2011 Medicare Part D Medication Therapy Management (MTM) Programs

June 30, 2011

FACT SHEET

Medicare Part D Medication Therapy Management (MTM) programs are enhanced for the 2011 contract year, building upon the expanded program requirements implemented in 2010 and through provisions of the Affordable Care Act (ACA). These expanded program requirements improve eligible beneficiaries' access to MTM services, increase the intensity of interventions, require the provision of written MTM summaries to beneficiaries, and provide for the collection of more robust data for outcomes analysis.

This Fact Sheet presents a summary of the MTM programs currently in place, with notable comparisons to findings reported in previous MTM Fact Sheets, and discusses additional steps that CMS is taking to analyze and implement best practices.

HIGHLIGHTS

Robust Medicare MTM programs are in place for 2011.

- Sponsors continue to refine their targeting criteria to not only meet the CMS requirements, but to optimize beneficiary selection.
  - Approximately 80% target beneficiaries with 3 or more chronic diseases.
  - 60% of the programs require beneficiaries to be taking 8 or more Part D drugs.
- Almost three-quarters of programs target beneficiaries quarterly and 20% target monthly.
- All targeted beneficiaries who are eligible are automatically enrolled into these programs, and one-hundred percent of the programs offer a comprehensive medication review (CMR), at least annually. All programs offer telephonic consultations and over one-quarter offer face-to-face CMRs.
- Sponsors perform on-going monitoring of the beneficiaries' medication use to identify medication-related issues through targeted medication reviews at least quarterly.
- Pharmacists are the leading providers of MTM services across all programs. A growing percentage of programs are using outside entities to provide their MTM services.

A number of activities are underway in 2011 to evaluate and improve MTM programs.

- MTM data are being validated to prepare for future outcomes analysis. The impact of MTM on high risk populations is being studied.
- Key research questions that may be addressed by CMS or others to evaluate MTM programs are presented.
- Section 10328 of the ACA requires improvements in Part D MTM programs including a mandate that the Secretary, in consultation with relevant stakeholders, develop a standardized format for the written summary and action plan that are given to Medicare beneficiaries as a result of the comprehensive medication reviews (CMRs). CMS has already begun to develop a draft format with input from the industry for implementation beginning in January 2013.
- MTM program information for beneficiaries is being prepared for inclusion in future government *Medicare & You* publications, and CMS is considering additional ways to increase beneficiaries' awareness of the value of MTM program services.

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BACKGROUND

The Medicare Modernization Act of 2003 (MMA) under title 42 CFR Part 423, Subpart D, established the requirements that Part D sponsors must meet with regard to cost control and quality improvement including requirements for MTM programs. The initial CMS regulations for these programs established a general framework that allowed sponsors' flexibility to promote best practices.

Requirements for 2011 are similar to the 2010 requirements, which were revised for greater consistency among the Part D MTM programs and to raise the level of interventions offered to positively impact the medication use of Part D beneficiaries. Part D MTM program requirements are described in Chapter 7 of the Prescription Drug Benefit Manual[1] and are summarized within this Fact Sheet when applicable.

REVIEW OF 2011 MEDICATION THERAPY MANAGEMENT PROGRAMS

Each Part D sponsor is required to incorporate a MTM program into their Plan's benefit structure. These requirements do not apply to Medicare Advantage (MA) Private Fee for Service (MA-PFFS) organizations, as described in 42 CFR §422.4 (a)(3). However, considering MA-PFFS organizations have an equal responsibility to provide a quality Part D product, CMS encourages these organizations to establish a MTM program for Medicare beneficiaries. Annually each spring, sponsors submit a MTM program description for CMS to review and approve for the next contract year.[2] Additionally, to promote evolving MTM best practices and to consider the best interests of the Medicare beneficiary, CMS allows certain mid-year positive changes to the Part D sponsors' approved MTM program. Part D sponsors may request changes for approval during specified update windows.[3]

The universe of active Part D contracts with an approved MTM program in 2011 includes 641 contracts (557 Medicare Advantage prescription drug plans (MA-PDs) and 84 standalone prescription drug plans (PDPs)). This compares to 678 contracts (585 MA-PDs and 93 PDPs) in 2010. Throughout this Fact Sheet, these will be referred to as MTM programs. Employer contract MTM programs have been included in the statistics for PDPs. This analysis includes characteristics of 2011 MTM program applications approved during the spring annual review and changes approved during the September and March update windows as of May 9, 2011.

Eligibility Criteria

Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for covered Part D drugs that exceed a predetermined level are targeted for the MTM programs, as described in § 423.153(d)(1). The cost threshold was lowered to $3,000 in 2010 and remains $3,000 for 2011. The annual cost threshold regulation will be revised for 2012 and subsequent years for the costs of covered Part D drugs in an amount greater than or equal to $3000 increased by the annual percentage specified in §423.104(d)(5)(iv). CMS continues to monitor sponsors' movement to more restrictive criteria.

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[1] Prescription Drug Benefit Manual. Chapter 7-Medication Therapy Management and Quality Improvement Program. Accessed June 1, 2011. http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter7.pdf

[2] Memo: Contract Year 2011 Medication Therapy Management Program (MTMP) Submission. Accessed June 1, 2011. http://www.cms.gov/PrescriptionDrugCovContra/082_MTM.asp#TopOfPage

[3] Memo: Process for Part D Sponsors to Request Changes to a Medication Therapy Management Program (MTM). Accessed June 1, 2011. http://www.cms.gov/PrescriptionDrugCovContra/082_MTM.asp#TopOfPage

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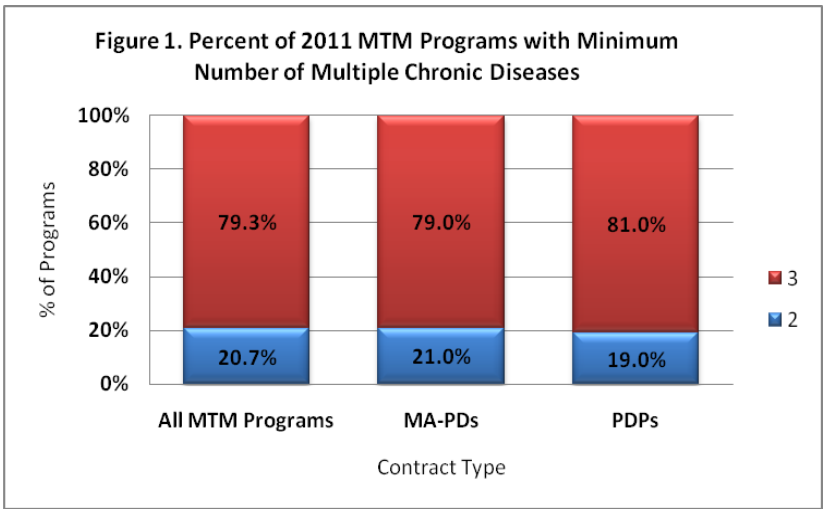
Criteria 1: Have Multiple Chronic Diseases

Sponsors are required to target beneficiaries with multiple chronic diseases, and they define the minimum threshold for eligibility into their MTM program. In 2010, CMS established both a ceiling and a floor in the minimum number of chronic diseases that may be required. Therefore, a plan sponsor has the discretion to determine whether to target beneficiaries with at least two chronic diseases or at least three chronic diseases. The percent of MTM programs by the minimum number of multiple chronic diseases that they target is shown in Figure 1. Approximately 79% of the current programs target beneficiaries with a minimum of three chronic diseases, compared to 72% requiring a minimum of three chronic conditions in 2010.



Sponsors may target beneficiaries with any chronic diseases or limit enrollment in their MTM program to beneficiaries having specific chronic diseases. In defining multiple chronic diseases for eligibility, 6.1% of 2011 programs are targeting beneficiaries with any chronic disease, and 93.9% are targeting beneficiaries with specific chronic diseases. This compares to similar findings for 2010 (4.6% of programs targeted beneficiaries with any chronic diseases and 95.4% targeted beneficiaries with specific chronic diseases).

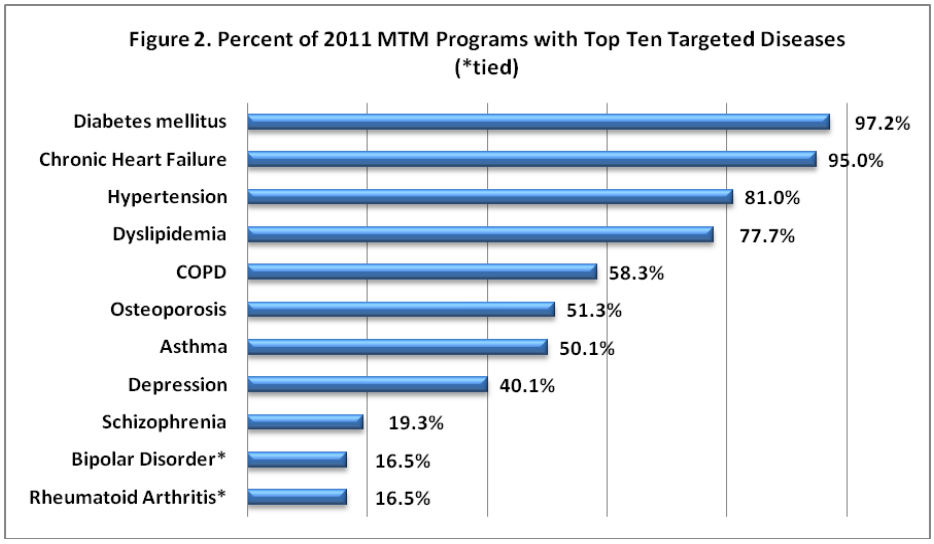
At a minimum, for targeting purposes beginning in 2010, sponsors must include at least four of the following seven core[4] chronic diseases: Hypertension, Heart Failure, Diabetes, Dyslipidemia, Respiratory Disease (such as Asthma, Chronic Obstructive Pulmonary Disease (COPD), or Chronic Lung Disorders), Bone Disease-Arthritis (such as Osteoporosis, Osteoarthritis, or Rheumatoid Arthritis), and Mental Health Diseases (such as Depression, Schizophrenia, Bipolar Disorder, or Chronic and disabling disorders).

The most frequently targeted diseases in 2011 are closely aligned with the same top diseases as targeted for MTM programs in 2007 through 2010, with the exception that Schizophrenia replaced Osteoarthritis as a top ten targeted disease in 2010 and 2011. Another Mental Health Disease, Bipolar Disorder, was tied for the tenth most targeted disease in 2011. Diabetes, Heart Failure, Hypertension and Dyslipidemia are the top targeted diseases.

Overall, the top ten targeted diseases align with the top drugs and classes of drugs utilized by Medicare Part D beneficiaries, which are Cardiovascular and Metabolic Syndrome agents and

[4] Based on an analysis performed ahead of the 2010 Call Letter, these conditions are prevalent in the Medicare population based on the analysis of the RxHCC Risk Adjustment model, pose a risk to the Medicare Trust Fund, and were already the most common diseases targeted by Part D MTM programs.

Psychotherapeutic agents.[5] Figure 2 provides the percentage of MTM programs for 2011 that target beneficiaries with these top ten diseases. Other beneficiary conditions that are targeted by more than 10% of these programs include: Alzheimer's disease (15.3%), Osteoarthritis (13.6%), and Kidney disease (11.7%). Analysis of how programs target beneficiaries with Kidney disease indicates that Diabetes Mellitus, Chronic Heart Failure, Hypertension, Dyslipidemia and Osteoporosis are also frequently targeted conditions for these programs. When submitting their MTM program application, sponsors are allowed to make multiple selections to denote all of the specific chronic diseases that they are targeting.[6]



Criteria 2: Taking Multiple Covered Part D Drugs

Each program sets the minimum number of covered Part D drugs a beneficiary must have filled for MTM program eligibility. In previous years, the minimum thresholds specified by sponsors were between two and fifteen. For 2010 and 2011, CMS also established both a ceiling and a floor in the minimum number of drugs that may be required (two to eight), considering in 2009 almost 90% of MTM programs were already targeting beneficiaries with a minimum threshold of 8 or fewer Part D drugs. Therefore, in 2011, sponsors may set this minimum threshold at any number equal to or between two and eight. For example, one sponsor may specify that a beneficiary must have filled a minimum of five covered Part D drugs to be targeted for their MTM program (along with meeting the other two MTM targeting criteria), whereas another sponsor may specify that the beneficiary must have filled a minimum of two covered Part D drugs.

The percent of 2011 MTM programs that target beneficiaries with the respective minimum number of covered Part D drugs is provided in Table 1 in aggregate and broken out by MA-PDs and PDPs. Approximately 60% in 2011 target beneficiaries who have filled at least eight covered Part D drugs, compared with 66% in 2010.

[5] Part D Data Symposium. October 30, 2008 and March 18, 2010. Presentations accessed June 1, 2011 at: http://www.cms.gov/PrescriptionDrugCovGenIn/09_ProgramReports.asp#TopOfPage

[6] These are not mutually exclusive.

Table 1. Percent of 2011 MTM Programs with Minimum Number of Covered Part D Drugs

Minimum Number of Covered Part D Drugs	% of All MTM Programs	% of MA-PD MTM Programs	% of PDP MTM Programs
2	5.8%	6.1%	3.6%
3	0.8%	0.9%	0.0%
4	2.8%	2.5%	4.8%
5	8.7%	9.0%	7.1%
6	6.7%	6.1%	10.7%
7	14.7%	14.9%	13.1%
8	60.5%	60.5%	60.7%

Sponsors indicate in their MTM program application if any covered Part D drug applies, if chronic/maintenance drugs apply, if disease-specific drugs related to the chronic diseases apply, or if specific Part D drug classes apply. Over one-third (37.9%) of all programs allow any Part D drug to qualify for this requirement, similar to 2010 (38.2%). The remaining programs require Part D drugs for chronic conditions (43.8%), disease-specific drugs related to chronic diseases (6.6%), or specific Part D drug classes (11.7%). A higher share of PDP programs target any Part D drug (51.2%) compared to MA-PD programs (35.9%). In contrast, a higher share of MA-PD programs target chronic Part D drugs (46.1%) compared to PDP programs (28.6%). This is also similar to results reported in the 2010 MTM Fact Sheet.

Criteria 3: Likely to Incur $3,000 for Covered Part D drugs

The sponsor must provide a description of the analytical procedure used when determining if a beneficiary is likely to incur this annual cost threshold for 2011. The description may include the specific threshold(s), formula, or information on their model used. MTM programs in 2011 continue to apply varying costing methodologies, but the majority of analyses are based on specific thresholds of $750 in Part D covered drug costs for the previous quarter or $250 the previous month. A number of programs also use historical data from the past 12 months.

Method of Enrollment

CMS revised the MTM program enrollment requirements in 2010. Sponsors must enroll targeted beneficiaries using an opt-out method of enrollment only. Therefore, in 2011, 100% of the programs are enrolling targeted beneficiaries using an opt-out enrollment.

Sponsors must target beneficiaries for enrollment in the MTM program at least quarterly during each plan year. Almost three-quarters (71.1%) of the programs identify targeted beneficiaries quarterly and 20.0% identify beneficiaries monthly (Figure 3). A smaller share identifies targeted beneficiaries more frequently than monthly. This is comparable to results reported in the 2010 MTM Fact Sheet.

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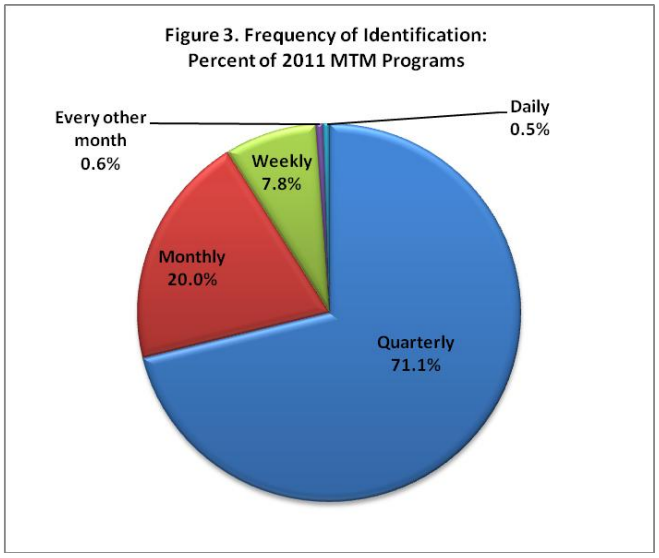


All of the MTM programs use drug claims data to identify eligible beneficiaries for their MTM programs in 2011. In addition, 27.3% of MTM programs use medical claims data to identify eligible beneficiaries. Similar to 2010, it is more likely in 2011 for MA-PD programs to use medical claims data to identify eligible beneficiaries (28.9% of MA-PD programs versus 16.7% of PDP programs). Sponsors use other types of data to aid with identification, and 2.5% (down from 4.0% in 2010) use information collected from the beneficiaries, and 4.3% (up from 2.2% in 2010) use lab data. These are not mutually exclusive categories.

At this time, information on the number of beneficiaries who are enrolled in the MTM programs cannot be reported. These data are currently undergoing data validation. See the Next Steps section of this Fact Sheet for more information on the expanded MTM program reporting requirements and plans for analysis.

MTM Program Services

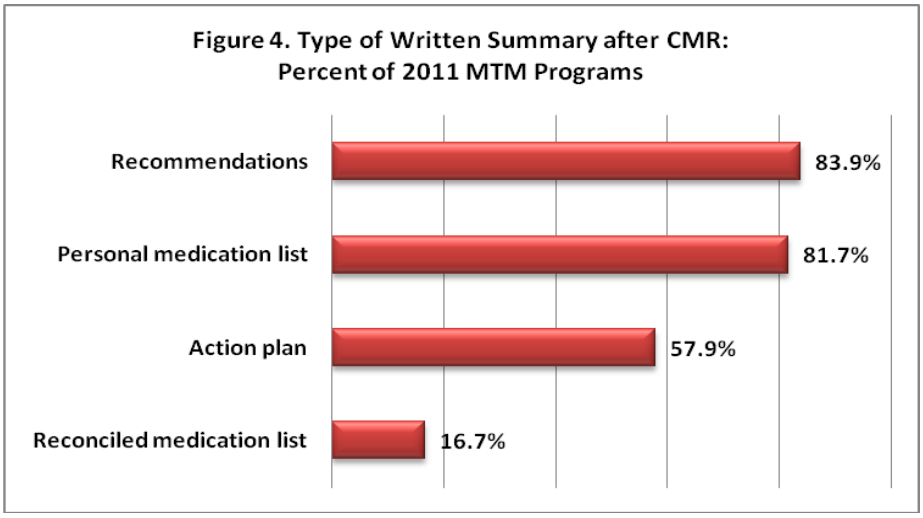
Sponsors must provide a minimum level of MTM services for each beneficiary enrolled in the program that includes interventions for beneficiaries and prescribers, offering an interactive comprehensive medication review (CMR) by a pharmacist or other qualified provider at least annually with written summaries, and performing quarterly medication reviews with follow-up interventions when necessary. Sponsors may offer additional value-added services beyond the required services.

Beneficiary Interventions

In 2011, 100% of MTM programs offer CMRs at least annually and perform targeted medication reviews at least quarterly. These are required interventions.

A CMR is a review of a beneficiary's medications, including prescription, over-the-counter (OTC) medications, herbal therapies and dietary supplements, that is intended to aid in assessing medication therapy and optimizing patient outcomes. The CMR must be completed through an interactive person-to-person consultation with the eligible beneficiary. This real-time interaction may be face-to-face or through other interactive methods such as the telephone. Every program offers the interactive, person-to-person CMR consultation via the phone, and roughly one-fourth (27.0%) of programs also offer face-to-face consultations (up slightly from 25.8% in 2010).

Furthermore, sponsors must implement a systematic process to summarize the interactive consultation. Sponsors must provide an individualized written summary to the beneficiary (e.g. a personal medication record, reconciled medication list, action plan, or recommendations for monitoring, education, or self-management). Figure 4 ranks these top four types of written summaries that are provided to beneficiaries by the MTM programs pursuant to a CMR in 2011. Multiple selections were allowed.



As mentioned in the Highlights and Next Steps sections of this Fact Sheet, the ACA requirement to improve MTM programs will result in specifying the content and format of beneficiary communications pursuant to a CMR. The three components of the proposed standardized format for the CMR written communication to the beneficiary are the Beneficiary Cover Letter, Medication Action Plan, and Personal Medication List. The purpose of the beneficiary cover letter is to introduce the Medication Action Plan and Personal Medication List and describe how the beneficiary can contact the MTM program. The Medication Action Plan describes the specific action items resulting from the CMR process, subsequent practitioner activities that may affect the beneficiary's tasks, and the beneficiary's responsibilities in the action plan. The Personal Medication List is a reconciled list of all the medications in use by the beneficiary subsequent to a CMR. The effective date for implementation of these program improvements is January 1, 2013.

For targeted beneficiaries enrolled in the MTM program that are in a long term care (LTC) setting, sponsors are not required to offer the interactive CMR. Sponsors must still perform quarterly medication reviews and offer interventions targeted to the beneficiaries' prescribers, as these are requirements for all beneficiaries enrolled in the program regardless of setting and regardless of whether or not they decline the CMR offer. The targeted medication reviews assess medication use, monitor whether any unresolved issues need attention, new drug therapy problems have arisen, or if the beneficiary has experienced a transition in care. Part D sponsors provide follow-up interventions as necessary.

Beyond the required services, sponsors provide additional value added services as shown in Figure 5. In 2011, referral for case management replaced refill reminder as the second most frequent additional beneficiary intervention. The 'Other' beneficiary interventions represent a collection of over 40 different miscellaneous interventions to improve medication use or perform utilization management. Multiple selections were allowed.

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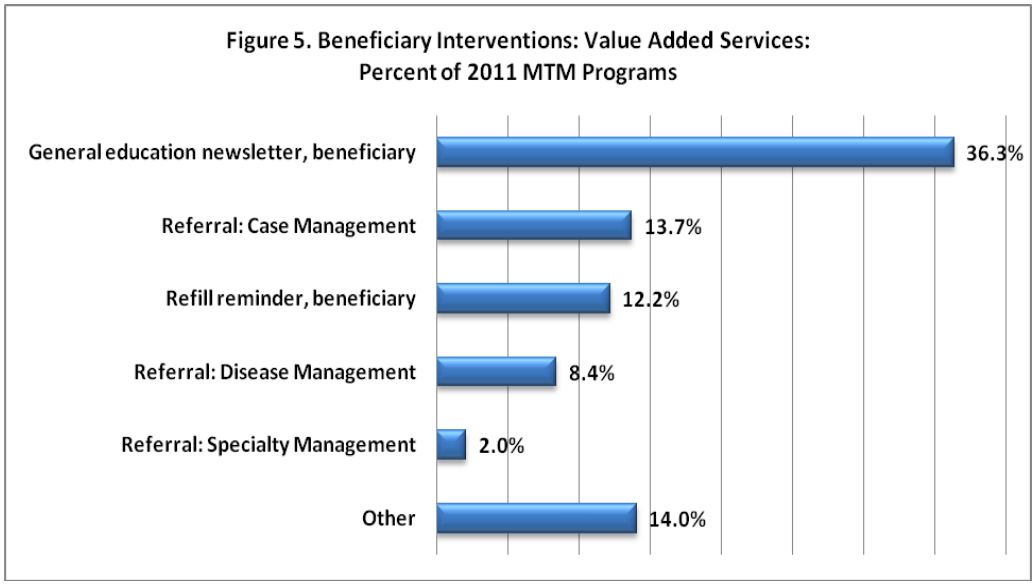


Specifying the goals of interventions and the process of care, such as service level expectations for a CMR, are being studied through an analysis of best practices. This study will analyze the impact of CMRs and MTM services on high risk populations in improving safety and lowering costs, and the results will be presented to stakeholders when available.

Prescriber Interventions

Sponsors are required to offer interventions to the beneficiaries' prescribers. In 2011, 100% of MTM programs offer interventions to prescribers to resolve drug therapy problems or optimize therapy. Almost 17% of programs provide a patient medication list to the prescriber.

In their 2011 MTM program application, sponsors indicate the methods of delivering these interventions to the prescriber: 92.0% fax the consultations, 78.9% provide mailed consultations, and 77.5% provide phone consultations. Sponsors may use multiple methods of communication.

MTM Providers

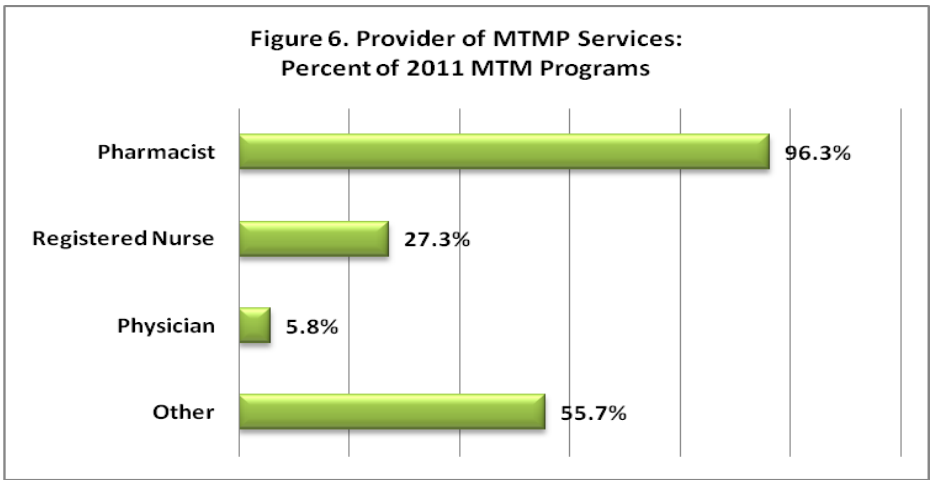
MTM is considered an administrative cost (component of the plan bid) by CMS. Part D Sponsors are required to explain how their fees account for the time and resources associated with their MTM program. They have the flexibility to determine the billing mechanisms and established fees for pharmacists and other qualified providers associated with providing the MTM services. These arrangements are between the Part D sponsors and the providers of the services.

Sponsors can utilize internal and/or outside personnel. In 2011, 37% of programs utilize internal staff (down from 46.8% in 2010), and 81.6% of programs utilize outside personnel (up slightly from 80.0% in 2010). No difference is observed between MA-PDs and PDPs in terms of the use of internal personnel to provide MTM; however, 82.6% of MA-PDs compared to 75.0% of PDPs utilize outside personnel.

Per CMS' requirements, the MTM services may be furnished by pharmacists or other qualified providers. Sponsors indicate that they will utilize pharmacists, physicians, registered nurses, and/or others. These are not mutually exclusive, and sponsors may utilize any single type of qualified provider or any combination of providers. In addition plan-reported data do not

distinguish between providers of interactive, person-to-person CMRs and providers of other services at this time.

Compared to previous program years, pharmacists continue to be the leading provider of MTM services (Figure 6). Overall, regardless of whether the sponsor is utilizing in-house and/or outside personnel, 96.3% of MTM programs in 2011 utilize pharmacists to provide the services. Fewer programs utilize physicians in 2011 (5.8%) than in 2010 (9.1%), although more programs utilize registered nurses in 2011 (27.3%) than in 2010 (21.2%). A large proportion of programs utilize other support staff to assist in providing these services (55.7%). A review of the "Other" provider category reveals that approximately 50% of those designated as other providers are pharmacy technicians and about 30% are patient care coordinators/case workers.



As mentioned above, over 80% of programs utilize outside personnel. Outside personnel may include a Prescription Benefit Management (PBM) company, MTM vendor, disease management vendor, community pharmacists, LTC pharmacists, or others. Of the programs that utilize outside personnel, 57.0% utilize a PBM (46.5% of all 2011 MTM programs), 0.19% utilize a disease management vendor (0.16% of all programs), 30.8% utilize a MTM vendor (25.1% of all programs), 25.2% utilize community pharmacists (20.6% of all programs), 12.0% utilize LTC pharmacists (9.8% of all programs), and 3.4% utilize other outside personnel (2.8% of all programs). Of the programs that utilize outside personnel in 2011, there is a decrease in the share of MTM programs that utilize a PBM, in comparison to 2010. Furthermore, it is possible that the share of programs that utilize community pharmacists is under reported because a number of MTM vendors utilize a network of community pharmacists to provide these services.

NEXT STEPS

CMS has expanded the data elements that sponsors are required to submit to CMS regarding their MTM programs as part of the 2010 and 2011 Part D Reporting Requirements.[7] Sponsors are required to submit aggregate participation statistics at the contract level, which include the number of beneficiaries eligible for MTM and the number of beneficiaries who opted out of the program. Beneficiary-level reporting is also required, including receipt of a CMR, the number of targeted medication reviews, number of prescriber interventions, and the change(s) in therapy directly resulting from the interventions. These data are due to CMS in February of each year,

[7] CY10 and CY11 Part D Reporting Requirements. Accessed June 1, 2011 at: http://www.cms.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage

enabling CMS to perform analysis of the MTM programs and interventions, evaluate the revised requirements, and identify additional best practices. The 2010 plan-reported data, which CMS received in February 2011, are currently undergoing data validation so that these data can be used for analytical purposes. Additional MTM program participation statistics will be provided to stakeholders when available. The availability of validated data also provides the opportunity for more robust MTM programmatic evaluation in combination with other CMS data sources.

Furthermore, CMS is exploring meaningful performance measures that could be used to evaluate the effectiveness and quality of the Part D MTM programs through collaborations with external stakeholders such as the Pharmacy Quality Alliance (PQA), as well as internal stakeholders such as the Agency for Healthcare Research and Quality (AHRQ), the Health Resources and Services Administration (HRSA), the CMS Center for Medicare and Medicaid Innovation, and others. The current validation and analytical efforts will be essential for developing a quality management roadmap for the MTM programs.

Key research questions that may be addressed by CMS or others in the future to evaluate MTM programs, identify best practices, and evaluate the effects of policy changes may include:

- What information and data are useful to enhancing beneficiary awareness of MTM programs and services?
- What is the best method for evaluating the quality of an interactive, person-to-person comprehensive medication review (CMR) and other interventions?
- Which MTM program eligibility criteria are most useful to beneficiaries in selecting a health plan?
- Which beneficiaries may derive the greatest benefit from a CMR, and other MTM services or interventions?
- What is the best method of delivering a CMR and other MTM services (e.g. face-to-face, telephonic, telehealth)?
- What is the complexity of beneficiaries receiving a CMR in comparison to the general Medicare beneficiary population in terms of predicted future health expenditures?
- Which health professional provides the most efficient and effective CMR, and which individuals are best suited to provide other MTM services and interventions?
- What effect does a CMR and other services have on beneficiary engagement, activation and satisfaction?
- Which patient safety reporting measures have the greatest impact on reducing drug-related morbidity and mortality in Medicare beneficiaries?
- What are the effects of CMRs and other MTM services on achieving the goals of better care for individuals, better health for populations, and lower per capita costs?
- What are the economic effects of MTM programs, and what is the return-on-investment from a CMR?

The development of a standardized format for the written summary and action plan given to Medicare beneficiaries as a result of the CMRs, specified in Section 10328 of the ACA, provides

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CMS with the opportunity to engage in beneficiary testing to begin understanding the impact of a CMR on beneficiaries. Information from the standardized format analysis combined with validated MTM program data is expected to provide increasing confidence in program integrity, the opportunity to develop care service expectations, and the ability to explore beneficiary MTM awareness initiatives. Furthermore, MTM program information for beneficiaries is being prepared for inclusion in future *Medicare & You* publications, and CMS is considering additional ways to increase beneficiaries' awareness of the value of MTM program services.

QUESTIONS

Questions regarding this Fact Sheet may be sent to: partd_mtm@cms.hhs.gov.