July 28, 2021

The Honorable Xavier Becerra Secretary US Department of Health and Human Services 200 Independence Ave SW Washington, D.C. 20201

Subject: Extending the CMMI Enhanced Medication Therapy Management Model to Ensure the Safety of Medicare Beneficiaries

Dear Secretary Becerra:

On behalf of the undersigned organizations representing patients, providers, public and private sector purchasers, health care innovators, pharmacy stakeholders, and health plans, we urge you to extend the Center for Medicare & Medicaid Innovation (CMMI) Part D Enhanced Medication Therapy Management Model (EMTM, the Model) that is set to expire on December 31, 2021. For the last four years, Medicare Part D beneficiaries enrolled in EMTM have benefitted from the innovations and clinical resources funded by the Model to ensure the safe use of medications as part of their care. Many EMTM interventions have demonstrated improved health outcomes and lower medical spending in Parts A and B, and closely align with best practices for medication therapy models that ensure safe, effective and appropriate medication use. In summary, EMTM continues to promote alignment of plan incentives, patient and physician satisfaction, and improved health outcomes, especially for vulnerable populations who stand to benefit the most from medication safety services, and is a step towards a more comprehensive and rational process of care to optimize medication use through Comprehensive Medication Management (CMM)¹ in practice, including prospective management of medication risk.

Specifically, we urge you to use Section 1115A authority to:

1) Apply key flexibilities from the EMTM Model to the Medicare Part D Medication Therapy Management program (MTMP) to allow plan sponsors to implement innovative best practices currently unavailable in MTMP;

AND,

2) Extend the EMTM Model beyond the December 2021 end date to better understand the full implications for savings and quality improvements from the first five years of the model test, without disrupting current programs and investments.

We applaud the Department of Health and Human Services' (HHS) commitments to ensuring seniors, people with disabilities, and all Americans receive equitable, high quality health care. Medicare beneficiaries – especially those who take multiple drugs, and Black, Latino, and other underserved communities located in pharmacy deserts – are at higher risk for adverse events that can have significant implications for cost and quality of care.² The lessons and opportunities uncovered by the EMTM Model

¹ https://gtmr.org/what-is-the-comprehensive-medication-management-process/

² Fewer Pharmacies In Black And Hispanic/Latino Neighborhoods Compared With White Or Diverse Neighborhoods, 2007–15 | Health Affairs

should play a critical role in improving Medicare Part D MTMP to ensure the safety and health of Medicare beneficiaries.

Prescription drugs are a critical component of high-value health care, including the management of high-cost chronic conditions. Approximately 46 million Americans enrolled in a Part D plan in 2020, 44 percent of which were in standalone prescription drug plans (PDPs).³ On average, beneficiaries in these standalone plans filled 3 prescriptions per month.⁴ While critical to treatment and prevention, drugs create risks as well. Studies have shown that for every dollar spent on prescription drugs, payors (including public and private employers) spend more than a dollar on the problems caused by these medications.⁵ Most importantly, adverse drug reactions (ADRs) are the fourth leading cause of death in the United States among older adults, in part due to the fact that one in three Americans take five or more medications.⁶ Black, Indigenous, and People of Color (BIPOC) will likely benefit most from additional investments in patient safety, including in medication risk and adherence.⁷ One study found that African American women, for example, are more likely to suffer from medication-related falls than White men or women.⁸

Since its inception in 2003, the Part D MTM program has required Part D plans to establish MTM services for enrollees who meet specific eligibility requirements, focused on an enrollee's chronic illness and number of prescriptions, to reduce the risk of adverse drug events and save health care costs. Unfortunately, the traditional MTMP has not met expectations. CMS explicitly designed EMTM in recognition that Part D plans were falling short of their potential to improve quality and reduce medical expenditures. Since the Model began, little has changed to address the shortfalls of Part D MTMP.

Fragmented incentives increase risk for patients on multiple drugs in Part D, particularly for beneficiaries in standalone PDPs. First, there is little to no financial incentive for standalone PDPs to invest in robust and collaborative MTM services; they do not benefit directly from preventing medical complications that arise from ADRs because these plans are not responsible for the resulting medical costs (e.g., hospitalizations). Until recently, standalone PDPs did not have access to Part A and B data at all, outside the EMTM Model. Therefore, PDPs outside Medicare Advantage rarely invest in or sustain MTM programs beyond the minimal requirements. Second, commonly used tools and processes to identify and address potential ADRs through existing MTMP services are outdated. For example, MTMP emphasizes siloed interventions to foremost improve medication adherence, rather than more salient patient care services, such as identification and management of simultaneous multi-drug interactions – including pharmacogenomics testing, as necessary.

³ Medicare Part D: A First Look at Medicare Prescription Drug Plans in 2021 | KFF

⁴ Medicare Part D Charts - Chronic Conditions Data Warehouse (ccwdata.org)

⁵ Watanabe, McInnis, Hirsch, Cost of Prescription Drug-Related Morbidity and Mortality, SAGE, UC San Diego Health, 2018

⁶ Preventable Adverse Drug Reactions: A Focus on Drug Interactions | FDA

⁷ Social disparities in patient safety in primary care: a systematic review (nih.gov)

⁸ Trends in fall-related mortality and fall risk increasing drugs among older individuals in the United States, 1999–2017 (wiley.com)

⁹ 42 CFR Section 423.153(d)

¹⁰ https://docs.house.gov/meetings/IF/IF14/20151021/104071/HHRG-114-IF14-Wstate-KocotL-20151021.pdf

¹¹ Part D Enhanced Medication Therapy Management Model Fact Sheet | CMS

¹² Evidence Supporting Enhanced Medication Therapy Management (cms.gov)

¹³ Medicare Part D's Medication Therapy Management: Shifting from Neutral to Drive (aarp.org)

Recognizing the importance of testing more patient-centered improvements to the MTM program, CMMI launched the EMTM Model demonstration on January 1, 2017.¹⁴ The goal of EMTM is to align incentives, lower overall Medicare spending through medical savings in Part A and B and reduce medication risk for enrollees. The Model includes several key elements and flexibilities to achieve these goals:

- Prospective payments for Part D plan sponsor capital investments;
- Quality incentive payments for reducing overall Medicare costs (i.e., shared savings);
- Flexibility to build innovative interventions and better target these interventions; and
- Standardized codes for documenting interventions.

The EMTM Model's flexibilities and incentives promote robust, interdisciplinary services that will lead toward a more rational approach to medication use found with the practice of CMM, which saves lives and reduces costs. ^{15,16} Specifically, the Model enables collaboration between plan sponsors, pharmacists, primary care physicians, and investment in advanced technology, all of which can substantially improve the safe use and efficacy of medications in Medicare beyond the traditional Part D MTM program. Successful EMTM programs elevate the role of the pharmacist as a medication expert in team-based care for patients with complex risks, while also adopting predictive algorithms to better target interventions based on patient-specific risk scores, which in other settings have been strongly associated with higher costs. ¹⁷ Some EMTM interventions also use call centers with geriatrics-trained pharmacists and have built networks of trusted, local community pharmacists. Many of these practices would be unavailable in traditional MTM, without the regulatory flexibility and capital investments made possible by EMTM.

The most recent publicly available evaluation (released in 2019) concluded that the EMTM Model is still evolving, and evaluators need more data to fully understand the results of the Model in terms of savings, especially as the interventions in the Model changed over time.¹⁸ The evaluation does not speak directly to improvements in health equity, service quality, or avoided ADRs.

We encourage the Administration to view the 2019 evaluation, and future evaluations, in the broader context of Part D and recent disruptions in health care due to the novel coronavirus pandemic. First, ending the EMTM Model prematurely or not adopting best practices from the EMTM experience would be a missed opportunity to build upon a unique shared savings approach that addresses a leading cause of morbidity and mortality among beneficiaries in Part D. Ending the model would leave hundreds of thousands of the most vulnerable beneficiaries to regress to the traditional MTMP that we know does not work well. Second, the coronavirus pandemic has created substantial challenges in comparing cost and quality results across populations and regions. An extension of the EMTM Model would allow evaluators more time to assess cost and quality data and prevent disruptions in critical EMTM services.

Despite inconclusive model-wide estimates of net savings in the second formal evaluation, individual participants have created robust programs that have demonstrated both savings and higher quality. However, EMTM participants would be unable to apply these successful tactics in the traditional MTMP without EMTM Model flexibilities around beneficiary targeting and intervention design. Stakeholders

¹⁴ Part D Enhanced Medication Therapy Management Model | CMS Innovation Center

¹⁵ Cost of Prescription Drug-Related Morbidity and Mortality - PubMed (nih.gov)

https://www.amjmed.com/article/S0002-9343(20)31173-6/fulltext

¹⁷ https://www.carekinesis.com/wp-content/uploads/2018 Cicali B Benefits Q Application of a novel medication-related risk stratification strategy.pdf

¹⁸ Evaluation of the Part D Enhanced Medication Therapy Management (MTM) Model: First Evaluation Report (cms.gov)

involved in the Model have expressed concern that the lack of model-wide savings represents an issue in Model design, particularly the shared savings payments, more so than a failure to deliver higher quality and lower medical spending.

CMS should build on these EMTM investments across the country by taking steps to extend the EMTM Model and adopt best practices from successful participants to Part D MTMP. In extending the Model, CMS could also narrow the scope of the EMTM requirements to best match successful programs, including the use of broader beneficiary qualification criteria than the traditional MTMP, the elevated role and reimbursement of pharmacists conducting interventions, incorporating physician and beneficiary feedback into MTM services, and leveraging technology to quantify risk beyond one-to-one drug interactions. If model parameters were to change, we ask that plan sponsors be given the opportunity review the proposed changes.

The EMTM Model offers a step in the right direction for the safety of Medicare beneficiaries who take multiple drugs. Ideally, the future of medication management in Medicare would include the adoption of CMM services, as defined by the Primary Care Collaborative, and include reimbursement for those services through Part B.¹⁹ The future should also include prospective pharmacy encounters. Such services would go beyond claims-based reconciliation and include the personalized identification of medication-related problems and active medication risk mitigation before medication issues can manifest at all.

In summary, to improve the use of medications for Part D beneficiaries, the undersigned organizations strongly urge you to use existing authority under Section 1115A to extend or expand an important program to ensure medication safety for millions of Americans on Medicare:

1) Apply key flexibilities from the EMTM Model to the national Part D MTMP, to allow plan sponsors to implement innovative best practices currently unavailable in MTMP;

AND

2) Extend the current CMMI EMTM Model beyond the current performance end date of December 31, 2021, to better understand the full savings and quality improvement implications of the first five years, without disrupting current programs and investments.

Again, thank you for your leadership in improving the Medicare Part D program. We would welcome the opportunity to discuss this issue with you and your staff further.

Sincerely,

Academy of Managed Care Pharmacy Aging Life Care Association American Academy of Home Care Medicine American Association of Colleges of Pharmacy

¹⁹ McInnis, Terry, et al., editors. The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. 2nd ed., Patient-Centered Primary Care Collaborative, The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. PCPCC Medication Management Task Force collaborative document.

American College of Apothecaries

American Pharmacists Association (APhA)

American Society of Consultant Pharmacists

American Society of Health-System Pharmacists (ASHP)

Avanti Healthcare

Chapman University School of Pharmacy

Coalition to Transform Advanced Care (C-TAC)

CPESN USA

Get The Medications Right Institute

Good Neighbor Pharmacy

Health Mart Pharmacy

H-E-B

Marshfield Clinic Health System

National Alliance of Healthcare Purchaser Coalitions

National Alliance of State Pharmacy Associations

National Association of Chain Drug Stores

National Association of Nutrition and Aging Services Programs

National Center for Farmworker Health (NCFH)

National Coalition on Health Care

National Community Pharmacists Association (NCPA)

New Jersey Health Care Quality Institute

Partners in Care Foundation

Pharmacy Quality Alliance

Price Chopper/Market 32 Supermarkets

Project Patient Care

Public Sector HealthCare Round Table

RxAnte, Inc.

Tabula Rasa HealthCare

Teachers' Retirement System of the State of Kentucky

The Gerontological Society of America

Thrifty White Pharmacy

University of Minnesota College of Pharmacy

Wellcare Health Plans

cc:

The Honorable Chiquita Brooks-LaSure, Administrator, Center for Medicare & Medicaid Services;

Elizabeth Fowler, JD, PhD, Deputy Administrator and Director, Center for Medicare & Medicaid Innovation.