

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

Statement of  
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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).<sup>1</sup>

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<sup>1</sup> 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.”<sup>2</sup>

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.<sup>3</sup> 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

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[Trends-and-Reports/MCRAdvPartDEnrolData/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-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report-Items/Contract-Summary-2015-10.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending)

<sup>2</sup> 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>

<sup>3</sup> 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...”<sup>4</sup> 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.”<sup>5</sup>

Medicare Part D Plan sponsors are required to incorporate an MTM program into their plans’ benefit structure.<sup>6</sup> 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.<sup>7</sup>

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

<sup>5</sup> 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>

<sup>6</sup> Centers for Medicare and Medicaid Services. “Medication Therapy Management.”

<https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/mtm.html>

<sup>7</sup> 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).<sup>8</sup> Currently, CMS requires plan sponsors to offer a minimum level of MTM services to each beneficiary enrolled in the program that includes<sup>9</sup>:

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.

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<sup>8</sup> Ibid.

<sup>9</sup> 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.<sup>10</sup>

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.<sup>11</sup>

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.<sup>12</sup> Although a number of organizations, including the American Pharmacists Association supported the

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<sup>10</sup> 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/ReqforCommentson2013ReportingRequirements\\_01102012.pdf](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/ReqforCommentson2013ReportingRequirements_01102012.pdf)

<sup>11</sup> Acumen LLC. Medication Therapy Management in Chronically Ill Populations: Final Report. August 2013. [http://innovation.cms.gov/files/reports/mtm\\_final\\_report.pdf](http://innovation.cms.gov/files/reports/mtm_final_report.pdf)

<sup>12</sup> 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,<sup>13</sup> 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.”<sup>14</sup>

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.”<sup>15</sup>

### **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

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<sup>13</sup> 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>

<sup>14</sup> Medicare Payment Advisory Commission. “Report to Congress: Medicare Payment Policy” March 2014. [http://medpac.gov/documents/reports/mar14\\_entirereport.pdf](http://medpac.gov/documents/reports/mar14_entirereport.pdf)

<sup>15</sup> 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.<sup>16</sup> 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.”<sup>17</sup>

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.<sup>18</sup> 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.

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<sup>16</sup> 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](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)

<sup>17</sup> 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](http://innovation.cms.gov/files/reports/mtm_final_report.pdf)

<sup>18</sup> 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/ehec/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:<sup>19</sup>

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

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<sup>19</sup> 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.<sup>20</sup>

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<sup>20</sup> 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/>