

EXAMINING THE MEDICARE PART D MEDICATION THERAPY MANAGEMENT PROGRAM

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FOURTEENTH CONGRESS FIRST SESSION

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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, DC.

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.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. Ladies and gentlemen, I ask all of our guests to please take their seats.

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, caregiver 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.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The Subcommittee will come to order.

The Chairman will recognize himself for an opening statement.

Today's hearing will examine the Medication Therapy Management (MTM) program, 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, caregiver 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 pharmacists 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.

I will now yield to the distinguished gentlelady from Washington, Rep. Cathy McMorris Rodgers.

Mr. PITTS. 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.

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

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 the 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 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 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 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 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 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 prescribers.

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:]

STATEMENT OF

TIM GRONNIGER

DIRECTOR OF DELIVERY SYSTEM REFORM
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

“EXAMINING THE MEDICARE PART D
MEDICATION THERAPY MANAGEMENT PROGRAM”
BEFORE THE

U.S. HOUSE COMMITTEE ON ENERGY & COMMERCE
SUBCOMMITTEE ON HEALTH

OCTOBER 21, 2015

U.S. House Committee on Energy & Commerce
Subcommittee on Health
“Examining the Medicare Part D Medication Therapy Management Program”
October 21, 2015

Chairman Pitts, Ranking Member Green, and members of the Subcommittee, thank you for the invitation and the opportunity to discuss the Center for Medicare and Medicaid Innovation’s (CMS Innovation Center) Part D Enhanced Medication Therapy Management (Enhanced MTM) model. This model will test strategies to improve medication use among Medicare beneficiaries enrolled in Part D. Medication therapy management (MTM), when implemented effectively, can improve health care quality and outcomes for patients and has the potential to lower overall health care costs. We appreciate the Subcommittee’s continued interest in improving Medicare beneficiaries’ access to quality, affordable, and well-coordinated health care.

Earlier this year, Health and Human Services Secretary Burwell announced measurable goals and a timeline to move the Medicare program, and the health care system at large, toward paying providers based on the quality, rather than the quantity of care they give patients. This initiative will ultimately create a payment environment that appropriately promotes and rewards better care management for persons with chronic illness. The CMS Innovation Center supports the development and testing of innovative health care payment and service delivery models and serves as a key component of CMS’s efforts to improve the health care delivery system.

Last month, CMS announced a model to test strategies to improve medication use among Medicare beneficiaries enrolled in Part D by extending and enhancing the use of MTM. MTM generally refers to activities meant to improve health outcomes by ensuring that patients are taking their medications safely and as prescribed, addressing any barriers to their doing so, and bringing any medication issues to the attention of the treating physician. MTM can improve health care and outcomes for patients and has the potential to lower overall health care costs. The Enhanced MTM model will assess whether providing selected stand-alone Medicare Prescription Drug Plans (PDPs) with regulatory flexibilities and an alternative payment methodology to realign financial incentives to design and implement innovative programs will

better achieve Medicare's original vision for MTM programs. Through this model, Part D plans will improve their investment in medication therapy management and identify new, effective strategies to optimize medication use and improve care coordination across Medicare.

Medication Therapy Management in Part D

The Medicare Modernization Act (MMA), which created the Part D program, required that every Part D plan offer an MTM program as a quality improvement feature.

MTM programs can generate cost savings and result in improved outcomes for patients in a variety of ways. Evidence has shown MTM can improve medication adherence^{1,2,3}, which is associated with medical cost savings even when accounting for changes in drug expenditures. MTM can also help to ensure that medications are taken properly and adverse drug events are avoided, particularly when new or high-risk medications are initiated, resulting in improved care for beneficiaries and savings from reduced hospitalizations and emergency department use. Improved accuracy of medication administration can both improve outcomes and reduce waste, especially for high-cost drugs where therapeutic goals may not be achieved and expensive regimens may have to be repeated if medications are not taken correctly. MTM programs also can improve the appropriateness of prescribing, ensuring that beneficiaries are receiving evidence-based therapies appropriate for their condition, potentially reducing complications and unnecessary medical costs in order to improve beneficiary outcomes. Finally, MTM can help to identify and eliminate duplicative therapies, as well as identify opportunities to switch to similar, lower-cost medications, both of which can reduce prescription drug costs.

Currently, Part D statutory and regulatory MTM provisions require uniform service offerings to enrollees who meet the plan's program criteria, based on numbers of medications, chronic conditions, and expected annual prescription drug costs. These criteria may lead to some beneficiaries who don't benefit from MTM being included in the programs, while missing some

¹ Carter BL, Arderly G, Dawson JD, et al. Physician and pharmacist collaboration to improve blood pressure control. *Archives of Internal Medicine* 2009;169:1996–2002.

² Carter BL, Rogers M, Daly J, et al. The potency of team-based care interventions for hypertension: a metaanalysis. *Archives of Internal Medicine* 2009;169:1748–55

³ Odum L, Whaley-Connell A. The role of team-based care involving pharmacists to improve cardiovascular and renal outcomes. *Cardiorenal Medicine* 2012;2:243–50.

beneficiaries who would benefit from MTM programs. The result is that Part D MTM programs may not always include the level of resources nor the type of activities that could have the greatest positive effect on beneficiary outcomes.

At the start of the Part D program, we believed that 25 percent of enrollees would qualify for MTM services. While CMS has made changes to the MTM program over the history of the Part D program in an effort to improve the efficacy of and beneficiary participation in the program, MTM program participation remains very low. Moreover, additional evidence that the program improves quality and generates medical savings⁴ supports the belief that more than 25 percent of enrollees could benefit from MTM services. In the 2010 Call Letter⁵ and subsequent regulation, we modified the criteria to reduce the variability in eligibility and level of service and to improve access to MTM services.

Enhanced MTM Model

On October 2, 2014, CMS released a Request for Information (RFI)⁶ seeking comments from stakeholders on potential models to test innovations related to plan design, care delivery, beneficiary and provider incentives, and/or network design in Medicare Advantage PDPs and other areas where Medicare works with health plans to provide care to beneficiaries. CMS received about 60 responses to the Part D section of the RFI. Stakeholders supported using MTM as a strategy to improve patient care, but noted that marketplace realities and current regulations disincen stand-alone basic PDPs from providing MTM beyond the level required for regulatory compliance.

CMS also convened a Technical Evaluation Panel (TEP) to explore these issues in November 2014, which included industry experts from the fields of prescription drug plan insurance design and operations, retail and specialty pharmacy, MTM clinical services delivery and support, behavioral health economics, and physician medical management. These participants supported the view that better alignment between Part D sponsors and Medicare financial interests

⁴ http://innovation.cms.gov/files/reports/mtm_final_report.pdf

⁵ <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/2010CallLetter.pdf>

⁶ <http://innovation.cms.gov/files/x/hpi-rfi.pdf>

combined with the flexibility to better focus resources on individuals at risk of medication-related issues could yield measurable improvements in the quality of MTM programs, patient care, health outcomes, total costs of care, and beneficiary and provider satisfaction.

Section 3021 of the Affordable Care Act (codified at Section 1115A of the Social Security Act) established the Innovation Center for the purpose of testing “innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care” for individuals covered by Medicare, Medicaid, or the Children’s Health Insurance Program.” Starting in 2017, CMS intends to implement a voluntary model test with five performance years under this authority that will assess whether providing Part D sponsors with additional financial incentives and MTM regulatory flexibilities better achieves the key goals of MTM— better health outcomes through improved medication use, and reduced risk of adverse events, including adverse drug interactions—while reducing net Medicare expenditures.

The Enhanced MTM model features a combination of regulatory flexibilities and an alternative payment methodology to realign financial incentives for basic standalone PDPs. Key elements of this model include:

- The ability to offer different MTM services to individual enrollees based on their level of medication-related risk, with interventions tailored to those enrollees’ specific barriers to improvement;
- The ability to offer a more expansive set of MTM related items and services, as well as cost sharing assistance to financially needy beneficiaries;
- The flexibility to experiment with alternative communication strategies to improve beneficiary, pharmacist and medical provider coordination and engagement;
- A plan-specific prospective payment to support more extensive MTM interventions that will be outside of a plan’s annual Part D bid and will therefore not impact plan premiums;
- The opportunity to qualify for a performance payment in the form of an increased beneficiary premium subsidy (in a future year) for plans that successfully achieve a two percent reduction in expected beneficiary fee-for-service (FFS) expenditures (net of model prospective payments);

- The ability to request beneficiary-level Parts A and B claims data and potentially Accountable Care Organization (ACO) alignment information from CMS to assist with identification and care coordination of individuals at risk of medication-related problems; and
- A new MTM encounter data collection effort leveraging existing work by industry experts to develop MTM-specific code sets, which will support the vision of the Office of National Coordinator for Health Information Technology (ONC) for prescription drug data interoperability.

Pharmacy and Pharmacist Role

CMS is granting basic, stand-alone PDPs the flexibility to design enhanced MTM programs that incorporate interventions beyond the standard MTM programs under Medicare. As a result, plans may propose an expanded range of MTM activities, including contracting with pharmacists to provide enhanced engagement or other services. Any financial compensation to pharmacists under this model would be provided by the participating PDP or contracted vendors, not CMS. CMS believes that pharmacists serve a vital role in ensuring that Medicare beneficiaries receive and properly use the prescription drugs upon which they rely. The Enhanced MTM model aligns financial incentives and grants flexibility for basic, stand-alone PDPs to test MTM interventions that could include increased reliance upon the pharmacist as a trusted community resource to ensure that targeted beneficiaries are taking their medications accurately and appropriately.

Geographic Scope

CMS has selected specific regions in which to test this model. Regions were evaluated based on variation in market competition, the range of geographic, population, and market characteristics, and the range of Parts A and B spending variance. The model will be tested in 11 states (through five of the 34 existing Part D Regions).⁷ CMS selected this set of regions to allow for a sufficiently powered model test with comparison regions and to be (in aggregate) broadly representative of national market characteristics. We grouped regions based upon characteristics

⁷ Selected Regions: Region 7 (Virginia), Region 11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona).

that would maximize generalizability of results to a national population, *e.g.*, geographic diversity, population size, number of Part D plans, and enrolled populations.

Eligible standalone PDPs in these regions can apply to vary the intensity and types of MTM interventions they offer based on beneficiary risk level and seek out a range of strategies to individualize beneficiary outreach and engagement. Interested organizations must apply to participate by response to a Request for Applications (RFA). CMS intends to release the RFA in the fall of 2015 through the Health Plan Management System. CMS will review applicants' proposed interventions and justifications to ensure that they meet a minimum threshold of clinical plausibility, are consistent with the utilization assumptions in the actuarial estimates, and that they are not likely to lead to adverse or unintended consequences.

CMS will waive current MTM program requirements for participating plans in the test regions during the performance period. Participating plans, which are limited to plans offering a basic benefit, are expected to work closely with their network pharmacy providers and local prescribers to accurately identify enrollees whose medication usage has caused, or is likely to cause, adverse outcomes and/or significant nondrug program costs. Enrollees who are identified will be contacted by their drug plans, pharmacists, or prescribers and offered targeted assistance in order to optimize medication use and avoid any medication-related problems.

Beneficiary Benefits and Protections

The model has been carefully designed to protect beneficiaries. PDPs in this model can only offer MTM-related items or services or lower cost sharing for financial need to targeted beneficiaries and cannot restrict benefits or raise cost sharing to discourage use of medically necessary prescription drugs as a model intervention. Participating PDPs will be expected to continue to meet all other non-waived current standards required by the Medicare program, including grievance and appeal processes. Eligible beneficiaries who do not want the Enhanced MTM items or services may opt out of any offered assistance at any time.

Monitoring and Evaluation

CMS will closely monitor model implementation, to ensure that model interventions are consistent with model rules and plan proposals, that additional model funding is being used for the appropriate purpose, and that the model is not leading to any adverse beneficiary outcomes. New MTM encounter data will be utilized to both monitor ongoing compliance with approved intervention plans and assess whether the plan interventions are correlated with outcomes such as mortality, emergency department utilization, hospital readmissions, or beneficiary satisfaction measures.

The independent evaluation will include the collection and analysis of qualitative and quantitative data in order to understand the context of the programs and to capture the nuances occurring at the sites. For the quantitative analyses, a longitudinal case-control study design will be used. Three years of pre-model data will be compared with three to five years of performance data collected at quarterly and annual increments during the model. Similar Part D plans that are not selected to participate in the model will be included in the comparison group. These comparison group plans will be selected to match the participating Part D plans along a variety of measurable dimensions, including but not limited to patient and market-specific characteristics.

Fee-For-Service Medicare beneficiaries enrolled in participating stand-alone basic PDPs may also be enrolled in other integrated care models, such as Next Generation ACOs, MSSP, and CPCI. CMS believes that this model will be complementary to, rather than duplicative of, ACOs and other integrated care models. PDPs and their pharmacy networks represent a new way of integrating pharmacists into the integrated care team, bringing additional core competencies, as well as opportunities for encountering and interacting with beneficiaries in different settings. We expect that sponsors may target some high-cost beneficiaries who may be experiencing difficulty managing their health conditions, but will more likely intervene with somewhat lower-cost beneficiaries at risk of becoming high cost given their drug regimens, adherence patterns, and health conditions. The performance-payment benchmark will be constructed using a matching procedure that takes into account beneficiaries' alignment to other Innovation Center and non-

Innovation Center programs in order to ensure that savings are not inappropriately attributed to the Enhanced MTM Model.

Conclusion

CMS believes that the Part D MTM Model will give PDPs stronger incentives and flexibility to improve prescription drug safety and efficacy. CMS looks forward to working with PDPs, pharmacists, 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 you may have on the Part D MTM Model.

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 five Part D regions selected for inclusion?

Mr. GRONNIGER. 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 five regions that are selected 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 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 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 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 use a risk-based approach to identify beneficiaries who need the project, who need the intervention the most, identify interventions that will sup-

port 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 "enhanced and individualized MTM strategy" 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 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.

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 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. 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 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 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 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 the important beneficiary services.

On the other hand, one of the drawbacks of any demonstration project is it is 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 getting plans to apply and to getting the process stood up for 2017.

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 will discuss with them.

I would also emphasize that even though the model is slated to run for 5 years 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 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 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 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 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.

As a result, they are visiting their pharmacist and the pharmacist 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 the pharmacy community, especially the independents and some of the chains, 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 underserved areas?

So 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 the back end?

Mr. GRONNIGER. Yes.

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 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 underserved areas. Sometimes they are the same but sometimes underserved areas could be in some metropolitan areas too where there is, we call those deserts for food and nutrition but I think that is true 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 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. OK. 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 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. OK. 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 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 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 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 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. 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 underserved 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, and particularly for acetaminophen, can be a really bad interaction problem—

Dr. MURPHY. OK.

Mr. GRONNIGER [continuing]. 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 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 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 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 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. OK. 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 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. OK. 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? 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 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—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 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 get the specific projects proposed by plan sponsors. 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, 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 Medicare benefit Parts A, B and D. Part D plans only have responsi-

bility for the drug part of the benefit. So 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 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 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 I would be happy to talk further about whether it makes sense to try to expand that.

Mr. COLLINS. And is this a 7-year program, as I understand it, this pilot?

Mr. GRONNIGER. It is a 5-year intervention with an extra 2 years run out to provide the premium subsidy for plans that perform well in the fifth year.

Mr. COLLINS. OK. 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 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 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 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 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 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 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 three or four pills in the other one and switch to the new bottle and those medicines are lost.

So in the long run, 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."

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 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 less than the current standards then that they can justify. But there is no incentive in place that can support that.

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, because, obviously, cost is the most relevant thing?

Mr. GRONNIGER. Yes.

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

And 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 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 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 a minority of the population nationwide but a nontrivial minority.

Mr. ENGEL. OK. 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 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. OK. 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 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 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, what is the need for this innovation model?

Mr. GRONNIGER. So we think that the Medication Therapy Management program to date hasn't delivered the benefits that we and others and Congress were intending 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. OK. And then 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. OK. 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 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 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 so everything that counts against them on the administrative side is something that they feel acutely.

By providing the ability to 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 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 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 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 in activities that are known to improve quality.

So 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 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 appears at the conclusion of the hearing.]

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.

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 LAWRENCE 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 the Medicare Part D 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:]

**Examining the Medicare Part D Medication Therapy Management (MTM)
Program:
Improving Medicare MTM for the Future**

Statement of
S. Lawrence Kocot
Principal and National Leader
Center for Healthcare Regulatory Insight
KPMG, LLP

Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
October 21, 2015

Chairman Pitts, Ranking Member Green, and distinguished members of the Subcommittee, thank you for this opportunity to testify on the Medicare Part D Medication Therapy Management (MTM) Program.

As Senior Advisor to the Administrator of the Centers for Medicare and Medicaid Services (“CMS”) during the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (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. Additionally, I was the project leader for the technical expert panel that was convened by the Brookings Institution and the MITRE Corporation to inform the development of the Part D Enhanced MTM Model recently announced by Center for Medicare and Medicaid Innovation (“CMMI”) at CMS.

The Medication Therapy Management Program in Medicare Today

The MMA amended the Social Security Act to provide a voluntary prescription drug coverage program for Medicare beneficiaries. As a result, subsidized prescription drug coverage has been available to Part D eligible Medicare beneficiaries through Medicare Advantage (“MA-PD”) or through a stand-alone PDP under Part D since January 2006. Today, nearly 40 million Medicare beneficiaries are enrolled in a Medicare-sponsored plan that provides prescription drug coverage, with approximately 24 million Medicare beneficiaries accessing their prescription drugs through a stand-alone prescription drug plan (PDP).¹

¹ Centers for Medicare and Medicaid Services. Medicare Advantage/Part D Contract and Enrollment. Monthly Contract Summary Report. October 2015. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics->

The value of providing Medicare beneficiaries with access to affordable prescription drugs has been recognized in numerous studies, as well as by the federal government. In 2012, the Congressional Budget Office (CBO) recognized the budgetary impacts of effective medication use by Medicare beneficiaries. They concluded that a “1 percent increase in prescription drug use would cause spending for medical services to fall by roughly one-fifth of 1 percent; likewise, a 1 percent decrease in prescription drug use would cause medical spending to increase by roughly one-fifth of 1 percent.”²

In a study published last month in the journal *Health Affairs*, researchers at RxEconomics LLC, a policy consulting firm, analyzed data on more than 1.5 million adults and children enrolled in fee-for-service Medicaid programs in 11 states to estimate the effect of medications to treat eight chronic non-communicable diseases. About 25 percent of beneficiaries studied were blind or disabled adults, 11 percent were other adults, and 64 percent were children. The researchers found that a 1 percent increase in overall prescription drug use was associated with decreases in nondrug Medicaid costs by 0.108% for blind or disabled adults, 0.167% for other adults, and 0.041% for children.³ The paper also reported that prescription drug use was highest among blind and disabled adults, with approximately 50 prescriptions filled per year, compared to just 20 per year for adults and 6 per year for children. The authors believe that their findings complement the CBO’s previous estimates, and more

[Trends-and-Reports/MCRAAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report-Items/Contract-Summary-2015-10.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending](https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf)

² Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare’s Spending for Medical Services. November 2012, pg. 4 <https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>

³ Roebuck MC, Dougherty JS, R Kaestner, and LM Miller. Increased Use Of Prescription Drugs Reduces Medical Costs In Medicaid Populations. *Health Affairs*, 2015; 34(9):1586-1593.

importantly, suggest that greater drug use can potentially lead to cost reduction for other types of medical care.

Although effective medication use can prevent or address acute and chronic illnesses and improve beneficiary health outcomes and reduce overall health care costs, prescription drugs are very often used inappropriately or sub-optimally, leading to adverse drug events, unnecessary hospitalizations, and other unintended health outcomes.

Through the MMA, Congress required that all Part D plans provide an MTM program so “that covered part D drugs... are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug events, including adverse drug interactions...”⁴ CMS has indicated that MTM should be a “patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence.”⁵

Medicare Part D Plan sponsors are required to incorporate an MTM program into their plans’ benefit structure.⁶ CMS requires Plan sponsors to account for MTM program services provided to targeted beneficiaries as an administrative cost (included in the plan bid), incident to appropriate drug therapy, and not an additional benefit.⁷

⁴ Pub. L. 108-173. Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Sec. 1860D-4 (c)

⁵ Center for Medicare. “CY 2015 Medication Therapy Management Program Guidance and Submission.” 7 May 2014, pg. 4. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoContractYear2015MedicationTherapyManagementProgramSubmission050714.pdf>

⁶ Centers for Medicare and Medicaid Services. “Medication Therapy Management.” <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/mtm.html>

⁷ Center for Medicare. “CY 2015 Medication Therapy Management Program Guidance and Submission.” 7 May 2014. <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoContractYear2015MedicationTherapyManagementProgramSubmission050714.pdf>

MTM services must be delivered by qualified health care professionals, including pharmacists, to targeted beneficiaries with multiple chronic conditions (sponsor may require two, but no more than three chronic conditions); who are taking multiple medications (sponsor may set minimum number between two and eight Part D drugs); and, who are likely to incur annual costs above a predicted level for that plan year (\$3,138 in 2015).⁸ Currently, CMS requires plan sponsors to offer a minimum level of MTM services to each beneficiary enrolled in the program that includes⁹:

1. Interventions for both beneficiaries and prescribers;
2. An annual comprehensive medication review (CMR) with written summaries in CMS' standardized format (must include an interactive, person-to-person, or telehealth consultation with the beneficiary or beneficiary's prescriber, caregiver, or other authorized individual performed by a pharmacist or other qualified provider, and may result in a recommended medication action plan) and;
3. Quarterly targeted medication reviews (TMRs) with follow-up interventions when necessary.

Part D plan sponsors must auto-enroll the targeted beneficiaries in MTM when they meet the eligibility criteria, and beneficiaries are considered enrolled unless they decline enrollment. The enrolled beneficiaries may refuse or decline individual services without having to disenroll from the MTM program.

⁸ Ibid.

⁹ Centers for Medicare and Medicaid Services. "2014 Medicare Part D Medication Therapy Management (MTM) Programs." Fact Sheet: Summary of 2014 MTM Programs. August 21, 2014.
<https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/cy2014-mtm-fact-sheet.pdf>

Challenges and Barriers to Success

Although many believed the MTM program would optimize the value of pharmaceutical use for Medicare beneficiaries enrolled in Part D, the program has not lived up to expectations. In a 2012 letter to all Part D plan sponsors, CMS recognized that “To date, it has not been possible to fully demonstrate the value and success of Part D MTM programs,” and vowed to collect additional data to better understand the level of MTM services received by targeted beneficiaries and to monitor outcomes.¹⁰

In an analysis published by Acumen LLC in August 2013, researchers found evidence that high performing MTM programs consistently and substantially improved medication adherence and quality of prescribing for important medications treating certain conditions (i.e., CHF, COPD, and diabetes). However, the same research indicates that there is substantial variation in performance across Part D parent organizations.¹¹

Despite uncertainty about the real impact of MTM for Medicare beneficiaries, in a proposed rule released at the beginning of 2014, CMS proposed to expand the MTM program by: (1) reducing the minimum number of chronic conditions required for MTM eligibility to two; and, (2) requiring a minimum of only two prescription medications with a total drug spend of \$620 per year for a beneficiary to qualify for mandatory MTM under Part D.¹² Although a number of organizations, including the American Pharmacists Association supported the

¹⁰ Centers for Medicare and Medicaid Services. “CY2013 Part D Reporting Requirements – Request for Comments” January 13, 2012. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/RegforCommentson2013ReportingRequirements_01102012.pdf

¹¹ Acumen LLC. Medication Therapy Management in Chronically Ill Populations: Final Report. August 2013. http://innovation.cms.gov/files/reports/mtm_final_report.pdf

¹² 79 FR 1917 “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” 1917 -2073.

expansion,¹³ MedPAC expressed concern about the expansion in its April 2014 report to Congress, noting “although the program has the potential to increase the quality of pharmaceutical care provided under Part D, we currently do not have sufficient data to determine how well it is working.”¹⁴

In response to public comments, CMS announced in May 2014, that it would not finalize the proposed rule revisions to eligibility that would have expanded the current Medicare MTM program. However, CMS noted that additional improvements for the program were still needed to address underperformance in the program:

“MTM has been shown to improve drug therapy outcomes and lower costs, and we agree that the use of community-based resources for providing MTM services shows promise in improving access and quality. We still have concerns that many sponsors are applying restrictive criteria to narrow the pool of targeted beneficiaries for MTM rather than optimizing the eligibility criteria to offer MTM to beneficiaries who will most benefit from these services. These programs are not living up to our expectations.”¹⁵

Aligning Incentives with Expectations for the Medicare MTM Program

Recognizing that the current MTM program should not be expanded without addressing some of the underlying issues that have hampered its success, CMMI, through a contract with

¹³ APhA supports MTM expansion in Part D proposed rule. April 1, 2014. <http://www.pharmacist.com/apha-supports-mtm-expansion-part-d-proposed-rule-0>

¹⁴ Medicare Payment Advisory Commission. “Report to Congress: Medicare Payment Policy” March 2014. http://medpac.gov/documents/reports/mar14_entirereport.pdf

¹⁵ 80 FR 7911. “Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.” 7911 -7966.

the MITRE Corporation and the Brookings Institution, convened a technical expert panel (TEP) to explore some of the major barriers to MTM program advancement. The TEP met in the fall of 2014 to inform the creation of the recently announced Enhanced Medication Therapy Management Model.

As a result of discussions with the TEP and consultations with a broader set of stakeholders, CMS observed that, rather than committing to the promise of MTM with substantial time and attention, 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. As a result, proactive approaches to improve care for Part D beneficiaries are neither incentivized nor rewarded by the current MTM program; rather, the emphasis is on procedural processes tied to CMRs and TMRs in order to meet uniform compliance standards for all patients. Similarly, the process of identifying beneficiaries for interventions is largely formulaic and fails to give plan sponsors the flexibility to deliver the right services to the right patients; beneficiaries are both over-identified and under-identified as “at risk” for experiencing medication-related issues. This formulaic targeting often results in a sub-optimal allocation of MTM resources, which diminishes the effectiveness of activities likely to have the greatest impact on beneficiary health outcomes.

Experts across the spectrum of plans, pharmacists, academics, and advocates have noted that the success of the MTM program is severely limited by a misalignment of financial incentives; they have also noted that plans that are responsible for a beneficiary’s broader health care needs, such as Medicare Advantage drug plans or private insurers, may be more effective at achieving the objectives of MTM because there is a financial incentive to do

so.¹⁶ As one stakeholder interviewed by Acumen observed, “Approximately 2/3 of Medicare enrollees select the standalone plan... [because] standalone plans are structured to keep drug costs down, immediately there is a major conflict with helping people get more medication [if non-adherent], even though doing so will ultimately lead to the most benefit, minimize the risk, and avoid downstream unnecessary medical visits and hospitalizations.”¹⁷

Given the lack of incentives for Part D sponsors to invest in more effective MTM, alignment of financial incentives could be an effective policy tool to motivate Part D plans, health care providers, and pharmacists to achieve more optimal MTM results and better health outcomes for Part D beneficiaries. Furthermore, better evidence is needed to understand how MTM is being used and what factors are most instrumental to its successful adoption and use.¹⁸ The recently announced Part D Enhanced MTM Model, set to launch in 2017 will be a critical first step for achieving these aims by aligning PDP sponsor and government financial interests. The Model promises to create incentives for more robust investment and innovation in better MTM targeting and interventions, providing flexibility to plans to better target the right interventions to the right patients, and helping to generate better evidence on how MTM can be more effectively deployed across the health care system.

¹⁶ Rucker, Lee. Medicare Part D’s Medication Therapy Management: Shifting from Neutral to Drive. AARP Public Policy Institute. http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/medicare-part-d-shifting-from-neutral-to-drive-insight-AARP-ppi-health.pdf

¹⁷ Acumen LLC. Medication Therapy Management in Chronically Ill Populations: Final Report. August 2013, at 131. http://innovation.cms.gov/files/reports/mtm_final_report.pdf

¹⁸ A November 2104 Agency for Healthcare Research and Quality (AHRQ) reinforced the need for better evidence. In an examination of 44 studies on the impact of MTM, AHRQ found evidence that MTM results in improvement when compared with usual care for some measures of medication adherence and appropriateness; medication dosing; health plan expenditures on medication costs; and, for patients with diabetes, the proportion hospitalized and costs of hospitalization. However, AHRQ concluded that the evidence is “insufficient for most other outcomes because of inconsistency in direction, magnitude, and precision, rather than lack of evidence.” Agency for Healthcare Research and Quality. “Medication Therapy Management Interventions in Outpatient Settings.” Comparative Effectiveness Review, Number 138. <http://effectivehealthcare.ahrq.gov/ehc/products/516/2002/medication-therapy-management-report-141114.pdf>

The Part D Enhanced MTM Model

As noted in the announcement by CMMI, the Part D Enhanced MTM Model has three major elements:¹⁹

1. Additional regulatory flexibilities to allow for more individualized and risk-stratified interventions;
2. A prospective payment for more extensive MTM interventions that will be “outside” of a plan’s annual Part D bid; and,
3. 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 through the model.

Enhanced and Individualized MTM Strategies

The first key feature of the new model is regulatory flexibility to permit PDP sponsors to risk-stratify the population enrolled in their plans based on medication-related risk and to allow different levels and types of MTM services, as well as cost-sharing assistance for financially needy enrollees who lack access to services.

- Plan sponsors will be required to produce written plans for their proposed protocols on how they will target beneficiaries, but they will not be required to limit interventions to pre-defined beneficiary categories. They may choose to prioritize beneficiaries with chronic diseases where treatment and outcome are highly dependent on medication; but they could

¹⁹ Centers for Medicare and Medicaid Services. “Announcement of Part D Medication Therapy Management Model Test” <http://innovation.cms.gov/Files/x/mtm-announcement.pdf>

also target transitions of care, poly-pharmacy combined with multiple prescribers, frequent utilization of health care services, social support needs, or first fills of certain drugs with difficult side-effect or complication profiles.

- Flexibility could encourage more communication and create opportunities for medication adjustment on a more ongoing basis for those beneficiaries who need it, while allowing for lower-touch interventions to lower-risk patients who may not need the same intensity in intervention.
- Experimentation to individualize beneficiary and prescriber outreach and engagement is encouraged by the Model.

New Prospective Payment

Prospective payments will be calculated and paid on a per-member-per-month (PMPM) basis, to provide funding for enhanced benefits, items, and services, which could include pharmacy or beneficiary incentives or additional support for interoperable data exchange on MTM services. This funding will be provided outside of the plan bid (as opposed to a plan “administrative cost” included in the bid) to encourage investment and innovation in interventions. The final approved PMPM amount will be paid per enrollee in the plan, regardless of how many enrollees are receiving the enhanced MTM services.

- The actual cost of this PMPM payment will vary by plan and be determined by the specific interventions proposed by the plans.
- Plans will be required to detail their specific targeting and cost assumptions in their application in order for CMS to evaluate the reasonableness of their approaches.

New Performance-Based Payments

A retrospective performance-based payment will reward performance and successful data and quality reporting. Plans that demonstrate reductions in Medicare Part A and B costs of care for their members by a minimum of 2 percent (net of model prospective payments) relative to a performance-payment benchmark will receive a fixed \$2.00 per-member amount increase in the government subsidy to the plan premium, which will decrease the beneficiary's portion of the premium and make the successful plans more competitive in subsequent years.

- Performance results in year one (2017) will translate to performance-based payment/premium reduction in year three (2019), and likewise for the next two years.
- If performance-based payments are earned in years four and five, the sponsor will receive payments in years six and seven (2022 and 2023), after the end of the performance period. Plans will be required to satisfactorily report all required model data elements in order to qualify for the performance payment.

Additional Program Elements

CMS will develop new MTM-related data and metric collection requirements for both monitoring and evaluation purposes, which all plans will be required to meet as a condition of model participation. Quality indicators will be developed based on clinical significance and a clear link to improved outcomes, CMS also expects each plan sponsor to identify and propose its own metrics for internal protocols and learning systems.

- The model aims to incentivize strengthened linkage among sponsors, pharmacies, and prescribers to detect and prevent medication-related risks, including complementing and reinforcing ACO-provider-based clinical management. It encourages sponsors to involve prescribers and treating physicians in the MTM referral and consultation process, and suggests sponsors seek to engage pharmacies more extensively in the MTM process.
- CMS may provide access to data on beneficiary alignment with integrated care models such as ACO alignment records managed in CMS' Master Data Management (MDM) system. Medicare Part A and B data for enrollees would be made available to sponsors upon request for operations involving quality improvement and/or care coordination.

Next Steps and Potential Challenges Ahead

Greater regulatory flexibility and fundamental realignment of incentives for providing more robust and meaningful MTM through the Enhanced MTM 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. In particular, this could encourage plan engagement with more providers, including pharmacists and physicians, to more systematically 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, such as the Pioneer ACO Model, Next Generation ACO Model, and Medicare Shared Savings Program that are incentivized to deliver higher value care to Medicare beneficiaries;

this could play an important role in helping to move overall Medicare payments from volume to value in the coming years.

Although there could be tremendous potential benefits to a plan sponsors' participation in the new model, there are many considerations and questions that Part D sponsors will likely ask before participating in the model. First and foremost, plan sponsors will have to consider whether incentives in the model are sufficient enough to invest the time and effort in the new model. Specifically, will Part D sponsors be able to achieve the required Parts A and B cost reductions (net of the model prospective payments) to achieve a minimum savings rate of 2% in order to qualify for the performance payment? Part D sponsors will have to develop a comprehensive strategy for how their proposed program elements will improve patient care and drive more value-based prescription use in the context of all Medicare costs. This will require a clear vision from the plan leaders and a strategy that can be effectively translated to those delivering enhanced care to patients.

Plan sponsors will also need to consider whether the efficiencies of more appropriate drug utilization (reductions in overprescribing, duplication of therapy, etc.) will offset the possible competitive disadvantage of higher drug costs that could result from more effective MTM. Additionally, the actual return on investment of providing more advanced MTM services may not be known for years, just as the improved care may have unknown market impacts that could affect drug costs. Each plan will need to undertake an internal assessment of how the program could affect their financial bottom line relative to improvements in patient care.

Given the opportunity for performance-based payments, plan sponsors will likely also want to know more about how CMS will evaluate cost savings in Parts A and B that can be

attributed to MTM efforts. Identifying the impact of MTM on costs beyond Part D may be a challenge, so plans will be looking for additional guidance on how the impact of their efforts can be accurately reflected through savings generated through other medical costs.

Finally, quality reporting requirements have not yet been established for the program. CMS has indicated that quality measures will be based on clinical significance and a clear link to improved outcomes, such as percentage of patients who had medication reconciliation after a transition of care, percentage of patients who had MTM services post discharge and were readmitted to a hospital within 30 days, the percentage of clinically significant drug events resolved, and the proportion of targeted beneficiaries for whom the plan sponsor provided medication history to electronic health records (EHRs). Plan sponsors will likely want to know the scope of these requirements and any additional administrative burdens and costs necessary to meet them.

Conclusion

The Enhanced MTM Model demonstration has the potential to unleash greater innovation in the MTM program to provide a higher quality prescription drug benefit for Medicare Part D beneficiaries. Importantly, the Model will enable CMS to produce new evidence about the effectiveness of medication therapy management interventions that may be applied to the Medicare Prescription Drug Program more broadly. If the objectives of the

demonstration are achieved, an enhanced MTM program could add significant value to Medicare by improving the health outcomes of beneficiaries enrolled in Medicare Part D.²⁰

²⁰ Kocot SL. Realigning Medicare Part D Incentives: A New Model For Medication Therapy Management. *Health Affairs* blog. 28 September 2015. <http://healthaffairs.org/blog/2015/09/28/realigning-medicare-part-d-incentives-a-new-model-for-medication-therapy-management/>

Mr. PITTS. Chair thanks the gentleman.
Now I recognize Mr. Merritt 5 minutes for his summary.

STATEMENT OF MARK 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 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. 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:]

Testimony of Mark Merritt
President & Chief Executive Officer
Pharmaceutical Care Management Association

Before the

UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH

“Examining the Medicare Part D Medication Therapy Management Program”

October 21, 2015

Introduction

Good morning. My name is Mark Merritt and I am President and CEO of the Pharmaceutical Care Management Association (PCMA). I appreciate this opportunity to appear before the Subcommittee for this hearing examining ways to improve medication management in Medicare Part D. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 253 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the Exchanges.

PCMA is proud of the role its member companies have played in the success of the Medicare Part D program. Part D continues to be a bright spot in American health care. By offering an abundance of competing choices in each region and using cost-saving tools like pharmacy networks, specialty pharmacies, and home delivery, the program has achieved unprecedented satisfaction ratings from its enrollees and has kept spending far below original projections.

While Part D generally works well, the Medication Therapy Management (MTM) program—in place since Part D's beginning—has not lived up to its promise, and we appreciate the Subcommittee's thoughtful examination of how the program could be improved. We believe under current requirements, MTM is misaligned on its incentives and misallocates resources. The intent behind the MTM program is commendable. From Part D's enacting legislation, the goal of MTM is to help ensure that "Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions." Unfortunately, the MTM program as currently practiced in Part D is not reaching its goal to optimize the use of prescription drug therapy. However, we believe CMS' Part D Enhanced MTM Model (Model) can provide plans the tools and flexibility to improve the program. . We encourage Congress to support implementation of the Model and allow it the time and space to generate better outcomes in Part D.

MTM Background

Congress created the Part D MTM program in Part D's enacting legislation in 2003. MTM refers to a variety of management activities and resources devoted to optimizing medication use by

specific patients. To participate in Part D, a plan must offer an MTM program in accordance with CMS rules. These programs generally include:

- interventions to promote coordinated care;
- an interactive comprehensive medication review and discussion with the beneficiary;
- a written summary (in CMS' standardized format) of recommendations for the enrollee;
- and
- monitoring and follow-up of the beneficiary's medication therapies.

MTM to Prevent Adverse Drug Events (ADEs)

According to CMS, the most common method for identifying enrollees for MTM comes through system edits, set up by the Part D sponsor or its contracted PBM. Additionally, PBMs have long provided tools that increase safety and eliminate waste in both Medicare and across all the benefits they administer.

For Part D MTM programs, PBMs use sophisticated analytics to see if there is a need to intervene with patients for reasons including helping enrollees move off high-risk drugs; removing, preventing, or resolving potentially harmful drug interactions; and discontinuing contraindicated drugs. PBMs can also help identify potential polypharmacy cases and, conversely, find cases of medication underuse for individuals with qualifying diagnoses.

MTM and the Importance of Adherence

Another important goal of MTM is to increase enrollee compliance with prescribed drug regimens, but evidence on population-wide, sustainable interventions has thus far been elusive. Taking medication in accordance with doctors' orders may seem like a simple or personal matter, but non-adherence is both a complicated and common problem. Nearly three out of four Americans report that they do not always take their drugs as directed. There are many reasons why people are not able to take their drugs as directed – including forgetfulness, lack of belief in the drug's effectiveness, being unsure the drug is working, fear of side effects, trouble taking the drug (especially with injections or inhalers), busy schedules that make pharmacy visits difficult, and the cost of drugs. Often there is no single reason someone does not take their drugs as directed, but rather a combination of reasons. One person may face different barriers at different times as he or she manages his or her condition.

Research has shown that adherence to prescribed therapy is important for producing good health outcomes and avoiding unnecessary costs. For example, a study in Health Affairs projected that improved adherence to diabetes drugs could avert nearly 700,000 emergency department visits and close to 350,000 hospitalizations annually, for a total savings of \$4.7 billion. Additionally, a study in JAMA suggested that improved access and adherence to drugs following the implementation of Medicare Part D saved Medicare about \$1,200 in hospital, skilled nursing facility and other costs for the subset of seniors who previously lacked comprehensive prescription drug coverage in the year after they gained coverage. Thus, improving adherence through MTM could improve outcomes for Medicare enrollees and potentially provide offsetting savings in Medicare Parts A and B. However, producing these types of effects across the entire Part D population and sustaining them over time has proven difficult thus far.

MTM Limitations

The current structure of MTM requirements significantly hinders Part D plans from making further advances in care. Despite the efforts of the government and Part D stakeholders, 10 years into the implementation of the Part D program, MTM has not lived up to its well-intended goals and PDPs and policymakers have learned little more about how to get to optimized drug therapy for enrollees. CMS itself has recognized that stand-alone Part D sponsors' existing incentives may not be well aligned with the Medicare program's interests in robust quality improvement, including the goals of delivery system reform in providing better care, smarter spending, and healthier people. The agency also notes that the "competitive market dynamics and Part D program requirements and metrics encourage investment in these activities only at a level necessary to meet minimal compliance standards."

Specifically, limitations with the current Part D regulations include:

- Requiring uniform service offerings to beneficiaries who meet the PDP's MTM program criteria;
- Misaligned incentives that undermine PDPs' ability to design and deploy innovative and creative measures to improve medication management; and
- Misallocation of resources as to which beneficiaries receive MTM.

Current Part D MTM regulations require uniform service offerings to beneficiaries who meet the plan's MTM program criteria, which must be expressed in numbers of drugs and chronic conditions, and expected annual prescription costs. These criteria, according to the agency, may both over-identify and under-identify beneficiaries who are either experiencing (or at risk of experiencing) medication-related issues and could benefit from MTM interventions. The result is that Part D MTM resources may be misallocated and accordingly fail to support those activities that are likely to have the greatest effect on patient care and beneficiary outcomes.

We hear reports from our own companies mirroring CMS' findings that current rules governing MTM result in misaligned incentives that are most prominent in stand-alone Part D plans. Unlike Medicare Advantage plans that manage the entire range of Medicare benefits (MA-PDs), stand-alone drug plans manage only the prescription drug benefit for enrollees. As a result, the incentive to design and deploy innovative and creative measures to improve medication management runs up against the reality that savings generated in Parts A and B of Medicare as a result of better adherence will not accrue to the Part D plan, which undertakes such an effort. In addition, increased spending for MTM benefits in a stand-alone drug plan puts upward pressure on beneficiary premiums for that plan while the savings in the traditional Medicare program benefits are not going to reduce plan premiums as they would in an MA-PD plan.

Misallocation of resources is also a result of requirements determining which beneficiaries receive MTM. Under current requirements, beneficiaries meeting targeting criteria for MTM are supposed to receive certain services and interventions, such as the annual comprehensive medication review (CMR). Beneficiaries are targeted for MTM according to the condition and number of drugs prescribed, and annual drug spending. However, if an enrollee declines the annual CMR—indicating the enrollee believes he or she is well controlled on medications or possibly is indifferent or even hostile to receiving an intervention—the plan sponsor is still required to perform other MTM services at least quarterly on an on-going basis for that individual. This can result in a waste of significant resources that could be used to prioritize MTM services for beneficiaries who want, need, and would benefit from them. Indeed, a CMS-sponsored report by Acumen recently found that for the three disease conditions studied (i.e., diabetes, CHF and COPD), MTM programs, on average, increased Part D costs annually by \$75

to \$181 per patient, with no clear proof that the current MTM programs as currently implemented have created robust or persistent improvements.

While our companies fully embrace the need to help improve medication use and to reduce the risk of adverse events, they agree with these findings and believe the current enrollee targeting criteria and extensive process requirements prevent the Part D MTM program from accomplishing its intended goals.

CMS Model Test

Given the current state of MTM in Part D and the need to improve it, we were very encouraged by CMS' recent release for the "Announcement of Part D Enhanced Medication Therapy Management Model Test." We strongly support its implementation and urge Congress to do the same. This Part D Enhanced MTM Model (Model) is designed to test changes to the Part D program that would achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and innovation in better MTM targeting and interventions. CMS anticipates the Model will begin on January 1, 2017. The proposed duration of the initial Model test performance period is five years, from CY 2017 through CY 2021.

CMS' aim is that the Model will result in stand-alone PDP sponsors and CMS learning how to "right-size" the investment in MTM services and identify and implement innovative strategies to optimize medication use, improve care coordination, and strengthen system linkages. The Model will specify neither the beneficiary targeting criteria nor the intervention activities that each participating sponsor must offer. Rather, the agency expects that "participating sponsors will experiment with and seek out a range of strategies to individualize beneficiary (and prescriber) outreach and engagement." Perhaps most importantly, the Model aims to offer a degree of financial alignment for MTM services by sharing a portion of the savings that accrue to the traditional Medicare program from MTM so that these savings can result in lower premiums for beneficiaries.

PCMA strongly supports CMS' development of the Model and applauds the agency for launching this important initiative. As we understand it, the Model was carefully constructed by experts at CMS over a multi-year period and incorporates input from myriad stakeholders who

have been performing Part D MTM activities. For our own part, PCMA has encouraged CMS for several years to test MTM models that would:

- Target MTM services on high-risk beneficiaries most likely to benefit from such interventions;
- Provide financial incentives for plans to offer and beneficiaries to participate in expanded MTM services;
- Recognize expenditures for expanded MTM services as quality improving activities for purposes of medical loss ratio (MLR) reporting requirements;
- Offer greater flexibility in MTM benefit design and the range of services;
- Focus on clinical outcomes rather than process measures such as medication counts or completed CMRs;
- Provide access to Parts A and B beneficiary data, including alignment with ACOs, for stand-alone PDPs; and
- Allow sufficient time for a range of MTM projects to be assessed before concluding a MTM Model program.

We believe the Model as proposed by CMS meets these principles and we look forward to its implementation. In time, we think the Model and similar initiatives that target patients who may be at risk for poor outcomes resulting from complications, contraindications, or non-adherence will provide evidence of the best ways to improve drug therapy to help patients manage their conditions. As this evidence is disseminated across the health system, PBMs will work with pharmacists, physicians, patients, clinicians, plan sponsors, and other stakeholders to incorporate what is learned into best practices for MTM with the aim of increasing adherence, improving health outcomes, and lowering costs.

What Congress can do on MTM

We believe the most effective way Congress can improve MTM in Part D is to support the implementation of the Model.

Specifically, we recommend these four steps:

- **Clear the Path for Model Implementation:** Congress should assure that the bureaucratic path for the rollout and implementation of the Model is clear, and that no unnecessary hurdles delay its planned implementation for the 2017 benefit year.
- **Incentivize Plans Outside the Model to do More:** Congress should assure that all Part D plans not participating in the Model may include any costs incurred to create and implement innovative MTM programs as a quality improving activity for purposes of Medical Loss Ratio (MLR), whether inside or outside the Model test. Doing so will encourage those plans outside the geographic footprint of the Model test to also innovate in what most agree is a flawed MTM system.
- **Refrain from Adding any New MTM Requirements:** Congress should refrain from adding requirements for the scope and practice of MTM services, allowing Part D plans flexibility to target those who would benefit most from MTM interventions. Given the potential of the CMS Model to produce robust evidence on which activities will work for which subsets of patients, we believe it is appropriate to allow the Model to proceed to accumulate the much-needed evidence base on appropriate use of drugs and patient adherence. To add additional requirements at this time is to risk compounding the challenges already imposed on a system with misaligned incentives and misallocated resources.
- **Rationalize and Catalog All Medicare Chronic Care Programs and Initiatives:** Congress should direct the Government Accountability Office (GAO), Medicare Payment Advisory Commission (MedPAC), or a similar body to produce a report that would detail all current and recent programs, initiatives, or demonstrations that coordinate some or all aspects of care for chronically ill individuals.

In addition to MTM, there are a variety of programs, demonstrations, or other initiatives in Medicare designed to treat the specific needs of chronic care patients. These include

the financial alignment demonstrations for dual eligibles, the chronic care management service recently recognized in the Medicare physician fee schedule, Accountable Care Organizations, and the Chronic Care Improvement Program, just to name a few. Following on a recent recommendation by the Urban Institute, these efforts in HHS and elsewhere in the federal government should be comprehensively catalogued and subjected to the same scrutiny as other care improvement activities.

While all stakeholders in the Medicare program share the goal of better care coordination for the chronically ill, a recent *New York Times* article suggests that the proliferation of so many efforts may be sowing confusion among beneficiaries, their families, and caretakers, who may be receiving multiple uncoordinated communications from multiple care providers. With respect to prescription drugs, to the extent that care coordination services are not synchronized and such initiatives are uncoordinated, it may lead to beneficiary confusion or even conflicting advice if, for example, a pharmacist and physician are not consistent in their communications. In addition, multiple communications about prescriptions and chronic conditions from multiple actors in the system may lead to beneficiary confusion or overload, potentially resulting in their tuning out all such communications. Better incentives to align and coordinate these efforts will benefit patient care and reduce costs.

A MedPAC or GAO report cataloguing each program, initiative, demonstration, etc. should include details on each project's specific goals, methods, and intended population. Additionally, the report should include recommendations where appropriate to assure the proliferation of projects do not negatively impact beneficiaries, duplicate efforts, or interfere with one another.

Additional Steps to Improve Part D and Chronic Care in Medicare

Closely related to improving MTM and improving care for those with chronic conditions, we are pleased to offer two additional ideas to improve drug therapy in Medicare: one to reduce inappropriate opioid use; another to increase market competition among manufacturers to lower drug costs.

- **Reduction of Inappropriate Opioid Use:** In tackling the problems associated with chronic illness and medication use, in addition to increasing adherence, we believe Congress should also examine the inappropriate uses of opioids. MedPAC recently highlighted problems associated with inappropriate use among long-time opioid users in Medicare Part D. Over one-third of Part D enrollees filled at least one prescription for an opioid in 2012 and enrollees with the highest use of opioids filled an average of 23 opioid prescriptions that year. According to MedPAC, opioids are associated with adverse events, including accidental overdose. In discussing opioid abuse, we provide appropriate exceptions for cancer patients and those with end-of-life conditions requiring opioids, but are instead focused on beneficiaries who may have ongoing chronic conditions or chronic pain.

In addition to the MedPAC findings, the Department of Health and Human Services Office of the Inspector General (OIG) recently found that some Medicare beneficiaries obtained drugs from alarmingly high numbers of pharmacies or prescribers. OIG recommended that CMS should seek legislative authority to restrict certain beneficiaries to a limited number of pharmacies or to a limited number of prescribers to prevent these beneficiaries from receiving inappropriate and unsafe drugs and to prevent fraud, waste and abuse. Any such restrictions, however, must balance safety with ensuring access to quality care for affected beneficiaries, and not apply to patients with cancer or other end-of-life conditions. This practice is currently used by 46 state Medicaid programs and by many health insurers in the private market.

We believe such a policy change would benefit Medicare enrollees and the program as a whole. In fact, the OIG stated that for beneficiaries who receive drugs from extremely high numbers of pharmacies or prescribers, using a “limited number of pharmacies or prescribers could reduce program costs and inappropriate utilization. It could also improve coordination of services and quality of care for these beneficiaries.” The Centers for Disease Control and Prevention also recently stated that abuse of opioid analgesics results in over \$72 billion in medical costs alone each year, comparable to costs related to other chronic diseases such as asthma and HIV. Further, an *American Journal of Managed Care*-published assessment of state Medicaid programs to limit patients at risk

of opioid abuse to certain pharmacies and providers found one-year savings of \$3.7 million in Connecticut, \$2.0 million in Iowa, and \$5.2 million in North Carolina.

In sum, we believe limiting individuals at risk for abuse or misuse of opioids to authorized pharmacies and authorized providers will maintain beneficiary access to needed medications, but prevent “drugstore shopping” or “doctor shopping” to obtain inappropriate quantities of controlled substances. For these reasons, we encourage Congress to consider these policies to restrict beneficiaries to specific pharmacies.

- **Enhancing FDA Review Capabilities to Bring More Drugs to Market, Enhancing Competition:** Especially for patients who take multiple drugs to treat multiple chronic conditions, affordability equates to access. A number of recently approved drug and biologic therapies have entered the market with historically high manufacturer prices. While many of these drugs represent needed breakthroughs to fight devastating and debilitating illnesses, their cost can be a barrier to access for patients who need these medications and strain health budgets in both the public and private sectors. Additionally, although drug trend has been historically low in recent years, current projections show that the greater availability and use of specialty drugs and clinical guidelines encouraging drug use at earlier stages are poised to dramatically increase overall drug trend. Rather than directly intervening in manufacturer pricing, policymakers could better encourage price competition in the marketplace by accelerating approval of drugs in development for conditions where the cost of existing medications is a barrier to treatment and where manufacturers of current therapies have little incentive to compete on price.

Recent events show that competition in the marketplace can drive significant savings on expensive drugs. Earlier this year it was reported that PBMs were able to negotiate a 46% discount with the manufacturer of the hepatitis C drug Sovaldi—saving billions—when a competitor drug was introduced into the market. Today, the FDA has programs in place to accelerate drug approvals for therapies to treat patients with serious conditions where current treatments are inadequate or nonexistent. Such programs base their criteria on various clinical and population factors. We urge policymakers to add a marketplace factor to those criteria—allowing accelerated approval for drugs where additional therapy

choices could enhance competition and thus bring down costs of the drugs and improve access for patients.

Additionally, the FDA should be fully funded and fully staffed to review all drug applications and especially to alleviate the widely reported backlog of generic drug applications.

I thank you for the opportunity to appear before the Subcommittee this morning. I would be happy to take any questions you may have.

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

STATEMENT OF JESSE 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 among 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.

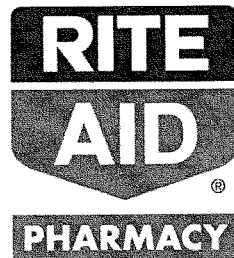
In addition to more effectively targeting and to more effectively target and reach beneficiaries most in need of MTM, we believe policy makers should explore ways to realign incentives in the program for plans, providers, and beneficiaries alike.

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

In closing, Rite Aid 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:]



Testimony

Jesse McCullough
Director of Field Clinical Services
Rite Aid Corporation

U.S. House of Representatives

Committee on Energy and Commerce
Subcommittee on Health

Hearing on:

“Examining the Medicare Part D
Medication Therapy Management Program”

October 21, 2015

2322 Rayburn House Office Building
Washington, DC

Chairman Pitts, Ranking Member Green, and Members of the Health Subcommittee, thank for opportunity to testify today on “Examining the Medicare Part D Medication Therapy Management Program.” My name is Jesse McCullough and I am the Director of Field Clinical Services for the Rite Aid Corporation. Rite Aid is one of the nation’s leading drugstore chains with nearly 4,600 stores in 31 states and the District of Columbia. On behalf of our company’s nearly 90,000 employees, including 12,000 pharmacists, I am honored to be here today.

I am a pharmacist and have a Doctor of Pharmacy degree from the University of Pittsburgh, School of Pharmacy. As Director of Field Clinical Services, I oversee all clinical programs for Michigan, Ohio, Pennsylvania, New Jersey and the District of Columbia. My primary objectives are improving performance of medication therapy management (MTM), immunizations, and quality measure based programs by identifying ways to reduce or eliminate barriers to providing these healthcare services to patients in the communities that we serve. I was involved in the launch of a pharmacy-based flu vaccination program in Pennsylvania and the initial launch of MTM services in 2006.

On behalf of the Rite Aid Corporation, I would like to thank Representatives Cathy McMorris Rodgers (R-WA) and Ron Kind (D-WI) for introducing legislation last Congress (H.R. 1024, the Medication Therapy Management Empowerment Act of 2013), which would enable Medicare beneficiaries to become eligible for MTM services if they suffer from a single chronic condition. Under their tremendous leadership, the bill garnered 170 bipartisan cosponsors, including 29 Members of the House Energy and Commerce Committee. Additionally, we would like to thank Chairman Pitts for convening the first congressional hearing on medication therapy management.

The Value of Community Retail Community Pharmacies and Pharmacists

Rite Aid and the community pharmacy industry provide access to prescription medications and over-the-counter products, as well as cost-effective health services such as immunizations and disease screenings. Access to these types of services is especially vital for Medicare beneficiaries as nearly two-thirds are suffering from multiple chronic conditions. Through personal interactions with patients, face-to-face consultations, and convenient access to preventive care services, local pharmacists are helping to shape the healthcare delivery system of tomorrow – in partnership with physicians, nurses, and others healthcare providers.

The national physician shortage coupled with the continued expansion of health insurance coverage in 2015 will have serious implications for the nation's healthcare system, including the Medicare program. Access, quality, cost, and efficiency in healthcare are all critical factors. Retail pharmacies and pharmacists stand ready to fill those gaps with high quality, cost efficient care and services to help ensure access for Medicare beneficiaries is not compromised. However, the lack of pharmacist recognition as a provider by third-party payors, including Medicare and Medicaid, has limited the number and types of services pharmacists can provide, even though fully qualified to do so.

It is critical that we appropriately frame the pharmacist's role in the healthcare system as we describe value. The pharmacist's role is to monitor medications' safety and efficacy within the drug delivery system. Pharmacists have historically displayed a high degree of success in regard to monitoring medication safety. With expanded opportunities within MTM, pharmacists are positioned to be the key drivers of medication efficacy to improve overall health while reducing healthcare spend as will be described at greater length momentarily.

The Importance of Medication Adherence

Medications are the primary intervention to treat chronic disease, and are involved in 80% of all treatment regimens.¹ Medicare beneficiaries with multiple chronic illnesses see an average of 13 different physicians, have 50 different prescriptions filled per year, account for 76 percent of all hospital admissions, and are 100 times more likely to have a preventable hospitalization.² Yet, medication management services are poorly integrated into existing healthcare systems. Poor medication adherence alone costs the nation approximately \$290 billion annually – 13% of total healthcare expenditures – and results in avoidable and costly health complications.³ Thus, given the importance of medications in achieving patient care outcomes and lowering overall healthcare costs, it is critical that policies are implemented that encourage greater care integration across the healthcare continuum and promote financial accountability for safe and appropriate medication use.

Pharmacy services improve quality of life and healthcare affordability. Helping patients take their medications effectively and providing preventive services, pharmacists help avoid more costly forms of care down the line. Pharmacists also help patients identify strategies to save money, such as understanding their pharmacy benefits and using generic drugs.

In particular, medication management services provided by community pharmacists improve patient care, enhance communication between providers and patients, improve collaboration among providers, optimize medication use for improved patient outcomes, contribute to medication error prevention, improve hospital and readmission cost avoidance figures, and enable patients to be more actively involved in medication self-management.

¹ <http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf>

² Ibid

³ <http://www.dmbc.ca.gov/library/reports/news/rci/totpb.pdf>

Medication Therapy Management Services

MTM is a service or group of services that optimize therapeutic outcomes for individual patients. Medication therapy management services include medication therapy reviews, pharmacotherapy consults, medication management, immunizations, health and wellness programs and many other clinical services. Pharmacists provide medication therapy management to help patients get the best benefits from their medications by actively managing drug therapy and by identifying, preventing, and resolving medication-related problems.

Rite Aid has been a long-time participant and supporter of MTM services. We have enrolled in networks with national MTM documentation platforms whenever possible. This includes having all 4,600 stores in our company enrolled with the OutcomesMTM and Mirixa platforms. We also have enrolled in regional opportunities to provide MTM services as we have honored our commitment to be able to offer these services to the customers and patients that we serve.

An abundance of literature shows that MTM and improved medication adherence leads to better use of medicines, thus improving health outcomes and reducing healthcare costs. In 2013, the Centers for Medicare and Medicaid Services (CMS) conducted a review of the Medicare Part D MTM program and found that it consistently and substantially improved medication adherence for beneficiaries with congestive heart failure (a type of cardiovascular disease), COPD, and diabetes. The study also found significant reductions in hospital costs. This included savings of nearly \$400 to \$525 in lower overall hospitalization costs for beneficiaries with diabetes and congestive heart failure. The report also found that MTM can lead to reduced costs in the Part D program as well, showing that the best performing plan reduced Part D costs for diabetes patients

by an average of \$45 per patient.⁴ The Congressional Budget Office (CBO) has also weighed in on the benefits of medication use and found that for each one percent increase in the number of prescriptions filled by beneficiaries, there is a corresponding decrease in overall Medicare medical spending.⁵ The CBO has recently applied its methodology in a review of the FY2016 National Defense Authorization Act (NDAA) which proposed to increase prescription copays for TRICARE beneficiaries. In its report the CBO stated:

Thus, while the higher copayments may deter some beneficiaries from filling prescriptions they no longer need or use, those higher copayments also could cause some chronically ill beneficiaries to stop taking their medications, resulting in more doctor visits and hospitalizations. As a result, CBO estimates that the \$4.9 billion in direct pharmacy savings would be offset by a \$1.1 billion increase in other federal spending for medical services (mostly from Medicare).

Similarly, a recent study published in *Health Affairs* examined the impact of changes in prescription drug use on medical costs in the Medicaid program. The study found that a one percent increase in overall prescription drug use was associated with decreases in total nondrug Medicaid costs by a percentage very comparable to that found by the CBO, as noted above.⁶

Several states have also implemented MTM programs and have seen notable program savings for both the state and the enrolled beneficiaries. CareSource, one of the country's largest Medicaid managed healthcare plans, contracted with OutcomesMTM™ to implement and oversee a

⁴ http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf

⁵ <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>

⁶ <http://content.healthaffairs.org/content/34/9/1586.full.pdf+html>

comprehensive MTM offering for Ohio Medicaid eligibles. In the first year of CareSource's face-to-face MTM program there were over 106,000 MTM services delivered and the program operated with a return investment greater than \$1.35 for every \$1.00, in drug savings alone. In the second year of the program (mid-2013 to mid-2014), the results improved to over 176,000 MTM services delivered and the return on investment was greater than \$2.17 for every \$1.00 spent, in drug savings alone. The North Carolina CheckMeds MTM program generated savings of approximately \$66.7 million in overall health care costs for the state which included \$35.1 million from avoided hospitalizations and \$8.1 million in drug product cost savings

A study of published research on medication adherence conducted by Avalere in 2013 concluded that the evidence largely shows that patients who are adherent to their medications have more favorable health outcomes such as reduced mortality and use fewer healthcare services (especially hospital readmissions and ER visits). Such patients are thus less costly to treat overall, relative to non-adherent patients. The study found that there was even wider range of cost offsets for patients demonstrating adherence to medications across particular chronic conditions. Studies have shown that for every \$1.00 increase in costs related to prescription drug spending for adherent patients, medical cost decreases by more than \$1.00. The magnitude of the decrease varies depending on a patient's condition. The studies reviewed looked at patients across the healthcare spectrum, including several that studied beneficiaries in Medicaid and Medicare:

- Roebuck et al., estimated that for every additional dollar spent on medicines for adherent patients, there were medical cost offsets of \$10.10 for hypertension, \$8.40 for congestive heart failure, \$6.70 for diabetes and \$3.10 for dyslipidemia. This translated into an annual per person savings of \$7,823 for congestive heart

failure, \$3,908 for hypertension, \$3,756 for diabetes and \$1,258 for dyslipidemia (Roebuck et al. 2011).

- Sokol et al., estimated that for every additional dollar spent on medicines for adherent patients, there was a reduction in total healthcare costs by \$7.00 for diabetes patients, \$5.00 for high cholesterol patients and \$4.00 for high blood pressure patients (Sokol et al. 2005).
- In a study of Medicaid patients with congestive heart failure, patients who were adherent to medications had fewer hospitalizations, lower incidence of ER visits and had overall costs that were 23 percent lower than non-adherent patients (Esposito et al. 2009).
- A study of Medicare patients found that for every 10 percent increase in adherence to diabetes medication, total healthcare costs declined between 9 and 29 percent (Balkrishnan et al. 2003).
- A subsequent study of Medicare patients diagnosed with diabetes found that patients who were adherent to cardiovascular drugs as part of their treatment therapy had lower total healthcare costs within the Medicare system over three years, with savings from medical costs outweighing additional costs from greater prescription drug use (Stuart et al. 2011).

- Another study found that patients who increased adherence to their diabetes medications were 13 percent less likely to be hospitalized or visit the ER relative to those who remained non-adherent (Jha et al. 2012). They also compared outcomes between people who decreased their adherence during this time to patients that remained adherent. For patients with lower adherence, they calculated a 15 percent higher likelihood of hospitalization or visiting the ER relative to patients who remained adherent. Due to these utilization impacts, the authors estimated that measures designed to increase adherence could generate potential healthcare savings of \$8.3 billion (Jha et al. 2012)

A 2011 *Health Affairs* article found that medication adherence leads to lower health care use and costs. The study found that, across the board, adherent patients spent significantly less than non-adherent patients. Combining the increases in pharmacy spending with the decreases in medical spending, average benefit-cost ratios from adherence for the four vascular conditions examined were 8.4:1 for congestive heart failure, 10.1:1 for hypertension, 6.7:1 for diabetes, and 3.1:1 for dyslipidemia.⁷

Medicare Part D MTM Program

Despite the proven value of medication adherence and MTM, the Medicare Part D MTM program historically has seen low enrollment and utilization rates. The original statutory and regulatory language contained a general framework and few requirements for the MTM program, leaving flexibility for plans to develop their programs. Current MTM restrictions require that Medicare Part D beneficiaries be diagnosed with multiple chronic conditions, be prescribed

⁷ <http://content.healthaffairs.org/content/30/1/91.full.pdf>

multiple medications, and meet a minimum annual cost threshold of \$3,138 in 2015 for their prescriptions before they are eligible for Part D MTM. In defining the targeting requirements, CMS states that sponsors cannot require more than 3 chronic diseases as the minimum number of multiple chronic diseases and cannot require more than 8 Part D drugs as the minimum number of multiple covered Part D drugs.

Plans are required to offer a minimum level of MTM services including interventions for both beneficiaries and prescribers, an annual comprehensive medication review (CMR) for the beneficiary, which includes a review of medications, interactive, person-to-person consultation, and an individualized, written summary of interactive consultation, and quarterly targeted medication reviews (TMRs).

CMS has also taken steps to improve the quality and measuring of the Part D MTM program, including recently establishing the MTM Completion Rate for CMRs as a full star rating measure beginning in 2016.

CMS and the Center for Medicare and Medicaid Innovation (CMMI) recently announced an initiative that would provide Part D plans with the opportunity to utilize enhanced MTM models and strategies, including innovate outreach and targeting strategies and tailoring the level of services to the beneficiary's needs. Rite Aid applauds the testing of Enhanced MTM models of care. However, the model is scheduled to last for five years, meaning that useful strategies would not be fully incorporated into the Part D program until 2023. Rite Aid urges lawmakers to explore new and innovative approaches to improving the MTM program that could be implemented in the short term. Seniors should not need to wait until 2023 to have access to improved MTM services.

Improving the Medicare Part D MTM Program

Even though CMS has made many programmatic changes over the years aimed at improving the MTM benefit, there has not been the expected increase in MTM eligibility, enrollment and utilization. In 2012, there were approximately 27.2 million people enrolled in either a MA-PD (9.9 million) or a PDP (17.3 million). Of the more than 27 million beneficiaries, only 3.1 million were enrolled in a MTM program (11.4%) and only 2.4 million received a CMR (8.8%). These figures fall well short of the CMS estimate that approximately 25% of the beneficiaries would be eligible for MTM.

Rite Aid has participated in MTM programs since their inception. We have helped thousands of patients get more out of optimizing their medication therapy. The fact of the matter is that we can do more. There are numerous challenges that exist which impede the uptake of Part D MTM services, such as a lack of incentives for plans, providers and beneficiaries, poor targeting of beneficiaries, lack of beneficiary awareness and provider participation and prohibitive documentation requirements.

Currently, plans are allowed to set their minimum number of chronic conditions required for eligibility at either two or three. According to the CMS MTM Fact Sheet, approximately 85% of programs opt to target beneficiaries with at least three chronic diseases in 2014. Similarly, plans can require that beneficiaries be prescribed up to eight medications before they are eligible for MTM (in addition to meeting the other requirements). These wide ranges are a contributing factor to the lower than projected eligibility levels in the MTM program.

Lack of patient awareness of the service is also a major barrier. Many patients decline the service secondary to believing that their physician(s) are completely on the same page as far as

their treatments and goals. This speaks to an underlying issue that suggests that we are trying to build a healthcare system that patients believe already exists. Additionally, many patients will consult with their physician before consenting to the service and physician endorsement and support of these services can be improved.

Finally, the documentation process through the various online platforms is often lengthy and can be highly variable from one vendor to the next, which negatively impacts the workflow in the pharmacy setting. While copies of the MTM documentation can be shared with the physician, it may not be practical for integration into electronic health records to prompt for follow up or provide the helpful data collected in the pharmacy that could further advance appropriate care.

Rite Aid believes reforming the Medicare Part D MTM program can be accomplished by doing a better job identifying beneficiaries who most need the services. Changes should be made to revise the eligibility requirements to include beneficiaries with certain single chronic conditions that have been shown to respond well to improved medication adherence.

We urge Congress to strengthen the MTM benefit in Medicare Part D by introducing and supporting legislation similar to that introduced by Senators Pat Roberts (R-KS) and Jeanne Shaheen (D-NH), S. 776, the Medication Therapy Management Empowerment Act of 2015, which will provide access to MTM for beneficiaries with diabetes, cardiovascular disease, COPD, and high cholesterol.

In addition to more efficiently targeting and reaching beneficiaries most in need of MTM, we believe policymakers should explore ways to realign incentives in the program for plans, providers and beneficiaries alike. For example, pharmacies may be incentivized by allowing

them to refer eligible beneficiaries for MTM services or providing for sharing in cost savings for pharmacies that perform well in MTM and medication-related metrics. Including incentives for beneficiary participation, such as a waiver or lowering of cost-sharing amounts, would encourage more beneficiaries seek out MTM services.

Prescribers can also be incentivized to educate their patients on the benefits and availability of the MTM service, as well as review any post-MTM feedback for their patients. Finally, realigning plan incentives to foster more robust MTM programs will be key. This could be accomplished by linking MTM and medication adherence related quality metrics to bonus payments and allowing Part D plans to share in any savings garnered in Medicare Parts A/B that are attributed to MTM.

Additionally, giving pharmacists provider status under Medicare could potentially empower the pharmacist to take immediate action to resolve drug therapy problems that are identified in the course of providing MTM services. Recognition of pharmacists as providers under Medicare Part B would help to provide valuable and convenient pharmacist services to millions of Americans, and most importantly, to those who are medically underserved and most in need of quality healthcare options.

Rite Aid urges the adoption of policies and legislation that increase access to much-needed services for underserved Americans. We applaud Representatives Brett Guthrie (R-KY) and G.K. Butterfield (D-NC) for their introduction of H.R. 592, the Pharmacy and Medically Underserved Areas Enhancement Act. This legislation would allow pharmacists to practice to their full capability by providing those underserved beneficiaries with services not currently reaching them (subject to state scope of practice laws). We believe that this would not only

reduce overall healthcare costs, but also lead to increased access to healthcare services and improved healthcare quality for underserved patients, and especially for patients with chronic conditions.

Conclusion

Rite Aid thanks Chairman Pitts, Ranking Member Green, Congresswoman McMorris Rodgers, and the Energy and Commerce Committee for their leadership and support on this important issue. Rite Aid is strongly committed to working with policymakers and other healthcare providers to strengthen the Medicare Part D MTM benefit for our nation's seniors.

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

STATEMENT OF RICHARD THOMAS 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 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, when they don't take their medications as directed, the repercussions are very severe. As I mentioned, they die or have 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:]

**Written Testimony
of
Dr. Richard Benson
Associate Medical Director of Stroke
MedStar Washington Hospital Center
Hearing Before
The House Energy and Commerce Subcommittee on Health
"Examining the Medicare Part D Medication Therapy Management Program"
October 21, 2015**

Introduction

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

My name is Richard Benson. I am the Associate Medical Director of Stroke at the MedStar Washington Hospital Center with the NIH Stroke Program in Washington, DC. As the only Comprehensive Stroke Center program in the Greater Washington Region, and as an ACGME certified vascular neurology fellowship training program site for the NIH training program, I work very closely with the Medical Director and the other NIH stroke team faculty members to develop, grow, and support this program.

Today, I also speak to you as a volunteer for the American Heart Association, a non-profit organization with more than 30 million supporters dedicated to building healthier lives, free of cardiovascular diseases and stroke. As a volunteer with the association, I have served as chair of the American Heart Association Missions' Committee for the Greater Washington Region, and was responsible for enrolling over 900 community members in the American Heart Association-sponsored Heart 360 "Check it, Change it" blood pressure self-management program.

Consequences of Medication Nonadherence for CVD and other Patients

The statistics are both startling and alarming: as many as half of 187 million patients in the U.S. do not take their medications as prescribed.

Poor medication adherence results in 125,000 deaths in the U.S. annually, and costs our health care system nearly \$300 billion a year in additional doctor visits, emergency department visits, and hospitalizations.

Unfortunately, poor medication adherence is particularly common among patients with cardiovascular disease (CVD), and when patients with CVD do not take medication as directed, the repercussions can be severe — and sometimes fatal.

For instance, if you have a family history of cardiovascular disease and don't take the medication needed to keep your high blood pressure in check, you are three times more likely to die from a heart attack, and four times more likely to die from a stroke.

The bottom line is that it is critical for all patients to realize that if they do not take their medications, they could suffer severe consequences.

So, why do patients not take their medicine? There are many reasons. They may forget. They may not be convinced of the medication's effectiveness, or are unsure that it is working. They may fear the side effects or have difficulty taking the medication. Or, it may be a combination of all these reasons that keeps patients from taking their prescriptions.

A Solution to Medication Nonadherence: Medication Therapy Management

However, there is hope. Medication therapy management (MTM) programs are an important intervention tool that can improve medication adherence. Research indicates that these programs can lead to better health outcomes, reduce the risk of adverse events, and help control health care costs.

For example, the American Pharmacists Association Foundation created a community-based MTM program that featured face-to-face counseling and educational classes with clinically trained educators and pharmacists to help control high blood pressure, cholesterol, and triglycerides for 12,000 employees of the city of Asheville, North Carolina and a local hospital system. The results were impressive and across the board.

Over a six-year period, the proportion of people who achieved the program's targeted blood pressure level increased, while the number of heart attacks and other cardiac events fell by more than half. So did the patients' use of emergency rooms and other hospital services for cardiac events.

In addition, health care costs paid by the employer declined by more than 45% and the percentage of health plan costs related to CVD decreased from just over 30% to just over 19%.

A 2013 CMS report on medication therapy management in chronically ill populations further showed that enrollees in MTM programs suffering from congestive heart failure (CHF) had improved medication adherence. This was particularly true for those enrollees who received a comprehensive medication review.

The report also demonstrated that MTM programs decreased hospital utilization and costs in diabetes and CHF patients receiving comprehensive medication reviews, resulting in per-patient hospital cost savings of \$526 for patients with congestive heart failure, and \$399 in savings for patients with diabetes.

Mr. Chairman, the American Heart Association supports policies that would ensure better access to these valuable services, especially for the patients who need them most. For example, the American Heart Association strongly believes that passage of the Medication Therapy Management Empowerment Act of 2015 is critical to ensuring that a greater number of Medicare beneficiaries receive access to MTM services.

This legislation would amend current MTM criteria to allow beneficiaries with a single chronic condition, such as high blood pressure, to be eligible for these services under Part D of the Medicare program.

As the subcommittee knows, each program currently sets the minimum number of chronic conditions a beneficiary must have to qualify for MTM program eligibility, allowing sponsors to set the minimum threshold at two or three. Unfortunately, approximately 82% of the 2015 programs target beneficiaries with at least three chronic diseases.

This means that a beneficiary with only high cholesterol may not have access to MTM services. The consequences could be devastating. These patients who do not adhere to their medications are at a

greater risk – 26% more likely – of a cardiovascular disease-related hospitalizations compared to patients who adhere to their cholesterol prescriptions.

While the MTM Empowerment Act of 2015 has not yet been introduced in the House of Representatives during this Congress, the American Heart Association salutes Representative McMorris Rodgers' past work on this issue and for introducing legislation similar to the MTM Empowerment Act of 2015 [H.R. 1024, "The Medication Therapy Management Act of 2013"]. This bipartisan legislation has received support from many members of this Committee and Congress in the past, and we urge that this bill be reintroduced in the House at the earliest opportunity so swift action can be taken.

CMS Enhanced MTM Pilot Program

The American Heart Association was also encouraged when the Center for Medicare and Medicaid Innovation (CMMI) announced its new enhanced model to test strategies to improve medication use among Medicare beneficiaries enrolled in Part D. MTM services currently offered by Part B plans fall short of their potential to improve quality and reduce unnecessary medical costs.

CMMI has taken an important step to provide these programs with regulatory flexibility and to innovate to find new ways and target strategies to improve health outcomes for patients.

We are particularly pleased that the model will provide incentives to support more extensive MTM interventions, services, and care coordination among both prescribers and pharmacists; allow prescription plans to request beneficiary-level Parts A and B claims data; and support new MTM encounter data collection efforts.

The demonstration project will also help us better understand how different medication adherence interventions affect health outcomes and the link between medication adherence, patient health care spending, and health care costs, and which approaches are the most successful. The American Heart Association strongly supports the MTM enhanced model as both seniors and the health plans that cover them could benefit from stronger adherence to prescription medication. We look forward to its launch in 2017.

Conclusion

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. And finally, we must provide incentives to the healthcare system to ensure patients receive the proper follow-up and support to continue taking their medicines as prescribed.

We know that taking their medications as prescribed gives patients the best opportunity to manage their chronic conditions and maintain their best possible health. Think about what a difference it might make in their lives. It could allow a patient to attend his grandchild's baseball game, or walk his daughter down the aisle. These are outcomes we can all support and work towards.

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

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 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, 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 often-times 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 a number of drug-related problems and work toward 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, my doctor takes care of that.

There is some perception that 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. 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 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. 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. OK. 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 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. OK. 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 there 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.

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 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 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 might contact you 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 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 OK, 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 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. 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 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 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 the patient getting to a location where the therapy is adjusted in a more timely manner.

Mr. GUTHRIE. OK. 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.

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 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.

Through that I can see pharmacists getting involved and doing a number of different additional things. Some of the low-hanging

fruit will be assessments to make sure immunizations are up to date with more regularity.

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

Mr. GUTHRIE. OK. 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. 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 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 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.

Ten years ago there were 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, 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. 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, 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 financial incentive—for plans to enter the MTM.

But, 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 there is no financial reward.

Mr. COLLINS. Would the others agree with that?

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

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 are 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, 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 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, 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. OK, 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. 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 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.]

[Material submitted for inclusion in the record follows:]

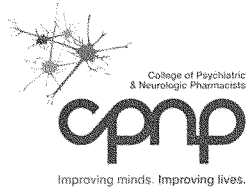
PREPARED STATEMENT OF HON. FRED UPTON

Today we are examining the Medicare Part D Medication Therapy Management program (MTM). This program has been in existence since the Medicare Prescription Drug Benefit began in 2006 after the enactment of the Medicare Modernization Act of 2003. The goal of MTM is simple—to ensure that Part D drugs are appropriately used by beneficiaries. Through more optimal utilization of prescription drugs in Part D, patients' health will be improved and medical costs can be lowered. This is important for seniors in Michigan and all across the country.

But over the past nearly ten years, the program has been somewhat of a missed opportunity to cut costs for seniors and the Medicare program. Under the current construct of the program, it has been difficult to engage seniors and coordinate care due to burdensome statutory and regulatory requirements. Today, only 8%, a rate lower than one out of every ten seniors enrolled in Part D even participate in MTM.

Last month, CMS announced a new innovation model titled, "The Part D Enhanced Medication Therapy Management Model." I am eager to hear from them today on the improvements this model will bring to MTM in the Part D space. We appreciate our witnesses for taking the time to talk with us about ways to advance this program so we can improve beneficiary care. I also want to thank Conference Chair McMorris Rodgers for her leadership on this issue.

I yield the remainder of my time to _____.



**Comments of the American College of
Clinical Pharmacy and the College of
Psychiatric and Neurologic Pharmacists**

**Submitted to the
Committee on Energy and Commerce
Subcommittee on Health:**

**“Examining the Medicare Part D
Medication Therapy Management Program”**

October 21, 2015



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The American College of Clinical Pharmacy (ACCP) and the College of Psychiatric and Neurologic Pharmacists (CPNP) appreciate the opportunity to provide the following statement to the House of Representatives Committee on Energy and Commerce, Subcommittee on Health related to the October 21, 2015 hearing entitled, "Examining the Medicare Part D Medication Therapy Management Program."

ACCP is a professional and scientific society that provides leadership, education, advocacy, and resources enabling clinical pharmacists to achieve excellence in patient care practice and research. ACCP's membership is composed of over 16,000 clinical pharmacists, residents, fellows, students, scientists, educators and others who are committed to excellence in clinical pharmacy practice and evidence-based pharmacotherapy.

CPNP is an association of specialty pharmacists who work to improve the minds and lives of those affected by psychiatric and neurologic disorders. These professionals apply their clinical knowledge in a variety of healthcare settings and positions ranging from education to research with the goal to apply evidence-based, cost efficient best practices in achieving patient recovery and improving quality of life.

Beginning with the introduction of the Medicare Prescription Drug, Improvement, and Modernization Act (also referred to as the Medicare Modernization Act or MMA) in 2003, ACCP and CPNP worked closely and diligently with Congress to ensure that the proposed prescription drug benefit not only enhanced beneficiary access to needed medications, but that the program's operational and quality standards assured that therapeutic outcomes will be fully optimized through the delivery of medication therapy management (MTM) services by pharmacists as a substantial and integral part of the overall drug benefit.

Following the passage of the MMA, a group of eleven pharmacists' professional associations worked to develop a consensus definition of MTM services. Our organizations were at the forefront of the regulatory rulemaking process, working to help develop an MTM program within the newly established Part D benefit that we hoped would deliver on its aims, assuring that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use.

In the preamble to the Part D final rule, CMS stated its belief that the MTM Program would be a "cornerstone of the Medicare Prescription Drug Benefit." MTM was intended to be to be a "patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence."¹ However, recently CMS has acknowledged that it has not been possible to fully demonstrate the value and success of the Part D MTM Program.²

Following the implementation of the Part D benefit and the launch of the MTM program, pharmacists across all practice settings worked tirelessly to deliver high quality patient care to beneficiaries within the Part D MTM structure and sought to make the program a success. Now, after almost a decade of experience, we are concerned that the Part D MTM program as it is currently structured – delivered primarily through prescription drug plans and detached from the patient's health care team and medical records – fails to support this patient-centric comprehensive approach and will never fully realize the full potential of effective, team-based medication management in terms of improved outcomes and lower costs.

This concern is shared by the Medicare Payment Advisory Commission (MedPAC). In a February 28, 2014 comment letter to CMS in response to the Fiscal Year 2015 Medicare Prescription Drug Benefit proposed rule, MedPAC stated that, "after seven years, it may be time to question whether MTM programs offered through PDPs – without the cooperation and coordination of a beneficiary's care team – have the capacity to significantly improve beneficiaries' drug regimens." The Commission went on to suggest that better medication management might be achieved through programs offered by ACOs,

medical homes, and other team-based delivery models, since providers working within these care models have more incentive to improve their patients' medication regimens and eligible patients may be more likely to participate in MTM programs and follow the advice they receive.

Like MedPAC, ACCP & CPNP support the Committee's commitment to improving medication management services for Medicare beneficiaries but question whether improvements to the Part D MTM program, as it is currently structured, is the most effective way to achieve this broader goal. Part D MTM is an administrative benefit delivered by the patient's Part D plan sponsor, rather than a comprehensive medical benefit coordinated through the patient's health care team. Part D MTM is largely driven using drug claims data and is narrowly focused on issues such as duplications in therapy, gaps in adherence, use of certain classes of medications, and generic substitution. Experience has shown that physicians may be reluctant to accept recommendations from drug plans with which they have no direct relationship.

ACCP & CPNP believe that medication management services, delivered in a comprehensive manner targeting high-cost, high-risk beneficiaries can result in significant improvements in improvements in drug therapy outcomes and contribute to lower overall health care spending by reducing hospitalizations and avoidable emergency room and physician visits. However, we remain concerned that the Part D MTM program as it is currently structured cannot ensure a true team-based, patient-centered approach to health care consistent with evolving delivery and payment models such as the patient-centered medical home (PCMH) and will ultimately fall short of realizing the full potential of effective, team-based medication management in terms of improved outcomes and lower costs.

We therefore urge the Committee to include reforms to the Medicare program that provide for coverage of comprehensive medication management (CMM) services provided by qualified clinical pharmacists as members of the patient's health care team. This team-based service of CMM is supported by the Patient Centered Primary Care Collaborative, (PCPCC), in which ACCP as well as the major primary care medical organizations are actively involved. CMM helps ensure that seniors' medication use is effectively coordinated, and in doing so enhances seniors' health care outcomes, contributing directly to Medicare's goals for quality and affordability. CMM can "get the medications right" as part of an overall effort to improve the quality and affordability of the services provided to Medicare beneficiaries.

CMM is a collaborative, team-based approach to patient care delivered by clinical pharmacists operating under formal collaborative practice agreements or clinical privileges granted by the health care setting in which the pharmacist practices. Effective CMM saves overall health care costs by reducing unnecessary use of more costly health care services. By helping ensure that seniors' medication use is effectively coordinated, this service is a benefit that enhances seniors' health care outcomes and contributes directly to Medicare's goals for quality and affordability.

Patients benefit from the delivery of CMM in terms of improved outcomes due to the increased individualized attention to medications and the role they play in the patient's therapeutic care plan. In addition, physicians and other care team members benefit when pharmacists apply their pharmacotherapeutic expertise in a collaborative process to help manage complex drug therapies.

CMM also contributes to enhanced productivity for the entire health care team, allowing other team members to be more efficient in their own patient care responsibilities. Physicians are able to dedicate more time to the diagnostic and treatment selection process, enabling them to be more efficient, see more patients, and spend more time providing medical care. Team members are freed up to practice at the highest level of their own scopes of practice by fully utilizing the qualified clinical pharmacist's skills and training to coordinate the medication use process as a full team member.

The central role that medications play in the care and treatment of chronic diseases is undeniable. According to data from the Centers for Medicare and Medicaid Services (CMS), medications are the fundamental treatment intervention in each of the eight most prevalent chronic conditions in Medicare patients. For the typical Medicare beneficiary, four of every five medical encounters result in a prescription order (new or refill) and 60% of seniors are taking 3 or more discrete prescription or non-prescription medications at any point in time. Furthermore, the importance of medications in the care and treatment of chronic illness will only increase as advances in biomedical research and innovation and breakthroughs in digital and personalized medicine bring new life-saving drugs and devices to patients and a new generation of cures and treatments.

Despite these facts, traditional practice models and payment policies result in disjointed prescribing and distribution of medications from unconnected professional "silos." No effective incentives currently exist in Medicare to support a coordinated medication management service for beneficiaries delivered by an effective inter-professional health care team. When combined with the continuing growth in the number and categories of medications -- and greater understanding of the genetic and physiologic differences in how people respond to their medications -- the current system, including the Part D MTM benefit, consistently fails to deliver the full promise medications can offer. We therefore urge the Committee to consider opportunities to integrate coordinated, team-based CMM delivered across all care settings (e.g. hospital, outpatient practice, managed care), and during transitions between care settings, throughout the entire Medicare program.

The burden of chronic physical and mental health conditions has far reaching implications for the Medicare program. Over 68% of Medicare beneficiaries have two or more chronic conditions and over 36% have four or more chronic conditions. In terms of Medicare spending, beneficiaries with two or more chronic conditions account for 93% of Medicare spending, and those with four or more chronic conditions account for almost 75% of Medicare spending.³

Currently, millions of complex, chronically ill Medicare beneficiaries receive care in a delivery system that is fragmented and insufficiently focused on quality and outcomes. This program deficiency not only fails to adequately meet patient needs but threatens the long-term structural and financial viability of the Medicare program. We applaud the leadership of the Committee in holding this hearing to explore opportunities to strengthen the Medicare Part D MTM program for both patients and for the Part D plans.

But in order to enhance access to high-quality care and to ensure the sustainability of the Medicare program as a whole, it is essential that progressive payment and delivery system improvements that have emerged and are being actively utilized in both public and private-sector integrated care delivery systems be facilitated and aggressively promoted -- especially those that measure and pay for quality and value, not simply volume of services, and that fully incentivize care that is patient centered and team based.

For more information on why a modernized, integrated Medicare program needs to systematically address medication use through the incorporation of CMM as a covered benefit, please refer to Appendix A. For more information on the potential for cost savings through the incorporation of CMM as a Medicare benefit, please refer to Appendix B.

Summary

As the committee continues its effort to examine opportunities to strengthen and enhance medication management services available to Medicare beneficiaries, ACCP and CPNP urge you to focus on models that promote and incentivize a truly patient-centered and inter-professional approach to medication related clinical care and medication safety.

ACCP and CPNP are dedicated to advancing a quality-focused, patient-centered, team-based approach to health care delivery that helps assure the safety of medication use by patients and that achieves medication-related outcomes that are aligned with patients' overall care plans and goals of therapy through the provision of CMM. Clinical pharmacists, working collaboratively with physicians and other members of the patient's health care team, utilize a consistent process of direct patient care that enhances quality and safety, improves clinical outcomes and lowers overall health care costs.

As part of the process of exploring opportunities to improve the quality of medication management services available to seniors, Congress should enact reforms to the Medicare program that provide for coverage of CMM services provided by qualified clinical pharmacists as members of the patient's health care team within its broader payment reform efforts. We would welcome the opportunity to provide further information, data, and connections with successful practices that provide CMM services to help further inform the committee about this service in the context of specific improvements to the Part D MTM program as well as the broader debate over Medicare payment and delivery system reform that will modernize and sustain the program for the future.

¹ CMS Memo to all Part D Sponsors. CY 2015 Medication Therapy Management Program Guidance and Submission Instructions. May 7, 2014. Accessed October 15, 2015. Available here: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoContractYear2015MedicationTherapyManagementProgramSubmission050714.pdf>

² CMS Memo to all Part D Sponsors. CY2013 Part D Reporting Requirements - Request for Comments. January 13, 2012. Accessed October 15, 2015. Available here: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/ReqforCommentson2013ReportingRequirements_01102012.pdf

³ CDC Report - Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries, United States, 2010. Available at: http://www.cdc.gov/pcd/issues/2013/12_0137.htm. Accessed October 15, 2015

Appendix A

Coverage for Comprehensive Medication Management Services for Medicare Patients:

"Getting the medications right" in a reformed and modernized program

The American College of Clinical Pharmacy (ACCP) and the College of Psychiatric and Neurologic Pharmacists (CPNP) urge Congress to enact legislation to provide Medicare patients with coverage for comprehensive medication management (CMM) within the Part B medical benefit. This direct patient care service, provided by qualified clinical pharmacists working as formal members of the patient's health care team, has been demonstrated to significantly improve clinical outcomes and enhance the safety of medication use by patients.

Effective CMM also saves overall health care costs by reducing unnecessary use of more costly health care services. By helping ensure that seniors' medication use is effectively coordinated, this service is a benefit that enhances seniors' health care outcomes and contributes directly to Medicare's goals for quality and affordability.

A needed benefit that contributes to more cost effective and patient-centered care

The importance of "getting the medications right" is widely recognized by health policy analysts and quality experts as a key to more efficient, cost-effective and patient-centered care.^{1 2} This is particularly critical for seniors because the central role that medications play in their care and treatment is undeniable:

- The typical Medicare beneficiary sees two primary care providers and five medical specialists in any given year. Four of every five medical encounters result in a prescription order (new or refill);³
- 66% of Medicare beneficiaries have two or more chronic diseases; 40% have four or more;⁴
- 60% of seniors are taking 3 or more discrete prescription or non-prescription medications at any point in time.⁴

Despite these facts, traditional practice models and payment policies result in disjointed prescribing and distribution of medications from unconnected professional "silos." No effective incentives currently exist in Medicare Part B to support a coordinated medication management service for beneficiaries delivered by an effective inter-professional health care team. When combined with the continuing growth in the number and categories of medications -- and greater understanding of the genetic and physiologic differences in how people respond to their medications -- the current system consistently fails to deliver the full promise medications can offer.

The too-common result -- particularly in Medicare seniors -- is a range of medication-related problems that frequently are either unrecognized or inadequately addressed:

- dosing "mistakes" that can result in either under treatment or preventable adverse events -- or both;

¹ Smith, MA et al. Why pharmacists belong in the medical home. *Health Affairs* 2010;29(5):906-13. (May 2010)

² Isettts, BJ et al. Managing drug-related morbidity and mortality in the patient-centered medical home. *Med Care* 2012;50:997-1001 (November 2012)

³ Pham, HH et al. Care patterns in Medicare. *NEnglJMed* 2007;356:1130-1139. (March 2007) ⁴ CMS Chartbook 2012. Centers for Medicare and Medicaid Services.

⁴ CDC/NCHS Statistical Data Brief. September 2010.

- inappropriate, ineffective, or unnecessarily costly medication choices for the established goals of care;
- duplicative or interacting medications;
- avoidable side effects;
- inconsistent adherence or other patient challenges or issues that directly reduce treatment success.

In short, the current medication use “non-system” fails to get the medications right far too often.⁵

Comprehensive Medication Management “gets the medications right”

CMM is a service provided directly to patients by qualified clinical pharmacists who practice as members of functional inter-professional teams. This care occurs in some health care settings today, including integrated private sector delivery systems, the Veterans Administration, some community health centers and other settings. But it is only rarely available to most Medicare beneficiaries – the people most in need and most likely to benefit from the service.

In the emerging environment of patient-centered medical homes (PCMH), the practice of CMM is now recognized as a core strategy to achieve better clinical outcomes and quality. The Patient-Centered Primary Care Collaborative (PCPCC) supports the practice of team-based CMM and has published a resource guide to assist with the integration of this service into clinical practice in the PCMH.⁶ Medicaid programs in North Carolina and Minnesota now support CMM within the practice and service components of their primary care delivery systems.⁷

What is comprehensive medication management and how does it work?

Working in formal collaboration with physicians and other members of the patient’s health care team, qualified clinical pharmacists:

- identify and document medication-related problems of concern to the patient and all members of the care team, using a consistent care process that assures medication appropriateness, effectiveness and safety;
- initiate, modify, monitor, and discontinue drug therapy to resolve the identified problems and achieve medication-related outcomes that are aligned with the overall care plan and goals of therapy; and
- engage and educate patients and families in fully understanding their medication regimen, supporting active patient engagement in the successful use of their medicines to achieve desired health outcomes.

In “getting the medications right,” CMM also contributes to enhanced productivity for the entire health care team, allowing other team members to be more efficient in their own patient care responsibilities. Team members are freed up to practice at the highest level of their own scopes of practice by fully utilizing the qualified clinical pharmacist’s skills and training to coordinate the medication use process as a full team member.

⁵ Farekh, AK et al. The challenge of multiple comorbidity for the US health care system. JAMA 2010;303(13):1303-1304 (April 7, 2010)

⁶ Integrating comprehensive medication management to optimize patient outcomes. PCPCC Resource Guide, Second Edition June 2012. Available at www.pcpcc.net

⁷ Minnesota statute 256B.0625 Subd. 13b, 2005. Available at www.revisor.mn.gov/statutes/?id=256B.0625

Who is a “qualified clinical pharmacist?”

A qualified clinical pharmacist:

- has a doctor of pharmacy degree (Pharm.D.) or possesses equivalent clinical training/experience;
- has a formal collaborative drug therapy management (CDTM) agreement with a physician/medical group or has been granted clinical privileges to provide the service by the care setting in which (s)he practices;
- is certified or eligible for certification in a pharmacy practice specialty recognized by the Board of Pharmacy Specialties (BPS).

Why is this benefit important to add to Medicare Part B?

In addition to the data previously described, there are additional reasons why this service can be of particular value to Medicare Part B beneficiaries:

- Nearly half of all Medicare beneficiaries’ medication use is “disconnected” from their medical benefits under Medicare Part B because they choose not to enroll in a Medicare Part D drug plan.
- While Part D plans offer a “medication therapy management” (MTM) program for limited numbers of beneficiaries, these programs are, by law, administrative in purpose and scope. Part D plan administrators – not patients or clinicians - determine who can access an MTM program.
- The benefit would be available for all Part B-enrolled beneficiaries regardless of how they access or pay for their prescription medications, including creditable coverage from private and/or supplemental plans.
- The benefit would provide improved outcomes and quality achievement in Medicare Part B, AND contribute directly to goals for cost savings within Medicare Part A, including reduction in avoidable hospitalizations, readmissions, and emergency department visits.

Action needed

“Getting the medications right” is an essential objective for a modernized, cost-effective and quality-focused Medicare program. Congress should enact legislation to reform Medicare Part B to cover comprehensive medication management services provided by qualified clinical pharmacists as members of the patient’s health care team.

Appendix B

THE EVIDENCE FOR VALUE OF COMPREHENSIVE MEDICATION MANAGEMENT SERVICES: "GETTING THE MEDICATIONS RIGHT" RESOLVES REAL PROBLEMS AND IMPROVES OUTCOMES

Growing evidence demonstrates the care quality and economic benefits of a **comprehensive approach to team-based medication management**. It also reveals that some commonly cited "medication problems" for patients, including seniors, are often not the leading reasons for treatment failures and incomplete achievement of clinical goals. "Medications" include prescription and non-prescription products, herbals, and vitamins/supplements.

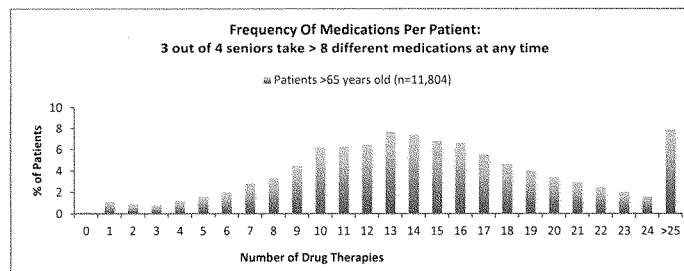
The data represented below reflect aggregated results from 19 distinct medication management service practices, provided by qualified pharmacists within settings such as community-based pharmacies, hospital-based clinics, free-standing medical clinics, and health systems. In all cases, a consistent and comprehensive process of care was used in the provision of the service. Data reflect 11,804 patients (over 65 years old) with 21,213 documented encounters. All patients received services between April 2006 and September 2010.¹

2 out of 3 Medicare Beneficiaries Need Access to Comprehensive Medication Management (CMM) Services

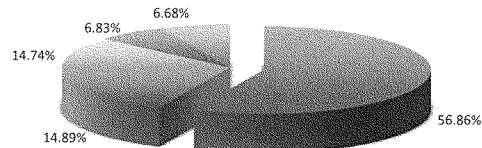
Of the 11,804 patients documented, 2 out of 3 seniors had 3 or more medical conditions and 2 out of 3 seniors were identified with 2 or more drug therapy problems.

Providing coverage for CMM services could help the Medicare program avoid:

Almost 6 million physician office visits, saving more than \$1 billion annually
670,000 emergency room visits, saving more than \$500 million annually



Types of Drug Therapy Problems:
Almost half of problems result from improper medication use.



Category of Drug Therapy Problem

- Improper Use (Dose too low/Different or additional drug needed/Wrong drug)
- Non-Adherence
- Adverse reaction
- Dose too high
- Unnecessary

HEALTH CARE SERVICES SAVINGS FROM CMM SERVICES

	11,804 patients (over 65 years old) 21,213 encounters			Medicare Part B Population Projections	Medicare Part B Population Projections**
Health care savings*	# of events avoided	# of referrals	\$ net savings	# of events avoided	\$ Gross Savings
Office visit (\$182)	9,146	838	\$1,512,056	23,789,053	4,329,607,646
Specialist visit (\$564)	549	149	\$225,600	1,427,967	805,373,388
Urgent care (\$182)	263	7	\$46,592	684,072	124,501,104
Emergency department visit (\$821)	1,033	12	\$838,241	2,686,868	2,205,918,628
Hospital admission (\$29,046)	69	15	\$1,568,484	179,471	5,212,914,666
Totals			\$4,190,973		

*Health care event savings and referral costs based on 2008 U.S. averages from Expenses per Visit for Ambulatory Visits and Inpatient Stay for 2008, Agency for Healthcare Research & Quality-Center for Financing, Access, and Cost Trends, 2010 and Genworth 2011 Cost of Care Survey, Genworth Financial 2011.

** Projections based on data collected over period: April 2006 to September 2010

(Endnotes) 1 Cipolle RJ, Strand LM, Morley PC. Pharmaceutical Care Practice: The Patient-centered Approach to Medication Management Services. 3rd edition. Copyright © 2012 by McGraw-Hill Companies, Inc.

**Examining the Medicare Part D Medication Therapy Management
(MTM)
Program:**

Statement for the Record by the American Association of Diabetes Educators

Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
October 21, 2015

On behalf of the American Association of Diabetes Educators (AADE), we are pleased to submit this Statement for the Record (Statement) in support of the Medicare Part D Medication Therapy Management (MTM) program to the Energy and Commerce Health Subcommittee (Subcommittee).

AADE is a multi-disciplinary professional membership organization dedicated to advancing the practice of diabetes self-management training (DSMT) as an integral component of health care for persons with diabetes, as well as lifestyle management for the prevention of diabetes for those at high risk. AADE represents more than 14,000 members, including nurses, dietitians, pharmacists, physicians, social workers, exercise physiologists and other members of the diabetes care team.

It is well established that diabetes is a major driver of health care costs, with health care costs for people with diabetes generally 2.3 times higher than that for the general population. Furthermore, diabetes is often referred to as a 'gateway disease' due to the many devastating complications that arise from unchecked diabetes. It is quite common for diabetes educators to treat patients with complex health needs involving multiple chronic conditions. For this reason, we believe we bring a unique perspective to the issues surrounding chronic care treatment and care coordination, and the importance of ensuring appropriate medication management in Medicare Part D as well as the Part B DSMT program.

The MTM program was developed to help beneficiaries better manage their medications. Part D plans have great flexibility in determining the eligibility criteria for their MTM program. Under the current design, plans are allowed to set their minimum number of chronic conditions required for eligibility at either two or three. Not surprisingly, CMS reports that in 2014 approximately 85% of programs chose to require beneficiaries have at least three chronic conditions to be eligible for MTM.

In 2013, CMS found that Part D MTM programs substantially improved medication adherence for beneficiaries with congestive heart failure, COPD, and diabetes. The study found that this led to significant savings in hospital costs, including reductions of nearly \$400 to \$525 in overall hospitalization costs for beneficiaries with diabetes and congestive heart failure. The report also showed that these services can reduce costs in the Part D program as

well. The best performing plan saved an average of \$45 per diabetes patient on the Part D side.

Despite the clear importance and proven value of medication adherence and MTM, the Part D MTM program historically has seen low enrollment and utilization rates. AADE notes the issue of low utilization issues also extends to the overall DSMT program, where CMS has noted in public rulemaking that DSMT remains a severely underutilized benefit.

We believe statutory changes are needed in both the MTM program as well as the DSMT program to ensure greater availability of medication adherence services for patients with diabetes. To enhance access to DSMT, we urge the Subcommittee to approve H.R. 1726 (Whitfield/DeGette/Reed), legislation which has already been vetted and approved by the Subcommittee and full E&C Committee on a bipartisan unanimous consent basis as part of health reform. This bill, which merely updates the 1997 DSMT statute to include Certified Diabetes Educators (CDEs) as DSMT providers, was scored by CBO and the CMS actuary as having a de minimis impact (asterisk) on the federal budget.

To enhance access to MTM, we believe a key statutory change includes revising the eligibility requirements so that beneficiaries with certain single chronic conditions will be eligible for MTM. As noted above, MTM can be beneficial for people with certain chronic conditions, specifically diabetes, cardiovascular disease, COPD, and high cholesterol. To help beneficiaries most in need of the advantages MTM provides, we urge the Committee to strengthen the MTM benefit in Medicare Part D by introducing and supporting legislation similar to that introduced in the Senate by Sen. Pat Roberts (R-KS) and Sen. Jeanne Shaheen (D-NH), S. 776, the Medication Therapy Management Empowerment Act of 2015, which will provide greater access to MTM.

Thank you for the opportunity to comment on this important issue.



Statement of the American Pharmacists Association

Hearing on:

“Examining the Medicare Part D
Medication Therapy Management Program”

October 21, 2015

10:15 a.m.

2322 Rayburn House Office Building

The American Pharmacists Association thanks Chairman Pitts, Ranking Member Green, and the members of the Subcommittee on Health for the opportunity to submit the following statement regarding the Medicare Part D Medication Therapy Management (“MTM”) Program for the record.

APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician office practices, ambulatory care clinics, managed care organizations, hospice settings and the uniformed services.

APhA appreciates the Committee’s recognition of the importance of high-quality care, including MTM, to the continued success of the Medicare Part D program. As a long-time advocate for Part D MTM program improvements, APhA strongly supports Congressional and federal agency efforts to foster innovation in the program.

As Congress and other policymakers consider methods for strengthening and enhancing MTM services, we encourage the removal of current barriers to beneficiary and provider participation and engagement in MTM programs. Expanding access to MTM services benefits patients and the Medicare program as whole by improving patient health outcomes attributable to effective medication management as well as overall quality of care. APhA encourages policymakers to consider the following issues when evaluating possible changes to the MTM program.

Pharmacists are committed to providing the highest quality of care possible to their patients, and, for many patients, pharmacist-provided MTM plays an essential part in optimal health outcomes. In its 2013 report on MTM programs, the Center for Medicare & Medicaid Innovation (“CMMI”) noted that “high-performing MTM programs” leverage both “trusted relationships” between pharmacists and patients and close coordination between pharmacists and prescribers.¹ We agree that these relationships are foundational and we appreciate and support programs that emphasize improvement in overall coordination of MTM services between pharmacists and prescribers, as well as other health care providers. Effective coordination of MTM services provides greater patient access to pharmacists’ services, more broadly utilizes pharmacists’ training and expertise, and permits physicians to identify and refer patients who could benefit from MTM or other medication management services.

Increased Patient Access

Despite the demonstrated benefits of MTM, and the Centers for Medicare & Medicaid Services’ (“CMS”) statement that MTM program should be “a cornerstone of the Medicare Prescription Drug Benefit,”² utilization rates for MTM services have consistently lagged behind expectations. APhA believes that eligibility criteria for services, which vary from plan to plan (although capped by guidance), may explain some of the underutilization. While we understand the necessity of baseline eligibility criteria, we suggest that the inclusion of a cost threshold (\$3,138 for CY 2015) for MTM services is unnecessary. If population-based targeting for MTM eligibility is

¹ *Id.* at 1948; CMMI, *Medication Therapy Management in Chronically Ill Populations: Final Report* (Aug. 2013).

² Centers for Medicare & Medicaid Services, *CY 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Programs: Proposed Rule*, 79 Fed. Reg. 1951 (Jan. 10, 2014).

desired, the number of chronic conditions a beneficiary has and the number of Part D drugs a beneficiary takes are likely better indicators than annual medication costs.

Additionally, MTM eligibility criteria should not supplant medical expertise. At present, plan determinations form the sole basis for MTM eligibility, and a patient's providers (who are most familiar with a beneficiary's medical history, problem list, and overall care plan) are not permitted to identify and refer patients for MTM services. In order to derive the greatest return on investment in MTM, we suggest that plans provide more discretion to health care providers, including pharmacists and prescribers, in the identification of patients who could potentially benefit from MTM services.

APhA also believes patient access and choice are critical components of effective MTM programs. Thus, APhA supports solutions that do not limit beneficiaries' ability to choose where they receive MTM services. As previously noted, CMMI has acknowledged that "high-performing MTM programs" leverage both "trusted relationships" between pharmacists and patients and close coordination between pharmacists and prescribers.³ Patients who prefer to see the pharmacist with whom they have a trusted relationship should have that option. Further, allowing patients to work with trusted, familiar providers may also improve beneficiary acceptance and utilization of MTM services.

Finally, current Medicare benefit designs and compensation structures make it difficult for pharmacists and other providers to engage fully in the provision of MTM and other services, and thus, limit patients' ability to access and benefit from coordinated team-based care. APhA strongly encourages increased flexibility and the removal of barriers preventing Medicare beneficiary access to pharmacists and other providers who are integral to concept of coordinated team-based care.

Technology Considerations

To create and maintain effective MTM programs, prescription drug plans ("PDPs") need to establish meaningful connections with pharmacists, pharmacies, prescribers, and patients, and they must be able to access Part A and B data in a timely manner in order to coordinate MTM service delivery effectively. This can be very challenging given the siloed nature of stand-alone PDPs. APhA has concerns that, due to the significant barriers in connectivity of PDPs with local pharmacists and prescribers, many of the strategies that are successful in private-sector MTM programs (*e.g.*, physician referrals or ordering consults via electronic health records ("EHRs"), reliance on local pharmacists for MTM services, and/or ordering Comprehensive Medication Reviews ("CMRs") or medication histories in advance of medical appointments) have not been incorporated into the Part D benefit. APhA encourages policymakers to engage in efforts to improve connectivity and information sharing between PDPs, pharmacists, and prescribers in order to better align the Part D MTM program with coordinated team-based care delivery models.

The most effective health care programs include the coordination and collaboration of all members of a patient's health care team. Pharmacists providing MTM have indicated to APhA that the lack of access to pertinent health information and appropriate health information technology when providing MTM services presents a major challenge. Coordination of care between pharmacists and prescribers, including the bidirectional exchange of pertinent clinical information such as the patient's goals of therapy, should underpin MTM programs. Because the Affordable Care Act did not provide funding to pharmacies to upgrade electronic systems, pharmacies may not have the resources to invest in new or improved technologies that facilitate interoperability. Thus, we recommend that, to the

³ *Id.* at 1948; CMMI, *Medication Therapy Management in Chronically Ill Populations: Final Report* (Aug. 2013).

extent possible, the Committee consider options that provide support and incentives for the implementation and adoption of systems with built-in EHR functionality for pharmacists providing MTM services.

Quality Measurement

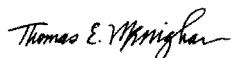
APhA supports performance incentive programs for PDPs and MTM providers based on quality metrics that are based on clinical significance and linked to improved outcomes. These should include a mixture of process (e.g., identification and resolution of drug therapy problems) and outcomes measures (e.g., hospital re-admission or emergency room encounters), and will require access to patient outcomes through Parts A and B encounter and claims data. APhA encourages the development of structured, standardized surveys of patient experience regarding the quality of services provided, as literature consistently demonstrates that patient experience is positively associated with clinical effectiveness and patient safety.

MTM Program Outreach and Awareness

Since the creation of the program, lack of awareness, on both the patient and physician levels, has proven to be a barrier to uptake and utilization of the Part D MTM services. Ongoing outreach and education about MTM services is crucial to creating and sustaining comprehensive MTM programs.

Pharmacists hope to continue working closely with Congress, federal agencies, plans, clinicians and other stakeholders to identify and implement MTM best practices that produce a substantial return on investment in pharmacist-provided MTM services and better integrate and coordinate MTM with other team-based health care services. On behalf of pharmacists, we again thank the Committee for recognizing the value of pharmacist-provided MTM services to high-quality patient care. As the Committee continues its work, we encourage you to use APhA as a resource. If you have any questions or require additional information, please contact Michael Spira, Senior Lobbyist, Government Affairs at mspira@aphanet.org or by phone at (202) 429-7507.

Sincerely,



Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice & Government Affairs
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Prescriptions for a
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"A Partnership for Advancing Medication Adherence"

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**Statement of Joel C. White
President
Prescriptions for a Healthy America
To the
Energy & Commerce Committee
Subcommittee on Health**

**Hearing Examining the Medicare Part D Medication Therapy Management
Program**

October 21, 2015

Chairman Pitts, Ranking Member Green, Members of the Subcommittee, thank you for holding this hearing to examine the Medicare Part D Medication Therapy Management (MTM) Program.

Prescriptions for a Healthy America (P4HA) is a non-partisan alliance of more than 50 members representing patients, providers, pharmacies, pharmacists, employers, and life science companies. We joined together to raise awareness of the growing challenges posed by medication nonadherence and to advance public policy solutions that will help reduce health care costs and improve the lives of patients across the nation through improved medication adherence. I was professional staff for the Committee on Ways and Means during the design, drafting and enactment of the Medicare Part D benefit. The comments in this testimony reflect my thoughts and those of many of our members, although our agreement on some of these issues is not uniform.

It is simple and true to state that drugs don't work in patients who don't take them. Poor medication adherence, or non-adherence, limits effective management and control of chronic illnesses. Non-adherence increases the likelihood of preventable disease progression, hospitalizations, avoidable ambulatory and emergency room visits, and other problems arising from poor health, which can significantly increase costs. In fact, according to the IMS Institute estimates misused and mismanaged use of medications result in more than 300 million annual incidences of avoidable medical services, including 10 million avoidable hospitalizations, 78 million outpatient encounters and 4 million ER visits that would not have occurred had medications been used appropriately. Poor medical outcomes, including more than 100,000 deaths, and advanced disease progression is also a result of poor medication use.

Because more than half of all Americans do not take their medications as prescribed, hundreds of billions of dollars in additional, unnecessary health costs are added to the



health spending ledger every year. In June of 2013, the IMS Institute issued a report estimating the U.S. healthcare system wasted over \$200 billion dollars in the previous year due to a lack of responsible medication use. That represented 8 percent of total healthcare expenditures in 2013.

This cannot and should not continue.

In a Medicare system that is fraught with inefficiencies, Part D continues to deliver comprehensive prescription drug coverage for a lower than expected cost. Additionally, 9 out of 10 seniors are satisfied with their coverage. But some aspects of the program, including the MTM benefit, are in need of modernization.

We support the following program improvements:

1. Improve eligibility criteria to better target services to those in need;
2. Revise required MTM services to provide better value to program enrollees; and
3. Realign incentives to provide services that improve outcomes and lower costs.

These changes will enhance the Part D program without undermining the current program's success in deliver a solid benefit, while holding down premiums and taxpayer costs, and still producing high satisfaction rates among enrollees.

Background

When Congress created the Part D prescription drug benefit, it required plans to offer an MTM benefit whose purpose was to ensure that covered drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Congress required the MTM program to be used in concert with drug utilization management program, quality assurance measures and systems to reduce medical errors, and programs to reduce fraud and waste. At the time Part D was created, Members of Congress envisioned these programs in concert would ultimately lower costs through more appropriate use of medications that also produce better therapeutic outcomes.

Unfortunately, ten years of evidence has produced a record that demonstrates the current MTM program has missed the mark. Low enrollment, services with questionable clinical impact and misaligned incentives lead us to believe MTM should be reformed to produce better outcomes, and more effectively target services to those in need.

1. Eligibility Criteria

The law establishes three eligibility criteria for the MTM benefit, which are minimum thresholds, and include: having more than one chronic condition, taking multiple drugs (between 2 and 8), and incurring annual costs for covered Part D drugs above a cost threshold (\$3,138 in 2015).



CMS estimates that 25 percent of Medicare Part D beneficiaries are eligible for the MTM benefit. Newly released MTM data show that, in 2012, only 11 percent (or 3.1 million enrollees) participated in an MTM program. Beneficiaries originally had to opt into the Part D MTM benefit, but CMS changed the requirement to an opt-out. This may have increased participation slightly, but did not address some of the structural problems with the MTM program design.

Sponsors may offer additional MTM services to an expanded population of beneficiaries who do not meet the statutory eligibility criteria. CMS has been tightening program rules to improve participation in, and value from, MTM programs. Despite this, the majority of Part D Plans adhere to the minimum targeting criteria. In fact, 85 percent of programs target beneficiaries with 3 or more chronic illnesses, and 52 percent of programs target beneficiaries with 8 or more drugs.

From this and in our research, we conclude that plans do not see much value in providing MTM benefits under the current structure and that the current program does not adequately identify patients who need medication management services. As CMS has indicated, plans are unable to reach many beneficiaries and many beneficiaries refuse the service because they simply do not see the value, among other issues.

We thus recommend updating the eligibility criteria to target services to those beneficiaries who need them most.

Recommendations

We recommend medication management services should be striated to target patients based on their risk for an adverse medical event. More specifically, Congress should repeal the eligibility criteria and replace them with the following structure:

- Patients should be ranked via a quantitative score based on when their medication regimen could be problematic and would therefore likely benefit from subsequent intervention.
- This score would take into account all of an individual patient's prescription medications based on the dosage form of each prescription (i.e. tablet, spray, gel, etc.), the dosing frequency (i.e. how many times a day), and additional administrative directions that could increase complexity (i.e. take prescription at specific times or with food, etc.).
- In addition to the complexity index (or score), the patient should be flagged when undergoing a transition in care or when a patient's clinical goals of care are not reached.

The latter indication would require coordinating care and data between Medicare Parts A and B and Medicare Part D. CMS should make beneficiary-level information on MTM, comprehensive medication reviews, and other plan activities available on a timely basis



and linkable to Parts A, B and D claims data in the chronic condition warehouse. Part D Plans should also have timely access to Parts A and B data for their enrollees. This access to data could provide critical information about enrollees' use and spending on medical services, risk for adverse health events and transitions in care. These data should be provided to PDPs on a regular basis in a format that is readily accessible to assist plan efforts in identifying and supporting at-risk beneficiaries.

2. Revise required MTM services

Currently, sponsors must offer a minimum level of MTM services to all eligible beneficiaries including: an annual comprehensive medication review (CMR), which is an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider for the beneficiary with an individualized, written summary in CMS' standardized format; and quarterly targeted medication reviews (TMRs) with follow-up interventions when necessary. The vast majority of plans - 95.8 percent of programs - offer the interactive CMR consultation via the phone, while 58.2 percent of programs also offer face-to-face CMRs, and 15.9 percent of programs offer CMRs through telehealth technologies.

Beyond the required services, some sponsors provide additional value-added services, including referrals for case, specialty or disease management, beneficiary education and refill reminder programs, indicating some plans see value in competing on additional services. Sponsors are also required to offer interventions to the beneficiaries' prescribers, including resolving drug therapy problems or optimizing therapy.

According to MedPAC, because neither the legislation nor subsequent CMS regulations provided specific guidance on how MTM programs should be designed or implemented, MTM programs differ in the kinds of interventions provided to enrollees and prescribers. Furthermore, the value of plan to provider intervention is questionable at best, partly because physicians are often reluctant to accept medical advice or direction from a plan with whom they have limited or no relationship.

Recommendations

Changes to services provided to Part D enrollees should enhance outcomes and reflect the movement away from paying for discrete services to paying for added value. Services should range from basic medication reconciliation to additional services that may improve adherence (i.e. medication synchronization) to more intensive and comprehensive medication management completed by a qualified clinical professional.

Plans should have the flexibility to contract for and apply the level of intensity of medication management based on the individual patient need/score.



3. Realign incentives to provide services that improve outcomes and lower costs

Plans that invest in MTM strategies are doubly disincentivized. First, their investments count against their medical loss ratio (MLR) score. Under Medicare's program rules, if an MA plan or Part D prescription drug plan fails to have an MLR of at least 85 percent, the plan must remit to the Secretary the product of: (1) the plan's total revenue, and (2) the difference between 85 percent and the plan's MLR. If a plan fails to have an MLR of at least 85 percent for three consecutive contract years, it will be subject to enrollment sanctions. If the plan fails to have an MLR of at least 85 percent for five consecutive contract years, CMS will terminate the plan contract. That is a serious disincentive for plans to spend dollars that ultimately may disadvantage them financially or that could ultimately disqualify the plan from participation in the program.

Second, any positive outcomes or savings accrue to others. Five star rating programs include adherence measures, but for beneficiaries, incentives to invest in their health are often an afterthought and rarely involve financial incentives. For providers of care, incentives in new care and payment models are rarely tied directly to medication adherence or persistence. For plans, investing in, say, cardiovascular MTM may mean a beneficiary doesn't incur a \$50,000 heart attack, but none of these savings make it back to the plan. In fact, from the plan perspective, the MTM investment is mostly pure cost.

This one-two punch means plans have little incentive to invest in robust MTM or adherence programs.

Recommendations

Congress should address each issue to ensure all actors are incentivized to improve outcomes and lower costs. At the very least, Congress should ensure that all MTM (and related medication management) activities are "quality improving" for the purpose of calculating the Medical Loss Ratio (MLR). CMS, in releasing their recent MTM demonstration program, is allowing this change, but only for plans geographically located in the test areas.

One model might be to allow plans to earn a share of savings achieved in lowering spending and/or improving health, similar to other shared savings models Congress and the Administration have authorized or tested over the past several years.

Because higher out-of-pocket costs are often the biggest barrier to medication adherence, Congress should explicitly allow plans to waive cost sharing associated with revised MTM programs. For beneficiaries, additional incentives like premium or cost sharing reduction programs should be available and should be tied to measures of adherence and persistence. Financial incentives could be tiered based on persistence (the longer someone is adherent, the more they can earn). For enrollees in an ACO or other APM, the law should allow the enrollee to share in any savings produced in the



program (the beneficiary would take the share as part of the 75 percent savings to taxpayers).

Moreover, even though a significant number of Medicare beneficiaries remain in the fee for service program, the health care system is evolving into integrated, risk-based and coordinated care models of payment and delivery. These programs create powerful incentives for payers and providers to improve outcomes, manage costs and meet quality measures. In other words, providers are being held more accountable for what they do, and new payment and delivery models attempt to break down the "silos" of healthcare spending in favor of incentives for patient care and spending that is better managed. Assuring appropriate medication use should be an integral part of all these models.

Conclusion

Mr. Chairman and members of the Committee, we believe Congress should reform the MTM program as quickly as possible as CMS conducts its research into what may work better in the future. While we see great value in and support the CMMI MTM demo, we note the current MTM structure will persist for years in those areas not covered by the research project. For reasons outlined above, this is not good for taxpayers or beneficiaries. We need Congress to act swiftly to improve the program and target services to those beneficiaries most in need.

We look forward to continuing our work with you to develop legislation to improving medication management and adherence and to lower the cost of health coverage for all Americans.



House Energy and Commerce Subcommittee on
Health

Hearing on: "Examining the Medicare Part D
Medication Therapy Management Program"

October 21, 2015

Statement for the Record
Submitted by ASHP



pharmacists advancing healthcare

American Society of Health-System Pharmacists

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ASHP (the American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the House Energy and Commerce Committee's Subcommittee on Health hearing on examining the Medicare Part D Medication Therapy Management Program.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 40,000 members include pharmacists, student pharmacists and pharmacy technicians. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, www.ashp.org, or its consumer website, www.SafeMedication.com.

Medications have become the first line of therapy to treat patients with chronic diseases and acute complex diseases such as cancer and heart failure. Breakthroughs in new medications have led to more Americans living longer, healthier lives. Along with development and approval of new medications, however, new challenges have also emerged. Within the Medicare community alone, nearly 70 percent of Medicare beneficiaries have one or more chronic conditions¹, and many of these beneficiaries are taking multiple medications. Lack of proper medication oversight and management can

¹ Centers for Medicare and Medicaid Services. Chronic Conditions Among Medicare Beneficiaries. Chartbook, 2112 Edition.

result in suboptimal therapeutic outcomes and in some cases, patient harm. For example, too many patients are unnecessarily readmitted to the hospital or have to visit the emergency department due to medication-related issues. These events also add to the costs absorbed by the Medicare Program.

As the medication use experts, pharmacists have the background and training necessary to ensure that patients make the best use of their medications, and are often the most accessible healthcare professional. Further, pharmacists today receive clinically-based doctor of pharmacy degrees, and many also complete post-graduate residencies, and become Board-certified in a variety of specialties. Pharmacists in hospitals and ambulatory clinics work with physicians, nurses, and other providers on inter-professional teams to manage patients' medications and ensure appropriate care transitions.

Care transitions alone are a significant cost driver to the Medicare Program. According to the Centers for Medicare & Medicaid Services, hospital readmissions among Medicare beneficiaries result in annual costs to the Medicare program of \$26 billion. Upon discharge from the hospital, many patients are in need of education about newly prescribed medications they must take, which often involves follow-up to ensure that medications are taken properly when they arrive home. Without it, many patients are re-admitted to the hospital, often within 30 days of being discharged. As a result, many

hospitals have now developed strategies to reduce readmission numbers by utilizing pharmacists to provide education on how to take new medications, answer questions or concerns patients have, or provide instruction on whether medications they were taking prior to hospitalization can be discontinued. Pharmacists often follow-up with patients after they return home to answer questions, and to ensure that their therapy is going as planned.

A recent study in the *American Journal of Health-System Pharmacy*² noted that patients assigned to receive pharmacist interventions in conjunction with physician hospital follow-up visits have a statistically significant lower rate of readmission within 30 days (9.2%) than those who did not receive pharmacist interventions (19.4%). Another study examined the development of a collaborative transitions of care program for heart failure patients³ in a 390-bed community hospital. Pharmacists performed daily medication profile reviews for high-risk heart failure patients, including appropriate discharge counseling. The result was a reduction in 30-day heart failure readmissions and a cost savings of roughly \$5,652 per patient.

In outpatient clinics, accountable care organizations, medical homes, and physician group practices, pharmacists are working collaboratively with other healthcare

² Impact of pharmacist intervention in conjunction with outpatient physician follow-up visits after hospital discharge on readmission rate; *Am J Health-Syst Pharm*—Vol 72 June 1, 2015

³ Development of a collaborative transitions-of-care program for heart failure patients; *Am J Health-Syst Pharm*—Vol 72 Jul 1, 2015

professionals to help patients manage their chronic diseases such as diabetes, high blood pressure, and heart failure. The value that pharmacists provide as medication-use experts has become more evident as the inter-professional team members increasingly rely on the expertise of pharmacists on medication-related issues. In addition to medication and chronic disease management, pharmacists can administer immunizations and perform preventative health-screening services such as blood pressure, glucose, cholesterol, and bone-density tests.

As the number of Americans reaching retirement continues to grow, the projected enrollment into the Medicare Program will correspondingly increase. At the same time, the number of uninsured Americans continues to decrease. The result is tremendous pressure being placed on a primary care infrastructure that cannot meet the burgeoning demand of care needs. This has left many Americans, including Medicare beneficiaries, with few options for obtaining basic healthcare services. Legislation before your committee, H.R. 592, the “Pharmacy and Medically Underserved Areas Enhancement Act” would address that gap in care by enabling pharmacists to better apply their full expertise and training to Medicare beneficiaries in underserved areas, pursuant to their state scope of practice. ASHP is a proud supporter of this legislation, and we believe it is a critical component of emerging care models that make best use of the expertise of each member of the care team.

Medication Therapy Management

In 2003, the Medicare Modernization Act created an outpatient prescription drug benefit within the Medicare Program, known as Medicare Part D. The new Part D program included a provision that required Part D plans to provide for medication therapy management (MTM) services to certain qualified Medicare beneficiaries. These beneficiaries must have multiple chronic conditions, must be prescribed multiple medications, and must have a minimum of \$3,000 in drug costs to be eligible for MTM services. ASHP believes this was a positive first step in identifying the most high-risk beneficiaries that would likely benefit from MTM services; however, we believe more needs to be done to ensure that patients receive appropriate education about their medications, and optimal outcomes are achieved. Therefore, ASHP supports the recent announcement by CMS to develop the Part D Enhanced Medication Therapy Management (MTM) Model. This model will test innovative strategies to optimize medication use, improve care coordination, and strengthen system linkages. ASHP believes that pharmacist-provided MTM services can achieve the dual objective of reducing costs to the Medicare program while improving the overall quality of patient care.

Conclusion

ASHP greatly appreciates the opportunity to provide a statement for the record on this important topic. We remain supportive of the MTM program within Part D and are pleased that CMS has begun the process of developing innovative approaches to MTM services aimed at more robust targeting and interventions. Additionally, ASHP members are at the forefront of new and innovative care delivery models that improve patient outcomes and avoid additional costs to the Medicare program. We believe that including pharmacists as non-physician providers in the Medicare program will help provide needed access to care for our nation's medically underserved patients. ASHP is committed to working with the Subcommittee on Health to advance healthcare delivery that is team-based and patient-centered, and reduces unnecessary costs to Medicare.

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October 21, 2015

House Energy and Commerce Committee
 Subcommittee on Health
 U.S. House of Representatives
 2125 Rayburn House Office Building
 Washington, DC 20515-6115

Dear Chairman Pitts and Ranking Member Green:

The Healthcare Leadership Council respectfully submits this statement for the record regarding the hearing entitled, "Examining the Medicare Part D Medication Therapy Management Program." Members of the Healthcare Leadership Council (HLC), a coalition of chief executives from all disciplines within American healthcare, applaud the committee for examining the existing Medicare Part D Medication Therapy Management (MTM) Program to make it more effective for patients. We agree with the subcommittee that "the program's incentives are not aligned and adherence to prescriptions is not as strong as possible."

Opportunities to strengthen MTM

HLC members are concerned that the way Medicare MTM is currently structured does not effectively reach patients. We suggest the following areas for improvement:

- **Revisit Eligibility Criteria:** MTM services currently target beneficiaries who have multiple chronic conditions, take multiple medications, or are likely to incur annual costs above a predetermined level. This criteria, as CMS has noted in its recent announcement of a Part D Enhanced Medication Therapy Management Model, may "both over-identify and under-identify beneficiaries who are either experiencing or at-risk of experiencing medication-related issues and could benefit from MTM interventions." Since the causes of non-adherence are myriad—and often depend on factors outside of the existing eligibility criteria (e.g., cost sharing, regimen complexity, medication beliefs, and depression¹)—it is important that plan sponsors be given the flexibility to better target the patients who need MTM services most. Special attention should be paid to patients with chronic conditions (particularly, those with multiple chronic conditions) as well as patients with low levels of health literacy. Other groups of people who may benefit the most include those who use several medications, those who have several health conditions, those who have questions about or problems with their medications, those who are taking medications that require close monitoring,

¹ Walid F. Gellad, Jerry Grenard, Elizabeth A. McGlynn. A Review of Barriers to Medication Adherence: A Framework for Driving Policy Options. Cited from Page 5. RAND: Santa Monica. 2009.

those who have been hospitalized, and those who obtain their medications from more than one pharmacy.

- **Data Sharing:** The lack of information sharing between different parts of the Medicare program inhibits the ability of plan sponsors to use best practices to improve medication adherence. With better data linkage, plans would be able to monitor patient use of medical services and target patients who need the most assistance. It would be especially helpful to share information on patients as they change venues of care and reach various disease state milestones.
- **MTM Activities:** The issue of patient adherence has been extensively researched, but the rates of non-adherence have not improved much in the past three decades. The current MTM program hampers this even more by requiring uniform service offerings for any MTM program. It is important that MTM allow flexibility for plan sponsors to better tailor interventions to suit the unique needs and challenges of different patients as well as develop new and innovative ways of more effectively reaching patients.
- **Areas of Overlap:** Because of the patient care imperative to ensure the best medication use possible, as well as the existence of many incentive and quality programs that promote MTM activities, it is possible that patients may be enrolled in multiple MTM programs. HLC is concerned that being part of multiple programs may confuse or frustrate patients, thereby negating the benefits of such programs. We encourage the committee to keep in mind the full spectrum of care providers (from standalone prescription drug plans (PDPs) to pharmacists to doctors to community health workers) and be aware that all sectors contribute expertise and insight to patient care.
- **Incentives:** As CMS noted, "Competitive market dynamics and Part D program requirements and metrics encourage investment in these activities only at a level necessary to meet minimal compliance standards." The way the program is structured creates disincentives for PDPs to offer innovative, robust MTM programs because savings created by improved medication use are often realized in the form of reduced hospitalizations and other clinical spending not related to the Part D program. We urge the committee to closely examine these incentives.

Part D Enhanced Medication Therapy Management Model

Given the challenges outlined above, HLC members are encouraged by CMS's recent Announcement to develop an Enhanced MTM Model. We strongly support the proposal's emphasis on "right sizing" MTM and testing innovative regulatory flexibility and payment incentives to target high-risk beneficiaries and provide them with the appropriate level and intensity of services.

In response to CMS's request for feedback on the proposed model, HLC submitted the following comments:

- **Regulatory flexibility:** HLC strongly supports CMS's efforts to test innovations in the Medicare Part D program. The Enhanced MTM Model's emphasis on regulatory flexibility will allow participating plans to stratify MTM services by beneficiary risk and offer different levels and types of MTM services, which should improve outcomes by targeting high-risk beneficiaries and providing them with the appropriate level and intensity of services. HLC favors incentivizing the early identification of risk factors for chronic illness, and the concept of the Enhanced MTM Model aligns with this vision.

We support the proposal's emphasis on "right sizing" MTM and also its decision to offer waivers that would allow various providers to offer interventions of a type that are not usually furnished in traditional MTM programs. While we believe the role of a pharmacist is fundamental to the clinical development of any medication management program, we look forward to drawing on the expertise of physician and nonphysician providers from all parts of the healthcare system as they work together to address barriers to optimized drug therapy.

HLC also strongly supports the notion of cost sharing assistance for financially needy enrollees because it aligns with HLC's vision of improving patient access to quality healthcare.

- **Geographic Scope:** The Announcement states that, "CMS intends to conduct the model test in the following Part D Regions: Region 7 (Virginia), Region 11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona)." Unfortunately, the way the model is designed creates a large competitive disadvantage for plan sponsors outside of the designated regions by limiting the geographic locations where these benefits will be available, despite the fact that they are available and successful today in other lines of business for sponsors operating outside of the designated regions. The design does not address the value of being able to offer these benefits to all Part D members to achieve better alignment of PDP sponsor and government financial interests and optimize therapeutic outcomes. As proposed, exclusion from the model will result in a potential delay of seven to ten years from today since the model does not start until 2017, runs for five years, and will be evaluated before making it available to a broader geographic area.

HLC recommends that CMS reconsider limiting the Part D Enhanced MTM model to only five regions. We recommend that qualified plan sponsors in other states be permitted to participate to enable them to offer the same range of benefits and incentives to their members to improve health quality and lower cost.

- **Payment incentives:** HLC welcomes the use of plan-specific prospective payments to support care management as well as performance payments as part of the Enhanced MTM model. HLC believes that a misalignment of incentives for

the standard MTM program has discouraged plans' investment in the program beyond meeting minimum CMS requirements. HLC supports performance payments as a way of offering plans greater reward in exchange for increased performance-based risk. HLC urges CMS to invest in research to determine whether these payment incentives will offset participating plan sponsors' increased resources in the Enhanced MTM model.

- **Stakeholder outreach:** HLC supports CMS's emphasis on seeking out strategies to individualize beneficiary and prescriber outreach and engagement. In particular, HLC is a proponent of using health information technology to facilitate more efficient and impactful interactions among prescribers, pharmacists, and beneficiaries. For example, the Announcement calls for "[g]reater reliance on clinical pharmacist screening or mediation of communications with prescribers," "[p]roviding beneficiary medication histories to physicians or other providers in accessible and clinically relevant formats," "[e]nabling physicians to order pharmacist consults directly from a standardized list of services on electronic medical record order entry screens," "[p]rospective medication refilling and pre-notification of prescription ordering, or prescription refill synchronization." All of these components will allow plans to better serve patients and provide high quality care.
- **Data Interoperability:** HLC welcomes CMS's efforts to develop MTM-specific code sets, because it aligns with ONC's vision of prescription drug data interoperability. HLC urges that CMS provide participating plans with an opportunity to participate in the process of developing the quality indicators that comprise the uniform set of MTM data elements. HLC also applauds CMS for attempting to link clinical and MTM data.
- **Learning Systems:** HLC appreciates CMS's emphasis on learning activities in this model, and supports the promulgation of lessons that can place all participating plans on a path to high performance. HLC members support knowledge-sharing broadly, but we request that CMS be more explicit about how plans' proprietary information can be appropriately protected while meaningfully participating in the Enhanced MTM model. In addition, we support broader sharing activities so that plan sponsors in states not permitted to participate in the model are not at a competitive disadvantage if and when the model is expanded to additional regions.
- **Stakeholder Collaboration:** HLC urges CMS to reconsider its stance regarding manufacturer and health plan collaborations. The announcement's restrictions on PDP sponsors' ability to make use of personnel affiliated with a manufacturer, manufacturer-financed coupons or discounts provided to a beneficiary or manufacturer-supplied educational materials is short-sighted. HLC believes that some types of interaction between PDPs and manufacturers are appropriate. Manufacturers have a great deal of expertise, and experience in dealing with issues of disease awareness and adherence and incentives in Part D and it is

important that all stakeholders (from pharmacists to industry) be able to share best practices. (Additionally, since PDP plans are at risk, it is unlikely that plans will use manufacturer collaboration to increase costs.) We encourage CMS to think creatively about ways stakeholders can work together to increase medication adherence.

- **Measure Development:** HLC appreciates CMS's acknowledgement that the final quality metrics for the program will need to be selected and developed collaboratively. To that end, HLC encourages CMS to rely on measures that have been developed through an intensive, transparent development and evaluation process such as the processes employed by national quality organizations like the Pharmacy Quality Alliance (PQA) and the National Quality Forum (NQF). These processes are designed precisely to provide validation of the rigor of the measure and ensure that measures reflect stakeholder consensus. In selecting measures, CMS should aim to include a range of measures that meet the above standards and reflect patient outcomes. In addition, HLC encourages CMS to work with stakeholders to choose measures that address clinical outcomes for the conditions selected by plans for enhanced MTM services to determine any potential effect that these services have on overall quality of care.

Finally, HLC encourages CMS to work with a broad range of stakeholders as it identifies measures and develops reporting specifications to assess plan performance and the overall impact of the demonstration. In addition to more direct stakeholder engagement, this will be best achieved through a public comment process that allows a full range of stakeholders to provide input into the final measure set, performance standards (e.g., for purposes of determining performance-based payments), and evaluation methods.

HLC's National Dialogue for Healthcare Innovation (NDHI) Initiative

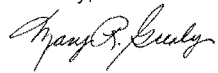
As part of HLC's National Dialogue for Healthcare Innovation (NDHI), established to bring together leaders from industry, government, academia, patient organizations, and all sectors of healthcare to discuss and develop consensus approaches to challenges affecting the course of healthcare innovation, HLC has formed a patient engagement and adherence workgroup. The workgroup, comprised of NDHI summit participants (HLC members and other diverse organizations from across the healthcare spectrum) will have a unique perspective and ability to develop comprehensive recommendations that will be beneficial to the patient.

The patient adherence workgroup has finalized its workplan, which includes a focus on how patient adherence can be supported throughout the care continuum, in acute and chronic care settings. We look forward to working on a set of care plan best practices to share with you as you work on "The Care Planning Act" (S. 1549) to help patients manage their chronic care planning and improve care coordination through care plans.

The workgroup will also seek to streamline federal medication therapy management (MTM) programs to make the current system more effective. The workgroup will meet throughout the fall and we look forward to sharing our findings from this and other workgroups with you when they are finalized.

Thank you again for the opportunity to provide a statement for the record. If you have any questions, please do not hesitate to reach out to me or Debbie Witchey at dwitchey@hlc.org or 202-449-3435.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary R. Grealy". The signature is fluid and cursive, with the first name "Mary" being the most prominent.

Mary R. Grealy
President


WWW.NCPANET.ORG

**Statement of the
National Community Pharmacists Association (NCPA)
Examining the Medicare Part D Medication Therapy Management Program
Energy and Commerce Committee: Subcommittee on Health
October 21, 2015**

Chairman Pitts, Ranking Member Green, and members of the Committee,

As the Committee examines the Medication Therapy Management (MTM) program in Medicare Part D, the National Community Pharmacists Association (NCPA) appreciates the opportunity to provide our perspective on the program, as well as recommendations on how the program can be enhanced as it enters its tenth year.

NCPA represents the interests of pharmacist owners, managers and employees of more than 22,000 independent community pharmacies across the United States. Together they represent an \$81.4 billion health care marketplace, employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescription medicines. Independent community pharmacists are proud to play a vital role in the Medicare Part D program, and have been on the front lines of providing medications, related counseling, and assistance with plans since the inception of the Part D program.

More than any other segment of the pharmacy industry, independent pharmacies are often located in the underserved and rural areas that are home to many Medicare recipients. In fact, independent pharmacies represent 52% of all rural retail pharmacies and there are over 1,800 independent community pharmacies operating as the only retail pharmacy within their rural communities.¹

Medication Therapy Management Program (MTM) under Part D: a work in progress

NCPA believes that prevention is the best medicine, and whether it's catching a medication error before it leads to a hospitalization or effective chronic disease management, MTM services present an opportunity to improve patient care while providing greater efficiencies within the healthcare system.

Recent evidence from both CMS data and the Congressional Budget Office (CBO) confirms the positive impacts associated with comprehensive medication reviews, a component of MTM, not only in relation to improved adherence and health outcomes, but also in medical savings.^{2,3} In addition to studies conducted by CMS and CBO, additional studies have shown that adherence and MTM services can lead to a reduction in overall healthcare expenditures.

MTM can lead to savings through different methods: a comprehensive medication review (CMR) is an opportunity for a pharmacist to review a patient's entire medication regimen, and identify potential cost-effective alternatives or eliminate duplicate therapies. MTM is also intended to improve medication adherence, which may increase drug spend through greater utilization, however studies have found that higher rates of

¹ Based on NCPA Analysis of National Council for Prescription Drug Programs (NCPDP) data, Rural Urban Commuting Area (RUCA) Codes, and 2000 U.S. Census data.

² CMS Center for Medicare & Medicaid Innovation, Medication Therapy Management in Chronically Ill Populations: Final Report, August 2013

³ Congressional Budget Office, Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services, November 2012.

medication adherence result in significantly fewer hospitalizations and lower health care costs, and that these savings are actually greater in patients over age 65.⁴

MTM services have proven to be a cost-effective care delivery model that provides enhanced quality to those that qualify. However, we remain concerned with the low enrollment figures for the MTM program, which we believe is due to variability in eligibility criteria for MTM set by Plan Sponsors, and the way MTM is structured in Part D, with little incentive for innovation. While we are encouraged by the recent announcement by the Innovation Center from CMS of a demonstration project examining new payment models for MTM, NCPA believes that changes to the current program can and should be made without the need to wait for final results of the Part D Enhanced MTM Model.

In fact, the Center for Medicare and Medicaid Innovation (CMMI) has already been studying the merits of MTM and released a set of recommendations on how the program can be improved overall. NCPA strongly recommends that CMS apply the findings from CMMI's review, *Medication Therapy Management in Chronically Ill Population: Final Report*. The study found that the best-performing Part D organizations were able to improve medication adherence and quality of prescribing while keeping health care costs (including drugs) from rising. In addition, the practices from high-performing MTM programs described in the CMMI report exemplify how NCPA believes MTM should be executed:

- establishing proactive and persistent CMR recruitment efforts;
- targeting and aggressively recruiting patients to complete a CMR based on information on medical events such as recent a hospital discharge in addition to scanning for the usual MTM eligibility criteria; and
- coordinating care by utilizing trusted community relationships including networks of community pharmacists to recruit MTM eligible candidates, and utilizing existing working relationships between MTM providers (pharmacists) and prescribers to make recommendations and discuss identified problems for patients.

NCPA's Recommendations for Medicare Part D MTM Reform:

- NCPA supports S. 776, the *Medication Therapy Management Empowerment Act of 2015*, which would revise the eligibility requirements so that beneficiaries with a single, specified chronic condition may be provided MTM. In addition, we strongly supported CMS' proposal to expand MTM eligibility criteria. We also support current efforts by CMS to gather feedback on MTM programs, including a review of current MTM programs and services and developing recommendations for changes and standards for Part D MTM programs, services, and documentation.
- The current Part D infrastructure is not built to support MTM expansion. As the healthcare payment paradigm shifts from a volume- to value-based system, we would strongly encourage the structure of the MTM benefit be reconsidered to one that is rewarded for quality improvement. We urge CMS to clarify that all MTM activities, including efforts to expand such activities beyond the regulatory minimum, are a 'quality improving activity' for the purpose of calculating the Medical Loss Ratio (MLR) and bidding for Part D plans.
- MTM billable services should be expanded beyond CMR to include targeted interventions that lead to positive outcomes before patients meet CMS defined MTM eligibility criteria. This could include pharmacist referrals of patients who are identified as appropriate candidate for MTM. We strongly believe that more beneficiaries can benefit from the Part D MTM program and we hope the Committee will work with CMS to create an innovative payment structure for MTM in the Part D program that aligns interests and provides meaningful quality improvement while providing overall savings to the cost of care.

⁴ M. Christopher Roebuck, Joshua N. Liberman, Marin Gemmill-Toyama and Troyen A. Brennan, Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending, *Health Affairs*, 30, no.1 (2011):91-99

- Revise the eligibility requirements so that beneficiaries undergoing a transition of care from one setting to another (identified either by provider referral or CMS notification of Part D Plans) may be provided MTM. Utilize community pharmacists to recruit MTM eligible candidates. Community pharmacists are in the best position to identify patients who need further intervention. In order to most appropriately and effectively recruit patients for MTM, a qualifying event(s) (independent of health plan) should be created. Events should be based on pharmacist judgment/criteria and could include the following: patient was hospitalized in previous month, or patient reports side effect. In addition, pharmacy claims metrics such as acute to chronic medication ratios, average number of medications within a class, new therapies in high risk categories, or use of more than 3 chronic medications could be utilized, as examples.
- It is important to expand the number of metrics related to MTM services and NCPA supports a move toward including more clinical and less process-based measures in rating Part D plans.
- NCPA strongly encourages the collection of data on the method by which the MTM medication review was delivered (telephonic or face-to-face), as well as monitor outreach methods used by plan sponsors. MTM delivered face-to-face or in an interactive tele health method with a trusted pharmacist will yield enhanced patient understanding of their medications, improved adherence, and lower costs. A study comparing MTM interventions found drug costs decreased for those who received service from community pharmacists, decreased somewhat for patients who received service from a call center pharmacist, and were unchanged for those who received MTM via educational mailings.⁵
- CMS should share summary Part A and B data with Part D plans (i.e. quarterly A and B spending by beneficiary, notification of which patients have been admitted to an institutional care provider) to support plan identification of beneficiaries that would be good candidates for MTM.

Conclusion

NCPA appreciates the Committee's interest in the Medicare Part D MTM program and strongly supports CMS' efforts to improve and expand beneficiary access to MTM. Overall reduction in total annual health expenditures was found to exceed the cost of providing MTM by more than 12 to 1 in a study examining clinical and economic outcomes of MTM.⁶

NCPA is committed to working with the staff and members of the Committee and we look forward to additional collaborative efforts between community pharmacists and other health care providers to improve the quality of care for Medicare beneficiaries while reducing health care costs.

⁵ Winston S, Lin Y. Impact on drug cost and use of Medicare Part D of medication therapy management services delivered in 2007. *J Am Pharm Assoc.* 2009;49(6):813-820.

⁶ Isett BJ, Schondelmeyer SW, Artz MB. Clinical and economic outcomes of medication therapy management services: The Minnesota experience. *J Am Pharm Assoc.* 2008; 48 (2):203-211.



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Statement
Of
The National Association of Chain Drug Stores
For
U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health
Hearing on:
“Examining the Medicare Part D
Medication Therapy Management Program”
October 21, 2015
10:15 a.m.
2322 Rayburn House Office Building

National Association of Chain Drug Stores (NACDS)
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Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Pitts, Ranking Member Green, and the members of the Subcommittee on Health for the opportunity to submit the following statement for the record regarding the Medicare Part D Medications Therapy Management (MTM) Program. NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to find ways to improve the Part D MTM program.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 115 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and nearly 60 international members representing 22 countries. For more information, visit www.NACDS.org.

The Value of Pharmacy

As the face of neighborhood healthcare, community pharmacies and pharmacists provide access to prescription medications and over-the-counter products, as well as cost-effective health services such as immunizations and disease screenings. Through personal interactions with patients, face-to-face consultations, and convenient access to preventive care services,

local pharmacists are helping to shape the healthcare delivery system of tomorrow—in partnership with doctors, nurses and others.

In addition to helping reduce post-acute care issues related to medication non-adherence, retail community pharmacists can provide high quality, cost efficient care and services. However, the lack of pharmacist recognition as a provider by third party payors including Medicare and Medicaid has limited the number and types of services pharmacists can provide, even though fully qualified to do so.

Retail pharmacies are often the most readily accessible healthcare provider. Nearly all Americans (89%) live within five miles of a community retail pharmacy. Recognition of pharmacists as providers under Medicare Part B would help to provide valuable and convenient pharmacist services to millions of Americans, and most importantly, those who are already medically underserved.

The national physician shortage coupled with the continued expansion of health insurance coverage in 2015 will have serious implications for the nation's healthcare system. Access, quality, cost, and efficiency in healthcare are all critical factors – especially to the medically underserved. Without ensuring access to requisite healthcare services for this vulnerable population, it will be exceedingly difficult for the nation to achieve the aims of healthcare reform. For this reason, we support H.R. 592, the “Pharmacy and Medically Underserved Areas Enhancement Act,” which would allow Medicare Part B to utilize pharmacists to their full capability by providing those underserved beneficiaries with services not currently reaching them (subject to state scope of practice laws).

Medication Therapy Management and Part D

Poor medication adherence costs the U.S. healthcare system \$290 billion annually.¹ Pharmacist-provided services such as medication therapy management (MTM) are important tools in the effort to improve medication adherence, patient health and healthcare affordability. Studies have shown that patients who are adherent to their medications have more favorable health outcomes, such as reduced mortality, and use fewer healthcare services (especially hospital readmissions and ER visits). These studies included patients with cardiovascular disease, chronic obstructive pulmonary disease (COPD), high cholesterol and diabetes.

MTM reduces long term healthcare expenses by improving healthcare outcomes. These savings inure to the benefit of beneficiaries through improved health outcomes and avoided health issues, the Part D plans through proper usage of medication and discontinuation of high risk and duplicative medications, and the Medicare program as a whole through decreased medical costs.

Current MTM restrictions require that Medicare Part D beneficiaries suffer from multiple chronic conditions, be prescribed multiple medications and meet a minimum annual cost threshold of \$3,138 in 2015 for their prescriptions before they are eligible for Part D MTM. The Centers for Medicare and Medicaid Services (CMS) has the authority to determine what constitutes “multiple conditions” and “multiple medications” required for MTM eligibility purposes and currently allows plans to select from anywhere between two and three conditions and two and eight drugs as the minimum required. According to the CMS MTM Fact Sheet, approximately 85% of programs opted to target beneficiaries with at least three chronic diseases

¹ Network for Excellence in Health Innovation, 2009

in 2014. This is a contributing factor to the lower than projected eligibility levels in the MTM program.

Legislative Remedy

NACDS believes revisions to the current targeting criteria for MTM eligibility should be pursued to ensure that MTM services are reaching the patients who would benefit the most. We support legislation that eases the “multiple chronic conditions” requirement by allowing beneficiaries to become eligible for MTM if they suffer from a single chronic condition that has been shown to respond well to improved medication adherence, including better health outcomes and reduced overall medical costs. Specifically, we support legislation that will provide access to MTM for beneficiaries with diabetes, cardiovascular disease, COPD and high cholesterol. Beneficiaries would still need to meet the other requirements for number of drugs and annual costs as well.

Evidence-Based Solution

An abundance of literature shows that MTM improves medication adherence and leads to better use of medicines. Services that improve medication adherence ultimately result in improved health outcomes and reduced healthcare costs. Below is a summary of recent studies and literature showing the benefits of MTM and improved medication adherence, including specific research showing the benefits for patients with diabetes, cardiovascular disease, COPD, and high cholesterol.

A 2013 report by CMS has demonstrated the impact MTM services can have on Part D beneficiaries. The report found that Part D MTM programs consistently and substantially improved medication adherence and the quality of prescribing for evidence-based medications

for beneficiaries with congestive heart failure, COPD and diabetes. The study also found savings of nearly \$400 to \$525 in lower overall hospitalization costs for beneficiaries with diabetes and congestive heart failure.²

Several states have also implemented MTM programs and have seen notable program savings for both the state and the enrolled beneficiaries. In 2012, CareSource, one of the country's largest Medicaid managed healthcare plans, began offering comprehensive MTM for individuals enrolled in Ohio Medicaid. In the first year of CareSource's face-to-face MTM program there was a return of investment greater than \$1.35 for every \$1.00 spent in drug savings alone. In the second year of the program (mid-2013 to mid-2014), the results improved to a return on investment of greater than \$2.17 for every \$1.00 spent, in drug savings alone. The North Carolina CheckMeds MTM program generated savings of approximately \$66.7 million in overall healthcare costs for the state, which included \$35.1 million from avoided hospitalizations and \$8.1 million in drug product cost savings.

A study of published research on medication adherence, conducted by Avalere in 2013,³ concluded that the evidence largely shows that patients who are adherent to their medications have more favorable health outcomes, such as reduced mortality and use fewer healthcare services (especially hospital readmissions and ER visits). Such outcomes lead to less expensive healthcare costs, relative to non-adherent patients.

² http://innovation.cms.gov/files/reports/mtm_final_report.pdf

³ [*Avalere, The Role of Medication Adherence in the U.S. Healthcare System, August 2013*](#)

The Medicare Payment Advisory Committee (MedPAC) has been studying the effects of medication adherence in the Medicare program. In 2014, MedPAC released their findings⁴ for patients newly diagnosed with congestive heart failure. The findings showed significant medical side savings for both the high and low adherent populations, compared to the non-adherent population.

Additionally, the Congressional Budget Office (CBO) has found that for each one percent increase in the number of prescriptions filled by beneficiaries, there is a corresponding decrease in overall Medicare medical spending. When projected to the entire population, this translates to a savings of \$1.7 billion in overall healthcare costs, or a savings of \$5.76 for every person in the U.S. for every one percent increase in the number of prescriptions filled.⁵ The CBO has recently applied its methodology in a review of the FY2016 National Defense Authorization Act (NDAA) which proposes to increase prescription copays for TRICARE beneficiaries. The CBO estimated that the \$4.9 billion in direct pharmacy savings would be offset by a \$1.1 billion increase in other federal spending for medical services (mostly from Medicare). Similarly, a recent study published in *Health Affairs* examined the impact of changes in prescription drug use on medical costs in the Medicaid program. The study found that a one percent increase in overall prescription drug use was associated with decreases in total nondrug Medicaid costs by a percentage very comparable to that found by the CBO, as noted above.⁶

⁴ http://www.medpac.gov/documents/reports/jun14_ch07.pdf?sfvrsn=0

⁵ <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>

Support Needed

Reforming the Part D MTM program should be accomplished through efficiently targeting beneficiaries who can most benefit from the services that will improve medication adherence and overall program effectiveness. Congress recognized the importance of MTM on a bipartisan basis, including it as a required offering in the Medicare Part D program. We urge Congress to build on this earlier action and strengthen the MTM benefit in Medicare Part D through support of legislation introduced by Sen. Pat Roberts (R-KS) and Sen. Jeanne Shaheen (D-NH), S. 776, the *Medication Therapy Management Empowerment Act of 2015*, which will provide access to MTM for beneficiaries with diabetes, cardiovascular disease, COPD and high cholesterol.

Enhanced MTM Model Test

NACDS is supportive of the initiative recently announced by CMS and the Center for Medicare and Medicaid Innovation (CMMI) to conduct a pilot allowing Part D plans the opportunity to utilize new and innovative approaches to MTM, such as more efficient outreach and targeting strategies and tailoring the level of services to the beneficiary's needs. NACDS believes the Enhanced MTM Pilot program presents an opportunity to create better alignment of program incentives for Part D prescription drug plans (PDPs), prescribers, pharmacies and CMS and has the potential to lead to improved access to MTM services for beneficiaries and greater medication adherence. Because the pilot is scheduled to last for five years (beginning in 2017), there exists the potential for delay in implementation of any successful approaches to the entire program until 2023 at the earliest. NACDS urges lawmakers to also explore new and innovative approaches to improving the MTM program that could be implemented in the short term.

⁶ <http://content.healthaffairs.org/content/34/9/1586.full.pdf+html>

Conclusion

NACDS thanks the subcommittee for consideration of our comments. We look forward to working with policymakers and stakeholders on this very important issue.



October 21, 2015

Rep. Joe Pitts (R-PA)
Chairman
 Subcommittee on Health
 Energy & Commerce Committee
 2125 Rayburn House Office Building
 Washington, DC 20515

Rep. Gene Green (D-TX)
Ranking Member
 Subcommittee on Health
 Energy & Commerce Committee
 2125 Rayburn House Office Building
 Washington, DC 20515

Re: Examining the Medicare Part D Medication Therapy Management Program

Dear Chairman Pitts and Ranking Member Green:

The Academy of Managed Care Pharmacy (AMCP or Academy) appreciates the opportunity to submit comments for the record on the hearing entitled: "*Examining the Medicare Part D Medication Therapy Management (MTM) Program*" held on October 21, 2015. AMCP appreciates that the Subcommittee is willing to consider stakeholders' perspectives associated with the Medicare Part D MTM program. AMCP strongly supports MTM programs, particularly those that focus on the ability of pharmacists to use their education and training to provide medication management in collaboration with other health care professionals to optimize beneficiary outcomes. In addition to interventions that improve adherence, MTM programs help ensure that beneficiaries receive the correct medication, ensure appropriate dosing and monitor for contraindications and potential adverse effects. AMCP supports the ability of prescription drug programs (PDPs) and Medicare Advantage programs with prescription drug benefits to provide MTM programs in a manner that meets the needs of the population served. AMCP believes that the recent enhanced MTM test model released by the Centers for Medicare and Medicaid Services' (CMS) and the Centers for Medicare and Medicaid Intervention (CMMI) is a positive step to providing flexibility to PDPs to design appropriate programs to improve the delivery of MTM services and also improve beneficiary outcomes. AMCP encourages Congress to gather data from the test model prior to enacting legislation to change existing MTM criteria.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's more than 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

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Medication-related problems are a significant public health issue within the healthcare system. The Food & Drug Administration's Adverse Event Reporting System estimates that more than 1.17 million¹ prescription related-adverse events occur each year, resulting in \$3.5 billion in medical costs annually.² Pharmacists participating in team-based care models have made positive contributions to patient care and safe medication use. Based on their focused education and training in medication management, they are uniquely positioned in the health care system to help optimize appropriate medication use, reduce medication related problems and improve health outcomes. As clinical experts working as part of an inter-professional team, pharmacists can assess whether medication use is contributing to unwanted effects and can help achieve the desired outcomes from medication use. In one significant example, a study of MTM programs in a large health system identified that 85% of patients had at least one drug therapy problem, and 29% of patients had five or more drug therapy problems.³ A pharmacist-led MTM program in that health system saved \$2,913,850 (\$86 per encounter) over a 10-year period. The total cost of MTM was \$2,258,302 (\$67 per encounter), for an estimated return on investment of \$1.29 per \$1 in MTM costs.⁴

The body of clinical and scientific literature on the positive impact on outcomes and costs associated with MTM and pharmacists' services continues to expand. To date, much of this research has not been associated directly with the Medicare Part D MTM program. In 2014, the Agency for Health Research and Quality (AHRQ) completed a systematic review of outpatient MTM programs under Medicare Part D.⁵ The review found some evidence of improvements in outcomes and rehospitalization rate reductions for beneficiaries with congestive heart failure and an increase in generic dispensing rates in community pharmacy, but overall found a very low correlation between MTM interventions and outcomes.⁶ AMCP's analysis of the systematic review found that many of the studies were published in 2004, before widespread adoption of more sophisticated MTM programs.⁷ Furthermore, the analysis disregarded some because of the interventions did not meet the targeting requirements of the MTM program.⁸ The AHRQ analysis demonstrates the need for additional research to assess the implications of MTM interventions on outcomes and costs. Additional research should not be limited to only the existing criteria for Part D MTM, but rather it should examine MTM services for Medicare Part D beneficiaries. In addition, the data collected by the enhanced MTM model, could be used to provide this much-needed data to fully examine the effectiveness of the MTM program. Through a partnership between the public and private sector, AMCP also recommends examining the impact of the use of health information technology on MTM outcomes.

¹ Food & Drug Administration's Adverse Event Reporting System Updated December 2013. <http://1.usa.gov/1W3FkGL>. Accessed October 20, 2015.

² Institute of Medicine. Committee on Identifying and Preventing Medication Errors. Preventing Medication Errors. Washington, DC: The National Academies Press 2006.

³ De Oliveria, Djenane, PhD, Amanda Brummel, PharmD, and David Miller, RPh. "Medication Therapy Management: 10 Years of Experience in a Large Integrated Health Care System." *Journal of Managed Care Pharmacy* (2010): 185-95.

⁴ *Ibid.*

⁵ MTM Interventions in Outpatient Settings. Agency for Health Care Research and Quality; November 17, 2014. <http://1.usa.gov/1LKNSF5>. Accessed October 20, 2015.

⁶ *Ibid.*

⁷ AMCP Comments to AHRQ on Systematic Review of Medicare Part D MTM. January 7, 2014. <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=17521>. Accessed October 20, 2015.

⁸ *Ibid.*

AMCP is taking proactive steps to help improve MTM programs in Medicare Part D and in other settings. AMCP recently convened an MTM Advisory Group that regularly meets to discuss ways to improve MTM programs. The Advisory Group includes both AMCP members and other stakeholders to allow robust discussion and recommendations for improvements. The Advisory Group is identifying the proper Systematized Nomenclature of Medicine (SNOMED) codes to communicate MTM services and ways to improve the delivery of MTM by electronically connecting health plans and PDPs with pharmacies and prescribers. Based on AMCP's collaborative work in MTM and in other areas, we will be positioned to provide recommendations for additional research opportunities and new areas of collaboration with the goal of adding to the data collected by the enhanced MTM test model.

The role of MTM services in Medicare Part D and other programs in improving medication use continues to expand. As noted above, AMCP supports MTM services conducted primarily by pharmacists. To more effectively provide these services, there is a need to recognize the services pharmacists provide under Medicare Part B. Recognition and payment of these services will result in pharmacists as full members of the health care team with a direct stake in patient care management and outcomes. Studies and practice-based experience have shown that when pharmacists are involved as members of the health care team, patient outcomes improve, patients report higher rates of satisfaction, and overall health care costs are reduced. AMCP encourages Congress to consider legislation to support pharmacists as providers.

Again, thank you for considering the views of stakeholders on the current and future Medicare Part D MTM program. AMCP encourages the Subcommittee and other Members of Congress to gather data from the expanded test model for MTM before making additional changes to the targeting requirements for MTM. If you have any questions, please contact Mary Jo Carden, mcarden@amcp.org, 703-683-8416.

Sincerely,



Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
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November 13, 2015

Mr. Tim Gronniger
Director of Delivery System Reform
Centers for Medicare and Medicaid Services
200 Independence Avenue, N.W.
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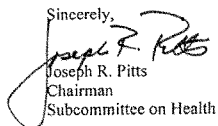
Dear Mr. Gronniger:

Thank you for appearing before the Subcommittee on Health on October 21, 2015, to testify at the hearing entitled "Examining the Medicare Part D Medication Therapy Management Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Tim Gronniger's Hearing
 "Medicare Part D MTM Program"
 Before
 E&C Health Subcommittee

October 21, 2015

Attachment — Additional Questions for the Record

The Honorable Representative Joseph R. Pitts

1. In response to questions posed by Ranking Member Green, you stated that if the CMS MTM model "data is strong enough and we were able to demonstrate improvements in quality, there would be opportunities to expand the model before the demonstration concludes in 2022." Understanding that the non-interference clause under Part D prevents CMS from interceding in the negotiations between pharmacists, plans, and manufacturers, would CMS need the support of new statutory authority to implement changes to the Part D MTM program? If not, could you please cite the statutory authority CMS believes it has to implement reforms under the MTM program, including the types of reforms permissible?

Answer: Section 1115A(c) of the Social Security Act grants the Secretary authority to expand successful Innovation Center models, if they either reduce Medicare expenditures without reducing the quality of care or improve the quality of care without increasing expenditures and meet other statutory criteria. If the Enhanced Medication Therapy Management model proves successful and satisfies these criteria, it could potentially be expanded (including on a national basis) under this authority. CMS does not anticipate that waiver of the non-interference clause would be required.

In addition to possible formal expansion under § 1115A(c) authority, the results of this model could also be used to inform policy in other ways. Specifically, lessons from this model could inform potential changes to MTM policies and rules in integrated care models, or be adopted by other types of health plans, such as those in state Medicaid programs or exchange plans. Whether additional statutory authority was required to implement such changes would need to be determined on a case-by-case basis.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (292) 235-2921
Minority (209) 275-3851

November 13, 2015

Mr. S. Lawrence Kocot
Principal
Center for Healthcare Regulatory Insight
1801 K Street, N.W.
Washington, DC 20006

Dear Mr. Kocot:

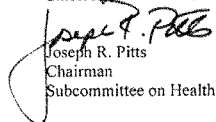
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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment



KPMG LLP
801 K Street NW, Suite 12000
Washington, DC 20006

Telephone +1 202 533-3000
Fax +1 202-533-8500
Internet www.us.kpmg.com

November 27, 2015

The Honorable Joseph Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce

The Honorable Gene Green
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce

Dear Chairman Pitts and Ranking Member Green:

Thank you for the opportunity to appear before the Subcommittee on Health at the October 21, 2015 hearing entitled "Examining the Medicare Part D Medication Therapy Management Program." By letter dated November 13, 2015, you provided an additional question for the record related to this hearing; my response to this question is enclosed. Please do not hesitate to contact me should you or the members of your subcommittees have any additional questions.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Lawrence Kocot". The signature is written in a cursive, flowing style.

S. Lawrence Kocot
Principal and National Leader
Center for Healthcare Regulatory Insight
KPMG, LLP

The Honorable Representative G.K. Butterfield**1. How do you see the role of pharmacies and pharmacists plan in the healthcare industry evolving, particularly as new models of care are explored and implemented?**

Pharmacists are among the most trusted and accessible health care providers; indeed, pharmacists are the most knowledgeable health care providers about prescription medicines and medication use.

According to the National Association of Chain Drug Stores, 93% of Americans live within 5 miles of a community pharmacy.¹ A growing number of pharmacies around the country include nurse practitioners and physician assistants to allow patients to receive additional health care services such as annual physicals, immunizations and treatment for non-emergency conditions. In light of the aging of the population and projected physician shortages, the role of the pharmacy in providing convenient access to care for acute and even chronic non-emergency care services will likely continue to grow and evolve. Pharmacists and pharmacies are well positioned to play a greater role in the health care system as new models of payment and delivery are explored and implemented. The real question is whether pharmacists and pharmacies will continue to innovate with payment and delivery models that are not primarily identified with a service linked to the sale of a pharmaceutical product. If pharmacists can be recognized and rewarded for the true value they deliver beyond putting pills in a bottle, the pharmacy could become a natural destination for the provision (and perhaps coordination) of a much greater range of health care services in the future.

¹ National Association of Chain Drug Stores. 2011-2012 Chain Pharmacy Industry Profile, p. 14

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2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (191) 225-2897
Minority (202) 225-3841

November 13, 2015

Mr. Mark Merrit
President and CEO
Pharmaceutical Care Management Association
325 7th Street, N.W.
Washington, DC 20004

Dear Mr. Merrit:

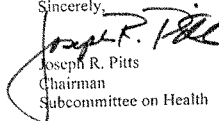
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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

Response of PCMA President and CEO Mark Merritt
 Questions for the Record
 “Examining the Medicare Part D Medication Therapy Management Program”
 October 21, 2015
 Committee on Energy and Commerce
 Subcommittee on Health

Q: It is clear that utilization of the Part D Medication Therapy Management program has been quite low since its inception. There may be a number of reasons contributing to this, but it seems that Part D plans have high eligibility criteria for their covered beneficiaries resulting in low participation. Why is it that most plans require three or more chronic conditions and eight or more prescription drugs?

Part D plan sponsors design their MTM programs around very specific statutorily outlined criteria that are reviewed and updated regularly by CMS. The Part D program regulations at 42 CFR §423.153 establish as benefit parameters for targeted beneficiaries no more than three chronic diseases and up to eight Part D drugs (See Attachment A). The CMS Part D benefit group updates these parameters on an annual basis through the Call Letter process. On April 7 of this year, this final guidance was published for the 2016 benefit year (See Attachment B). According to CMS’s guidance, “[s]ponsors must enroll targeted beneficiaries using an opt-out method of enrollment only.” In other words, the beneficiaries who are automatically enrolled in the program are those who meet the stated regulatory criteria.

Generally speaking, plans in the marketplace follow the program parameters. Unfortunately, this one-size-fits-all approach has not been effective in identifying appropriate beneficiaries, or in getting beneficiaries once identified to engage in the program. In addition, with the uncertainty of how MTM costs that are incurred with respect to activities that exceed the regulatory parameters are treated under the Part D medical loss ratio rules, plans are reluctant to undertake the risks involved in diverging from the regulatory standards.

As discussed in my written testimony,

We hear reports from our own companies mirroring CMS’ findings that current rules governing MTM result in misaligned incentives that are most prominent in stand-alone Part D plans. Unlike Medicare Advantage plans that manage the entire range of Medicare benefits (MA-PDs), stand-alone drug plans manage only the prescription drug benefit for enrollees. As a result, the incentive to design and deploy innovative and creative measures to improve medication management runs up against the reality that savings generated in Parts A and B of Medicare as a result of better adherence will not accrue to the Part D plan, which undertakes such an effort. In addition, increased spending for MTM benefits in a stand-alone drug plan puts upward pressure on beneficiary premiums for that plan while the savings in the traditional Medicare program benefits are not going to reduce plan premiums as they would in an MA-PD plan.

Misallocation of resources is also a result of requirements determining which beneficiaries receive MTM. Under current requirements, beneficiaries meeting targeting criteria for MTM are supposed to receive certain services and interventions, such as the annual comprehensive medication review (CMR). Beneficiaries are targeted for MTM according to the condition and number of drugs prescribed, and annual drug spending. However, if an enrollee declines the annual CMR—indicating the enrollee believes he or she is well controlled on medications or possibly is indifferent or even hostile to receiving an intervention—the plan sponsor is still required to perform other MTM services at least quarterly on an on-going basis for that

individual. This can result in a waste of significant resources that could be used to prioritize MTM services for beneficiaries who want, need, and would benefit from them. Indeed, a CMS-sponsored report by Acumen recently found that for the three disease conditions studied (i.e., diabetes, CHF and COPD), MTM programs, on average, increased Part D costs annually by \$75 to \$181 per patient, with no clear proof that the current MTM programs as currently implemented have created robust or persistent improvements.

While our companies fully embrace the need to help improve medication use and to reduce the risk of adverse events, they agree with these findings and believe the current enrollee targeting criteria and extensive process requirements prevent the Part D MTM program from accomplishing its intended goals.

...Congress should assure that all Part D plans not participating in the Model may include any costs incurred to create and implement innovative MTM programs as a quality improving activity for purposes of Medical Loss Ratio (MLR), whether inside or outside the Model test. Doing so will encourage those plans outside the geographic footprint of the Model test to also innovate in what most agree is a flawed MTM system.

In the 2015 Medicare Part D proposed rule, CMS sought to lower the thresholds for the current MTM eligibility criteria so that more beneficiaries would qualify. PCMA submitted extensive comments on the proposal (See Attachment C), where we detailed the many shortcomings of this approach.

Q: It seems like a way to significantly limit people's eligibility for the program. Can you comment on this?

As noted above, there is significant consensus that the existing CMS eligibility requirements for the MTM program are poorly targeted and ineffective. Indeed, after receiving extensive comments on the proposed 2015 Medicare Part D rule, which would have significantly expanded the criteria, CMS was convinced that the existing construct does not work and thus backed away from its expanded benchmarked auto-enrollment criteria.

We are pleased with the new CMS Model Test for MTM, as it is not simply expanding eligibility for a dysfunctional program but instead providing for the possibility of new parameters that will target appropriate beneficiaries and provide incentives to help assure that increased numbers of patients will participate.

