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

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"Examining the Medicare Part D Medication Therapy Management Program"

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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, Ardery 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 savings[4] supports the belief that more than 25 percent of enrollees could benefit from MTM services. In the 2010 Call Letter[5] 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 disincent 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.