ADVANCING MEDICATION THERAPY MANAGEMENT QUALITY MEASUREMENT

A report from the PQA Quality Innovation and Research Initiative for Medication Therapy Management

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EXECUTIVE SUMMARY

The Centers for Medicare & Medicaid Services (CMS) requires Medicare Part D plan sponsors to establish a medication therapy management (MTM) program designed to ensure covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events. Plan sponsors are required to target enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet an established cost threshold for covered Part D drugs, or are at-risk beneficiaries under a drug management program. CMS has made significant changes to the MTM program requirements over the years to enhance enrollment, improve the quality of services, reduce gaps in care, and most recently for 2025, to promote consistent, equitable, and expanded access to MTM services.

Part D MTM programs include high-touch interventions designed to engage patients and their care teams. At a minimum, MTM services include interventions for both patients and prescribers, an annual comprehensive medication review (CMR) with written summaries in a standardized format, quarterly targeted medication reviews (TMRs) with follow up interventions, and information about safe disposal of prescription medications that are controlled substances.

The Pharmacy Quality Alliance (PQA) developed and stewards the current health plan performance measure used in the Part D Star Ratings to evaluate MTM quality, which focuses on the MTM Program Completion Rate for CMR. Although this existing CMR process measure serves an important purpose to focus plan sponsors on delivering required MTM services, PQA's members and other stakeholders have continued to explore new MTM concepts that are patient-centered, clinical and outcome focused, and assess the quality versus quantity of MTM services. However, development of new MTM measures is challenging given the lack of readily available data that reflect the clinical aspects of MTM services, variability in plan sponsor eligibility targeting criteria, and limited high quality studies on MTM services to support a process-outcome linkage.

To address these challenges, PQA launched a national initiative in 2023 aimed at improving the quality and measurement of MTM services. This initiative was conducted through the PQA Quality Innovation and Research Center (QuIRC), which is designed to accelerate progress in medication use quality through pilot, demonstration and research projects and consensus-building events. QuIRC answers the difficult questions needed to deliver the next generation of medication use quality measures and tools for improving medication use outcomes.

As an essential initial step in this initiative to build a case for new quality measures, PQA:

- Conducted an environmental scan that included peer-reviewed and grey literature, federal resources, and two stakeholder surveys;
- Held an in-person convening event, public comment period, and follow-up webinar; and
- Published this report containing the call to action.

This call to action describes the critical actions necessary to improve the quality and measurement of MTM services. The elements of the call to action are not listed in priority order, rather they represent a range of interrelated and necessary focus areas from quality improvement to quality measurement.

CALL TO ACTION

I. Investigate optimal MTM eligibility and targeting criteria for achieving program goals.
II. Enhance collaboration between prescribers, MTM providers, and plan sponsors to better address patient goals of care and implement appropriate medication changes.
III. Optimize patient and prescriber awareness of Part D MTM services and the benefits patients may receive.
IV. Amplify the patient voice to improve the patient-centeredness of MTM programs.
V. Strengthen requirements for the use of standardized health information technology for documentation of MTM services.
VI. Increase consistent use of the PQA Medication Therapy Problem Categories Framework through stakeholder education.
VII. Develop new performance measures for MTM quality.
VIII. Prioritize research to optimize the Part D MTM program and services.

INTRODUCTION

Since implementation of the Medicare Part D prescription drug benefit program in 2006, the Centers for Medicare & Medicaid Services (CMS) has required plan sponsors to establish a medication therapy management (MTM) program designed to ensure covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events.[1, 2] Adverse drug events are preventable and a serious public health threat.[3] The combination of an aging population, increased use of medication therapy to support positive health outcomes, and significant opportunity to optimize medication use among older adults[4] underscores the importance of programs like Part D MTM.

Part D MTM programs include high-touch interventions to engage patients and their care teams. At a minimum, MTM services include interventions for both patients and prescribers, an annual comprehensive medication review (CMR) with written summaries in a standardized format, quarterly targeted medication reviews (TMRs) with follow up interventions, and information about safe disposal of prescription medications that are controlled substances. Part D plan sponsors are required to target enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet an established cost threshold for covered Part D drugs, or are at-risk beneficiaries under a drug management program.[1, 2] CMS has changed the Part D MTM program requirements over the years to enhance enrollment, improve the quality of services, and reduce gaps in care.[5]

The Pharmacy Quality Alliance (PQA) developed the *Completion Rate for Comprehensive Medication Review* (CMR) performance measure[6] (referred to by CMS as MTM Program Completion Rate for CMR) to assess the percentage of beneficiaries eligible for MTM who received a CMR during the measurement year. Over the course of its implementation in the Medicare Part D Star Ratings, plan sponsor performance on the measure improved consistently and significantly. When the measure was first introduced to the Star Ratings in 2016, average measure rates were 16% and 31% for stand-alone Medicare prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MAPDs), respectively. In the 2024 Star Ratings, performance was 56% for PDPs and 84% for MAPDs.[7] Although the measure has been essential to focus plan sponsors on CMR completion for eligible beneficiaries, PQA has continued to engage stakeholders to explore opportunities to develop additional quality measures beyond the process of CMR completion to focus on service quality and clinical endpoints.

Industry initiatives have aimed to advance MTM quality and measurement. For example, stakeholders created frameworks for standardized documentation of MTM services, which is critical for clinical quality measures.[8, 9] The CMS Innovation Center also aimed to advance MTM through a five-year demonstration project, the Part D Enhanced MTM model (Model). From January 2017 through December 2021, the Model tested whether modifications to traditional Part D MTM requirements for PDPs incentivized better medication management interventions, improved therapeutic outcomes, and reduced expenditures.[10] Although there were no statistically significant impacts on Medicare Parts A and B expenditures or improvements on intermediate measures of medication use for the overall enrollee population in Model-participating plans, lessons learned from the Model can support future efforts by plan sponsors, policymakers, and other relevant stakeholders to improve traditional Part D MTM programs.

PQA has continued to engage stakeholders to explore opportunities to develop additional quality measures beyond the process of CMR completion to focus on service quality and clinical endpoints.

Over the years, PQA increasingly heard from stakeholders that more attention was needed related to Part D MTM program quality and measurement. The urgency for action increased after CMS' Contract Year (CY) 2024 Medicare Advantage and Part D proposed rule (87 FR 79452) was published in December 2022, which proposed substantial expansion to eligibility criteria for the Part D MTM program.[11]

To address stakeholder needs, in June 2023, PQA launched the Quality Innovation and Research Initiative to Advance Medication Therapy Management Quality Measurement – a multiphase national initiative to improve MTM quality and measurement. As an essential initial step in this initiative to build a case for new quality measures, PQA:

- Conducted an environmental scan including peer-reviewed and grey literature, federal resources, and two stakeholder surveys;
- Held an in-person convening event, public comment period, and follow-up webinar; and
- Produced this final report containing the call to action.

On April 4, 2024, prior to publication of this report, CMS issued the CY 2025 Medicare Advantage and Part D final rule (89 FR 30448) that finalized expanded eligibility criteria for the Part D MTM program.[12] Initial implications of these regulatory changes are reflected in this report.

Following a description of our approach to this initiative, we summarize the information gathered, organized by each element of the call to action. This call to action describes the steps necessary to improve the quality and measurement of MTM services. The elements of the call to action are not listed in priority order, rather they represent a range of interrelated and necessary focus areas from quality improvement to quality measurement.

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METHODS

The robust information gathered for this initiative was an essential initial step to build a case for new quality measures, which includes reviewing published and grey literature, the regulatory environment, and interested party needs and capabilities.[13] PQA engaged a planning committee composed of six members, including MTM stakeholders from academia, health systems, payers, pharmacy, MTM providers, and a patient who receives MTM services (refer to Appendix A). The planning committee worked collaboratively with the PQA project team to inform the environmental scan approach, draft call to action, PQA Convenes event, public comment analysis, and final report.

The robust information gathered for this initiative was an essential initial step to build a case for new quality measures.

LITERATURE REVIEW

The PQA Quality Innovation and Research Initiative to Advance Medication Therapy Management Quality Measurement launched in June 2023 with a robust environmental scan including peer-reviewed and grey literature, federal resources, and two stakeholder surveys. The PubMed database was used to search for articles using the keywords "Medicare" with "medication therapy management", "comprehensive medication review" and "targeted medication review". Grey literature was assessed to understand policies and further contextualize findings from the literature review.

An iterative approach was taken to refine the project scope and identify inclusion and exclusion criteria. Peer-reviewed original research articles were considered in scope if the studies were conducted after the inception of the Part D MTM program in 2006; aligned with the MTM requirements specific to the Part D program; discussed or evaluated Medicare beneficiaries only; and focused on key areas of interest, such as the Part D Enhanced MTM model, evidence of MTM outcomes, patient perspectives, and health equity. Review articles and grey literature were in scope if they focused on the Part D MTM program and key areas of interest, including background information on the program. Articles were considered out of scope if they focused on broad medication management, comprehensive medication management, medication reconciliation, or focused on a topic outside of PQA's interests for this initiative, such as patients' willingness to pay for MTM services or reimbursement for MTM services. These exclusion criteria were determined based on our objective and interests specific to advancing the quality and measurement of Part D MTM services.

SURVEYS

Two surveys were conducted aimed to characterize the industry's use of MTM quality measures and to better gauge documentation practices related to MTM services. Through a snowball approach, stakeholders were encouraged to participate and share each survey within their organizations and with colleagues between June 28 and August 9, 2023. Survey responses were de-identified and aggregated. Of the nearly 200 MTM stakeholders invited to complete both surveys, 46 completed the MTM Quality Measures Survey, and 39

completed the Medication Therapy Problem (MTP) Categories Framework Survey. The types of organizations most represented among survey respondents were health plans, academia, and health systems.

PQA CONVENES

The information from the environmental scan informed a draft call to action to advance the quality of MTM. Environmental scan findings also informed discussions at a PQA Convenes event on November 2, 2023. The event brought together nearly 100 PQA members and other MTM stakeholders to help build consensus on the research, measurement, and other strategies needed to evolve the national approach to evaluating the quality of MTM services. Participants discussed the state of MTM practice, learnings from the Part D Enhanced MTM model, implications of recent policy proposals, equity issues with MTM, and opportunities to improve MTM quality measurement. Through an interactive polling session at the end of the event, participants indicated their level of support for eight elements of a draft call to action developed by PQA based on the environmental scan and input from the planning committee and meeting panelists.

PUBLIC COMMENT PERIOD

PQA held a public comment period from December 11, 2023, to January 12, 2024, to gather broad input from its members and other MTM stakeholders on the draft call to action. PQA received 199 total comments from 34 individuals. Many commenters agreed that the Part D MTM program and related quality measurement have opportunities for improvement. However, there was variation in recommendations for how and what should be done to address program quality and measurement. These comments were thoroughly analyzed using an inductive approach to thematic analysis and summarized for a public webinar on February 29, 2024. The quotations in green italics throughout this report are derived from public comments.

The April 2024 final rule expanded targeting criteria for the Part D MTM program to ensure more consistent and equitable access to MTM services.[12] Input for this PQA initiative from surveys or public comments was received before CMS issued the final rule.

LIMITATIONS

This initiative is limited by the narrow scope on Part D MTM. MTM services can overlap with other medication related activities and can be conducted with patients who do not meet CMS' requirements for eligibility. Information related to other medication management activities was not included. These limitations prohibit generalizing to other populations, settings, and services. Furthermore, the environmental scan did not include a systematic review with precise search criteria to answer a specific question. Instead, the literature review aimed to summarize the available evidence and other program information (e.g., eligibility changes) that help to describe various aspects related to improving the quality and measurement of MTM services.

RESULTS

The methods described above resulted in a refined call to action describing the critical steps necessary to improve the quality and measurement of MTM services. The elements of the call to action are not listed in priority order, rather they represent a range of interrelated and necessary focus areas from quality improvement to quality measurement.

CMS stated that the increase in restrictive criteria is believed to limit access to MTM for vulnerable, clinically high-risk beneficiaries and was a main driver of eligibility gaps and inequitable beneficiary access to MTM services.

I. INVESTIGATE OPTIMAL MTM ELIGIBILITY AND TARGETING CRITERIA FOR ACHIEVING PROGRAM GOALS.

Variability in MTM Program Eligibility and Targeting

CMS historically provided plan sponsors with flexibility within MTM eligibility criteria requirements. With this flexibility, some plan sponsors adopted restrictive criteria, resulting in missed opportunities to improve patient outcomes through MTM interventions among patients who could benefit from the services.[14-16] Generally, inequities with MTM services have been identified in the following areas:

- Eligibility for MTM among dually enrolled and low-income beneficiaries;[17]
- Opt-out rates among Black, Hispanic, and Asian beneficiaries;[18]
- Offer of CMR for Black, Hispanic, low-income, dually enrolled, and those with any hospitalization or who reside in areas with poor healthcare access or quality;[17-19] and
- Receipt of CMR among Asian, Hispanic, North American Native, dually enrolled, those with any hospitalization or an emergency department visit, and who have a higher number of comorbidities.[17]

At the start of the Medicare Part D program, CMS expected approximately 25% of beneficiaries to be eligible for MTM services.[11] In the December 2022 proposed rule, CMS stated that MTM eligibility rates have steadily declined over time to 8% in 2020. Along with decreasing eligibility rates, CMS observed convergence to the most restrictive targeting criteria permitted.[11] In the April 2024 final rule, CMS stated that the increase in restrictive criteria is believed to limit access to MTM for vulnerable, clinically high-risk beneficiaries and was a main driver of eligibility gaps and inequitable beneficiary access to MTM services.[12]

Changes to MTM Program Eligibility and Targeting Criteria

For this initiative, PQA received public comments on the draft call to action after CMS had proposed, but not yet finalized, expansion of Part D MTM program eligibility. Public commenters generally agreed MTM program eligibility and targeting requirements should change. However, recommendations for how eligibility and targeting requirements should change varied. Some commenters recommended expanding access to MTM services so anyone who wants or needs them has access. Further, they suggested the need for services cannot be defined by a set of criteria since anyone taking medications can be at risk.

"If we want to be patient-centered, it seems all Medicare patients should actually have access to MTM."

Some commenters expressed that no changes are needed for eligibility and targeting and current program flexibility parameters are appropriate. Other commenters conveyed the need for flexible targeting criteria to enable plan sponsors to select populations most in need of services and to promote local community efforts for strengthening health equity. Some commenters suggested that expanded eligibility for MTM services would increase plan costs and premiums, and therefore the program should have more restrictive criteria to focus resources on those who would receive the most benefit. Others suggested criteria should focus on those who are most vulnerable to adverse outcomes or medication-related problems

instead of basing eligibility on diseases or conditions. One commenter pointed to the results of the Enhanced MTM model[10] and suggested they do not justify the expansion of services.

> ***"It is important to better identify patients who are at risk or are vulnerable to adverse outcomes rather than those with a disease state that may be well controlled."***

In the April 2024 final rule, CMS finalized MTM program changes aimed to address key drivers of eligibility gaps by reducing marked variability across plan sponsors and ensuring more equitable access to MTM services. Effective January 1, 2025, plan sponsors' targeting criteria for identifying beneficiaries who have multiple (i.e., two to three) chronic diseases must now include all ten codified core chronic diseases. Plan sponsors retain the flexibility to target other chronic diseases beyond the ten required.

CMS also updated the methodology to determine the cost threshold for program eligibility to the average cost of eight generic drugs, which will be $1,623 for 2025. The requirement remains to include at-risk beneficiaries under a drug management program,[20] including those who are at risk for misuse or abuse of frequently abused drugs.[21] Although CMS retained eight as the maximum number of drugs a plan sponsor may require for targeting, all Part D maintenance drugs must be included with flexibility to target additional or all Part D drugs.

Table 1 illustrates the changes to the Part D MTM program eligibility and targeting criteria from CY 2024 to CY 2025. CMS estimated the number of Part D enrollees eligible for MTM will increase from 3.6 million (7% of Part D enrollees) to 7.1 million (13% of Part D enrollees) based on updated 2022 data.[12]

MTM Program Eligibility and Quality Measurement

With expanded MTM program eligibility requirements for 2025, the denominator of the PQA CMR measure will accordingly increase to a meaningful extent. This constitutes a substantive measure update even though the measure specifications have not changed.[12] Therefore, the CMR measure will move from the Part D Star Ratings to the display page for the 2025 and 2026 measurement years, returning as a new measure to the Star Ratings program no earlier than the 2027 measurement year for the 2029 Star Ratings.

During this time, PQA welcomes suggestions for specification changes to improve the CMR measure. CMS may consider PQA's suggestions on this measure for future years (i.e., beyond 2029 Star Ratings) pending advance notice and rulemaking. However, the need remains for new measures focused on quality rather than quantity of MTM services. The increased standardization of Part D MTM program eligibility and targeting criteria will support more research on MTM eligibility, MTM services, and related outcomes,

Table 1. Comparison of Medicare Part D MTM Program Eligibility and Targeting Criteria: 2024 and 2025

	Contract Year 2024	Contract year 2025
Multiple Chronic Diseases	A maximum threshold of 3 chronic diseases Must include at least 5 out of 9 CMS-defined chronic diseases	A maximum threshold of 3 chronic diseases Must include all 10 codified core chronic diseases*
Drugs	A minimum of 2 to 8 covered Part D drugs	A minimum of 2 to 8 covered Part D drugs Must include all Part D maintenance drugs, with flexibility to include additional or all covered Part D drugs
Cost	At least $5,330 in annual costs for covered Part D drugs	The average cost of eight generic drugs ($1,623 for 2025)

*Alzheimer's disease, bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis), chronic congestive heart failure, diabetes, dyslipidemia, end stage renal disease, HIV/AIDS, hypertension, mental health (including depressions, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions), and respiratory disease (including asthma, chronic obstructive pulmonary disease, and other chronic lung disorders).

Any change to eligibility and targeting criteria, like those finalized in the April 2024 final rule, will necessitate a new evaluation of equity and quality of MTM services.

ultimately advancing the field toward the development of consensus- and evidence-based MTM quality measures.

Stakeholder Involvement

Any change to eligibility and targeting criteria, like those finalized in the April 2024 final rule, will necessitate a new evaluation of equity and quality of MTM services. Illuminating the impact of changes to program eligibility and targeting is an area for PQA to support, alongside the well-established relationships with academic partners, plan sponsors, and MTM providers. Feedback and research can support CMS' goal to continue to improve Part D MTM program eligibility and equity within their authority.

II. ENHANCE COLLABORATION BETWEEN PRESCRIBERS, MTM PROVIDERS, AND PLAN SPONSORS TO BETTER ADDRESS PATIENT GOALS OF CARE AND IMPLEMENT APPROPRIATE MEDICATION CHANGES.

Improved collaboration, including team-based care, is needed among MTM stakeholders to better address patients' goals of care and implement appropriate medication changes. Research on patient perspectives of MTM services highlights the importance of the relationship between a patient's pharmacist and prescriber.[22, 23]

"When systems are integrated communication between them is easier and better. In health systems, this is not as much of an issue, but in a community setting, where data exchange is more limited, then this is more of an issue."

Public commenters stated that establishing a more collaborative working relationship between prescribers, MTM providers, and plan sponsors may improve patient participation, better meet patient preferences, increase acceptance of MTM providers' recommendations or interventions, and ultimately improve patient outcomes. Commenters also mentioned this element could alleviate prescriber burden and burnout through a more collaborative approach to optimizing medications and educating patients. Commenters supported further research in this area to better understand shared decision making, support collaboration initiatives, and address barriers such as limited interoperability.

Interoperability is likely a lynchpin to enhance collaboration related to clinical information systems and data infrastructure[24-31] and to address the challenges of follow-up and communication with prescribers.[25, 30] Enhanced MTM model participants and industry stakeholders suggested care coordination can be improved by enhanced interoperability and timely two-way exchange of information between MTM providers and prescribers.[10] CMS also encourages coordination of care through MTM services by sharing information across providers to reduce duplicate therapies and drug-drug interactions. They note that beneficiaries should be encouraged to take their medication action plan and personal medication list from their annual CMR to their annual wellness visit or other medical encounter.[32]

Stakeholder Involvement

PQA can play a role in bringing together prescribers, MTM providers, health plans, and health information technology (HIT) vendors to facilitate collaboration and identify best practices to enhance collaboration to optimize medication therapy focused on patients' goals of care.

III. OPTIMIZE PATIENT AND PRESCRIBER AWARENESS OF PART D MTM SERVICES AND THE BENEFITS PATIENTS MAY RECEIVE.

Patient Awareness

Literature suggests patients' awareness and understanding of MTM is lacking and an increase in awareness and knowledge of MTM may further promote service utilization, acceptance, and perceived value.[22, 33] Attendees of the PQA Convenes event and commenters voiced this sentiment as well. Reasons Part D beneficiaries decide not to receive a CMR include perceived risk of service utilization (e.g., spending time to receive MTM without receiving benefits) and influences of family or friends.[22] In contrast, perceived

susceptibility to medication-related problems and expectations of a positive outcome were positively associated with beneficiaries' decision to engage in a CMR.[22] Therefore, beyond just awareness, efforts to improve patients' and caregivers' understanding of MTM, its purpose, and potential benefits may increase acceptance and utilization of MTM services.

"Many new beneficiaries who become eligible for Medicare are unaware of the MTM service benefit."

Commenters emphasized that efforts to increase patient awareness should be strategic and not lead to patient abrasion or burden, which they stated as an issue associated with the MTM program and relates to multiple, irrelevant, or overlapping communications resulting in confusion or disengagement. Other commenters expressed that many health plans already engage in efforts to increase patient awareness. In fact, CMS expects plan sponsors to avoid passive outreach and use more than one approach to reach all eligible targeted beneficiaries.[32] CMS recently emphasized their expectation for plan sponsors to develop effective engagement strategies based on the plan sponsor's beneficiary population and business model, promote the value of MTM services, and ensure plan representatives are familiar with the program.[32]

Efforts to improve patients' and caregivers' understanding of MTM, its purpose, and potential benefits may increase acceptance and utilization of MTM services.

Prescriber Awareness

Attendees of the PQA Convenes event and multiple commenters pointed out that an increase in awareness of MTM services is also needed for prescribers. Prescribers are more likely to review and accept MTM providers' recommendations if they are aware of the services and know to expect recommendations from MTM providers. Prescribers could also help educate patients on MTM services and help identify who may benefit from MTM. Their awareness will enable enhanced collaboration, which is needed among MTM stakeholders.

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Stakeholder Involvement

While PQA can play a supportive role in these efforts, collaboration between plan sponsors, MTM providers, prescribers, and patients is needed to achieve this goal. Stakeholders should continue to provide input to CMS on how best to engage with MTM eligible beneficiaries, including improving information available on CMS' websites about Part D MTM programs or information Part D plan sponsors are required to include on their websites about the sponsors' MTM programs.[32]

IV. AMPLIFY THE PATIENT VOICE TO IMPROVE THE PATIENT-CENTEREDNESS OF MTM PROGRAMS.

As CMS' person and family engagement strategy suggests, when the health, safety, values, and goals of the individual are considered, health care delivery improves.[34] Patient-centered care may or may not include the patient voice, but when input from patients is constant and embedded within organizational culture, the patient voice is more likely to be consistently and prominently represented.[35] Amplifying the patient voice can be done through engagement efforts such as experience surveys, qualitiative or quantitative research, and use of patient-reported outcome measures (PROMs). Creating an environment where patients are valued as partners in their health journey can empower patients to share their experience, goals, and suggestions for improvement.

Understanding how Medicare beneficiaries perceive the Part D MTM program is essential for improving the patient-centeredness of services. Literature on beneficiaries' perspectives of Part D MTM investigated aspects of the services that are important to beneficiaries and reasons associated with service acceptance, such as:

- Perceived susceptibility to medication-related problems[22]
- Perceived value[23, 36] and expectations associated with the services[23, 37]

- Convenience in the mode of telephonic delivery, familiarity with the provider, and physician involvement[22, 23, 37]
- Products received after engaging in MTM, such as the medication list,[23, 38, 39] and
- The impact MTM services had on beneficiaries.[36, 37]

One article described how patients liked the educational aspect of MTM the most and how the value of receiving updated information on their medications helped them better manage their medications. This study captured how patients reported being empowered and having more confidence with their medications after receiving MTM services.[37] Beneficiaries from another study also indicated that the MTM services they received were helpful, easy to understand, and valuable.[36] Patients reported that they found value in Enhanced MTM services when issues such as new or high-risk medications were identified and addressed.[10] Further, beneficiaries were more likely to participate in a service when offered and delivered by a community pharmacist with whom they had an existing relationship.[10] This was also emphasized at the PQA Convenes event that relationships are a key element to success, given that patients are more likely to respond to someone they know. Patient and caregiver discussions during the PQA Convenes event also emphasized the need for follow-up and continuity to support building personal relationships and trust. From the Part D Enhanced MTM model, participating plan sponsors and other stakeholders overwhelmingly supported an individualized approach to delivering MTM services designed around a beneficiary's unique needs rather than a "one-size-fits-all" approach.[10]

Positive and critical insights from active engagement with beneficiaries and their care partners are needed to enhance the delivery of the MTM program and address what matters.

Along with the annual CMR, CMS requires written summaries of the CMR to be provided to beneficiaries in CMS' standardized format (OMB control number 0938-1154),[40] and the summary should be provided within 14 calendar days of the service. The written summary includes what used to be called a medication action plan as well as a personalized medication list to summarize what was discussed as a part of the CMR service. Beneficiaries have expressed difficulty in managing various medication-related documents from their multiple health care providers, including the standardized format.[39] Although changes to the standardized format have been made,[41] more work is needed to continue to improve the usability of these documents. Positive and critical insights from active engagement with beneficiaries and their care partners are needed to enhance the delivery of the MTM program and address what matters.

"More and more members are asking to be on the DNC, do not call list [because] they are extremely tired of being asked year over year to participate in this and that program."

Through the PQA Convenes event and public comments, there was agreement on the importance of the need to amplify the patient voice. Some public commenters emphasized that it is important to hear patients' voices regarding opting in and out of services to avoid patient burden. Some also commented that patients should be able to opt-out without a negative impact on a plan sponsor's performance, and plan sponsors should receive credit for engaging with patients to make them aware of MTM even if the patient declines completion of the services. One commenter suggested changing the "opt-in" and "opt-out" language as this may confuse some patients. Amplifying the patient voice may help avoid the burden of additional communication and outreach that patients may not want. Using familiar language rather than industry terms is also an important aspect of engagement with patients.

The patient voice is also needed from a measure development perspective to ensure measures are centered around the patient and translate to optimal outcomes and benefits.

Equity and Access

Public commenters encouraged diverse patient representation in engagement efforts and recommended additional research on MTM equity, such as how the availability of MTM services may differ between populations. Some commenters suggested collaborating with providers to amplify patients' voices and capture their preferences. A few public commenters also mentioned structural barriers and that available resources need to be considered. This includes access to high quality technology and video capabilities useful to assess patients' understanding of their medications and their preferences regarding the services, and to tailor the discussion to patients' individual needs.

"Patients and those with a caregiver relationship are critical to ensuring that [a] measure translates to better outcomes and satisfaction."

Patient Voice and Measurement

The patient voice is also needed from a measure development perspective to ensure measures are centered around the patient and translate to optimal outcomes and benefits. Patients can be involved in measure development through virtual communities (e.g., social media, chat rooms, networking sites); a measure working group to provide recommendations on key measure decisions; a communications workshop to focus on language, displays, or framing; an interview to provide in-depth input on a subject; or through a survey to collect information on broad concepts or prioritize options.[42] Involving patients and their caregivers helps measure developers produce easily understood, high-quality measures that are relevant and useful to consumers.[43]

Stakeholder Involvement

Patients and caregivers are the essential stakeholders in amplifying the patient voice to improve the patient-centeredness of MTM services and quality measurement. CMS, PQA, Part D plan sponsors, MTM providers, and researchers should play a key role in amplifying the patient voice, while being mindful of patient burden and ensuring populations who experience inequities in care are included in these efforts.

V. STRENGTHEN REQUIREMENTS FOR THE USE OF STANDARDIZED HEALTH INFORMATION TECHNOLOGY FOR DOCUMENTATION OF MTM SERVICES.

Current MTM Program Reporting Requirements

Part D sponsors are required to report certain data elements to CMS for each beneficiary enrolled in their MTM program (OMB control number 0938-0992).[44] However, the information reported to CMS on MTM are of limited use to infer clinical quality. For example, the 2023 Part D MTM reporting requirements included:[45, 46]

- Beneficiary identifiers
- Presence of cognitive impairment
- Residence in long term care
- Date of MTM program enrollment
- Targeting criteria met per CMS and per the plan sponsor
- Opt-out date and reason
- Offer of CMR and date
- Receipt of CMR with written summary in standardized format and date
- Method of CMR delivery
- Type of qualified provider who performed the CMR
- Recipient of the CMR (beneficiary, prescriber, caregiver, or other)
- Number of TMRs and date
- Number of MTP recommendations
- Number of MTP resolutions
- Number of communications sent to beneficiary regarding safe disposal of medications
- Method of delivery for information regarding safe disposal of medication

These reporting requirements comprise the MTM-related data available to use in potential quality measures. However, these data have limited utility for quality measurement because they do not characterize the clinical aspects of MTM services provided to the beneficiary in an encounter-based manner.

In 2016, CMS encouraged Part D plan sponsors to develop the capacity to collect and report MTPs at the beneficiary-level using a standard framework,

categories, definitions, and terminology.[47] Although MTM program reporting requirements have remained fundamentally unchanged since that time, CMS recently encouraged plan sponsors to adopt standardized HIT for documentation of MTM services.[32]

Part D Enhanced MTM Model Reporting Requirements

The Model provided an opportunity for participants to offer innovative MTM programs aimed at improving quality of care while also reducing costs. To accurately monitor participating plan sponsors' implementation of their approved enhanced MTM program and evaluate the Model's overall success, CMS collected enhanced MTM encounter data that leveraged existing structured healthcare terminology, primarily SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms).[48] SNOMED CT is designated as a national standard for electronic exchange of clinical health information.[49]

Model participants were encouraged but not required to use starter SNOMED CT code value sets. New codes could be requested, and value sets were intended to be refined over the course of the Model.[10, 48] At the onset of the Model, CMS acknowledged that participants may not all be at the same level of readiness regarding the use of HIT in tracking medication use and patient outcomes.[48, 50] Accordingly, the reporting requirements were highly flexible to accommodate as much detail about encounters as participating sponsors were able to provide. CMS anticipated that sponsors' ability to map current data and text fields to SNOMED CT codes would improve over time.[48]

Stakeholders were hopeful the Model reporting requirements would advance standardized MTM encounter documentation, including but not limited to, referrals, identification of medication therapy problems, procedures (services and interventions), and outcomes to recommendations, including sequencers to indicate the order of the services provided.[48] External stakeholders were engaged to promote the standardized use of SNOMED CT. For example, the Pharmacy HIT Collaborative produced several guidance documents to help sponsors map encounters with SNOMED CT.[48, 51]

CMS expected that sponsors, government stakeholders, and industry/professional organizations would collaborate toward the goal of using standardized clinical documentation of MTM services over time, so that best practices could be identified and shared. However, there was significant use of non-standardized free-text coding when a relevant SNOMED CT code did not exist, and the flexibility allowed under the Model resulted in substantial variability in the implementation of SNOMED CT by participating plan sponsors for Model encounter documentation.[10]

Variation in Documentation of MTM Services

The literature review identified considerable variation among plan sponsor program design, service implementation and practice, and clinical information software, as well as a lack of data standardization and interoperability.[25-28, 52-55] Public comments similarly indicated a wide range of areas in need of standardization including practice standards, documentation, and reporting. Commenters expressed concerns regarding the burden of Part D MTM program reporting requirements but also articulated the importance of standardized HIT for documentation of MTM services as a prerequisite for interoperability and quality measurement.

> ***"...adding another system or process to allow for standard documentation will only take away time and resources for MTM work. I do not think we can strive for standard documentation until integration is possible."***

Some commenters voiced concern that pharmacies are not ready for increased standardization given the existing system variation, administrative and technological burden, costs, and inefficiencies in an already overburdened system. One commenter expressed that MTM providers should not have to submit all clinical documentation to plan sponsors, and plan sponsors should not have to collect and report broad clinical documentation to regulatory agencies. Another commenter promoted the idea of being able to choose which MTM vendor to use and suggested adoption by vendors are critical to promote standardized documentation of MTM services. Survey respondents also highlighted the need for balance between standardization and flexibility.

One survey respondent suggested regulatory bodies should require the use of SNOMED CT to promote widespread use. Although most survey respondents

indicated they were familiar with SNOMED CT, few reported using the terminology. Some respondents suggested the widespread adoption and use of SNOMED CT could improve the quality of MTM measurement.

"As participants of the Enhanced MTM model, we support using an approach that captures key data elements using a standardized language, which if widely adopted, would help ensure consistency in how health plans are reporting MTM information."

Benefits of Using Standardized HIT for Documenting MTM Services

Care provided by pharmacy professionals tends to be documented using proprietary interfaces and often uses free text as opposed to structured, computer-readable data.[56] Pharmacy professionals have specifically noted that growth and sustainability of services like MTM will remain inhibited without interoperability standards for both clinical data and payment.[57]

CMS recently encouraged plan sponsors to adopt standardized HIT for documentation of MTM services.[32] They pointed to the CMS Interoperability Rule that encourages the use of Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)-based application programming interfaces and encourage MTM providers to use FHIR-enabled MTM platforms to facilitate integration of MTM service elements into prescribers' electronic health records (EHRs).[32, 58, 59]

Use of standardized coding systems, such as SNOMED CT, for documentation of MTM services is critical for quality measure development. Other benefits of using standardized coding systems include improved efficiency for MTM providers, consistent clinical recordkeeping, more efficient transfer of information between health care providers and beneficiaries (e.g., care coordination, team-based care), and better data collection and analysis to assess the impact of MTM services on patient care.[32]

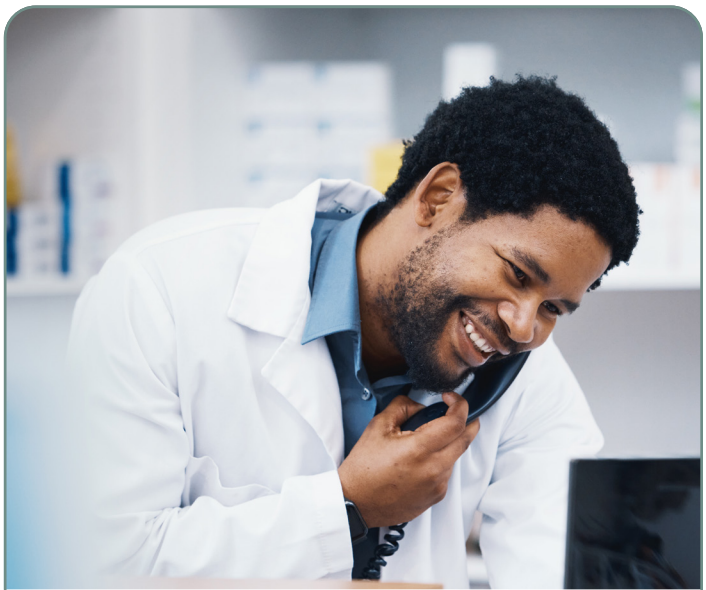
Combining standardized coding systems and industry-supported templates supports the expanding documentation and communication needs for MTM services as well as Part D MTM program reporting and patient information requirements.[32] For example, the HL7/National Council for Prescription Drug Programs (NCPDP) Clinical Document Architecture (CDA) MTM templates are intended for the exchange of medication-related information, including assessment results, recommendations for modification to medication regimens, recommendations for other services (e.g., dietary, laboratory), and the result of interventions among providers, payers, pharmacy benefits managers, and patients.[60]

From PQA's perspective, the most significant underlying challenge to overcome related to developing new MTM quality measures is the availability of standardized data. Adoption of standardized HIT with standardized coding systems for documenting MTM services is essential to advance MTM quality measurement. However, standardized documentation of MTM services does not eliminate the need for MTM practice standards.

Adoption of standardized HIT with standardized coding systems for documenting MTM services is essential to advance MTM quality measurement.

Stakeholder Involvement

Incentives and adoption of HIT standards are prerequisites for MTM measure development. Although PQA can play a supportive role to advance the adoption and use of standardized HIT for documenting MTM services, aligned and concerted efforts are needed from multiple stakeholders, including CMS, Office of the National Coordinator for Health Information Technology (ONC), NCPDP, plan sponsors, pharmacists and other MTM providers, and MTM technology vendors.



VI. INCREASE CONSISTENT USE OF THE PQA MEDICATION THERAPY PROBLEM CATEGORIES FRAMEWORK THROUGH STAKEHOLDER EDUCATION.

This element focuses on the need for pharmacists and other MTM providers to use a standard approach to documenting the patient care process, including the identification and resolution of MTPs, using the PQA MTP Categories Framework (Appendix B).

Rationale for the PQA Medication Therapy Problem Categories Framework

Optimization of medication use is accomplished by following a consistent patient care process.[61] In this patient care process, providers should assess each medication for appropriateness, effectiveness, safety, and patient adherence. These four areas are the cornerstone of identifying MTPs. An MTP is defined as any undesirable event experienced by a patient that involves, or is suspected to involve, medication therapy, and that interferes with achieving the desired goals of therapy and requires professional judgment to resolve.[62] MTPs can include unnecessary medications, ineffective medications, non-optimal dosages, need for additional monitoring, adverse events, adherence concerns, and cost issues.

Optimization of medication use is accomplished by following a consistent patient care process.

Although there is some evidence demonstrating the clinical impact of MTM services on identifying and resolving MTPs, the lack of standardized definitions has been a barrier to support meaningful assessment and quality measure development. To address this need, PQA convened a technical expert panel (TEP) to develop the PQA MTP Categories Framework in 2017 through a consensus-based process.[9] The group incorporated extensive input from MTM stakeholders and leveraged MTP categories established in the pharmacy literature.[62]

The framework is intended to standardize how MTPs are categorized and documented. To promote standardized documentation, the TEP mapped SNOMED CT codes to the MTP categories, medication therapy interventions/recommendations, and the status of the interventions to indicate resolution of the problem.

Originally developed for use in MTM quality measures, such as PQA's *Medication Therapy Problem Resolution* monitoring measure,[63] the MTP Categories Framework has broader applicability and is used in clinical practice, quality improvement initiatives, research, and education.

Use of the PQA Medication Therapy Problem Categories Framework

The PQA MTP Categories Framework is available upon request. Since PQA started tracking in July 2022, there have been over 130 requests, including several international inquiries. Requestors represented a diverse range of stakeholder groups, ranked as follows:

1. Academic institutions
2. Health systems
3. Health plans
4. Community pharmacies
5. Specialty pharmacy providers
6. Associations, foundations, or research institutions
7. Consulting groups
8. MTM vendors
9. Pharmacy benefit managers
10. Health technology vendors
11. Physician provider organizations
12. Data analytics organizations
13. Government agencies

The framework has been requested for a variety of applications, all aligned with its intended purposes. A higher proportion of requests come from academic institutions for use in pharmacy school curricula, research, quality improvement, and clinical practice. Similar themes emerge in requests from other stakeholder groups, demonstrating the usefulness of standardized assessment and documentation of MTPs across various settings. Applications of the framework include implementation in clinical practice workflows and EHRs, research study design, quality improvement initiatives, and continuing professional education. This widespread interest underscores the framework's relevance and utility in advancing standardized documentation of MTPs in MTM services.

"...MTPs are valuable as a framework for the provision of care."

Survey respondents reported using the PQA MTP Categories Framework for standardized documentation

of clinical practice, quality improvement, and research. Public commenters generally supported use of the framework. Commenters stated the need for education of MTM providers on how to use the framework to support increased adoption and consistent application. The framework was described as useful for assisting with standardizing both the process of care and documentation of care. Increased standardization is particularly important because MTM technology vendors may vary in their approaches to MTM service documentation.

Commenters stated the need for education of MTM providers on how to use the framework to support increased adoption and consistent application.

A concern expressed by some public commenters regarding the PQA Medication Therapy Problem Resolution monitoring measure was that MTPs are subjective, can be interpreted differently, and should not be used to assess quality. This reinforces the need for provider education to support consistent application of the framework, which would greatly reduce variability of MTP assessment.

SNOMED CT and Medication Therapy Problem Resolution

PQA and industry stakeholders mapped the MTP Categories Framework to SNOMED CT codes, which is essential for structured clinical documentation. CMS recently communicated the expectation for plan sponsors to have a process in place to measure, analyze, and report the outcomes of MTM programs, determine whether goals of therapy have been reached, capture medication therapy recommendations and resolutions made as a result of the MTM recommendations, and capture beneficiary satisfaction.[32] CMS defined a medication therapy recommendation as a suggestion to take a specific course of action related to the beneficiary's medication therapy. They also provided examples of medication therapy problem recommendations and resolutions. The examples provided align closely, though not completely, with the definitions, terminology, and example scenarios in the PQA Medication Therapy Problem Resolution monitoring measure specifications and associated SNOMED CT codes. Further consensus-building is needed to ensure industry alignment and consistent use of definitions and terminology related to medication therapy problems and resolution.

Further consensus-building is needed to ensure industry alignment and consistent use of definitions and terminology related to medication therapy problems and resolution.

Stakeholder Involvement

PQA will coordinate action related to this element and welcomes stakeholder input to ensure education and training are effective to advance use of the PQA MTP Categories Framework as part of a systematic approach to MTM and other pharmacist-provided services. Support from external experts will be essential to promote informed, consistent, and expanded use of the framework. PQA can also collaborate with other organizations on further evaluation and consensus-building for industry alignment and consistent use of related definitions, terminology, and relevant SNOMED CT codes.

VII. DEVELOP NEW PERFORMANCE MEASURES FOR MTM QUALITY.

Existing MTM Quality Measures and Gaps

Eight MTM-related measures were identified in the environmental scan for this initiative, including two performance measures, four monitoring measures, and two quality improvement indicators (QIIs) **(see Table 2 on the following page)**. PQA describes the intended use of these types of measures as follows:

- *Performance measures* are intended to evaluate the quality of healthcare processes, intermediate outcomes, or outcomes. PQA performance measures may be used in accountability programs (e.g., public reporting, benchmarking, external comparisons, performance payments). Performance measures require the use of standardized reporting.
- *Monitoring measures* are intended to promote standardized documentation and reporting of healthcare processes, intermediate outcomes, or outcomes. PQA monitoring measures may be used for standardized reporting requirements for monitoring or surveillance purposes but not for accountability programs.

Table 2. MTM-Related Quality Measures (listed alphabetically)			
Measure Name	Description	Steward Measure Type	Use
Care for Older Adults (COA)[64]	The percentage of adults 66 years of age and older who had each of the following during the measurement year: • Medication Review. • Functional Status Assessment. • Pain Assessment.	NCQA Performance measure	HEDIS and Medicare Part C Star Ratings (COA – Functional Status Assessment will be added to the 2027 Star Ratings)[12]
Completion Rate for Comprehensive Medication Review (CMR)[6]	The percentage of individuals enrolled in MTM and eligible for a CMR that received a CMR during the measurement year.	PQA Performance measure	Medicare Part D Star Ratings program (moving to Part D display page for the 2025 and 2026 measurement years)[12]
Medication Therapy Problem Resolution (MTPR)[63]	The percentage of medication therapy interventions that resolve MTPs among individuals participating in a MTM program.	PQA Monitoring measure	Standardized reporting Internal quality improvement
Percentage of Beneficiaries Discharged from the Hospital Who Received Enhanced Medication Therapy Management Services[48, 65]	The percentage of high-risk patients that have been discharged from the hospital and that received enhanced MTM services within seven days. Note: Adapted from PQA specifications	CMS adapted Monitoring measure	Part D Enhanced MTM model
Percentage of Enhanced MTM Recommendations That Were Implemented[48]	Percentage of encounter records for enhanced MTM recommendations that have a corresponding change in Part D claims.	CMS Monitoring measure	Part D Enhanced MTM model
Percentage of Targeted Beneficiaries with At Least One Medication Therapy Issue[48]	Percentage of targeted beneficiaries for whom at least one medication therapy issue is identified.	CMS Monitoring measure	Part D Enhanced MTM model
Provision of Medication Therapy Management Services Post Hospital Discharge[66]	The percentage of high-risk patients that have been discharged from the hospital and that received MTM services within seven days.	PQA QII	Internal quality improvement
Readmission of Patients Provided Medication Therapy Management Services Post Hospital Discharge[67]	The percentage of high-risk patients that received MTM from a pharmacist within seven days post hospital discharge that are readmitted within 30 days of their discharge.	PQA QII	Internal quality improvement

- *QIIs* are intended to assess improvement of healthcare processes, intermediate outcomes, or outcomes from baseline within a population/organization. PQA QIIs may be used for self-assessment (e.g., internal quality improvement), and do not require the use of standardized reporting.

CMS' monitoring measures used by participants in the Part D Enhanced MTM model were not tied to performance payments and were for informational and monitoring purposes only.[48]

The PQA CMR measure is the only existing performance measure developed, tested, and endorsed for assessing MTM programs or services. Survey respondents commented on the limitations of the CMR measure, citing its lack of usefulness for evaluating the quality of MTM services. As discussed previously, the CMR measure heightened attention about the importance of MTM services and should be retained in the Part D Star Ratings until alternative or complementary measures are available. CMS' emphasis on outcome and patient-reported measures,[68] in addition to stakeholder demands, provides opportunities for new MTM measures to assess the quality of, rather than completion of, CMRs and other MTM services.

The CMR measure heightened attention about the importance of MTM services and should be retained in the Part D Star Ratings until alternative or complementary measures are available.

The PQA *Medication Therapy Problem Resolution* monitoring measure was developed to standardize documentation and reporting of medication therapy interventions by health plan MTM programs. The measure may be used for standardized reporting for monitoring and surveillance purposes but not for accountability programs. A unique characteristic of the measure is that it does not use claims data, but rather uses MTM encounter documentation using SNOMED CT and RxNorm codes. Medication therapy interventions are defined as actions taken to prevent or resolve an MTP.[8] MTP resolution is defined as the documentation indicating the intervention was performed, and then, the MTP was resolved. As described above, these definitions and terminology are similar but not completely aligned with recent examples provided by CMS of medication therapy recommendations (the *Medication Therapy Problem Resolution* measure uses the term medication therapy intervention) and medication therapy problem resolution.[32] To date, the *Medication Therapy Problem Resolution* measure is not widely used.

Surveys indicated the *Medication Therapy Problem Resolution* monitoring measure is useful to consistently evaluate the impact of MTM in resolving MTPs. However, measure complexity and lack of clarity regarding practical application pose challenges to implementation. Some survey respondents reported tracking MTP recommendations or intervention outcomes without using the PQA specifications.

Commenters provided feedback on the PQA *Medication Therapy Problem Resolution* monitoring measure and a similar monitoring measure, *Percentage of Targeted Beneficiaries with At Least One Medication Therapy Issue*, used in the Model. These commenters suggested that these related measures could incentivize plan sponsors to target beneficiaries who are most likely to have MTPs that are easily resolved. Some commenters emphasized the need for careful consideration of quality measures to avoid incentivizing such unintended consequences. As described above, the intended use of the PQA monitoring measure excludes performance measurement or use in accountability programs.

Several survey respondents reported using the two PQA MTM QIIs, *Provision of Medication Therapy Management Services Post Hospital Discharge* and *Readmission of Patients Provided Medication Therapy Management Services Post Hospital Discharge*. These QIIs promote medication reconciliation post discharge by MTM providers and align with a HEDIS health plan measure,[69] and can be used to assess outcomes associated with MTM services. Some respondents reported that lack of access to timely hospital discharge data limits use of these QIIs.

Several survey respondents reported using satisfaction as a measure of MTM service quality, including satisfaction of members, providers, and plan sponsors. Some organizations reported evaluating outcomes, health care utilization, and cost, although specific information such as definitions, data sources, or measure specifications were not provided. Suggestions for new measure development included initiation or optimization of guideline-directed medication therapy (e.g., heart

failure, chronic kidney disease), clinical endpoints (e.g., hypertension, diabetes, obesity, depression), care coordination, and social determinants of health identification and resolution.

As PQA advances new measure development for MTM, there are important considerations for each proposed measure concept. PQA uses a systematic, transparent, and consensus-based process to conceptualize, specify, test, refine, endorse, and maintain measures of medication use quality. Performance measures are evaluated against the standard criteria of importance, scientific acceptability, feasibility, and usability. To meet the criterion of feasibility, the data needed to calculate a measure must be readily available, implemented, and retrievable without undue burden. In fact, data source availability substantially influences the reliability, validity, feasibility, and usability of a measure.[70, 71] Therefore, before proceeding with measure development, PQA considers the feasibility and methods of collecting data, ideally in a structured format, when contemplating measure data sources. This issue is highlighted in further detail in Element V.

To meet the criterion of feasibility, the data needed to calculate a measure must be readily available, implemented, and retrievable without undue burden.

In addition to feasibility, the criterion of importance is essential to meet prior to proceeding with measure development. Importance, in part, represents the extent to which the measure focus is evidence based, which is discussed further below.

Evidence to Support Measuring Outcomes

Public commenters often pointed to the need for measuring outcomes, suggesting clinical outcomes and alignment with existing measures focused on blood pressure, A1C control, and smoking status. However, it is often challenging to attribute an outcome to the processes of care that influenced that outcome from a measurement science perspective. Therefore, an essential component of quality measurement is to understand the evidence supporting the linkage between the process (e.g., provision of MTM services) and the outcomes (e.g., adherence, adverse events).[72]

"We believe that the best metric of success would be measurement of known clinical outcomes related to medication (e.g. blood pressure control, A1c control, etc.), rather than volume based measures or those that require subjective interpretation."

Of the five criteria used for consensus-based quality measure evaluation, evidence falls under the first criterion of importance.[73] To meet the criterion of importance, the evidence base must demonstrate at least a moderate degree of certainty that the process-outcome link will have a net benefit (e.g., improved outcomes, reduced adverse events, costs avoided). While the current CMS Consensus Based Entity (CBE) guidance does not define 'moderate degree of certainty,' the quality measurement industry has a precedent for making these conclusions based on the quantity of the evidence, the quality of the body of evidence, and the consistency of results.[72]

The assessment of the quantity, quality, and consistency of results should ideally be conducted and published in a systematic review. In 2015, the Agency for Healthcare Research and Quality sponsored a systematic review focused on MTM, though not specific to Medicare.[74] The review concluded that evidence is insufficient for most outcomes due to inconsistency and imprecision stemming from variation in populations and interventions. PQA's literature review conducted as part of the environmental scan, that focused on Part D MTM and included more recent evidence, also concluded that limitations prevent understanding the association between MTM services and outcomes.

The review concluded that evidence is insufficient for most outcomes due to inconsistency and imprecision stemming from variation in populations and interventions.

CMS provided a list of studies to support potential pathways towards achieving the goals of the Part D Enhanced MTM model. However, the listed studies focused on medication-related interventions not specific to MTM and related outcomes (e.g., medication adherence),[75-92] or populations that are not specific

to the Part D MTM program (e.g., pediatric),[93-103] or were prescriber-focused rather than patient-focused interventions.[104] Therefore, despite this evidence supporting the importance of MTM and related services, it does not satisfy requirements to establish the process-outcome linkage for a quality measure.

The changes to the Part D MTM program finalized in the April 2024 final rule may enable stronger studies with more consistency in the populations studied since the eligibility and targeting criteria for the MTM program will be more standard than ever before. This is needed to better understand the process-outcome linkage and reduce study design limitations. Realistically, as others have noted,[105] there is a great deal of heterogeneity among the MTM-eligible population, and identifying a single clinical endpoint common to all with sufficient underlying evidence will likely remain a challenge. Further details about the studies reviewed will be published elsewhere.

Patient-Reported Measures

Public comments described a patient centered MTM measure as one that focuses on goals of care, satisfaction and experience, and the CMS-defined goals of the CMR, including improved medication knowledge, empowerment, and addressing questions and concerns. In contrast, some commenters suggested that patient reported MTM measures are subjective and do not impact outcomes.

PQA and collaborators have conducted research on MTM services that underscores the opportunity for patient-reported outcome performance measures, in addition to the need for a more traditional quality measure assessing other aspects of the services.[53, 54, 106, 107] Understanding quality of services from multiple dimensions can elevate the opportunities to meet the needs of both patients and the broader MTM stakeholder community.

Stakeholder Involvement

In the April 2024 final rule, CMS encouraged the industry and PQA to develop new quality measures that CMS may consider for use in the Star Ratings program in the future. In the interim, CMS also suggested that plan sponsors may leverage effective MTM programs to improve several measures in the Part D Star Ratings and display page, such as medication adherence, polypharmacy, and gaps in therapy. PQA will continue to explore developing new measures of quality for MTM services in collaboration with members and other MTM stakeholders.

VIII. PRIORITIZE RESEARCH TO OPTIMIZE THE PART D MTM PROGRAM AND SERVICES.

In addition to prioritizing research focused on element I in this call to action to optimize MTM eligibility and targeting, research gaps to advance MTM quality and measurement are highlighted below. The need for sharing of best practices was frequently expressed through public comments. Therefore, identifying and communicating learnings and best practices for MTM programs and services is also critical.

The need for sharing of best practices was frequently expressed through public comments.

MTM Process-Outcome Link

Enhancing the designs of studies evaluating Part D MTM is necessary, such as employing adequate controls for confounders and bias, and isolating program features and their impact on outcomes. CMS reported in the April 2024 final rule that commenters concurred with researchers in recommending to CMS that future studies of MTM increase study size and incorporate

multiple geographically diverse sites to bolster the reliability of results.[12] CMS pointed out that they routinely analyze Part D MTM program data and agreed that additional analyses would be beneficial to assess MTM program effectiveness.[12] Notably, CMS previously commissioned a study of the MTM program,[108] and it is one of the better designed studies in the evidence base. However, the study was published over a decade ago, and many changes to the MTM program have since occurred, necessitating an update.

Enhancing the designs of studies evaluating Part D MTM is necessary, such as employing adequate controls for confounders and bias, and isolating program features and their impact on outcomes.

Public commenters suggested the need for research to validate the connection between MTM and improved outcomes. Specific outcomes mentioned were total healthcare utilization and expenditures, return on investment, patient and MTM provider satisfaction, patient and prescriber acceptance of recommendations, and various clinical outcomes (e.g., blood pressure and A1C control). Comments suggested the need to understand how MTM services are impacted by risk-sharing and value-based models, including effective strategies for how savings can be shared. Further, commenters expressed the need for research on inequities associated with MTM services. Suggestions included how to assess and improve inequities, differences in MTM availability, and effectiveness of MTM across diverse populations.

Access to Data from the Part D Enhanced MTM Model

All CMS Innovation Center models are rigorously evaluated, and other model data, but not Part D Enhanced MTM model data, are available to researchers or are publicly available.[109] Research Identifiable Files (RIF) for many models are available through the CMS Research Data Assistance Center (ResDAC), although access requires registration with associated fees. Public Use Files (PUF) on some models are also available publicly without registration requirements or fees. Enhanced MTM model data need to be readily available to researchers to ensure transparency and support external research and learnings. Lessons learned from the Model can support future efforts by plan sponsors, stakeholders, and policymakers to improve traditional Part D MTM programs.

Enhanced MTM model data need to be readily available to researchers to ensure transparency and support external research and learnings.

Public comments from this PQA initiative support the idea that there is still benefit to learn from the Model despite the published evaluations.[10] Multiple commenters expressed that these data could help further understand barriers and challenges to MTM implementation, provide insights into various aspects of the services, and ultimately allow for the improvement of MTM. However, another commenter mentioned how increased access to these data does not solve the problem of creating consistency in MTM delivery.

"The purpose of a pilot program is to learn from what did or did not work even if the ultimate goal was not achieved. There can still be learnings from the various models that were utilized in the project."

In the April 2024 final rule, CMS stated they will continue to review the Model's results and collaborate with interested parties to identify best practices and lessons learned to improve the program.[12] CMS reminded stakeholders that plan sponsors are currently required to report MTM program beneficiary-level data and researchers may request access to a Part D MTM data file through ResDAC, which could be linked to encrypted beneficiary and demographic variables in the CMS Chronic Conditions Data Warehouse (CCW).

Patient Preferences

Commenters highlighted the need to determine patient preferences regarding the process of MTM, including how they prefer to learn about the program, factors associated with accepting services, the preferred setting in which to receive services, their preference for receiving information after the services, and their perceived value of the services. This need is highlighted in further detail in Element IV.

Unintended Consequences

The importance of ongoing research to assess MTM and any potential unintended consequences was a common sentiment among public commenters. Unintended consequences of MTM programs, services, and quality measurement need to be considered, characterized, and investigated. Unintended consequences may include siloing of care or fragmenting relationships between patients and prescribers. It may also be worth investigating the association between misalignment of incentives and unintended consequences.

Stakeholder Involvement

MTM stakeholders, including PQA, academic partners, CMS, plan sponsors, MTM providers, and MTM technology vendors, should prioritize conducting studies that meet the rigor to support the connection between MTM services and outcomes, including issues with equity and other potential unintended consequences. Further establishing the connection between the process and outcomes of MTM will foster a better understanding of the evidence needed to support development of new quality measures. PQA will continue to collaborate with researchers and other MTM stakeholders to solicit and emphasize patient preferences and identify best practices. Researchers and other interested stakeholders should continue to encourage CMS to make the Part D Enhanced MTM model data available.

CONCLUSION AND NEXT STEPS

The totality of the information gathered during this first phase of PQA's Quality Innovation and Research Initiative to Advance Medication Therapy Management Quality Measurement was used to draft and refine the elements of the call to action. These efforts illuminated the ongoing challenges to assessing MTM quality in a meaningful and consistent way. The call to action includes several elements, is multifaceted, and requires partnerships and coordinated efforts from a multitude of stakeholders across the industry.

To create an environment conducive to quality measurement and improve the quality of MTM services, it is imperative that stakeholders prioritize and address these challenges, which include:

- Lack of readily available, electronic, and structured clinical data.
- Non-standardized clinical information systems and data infrastructure, which hinders measurement and collaboration among plan sponsors, prescribers, and MTM providers.
- Inconsistent service delivery and documentation of service delivery.
- Confusion and dearth of awareness among patients and prescribers related to how the services can be beneficial.
- Lack of integration of patients' perspectives, experiences, goals, and suggestions on how to best meet their needs and improve the quality of services.
- Insufficient quality, quantity, and consistency of the evidence to establish the impact of MTM services on patient clinical outcomes.

These issues have created a current state where measuring the quality of MTM services in a standardized fashion is a formidable challenge. The ability to take action on some of the elements is inhibited by interrelated challenges and a dependency on stakeholder collaboration. To promote and measure the quality of MTM services, stakeholders are called upon to act where they have agency to affect change and demonstrate progress toward overcoming these challenges. Aligning incentives across all stakeholders would catalyze these necessary efforts.

This call to action, combined with significant programmatic changes, is an opportunity to advance the quality and measurement of MTM services. Although a new measure is the ultimate goal, the industry must come together and tackle the challenges that are discussed here to enable appropriate assessment of quality and, ultimately, result in better care and optimal patient outcomes.

ABOUT PQA

PQA, the Pharmacy Quality Alliance, is a national quality organization dedicated to improving medication safety, adherence and appropriate use. A measure developer, researcher, educator and convener, PQA's quality initiatives support better medication use and high-quality care. PQA was established in 2006 as a public-private partnership with the Centers for Medicare & Medicaid Services. PQA was created because prescription drug programs were a major area of health care where there was no organization or national program focused on quality improvement. Today, PQA is an independent, non-profit organization with nearly 220 diverse members across health care.

The ***PQA Quality Innovation and Research Center*** **(QuIRC)** is a strategic initiative to accelerate progress in medication use quality and focus on clinical outcomes and provider contributions to care. Developing accurate and responsive outcomes-focused measures requires innovative approaches to measure development and research to ensure that measures are valid and useable in real-world settings. Through pilot, demonstration and research projects and consensus-building events, QuIRC answers the difficult questions needed to develop new, complex measures and effectively implement them.

PQA Convenes brings together national leaders in medication use quality to build consensus and develop plans of action to promote innovative and timely opportunities for improving patient care and outcomes. A gathering of diverse thought leaders and decision makers, PQA Convenes is designed to:

- Explore how medication use quality and pharmacist-provided care can improve care delivery, patient and provider experiences, and patient outcomes.
- Clarify unmet market needs, gaps in care, or interventions that can be realized through research, education, and collaboration.
- Provide a collective call to action, which can include (a) white papers or consensus statements; (b) follow-up or expanded convenings; and (c) communications and engagement strategies to build broader awareness.

Visit pqaalliance.org to learn more.

APPENDIX A: ACKNOWLEDGEMENTS

PQA thanks the six planning committee members, whose collaborative work with our project team informed the environmental scan approach, draft call to action, the PQA Convenes event, public comment analysis, and final report.

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APPENDIX B: PQA MEDICATION THERAPY PROBLEM CATEGORIES FRAMEWORK

Medication Related Needs	Medication Therapy Problem Category	Medication Therapy Problem Rationale
Indication	Unnecessary medication therapy	Duplicate Therapy
		No medical indication at this time
		Nonmedication therapy more appropriate
		Addiction/recreational medication use
		Treating avoidable adverse medication reaction
	Needs additional medication therapy	Preventive therapy
		Untreated condition
		Synergistic therapy
Effectiveness	Ineffective medication	More effective medication available
		Condition refractory to medication
		Dosage form inappropriate
	Dosage too low	Dose too low
		Frequency inappropriate
		Incorrect administration
		Medication interaction
		Incorrect storage
		Duration inappropriate
	Needs additional monitoring	Medication requires monitoring

CHART CONTINUES ON PAGE 28

Medication Related Needs	Medication Therapy Problem Category	Medication Therapy Problem Rationale
Safety	Adverse medication event	Undesirable effect
		Unsafe medication for the patient
		Medication interaction
		Incorrect administration
		Allergic reaction
		Dosage increase/decrease too fast
	Dosage too high	Dose too high
		Frequency inappropriate
		Duration inappropriate
		Medication interaction
	Needs additional monitoring	Medication requires monitoring
Adherence	Adherence	Does not understand instructions
		Patient prefers not to take
		Patient forgets to take
		Medication product not available
		Cannot swallow/administer medication
	Cost	More cost-effective medication available*
		Cannot afford medication product

* Although the medication therapy problem rationale, more cost-effective medication available, is placed under the medication-related need of adherence, it may not necessarily relate to adherence directly or represent a patient-specific medication therapy problem.

Last Update: July 2017

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APPENDIX C: LIST OF ACRONYMS

CBE	Consensus Based Entity
CCW	Chronic Conditions Data Warehouse
CDA	Clinical Document Architecture
CMR	Comprehensive medication review
CMS	Centers for Medicare & Medicaid Services
COA	Care for Older Adults
CY	Contract Year
EHR	Electronic health records
FHIR	Fast Healthcare Interoperability Resources
HEDIS	Healthcare Effectiveness Data and Information Set
HIT	Health information technology
HL7	Health Level Seven
MAPD	Medicare Advantage prescription drug plan
MTM	Medication therapy management
MTP	Medication therapy problem
MTPR	Medication Therapy Problem Resolution
NCPDP	National Council for Prescription Drug Programs
NCQA	National Committee for Quality Assurance
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
PDP	Prescription drug plan
PQA	Pharmacy Quality Alliance
PROM	Patient-reported outcome measure
PUF	Public Use Files
QII	Quality improvement indicator
QuIRC	Quality Innovation and Research Center
ResDAC	Research Data Assistance Center
RIF	Research Identifiable Files
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
TEP	Technical expert panel
TMR	Targeted medication review

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