Testimony of Mark Merritt

President & Chief Executive Officer

Pharmaceutical Care Management Association

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"Examining the Medicare Part D Medication Therapy Management Program"

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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.