thank you, Mr. Hopkins. Mr. Merritt?

MR. MERRITT. I would just harken back a little bit to what the purpose of the claims payment process is. There are a number of responsibilities that we have, and of course, the question of how we do it. It is important that we pay the right amount of the claim, and that we do so in an efficient and cost-effective way. We also need to make sure there aren't improper drug interactions of people being prescribed one drug from one doctor, another from another doctor, maybe filling it at a different pharmacy as well. PBMs have that information where we can sort that out. Also, we have to comply with a number of laws from Medicare, HHS, OIG, and of course, our private payers and so forth.

Now, in terms of prompt pay, we do think it is happening right now voluntarily. Our companies pledge to pay it within 30 days because that is our standard business practice in the commercial marketplace. That is also the way FEHBP does it. That is the way Medicare pays doctors and hospitals. So in terms of do in Rome as the Romans, that is the way doctors and hospitals get paid, in 30 days, 95 percent clean claims and Medicare. So we would ask that as this is being considered, it should be viewed as a level playing field and not changing the rules for one particular part of healthcare.

MR. BROWN. Thank you. Mr. Chairman, I apologize for the length. I have a unanimous consent request from a beneficiary testimony that we would just like to submit, if that is possible.

MR. DEAL. Without objection.

[The information follows:]

TESTIMONY OF THE CENTER FOR MEDICARE ADVOCACY, INC.

Before the Health Subcommittee, Committee on Energy and Commerce

May 23, 2006

The Center for Medicare Advocacy, Inc. (the Center) submits these comments for the record of the hearing concerning the federal government's relationship with pharmacists.

Founded in 1986, the Center is a national, non-partisan educational and advocacy organization that identifies and promotes policy and advocacy solutions to ensure that elders and people with disabilities have access to Medicare and quality health care. The Center's national office is in Connecticut, with offices throughout the country, including Washington, D.C. The Center represents thousands of individuals in Medicare appeals each year, responds to calls and e-mails from individuals all across the United States, and provides support to CHOICES, the Connecticut state health insurance assistance program. Requests to the Center for assistance have increased exponentially with the advent of Medicare Part D.

The Center first wants to thank pharmacists for their efforts on behalf of our clients as the new Medicare Part D prescription drug program is being implemented. Pharmacists have worked diligently to help identify the plans in which beneficiaries were enrolled, to provide beneficiaries with useful information in making plan choices, and to help them in accessing the exceptions and appeals processes. Pharmacists have worked with state health insurance assistance programs (SHIPs) and advocacy organizations such as the Center to identify Part D problems and to ensure that the problems are corrected both individually and systematically.

Despite these efforts, difficulties have occurred at the pharmacy counter and continue to occur. Many of these problems arise because of structural problems with Part D that make accessing drug coverage difficult for low-income individuals and other individuals who are dually eligible for Medicare and Medicaid (dual eligibles). Other problems arise because of systems problems that are more than just initial "glitches" in the implementation of Part D.

Problems at the pharmacy concerning the Point of Service (POS) option:

a) January problems: In anticipation of potential automatic enrollment issues for people dual eligibles when they transitioned for Medicaid to Medicare drug coverage on January 1, the Centers for Medicare & Medicaid Services (CMS) established a process known as a Point-of-Sale solution (POS). The idea was to make sure that full dually eligible individuals experienced no gap in drug coverage. The POS process is a special type of facilitated enrollment that allows beneficiaries who present at a pharmacy with evidence of both Medicaid and Medicare eligibility, but without current enrollment in a Part D Plan, to have a claim submitted to the POS contractor, WellPoint, Inc., of Indianapolis.

The POS process, as designed to work in January, is as follows:

- A full dually eligible individual presents at the pharmacy with either a Medicaid card or previous history of Medicaid billing in the pharmacy system patient profile.
- Pharmacist bills Medicaid and the claim is denied.
- Pharmacist requests photo identification and checks for Part D enrollment by submitting an "E1 query to the TrOOP facilitator" and the pharmacist also checks for A/B Medicare eligibility by requesting Medicare card; or calling 1-800-Medicare; or requesting to see a Medicare Summary Notice (MSN).
- If the individual is verified to have dual eligibility and has not been enrolled in a Part D plan, the POS Contractor will immediately submit an enrollment transaction on behalf of the dual to enroll him or her into a POS Contractor plan retroactively to the effective date of dual eligibility (or January 1, 2006). Normal rules for duals opting out of the plan would apply.

Some beneficiaries who attempted to use the POS process in January encountered difficulties. Despite CMS's claims of providing education to pharmacies about POS, some pharmacies were unaware of the process and so did not use it. Advocates often sent beneficiaries back to the pharmacy with fact sheets about POS in hand to make sure that the pharmacies had sufficient information to make the process work for them.

b) Continuing problems: The POS problems continue, even after the initial transition of duals from Medicaid to Medicare drug coverage, and in particular for those who newly become new dually eligible for both Medicare and Medicaid.

Individuals with Medicaid lose their Medicaid drug coverage on the first day of the month that they become eligible for Medicare, even if they have not enrolled in a Part D plan. The state will transmit information about them to CMS when the state becomes aware of their new dual eligibility status. It is unclear, however, whether and when states will have that information. It may be several months before CMS enrolls a new dual into a Part D plan and coverage becomes effective, potentially leaving the dual eligible person without drug coverage for an extended period of time.

New dually eligible individuals should be able to use the POS option at the pharmacy that facilitates enrollment into the point of service contractor. Again, this system was designed to avoid gaps in coverage for those who lose Medicaid drug coverage because they are eligible for drug coverage under Part D.

Unfortunately, we still hear from beneficiary advocates that pharmacies are either unaware of the option (the same problem that occurred in January) or that claim that the POS option is not available. For example, a woman from Michigan who had Medicaid and who became eligible for Medicare in May needed four injections prior to her scheduled liver surgery. When she went to the pharmacy Medicaid rejected the claim for the injections because the injections, which were to be self-administered, are covered by Medicare Part D. A Michigan SHIP counselor called the pharmacy on behalf of the

woman, but the pharmacy refused to use the POS system to bill WellPoint. No other pharmacy within a small radius would use the POS option. Through advocacy by the woman and the SHIP counselor, Michigan Medicaid eventually agreed to pay for the four injections. A CMS caseworker agreed to work with the SHIP counselor to ensure that the woman was auto-enrolled into a Part D plan with an effective date retroactive to her Medicare eligibility. Without such advocacy at the state and federal level, the woman would not have had access to the injections she needed before her surgery.

Problems when full low-income subsidy individuals reach the "doughnut hole":

Dual eligibles are automatically eligible for the full low-income subsidy or "extra help" amount, and so should not lose drug coverage during the "doughnut hole" or coverage gap. Nevertheless, Connecticut CHOICES volunteers in north central Connecticut report that dual eligibles are being told at the pharmacy counter that they have reached the $2250 initial coverage limit and so must pay the full cost of their drugs. The pharmacies base their statements on the information they receive from the Part D computer system and refuse to acknowledge that those eligible for the full low-income subsidy should continue to receive assistance even after the initial coverage limit amount is met. In addition to being unaware of how the low-income subsidy is calculated, the pharmacies are unaware that Medicaid no longer pays for the full amount of prescriptions for duals. The pharmacies have been advising the dual eligibles to contact their Medicaid case worker. As a result, dual eligibles are leaving the pharmacy counter without necessary medicine and with incorrect information about how to resolve the problem.

Problems identifying proper co-payment amounts:

Similar issues arise when the pharmacy's computer shows the beneficiary is supposed to pay a higher co-payment amount than the low-income subsidy award letter for the Social Security Administration (SSA) indicates. Pharmacies are bound by what comes up on their computer and often are not willing or able to override the information in their computer. Problems sometimes remain even after CMS and SSA have told beneficiaries and their advocates that the computer system issue has been resolved. A Connecticut woman was informed by SSA that she was eligible for the full low-income subsidy, with co-payments of $2 and $5, but the computer system shows that she must pay a 15% co-insurance for her drugs. Despite intervention by the Center, by CMS, and by SSA, the issue still is not resolved, and the pharmacy continues to charge her the higher cost-sharing. The woman cannot afford to pay and so has gone without some needed medications.

Problems for dual eligibles who cannot afford the Part D co-payment amounts:

Part D imposes prescription drug co-payments for the first time on a substantial number of dual eligibles, including the 1 million dual eligibles in California (approximately one-sixth of the dual eligible population). While the co-payments for duals are supposed to be minimal, for someone living on $817 (100% of the federal poverty level for an individual) or less each month, $3 per prescription is a fortune. As a beneficiary from

New York wrote to the Center recently, she lives on Social Security disability benefits and cannot afford to pay the $3 co-payment every time she goes to the pharmacy. In addition to California and New York, Florida, Texas and Illinois, which also have large dual eligible populations, are not providing any assistance with co-payments.

Previously under Medicaid pharmacies waived co-payments and distributed prescriptions to Medicaid recipients who could not afford to pay; no one left the pharmacy without his or her medicine. Under Medicare, pharmacies do not have the authority to waive co-payments uniformly. Co-payments may be waived on a case-by-case basis, but pharmacies have been told to exercise this authority in only limited circumstances. As a result, dual eligibles who used to get their medications when they could not pay the minimal Medicaid co-payments are now walking away from their pharmacies without prescriptions.

Even when states pay co-payments for duals, the systems do not always work, and pharmacies still charge duals co-payments. Despite the fact that Connecticut has legislated coverage of Part D co-payments for duals, a nurse from Marlborough, Connecticut contacted the Center because her mental health clients are still being charged co-pays for their drugs, and they cannot afford their medications.

Problems getting access to covered drugs:

Just as pharmacy computer systems do not always contain correct information about cost sharing amounts, the systems do not always contain correct information about whether a drug is covered for a particular beneficiary. When coverage disputes are resolved in favor of the beneficiary, the favorable resolution may not show up in the pharmacy's computer system. The system will indicate that the drug is not covered, even though the plan has agreed to cover the drug. The beneficiary must either pay for the drug out-of-pocket and seek reimbursement or re-contact the plan, sometimes several times, to get the problem resolved.

Problems concerning notice at the pharmacy of rights to get a coverage determination and to appeal:

CMS, in documentation filed under the Paperwork Reduction Act to support Part D standardized notices, said that "[c]onsumer research supports providing information at the point in time that the individual needs it to make a decision. Providing the information separately from the point of service would reduce its effectiveness." The regulations adopted by CMS to implement Part D appeals protections are contrary to the consumer research and call into question whether beneficiaries will know how to begin the appeals process.

A Medicare beneficiary generally first learns that her Part D drug plan will not pay for or otherwise provide a requested prescription at the pharmacy. The Part D regulations do not require that detailed notice describing the denial and subsequent appeal rights be provided at the pharmacy, however. Instead, the regulations require each drug plan to

arrange with pharmacies within their network to either post a generic notice telling beneficiaries to contact the plan if they disagree with the information provided by the pharmacist or to distribute such a generic notice. A beneficiary who wants further information or who wants to appeal must first contact the plan to get a coverage determination that will inform him or her of appeal rights that might ensue from the denial.

Many Medicare beneficiaries who are frail, or who have limited mental capacity, or who have limited reading or English skills will be unable to contact their drug plans, and so will lose out on the protection that the Part D appeal process may provide. Particularly for dual eligibles and other low-income beneficiaries, this system of notifying beneficiaries of their rights may violate Constitutional due process principles.

Medicare beneficiaries with the capacity to contact their drug plan for a coverage determination that is the pre-requisite for filing a Part D appeal still may not have knowledge of their rights under the regulatory system. Medicare beneficiary advocates across the country indicate that most pharmacies have chosen the option of posting the notice rather than handing the notice to beneficiaries when coverage is denied or other questions about coverage arise. Because CMS only requires the posted notices to be the size of a distributed notice, posted notices are generally on standard-sized paper in standard-sized 12-point font. As a result, advocates report that many of the posted notices are hard to find among other notices posted at the pharmacy and are hard to read.

Even if CMS had agreed that detailed information about the reason for the denial of drug coverage and appeal rights should be distributed at the time of the denial at the pharmacy counter, it is unclear whether pharmacies would be able to provide that information. One of the Part D implementation problems reported by pharmacies was the inability to receive an explanation from a drug plan of the reason for denial at the time a claim was denied, or, if explanations were received, inconsistent coding and explanations from different plans. In April 2006 CMS announced that health plans, pharmacists, and pharmacies had agreed on standardized electronic messaging to be used when a drug is not covered, when prior authorization is required, when quantity limitations have been exceeded, or when the pharmacy is not part of a plan's network. It is unclear whether, or the extent to which, the uniform coding system is being used. Once the standard codes are in place, and if they are used uniformly by all plans, impediments to the ability of pharmacies to provide detailed information about a denial of coverage should be reduced.

Recommendations:

To ensure that transactions at the pharmacy counter work more smoothly and that Medicare beneficiaries get their medically necessary drugs, the Center for Medicare Advocacy recommends:

- CMS should increase education to pharmacies and pharmacists to ensure that they understand and are familiar with all systems to assist Medicare beneficiaries when problems arise, and to monitor compliance with systems such as the POS option.
- CMS should work with states to identify Medicaid recipients who are about to become Medicare eligible sufficiently in advance to auto-enroll them in a Part D plan before they lose Medicaid drug coverage. Alternatively, Medicaid coverage should continue for these individuals until they are enrolled in a Part D plan.
- CMS and Congress should regularly monitor computer systems for accuracy of information concerning co-payment amounts and coverage.
- CMS should develop back-up systems to address, in real time, problems with co-payment amounts and drug coverage so that no beneficiary leaves the pharmacy without a prescription or is charged more than she should be charged.
- Congress should eliminate co-payments for dual eligible individuals, or require pharmacies to provide medically necessary medications to those without the means to pay.
- CMS should amend its regulations, or Congress should enact legislation, to require that notice be given at the pharmacy that a drug plan will not pay for a drug, that such notice constitute the coverage determination and, and that such notice explain the beneficiary's right to file an appeal and the process for doing so.

Overall recommendation: Create a single, standard Medicare prescription drug benefit administered by the Medicare program and uniform nationwide.

Many of the problems and issues described above, including problems involving computer systems, arise from or are complicated by the number of plans available and the fact that each plan has its own design, including formulary, cost-sharing structure, transition processes, exceptions and appeals processes.

Thank you for the opportunity to submit testimony.

MR. DEAL. Dr. Burgess.

MR. BURGESS. Thank you, Mr. Chairman.

You know, as I hear you all talk, and Dr. Harden, I feel your pain. I spent years in private practice of medicine, and yes, I recognize that you don't negotiate a contract with your price takers.

We fought the prompt pay issue a lot in Texas with physicians and insurance companies, and eventually worked out a program where we would be paid within 45 days. Now, most of that was based on electronic fund transfers, and I guess I am a little surprised to find that with today's technology, 10 years later, that this isn't all done on electronic fund transfers. I think that would obviate the difficulty with having to switch something in the middle of the month, but I mean, we have representatives here who tell us is this not a possibility that the turnaround on the claim is with 48 to 72 hours after it is submitted electronically?

MR. MERRITT. I harken back to, again, what our responsibilities are, and then I will answer your question directly.

First of all, what happens is we have to detect a lot of things. What happens at the pharmacy counter is a person walks up, and before he or she pays a co-pay, the pharmacist will plug in to the system to see is this person insured. If so, is this drug part of their formulary? If so, what is the co-payment? The customer then pays the co-payment and walks out the door, but there is a lot of stuff that happens after that that we fit into a standard process, because we have such huge volume. Typically--

MR. BURGESS. Well, I guess that really is where I have the question. If you have the huge volume, you are making it harder on yourself only paying once a month. Oh, my gosh, you must be inundated with claims that one payment day.

MR. MERRITT. Well, we don't pay them just once a month. We batch often. It depends on the company. Some people batch the claims weekly, maybe every two weeks, and then mail out a check when they have done the proper fraud checks and making sure that these are correct. First of all, a number of companies do sample up to 25 percent of the claims to make sure that they are being processed properly, that there aren't doctors who are liars, and pharmacies who are liars--

MR. BURGESS. I will grant you the regulatory environment we have given you to work in is probably not conducive to things happening quickly, but again, I have always been amazed that there have to be laws to tell people to pay their bills. I mean, it used to bug me when I was in practice as well.

Let me switch gears just for a moment, and Mr. Hallberg, you brought up the dispensing fee issue. Now what do you pay your pharmacists on your CCRX plan? Do you pay a dispensing fee?

MR. HALLBERG. Yes, sir, we do. It does vary by the pharmacy and those are negotiated with the various chains and independents.

MR. BURGESS. Okay. So you can't tell us--you don't have a set dispensing fees that you provide?

MR. HALLBERG. We have various sets.

MR. BURGESS. You also made the statement, which I like to hear, that you do encourage and you try to facilitate generic prescribing.

MR. HALLBERG. Yes.

MR. BURGESS. Has that been a burden for your pharmacists?

MR. HALLBERG. Has it been a burden, no. In fact, our pharmacists are very, very engaged in the process as I indicated with a generic dispensing rate of 60 percent and climbing, it clearly indicates that the pharmacies are able and willing to outsurpass the industry standards. Generally, they are very committed to, you know--in this environment, not only does it save the Federal government sometimes--

MR. BURGESS. I will stipulate that. Have you provided information to this committee before? I would appreciate that you have more than

one dispensing fee, but is that proprietary information that you can't make available?

MR. HALLBERG. Generally speaking it is proprietary information, but I would be glad to work with the committee to articulate the concepts and methodologies.

MR. BURGESS. Well, Mr. Chairman, if it is all right with you, I think that would be helpful to look at that. At least, I would like to.

Finally, in the time that is allotted to me, we have got 30 seconds. Can either Mr. Hopkins or Mr. Merritt define a clean claim for us?

MR. HOPKINS. WellPoint defines a clean claim that comes into the adjudication system, passes through all the edits that are in place, and the pharmacy receives an approved POS response back saying it is authorized for payment.

MR. BURGESS. And how long does that take?

MR. HOPKINS. Generally, if the systems are working appropriately, it is within a second, depending on how claims processing systems work.

MR. BURGESS. And so that claim would be presented for payment within that timeframe?

MR. HOPKINS. When WellPoint returns an authorization for payment, we are indicating to the pharmacy that the claim has passed through the edits and we are authorizing payment. WellPoint will also do some analysis on the claims in between when we receive the claim and when we produce the electronic information. We do this in case we find anything else, but generally, it is approved for payment.

MR. BURGESS. Give me an example, what would some of those edits be?

MR. HOPKINS. We do additional analysis on claims to make sure that there is an appropriate relationship between the day's supply dispensed and the dosage. Some pharmacies will submit 100 quantity in a 30-day supply when it is a once-a-day drug, so we are looking for inappropriate relationships or inappropriate prescription prescribing. General safety precautions or precautions around fraud.

MR. BURGESS. But none of those edits would involve the reimbursement rate?

MR. HOPKINS. Some of the edits you can do in a point of sale system live which will stop the claim at the beginning, other edits you can't. They are not generally tied around the reimbursement or the rate that is applied to the claim, but they are necessary to make sure that we are protecting the fiduciary responsibilities of our clients.

MR. BURGESS. Can anyone tell me is there any premium paid if a claim actually falls outside the agreed 30-day timeframe? Do you then bill usual customary rate, or are you still bound by the negotiating rates, Dr. Harden?

DR. HARDEN. No, there is no premium paid.

MR. BURGESS. There is no penalty or encouragement that CMS has to ensure that the payments are promptly received? Obviously, cash flow is something that keeps coming up and keeps coming up.

DR. HARDEN. Not that I am aware of, and on the clean claims, I would say that high 90 percent of the claims are adjudicated immediately. The type of review that is done by the PBMs after the claim is paid is the type that we have heard about today. So the claim goes in basically as a clean claim almost immediately. The patient needs the medication at that point. The PBMs do audits later to ensure that the claims are, indeed, clean. We found if they find that there may have been a mistake in the day's supply or something like that, a clerical error, they will recoup the entire amount of the prescription even though the patient had received the medication. The medication was prescribed by the physician and they recoup that amount also because basically of a clerical error.

So clean claims I would say, you know--

MR. BURGESS. Who negotiated your contract for you? I am just kidding.

Mr. Chairman, I will yield back.

MR. DEAL. We are going to go with a real quick second round of questions here. Since we didn't have any beneficiaries I guess everybody left, but we have got a few more questions that some of us would like to ask.

Let us talk about prior approval. That has been one of the issues that has come up from time to time. Dr. Harden, how much of an issue is prior approval at the pharmacy level?

DR. HARDEN. At the pharmacy level, it can be rather burdensome, and of course, we have got prior approval. We have got step therapy, which means that you must try certain drugs beforehand. Prior approval takes a lot of the time of physicians and pharmacists to try to get a prior approval through, and it takes the patients' time. It delays the patient getting the needed medication in the proper amount of time. I understand possibly why prior approval is needed in order to ensure that the drugs that PBMs receive the most rebates on are used first, but it does require a lot of time that should be spent with the patient and educating that patient on the drug, educating that patient on the management of their therapy.

MR. DEAL. Mr. Hopkins, Mr. Merritt, is that the basis on which prior approval is based is to make sure that the patient is using the drug that you have negotiated the best price with the manufacturer on?

MR. HOPKINS. There can be several different things that you look at for a prior authorization process. One can be a safety program, one can

be a formulary medication. There are several different reasons, but you know, for Part D, the prior authorizations or the typical programs you would have in place in a commercial program have not been in place at the beginning of the year to ease the burden on pharmacists. At some point this year, they will be put in place, but prior authorizations are not just about driving rebates. You have to look at the quality and safety aspects of them also.

MR. DEAL. Mr. Merritt, do you want to add something?

MR. MERRITT. I would agree with that and I would say there are other compliance issues as well. For instance, right now it is unclear on some drugs that could qualify in Medicare for Part B or Part D. The Office of Inspector General has made it very clear they want us to put a good faith effort into determining that payments are made in the right accounts. That is something that sometimes takes some time. We are working with the Pharmacy Quality Alliance too. Some of our member companies are involved with pharmacies' plans, CMS, and so forth, to streamline where there are issues in prior approval. I think CMS put out a notice this morning that I haven't had a chance to fully read because we have been otherwise engaged on clearing up the messaging process and making messaging a little more streamlined between plans and pharmacies. But there are good reasons on prior approval that we are concerned about. There are other issues, for instance, with addictive drugs or narcotics like OxyContin and so forth. We want to make sure there hasn't been doctor shopping going on or pharmacy shopping where people get two or three scripts and try to fill them simultaneously at different places. We need to guard against that because PBMs have the clearinghouse of all this benefit information, and pharmacies and doctors don't have that.

MR. DEAL. Let me stop you right there. Suppose you find that that is going on. What do you do?

MR. MERRITT. Well, Tim may be in a better position to answer it from an operational point of view, but that would be something where we wouldn't pay that particular claim and would alert the pharmacist and the physician about the situation.

MR. HOPKINS. The PBM claims processing systems are generally set up with safeguards that will reject those types of claims at the point of sale, so if you have somebody who is going to multiple pharmacies on a given day getting the same drug, generally most systems will reject that claim at the point of sale.

MR. DEAL. So you leave it up to Dr. Harden to tell them he can't fill the prescription? Does anybody report this to law enforcement officers? Are you allowed to do that?

MR. HOPKINS. Generally from my experience in pharmacy practicing as a practicing pharmacist in the State of Ohio, when you have something suspicious going on with a patient it is your obligation to report it. Either report it to the physician or report it to law enforcement.

MR. DEAL. Do you tell the pharmacist why you are not giving approval? Do you tell the reason or do you just say it is not approved?

MR. HOPKINS. On a situation that Mr. Merritt brought up, we would send a message back that said, you know, duplicate drug dispensed at multiple pharmacies.

MR. DEAL. Okay.

DR. HARDEN. Mr. Chairman, I would submit that that is not really a question of prior approval. The earlier testimony was that they do track drugs and they have a central clearinghouse to ensure that a patient is not physician shopping or pharmacy shopping. So that is not really a prior approval issue, because they do that on a regular basis as far as payment of claims.

MR. DEAL. Well, my time is just about gone, but I would say a few things that I think the industry needs to work on. One is the prompt payment issue, and hopefully electronic transfers average will go up from the 30 percent Mr. Hallberg talked about to 90-plus percent. I think that will take care of a lot of those issues. The other is the prior approval issue, and the next one is the adjudication of appeals in a prompt and expeditious fashion. We haven't had time to talk about that aspect of it, but I see those as being three of the major areas where we get the complaints and may be put in a position where we have to offer some solutions that we would much prefer if you all would offer those solutions.

Mr. Brown.

MR. BROWN. Mr. Chairman, since my round of questions took 10 minutes rather than 5; I will just relinquish my time to Mr. Burgess.

MR. DEAL. Dr. Burgess.

MR. BURGESS. Well, I thank the Chairman and Ranking Member for yielding. Dr. Galluzzo, you mentioned in your testimony that in a long-term care facility, you are not allowed to talk to patients about signing up for the drug plan, is that correct?

MR. GALLUZO. CMS considers anything really that we say to the residents and their family as steering.

MR. BURGESS. That was not the experience we had in Texas. I had several nursing homes in Gainesville who complimented me on what a good job CMS had done coming in and getting people signed up for their plans. Was that because CMS did it and not the nursing home operator?

MR. GALLUZO. It is not the nursing home operator. It is the pharmacist that is not allowed to really talk to the resident about making

suggestions about the prescription drug plans. They consider that steering. In Ohio, as I said earlier, State surveyors, when they go into the facilities, are actually questioning administrators, DON, and the residents--has the pharmacy been in to talk to you about your prescription drug plan? They don't allow us to discuss it with the residents and their families.

MR. BURGESS. Mr. Chairman, I would just submit--

MR. DEAL. Would the gentleman yield?

MR. BURGESS. I would be happy to yield, Mr. Chairman.

MR. DEAL. Let me go to the next aspect of that. It was alluded to by Mr. Wirth, I believe, and that is steering which is being allowed. That is the complaint that is going against some of the companies that you were not disqualified from advising people as to how to sign up is my understanding. Now some of the information that these people may have signed has become the basis for solicitations of those individuals by the companies to either go to a mail order plan or selling them other alternative insurance proposals. Mr. Hopkins, have you heard that complaint? If you haven't, you have heard it now.

MR. HOPKINS. At WellPoint, we have an open network philosophy. I don't see Dr. Harden's card, but it looks like it has got several chain logos on the card. We don't have logos on the member's identification cards, and we encourage them to use pharmacies they want to use, whether it is an independent pharmacy or a chain pharmacy.

MR. DEAL. Specifically what I am talking about is when certain representatives of certain companies that were writing coverage were involved in the signup process. Apparently certain forms may have been signed by those individuals so that their personal information now becomes a basis for solicitation of other products or alternative delivery, such as mail order drugs, rather than going to the local pharmacist to have the prescriptions filled. It seems extremely inconsistent that we would prohibit these folks from being involved in the process as a conflict of interest, and then on the other hand, have their back stabbed twice when those who were not so prohibited are using that information to try to get people not to go use their services but to go mail order. That, to me, is the great inequity here.

MR. MERRITT. Congressman, I am not aware of that particular thing. We will look into it. I have not heard of that before you bringing it up.

MR. DEAL. If you talk to Dr. Harden, I think he can give you some specifics.

MR. BURGESS. Reclaiming my time, I guess I would just ask the Chairman, we are going to fine tune, obviously. There will be a Medicare Part D 2.1 and 2.2 going forward, and this may be one of the areas where it does make no sense to cut the primary care pharmacist out

of the discussions with the patients and their families about how they can best be served.

I would also offer that in my area of North Texas, I got Mr. McClellan to promise me that the next time he rolls up a Part D program that he won't include the dual eligibles until we have been in it for a month or six weeks. In retrospect, that may not have been the smartest way to go about it, but people who were enrolled in the default program where they found that their medicines weren't covered or were only covered at great expense--I am talking about the dual eligible population--we were pretty aggressive in my Congressional office about if they were willing to let us take that on a constituent case, we would pursue that with CMS and got a favorable ruling every time we tried. In fact, it was one individual that came to my Medicare events, very bittered about the program because now he is paying $300 a month for his daughter's Tegretol, and that didn't sound right. We pursued it, and sure enough, the assignment was probably inappropriate for that individual, but it was a bed bound cerebral palsy patient who couldn't really participate in the discussion, and we got that straightened out for them. It really was not difficult to do, it was just simply someone being willing to pick up the phone and call someone and say this is not working out.

I just wondered, have you had similar input from Congressional offices in your district, in your area of Ohio?

MR. GALLUZO. We really haven't. The program is only in its fifth month, and we are trying desperately to work it out with all the PDPs because the way things are going we are going to have to work with these PDPs for as long as I am in the business.

MR. BURGESS. Sure.

MR. GALLUZO. There are always going to be kinks when you start something.

MR. BURGESS. Exactly right, and that was my point. These won't endure. The things that were inappropriate during the first weeks of the program, if we can correct those and get the program working well for that patient, after all, that is the bottom line. That is what all of us are wanting to do. And I guess, you know, if it takes a Member of Congress to be involved in that, then I think that is one of our responsibilities and that is one of the things we should do, but if you find cases like that in your neighborhood, I would encourage you to get your Member involved and have him take it as just a regular constituent inquiry, just like you would a Social Security check or a GI benefit that didn't come around in the proper time.

Mr. Chairman, just in the time I have left, I guess I would just offer the following observation. This program, for all its faults, is something that has been necessary and needed by America's seniors for a long time,

and I thank every one of you sitting at the table for the part you are playing in getting this thing up and off the ground. To me, it has been a real revelation that a government program could, in fact, work as well as it did. I don't know that I was optimistic that HHS Secretary and the Administrator would get to this point and have the program functioning as well as it is, and I think that is a tribute not only to them, but a tribute to everyone that is sitting at this table who has worked with this committee over the months and years that it has taken to provide this benefit. There are a lot of rough edges that we can continue to knock off. I think you have heard the willingness of the Chairman to listen to those suggestions.

Mr. Chairman, I really don't have anything else to say, but I think it will be helpful if there are suggestions from this group we have in front of us that we seriously take those to CMS and I know the Secretary is committed to having a better program next year than the program that exists this year.

DR. HARDEN. Dr. Burgess, if I might add to that. CMS has been extremely helpful. We have reported instances that we felt needed correction, and they are part of the program, and they have been extremely well to respond in a timely manner and to investigate and find out where the problems were. We appreciate them very much.

MR. BURGESS. CMS or HCFA, not being HCFA anymore, but CMS is certainly a kinder and gentler form of government oversight.

So thank you, Mr. Chairman. I will yield back.

MR. DEAL. I would echo what Dr. Burgess has said. We appreciate what all of you have done to make this program as successful as it has been. It is not something that in 32 million people that you can enroll and get it going in the short timeframe we have been looking at, and we know that it was with the cooperation of each of you and the members of the groups that each of you represent. We want you to express our appreciation for your efforts in that regard, and particularly we express our appreciation to each of you for taking time to be a witness today.

With that, this hearing is concluded.

[Whereupon, at 2:35 p.m., the subcommittee was adjourned.]

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