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Survey of Medicare Part D Plans' Medication Therapy Management Programs

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Abstract

Purpose: The Medicare Prescription Drug, Improvement and Modernization Act of 2003 included a provision for programs, termed Medication Therapy Management (MTM) programs, focused on optimizing therapeutic outcomes for patient with multiple medications and multiple conditions. The broad definition of MTM program in this Act allowed Prescription Drug Plans (PDPs) and Medicare Advantage Drug Plans (MA-PDs) to develop a wide variety of MTM services. The purpose of this survey was to describe and summarize the enrollment criteria and benefit design for MTM programs being offered throughout the United States in 2006.

Methods: A 12-item survey with mostly open-ended questions was administered by phone to MTM benefit plan managers from lists obtained from CMS. Data was abstracted from the surveys and categorized after the responses were collected with the following research questions in mind: 1) What characteristics are required for a patient to be enrolled in an MTM program?; 2) What types of services are provided by MTM programs?; and 3) How are those MTM services being provided to patients? **Results:** Surveys were obtained from 70 health insurance plans covering 12.1 million Medicare enrollees, and representing 21 distinct MTM programs. 90.5% of MTM programs restricted their enrollment based on number of disease states, with a median of 3 (range 2-5). 57.1% of MTM programs restricted enrollment based on the type of chronic condition. 95.2% of MTM programs had requirements for the number of medications necessary for enrollment in the program, with a median of 6 (range 2-24) medications necessary. The most frequently provided MTM services were patient education (75.0% of programs), patient adherence (70.0%), and medication review (60.0%). The median number (range) of different service types provided by MTM programs was 3 (2-7). 76.1% of MTM programs used mailed interventions, 90.4% used in-house call centers, and 19.0% contracted with pharmacies to provide some or all of their MTM services.

Conclusion: MTM programs currently offered by PDP's and MA-PD's are highly variable. Definitive evidence supporting many of the most common interventions is lacking.

Introduction

In 2003, the Medicare Prescription Drug, Improvement and Modernization Act (MMA) was enacted that included a prescription drug benefit for Medicare beneficiaries (Part D).¹ Included in this act was a provision for optimizing therapeutic outcomes for patients with multiple medications and multiple conditions. These programs, termed Medication Therapy Management (MTM) programs, are administered by Prescription Drug Plans (PDP) and Medicare Advantage Drug Plans (MA-PD). Beneficiaries that qualify for MTM services are persons with multiple chronic diseases, on multiple chronic medications, and likely to incur annual Part D drug costs in excess of an amount specified by the Secretary of Health and Human Services (\$4000 for 2006). MTM programs may include elements that promote enhanced understanding of medication use, increased adherence to therapy, and detection and reduction of adverse events or potential adverse events. Funding for these programs is provided to the drug plans (PDP's and MA-PD's) based on a negotiated contract with the Centers for Medicare and Medicaid Services (CMS) and is included in the administrative costs submitted by the drug plans.^{2,3}

There are a range of programs that could fall under the definition of a MTM program as provided by the MMA, and as interpreted and further elucidated by CMS.² Provision of the services could occur via mailed letters, phone conversations, or face-to-face interactions with the clinician. Each of these methods has its' theoretical benefits, with mailings likely to be the least expensive option and with face-to-face interactions with a clinician likely to produce the best clinical results.⁴⁻⁷ In addition to the method of delivery, the content of the program is very important. Some programs have focused on reducing the number of medications or on cost-savings,^{5,8,9} while other programs have focused on reducing potential adverse drug events, improving patient clinical outcomes, or raising quality of life.¹⁰⁻¹⁴

Information about currently employed enrollment criteria and MTM benefit design is crucial to efforts for designing practical, rational, evidence-based MTM programs. It is also helpful to beneficiaries and clinicians when choosing or assisting with selecting an insurance plan. Unfortunately, this information was not made available to the public by CMS. The purpose of this survey was to describe and summarize the enrollment criteria and benefit design for MTM programs being offered throughout the United States.

Methods

Two contact information lists obtained from CMS were used to identify MTM benefit plan managers (pharmacy contact information for Part D approved plans and MTM contacts for Part D plans). Plans were contacted in a non-randomized fashion, with larger and National providers contacted first. A 12-item questionnaire was developed by the American Pharmacists Association (APhA) to survey MTM benefit plan managers about enrollment criteria and benefit design (see Appendix A). To ensure completeness, the questionnaire contained mostly open-ended questions and was administered by phone, and in some cases follow-up email, by the study investigators, Bough, Burns, and Pharm.D. Candidate Jill Garlisch. The survey was pilot tested with two Part D MTM plan managers for clarity and appropriateness of terminology for the

health plan setting. Responses from the MTM benefit plan manager were collected by the study investigators, formatted, and forwarded to that benefit plan manager for verification of the information. After being reviewed, the survey was returned to one of the study investigator's (MB) and the responses checked against the original responses to ensure they were consistent. Where permission has been given, these surveys have been posted on the APhA web site www.aphanet.org.

A data abstraction form was developed to extract information from the surveys for the purpose of summarizing the collected survey data. This abstraction form was developed with the following research questions in mind: 1) What characteristics are required for a patient to be enrolled in an MTM program; 2) What types of services are provided by MTM programs-?; and 3) How are those MTM services being provided to patients?

Examples of enrollment characteristics included in the abstraction form were whether the program would be provided to all or some beneficiaries meeting certain characteristics. If access to the MTM program was restricted, the types of restrictions imposed (number and types of disease states; number of medications; spending requirement on Part D medications) were recorded. The types of services provided by MTM programs were divided into 2 categories that encompass the scope of services provided and the type of provider offering the services. Examples of scope include whether the program involved education, compliance, monitoring, medication review, or other services. The method provision of the MTM program, as a proxy for program intensity, was assessed via the method of content delivery (mail, telephonic, or face-to-face) and the frequency of interventions.

Information spreadsheets regarding the numbers of enrollees in each Part D plan were obtained from the CMS website and matched with the survey data using the insurance plan names.^{15, 16} These spreadsheets contain summaries of plan enrollment divided by either State (for PDP's) or by County (for MA-PD's). They exclude all plans with less than 1% of enrollment (in a State or County respectively), beneficiaries enrolled in an Employer Group-Only Plan, out of area beneficiaries, and beneficiaries without a valid address in the CMS database. These two spreadsheets included 18.0 million of the estimated 20.7 million Medicare beneficiaries who had enrolled in Part D prior to April 27, 2006. As a result of this discrepancy, our estimates of how many beneficiaries were covered by the surveyed health plans were underestimates.

Data was collected and stored using Microsoft Excel 2003 SP2 (Microsoft Corporation, Redmond, WA) and analyzed using SPSS v.13.0 for Windows (SPSS Inc., Chicago, IL).

Results

Surveys were obtained for 70 health insurance plans, representing at least 50 different PDP plans and 221 MA-PD plans (3 health insurance plans did not provide how many PDP and MA-PD plans they offered). The MA-PD and PDP plans in this study cover at least 12.1 million Medicare out of a total of 20.7 million enrollees who either voluntarily enrolled in a PDP (8.9 million), MA-PD (5.9 million), or were Medicare – Medicaid dual eligible and were automatically enrolled in a plan (5.9 million) as of April 27, 2006. This represents at least 58.5% of the total PDP/MA-PD population.

There were 21 distinct MTM programs offered by the 70 health insurance plans. The remaining results will be presented as they apply to these 21 MTM programs and not by

insurance plan. Where the numbers of enrollees were provided, this number applies to the total number of beneficiaries from which the MTM program will select eligible subjects, and not to the number of subjects offered the MTM services.

MTM Enrollment Criteria

Enrollment criteria were the same within MTM program - insurance plan pairs or groups, with one exception. This exception was a contracted MTM program that allowed the insurer to define their own enrollment criteria but then provided the same services to all enrolled beneficiaries. There were 3 insurance plans we surveyed which contracted with this MTM program.

Almost all of the surveyed MTM programs had restrictions on eligibility. One small insurance plan (<50,000 enrollees), contracting with the MTM program mentioned above, offered their program to all their beneficiaries. The other two insurance plans contracting with this MTM program had restrictions on enrollment. Nineteen MTM programs (representing 90.4% of the MTM programs and affecting approximately 11.1 million enrollees) are being offered only to those beneficiaries who meet predefined criteria. One MTM program (representing 4.8% of the MTM programs and 0.9 million enrollees) did not provide information on enrollment criteria. A breakdown of the enrollment criteria is provided below.

Nineteen of the MTM programs (representing 90.5% of MTM programs and 11.2 million enrollees) have enrollment criteria that restrict their MTM services to patients with a given number of disease states. One MTM program (representing 4.8% of MTM programs and <50,000 enrollees) had no disease state restrictions and one program (4.8% of MTM programs; 0.9 million enrollees) did not provide information on enrollment criteria. Of the 19 programs that restricted enrollment based on the number of disease states or diagnoses, the median number (range) of disease states were 3 (2-5). Table 1 provides further detail on the number of conditions required by programs for enrollment.

Many programs further restricted enrollment by limiting the conditions from which the chronic diseases requirement must be drawn. In other words, only patients with certain conditions were considered for enrollment. Twelve MTM programs (57.1% of MTM programs; 4.0 million enrollees) restricted the MTM service to beneficiaries with certain predefined conditions while 8 programs (38.1% of MTM programs; 7.2 million enrollees) had no specific restrictions other than the conditions be chronic. Among the 12 programs that restrict entry to certain conditions, the median number (range) of conditions included in those restrictions was 5 (2-8). The most common disease states included in the restrictions were diabetes mellitus (12 programs), congestive heart failure (10 programs), asthma (8 programs), hypertension (8 programs), and hyperlipidemia (8 programs). The complete list of included conditions is provided in table 2.

The MMA specified that Medicare beneficiaries should be offered MTM if their annual Part D medication expense was greater than an amount specified by the Secretary of Health and Human Services; \$4000 for the year 2006. Twenty MTM programs (95.2%) had a spending threshold that had to be met before enrollment in the program was offered. One program did not provide information on their inclusion criteria. Of the 20 programs that reported spending thresholds, 19 (representing 95.0% of the subset and 11.0 million enrollees) had a spending threshold of \$4,000 per year (estimated), although the methods of estimating this threshold

differed between programs. One program (representing 5.0% of the subset and 0.2 million enrollees) had a threshold of \$3,600 or less per year (\$300 or more in any one month period).

Finally, twenty of the programs (95.2% of MTM programs; 11.2 million enrollees) required that a certain number of chronic medications be filled before the MTM program was offered to patients. One program did not provide this information. Of the programs reporting restrictions on the number of medications needed for inclusion in their MTM program, the median number (range) of medications was 6 (2-24).

MTM Benefit Design

Once enrolled in an MTM program, there were marked differences in the types of services offered to targeted MTM beneficiaries. There were often differences within a program as to what benefit was offered to one person compared with another. Six MTM programs (representing 28.6% of MTM programs and 7.0 million enrollees) offered a tiered MTM service benefit, while 15 programs (71.4% of MTM programs; 5.1 million enrollees) offered the same MTM services to all targeted enrollees. The methods of how beneficiaries were triaged to one level of the tiered benefit versus another were not elucidated and in some surveys were stated as being proprietary.

The breadth of services offered was assessed by categorizing the described services into predefined groups. Twenty of the 21 programs (representing 95.2% of MTM programs and 12.1 million enrollees) provided information that was detailed enough to categorize the MTM services. 1 MTM program (4.8% of programs; <500,000 enrollees) did not provide enough information to categorize their MTM services. The most frequently reported services were patient education (75.0% of programs), patient adherence (70.0%), and medication review (60.0%). It is important to note that some services may be offered only to a subset of targeted beneficiaries in programs with tiered benefits. The median number (range) of different service types provided by MTM programs was 3 (2-7).

The methods by which the MTM services were provided were also assessed. For this question, data was available from all 21 MTM programs. Three-quarters of all plans were using mailed information for some or all of their MTM beneficiaries. In-house call centers were also very popular, being used in 90.4% of programs and available to all targeted MTM beneficiaries 57.1% of the time. Contracted call centers were used in 14.3% of programs. In-house case managers and contracted pharmacies were used by a limited number of programs. One program (4.8% of programs) contracted with pharmacies to provide telephonic MTM services. Four of the 21 programs (19.0%) contracted with pharmacies to provide face-to-face services.

Programs provided MTM services with varying frequency, from once monthly (14.3% of programs) to once annually (14.3% of programs). Five (23.8%) programs chose not to specify a frequency, describing their program as providing MTM services at a frequency specific to the patient's need. Some programs (9.5%) specified an irregular schedule with more frequent follow up initially.

Where either in-house or contracted face-to-face services were part of the MTM benefit, two of nine (22.2%) programs offering face-to-face visits had restrictions placed on the number of visits allowed. Three of nine (33.3%) did not have restrictions. Information on restrictions was not provided by 4 of 9 (44.4%) programs.

Finally, the MMA states that the medication therapy management may be "furnished by a pharmacist" and "shall be developed in cooperation with licensed and practicing pharmacists and physicians." As such, we were curious as to the provider types employed or contracted by MTM

programs to provide the services. Pharmacists were employed or contracted to provide MTM services by 95.2% of the programs. Nurses were the next most commonly employed or contracted provider type, with 47.6% of the programs choosing this option. Physicians were employed or contracted to provide MTM services by 14.3% of plans, the same proportion as pharmacy technicians and social workers. Other provider types included were behavioral health staff and “case managers.” One MTM program listed its provider(s) as the (PBM) staff, and did not provide details as to the provider type.

Discussion

This study captures the MTM programs offered by many of the largest PDP and MA-PD plans throughout the United States. It involves plans that cover at least 12.1 million of the 20.7 million Medicare beneficiaries who either voluntarily enrolled in a PDP (8.9 million), MA-PD (5.9 million), or were Medicare – Medicaid dual eligible and were automatically enrolled in a plan (5.9 million) as of April 27, 2006. This represents 58.5% of the total PDP/MA-PD population. To the best of our knowledge, this analysis is the first description of MTM programs developed as part of the MMA. However, the concepts underlying MTM programs are derived from a wide body of literature, with a considerable amount of research supporting some practices.

MTM programs in our survey generally restricted enrollment to patients with a certain number of conditions or medications. In several cases, beneficiaries had to have multiple conditions from a list of unrelated chronic conditions to qualify for the MTM benefit. There appeared to be little consistency as to which conditions were selected, with only diabetes mellitus and heart failure being uniformly targeted. While some plans offered much less restrictive enrollment criteria, patients were triaged or directed to different levels of care based on undisclosed methods. The literature supports that patients with multiple chronic conditions, multiple providers, and those with greater than 5 medications are at an increased risk of experiencing adverse effects.¹⁷⁻²³ There is little or no support for the further restriction of enrollment to certain chronic conditions. Although there may be a perceived economic incentive to do so in some cases (eg. diabetes and heart failure are costly conditions with many treatment options available), the fiscal impact of a “polypharmacy” or MTM program may be less dependent on the condition being treated and more dependent on the potential of the involved medications to result in benefit or cause harm. Furthermore, it may be most dependent on patient-specific factors, such as willingness or ability to adhere to therapy and the out-of-pocket cost burden of the care compared with available resources.²⁴⁻²⁶

The broad definition of MTM, provided in the MMA, allows for many different types of programs to be offered. Mailed educational pamphlets, programs that identify indicated medications missing from a patient’s profile using claims data (eg. beta-blockers post-MI), and medication reviews with or without identification and resolution of drug problems are all examples of MTM programs fulfilling the MMA requirements. Many studies have been published demonstrating improved outcomes with polypharmacy clinics,^{5, 10, 27-32} disease state management programs,³³⁻³⁷ and interventions to improve adherence.³⁸⁻⁴⁰ A complete review of all such studies is beyond the scope of this discussion, but is available in several excellent systematic reviews and meta-analyses.^{22, 24, 41-49}

Other types of services employed by MTM programs have less evidence supporting their use. Some services look promising but have limited evidence, such as medication reconciliation after hospital discharge⁵⁰⁻⁵³ and medication reviews in the community setting.⁵⁴ Telephonic services have shown mixed results and may be more dependent on other factors, such as condition being treated, patient cognitive ability, and program intensity.^{55, 56} Notably, there is a dearth of well-controlled studies on the effectiveness of mailed educational pamphlets and their impact on patient knowledge, adherence to therapy, or reduction in adverse drug events.^{4, 57, 58} Despite this, these programs formed the backbone of most of the MTM programs, being offered to approximately three-quarters of all MTM beneficiaries.

Another important topic worth further discussion is that of program breadth and intensity. In this survey, there was a wide range in the types and number of services being offered. Broad programs are those offering more types of MTM services. Broad programs could theoretically provide a more comprehensive service from identification of new problems to resolution of those problems through direct consultation with the patient's physician to monitoring the patient's progress at follow-up visits. These concepts have been proposed in consensus documents adopted by several National pharmacy organizations.^{59, 60} Program breadth appears to be an important factor in impacting adherence to therapy in some conditions, where more complex and holistic practices appear to have improved outcomes.^{22, 61} Program intensity refers primarily to the amount of time a clinician spends with patients, but also with how that time is spent. Time spent with a patient has been associated with better outcomes in diabetes self care programs and in the IMPROVE study.^{27, 42} It is still not clear what the optimal duration is for interventions and if that timing is dependent on the complexity of the condition (eg. lifestyle changes with diabetes compared with hypertension) or if other factors may be more important, such as the presence of depression.

With the MMA, there is a significant opportunity for community and other interested pharmacists to become involved in clinical activities and enhancing patient care. As expected, pharmacists are intricately involved in providing some or all of the MTM services, with all but one of the surveyed programs involving a pharmacist in patient care. Ninety percent of programs elected to provide the some or all of their MTM services in-house. In contrast, only 19% of MTM programs contracted a pharmacy to provide some or all of their MTM services. Despite the small number of plans contracting with pharmacies, a surprisingly large number of beneficiaries are covered by these insurers. Approximately 7.5 million lives were covered by programs contracting with pharmacies to provide face-to-face MTM services. However, estimating the number of patients who may actually arrive at the pharmacies requesting their services is not possible because of MTM enrollment criteria and tiered benefits. A recent review of community pharmacy practice indicated that prior to the MMA, most pharmacies were not engaged in providing patient clinical care services.⁶² A follow-up survey, after the effects of MMA-related MTM services are offered to patients, would provide useful information on the interest of community pharmacists in providing MTM services, as well as the potential impact of and capacity for MTM programs in the community pharmacy setting.

Limitations

This survey has many important limitations that must be considered. Selection of health plans was not random, and largest and/or national health plans were specifically targeted for interview. As a result, the extrapolation of these results to smaller and regional health plans may not be accurate. Although no health insurers directly refused to answer the initial questionnaire, many did not respond even after several attempts to contact them. This selective response from health insurers may result in a selection bias, although it is not possible to determine if one does exist or how it may impact our findings. The survey was initially conducted using an open-ended format and was later categorized. While this allowed maximum flexibility to explore the many different methods for selecting beneficiaries and MTM program offerings, it may have led to inconsistent reporting of the programs and omission of some relevant information. However, given the lack of information on MTM program offerings, we believed this was the best method of allowing insurers to best represent their programs without having to place them in potentially arbitrary or inaccurate classifications. We therefore developed the data abstraction tool after collecting information on several of the programs.

Conclusion

MTM programs currently offered by MA-PD's and PDP's are highly variable. Enrollment criteria exist for the vast majority of programs and range from the simple criteria proposed in the MMA (patients with multiple chronic conditions, multiple medications, and spending on medications exceeding \$4000 per year) to complex, potentially highly restrictive criteria (patients having X of the following X conditions; or patients with 5 chronic conditions; or patients taking more than 23 medications). Once enrolled in an MTM program, the benefits were equally variable with some programs offering mailings or limited phone support services and others offering a range of services depending on patient needs. Evidence supporting many of these interventions is lacking.

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Tables

Table 1. Number of chronic diseases required for enrollment in a MTM program.

Number of chronic diseases required for MTM enrollment	Number of programs with stated requirement	Potential number of enrollees affected (in millions)
2	7*	5.0
3	5*	1.4
4	3	4.4
5	3	0.5

*One MTM program had different enrollment criteria for each of its' three contracted insurance providers. One insurance plan required 2 chronic conditions and one required 3 chronic conditions for enrollment; the last insurance plan provided the MTM program to all of its beneficiaries without restrictions. These results are not included in the table. One MTM program did not provide information on enrollment criteria.

Table 2. Chronic conditions to which enrollment in a MTM program is restricted in the 12 of 21 programs having such restrictions. Beneficiaries were required to have multiple conditions from this list, the number of which varied by MTM program (for example, 3 of the 5 following conditions), to qualify for the program.

Chronic condition	Proportion of programs including condition (%) N=12?	Potential number of enrollees affected (in millions)
Arthritis	25.0	0.5
Asthma	66.7	3.0
CAD	25.0	1.1
CHF	83.3	3.1
COPD	41.7	1.7
CRF	25.0	0.6
Depression	16.7	0.5
DM	100.0	4.0
HTN	66.7	2.6
Hyperlipidemia	66.7	2.6
Pain	8.3	0.2

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Table 3. MTM services offered by 20 of the 21 MTM programs. Note that some services may be offered only to a subset of beneficiaries in programs with tiered benefits.

Type of MTM service	Proportion of programs offering service (%) n=20?	Potential number of enrollees affected (in millions)
Patient education (instruction provided to a patient individually, in group sessions, or mass mailings)	75.0	7.4
Patient adherence (provision of targeted education, counseling, and/or tools for improving adherence to prescribed medications)	70.0	6.8
Patient counseling (patient advice or guidance, provided specific to a patient's needs)	40.0	8.4
Patient monitoring (maintenance of patient records for assessment and long term follow-up)	30.0	4.5
Medication review (patient interview, with or without contacting prescribers and other sources of information, to develop a list of medications a patient is currently taking and/or has taken in the past)	60.0	5.1
Drug therapy problem (DTP) assessment (assessment of a patient's current drug regimen to determine the potential for and/or existence of drug-drug, drug-disease, or drug-food interactions or problems)	55.0	5.6
Physician consultation (contact with the patient's primary care or other prescribing physician when a potential DTP exists and provision of recommended alternative therapies)	20.0	3.7
Therapy tools and/or education for physicians (provision of patient-specific reports, physician prescribing pattern feedback, therapeutic guidelines, and other tools designed to influence medication use)	15.0	1.3
Other*	35.0	2.7

*Examples of some of the "other" services provided were non-specific targeted programs for certain conditions and/or medications (potentially a type of DTP assessment) and cost reduction programs.

Table 4. Method of MTM service provision by 21 MTM programs.

Method of MTM service provision	Proportion of MTM programs using the method (%)			Potential number of enrollees affected (in millions)		
Eligible MTM beneficiaries:	None	Some	All	None	Some	All
Mailed information	23.8	4.8	71.4	0.5	0.2	11.4
In-house call center	9.5	33.3	57.1	4.3	4.3	3.5
In-house case manager	71.4	19.0	9.5	8.6	3.4	0.0
Contracted call center	85.7	9.5	4.8	5.6	6.5	0.0
Contracted pharmacies (telephonic)	95.2	4.8	0.0	9.0	3.1	0.0
Contracted pharmacies (face-to-face)	81.0	9.5	9.5	4.6	6.5	1.0
Other	90.5	4.8	4.8	8.1	3.1	0.9

Appendix A.

Appendix A. Items in APhA Survey on Enrollment Criteria and Benefit Design for 2006 Medication Therapy Management Plans

1. Medicare Part D Plans offered by [Name of Plan], Inc.: PDP or MA-PD?
2. Will the organization be offering PDP, MA-PD, or both? Same MTM benefit if both (yes, no)?
3. Will MTM be provided by PBM or contracted staff? What type of delivery method (face-to-face, telephonic, by mail, other) will the plan use to provide MTM services? Who will be the provider? (pharmacist, other)
4. Can pharmacists still contract with the plan to provide MTM services in 2006?
5. What are the disease requirements (number of diseases, specific diseases) for enrollees to be eligible for MTM services, how many medications must an enrollee be taking to be eligible for MTM services, and what is the drug spend requirement for an enrollee to be eligible for MTM services?
6. What types of MTM services are offered (kinds of services, quantity of visits)?
7. How often does the plan provide for MTM services (e.g., annually, twice a year, quarterly)?
8. How will outcomes of MTM services be measured?
9. Are the MTM services protocol driven?
10. How is the plan being marketed to patients? Is MTM mentioned in marketing?
11. How are patients being enrolled in the plan (opt-in, opt-out)?
12. When will the MTM benefits of the plan roll out (e.g., January 2006, mid-2006, later)?

Abbreviations used: APhA, American Pharmacists Association; MA-PD, Medicare Advantage–Prescription Drug Plan; MTM, medication therapy management; PBM, pharmacy benefit manager; PDP, prescription drug plan.