

A Summary of Medication Therapy Management Programs in the Medicare Modernization Act and the Center for Medicare & Medicaid Services'

Prepared by the American Society of Health-System Pharmacists, August 2006

On December 8, 2003, President Bush signed into law the Medicare Modernization Act of 2003 (MMA). Under the MMA and its implementing regulations, Part D prescription drug plan sponsors (PDPs) are required to establish a medication therapy management program (MTMP) that is designed to optimize therapeutic outcomes for targeted beneficiaries by improving medication use and reducing adverse events.

ASHP supported the inclusion of this provision in the MMA as a first step towards recognizing the pharmacist's role as the provider of Medication Therapy Management (MTM) services under Medicare.

While comprehensive data on the administration of MTMPs has yet been made available, preliminary information has indicated that these programs are not being provided in such a way to best meet the needs of high-risk patients. Both Congress and CMS have provided PDPs with wide latitude in designing their MTMPs, and this has resulted in narrowly drawn eligibility criteria and a limited scope of programs to only the lowest-level of services. ASHP supports regulatory and/or legislative action that would establish a minimum framework of services and eligibility for all MTMPs.

Below is a program overview of the Medicare Part D MTMPs:

Targeted Beneficiaries

Beneficiaries targeted for MTMPs are defined in statute as individuals who:

- a. Have multiple chronic diseases, such as, but not limited to, diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure,
- b. Are taking multiple covered Part D drugs; AND
- c. Are identified as likely to incur annual costs for covered Part D drugs that exceed the level specified by the Secretary of Health and Human Services.

CMS regulations have given PDPs discretion to design qualifying beneficiary criteria, however the agency does recommend that plans take notice of the statutory examples listed above of chronic diseases when developing their plan.

CMS also set a \$4,000 threshold of annual costs that PDPs are to use for the purpose of identifying targeted beneficiaries eligible for MTMP services in 2006. Further clarification by CMS staff notes that the \$ 4,000 takes into account all true-out-of-pocket spending for covered Part D drugs.

Preliminary information has indicated that at least two large PDPs project that only 1% of their beneficiaries will qualify for MTM in 2006.

Provider of Service

The statutory language notes that MTMP services may be provided by a pharmacist or other qualified provider. CMS does not specify who will provide MTMP services, but notes it should be a qualified provider and that such determination should take into account beneficiary needs. CMS has acknowledged in its guidance that face-to-face interactions can be advantageous, as can ongoing beneficiary-provider relationships.

CMS reports that the Medicare Part D plans submitted the following projected arrangements for MTMPs in 2006: 46% will provide in-house MTM, 36% will outsource to a third party, and 17% of PDPs will provide a combination of the two.

Preliminary information finds that some prescription drug plans are providing face-to-face interactions between patients and pharmacist as primary method of delivery for an often narrowly defined beneficiary population, while others are relying mostly on telephone communications and mail or emailed education materials. Providers of the service range and include nurses, pharmacists and other practitioners. Some plans are utilizing a tiered delivery method, in which face-to-face contact is utilized on an infrequent basis, and only after less direct approaches are used.

Patient Eligibility

Plans vary widely in their patient eligibility requirements. While some do not require a specific number of disease states, others do mandate that a particular threshold be met. In addition, plans vary with regard to the number of medications a patient must be taking to qualify for MTMP services. For example, while one plan requires that a patient have two or more chronic diseases and eight or more unique medications to qualify, another plan requires a patient to be taking 10 or more medications and have at least 4 disease states among a defined list of several conditions.

Scope of MTMP Services

MTMP is loosely defined in statute, noting that it can include elements designed to promote the following for targeted beneficiaries:

- Enhanced enrollee understanding through beneficiary education and counseling of appropriate medication use and the reduction of the risk of potentially adverse events associated with the use of medication,
- Increased enrollee adherence to prescription medication regimens through, for example, medication refill reminders, special packaging, compliance programs, and other appropriate means,
- Detection of adverse drug events and patterns of over-use and under-use of prescription drugs.

CMS envisions MTMPs potentially offering a range of services, from simple to complex. This may include, in addition to those mentioned in the statute, but is not limited to:

- Performing patient health status assessments
- Formulating prescription drug treatment plans
- Managing high cost “specialty” medications

- Evaluating and monitoring patient response to drug therapy
- Providing patient education and training
- Coordinating medication therapy with other care management services
- Participating in state-approved collaborative drug therapy management

Limited information is available about the parameters of MTMP services, but preliminary data indicates that many programs are providing calling access to beneficiaries for drug-related questions and in certain cases, face-to-face comprehensive medication review and follow up. Services range and may include answering questions about medications and safety concerns, as well as the monitoring of compliance.

Quality Measurement

CMS did not define a minimum package of services that all plans would be required to offer through their MTMPs, noting that insufficient standards and performance measures exist to support further specification for MTMP services and service level requirements.

At the urging of ASHP and other groups, CMS supported the establishment of the Pharmacy Quality Alliance (PQA). The PQA is made up of various stakeholders and is responsible for identifying best practices and other quality assurance measures that will best serve the Medicare patient population. The Alliance is also specifically charged with developing metrics that can be used to measure the effectiveness of MTM efforts by pharmacists, PDP's, and eventually any payer.

While the initial report of the PQA will be based on claims data for determining quality, ASHP would like PQA to identify a more robust and complex set of quality measures. ASHP, which is a voting member of the PQA, would like CMS to work towards the adoption of such standards establishing patient care measures that integrate the pharmacists role in MTM. ASHP also would like CMS to provide the resources and support necessary develop a publicly available and useful measure set that works towards identifying true therapeutic outcome determinations.

Payment for MTMP Services

Regulation requires that any fees paid in conjunction with the provision of MTMPs shall take into account the time and resources necessary to implement the services, but it is not specified in statute or the implementing regulations how these fees will be paid.

CMS does not believe that it has the authority to mandate specific payment levels or to adjudicate specific disputes regarding fees. CMS will require PDPs to describe their fee structure as part of their application process, including an explanation of those fees attributable to MTMP services. CMS notes that fees for MTMP services are separate and distinct from dispensing fees.

Currently MTMPs are considered part of the plans' administrative costs. Particularly for drug-only prescription drug plan sponsors, this provides limited economic incentive for the PDPs to offer meaningful medication therapy management programs. ASHP has therefore suggested creating a distinct revenue stream for such program, allowing for performance-based measures.

It is important to keep in mind that Congress and CMS purposely left significant discretion for the plans to design their MTMP. As a result, many questions the pharmacy community has are left unanswered in the statute and regulations. ASHP will continue to monitor this closely.

Overall, appropriate uniform quality measures, financial incentives, patient access, and public information will be essential to meeting the medication management needs of high-risk patients.