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EXAMINING THE MEDICARE PART D MEDICATION THERAPY MANAGEMENT PROGRAM

WEDNESDAY, OCTOBER 21, 2015

House of Representatives

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The subcommittee met, pursuant to call, at 10:15 a.m., in Room 2322 Rayburn House Office Building, Hon. Joe Pitts [chairman of the subcommittee] presiding.

Members present: Representatives Pitts, Guthrie, Shimkus, Murphy, McMorris Rodgers, Lance, Griffith, Bilirakis, Long, Ellmers, Bucshon, Brooks, Collins, Green, Engel, Butterfield, Castor, Sarbanes, Matsui, Schrader, Kennedy, and Pallone (ex officio).

Staff present: Clay Alspach, Chief Counsel, Health; Graham

Pittman, Legislative Clerk; Chris Sarley, Policy Coordinator, Environment and Economy; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Health Policy Coordinator; Tiffany Guarascio, Deputy Staff Director and Chief Health Advisor; Ashley Jones, Director of Communications, Member Services and Outreach; Rachel Pryor, Health Policy Advisor; and Samantha Satchell, Policy Analyst.

Mr. Pitts. Ladies and gentlemen, I ask all of our guests to please take their seats, and the clocks are a little slow.

It is 10:15 so the subcommittee will come to order. The chairman will recognize himself for an opening statement.

Today's hearing will examine the Medication Therapy Management program MTM, which is part of the Medicare Part D prescription drug program.

The Part D program was established as part of the Medicare Modernization Act, MMA, in 2003. MMA required Medicare Part D prescription drug plans to include Medication Therapy Management services delivered by a qualified healthcare professional, including pharmacists, beginning in 2006.

Medications can save or improve lives, but taken incorrectly or in excess they can make patients worse. With thousands of prescription drugs on the market, frequently no one prescriber, care giver or manufacturer knows the total picture for each patient.

MTM services target beneficiaries who have multiple chronic conditions such as diabetes, asthma, hypertension and congestive heart failure. Such beneficiaries likely take multiple medications and are likely to incur very expensive annual medical costs.

The pharmacist can play an important part in MTM. We will be hearing from pharmacists as they describe their role and apply

their extensive medication knowledge as medication experts with the intent of improving patient health outcomes.

Medication management is vital to ensuring that covered Part D, or prescription drugs, are appropriately used to optimize therapeutic outcomes.

As we have heard from our senior constituents, they rely on the Part D program and Congress has a responsibility to ensure that the MTM program is working as intended.

Today we have two panels, including the administration's witness from the Centers for Medicare and Medicaid Services, CMS, the director of delivery system reform.

Additionally, we will hear from a panel of experts and stakeholders as to their ideas and recommendations for possible improvement in this evolving program.

Does anyone on my side of the aisle seek time? If not, I will yield back and now recognize the distinguished ranking member of the subcommittee, Mr. Green, 5 minutes for his opening statement.Mr. Green. Thank you, Mr. Chairman, and good morning.

It is very real today, and thank our witness for being here. The costs for medication adherence include increased hospitalizations, doctor and emergency room visits and preventable disease regression.

Studies have shown that these add up to costs to the health care system of an estimated $290 billion each year. When patients

adhere to their medications, the data demonstrates that they are much more likely to have improved health outcomes, use fewer health care services such as ER visits and rehospitalizations.

This is particularly true for patients with one or multiple chronic conditions, as medications are involved in 80 percent of all treatments for chronic disease interventions.

Proper medication adherence leads to improved health care outcomes and better disease management. The avoidance of dangerous and costly complications later on is advantageous to the Medicare program at large through decreased medical spending.

Recognizing the value of proper medication adherence, Congress created Medication Therapy Management, MTM, program as part of the Medicare Modernization Act of 2003. The MTM program was intended to better integrate medication management services to the Medicare Part D program.

Specifically, the goal of MTM is to ensure that covered Part D -- the drugs -- are appropriately used to maximize their therapeutic benefits for Medicare beneficiaries enrolled in stand alone prescription drug plans and Medicare Advantage prescription drug plans.

However, it is widely recognized that Part D MTM program is not meeting its full potential and reforms are needed so that seniors can better access these important services.

Current statute of regulatory requirements for MTM require

services offered based on fairly rigid criteria, which has led to mismatched enrollment and beneficiaries who will likely benefit from the MTM programs being missed.

MTM restrictions adhere that -- require that in order for a Medicare Part D beneficiary to be eligible for MTM they must have multiple chronic conditions, be prescribed multiple medications or meet an annual cost threshold for prescription drug spending.

These prescriptive criteria seem like an oversimplification of patients who may benefit from MTM services and have been cited as a contributing factor to low MTM participation.

Another factor that may be contributing to low participation is that the program requires cooperation among several groups, some of which may have competing interests. It is time to look for ways to effectively target seniors who would greatly benefit from the medication management services and realign incentives so that the benefits to patients in the health care system can be fully realized.

Last month, the Center for Medicare and Medicaid Services announced a model test of strategies to improve medical medication adherence among beneficiaries who are enrolled in Part D plans by expanding and improving the use of MTM.

This model will run out of the CMS's Center for Medicaid -- Medicare and Medicaid Intervention which was created by the

Affordable Care Act. The enhanced MTM model will assess whether providing stand alone Medicare prescription drug plans with additional flexibility and alternative payment methods increase enrollment and better achieve Congress' vision for the MTM programs.

I recognize and appreciate CMS for its agency's efforts to improvement to the program throughout its history and for piloting the enhanced MTM model.

However, demonstration projects are naturally limited in scope and we won't have full results until 2022. Participation remains very low and, according to CMS, more than 25 percent of the enrollees would benefit from MTM services.

I look forward to working with my colleagues on appropriate legislative solutions to reform the Part D MTM program to provide the completion of the demonstration project.

I thank you and I yield the balance of my time to my colleague from California, Congresswoman Matsui.

Ms. Matsui. Thank you so much and thank you, Mr. Chairman, for holding this important hearing today on the topic of medication therapy management, or MTM.

MTM helps seniors take their medications safely, correctly and increases their adherence. It is an important tool that has been shown to save the system money.

If people, especially seniors, had the proper training and

education about how, why and when to take their medications, their conditions don't end up untreated, saving unnecessary hospital visits and other complications.

Not only does this save the system money but it truly benefits the senior, especially those with multiple chronic conditions who may be filling up to 50 different prescriptions per year.

It is important that we ensure that seniors have access to MTM within the Medicare program and I look forward to hearing from our witnesses today about we are ensuring that that happens.

Thank you, and I yield back.

Mr. Pitts. The chair thanks the gentlelady.

As usual, the written opening statements of the members will be made a part of the record. We have another hearing in Energy and Commerce going on downstairs so members will be shuttling back and forth.

On the first panel, we have Mr. Tim Gronniger, director of Delivery System Reform Centers for Medicare and Medicaid Services.

Your testimony -- written testimony will be made a part of the record. We would ask you to take 5 minutes to summarize your testimony and then we will do questions.

So at this point, Mr. Gronniger, you are recognized 5 minutes for your summary.

STATEMENT OF TIM GRONNIGER, DIRECTOR OF DELIVERY SYSTEM REFORM, CENTERS FOR MEDICARE AND MEDICAID SERVICES

Mr. Gronniger. Thank you.

Good morning, Chairman Pitts, Ranking Member Green and members of the subcommittee. Thank you for the invitation and opportunity to discuss CMS's new Part D enhancement Medication Therapy Management model, or enhanced MTM model.

We appreciate your continued interest in improving Medicare beneficiaries' access to quality, affordable and well-coordinated health care.

MTM, when implemented effectively, can improve health care quality and outcomes for patients and has the potential to lower health care costs by helping to address medication-related issues such as risk of side effects, gaps in adherence to therapy, duplicative therapies and other issues that could jeopardize patient health and lead to unnecessary risks.

MTM and Medicare is a plan-based set of services that tries to improve health outcomes by ensuring that patients -- that patients are taking their medications safely and as prescribed, by addressing any barriers to their doing so and by bringing any issues to the attention of treating clinicians.

For a variety of reasons, CMS believes that the true benefits of MTM programs have not been realized yet in Medicare.

While CMS has made changes to MTM programs over the last decade and in consultation with stakeholders, participation in such programs remains very low with only about 11 percent of beneficiaries enrolled in MTM programs today.

Performance data and our interviews with industry experts suggest that misaligned incentives have led Part D plans to focus on meeting minimum technical requirements rather than trying to identify opportunities to improve the health of Medicare beneficiaries.

Specific concerns include that plan sponsors are not rewarded for improvements in the quality of care received through MTM programs.

Plan sponsors cannot receive any benefit from reductions in spending in Parts A and B of Medicare so their interests are not entirely financially aligned with those of the Medicare program or beneficiaries.

And compounding that, competitive pressure to keep premiums low to attract enrollment means that investment in MTM services comes at a competitive cost without any financial gain.

Despite these obstacles, we believe that Part D needs a strong MTM program because there are a number of barriers that can prevent beneficiaries from taking their medications safely and as prescribed.

For example, some beneficiaries have difficulty with

forgetfulness and memory issues, the physical taking of pills and opening pill bottles, the cost of cost sharing for medications, medications prescribed by multiple prescribers without a coordinated process to reconcile those prescriptions.

Pharmacists, Part D sponsors and other experts have identified many ways that MTM programs can be improved if we align incentives and provide flexibility in program design. Opportunities include improved patient education, medication reconciliation, reminder programs in packaging, refill synchronization and risk-based targeted interventions with beneficiaries and prescribes.

Industry experts suggested that more targeted and differentiated interventions to help patients understand their medications on a more frequent basis are required -- smaller bytes of information at learning points such as care transitions, starts of new medication and around annual wellness visits, for example.

A few notes on the model itself -- through this project, CMS will test whether providing Part D plans with regulatory flexibilities, aligned financial incentives and access to Medicare claims data will better achieve Medicare's original vision for MTM programs.

The enhanced MTM model will incentivize plans to right size their investment in MTM services by expanding enrollment and improving the coordination of care experienced by beneficiaries.

Key elements of the model include the ability to offer different MTM services to individuals based on their level of medication-related risk with interventions tailored to those enrollees' specific barriers to improvement, including cost sharing assistance to beneficiaries who need it, prospective payments to support more extensive MTM interventions that will be outside of a planned annual Part D bid and premium.

The model also includes the opportunity for plans to qualify for a performance-based payment in the form of an increased premium subsidy for plans that successfully reduced medical spending in Parts A and B of Medicare.

The ability to access Parts A and B claims data from CMS will also support plan participants by helping to identify and coordinate care for individuals enrolled in the MTM models.

A couple of notes on pharmacy and pharmacists' role in the program. This model provides potential opportunity for plans to invest in pharmacist-based MTM programs at the local level for the opportunity for direct beneficiary engagement is greatest.

Pharmacists might be well positioned to identify candidate beneficiaries starting new medications with risky side effect profiles, to help patients receiving medication assistance devices such as pill splitters or mobile phone reminder apps, synchronized refills to provide home delivery and cost sharing assistance and to provide counseling advice tailored to the

patient's needs and situation.

In conclusion, CMS believes that the enhanced MTM model will give prescription drug plans stronger incentives and flexibility to improve prescription drug safety and effectiveness working with beneficiaries, pharmacists and prescribers.

CMS looks forward to working with these and other stakeholders in the coming months and years to learn more about ways to maximize the benefits of MTM to promote better care, smarter spending and better health for Medicare beneficiaries.

I thank the subcommittee for the opportunity to share our plans for this important demonstration and would be happy to answer any questions that you may have on the model.

[The prepared statement of Mr. Gronniger follows:]

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Mr. Pitts. The chair thanks the gentleman. Again, thank you for coming. Thank you for your testimony. I will begin the questioning, recognize myself for 5 minutes for that purpose.

Mr. Gronniger, can you provide a range of how many plans you expect to participate in the innovation model from the 5 Part D regions selected for inclusion?

Mr. Gronniger. We haven't yet -- we haven't identified a cap or a limit on participation in the model. That model is open to any plans that would like to participate and can submit qualifying applications.

In the regions that are selected -- the 5 regions -- there are about 13 to 15 plans in each region. So that would be the maximum and we will be identifying and evaluating applications and so we will find out the number of applications as we go through that process.

Mr. Pitts. It is my understanding that the regions chosen for participation were evaluated on a number of criteria, such as variation in market competition and range of Parts A and B spending.

Can you provide any more insight into how these regions were selected?

Mr. Gronniger. Yes, sir.

In designing all of the innovation center models including this one, we look to make sure that we have sufficient number of

participants to power the evaluation design and in this case we needed to -- we needed about that many regions to get an appropriate number of beneficiaries and plans participating.

As I mentioned, we hope that all or most plans in those regions will submit good applications. We wanted to make sure that the participants were representative of the national market as a whole as well as being able to identify areas with higher and lower Medicare spending that had different types of areas of the country whether rural or urban to make sure that the intervention -- that the evaluation could identify a nationally representative result.

Mr. Pitts. Can you briefly summarize how the innovation model will work to realign financial incentives and regulatory constraints that PDPs currently face when trying to implement meaningful MTM programs?

Mr. Gronniger. Yes, sir.

Today, Part D plans offering MTM programs are required to offer a certain set of services and are required to define a minimum number of patients who are eligible for these programs based on criteria such as how many chronic conditions a patient has, how many -- how many drugs the patient is taking and expected spending for the course of a year.

We know that more than 11 percent of Medicare beneficiaries can benefit from MTM programs. Previous work by CMS and other

experts suggest that 25 percent or even more could benefit from these programs and we also know that there are certain beneficiaries who fall under those criteria who could benefit from interventions.

Patients who are taking drugs such as blood thinners that are unusually risky even if it is the only drug that they are taking can benefit from counseling and management of those therapies.

So we are providing in this model the flexibility to identify -- use a risk-based approach to identify beneficiaries who need the project, who need the intervention the most, identify interventions that will support that patient's care needs in collaboration, potentially, with pharmacists, with the patient's physicians and will provide a more comprehensive set of interventions that can support care improvement.

For the alignment on incentives, never before has a Part D model provided an incentive for Part D plans to manage or contribute to managing the overall cost and quality of care for patients.

So this will allow Part D plans to benefit if they are able to lower overall medical spending directly by receiving a $2 premium reduction later on in the model. That will provide competitive benefits if they are able to measure the effects of this program.

Mr. Pitts. Cost sharing assistance for financially needy

enrollees is referenced as, quote, "enhanced and individualized MTM strategy," end quote in the announcement from CMS on the MTM innovation model.

Will the individual PDPs or CMS be defining who is financially needy?

Mr. Gronniger. So the -- that is a good question. Thank you, sir.

We are asking for plans to provide us ideas on the right types of interventions that are needed here and so we are hoping to see a diversity of programs created and identified.

Plans will -- if they choose to take advantage of this option, then they will need to submit a detailed plan around what types of interventions and what types of medications and what situations would give rise to offering cost sharing assistance.

If a patient says -- tells a plan that cost sharing is an impediment to accessing needed therapy, then that is the type of situation that this model is intended to allow the MTM program to identify. We are not intending that plans would get deep into income determination.

Mr. Pitts. And you will be defining what cost sharing assistance entails?

Mr. Gronniger. We will be evaluating proposals from plans and working with them on the right parameters for that type of assistance.

Mr. Pitts. And can we expect this will be elaborated on in the request for applicants?

Mr. Gronniger. Because we are going to -- the request for applications will include what the plans need to submit to us and we will then take those applications and work with plans to make sure that it is the intervention that makes sense.

Mr. Pitts. Thank you. My time has expired.

The chair recognizes the ranking member, Mr. Green, 5 minutes for questions.

Mr. Green. One of the great successes of the Affordable Care Act is that it not only provided health -- lifesaving health insurance coverage to millions of Americans but it also changed the way we pay for health care.

The ACA has indisputably put our healthcare system on the path toward one that reimburses for value instead of volume. Patients now have the option to be cared for in a more integrated system such as accountable care organizations and patient-centered medical homes.

Mr. Gronniger, in your testimony you wrote that the enhanced MTM model will be complementary rather than duplicative of the ACOs and other integrative care models.

Can you elaborate on that interaction?

Mr. Gronniger. Yes. Thank you, sir.

So for most ACOs, the number of plans that are supporting

care for their -- the number of prescription drug plans that are providing drug benefits for their aligned populations could be anywhere from 15 to 20 or 30 plans and those plans are often in a better position to understand the scope of the patient's medication-related issues and needs because they have access to the full set of data or nearly the full set of data on the drugs that that patient is using.

Today, though, as we have discussed, there isn't a strong incentive for plans to engage with ACOs or other physicians who are managing the care of their patients overall. And so that physician may not be able to see the full picture that they need to see of the medications that the patient is taking.

This model will create the opportunity for a pathway that plans can invest in MTM services that could include linkages with physician groups to provide better information to the physician managing the patient's medications and overall care and so enhance the work of an ACO or other alternative payment model.

Mr. Green. Is it fair to say that an enhanced MTM model has the potential to not only work alongside newer patient-centered medical care models but actually have a multiplying effect on the benefits that the patients may receive?

Mr. Gronniger. Yes, sir.

We think that there are numerous opportunities for these programs to support the care that -- the care management

activities that ACOs and other physician organizations are trying to promote to improve the quality of care that their patients are experiencing.

Mr. Green. I want to thank you for your work on the MTM program. I believe the enhanced MTM model is an excellent step and I am happy that CMS has dedicated the time and effort to thoughtfully improve this -- the important beneficiary services.

On the other hand, one of the drawbacks of any demonstration project is it by nature limited in scope and will only have results until 2022.

Are these specific aspects of the Medication Therapy Management program would benefit from change prior to the completion of the enhanced medication therapy model?

Mr. Gronniger. We are in the process of standing up the model right now so we are still working on the front end part of the -- of getting plans to apply and to getting the process stood up for 2017.

We do think that -- we allowed 5 years for the model to work and to provide adequate time for evaluation because we heard that these types of interventions there needs to be a lot of experimentation.

It is going to take a process of refinement. Plan participants can also propose updates to their programs on an annual basis that we can -- that we will discuss with them.

I would also emphasize that even though the model is slated to run for 5 years we will provide -- we will be evaluating it on an annual basis. And so we will have the opportunities to engage with you as well as to make any needed course corrections in the interim.

Mr. Green. But during that 5-year period if you have some type of real success you could actually put those in place even before the 2022?

Mr. Gronniger. If the -- if the data is strong enough and if we are able to demonstrate improvements in quality then there would be opportunity for extension earlier than 2022, yes.

Mr. Green. Procedures choosing Part B -- Part D plans transparency and ease of understanding are critical to ensure every beneficiary selects the plan that is most appropriate for that individual.

One component, I believe, that has been very helpful in this regard is the use of star ratings in the Part D program. Can you discuss why CMS decided to add a comprehensive medication reviews to the star rating measurement beginning next year?

Mr. Gronniger. Yes.

So we have -- we are constantly looking at improving our quality rating systems and our quality performance systems. We have had the star program in Part D for a number of years now.

We have also been aware of issues and we have worked over

the years to try to improve enrollment in and to scope of the MTM program.

And one opportunity for that was to promote the use and adoption of comprehensive medication reconciliation under the existing MTM program and we thought that by including a star rating on that that would provide some incentive for plans to improve.

And that is work that we still feel is important. We think that CMRs are something that is valuable for beneficiaries and that will be happening across the country and supporting improvement in plans that are not in this intervention.

Mr. Green. Thank you, Mr. Chairman.

Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentleman from Illinois, Mr. Shimkus, 5 minutes for questions.

Mr. Shimkus. Thank you, Mr. Chairman.

I am glad I follow my friend from Texas because he did -- had to put in his little plug for the ACA.

[Laughter.]

Well, the plug I have is it look likes it is going to be 10 million under enrolled and that most people I talk to are paying more and getting less coverage. So a little tit for tat just to show that there is differing views on that piece of legislation.

But that is not what we are here to talk about so we are glad to have you here.

So I come from a very large district in southern Illinois -- 33 counties. Many of my seniors, most in need, the pharmacist might be the only health care provider that they have consistent access to in this area that we are talking about today.

You know, as a result, they see their pharmacist -- they are visiting their pharmacist and the pharmacist can -- many times, you know, they can -- they can start asking them because they look maybe jaundiced a little bit when they come in or then they can start asking these questions.

So in this process I am kind of excited about this but, of course, we will make sure that as this -- that the pharmaceutical -- that the pharmacy community, especially the independents and some of the chains, you know, they are involved in this process.

Do you track and have evidence showing how this relationship translates when it comes to outcomes and emergency room usage and hospital utilizations in rural and under served areas?

So is there way each kind of -- the thing we have is this cost benefit analysis, right? So if we are going to move to this new model, if they are able to identify stuff through the management practices are you trying to track the savings on, you know, the back end?

Mr. Gronniger. Yes.

We are -- yes and yes. We are very attentive to the issues facing rural communities and difficulties accessing providers and

traveling long distances.

We have also heard from many community pharmacists that the current MTM program really doesn't touch them very often and we think that that is largely a result of the misaligned incentives and regulatory barriers that we have discussed.

We are hopeful that this will provide a pathway for investment in some of those services that can be delivered often by local community pharmacists, potentially by others.

Today, a lot of MTM programs are provided by national or regional contractors and many of them are very competent and capable and also able to engage with local pharmacists. But because there is not a strong incentive to invest, we think that they are mostly in the cost minimization approach rather than recognizing the full potential here.

So yes, we think that this will create an opportunity for support of that and we will also be tracking on a granular level sort of the intervention by intervention where the -- what is happening in this program and where there are benefits being provided.

Mr. Shimkus. Yes, so we want to make sure you remember the rural and the under served areas. Sometimes they are the same but sometimes under served areas could be in some metropolitan areas too where there is -- you know, we call those, you know, deserts for food and nutrition but I think that is true, you know,

in some of the health care delivery issues, also.

You mentioned that current MTM statutory and regulatory provision limitations may lead to some beneficiaries who don't benefit from MTM being included in the programs while missing some of the beneficiaries who would benefit from the MTM programs.

Can you give us some more specifics on what changes you think might be needed to include more people that could benefit from the program and removing those who don't benefit from the program?

Mr. Gronniger. Sure.

So, for example, we talked about the need for a cost threshold and the minimum number of chronic conditions to qualify for MTM programs today.

We know that diabetic patients often take drugs that are risky and can result in hospitalizations and other adverse events if they aren't managed well.

Today, being diagnosed as a diabetic alone doesn't qualify you for an MTM program. Under this program, the plan sponsor and participant would be able to suggest risk-based intervention such as even just one condition such as diabetes that could qualify a patient for counseling or other types of MTM interventions.

Mr. Shimkus. And in my remaining time, you state that CMS believes pharmacists serve a vital role in ensuring that Medicare beneficiaries receive and properly use prescription drugs upon which they rely.

Can you tell us how we have seen that role increase and evolve over time with the implementation of Part D?

Mr. Gronniger. Yes.

We talked to a lot of pharmacy groups and pharmacists and I think that it is fair to say that many of these organizations view themselves, as you mentioned, as part of the health care continuum and want to provide more support for their patients than merely filling a script and we think that this model is an opportunity to support that work.

Mr. Shimkus. Thank you very much.

Thank you, Mr. Chairman.

Mr. Pitts. Chair thanks the gentleman and now I will recognize the gentlelady from Florida, Ms. Castor, 5 minutes for questions.

Ms. Castor. Thank you, Mr. Chairman, for calling the hearing today.

Mr. Gronniger, I am pleased to see that CMS is working to improve the Medication Therapy Management program through the enhanced MTM model.

The efficiencies that can be achieved haven't been maximized over the past few years and this definitely is a step in the right direction.

I have a question regarding whether the model -- what the model will look like from the patient's perspective. At first

glance, most of the provisions of the medication therapy management model appear to target the insurer rather than the patient.

I understand the rationale behind the restrictions on direct marketing. But I am wondering if Medicare beneficiaries understand what the MTM is when it is offered to them.

Personally, I wonder if beneficiaries are naturally skeptical when an insurance company says here, we have additional services for you. Given that, historically, there has been a very low participation in the MTM program.

Has CMS considered undertaking any actions to improve beneficiary awareness and engagement?

Mr. Gronniger. Yes.

So we have historically included language in the Medicare & You Handbook that is mailed out every year as well as on Medicare.gov to explain what MTM programs are in case patients are contacted by their insurer.

We also encourage beneficiaries if they think they could benefit from these types of services to contact their Part D plan directly.

And this model, because the interventions are going to be very tailored and sometimes may operate at first in the background of the beneficiary and the beneficiary will not know beforehand whether they will qualify under the plan's tailored intervention,

we are not going to be doing prospective outreach from CMS on this other than providing, again, language explaining what the project is and making sure that we are able to direct people to the right source to answer questions.

We think, though, that part of the reason for low enrollment in the past is that plans have the ability to engage with beneficiaries as well as through trusted intermediaries like pharmacists and physicians.

And so we think that there are multiple ways that further engagement could -- further engagement with those stakeholders and those providers can support better enrollment in the program.

Ms. Castor. Does it make sense to tackle some of the more expensive chronic conditions, for example, diabetes? Do you have something that is targeted to certain populations like that?

Mr. Gronniger. We have seen diabetes as the most targeted chronic condition in MTM services today and we expect that it will probably continue to be one of the most targeted.

We have heard that chronic conditions that are very reliant on medication therapy such as chronic obstructive pulmonary disorder -- congestive heart failure -- are likely to be candidates for intervention.

But we are not prescribing that beforehand. We want to see a diversity in innovation and the offerings from plans here and then we will hopefully be able to learn what works.

Ms. Castor. Okay. Thank you for your work on it and we will look forward to a report back that you have achieved greater efficiencies in the MTM.

Thank you.

Mr. Pitts. Chair thanks the gentlelady and I recognize the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Dr. Murphy. Thank you for being here today. This is very informative.

Can you just help me understand the difference between a model test versus a demonstration?

Mr. Gronniger. So we -- I think in this case there is not an important difference. This is a model test. I think it is a difference between statutory and common language.

So this is a demonstration project being tested under the innovation center's authority.

Dr. Murphy. So there is not, for example, statutory authority for a model test. Is that what you are saying?

Mr. Gronniger. We can get back to you on the exact wording of how this works in the statute. But, yes, this is operated under the innovation center's authority to test models.

Dr. Murphy. Okay. Thank you.

So in the announcement for the MTM innovation model you say that one of CMS's research questions -- what is the impact on patient outcomes and satisfaction -- how are you measuring and

what are you using to measure patient satisfaction and outcome?

Mr. Gronniger. So we are going to be conducting beneficiary surveys to understand the -- how this program is experienced by involved beneficiaries to CFA, both if they like the program, if they have appreciated the services available, if they felt that it has improved to a better understanding of their medication.

We are going to be working with experts, with pharmacists and plans and other -- and physician organizations to define the right quality measures for the program.

There aren't a consensus set of quality measures right now for MTM services. So we are going to have to work with others to build them.

Dr. Murphy. So is there a -- for example, we have been talking about diabetes here as one example in chronic illness. Do you have any kind of questions or areas at least you are thinking of in a direction with that yet?

Mr. Gronniger. We don't have any quality measures for MTM specific to diabetes that we are envisioning and these are -- these are draft.

But we put it out in our announcement to plans, things like medication-related problems identified and resolved would be the type of quality measures.

Dr. Murphy. So side effects, et cetera?

Mr. Gronniger. Yes.

Dr. Murphy. Can I suggest here then -- so there has been a number of studies, for example, that have identified people with chronic illness, such as diabetes, heart disease, et cetera, have a much higher risk of depression, like, double the rate.

When you have untreated depression and a chronic illness, the cost doubled, for multiple reasons, some of them actually primary neurological and how the body no longer fights -- it doesn't have the same immune levels, exacerbation of illness, et cetera.

But crossing over from that, for example, with diabetes, cardiovascular disease, et cetera, persons with severe mental illness have a much higher risk of those not only primarily because they perhaps are not caring for themselves as well, they don't keep appointments, they may fear the doctors because of hallucinations, delusions, et cetera, but also when they are taking a second generation anti-psychotic, for example, higher risk for diabetes, higher risk for cardiovascular disease -- I think type 2 diabetes is one and so it is extremely important.

When I have seen studies where, for example, Jewish Healthcare Foundation in Pittsburgh, is monitoring folks. They screen them at the same time for depression when they are diabetic or heart disease.

They intervene quickly and they actually find that overall costs go down and they can use less medications to treat.

So I hope you will use a broader, coordinated and integrated care model to look at and not just do you have symptoms of side effects or not. But are those being addressed in a more global perspective and a multi disciplinary way to try and address these issues.

It is one of those things that -- and I know Medicare is moving towards, in some way, with this integrative model can be extremely important in addressing those. But if we don't ask those, it is a problem.

The second issue I want to get into is pain management. Some have said the elderly, actually, is under served in terms of managing pain.

But the other issue is oftentimes the way you can quiet someone down is just give them some opiates for their pain, and then we run higher risks of addiction issues.

Not from someone who has set out to be a drug addict but we give them so much opiates that they end up having an addiction to that.

Is that something you will also be monitoring in terms of how pain is managed and other sensitivity to opiates?

Mr. Gronniger. Yes, and so first, I would say I appreciate your comments and suggestions for managing mental health medications and their interactions with other chronic diseases and we will take that back. I think they were great suggestions.

For opiates and other pain medications, we think that that is one area that applicants might want to target for the reasons you identify.

MTM programs also attempt to look at the over the counter medications that patients are taking, which can -- and particularly for acetaminophen, can be a really bad interaction problem --

Dr. Murphy. Okay.

Mr. Gronniger. -- for opiates. And so we think that there are opportunities there to improve care and avoid risks and we hope that plans will take advantage of that.

Dr. Murphy. Let me suggest something too, and pharmacists can be helpful -- with the Affordable Care Act, there is at least 3 questions that are asked as someone is discharged. Like, for an emergency room, you have to fill out surveys, at least 3 questions that deal with pain.

And since hospitals are finding themselves scored on this, I think there is almost an incentive for them to hand out more pain medication because it affects how much they are going to get paid.

And then without follow-up -- this committee has done a lot of work on looking at substance abuse and addictions issues and I hope you look at that whole picture of things.

But thank you so much for your focus on this. This could

be innovative. Appreciate that.

I yield back.

Mr. Pitts. Chair thanks the gentleman and now recognizes the gentlelady from California, Ms. Matsui, 5 minutes for questions.

Ms. Matsui. Thank you, Mr. Chairman.

Traditionally, patients have been eligible for MTM services if they meet fairly rigid criteria regarding either the number of prescriptions utilized, the number of chronic diseases or the total amount of prescription drug spending. However, there seems to be an oversimplification of patients that may benefit from MTM services.

Mr. Gronniger, in the past, CMS has recommended that Part D plans offer MTM services to additional patient groups beyond the baseline requirements, and you have already -- we have already talked about patients at high risk for opiate abuse.

Are there other groups of patients that are under represented in the MTM programs?

Mr. Gronniger. Yes.

I think that -- it is probably fair to say because of the low enrollment we think that the patients overall are under represented in the programs and we think that there are a multitude of condition-specific opportunities available here including in areas where there is already investment in, like, diabetes and

congestive heart failure.

So we think that there are going to be a wide range of opportunities. Congressman Murphy just mentioned a couple of good ones as well.

So I think yes and I think we are going to probably have a large amount of good ideas on the table as we go through the applications.

Ms. Matsui. I would also consider too that there are different populations involved here, which might cause some concern amongst some patients as to communication, and I was wondering whether that is a consideration also. I am looking at California a large diversity, different ethnic populations.

Has there been consideration in that regard?

Mr. Gronniger. Yes.

So I think inherent to any successful project and application and intervention here is going to be an ability to engage with beneficiaries to help them understand their -- the medications that they are taking.

And so plans are going to have to look closely at their enrollees to understand what they need to be successful, to communicate with them.

Whether it is working with the pharmacists in their neighborhood or whether it is something based out of a physician office or some other organization that can reach beneficiaries

who need to -- who can understand their medications better. I think that that will have to be a part of these models.

Ms. Matsui. Okay. Thank you.

I noticed in the new model at CMMI that there is a particular emphasis on risk-based interventions. Can you speak to how a risk-based approach in MTM might improve outcomes?

Mr. Gronniger. Yes, and it gets to the flexibilities and incentives that you mentioned earlier. We think that the intent of the statute and the regulations to say the MTM services, we know, aren't for everybody but they -- so we need to limit them to individuals with multiple chronic conditions and with spending expected to exceed a threshold would make sense on some levels and that we know that it is not for everybody.

However, we know that there are individuals who don't reach those thresholds who can benefit like individuals on blood thinners, medications that can have fatal consequences if not managed appropriately.

Even if it is the only drug that that patient is taking they wouldn't qualify for MTM under the current programs. So we think that that is an example of an area where we are providing the ability to reach beyond the current thresholds.

Ms. Matsui. Okay. Well, thank you very much, and I yield back.

Mr. Pitts. Chair thanks the gentlelady and now recognizes

the gentleman from New York, Mr. Collins, 5 minutes for questions.

Mr. Collins. Thank you, Mr. Chairman, and thank you, Mr. Gronniger, for your testimony.

Obviously, from the questions and the tone we are just all trying to better understand what is going on and, clearly, looking out for patient safety and costs at the same time are admirable goals and I think all of us can agree that is a good thing.

So just, really, a couple of questions as I have heard some of the testimony. Am I correct that the MTM program -- a beneficiary has to agree with their provider to enter their program?

Mr. Gronniger. So beneficiaries can opt out of the program at any time and they will be contacted by the plan, generally, speaking, and it will depend on the intervention and it will require some work with the plans to identify exactly the type of intervention for the right type of patient. Sometimes it might be something as simple as an extra communication at the pharmacist level.

So they might not feel like they are enrolled in anything but plan patients will have the opportunity to opt out at any time.

Mr. Collins. But why would a patient opt out? I mean, if we are looking after their health to make sure they are not taking drugs that could interfere, et cetera, and putting aside the cost factor, why would a beneficiary opt out?

Mr. Gronniger. I would think that beneficiaries wouldn't and shouldn't and I wouldn't recommend to any of my relatives to opt out.

It is possible that they would -- if they -- some beneficiaries don't find the current program where they do an interview, a comprehensive medication review with, say, a pharmacist and they have to spend 45 minutes talking to that person, some people find that an imposition.

And so under the current program, some patients opt out. We think that under a better designed program many fewer would agree to participate.

Mr. Collins. Is there anything that would -- I mean, clearly, I am assuming the cost benefit which accrues to both the government and the carriers but also information that would be available to patients if they tried to opt out that they might get something that would say, you know, should you rethink this -- you should rethink this. Does that type of thing happen or if somebody opts out they just opt out?

Mr. Gronniger. We are going to have to figure that one out as we -- as we get the specific projects proposed by plan sponsors. We think -- and that will include discussion of how the communications work with beneficiaries.

We think that a well designed program should be sort of self-evidentially beneficial to beneficiaries.

Mr. Collins. Right, I agree. So --

Mr. Gronniger. And so we hope that that is what we will see and that we will see much lower rates of opt out. Only about 1 percent of beneficiaries in all of Part D receive comprehensive medication reviews. Right now, we would expect that use of the interventions in this program would exceed that in these regions.

Mr. Collins. So now, as you bring this forward, western New York -- I represent the very rural area of eight counties and 105 towns in western New York.

We have an extraordinarily high enrollment in Medicare Advantage. It has just been adopted in our area probably, like, no other. Now, am I correct that the MTM program does not apply to Medicare Advantage plans?

Mr. Gronniger. Yes, that is right, sir.

Mr. Collins. And why would that be?

Mr. Gronniger. So one of the reasons that we are pursuing this project is that we recognize that the incentives for Part D plans are different from Medicare Advantage plans.

Medicare Advantage plans have responsibility for the total -- the total Medicare benefit Parts A, B and D. Part D plans only have responsibility for the drug part of the benefit. So they have a different -- they have a different financial perspective on this than anybody.

Mr. Collins. So the assumption would be someone in Medicare

Advantage, those providers are already looking at the interaction of A, B and D and should already be doing this? Is that the idea?

Mr. Gronniger. We aren't assuming that and, in fact, we have data suggesting that there are issues in Medicare Advantage as well. So we aren't -- we aren't saying that this isn't something that could benefit Medicare Advantage patients.

But as a first step and a first evaluation, we think this is where we have the greatest needs. We would look at whether we should expand it to Medicare Advantage in the future.

Mr. Collins. So that also begs the next question on Medicaid. You would certainly have individuals in Medicaid that have the comorbidities as well as cost and so forth.

Is there any thought that this MTM program should also move into the Medicaid world?

Mr. Gronniger. It is a good question.

I think that some of the evidence that we have seen from -- supporting the use of Medication Therapy Measurement programs has come from the Medicaid world.

States have the ability to offer this service under Medicaid today and we -- I would be happy to talk further about whether it makes sense to try to expand that.

Mr. Collins. And is it also -- I know my time is running out -- is this a 7-year program, as I understand it, this pilot?

Mr. Gronniger. It is a 5-year intervention with a 7 -- with

an extra 2 years run out to provide the part -- the premium subsidy for plans that perform well in the fifth year.

Mr. Collins. Okay. Well, again, my time has expired. Thank you for that testimony.

Mr. Chairman, I yield back.

Mr. Pitts. Chair thanks the gentleman.

I now recognize the gentleman from Oregon, Dr. Schrader, 5 minutes for questions.

Mr. Schrader. Thank you, Mr. Chairman.

I appreciate you being here, Mr. Gronniger.

I would like to follow up a little bit on the Medicare Advantage piece and, you know, it is a big part of prescription drug delivery in my part of the world and patently very successful by all accounts.

Wondered if you could elaborate what time frame might there be an opportunity for Medicare Advantage to also have the same incentives.

It seems smart to line all prescription drug plans incentives along the same lines. Everyone is playing from the same deck of cards and wondered when that might happen.

Mr. Gronniger. Sure. So Medicare Advantage prescription drugs plans today are required to offer the same set of MTM services and interventions that stand alone Part D plans are. So Medicare Advantage plans do offer the currently existing set of

services that we have been trying to improve over the last 10 years.

This model has focused on Part D stand alone plans because of the -- the misalignment of financial incentives is greatest there and we think that the greatest opportunity to demonstrate the benefit of the program are the largest in the shortest amount of time there.

We don't have plans to expand it to Medicare Advantage right now but it is something I would be happy to talk with you about -- you and others about over the coming months and year.

Mr. Schrader. I appreciate that, because I think there is an opportunity and we want to make sure that as, you know, we hopefully get better healthcare outcomes from whatever healthcare delivery system continues to go forward that we align them somewhat similarly so, again, we don't get this duplication -- some of the things you are trying to avoid, actually, with the new rules.

And I guess I would ask the chair if it would be possible to include a piece of information and some concerns put forward by the National Association of Chain Drug Stores dated October 16th as part of the record to -- for further consideration.

Mr. Pitts. Without objection, so ordered.

Mr. Schrader. And I yield back the rest of my time.

Mr. Pitts. Chair thanks the gentleman and now recognize the

gentleman from Indiana, Dr. Bucshon, 5 minutes for questions.

Dr. Bucshon. Mr. Chairman, I don't have any specific questions, just a few comments.

I think -- I was a practicing cardiovascular surgeon before and there are many barriers to patients properly taking their medications and being in compliance and this is some of those.

Other areas, I think, of interest to me are prepackaging patients with certain amount of medicines they have to take on a daily basis.

As many people know, patients already go home and take the little pill counters and put them in there themselves. But I am very intrigued about prepackaging at pharmacies, which some are doing now, where patients will just get a packet and all their medicines will be in there and it helps with the compliance issue and it also helps, I think, the pharmacist also and the pharmacy because less wasteful product, so to speak, where patients have pill bottles renewed and still have 3 or 4 pills in the other one and switch to the new bottle and those medicines are lost.

So in the long run, there is a -- you know there is a cost savings there probably for the health care system overall. So I appreciate your efforts at CMS to improve the quality of care for patients and I yield back, Mr. Chairman.

Mr. Pitts. Chair thanks the gentleman.

I now recognize the gentleman from New York, Mr. Engel, 5

minutes for questions.

Mr. Engel. Thank you very much, Mr. Chairman.

I am always pleased when our subcommittee comes together in support of a particular cause and I just want to say that Medicare Part D Medication Therapy Management program is a very great example, and I thank our witness and look forward to the second panel as well.

Mr. Gronniger, you note in your testimony CMS's belief, and I am going to quote it, "that the Part D MTM model will give prescription drug plans stronger incentives and flexibility to improve prescription drug safety and efficacy," and that is a quote.

Can you talk a little bit about why plans don't feel such incentives currently or, perhaps put differently, why isn't there already an incentive to improve prescription drug safety? Is there any reason that this wouldn't already be a goal?

Mr. Gronniger. Yes.

So it is not that Part D plans aren't trying to deliver the best care for patients and that clinicians managing care aren't trying to deliver the best care and that many cases do have the, you know, the desire as well as the financial incentives.

I think that the example that Dr. Bucshon just gave is a great one of prepackaging medications is something that can help patients remember to take the right drugs. It can help them with

the difficulty of opening bottles.

But right now, there is just not an incentive for plans or pharmacists to invest if it costs anything -- if it costs less than the current standards then that they can justify. But there is no -- there is no incentive in place that can support that.

There is no -- there is no true up at the end that says you have done better on the medical side of the benefit so we are going to provide some support for your work. And so because it cuts against the competitive pressures in Part D to keep the premium low, to keep enrollment high, we just don't see the investment that we think is probably beneficial here.

Mr. Engel. And you don't see it down the road either, I mean, because, obviously, cost is the most relevant thing?

Mr. Gronniger. Yes.

So Part D plans are incentivized to manage the -- and minimize the spending on prescription drugs and they, unless they are Medicare Advantage plans, are not responsible for the total cost of care of the benefit.

And that -- you know, that makes sense in certain contexts but it also makes sense to test approaches to making them more attentive and more focused on how the drugs that the patients are taking are supporting the overall patient care.

And that is why we have created an incentive to provide to plans so that if they do demonstrate that they can reduce costs

on areas where we know that pharmacists and MTM type interventions can drive cost savings then plans should have the opportunity to share in that as long as beneficiaries from lower premiums.

Mr. Engel. Thank you.

I can see from your testimony that CMS put a significant amount of thought into defining the test area with the new MTM model and I can also see from your testimony that CMS has already carefully considered evaluation methods for this model.

I have a clarification I would like. Why did CMMI choose to make only plans with the basic benefit eligible to participate in the new model?

Mr. Gronniger. Sure.

So like we have talked about for some of the evaluation parts of this, we are -- we want to make sure that we get the best test of this model and the best defined set of patients and plans possible.

The basic plans are a clearly defined set of patients and populations who -- where we believe there is significant need for these services. Over time, just as with Medicare Advantage, we would want to look at whether it makes sense to expand to enhance coverage as well.

Mr. Engel. So what percentage of plans overall will be participating in this model nationwide?

Mr. Gronniger. Nationwide, I am not sure of the percent

overall. It is in 5 regions and I think there are 34 PDP regions. So it will be -- you know, it will be a minority of the population nationwide but a nontrivial minority.

Mr. Engel. Okay. Thank you very much.

Thank you, Mr. Chairman. I yield back.

Mr. Gronniger. The chair thanks the gentleman. I now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. Griffith. Thank you very much, Mr. Chairman. Appreciate it. Appreciate you being here with us today. I am glad that Virginia is in the program area that is going to be tested.

The CMS and Center for Medicare and Medicaid Innovation recently announced plans to conduct a pilot allowing Part D plans the opportunity to utilize new and innovative approaches to Medication Therapy Management.

I have been a supporter of this and expanding the MTM program and cosponsor of Cathy McMorris Rodgers' bill to do so because I think better adherence to medication will keep our seniors healthy and lower our cost for chronic care.

Does CMS plan on rolling out successful approaches, those that prove to be successful, to the entire Part D MTM program before the end of the 5 years that the pilot is scheduled to take place or to last?

Mr. Gronniger. So for all innovation center projects our goal is to identify pilots and demonstrations that both improve the quality of care experience by patients and reduce program costs and if they meet those tests in the evaluation then there is the opportunity to expand them on the larger scale or even nationwide.

So that would be our hope for this model as well that we get really strong results and that we are able to expand it and to provide these types of improvements on a nationwide basis if we can get the research base behind it.

Mr. Griffith. And if you discover that before the end of the 5-year period, do you feel like you will roll it out before the end of that 5 years?

Mr. Gronniger. We will always be contingent on the data and making sure that we are -- that we have a clear understanding of how the program is working for patients and for the Medicare program.

But we went with 5 years not because we wanted to wait 5 years but because we heard from plans and other stakeholders that there was a lot of experimentation that is going to be required here and it is going to take some time to get it right.

And so we wanted to make sure we allowed for that and not find ourselves feeling like we really got up and running year 3 and the project is over. So we wanted to make sure that there

is the opportunity to identify successful projects.

If we are able to find that things work great in year 1 and year 2, then we would be happy to talk with you and others about the right way to expand that and scale it up sooner than 5 years.

Mr. Griffith. Okay. I appreciate that.

I am glad you are here and given your role at CMS I wanted to go off subject a little bit and mention another Part D reform that I think is important. I know others disagree with me. But I know that last year CMS released a broad rule which was ultimately not finalized.

That rule contained a provision to allow for any willing pharmacy to participate in Part D preferred network programs. This is an issue of great importance for rural seniors and pharmacies that I represent.

Seniors ought to be able to go to their local community pharmacy and get the lowest price possible instead of being told by an insurance plan they need to travel upwards of 20 miles to go to different -- a different drug store.

Now, in my district, that doesn't sound like a lot, I guess, if you come from a flat land area. But I represent the mountainous parts of Virginia and in my district that 20 miles could result in up to an hour in travel time.

In fact, from Haysi to Clintwood is only 18.1 miles. Those are two towns in Dickenson County in my district but the mayor

of Haysi tells me that if he is going to a meeting in the county seat in Clintwood, he plans on an hour because any weather condition, a coal truck, a timber truck or any traffic problem of any sort or nature on a mountain road means you are not going to get there on time.

So he makes plans to travel an hour and it is just not right to have our seniors having to make plans to travel an hour to get to the pharmacy that may be designated by computers being close by but is not in reality.

So that is my Congressman Welch and I, along with 59 bipartisan cosponsors, have a bill in, H.R. 793, to ensure senior access to local pharmacies and we are hopeful that that will go forward and encourage CMS to take a look at this and would love to know if you had any comments.

Mr. Gronniger. Yes, sir.

Thank you, and I do come from flat lands in Kansas where we go by about a mile per minute. If you have to take longer than that then we are unhappy about it.

The specific provisions you reference in the rule from last year we don't intend on in pursuing those at this time. We do think that improving the -- and making sure that the pharmacy networks in Part D are robust is an important project and it is something that we are continually looking at.

Mr. Griffith. Appreciate it very much and yield back.

Mr. Pitts. Chair thanks the gentleman. I now recognize the gentleman from Maryland, Mr. Sarbanes, 5 minutes for questions.

Mr. Sarbanes. Mr. Chairman, I don't have any questions. I just want to associate myself with the comments of Mr. Griffith on the annual pharmacy provision. I yield back.

Mr. Pitts. Chair thanks the gentleman. All right. We will go to Mr. Long from Missouri, 5 minutes for questions.

Mr. Long. Thank you, Mr. Chairman.

Mr. Gronniger, the -- what is the need for this innovation model?

Mr. Gronniger. So we think that the project -- that the Medication Therapy Management model to date -- Medication Therapy Management program to date hasn't delivered the benefits that we and others and Congress were intending for when it was created in 2006.

We think that there is a lot of need for better management of prescription drugs for the Medicare population and we think that the current program hasn't delivered largely as a result of misaligned financial incentives and regulatory barriers that we are trying to address in this project.

Mr. Long. Okay. And then in -- back in 2012 November, I think, the CBO identified the cost savings potential of medication adherence in the Medicare program.

And does CMS believe the program is designed to encourage

medication adherence, can improve the quality for beneficiaries and decrease costs?

Mr. Gronniger. Yes, absolutely.

We think that increasing adherence is likely to be one of the major tools in the toolkit successful applications here.

We think that applicants will also look at projects to address side effects, to address duplicative therapies if any are identified and look at managing potential risks of drugs. So we think that improving adherence is likely to be one aspect of many of these programs.

Mr. Long. Okay. Thank you.

You have covered a couple of my questions I had a little earlier. So with that, Mr. Chairman, I yield back.

Mr. Pitts. Chair thanks the gentleman. I now recognize the ranking member of the full committee, Mr. Pallone, 5 minutes for questions.

Mr. Pallone. Thank you, Mr. Chairman.

Mr. Gronniger, I am very pleased that just over 5 years ago the Affordable Care Act was signed into law and the legislation expanded insurance to those who needed it the most and provided important provisions -- protections for our most vulnerable citizens.

So I would just like to ask you about one aspect of the law that pertains to Medication Therapy Management and that is the

medical loss ratio, or MLR.

Has CMS issued specific criteria as to what MTM services must contain in order to be considered quality improvements?

Mr. Gronniger. Yes.

So this is one of the regulatory and financial issues that we haven't discussed today. But the medical loss ratio rules stipulate that MTM programs today are counted as administrative costs and so it is a further reason that plans feel the financial need to minimize the investment in these programs.

Under the model we will treat them as quality improvement activities and so they will not be counted against the plan, so to speak, in the calculation of MLR.

Mr. Pallone. So I think -- so I just -- I mean, you just want to elaborate a little more on CMS's decision to adjust the treatment of MTM services for purposes of the calculation of MLR? You want to just talk about that a little more? Is it just because as a means of encouraging it?

Mr. Gronniger. Yes.

So plans today need to meet the minimum MLR to participate in the program and this -- so everything that counts against them on the administrative side is something that they feel acutely.

By providing the ability to take it out -- take something that is a quality-enhancing activity like MTM services out of the numerator, so to speak, out of the calculation it will allow plans

to look at the investments that they need to make here and to right size them on the benefits of the program itself rather than on a compliance checklist.

Mr. Pallone. All right. Let me ask you about the low income subsidy patients. On average, Part D patients who receive the low income subsidy tend to be in a poor state of health and subsequently need to take more prescriptions.

And given that this is a more vulnerable population I am interested in how well the MTA program is being applied to our LIS patients. To date in Part D what proportion of MTM-eligible Part D beneficiaries are LIS enrollees?

Mr. Gronniger. I will get back to you on the specific numbers, sir.

Today, enrollment in MTM programs is slightly higher for LIS beneficiaries than for other beneficiaries and we think that under the -- under this model it is likely low income beneficiaries including LIS beneficiaries are likely to be people who successful plans study and try to target for specific tailored interventions to help them access their medications.

We think that by -- we know that LIS enrollees are also in basic plans which are the plans that are eligible to apply here. So we think that it is likely to support improvements in care for LIS beneficiaries through that channel as well.

Mr. Pallone. So is there anything else you could say about

how the rates of MTM participation compare between LIS enrollees and other beneficiaries other than what you mentioned?

Mr. Gronniger. Let me get back to you on the specific numbers on that one, sir.

Mr. Pallone. All right.

Mr. Gronniger. We think that this will improve the ability of plans to engage with LIS beneficiaries.

Mr. Pallone. Are there elements in this CMMI-enhanced MTM model to specifically target the low income subsidy patients?

Mr. Gronniger. The particulars of the interventions including beneficiary communications and the conditions targeted are something that plans are going to propose and we are going to work out what plans around the right way for that intervention to happen.

So it is something where we hope to see diversity of approaches and innovation from the participants and applications.

Mr. Pallone. All right.

And my last question is will CMS be tracking MTM participation and rates of comprehensive medication review amongst these low income subsidy beneficiaries?

Mr. Gronniger. Yes, definitely.

Mr. Pallone. All right. Thank you so much. Thank you, Mr. Chairman.

Mr. Pitts. Chair thanks the gentleman and now recognize the

gentlelady from North Carolina, Ms. Ellmers, 5 minutes for questions.

Ms. Ellmers. Thank you, Mr. Chairman, and thank you, Mr. Gronniger, for being with us today.

And I apologize for coming in late and you may have already addressed the question that I have for you. But in relation to the Medication Therapy Management program, you know, CMS already acknowledging that the Medicare Part D program itself has been utilized lower than had been expected.

I was just wondering, and there again, I know, there have been many discussions, especially the pilot program that is going to move forward -- that was another one of my questions.

But if you can just identify for me what you think the reasons are that this program has not been as successful as anticipated.

Mr. Gronniger. Sure, and it gets back a little bit to the question that Ranking Member Pallone asked.

We think that under the construct today Part D plans operate in a very competitive market. They need to keep premiums low to -- both to attract enrollees as well as to qualify as low income subsidy benchmark plans which qualifies them for some automatic enrollment.

So in that circumstance, plans are -- have to look very hard at where they invest and where they try to do quality improvement activities, and because MTM services cost money, not necessarily

a lot of money, but plans really are discouraged in some ways by the current structure from investing inactivities that are known to improve quality.

So this is a -- you know, this is a required service for plans in Part D so they do it and we have defined how to do it and we have tried over the years to expand the number of people involved as well as the flexibility of what can be offered.

But, you know, we have some statutory constraints as well as regulatory history. So this is an attempt to step outside of that box and say we know that there are potential interventions here that can benefit patients.

Let us create a model that is sustainable for a plan to invest in those services, provide the technical investment that can work with -- work with local pharmacists, that can work with the patient's physicians, that can provide better counseling to patients and better understanding of their medications, provide a framework for that and hopefully we will see -- we will see this program take off.

Ms. Ellmers. Great. Thank you so much for your time, and with that, Mr. Chairman, I yield back.

Mr. Pitts. Chair thanks the gentlelady.

That concludes the questions of the members present. I am sure we will have follow-up questions and other members who may be in another hearing will want to ask questions.

We will send them to you in writing. We ask that you please respond promptly. Thank you very much for your testimony, your time and very informative.

While the committee sets up for the second panel, the committee will stand in recess for 3 minutes.

[Whereupon, the above-entitled matter recessed at 11:23 a.m. and resumed at 11:29 a.m.]

Mr. Pitts. Ladies and gentlemen, if you will take your seats. The subcommittee will reconvene. I would like to submit the following documents for the record: statements from the American College of Clinical Pharmacy and the College of Psychiatric and Neurologic Pharmacists, from the American Association of Diabetes Educators, from the American Pharmacists Association, from Prescriptions for a Healthy America, from the American Society of Health System Pharmacists, from the Healthcare Leadership Council, from the National Community Pharmacists Association and from the National Association of Chain Drug Stores and from the Academy of Managed Care Pharmacies.

Without objection, those will be entered into the record.

[The information follows.]

**********COMMITTEE INSERT **********

Mr. Pitts. I am pleased to welcome the second panel at this time and I will introduce them in the order of their presentation.

First we have Mr. Lawrence Kocot, principal and national leader, Center for Healthcare Regulatory Insight, KPMG. Secondly, we have Mr. Mark Merritt, president and chief executive officer of the Pharmaceutical Care Management Association. Thirdly, Mr. Jesse McCullough, director, Field Clinical Services, Rite Aid Corporation, and finally, Dr. Richard Thomas Benson, associate director of stroke, MedStar Washington Hospital Center.

You will each -- first of all, your written testimony will be made a part of the record. You will each be given 5 minutes to summarize your testimony and we welcome you. Thank you for coming, and Mr. Kocot, you are recognized 5 minutes for your summary.

STATEMENTS OF LAWRENCE KOCOT, PRINCIPAL AND NATIONAL LEADER, CENTER FOR HEALTHCARE REGULATORY INSIGHT, KPMG LLP; MARK MERRITT, PRESIDENT AND CEO, PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION; JESSE MCCULLOUGH, DIRECTOR, FIELD CLINICAL SERVICES, RITE AID CORPORATION; RICHARD THOMAS BENSON, ASSOCIATE DIRECTOR OF STROKE, MEDSTAR WASHINGTON HOSPITAL CENTER

STATEMENT OF MR. KOCOT

Mr. Kocot. Thank you, Mr. Chairman.

Chairman Pitts, Ranking Member Green and distinguished members of the subcommittee, thank you all for this opportunity to testify on behalf -- on the Medicare Part D Medication Management -- Medication Therapy Management program.

My name is Larry Kocot and I am currently principal and national leader of the Center for Healthcare Regulatory Insight at KPMG.

As a former senior official with CMS during the implementation of the MMA I was an active participant in the implementation of Medicare Part D. Specifically, I was involved in the development of the original MTM program requirements and regulations.

More recently, I was the project leader for the technical expert panel convened by the Brookings Institution and the MITRE Corporation to inform the development of the Medicare Part D

enhanced MTM model recently announced by CMMI.

The MMA amended the Social Security Act to provide subsidized prescription drug coverage to Medicare beneficiaries through Medicare Advantage and through a stand alone PDP.

Today, nearly 40 million Medicare beneficiaries are enrolled in a Medicare-sponsored plan that provide prescription drug coverage with approximately 24 million Medicare beneficiaries accessing their prescription drugs for a stand alone PDP.

Effective medication use can prevent or address acute chronic illnesses and improve beneficiary health outcomes and reduce overall healthcare costs.

However, prescription drugs are often inappropriately used or suboptimally used, leading to adverse drug events, unnecessary hospitalizations and other unintended health outcomes.

Noting the great benefits as well as the potential risks of providing prescription drug benefit coverage to Medicare beneficiaries, Congress required that all Part D plans provide an MTM program to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events.

While the MTM program has had a positive impact on the health outcomes of some Medicare beneficiaries, the program has not lived up to expectations. Some plan sponsors view MTM as a necessary cost of participating in the Part D program and they do the minimum necessary to engage patients to satisfy CMS requirements.

Experts across the spectrum of plans, pharmacists, academics and advocates have noted that the success of the MTM program is severely limited by the misalignment of incentives.

Furthermore, better evidence is needed to understand how MTM can more effectively be used and what factors are most important to broader adoption and use.

Recognizing the limitations of the current program CMMI convened a technical expert panel to explore some of the major barriers to MTM program development and advancement.

As a result of the tech discussions and consultations with a broad array of stakeholders, CMMI recently announced the enhanced MTM model demonstration.

This demonstration has three important elements. First, it will provide additional regulatory flexibilities to allow plan sponsors to design more individualized and risk stratified interventions.

Second, it will realign the incentives to provide a prospective payment for more extensive MTM intervention investment that will be outside of the plan's bid, and third, it will provide a performance payment in the form of an increased direct premium subsidy for plans that successfully achieve a certain level of reduction in fee-for-service expenditures and fulfill quality and other data reporting requirements under the model.

Greater regulatory flexibility and a fundamental realignment of incentives for providing more robust and meaningful MTM through the enhanced model will encourage plan sponsors to deliver a more patient-centric and comprehensive approach to improve medication use in Part D.

Likewise, the program could create new competitive opportunities for Part D plan partnerships that leverage data sharing and provider communications to bring greater value to the Medicare program and Medicare Part D beneficiaries.

This could encourage plan engagement with more providers including pharmacists and physicians to more systemically collaborate, coordinate patient care and optimize drug therapy.

Additionally, the model could better align Part D and the goals of MTM with other CMS programs incentivize to deliver higher value care to Medicare beneficiaries such as the Medicare Shared Savings Program.

There are a number of factors that Part D sponsors will consider before participating in the model, some of which are outlined in my testimony.

Nonetheless, I believe the enhanced MTM model is a critical first step to aligning the PDP sponsors and government financial interests.

The model promises to create incentives for more robust MTM investment. It will provide flexibility to better target the

interventions to the right patients at the right time and it will help generate better evidence on how MTM can be more effectively deployed across the health care system.

The enhanced MTM model demonstration has the potential to unleash greater private sector innovation in the MTM program to provide higher quality prescription drug benefit for Medicare Part D beneficiaries.

If the objectives of the demonstration are achieved, the MTM program could add even greater value to Medicare by improving the health outcomes of beneficiaries in Medicare Part D.

Thank you, Mr. Chairman, for this opportunity to appear before the subcommittee. I am happy to take any questions.

[The statement of Mr. Kocot follows:]

**********INSERT 2**********

Mr. Pitts. Chair thanks the gentleman.

Now I recognize Mr. Merritt 5 minutes for his summary.

STATEMENT OF MR. MERRITT

Mr. Merritt. Good morning, Chairman Pitts, Ranking Member Green and the other members of the panel. Thank you for having me today.

I am president and CEO of the Pharmaceutical Care Management Association. My name is Mark Merritt and I appreciate the opportunity to be here today and talk about an issue which actually has a lot of synergies among different stakeholders in health care and that is improving MTM and Medicare Part D.

PCMA, my trade association, represents America's pharmacy benefit managers which administer prescription drug plans for over 250 million Americans with coverage through employers, unions, FEHBP, Medicare and other programs.

We are probably best known for what we do in Part D because it is such a popular successful program. But it is a program that can be improved.

We do offer high quality benefits -- affordable benefits. We do this by offering an array of choices to consumers by negotiating discounts with manufacturers, with retailers, establishing affordable pharmacy networks and offering innovative convenience tools like home delivery for prescription refills.

We also use sophisticated analytics to prevent harmful drug

interactions and improved patient safety. On this note, the Part D statute includes the Medication Therapy Management provisions that are designed or the goal of them anyway is to improve adherence, reduce adverse drug effects and make sure there is not under use or overuse of prescription medications.

And I think we all agree the promise of MTM has not been fully realized and that there is an opportunity here with the CMMI model to get it right.

The reason there have been problems have been stated from some others but let me just kind of go through our list here. You know, first, the one size fits all MTM requirements that are currently there prevent Part D drug plans from focusing on the beneficiaries who could really benefit most from the services.

However, we are required to provide the same uniform services to every eligible patient regardless of their level of need, their level of compliance, their condition or their willingness to participate in the program in the first place.

It would be much more productive to let plans develop innovative programs that treat patients like individuals according to their particular needs, circumstances and receptivity to MTM services.

Second, even when MTM services appear to be working in Part D, the stand alone plans have had little visibility into the patient outcomes or economic savings they may generate in Medicare

Parts A and B.

Third, the existing MTM program offers no economic incentives to innovate or improve MTM services. In fact, they are somewhat of a disincentive to do so, since it is unclear whether investments that go beyond the bare minimum are treated as administrative rather than quality improvement expenditures in the medical loss ratio calculations.

In this light, we would encourage CMS to explore new approaches that would improve the program in six ways. First, let plans target high-risk beneficiaries most likely to benefit from such interventions.

Our plans have broad knowledge not just in Medicare but all across America in all these different programs to target people in different ways. The more flexibility we have the better.

Second, if we have greater flexibility and a better range of services, we will do better for patients, do better for the program.

Third, we need financial incentives for plans to innovate and expand MTM services. As Mr. Gronniger said, right now our top goal is to provide the best benefits at the lowest premiums, lowest cost sharing we can find, and if MTM has been kind of a low return project so far because of the way it is structured, there is not going to be a huge amount of investment in there if it comes to the expense of premiums or other things that patients

really value.

Fourth, we like to count expenditures for expanded or innovative MTM services as quality-improving activities for purposes of MLR.

Then five, we want to focus on clinical outcomes instead of just procedural or process measures like medication counts or completed CMRs.

It is not that those are not important, but outcomes that people are looking for, both clinical outcomes, economic outcomes and that is what we need to focus on.

And six, stand alone PBMs should have access to Part A and B beneficiary outcomes data including alignment with ACOs.

To its credit, CMS is working collaboratively with stakeholders and understands that the current requirements are preventing the MTM program from realizing its potential. We have had very productive discussions with them, as have other stakeholders here today.

CMMI's new Part D enhanced MTM model program largely addresses our concerns and offers new hope that the original goals of MTM can be realized starting in 2017.

So, in conclusion, our hope is that Congress and CMS regulators will allow this program to get off the ground and resist the temptation to add new MTM requirements in the meantime.

The model needs time to build momentum, produce results and

fulfill the original goals of the MTM program.

Thank you for your time and I look forward to answering questions you might have.

[The statement of Mr. Merritt follows:]

**********INSERT 3**********

Mr. Pitts. Chair thanks the gentleman and now recognizes Mr. McCullough 5 minutes for your summary.

STATEMENT OF MR. MCCULLOUGH

Mr. McCullough. Chairman Pitts, Ranking Member Green and members of the House Energy and Commerce Health Subcommittee.

My name is Jesse McCullough and I am the director of Field Clinical Services for Rite Aid Corporation. I oversee Rite Aid's clinical programs in Michigan, Ohio, Pennsylvania, New Jersey and the District of Columbia.

My primary objectives are improving performance of Medication Therapy Management, immunization and quality measure-based programs by identifying ways to reduce or eliminate barriers to providing these health care services to patients in the communities that we serve.

We greatly appreciate this opportunity to testify because we feel strongly about the ability of MTM to improve the quality and affordability of health care services.

My written testimony goes into greater detail but I would add this statement is consistent with the policy positions of the National Association of Chain Drug Stores of which Rite Aid is a member.

For my oral testimony, I would like to summarize the importance of MTM, some progress in advancing it and challenges and opportunities for its improved utilization.

First, the importance of MTM. Medications are the primary

intervention to treat chronic disease and are involved in 80 percent of all treatment regimens. Medicare beneficiaries with multiple chronic illnesses call on 13 different physicians on average, have 50 different prescriptions filled per year, account for 76 percent of all hospital admissions and are one hundred times more likely to have a preventable hospitalization.

Yet, medication management services are poorly integrated into existing health care systems. Poor medication adherence alone cost the nation approximately $290 billion annually, 13 percent of total health care expenditures and results in avoidable and costly health complications.

My written testimony details numerous studies that demonstrate MTM's ability to help fix this. The Centers for Medicare and Medicaid Services and the Congressional Budget Office have reached positive conclusions about MTM improper medication use.

Several states have implemented MTM programs and have seen notable savings for the state and beneficiaries. An MTM program in Ohio returned $1.35 for every $1 invested in the first year and $2.17 for every dollar invested in the second year. This is one example amongst many.

Now about progress in leveraging MTM. Despite the proven value of MTM, the Medicare Part D MTM program has seen low enrollment and utilization rates. Current restrictions limit

the eligible population too dramatically. That said, plans are required to offer a minimum level of MTM services and CMS has taken steps to improve the quality and measuring of the Part D MTM program.

CMS and the Center for Medicare and Medicaid Innovation recently announced an initiative that would provide Part D plans the opportunity to utilize enhanced MTM models and strategies. Rite Aid applauds that.

Although the testing phase for the program is 5 years, meaning that it will take a long time to incorporate useful strategies across the Part D program.

So where are the challenges and opportunities that can be addressed now? Rite Aid has participated in MTM programs since their inception. We have helped thousands of patients get more out of MTM to optimize their medication therapy.

The fact of the matter is we can do more.

There are numerous challenges that exist which impede the uptake of Part D MTM services such as lack of incentives for plans, providers and beneficiaries, poor targeting of beneficiaries, a lack of beneficiary awareness and provider participation and prohibitive documentation requirements.

Rite Aid believes reforming the Part D MTM program can be accomplished by better identifying beneficiaries who most need the services. Changes should be made to revise the eligibility

requirements to include beneficiaries with single chronic conditions that have been shown to respond well to improved medication adherence.

One of the committee's members, Congresswoman McMorris Rodgers, introduced legislation last Congress that would have made such changes. Under her outstanding leadership, the bill garnered 170 bipartisan cosponsors including 29 current Energy and Commerce Committee members.

This Congress there is similar legislation that has been introduced in the Senate, S. 776, the MTM Empowerment Act. This bill would provide access to MTM for beneficiaries with diabetes, cardiovascular disease, COPD and high cholesterol.

We encourage Congress to advance this vital legislation to allow more Medicare patients to have access to MTM services.

In addition to more effectively targeting and to more effectively target and reach beneficiaries most in need of MTM, we believe policy makers should explore ways to realign incentives in the program for plans, providers and beneficiaries alike.

I would welcome the opportunity to elaborate more on these topics further during the Q and A portion.

In closing, Rite Aide would like to thank Congresswoman McMorris Rodgers, the committee for their leadership on this important issue.

Our company and industry look forward to serving as a

resource as Congress explores ways to strengthen the Medicare Part D MTM benefit for our nation's seniors.

Thank you for the opportunity to be part of this vital discussion.

[The statement of Mr. McCullough follows:]

**********INSERT 4**********

Mr. Pitts. Chair thanks the gentleman and now recognizes Dr. Benson 5 minutes for your summary.

STATEMENT OF DR. BENSON

Dr. Benson. Thank you, Chairman Pitts, Ranking Member Green and members of the subcommittee for holding this important hearing and inviting me to testify.

Today, I speak not only as associate medical director of stroke at MedStar Washington Hospital Center but as a volunteer for the American Heart Association and its more than 30 million supporters dedicated to building healthier lives free of cardiovascular disease and stroke.

The statistics are alarming. Over 93 million Americans don't take their medications as prescribed. Poor medication adherence results in 125,000 deaths in the United States annually and costs our health care system nearly $300 billion a year in additional doctor and emergency department visits and hospitalizations.

Poor medical -- poor medication adherence is particularly common among patients with cardiovascular diseases, which is the number-one cause of death in this country and stroke is the number one cause of disability among adults.

And with patients with CVD do not -- when they don't take their medications as directed the repercussions are very severe. As I mentioned, they die or loss with major disability.

So why don't patients take their medications? There are

many reasons. They may forget. They may think the medication is not working. They may fear the side effects or are having difficulty taking the medication, or it may be a combination of all of these.

However, there is hope. Medication Therapy Management programs can improve adherence. Research indicates that these programs can lead to better health outcomes, reduce the risk of adverse events and help control health care cost.

For example, the American Pharmacists Association Foundation created a community-based MTM program focussed on CVD risk factors such as hypertension and hyperhypercholesterolemia.

The results were impressive and across the board. The proportion of program participants achieving targeted blood pressure level increased while heart attacks and other cardiac events fell by more than half as did patients' use of emergency room and other hospital services.

In addition, health care costs paid by employers declined by more than 45 percent and the percentage of health plan costs related to CVD decreased from approximately 30 percent to 19 percent.

A 2013 CMS report showed that patients suffering from congestive heart failure and diabetes enrolled in MTM programs had improved medication adherence with considerable hospital cost savings.

This was particularly true for those who received comprehensive medication review. The American Heart Association supports policies that would ensure access to these vulnerable services, especially for patients most in need.

Passage of the Medication Therapy Management Empowerment Act of 2015 is critical to ensuring that a greater number of Medicare beneficiaries have access to MTM services.

It would amend current MTM criteria to allow beneficiaries with a single chronic condition such as hypertension, high blood pressure, to be eligible for these services.

While the MTM Empowerment Act of 2015 has not yet been introduced in the House this Congress, we salute Representative McMorris Rodgers' past work on this issue and for introducing legislation similar to this act.

The American Heart Association was also encouraged when the Center for Medicare and Medicaid Innovation announced its new enhanced model to test strategies to improve and strengthen medication use among Medicare beneficiaries enrolled in Part D.

MTM services currently offered by Part D plans falls short of their potential to improve quality and reduce unnecessary medical costs.

This is an important step to provide these programs with regulatory flexibility and to identify new ways and strategies to improve Medicare patients' health outcomes.

The American Heart Association strongly supports the MTM enhanced model as both seniors and health plans that cover them could benefit from stronger adherence to prescription medication. We look forward to its launch in 2017.

In conclusion, the American Heart Association believes that Medication Therapy Management services play a critical role in ensuring patients meet their health care needs. We support greater access to these services and better patient education about medication adherence.

We further advocate for improved care coordination between providers and utilizing existing relationships between pharmacists and prescribers to identify and help reduce barriers to improve drug adherence for those most at risk.

It could allow a patient to attend his grandchild's baseball game or walk his daughter down the aisle. These are the outcomes we can all support and work towards.

I thank you for giving me the opportunity to testify on this important issue and I would be happy to answer any questions.

[The statement of Dr. Benson follows:]

**********INSERT 5**********

Mr. Pitts. Chair thanks the witnesses for their testimony and we will now begin questioning. In the interests of my colleagues' request, I will now recognize Ms. McMorris Rodgers for her 5 minutes of questions.

Ms. McMorris Rodgers. Well, thank you, Mr. Chairman, and thank you for holding this hearing on MTM and appreciate all the witnesses being here and providing your insights.

I think we recognize that there is a lot to be gained if we could focus more on getting the program to function more efficiently but also the impact that it has on medication adherence, which is a goal that we can all share.

Certainly, community pharmacists have been at the forefront of providing services such as medication therapy management. Pharmacist-provided services such as MTM are important tools in our effort to improve medication adherence, patient health as well as to improve health care affordability.

I wanted to applaud Rite Aid for their active management and leadership on this issue, engagement with nearly 12,000 pharmacists across the country that are on the forefront every day interfacing and treating patients.

And Mr. McCullough, I wanted to start by just asking if you would review -- I know you highlighted some but as you think about, you know, the current program, the Medicare Part D MTM program, just review some of the benefits, the challenges that you are

seeing day in and day out at Rite Aid.

Mr. McCullough. Well, the biggest challenge that -- well, let me start with the benefit. We have the opportunity with nearly 12,000 pharmacists trained to provide MTM services to be able to contract with a number of different plans to provide these services and we do that anywhere we can. It has been tremendous.

That being said, the identification of patients who are eligible is probably one of the bigger challenges that we have. Being able to expand that eligibility would be vital to help in a number of ways.

As it is right now, the patients that come to us they are oftentimes very, very complicated. They have a number of issues going on and what we try to do is we try to engage them to help make sure that any disease state that they have is being appropriately treated and any treatment that they have has a corresponding disease state for which it matches up, and through that process they identify, you know, a number of drug-related problems and work towards the resolution and the documentation to be able to communicate with other providers to make sure that we are all on the same page.

Some of the biggest things that we have is just being able to get people in the door for these services. So while people may be eligible, getting them to accept that service is sometimes challenging. You have a number of patients that are somewhat

skeptical.

They may be a little naive of what the benefit of that program is and I would suggest those are a couple of bigger things that we see is we say well, you know, my doctor takes care of that.

There is some -- there is some perception that, you know, the health care -- there is a health care system that exists that is different in their mind than what actually exists.

Ms. McMorris Rodgers. So address what you think a successful MTM program would look like and then also highlight the populations that you think will benefit most.

Mr. McCullough. I think what would be most successful is where we can intervene the earliest. You know, the old expression goes an ounce of prevention is worth a pound of cure. So the earlier we can intervene in any chronic disease state, and diabetes, COPD, cardiovascular disease are ones that come to mind very, very quickly.

But anything that we can do earlier in the process will prevent disease progression and ultimately that will do is that will eliminate health care costs downstream.

So if we can intervene with a diabetic to prevent morbidity such as blindness, amputation, so on and so forth, those are benefits that have direct -- that are direct cost related to the health care system and then there is also quality of life things that come in as well.

Also, earlier intervention can prevent kidney disease progression like that. You know, diabetes is probably one of the low-hanging fruits, cardiovascular disease.

But, essentially, I am probably of the mind set that any chronic disease state is fair game to start early on to prevent that progression.

Ms. McMorris Rodgers. Great. Okay. Thank you, and thank you, Chairman, for yielding me this time.

Mr. Pitts. You are welcome. Thank you.

Chair now recognizes the ranking member, Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

The CBO estimates that last year Medicare Part D spent $65 billion on prescription drugs. Despite the impressive magnitude of the spending we haven't developed a successful system that ensures we are doing all we can to help beneficiaries overcome any obstacles to taking that medication as prescribed.

This issue is not new and, in fact, 25 years ago the Office of Inspector General issued a report entitled "Medication Regimens: Causes of Noncompliance."

Yet, a quarter of a century later, we have made little progress and I want to add 25 years ago we didn't have some of the great pharmaceuticals that we can take for our illnesses.

That being said, we do have several examples, many noted in

the testimony of our witnesses of outstanding success in the area. I would like to take advantage of the four different perspectives we have on our second panel.

Can our witnesses comment on what characteristics are the most important to incorporate in any MTM intervention in Part D, moving forward to achieve the outcomes of what we have seen in Medicaid and in private sector.

In response I would be interested in understanding what you see as a top barrier right now to achieving the success in Medicare Part D MTM and how the characteristics you identified would overcome that barrier.

Mr. Kocot. I guess I will start. Well, first, I think what CMMI has done in constructing this model does address some of these questions.

First, a prospective payment to allow plans to invest up front into MTM interventions and target patients that have the most need is a real good start.

Secondly, having a reward on the back end for outcomes as opposed to processes is a very good result. There are some challenges with that, obviously, but we will work through those challenges.

Those are two very good -- very good starting points for CMS to start with because the way that the program was structured before, as was said earlier, the goal of prescription drug plans

is to compete in the marketplace based on premium, and if you are focusing on lowering the premium then you are not going to be investing a lot of cost or a lot of money into prevention and some of the other things that are necessary.

CMS, under the current program, allows people to allocate or allows plans to allocate money but it has to be included in their administrative costs within their bid.

Taking this outside of the bid and putting this as a prospective payment is going to make a huge difference in the ability in plans to invest more freely, more creatively and more innovatively.

Mr. Green. Okay. Mr. Merritt?

Mr. Merritt. I would agree with what Larry has said. I think the key is we need to let innovation start working because there are ways to reach these people.

But right now, you have a lot of people who maybe are the wrong people to be targeting because they are full compliant on their medications.

Maybe they are people who aren't interested in participating and a whole host of other reasons. You have prescriber abrasion where prescribers are getting asked by patients.

What is this called, this MTM thing, and the prescriber will say, I don't know -- I don't take the call -- it's not for me -- don't talk to them. So we need more coordination. I think these

incentives will help be more coordination between the plan and the prescriber, the pharmacist, the patient.

Right now, people are subject to so much noise in their life in general and noise just on your phone, getting calls for refills and so forth.

The thought of, for a lot of people, getting on a phone call and talking for 15 or 20 minutes about something to somebody on the other end of the line or waiting in line at the pharmacy and talking for 15, 20 minutes, a half hour.

They don't have the time to do it, they are not interested in doing it and I think there are ways to change that. But we need to let innovations start working so we can see the stuff the works and do more of it.

Mr. Green. Mr. McCullough.

Mr. McCullough. I would just add in addition I think the top barrier, as you asked for, Mr. Green, is that the identification of the appropriate patients to impact.

You know, we have an awful lot of patients that come in our stores every day that would benefit from earlier intervention. So by being able to get earlier access to care I think you can have a lot of cost effective interventions that will save us money in the long run.

Mr. Green. Dr. Benson.

Dr. Benson. My idea of a excellent MTM intervention would

be to truly embrace healthcare wellness and not illness.

When we create a medical home for each individual, as we have talked about, in a medical neighborhood where a physician would go -- where a patient would go to his or her physician, be evaluated, medications are prescribed, that patient would then go to a pharmacist, have the prescription filled.

The pharmacist would be there, be an intermediary who can explain the side effects of the medication and also help with possibly checking blood pressure or blood sugars periodically.

If there is an abnormal value that information would be relayed back to the physician and then that patient could go back to physician and we are truly creating a neighborhood of health and Wellness where we are catching abnormalities early. We are catching people who are not being compliant.

We are truly developing a medical home and a medical neighborhood to deal with these diseases.

Mr. Green. Thank you, Mr. Chairman. I know I am out of my time but, Mr. Kocot, you recently wrote an article for Medication Therapy Management health fair's blog and you described the status of an MTM program as well as upcoming CMMI Part D.

I am interested in your thoughts and we will -- we might contact you on -- you know, as we go further. So thank you.

Mr. Kocot. Be happy to. Thank you.

Mr. Pitts. Chair thanks the gentleman. I will now

recognize myself 5 minutes for questions. Mr. Kocot, we will start with you.

Can you elaborate on your experience at CMS in developing the original MTM program, please?

Mr. Kocot. Sure. Congress actually established the MTM program through the MMA, as you know, and Congress left it to CMS to fill in some of the blanks and that is the number of drugs that would qualify, the number of chronic conditions and the dollar amount.

As you will recall, Mr. Chairman, when we were implementing the MMA and, specifically, Part D we didn't know whether anyone was even going to provide a prescription drug benefit at the time.

We were hoping people would come if we set up the party. The other thing we didn't know was whether it would be affordable. And then finally, with regard to the MTM program, we didn't have a lot of evidence on what would work.

So the idea behind setting up the MTM program the way that we did was to get it set up, get it running, make it affordable and then learn through the process, learn through time and then add and develop the program.

As you may know, the CMS, when we rolled out the Part D final rule, we called the Part D or the Medication Therapy Management program, we said it had the potential to be the cornerstone of the Part D benefit. And I truly believe that that is true still

and it will become the cornerstone of the Medicare Part D benefit.

But it is going to take some innovation and that is what this model is intended to bring to it. It is probably overdue but it is about time.

Mr. Pitts. Looking to the future, if you will just continue a moment, what can Congress do to make sure MTM is reaching its fullest potential?

Mr. Kocot. Well, I think one of the things that Mark said is important and that is, you know, let this model work. Don't allow administrative barriers to get in the way.

There is other things that we may want to experiment with. CMS has been very adamant about marketing this new benefit or this new model to beneficiaries.

We have got to do more to engage beneficiaries in their care. We are just not doing enough of that and that may be -- that may be a barrier to engaging people in the care.

There is a fine line between marketing and overdoing it with beneficiaries and using this in ways that you shouldn't but we also need to engage them and we should explore new ways to develop programs to do that.

Mr. Pitts. Thank you. Mr. Merritt, what flexibility to do plans need to enhance the MTM program for their beneficiaries and does the CMS model provide you with that flexibility?

Mr. Merritt. We are very encouraged by the CMMI model. It addresses virtually all the concerns that we have mentioned from economic incentives to flexibility.

In terms of flexibility, right now there is the assumption that okay, you have to have several classes of problems and several different conditions, and it may just be one condition -- a blood thinner.

It could be opioid. It could be diabetes. It could be a whole host of things and there are different ways to identify individuals. Right now, we need to find individuals who need the help, who want the help and that we can really talk to about it.

There is almost no awareness right now among people about this particular program and a cold call from us or a question from a pharmacist at the counter is not going to kind of move them right now.

So we need to really find ways to target individual groups of people and really go after them, educate them, find other providers that they want to talk to.

Maybe they want to talk to the plan. Maybe they want to talk to the doctor, maybe the pharmacist. But we need to get to know those people better. This will help us do that.

The problem we have with existing law is we have to treat everybody the same, give them all the same uniform treatment. They don't all need the same treatment. You don't market any

other program like that. We need that flexibility.

Mr. Pitts. What are the implications for plans that activities associated with MTM will be counted as quality improving activities in the medical loss ratio? What does that mean for plans?

Mr. Merritt. Well, the medical loss ratio really, in a sense, punishes additional administrative expenses. If more spending on MTM is viewed as an Administrative expense, the plan is going to get punished. You are going to have given rebates back and it is just a huge disincentive to move in that direction.

The intriguing thing about the CMMI model is you will have separate payments that are outside of the whole MLR, outside of the bid where patients -- where plans can have flexibility to invest in these things to get a return on that investment to see what works.

Right now, the challenge is if we are going to spend more money than the bare minimum that is required, that money will be largely counted as administrative costs. It will undermine premiums.

It will make products less competitive and there is just no incentive to do it, considering what people really want is lower premiums and real access to drugs. That is the most --

Mr. Pitts. Thank you. Thank you.

Mr. McCullough, please discuss how MTM works in practice and

give me a real life example of a success story.

Mr. McCullough. Yes, sir.

In practice, what we do is when we have the opportunity to sit down with the patient to provide MTM service and, more specifically, the comprehensive medication review, is we sit down and we assess the patient to make sure that every medical condition they have has an appropriate treatment and every treatment that they have on board has a corresponding medical condition.

Through that process, we also do some physical assessment to make sure that the therapies that they are on are actually achieving clinical goals to the benefit of the patient.

And through that whole process we identify different drug-related problems that we then collaborate with the prescribers to look to resolve, be that increasing a dose, decreasing a dose, adding a medication, removing a medication. You know, those are some very common things.

Additionally, what we do is we then provide documentation to the patient around different actions that they can take to improve their health as well as documentation for them to be able to share with other providers, which would be a comprehensive list of a medication -- personal medication record.

That is, arguably, one of the most important things that prescribers look for is to have a current list of medications so they know what to work from.

As far as an individual example, we had an opportunity where we provided care to a patient -- I believe the patient was in the state of Tennessee -- where it was discovered that the patient was receiving continuous treatment for a urinary tract infection that was not necessary.

And what was happening is that was creating respiratory complications and this patient was then put on a number of inhalers and steroids and what not to treat that.

Through the comprehensive medication review process, we identified that root cause. We were able to get that root cause resolved -- the patient's symptoms resolved.

They were able to discontinue the respiratory medications and the word we got back is that that saved tens of thousands of dollars in health care costs.

Mr. Pitts. All right. Thank you.

The chair now recognizes the vice chair of the subcommittee, Mr. Guthrie, 5 minutes for questions.

Mr. Guthrie. Thank you very much, and my question is for Mr. McCullough.

As a pharmacist, you are aware of the important role that pharmacists can play in delivering care to patients we have talked about this morning.

Actually, I have another bill -- it is H.R. 592 -- that would allow Medicare reimbursement for some of the basic services that

pharmacists provide they are allowed to perform under their own state law.

Can you address some of the things that pharmacists can do but aren't reimbursed for in Medicare?

Mr. McCullough. Yes, sir. I would be happy to do that. Thank you.

I will just start off by just saying from my perspective I believe that the pharmacist has a specific goal in the health care community and that is to monitor health care safety and efficacy.

We do an excellent job with safety as we look for drug interactions and drug allergies with every prescription that we fill in the community setting.

Where we have a tremendous opportunity is in how do we make sure that the patient's therapy is as efficacious for them as possible and to that simple monitoring tests would be some of those very simple tests that we could be looking at.

There are some medical conditions that monitor blood pressure with a cuff and a stethoscope. But there are other ones where you have to do some simple blood tests, which are allowed by state laws, and that does vary from one state to the next.

But those are tests that we could do where we would be able to intervene and collaborate with prescribers to adjust therapies more appropriately.

However, as it is right now, we do not have the capacity to

be able to be able to bill for services like that, which would be very simple and very timely interventions to help increase -- you know, increase the patient getting to a location where their -- where the therapy is adjusted in a more timely manner.

Mr. Guthrie. Okay. Thank you.

And some of the questions I also have you touched on in your opening statement -- your 5 minutes. But I think you said at the end you wanted, hopefully, a chance to elaborate.

So I am going to ask some questions, because you kind of addressed that you would maybe get a chance to elaborate. You have already talked about the role that pharmacists play under the current MTM program.

Could you talk about how the role could potentially change under the MTM model test out of CMS?

Mr. McCullough. I think that through that you are going to see some different changes just by the new models that come forth and what I expect to see is just a number of different strategies used to identify different groups of patients, groups that will be more responsive.

You know, I think that that is one of the biggest things that we can get out of this is to be able to demonstrate that earlier action through more appropriate patient identification would be -- would be one of those things to look for.

Whenever we are able to intervene earlier in the disease

process I fully believe that we can change the trajectory of that disease progression to the benefit of the patient.

You know, through that I can see pharmacists getting involved and doing a number of different additional things. You know, some of the low-hanging fruit will be, you know, assessments to make sure immunizations are up to date, you know, with more regularity.

I think there is a number of things like that that you will see come to light.

Mr. Guthrie. Okay. Thanks.

I know that pharmacists and pharmacies particularly played an instrumental role implementing the Part D program.

Has the role of the pharmacy changed since the introduction of Medicare Part D?

Mr. McCullough. You know, it is interesting. When I was talking with Mr. Kocot here before we started and I was dispensing when Medicare Part D was implemented and that was an interesting time, it was great because we were able to get more people accessed to medications that, you know, in December of 2005 there were different conversations than there were in January of 2006.

Since that time, what we have seen is we have seen pharmacists become more instrumental in educating beneficiaries around their benefit -- their benefit design.

But additionally you have seen the role of the pharmacist expand through the advent of MTM services that was brought through

with Medicare Part D.

But also we have seen a rapid expansion in the last 10 years with immunization services that are provided in the community setting.

You know, 10 years ago it was -- there was a limited number of states and now, I believe, every state in the union offers some level of significance with pharmacy-based immunizations.

Mr. Guthrie. Thank you. I just have a few -- about 30 seconds.

You said -- 30 seconds for an answer -- when Mr. Pitts talked to you, you talked about the benefits of the MTM program. What are some of the challenges you have seen in trying to implement or -- at Rite Aid?

Mr. McCullough. We contract with whoever we can because we want to provide service to whoever we can, and I believe Mr. Merritt made the comment that some of the challenges is when you are reaching out the patients to get them to enroll there is some resistance, there is some hesitancy, one, because they are not aware of the benefit.

They don't know what all is entailed with that. They consult with the physician who says, I am not sure about what is going on.

I would even suggest that there is some community-based resources such as senior centers that I have heard specific

examples of that would say hey, if somebody calls you with something that sounds too good to be true it might be too good to be true.

So, you know, I think there is a huge opportunity to drive awareness with that population as to this is something that you may have as a benefit and if you have a benefit you should very much take advantage of that and then, additionally, working with other members of the health care team to make sure that you have their buy-in and endorsements and support.

Mr. Guthrie. Well, thank you. Thank you for those answers.

My time has expired. I yield back.

Mr. Pitts. Chair thanks the gentleman.

I now recognize the gentleman from New York, Mr. Collins, 5 minutes for questions.

Mr. Collins. Thank you, Mr. Chairman.

Maybe to follow up a little bit on what Mr. Guthrie was getting at, and maybe what you said a little bit, Mr. McCullough.

Motherhood and apple pie -- I mean, this, on the one hand, sounds like that. I mean, you have got Democrats and Republicans here universally agreeing anything we can do to help patients treat their diseases better, save money at the same time both for the federal government and plans. If that is not motherhood and apple pie I don't know what is.

So it comes back to, you know, the question of how do we get

more plans involved, how do we get more beneficiaries involved and maybe at some point confirming the cost benefit is real and it is not so nebulous that it is manipulated.

But one particular question for Mr. Kocot, I think your written testimony anyway said basically there is not a lot of incentive -- financial incentive -- for plans to enter the MTM.

But, you know, on the star bonus payments, as I understand it anyway, one of the quality measures is drug related.

So if have at least understood from some in the industry that the MTM plans have helped them in that particular criteria within their -- to get their star ratings up, would you comment on that, Mr. Kocot, whether you agree or not that --

Mr. Kocot. Sure. As you know, the financial rewards of the star ratings go to the MAPDs and the prescription drug plans do get a star rating. But it is not as powerful because of the financial rewards that are associated with the star program for Part D.

So there is a different incentive. Certainly, they get a star ranking and they get that moniker next to their name as a plan. But that is certainly not as powerful as the financial incentives that the new model does establish for MTM.

Mr. Collins. So a question I asked earlier, the gentleman from CMS, was why not Medicare Advantage and why not Medicaid.

Now, the answer on Medicare Advantage was those companies

offering those plans they are already coordinating and integrating A, B and D and that there is really not the need for the incentive because they are already covering the costs.

Would you agree with CMS's position that an MTM pilot or an MTM program would not really be cost advantageous to the taxpayers in the Medicare Advantage world because it is already being done?

I mean, is that -- and anyone who might want to jump in on that?

Mr. Kocot. I will start. I think what Mr. Gronniger was trying to say was that the incentives are aligned more fully in the Medicare Advantage program than they are in Part D and I thought I heard him say that we want to experiment with Part D and if things look like they are effective we could try to adopt more for the Medicare Advantage program.

I don't think he ruled it out. But I think this is a good place to start because the contrast is very stark. The incentives are totally misaligned in Part D for a plan to invest in better care because it just doesn't -- there is no financial reward.

Mr. Collins. Would the others agree with that?

Mr. Merritt. Yes, I would agree with that.

I mean, the reality is because the MTM current setup is so inflexible there just hasn't been a lot of information. There is not a lot of data.

There is not a lot of outcomes reports on it and the

assumption is the Medicare Advantage plans they have better access and reasons to be able to get there.

The stand alones, clearly, can't get there. They don't have the incentives. They need this kind of support and I do think it is a good place to start.

Mr. Collins. One last question, as my time expires here.

Is there a geographic area in the country that seems to have adopted MTM more than others and, if so, why and what have they found?

Or is this kind of a difficult issue across the whole country? Or is there any early adapters that you can think of? Not really?

Mr. Kocot. We have some anecdotal evidence that MTM has taken hold in certain communities. But I don't have any real evidence to offer you that MTM is more prevalent in one plan versus another or in one geographic area versus another.

I think it comes back to that issue of incentives and all Part D plans have to live within the same rules.

Mr. Collins. So, really, where we might wish upon a star even that this was being better adapted by patients and plans, it is -- what you are referring to, the incentive piece and maybe the hard evidence of cost benefit analysis and it also sounds like really almost an educational piece wouldn't hurt and into even the community where, you know, you stress, patient safety -- somebody is taking 19 drugs, you got to figure there could be an

issue there somewhere and if the patient is going back, you know, it is push pull.

So anyway, thank you for your testimony and with that, Mr. Chairman, I yield back.

Mr. Pitts. Chair thanks the gentleman. I now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. Griffith. Thank you very much, Mr. Chairman.

Mr. Merritt, it is evident that the utilization of the Part D MTM program has been low since its inception. There may be a number of reasons for that.

But one might be that Part D plan set an unreasonably high eligibility criteria for covered beneficiaries. Why is it that most plans require three or more chronic conditions and eight or more prescription drugs?

Mr. Merritt. Well, I mean, we comply with what is in the MTM statute right now. So there is certainly, I would say, within our industry the certainty and intention to make this work.

It is just very difficult to make it work when you have to have uniform services for every single person regardless of their needs, their interest in the program, their receptivity, what drugs they are taking and so forth.

So it is in our interest to see this thing work. It has just been structured in a way where it is just difficult to work and not just from our perspective.

I think everybody here, all the different stakeholders would say for different reasons it is very hard to get this off the ground the way it has been.

We are hopeful, though, with the CMMI model that those barriers will be removed and I think all the stakeholders here think there is a really good chance of success if we let this program work.

Mr. Griffith. So you don't think that the high barriers are causing a problem at this point or they are not designed to reduce the number of folks who take advantage of it?

Mr. Merritt. No. I don't concede that there are high barriers. I just concede we are complying with what the standards are right now. And one of the good things about the standards with the CMMI program is it is reducing the number of conditions that make somebody eligible for this program.

So there may be somebody with one condition that makes them eligible. There may be somebody with two. So it is in our interest to make sure that the utilization is done right and I think the challenge for all of us just hasn't been the incentive or the structure to make it work yet.

Mr. Griffith. All right. Dr. Benson, you wanted to get in on this.

Dr. Benson. Yes. No, I agree that the issue is multi factorial but I definitely support allowing single chronic

conditions to be an eligibility criteria.

As a representative of the American Heart Association, hypertension is one of the most common as well as treatable conditions that can decrease a lot of deaths in this country and that is a single condition, as well as diabetes.

We have talked about that today is also a single chronic condition. So I definitely advocate that as a representative of the American Heart Association, allowing individuals with a single chronic condition to also be eligible for the program.

Mr. Griffith. Okay, and I appreciate that.

Also, Mr. Merritt, the Pharmaceutical Care Management Association has stated that expansion of MTM eligibility would result in increased costs to the plans and therefore could lead to increased beneficiary premiums and costs to the federal government without adding any clear value to the program.

Do you disagree with that? And then if you do what would you say to those who argue that well run MTM programs can result in reduced prescription drug prices as found by CMS when they studied the Part D MTM program?

Mr. Merritt. Sure. I mean, that statement is true if there aren't the economic incentives to get the job done right.

Right now, with the way the medical loss ratio calculations are calculated, any additional innovative things that we do on MTM are counted as administrative costs, not medical costs, which

punish the plans and force some to give rebates.

And so with economic incentives not only do we have a reason to pursue this without having to sacrifice premiums or access to drugs and so forth but if it is set up this way where it is outside of the whole MLR calculation we have every incentive to really go for it and use all the innovative tools we have to make it work.

Mr. Griffith. I appreciate that. Appreciate all of you all being here today, and with that, Mr. Chairman, I yield back.

Mr. Pitts. The chair thanks the gentleman. That concludes the questions of the members present. As always, we will have follow-up questions and members who couldn't be here will have questions.

We will submit those to you in writing. We ask that you please respond promptly. I remind members that they have 10 business days to submit questions for the record. Members should submit their questions by the close of business on Wednesday, November the 4th.

Excellent hearing. Excellent testimony. Good program with bipartisan support and we look forward to progress that we will be making on this issue.

So without objection, the subcommittee is adjourned.

[Whereupon, at 12:24 p.m., the subcommittee was adjourned.]