

Medicare Part D's Medication Therapy Management: Shifting from Neutral to Drive

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Federal law requires Medicare Part D prescription drug plans to offer medication therapy management (MTM) programs to help targeted enrollees avoid drug-related problems and optimize medication benefits. In 2006, such programs were hailed as a “win-win” proposition for plans, pharmacists, and beneficiaries.¹ However, six years later, MTM participation is lower than predicted, and it is still not possible to evaluate whether Part D MTM programs are working as intended. This has frustrated Part D plan sponsors and the federal government alike, especially considering MTM's success in Medicaid and in the private sector. This *Insight on the Issues* proposes policy options for demonstrating and increasing MTM's effectiveness within Part D.

Background and Program Expectations

To most people, the term “pharmacists’ services” may conjure up traditional pill-counting and dispensing functions. Since 2006, however, Medicare’s voluntary prescription drug benefit, Part D, has played an important role in expanding the scope of such services. Part D plans must provide medication therapy management (MTM) programs to help eligible enrollees avoid drug-related problems and achieve desired clinical benefits from medications.²

MTM is defined as a systematic process of collecting patient-specific information, assessing medication therapies to identify and prioritize medication-related problems, and creating a plan to resolve them.³ Historically, MTM services represent a bundling of “pharmaceutical care” interventions integral to a patient-centered practice model where a pharmacist works directly with patients, along with prescribers and other

clinicians, to help patients achieve intended drug therapy outcomes.⁴

This model formed the backbone of what was expected to be an effective Part D MTM benefit. Many observers might have anticipated creation of a well-defined MTM program, with participation by enrollees who truly benefited from enhanced pharmaceutical care. This would likely be undergirded by a comprehensive network of MTM-providing pharmacists, whose education and training distinguishes them as logical MTM providers (but not necessarily exclusive MTM providers under Part D).⁵

However, some key program results remain a mystery, and participation is much lower than expected, both by enrollees and by community-based clinicians who may provide MTM services. Pharmacists who have successfully integrated MTM services into their workflow (including being compensated for Part D MTM services—a discretionary payment for drug plans⁶) are the exception rather than the norm.

Moreover, the government's own evaluation of Part D MTM found "limited evidence to determine which beneficiaries would benefit most from MTM, which features achieved the desired outcomes, and which outcomes should be measured to compare MTM program performance."⁷

This *Insight on the Issues* examines current program requirements, shifting program parameters, and success in several MTM programs conducted outside of Part D. It also identifies several changes planned for Part D MTM, and offers policy options to bolster MTM's contribution to beneficiaries' health, and ideally, to the health of the overall Medicare program as well.

Scope of Services

For Part D drug plans, MTM's scope of services has evolved over time. Initial regulations established "a general framework that allowed sponsors flexibility to promote best practices."⁸ Thus, the Centers for Medicare & Medicaid Services (CMS) did not restrict MTM providers to pharmacists, nor did CMS specify how to provide services.

In Part D's early years, plans could satisfy the law's intent by mailing letters to targeted patients about their drug therapy, thus legally bypassing any real-time person-to-patient communication. Such low-tech interventions helped plans minimize MTM program costs, which must be incorporated into plan sponsors' annual prospective bids to CMS. Further, MTM services must be provided to eligible enrollees at no charge.

These fundamental administrative elements were set prior to 2006, yet the scope of MTM services, defined annually by CMS, has expanded since

then. Presently, Part D MTM programs must provide these service elements:

1. Interventions for both beneficiaries and prescribers.
2. Annual comprehensive reviews for beneficiaries that (a) are conducted by a pharmacist or other "qualified provider," (b) are performed face-to-face or by telephone, and (c) feature written summaries with medication action plans and personal medication lists. Such reviews are to assess use of prescribed medicines, nonprescription products, and dietary supplements. The structure and length of such reviews are up to each plan.
3. Quarterly, targeted comprehensive reviews, with follow-up interventions when necessary.

Recent implementation of such services leaves room for improvement. For example, CMS reported that in 2011, while 100 percent of MTM programs communicated with prescribers about resolving drug problems or possibly optimizing drug therapy, faxing was the most common method used (reported by 92 percent of MTM programs), followed by postal mail and telephone.⁹ Only about one-sixth (17 percent) of MTM programs shared a patient's medication list with prescribers.

These results do not reveal the extent to which MTM clinicians' recommendations may have generated desired therapy changes—something that plans must report to CMS annually, but that had not been released at time of publication. Moreover, MTM communications may risk lack of relevant feedback to prescribers (e.g., with few programs sharing a comprehensive list of medicines a patient is using). With quarterly medication reviews, feedback could be

at least three months old by the time a prescriber receives it. More timely and robust data exchange between prescribers and MTM providers proved to be a key element in MTM programs outside of Part D, discussed later.

As for Part D enrollees’ acceptance of some key MTM services, new data are not promising. In 2012, CMS reported that only 8 percent of MTM enrollees (who were not in long-term care facilities) received comprehensive medication reviews in 2010¹⁰—something that must be offered to all MTM participants in 2010 and later years. This very low participation suggests a need for a beneficiary-level incentive to say “yes” to a comprehensive review.

Interestingly, two-thirds of people age 65 years and older who responded to a national poll in 2012 reported that their doctor “or health care provider” had performed a comprehensive medication review.¹¹ Whether these respondents were eligible for Part D MTM is unknown, as is who extended the offer, how their review might have differed in scope from a Part D review, and what if

any therapy changes might have resulted following the review.

Eligibility

Under Part D, free MTM services are generally reserved for enrollees who meet criteria related to their annual Part D drug costs, number of prescription drugs, and prevalence of certain chronic diseases. These criteria, set by CMS with some flexibility for plans, have changed since 2006. For example, eligible enrollees originally had to opt in to the MTM program; they would be solicited for MTM services only annually; and prior to 2010, eligible enrollees had to be taking two to fifteen drugs.

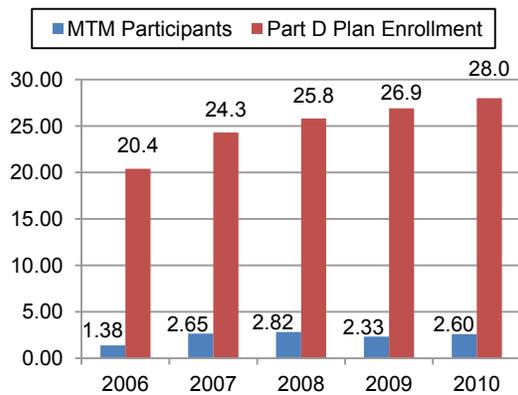
Today, enrollment is opt out; plans must target enrollees at least quarterly; and enrollees must take between two and eight drugs. The dollar threshold has also changed: Originally \$4,000, CMS dropped it to \$3,000 in 2010. For 2012 and beyond, the threshold is \$3,000 plus a mandatory annual percentage increase.¹² These changing criteria have limited methodologically sound research on Part D MTM’s effectiveness over time. Table 1 details eligibility criteria.

Table 1
Part D Medication Therapy Management Eligibility Criteria, 2011–2012

2011 Experience	2012 Specification
Cost threshold was \$3,000	Annual drug costs \geq \$3100.20, representing the total of plan’s costs and enrollee’s costs, plus annual percentage increase specified in 42 CFR §423.104(d)(5)(iv)
Almost three-fourths of programs did quarterly targeting; 20% did monthly targeting	Qualified enrollees must opt out of participating; target enrollees at least quarterly
75% of programs required beneficiaries to be taking 7–8 prescription drugs	Minimum threshold for number of different prescription medicines ranges from 2–8
Most frequently targeted diseases were, in order: diabetes, chronic heart failure, hypertension, high cholesterol, chronic obstructive pulmonary disorder, osteoporosis, asthma, depression, schizophrenia, bipolar disorder, rheumatoid arthritis	Target beneficiaries with 2–3 “core” chronic diseases

Sources: CMS: “Medicare Part D MTM Programs,” Fact Sheet, June 2011, and “2012 Plan MTM Program Eligibility Information,” Sept. 2011, <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html>.

Figure 1
Participation in Part D MTM Programs
(in millions), 2006–2010



Sources: MTM data: D. Berwick, response to questions from the Committee on Ways and Means, U.S. Congress, following his testimony on Feb. 10, 2011, submitted for the *Congressional Record*, <http://waysandmeans.house.gov/UploadedFiles/BerwickQFRs.pdf>; Total Part D Plan enrollment, excluding retiree drug subsidy enrollees: *The 2012 Annual Report of the Medicare Trustees*, table IV, B8, p. 164, April 2012, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2012.pdf>.

CMS Concerned by Lower-than-Expected MTM Participation

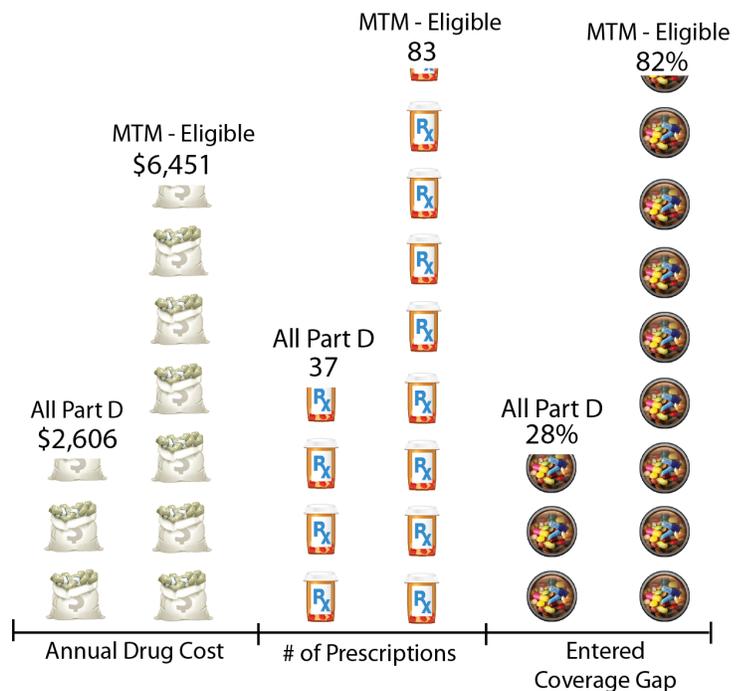
In 2010, CMS predicted that reducing the dollar eligibility threshold (to \$3,000) in annual Part D-covered drug expenditures would result in 25 percent of Part D enrollees qualifying for MTM programs.¹³ Instead, the eligibility rate dropped from 11 percent in 2008 to 9.1 percent in 2010;¹⁴ the 2011 rate had not been reported by publication time. The actual number of participants has been stagnant since 2007 (figure 1). CMS recently expressed concern that sponsors are restricting MTM eligibility criteria to limit the number of qualified enrollees.¹⁵ In 2012, for example, seven of the ten largest national stand-alone plans require the maximum threshold of eight drugs.¹⁶

New CMS data reveal a comprehensive portrait of Part D MTM-eligible enrollees versus those who are not MTM-eligible. Between these two groups, in 2010 there was a 2½-fold variation in average annual drug costs,

more than a twofold variation in total prescriptions filled, and almost a threefold difference in the percentage of enrollees who entered the Part D coverage gap (see figure 2). (In 2010, this “doughnut hole” gap left enrollees who did not receive the low-income subsidy (LIS) fully exposed to their drug costs. Effective in 2011, this gap is being closed gradually through gap-only drug discounts.) About half (51.3 percent) of all MTM-eligible enrollees received the LIS in 2010.¹⁷ This subgroup tends to use the most prescription drugs, and in 2009, they represented more than 80 percent of all high-cost Part D enrollees.¹⁸

These data characterize people eligible for MTM (figure 2), but how closely they resemble actual recipients of MTM services has not been shared publicly.

Figure 2
Drug Costs and Utilization, All Part D Enrollees versus MTM-Eligible Enrollees, 2010



Source: AARP Public Policy Institute representation of MTM data in: C. Tudor, “State of Part D: 2006-2012,” CMS Medicare Prescription Drug Benefit Symposium, March 20, 2012, <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/ProgramReports.html>.

For example, CMS is studying the relationship between MTM-eligible LIS enrollees and those who received MTM in 2010, but their actual participation has not been reported.¹⁹ Understanding clinical and economic effects of MTM services provided to LIS enrollees could prove strategic, as the Medicare Payment Advisory Commission reported that their drug costs represent 55 percent of total Part D expenditures.²⁰ Other researchers found that LIS enrollees, and those who are dually eligible for Medicare and Medicaid with common chronic conditions, are more likely to incur a hospitalization than non-LIS/non-dual-eligible people.²¹ Given the success of some Medicaid MTM programs in reducing overall program costs through robust prevention of drug-related problems (see discussion below), it is unfortunate that this verdict is still out for Part D MTM.

In sum, eligibility alone is but one part of the Part D MTM equation.

MTM Is Showing Promise in Other Drug Benefit Programs

Several MTM programs outside of Part D have yielded positive results. For example, Minnesota Medicaid started providing MTM in 2006, reimbursing pharmacists to provide and document MTM to people taking four or more prescription drugs to treat two or more chronic diseases; or when a recipient's drug therapy problem caused, or was likely to cause, significant nondrug program costs. A 2007 evaluation found that more than one-third (36 percent) of Medicaid MTM recipients with diabetes achieved optimal care standards, versus the statewide average of diabetes performance standards of 6 percent.²²

Also in Minnesota, a 10-year evaluation of MTM provided to integrated health system patients estimated a return on

investment of \$1.29 per \$1.00 in MTM administrative costs.²³ This was based on estimated cost savings for avoided physician office visits, urgent care, and emergency room visits that the MTM intervention helped prevent. MTM services, paid out-of-pocket by the patient or reimbursed by insurance, were delivered face-to-face only. Evidence-based clinical goals of therapy helped determine patient-specific targets.

In 2000, Iowa implemented a nine-month pharmaceutical case management program for Medicaid recipients who were taking four or more prescription medications. Pharmacists met with more than 900 patients, two-thirds of whom were age 45 years or older. They found an average of 2.6 medication-related problems per person. Pharmacists' most frequent recommendations were to add a medication (52 percent of patients), change a medication (36 percent of patients), or discontinue a medication (33 percent of patients). Across the program, physicians accepted just under half (49.2 percent) of pharmacists' recommendations. Even so, Medicaid patients age 60 years and older still benefited from pharmacists' case management services; these patients realized a decrease in use of medications considered inappropriate for the elderly.²⁴

Iowa's present Medicaid MTM-like program relies on pharmacist-physician teams: Either team member can recommend a patient for interventions, and physicians must approve or modify medication action plans. Under this program, both pharmacists and physicians can be reimbursed for drug therapy management services.²⁵

The above examples benefited from elements that may differ from current Part D MTM practice, such as (1) interventions delivered face-to-face by pharmacists; (2) regular and frequent

Connecticut: Recent Medicaid MTM Trailblazer Expands Focus to Dual Eligibles

In 2009, with funding from a CMS Medicaid transformation grant, Connecticut began a MTM pilot via a primary care medical home model.²⁶ Pharmacists met with 88 Medicaid patients who averaged nine to ten medical conditions and used an average of 15 chronic medications. Within 10 months, pharmacists had identified more than 900 drug therapy problems, 80 percent of which they resolved in four visits. Estimated annual savings were \$1,123 per patient on medication costs, and \$472 per patient on medical and hospital costs. In addition to these economic savings, patients realized a 28 percent improvement in achieving clinical therapy goals between their initial pharmacist visit and their last visit. Pharmacists had full access to patients' electronic health records, and were reimbursed for MTM services in this pilot.

Since then, Connecticut is one of 15 states that CMS awarded \$1 million each in 2011 under its State Demonstrations to Integrate Care for people who qualify for both Medicare and Medicaid (dual eligibles).²⁷ This federal funding was granted to help states develop plans to coordinate care for dual eligibles. Among Connecticut's dual eligibles age 65 years and older, 42 percent have three or more chronic conditions, and 38 percent have a serious mental illness. Thus, management of complex drug regimens might be quite challenging for this population.

As part of Connecticut's proposed Health Neighborhood model, dual eligibles would receive supplemental benefits including medication therapy management, building on the state's successful pharmacist-led Medicaid pilot. Connecticut's April 2012 proposal notes that medication management "is one area expected to generate medical savings through reduction in polypharmacy [uncoordinated use of multiple medicines], offset by an improvement in medical adherence which could decrease hospitalizations and acute care expenditures under Medicare."²⁸

In addition to the 15 states that were awarded planning grants, at least 10 other states issued proposals to CMS in April 2012 for dual-eligible integrated care demonstrations.²⁹ Proposals from North Carolina, in the former group; and Ohio, in the latter group, are among those that also incorporate medication management services.³⁰ While MTM represents only one component of these very comprehensive plans, its inclusion sends an important policy message supporting MTM's potential role in enhancing care coordination for some of the most vulnerable federal/state beneficiaries. As this *Insight* went to press, some states' proposals were undergoing public review, and even the original 15 states are reportedly not guaranteed a green light from CMS for implementation.

visits, often monthly; (3) timely access by MTM provider to patient's complete medical, hospital, and lab data; (4) standardized documentation of MTM interventions, follow-up, and tracking of patient progress toward clinical goals;

(5) standardized billing process, and reimbursement of MTM providers; (6) eligibility independent of patient's annual prescription drug costs; and (7) program success that could be gauged by documented savings

systemwide, rather than a singular focus on pharmaceutical expenditures.

These elements represent a sample of those that are reportedly critical to the success of some non-Part D MTM programs.

Changes for Part D MTM in 2012–2014

Meanwhile, CMS is or soon will be implementing additional MTM changes,³¹ including: (1) increasing the annual dollar threshold to \$3,000 plus the percentage specified in 42 *Code of Federal Regulations* §423.104(d)(5)(iv); (2) incorporating in the CMS “Medicare Plan Finder” website MTM eligibility and program features, and general MTM information in the annual *Medicare and You* handbook mailed to all beneficiaries; (3) requiring plans to include, in their annual bid, a discussion of how they develop MTM fees paid to pharmacists or other MTM providers, if such fees are paid; (4) requiring plans to report more specific details of MTM interventions and results (such as the number of changes made to drug therapy based on MTM interventions);³² (5) requiring plans to assess each quarter “at risk” people who are not already enrolled in MTM (2013); and (6) using a standardized format for patients’ medication action plans and summaries of comprehensive medication reviews (2013).³³ Also, the percentage of MTM-eligible enrollees who received a comprehensive medication review will become a “display” measure in 2013, and advance to a full program measure in 2014.³⁴ As other MTM-related quality measures are developed, CMS will consider them for adoption as well.³⁵

Recent Federal Regulatory Action Supporting MTM

The Affordable Care Act (ACA) (P.L. 111-148) authorized grants for “medication management services” in all practice settings (Sec. 3503), noting that

such services will help manage chronic disease, reduce medical errors, and improve patient adherence to therapies while reducing acute care costs and hospital readmissions. The goal of this provision is to produce measurable MTM results and to replicate them in Medicare, Medicaid, state health insurance exchanges, and other programs. The Agency for Healthcare Research and Quality (AHRQ) is the lead implementing agency, but no funds were appropriated. Regardless, an important first step came in 2011, when AHRQ published a detailed MTM research agenda that closely parallels the intent of Sec. 3503.³⁶

Meanwhile, through AHRQ’s Effective Health Care Program, a multicenter trial was conducted to test the effectiveness of MTM interventions. The trial enrolled 600 people age 65 years and older who were at high risk of adverse drug events. One-third received no MTM (representing usual care or the control group); one-third received MTM based on information gleaned solely from patient interviews (this “mirrors the scenario encountered by most community-based pharmacists”); and one-third received MTM from pharmacists who had access to prescribers’ clinical data. The standard intervention was two face-to-face MTM visits from a pharmacist over six months. When published, results could further inform development of more effective MTM.³⁷

Policy Considerations

Part D’s inherent structure makes it particularly challenging to create and sustain robust MTM programs. Evidence of their success requires consistent documentation of MTM interventions and their effect on clinical outcomes. Potential savings from avoided drug-related problems that could otherwise

drive up costs across Medicare should also be consistently tracked.

Presently, Medicare Advantage/ Prescription Drug plans are aligned to potentially demonstrate MTM's value to Medicare overall: Such plans are at risk for medical, hospital, and prescription drug costs, with commensurate data access. However, two-thirds of all Part D enrollees select stand-alone prescription drug plans (PDPs), which are at risk for prescription drug costs only. Such plans are not currently incentivized to track, modify through MTM interventions, or reduce costs beyond Part D. The proportion of PDP enrollees has remained fairly stable since Part D's inception.

In 2012, CMS acknowledged, "it has not been possible to fully demonstrate the value and success of Part D MTM."³⁸ To help reduce this deficit and to incentivize MTM for multiple stakeholders, discussed below are policy options that could support enhanced MTM programs.

- **Offer MTM shared savings:** The CMS Medicare Shared Savings Program will reward accountable care organizations (ACOs) that lower their health care cost growth while meeting 33 performance standards addressing quality of care.³⁹ About half of the standards involve medication management, monitoring drug therapy to achieve clinical goals, therapeutic appropriateness, and provider-patient communication—areas with which MTM services align closely.

Since Part D's inception, plans have incorporated MTM program costs into their annual CMS bid, and must provide MTM services at no charge. Providing plans with an opportunity to share in savings from avoided drug-related problems that are detected and resolved through MTM interventions

could give plans resources to create more robust MTM programs. This could be piloted through the CMS Center for Medicare and Medicaid Innovation (CMMI), and would complement implementation of CMMI's ACO initiatives. Some pioneer ACOs already embrace expanded roles for pharmacists in team-based care models.⁴⁰ New collaboration principles for Medicare ACOs and Part D plans that may wish to share "greater accountability for overall health outcomes," issued by CMS in 2012, are positive developments.⁴¹

- **Reduce cost sharing for MTM participants:** Currently, Part D plans' flexibility in terms of setting prescription cost-sharing amounts is built around formulary tiers and preferred pharmacy networks. (Cost sharing for LIS enrollees is set in statute, while cost sharing for non-LIS enrollees is determined annually by plan sponsors.) To boost participation in MTM services, plans could offer reduced cost sharing for prescriptions or for monthly premiums, to enrollees who undergo comprehensive medication reviews, for example. MTM-related cost-sharing reductions have also been proposed in conjunction with value-based insurance design.⁴²
- **Explore alternate eligibility criteria:** As noted previously, within the universe of MTM programs, Part D appears to be unique in setting statutory minimum drug cost thresholds for eligibility. Other criteria that may help to appropriately target beneficiaries for MTM interventions include an individual's (a) previous-year total Medicare expenditures (Parts A, B, D), including hospital admissions and readmissions due to drug-related problems; (b) reliance on

multiple prescribers who practice in unaffiliated, nonintegrated settings; (c) nonadherence and duplication of therapy,⁴³ (d) level of cognitive impairment, especially combined with LIS eligibility; and (e) functional limitations and level of assistance required for activities of daily living.⁴⁴ Through CMMI pilots, Part D sponsors could test these and other criteria to help ensure that MTM interventions are targeted to enrollees who are most likely to benefit.

- **Provide MTM as a Part B-covered service:** Medicare's A/B/D framework treats inpatient care, physician and outpatient services, and prescription drugs in their respective silos, but this is an artificial division for beneficiaries who require care to be coordinated across programs.⁴⁵ Providing MTM through Part B could help to minimize such silos, complement ACO models, build valuable clinical care coordination across providers, and potentially reduce economic disincentives (most evident in stand-alone PDPs) for robust MTM programs. In addition, as part of a clinical visit that commonly includes a prescription, prescribers and other care team members could refer patients for MTM. Doing so could help to boost patient buy-in for MTM interventions. Presently, a drug plan invites a patient for a comprehensive medication review independently of a medical visit. This detached process may reduce enrollee and prescriber buy-in for MTM.

This range of policy options runs the regulatory gamut, from requiring legislative action (covering MTM through Part B) to possible CMS guidance through its annual Part D "call letter" for plans. Demonstrating MTM's return on investment, however, often requires patience that favors neither the

(1) annual federal budget "scoring" protocol, (2) annual prospective Part D bid process, nor (3) stand-alone drug plans' disinclination to track savings beyond Part D. Forthcoming MTM case studies in insurance programs other than Part D may prove enlightening, but if history is any guide, federal "scorers" will hold out for Medicare relevancy.

Conclusion

To date, Medicare Part D policy debates have centered largely on the benefit's principal goal of enhancing access to prescription drugs. This includes the ACA provision to close the Part D coverage gap, which continues through 2020. Meanwhile, secondary goals of optimizing the quality of medication therapy and preventing drug-related problems are gaining traction, bolstered in part by adoption of new clinical quality measures (such as adherence to drug therapy) for determining CMS star ratings. Another example of drug therapy management challenges is research that found that just four medications or drug classes were responsible for 67 percent of adverse drug event-related hospitalizations of older adults.⁴⁶

Since 2006, Part D medication therapy management programs have evolved slowly, with many programmatic changes, no dedicated budget, and no opportunity for shared savings. This has resulted in a conglomerate of MTM programs facing increasing challenges to demonstrate success, along with an increasing need to enhance Part D's value across the full Medicare program.

The ACA reaffirmed MTM's value by authorizing grants for "medication management services" in multiple settings, a related assessment with which AHRQ is proceeding. As patient-centered care matures alongside quality metrics, there is a growing recognition

that “more powerful solutions are necessary to promote overall medication quality, not just adherence to a checklist at discharge.”⁴⁷ MTM has the potential to represent just such a solution.

Further, other researchers have called for a closer examination of care transitions and hospital readmissions, with an emphasis on studying and supporting “the critical roles of ambulatory care clinicians

in ensuring patient safety before, during and after hospitalization.”⁴⁸

Medication therapy management programs can serve as a bridge across care settings, and help to bolster clinician-patient interface around patient preferences and effective outcomes. With refinements, today’s Medicare Part D MTM—stuck in neutral—should shift into drive.

Endnotes

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