

Sound Medication Therapy Management Programs

VERSION 2.0

**This document is endorsed or supported
by the following organizations:**

- AARP
- Academy of Managed Care Pharmacy
- American Association of Colleges of Pharmacy
- American College of Clinical Pharmacy
- American Pharmacists Association
- American Society of Consultant Pharmacists
- College of Psychiatric and Neurologic Pharmacists
- Employers Health Purchasing Corporation of Ohio
- Food Marketing Institute
- National Association of Chain Drug Stores

Preface

Spurred by the Medicare Modernization Act's (MMA's) inclusion of the medication therapy management (MTM) requirement, the Academy of Managed Care Pharmacy (AMCP, the Academy) and other organizations recognized a lack of clear definition of what specific elements would constitute a sound MTM program. To fill that gap, the Academy assembled a variety of stakeholder organizations that were willing to work on a consensus document that would define those elements.

The stakeholder group used interactive discussion through both face-to-face meetings and e-mail correspondence in drafting the document. AMCP was responsible for assembling the work group and for drafting and disseminating the document. This initiative was funded through a restricted grant from Merck/Schering-Plough (MSP).

The stakeholder work group consisted of the following organizations:

- AARP
- Academy of Managed Care Pharmacy
- American Academy of Family Physicians
- American Geriatrics Society
- American Pharmacists Association
- American Society of Consultant Pharmacists
- Case Management Society of America
- Department of Veterans Affairs
- National Business Coalition on Health

In order to gain insight from health care professionals who had built MTM programs, AMCP identified and recruited a resource panel of 15 representatives from health plans, pharmacy benefit management companies (PBMs), and integrated health care systems (see Appendix A). These people brought expertise in medication therapy management and served as a resource for the stakeholder group while the consensus paper was being developed.

The project facilitator used an interview instrument developed by the stakeholder work group to solicit input from the resource panel. The resource panel input ensured that the consensus paper had applicability in real-world health care practice. These resource organizations also had the opportunity to review and comment on a draft of the consensus document.

Additionally, other pharmacy organizations provided input on drafts of the document. We are pleased to have received comments from the American Association of Colleges of Pharmacy, the American Society of Health-Systems Pharmacists, the College of Psychiatric and Neurologic Pharmacists, and the National Association of Chain Drug Stores.

The project began in September 2005; the original *Sound Medication Therapy Management Programs* document was completed by February 2006. AMCP contracted with Pete Penna, PharmD, to facilitate the stakeholder meetings, conduct interviews with the resource panel, and draft the document.

In late 2006, the Academy undertook a project to validate the content of the document in the marketplace. AMCP received a second grant from MSP to validate the consensus document. The National Committee for Quality Assurance (NCQA) performed the project's field work under contract to the Academy.

While the formulation of the consensus document included input from a significant number of organizational representatives, several outstanding questions remained:

1. To what extent are the identified program features considered good/best practice or representative of "floor requirements" within the wider industry?
2. To what extent does the wider public, including public and private purchasers of MTM programs, consider the identified program features comprehensive and sufficient?
3. Do organizations purporting to offer MTM programs offer all the program features identified by the consensus document or, alternatively, different features?

AMCP undertook the project to address these questions by taking the following steps:

1. The Academy convened a project advisory panel to provide consultation on the structure and the project's work products. The advisory panel was asked for guidance on the project tasks, review of the results of the field work analysis, and agreement on a final project report. The panel encompassed a variety of stakeholder perspectives to ensure that the project results were responsive to the needs of patients, providers, and payers. The following organizations served on the advisory panel: AARP, American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), the American Geriatrics Society, the American Pharmacists Association, America's Health Insurance Plans, Employers Health Purchasing Corporation of Ohio, the Physician Practice/Pharmacy Quality Improvement Organization Support Center (PPP QIOSC) at FMQAI (the Florida QIO), the National Quality Forum, and the Pharmaceutical Care Management Association.
2. The Academy, in conjunction with NCQA, selected health plans and PBMs to identify which of the features noted in the consensus document each program included and to what degree. The project identified how plans compare against these features and the operational aspects described by the consensus stakeholder group. The project measured and described how the inclusion of such features or aspects affected the operational success of the MTM program.
3. Additionally, following the development of the NCQA report, the Academy shared the report with the advisory panel and determined what changes to the original document should be made. The Academy then coordinated the necessary revisions with input from original consensus group members as appropriate.

On the basis of recommendations contained in the report, the Academy has revised the *Sound Medication Therapy Management Programs* document and is issuing it as version 2.0. A glossary developed by the stakeholder work group that drafted version 1.0 is included as Appendix B.

Introduction

The purpose of this document is to help guide designers of MTM programs to identify the critical elements that support an effective, sound MTM program and allow these programs to be constructive in encouraging positive patient outcomes. This guide also can help purchasers of MTM programs evaluate programs and provide a basis for assessing programs established by Medicare Part D plan sponsors and other MTM program sponsors.

MTM programs are developed by health plans or other health care entities focused on optimizing patient therapeutic outcomes. MTM services are components of MTM programs and are delivered by health care professionals.

This document is not intended to be a prescriptive document, to imply oversight, or in any way to impinge creativity or innovation. MTM programs by their nature should be evolving, flexible and responsive to patient and health care system needs.

Background

For modern prescription medication therapies to be most effective, several things must occur:

- The right medication must be prescribed at the correct dose and for the proper duration.
- The medication must be accessible to the patient. The patient must get the prescription filled and must be adherent to the therapy.
- Patients must be monitored to ensure that best outcomes are achieved, that the objectives of therapy are being met, and that adverse events are avoided or minimized.
- Patients and caregivers must be properly educated and counseled and patients' medication therapy properly managed.

This is particularly true for patients who are at high risk as a result of chronic medical conditions and/or complex medication regimens. MTM programs that implement effective MTM services greatly enhance patient care, leading to improved overall health while at the same time decreasing overall health care system costs by reducing improper medication use, preventing adverse drug events and other undesirable outcomes, and supporting achievement of therapeutic goals.

The MMA recognizes the value of medication therapy management. The Act requires prescription drug plans (PDPs) and Medicare Advantage plans (MA-PDs) that offer prescription drug coverage to have an MTM program for those beneficiaries who meet high-risk eligibility criteria. As defined in the Medicare prescription drug benefit regulations issued by the Centers for Medicare & Medicaid Services (CMS), MTM programs are defined as programs of drug therapy management whose goal is to ensure that medications provided to the eligible beneficiaries are appropriately used to (1) optimize therapeutic outcomes through improved medication use and (2) reduce the risk of adverse events.

There are cases of self-insured employers and state Medicaid programs turning to MTM services as well to ensure that medications are being used to optimize outcomes.^{1,2} While such activities are not yet widespread, they are increasing and are an indication of things to come. In addition, there are well-documented activities that fit the MTM definition that have been introduced in such diverse settings as the Department of Veterans Affairs hospitals and clinics, health plans, integrated health systems, hospitals, and community pharmacies. Examples include the following:

- *Drug therapy management clinics, such as anticoagulation clinics; transplant programs; and HIV, hepatitis C, psychiatric, and lipid management clinics.* These programs are set up to ensure that patients are taking their medications correctly and that drug-related problems are identified and managed. For example, anticoagulation clinics are typically run by an integrated health system or hospital to manage patients who require anticoagulation therapy. Such clinics have been documented to reduce hospitalizations, morbidity, and mortality in patients who must use these medications.
- *Comprehensive medication reviews conducted by pharmacists (e.g., “brown-bag” programs).* These are programs in which a patient brings all the medications he or she is taking (prescription, nonprescription, and dietary supplements) to the pharmacist, physician, or other health care provider to review the appropriateness of each medication and ensure that the patient is taking them correctly to avoid drug-related problems.
- *Drug utilization review projects and other programs dealing with appropriate medication therapy or patient safety.* Managed care organizations and providers often run computer programs to identify patients at risk for specific medication problems. Examples include screening to identify asthmatic or heart failure patients who are not using appropriate medications and patients prescribed antidepressants who have discontinued their medications early.
- *Prescription drug adherence clinics and case management adherence programs.* These are programs set up to identify patients who have been prescribed medication for a chronic condition (e.g., diabetes, lipid disorders, asthma, psychiatric problems, hypertension) and are no longer taking their medication. The goal of the program is to increase the number of patients who are adherent with their medication therapy, thereby achieving positive clinical outcomes.

Medication therapy management programs are of significant interest to several health professions since it is anticipated and expected that they will play key roles in such programs. As these professions come together to determine how best to deliver such programs and services, they are searching for guidance as to how these programs might be structured. The need for consensus on the essential components of an MTM program springs from 2 factors:

1. Experience shows that the Medicare program establishes precedents in coverage decisions that are often replicated in both state-based health care programs and the private sector. On the basis of this history, it can be anticipated that MTM programs may become a routine part of health care in this country. Since there are costs associated with providing these services, it will be important to define successful business models, including incentives, that are based on a widely accepted understanding of what constitutes an appropriate MTM program.

2. To date, CMS has chosen not to issue a strict definition of what constitutes an acceptable MTM program. Although there are some experiences with medication therapy management, there is not one universally accepted set of parameters that can adequately define MTM services. CMS encourages the multiple Part D sponsors to be innovative in the approaches used to meet the Medicare requirement for offering an MTM program. These innovations will target a variety of patients with a broad array of diagnoses that depend on appropriate medication therapy to generate positive outcomes. It is expected that once CMS has data from 2 or more years of implementation of MTM programs, the agency will be able to identify those programs that work most effectively and that these approaches will be the basis for future regulatory oversight and guidance in this area.

Spurred by the MMA's inclusion of the MTM program requirement, numerous initiatives have been undertaken to define medication therapy management services. In 2004, a group of 11 national pharmacy organizations developed a consensus document on the service components of medication therapy management.³ In 2005, the American Pharmacists Association and the National Association of Chain Drug Stores Foundation developed a model guide for community pharmacists to use in effectively delivering MTM services in the community setting.⁴ Additionally in 2005, the Academy of Managed Care Pharmacy and the American Society of Health-System Pharmacists published the results of an executive session convened to discuss the implementation of medication therapy management under the Medicare Part D benefit.⁵

What is lacking today is a clear identification of what elements would constitute a sound medication therapy management program. From a programmatic standpoint, MTM programs are in a formative stage with no specific "best practices" or quality assurance standards having been fully articulated or evaluated. Although definitions and frameworks for MTM services have been drafted, no detailed guidelines have been established for MTM programs. This document addresses that gap by outlining the critical elements for an MTM program. The members of the organizations represented on the consensus panel that drafted version 1.0 are in the best position to help define these elements. The settings they represent find value in the interdisciplinary systematic approach to health care delivery that is an essential piece of organized patient care at both the population and individual patient level. Included in the document is input from additional organizations dedicated to establishing sound MTM programs.

Important Features Of a Sound MTM Program

The safe, effective, appropriate and economical use of medications is the overarching goal of MTM programs. To achieve these objectives, MTM designers should consider several elements. The following list comprises features, principles, and approaches to MTM that the consensus group believes are important elements of a sound MTM program:

1. *Patient-centered approach.* Effective management of a patient should consider such aspects of that patient's environmental, social, and medical status that may be factors. A patient-centered approach to managing and implementing MTM programs will help ensure that the correct medication, including dose and dosing regimen, is prescribed. It is inherent in such an approach that decisions will be made based on current and accurate medical information.
2. *Interdisciplinary, team-based approach.* Services offered by MTM programs should be delivered by an interdisciplinary MTM team led by a qualified pharmacist or other health care professional; MTM team members should have expertise in the specifics of the medications in question. The inclusion of different perspectives will often highlight problems that may be unforeseen when only the prescriber and patient are involved. Ineffective use of medications is a multifactorial problem. Effective MTM programs address these factors as well as the root causes of suboptimal use of medications and the fundamental changes that will be necessary. No single health care professional has all the answers to all these problems for all patients. Therefore, MTM programs may involve representatives of a variety of professions so that more effective programs can be delivered.
3. *Communication.* Effective communication and sharing of pertinent care information between those parties involved in the prescribing, dispensing, monitoring, and educational components are vital to the successful use of medications.
4. *Population and individual patient perspective.* MTM programs are developed for target patient populations so that services can be individually delivered to patients.
5. *Flexibility for broad applications.* Programs can be designed and implemented to address the needs of additional at-risk patient populations.
6. *Evidence-based medicine.* The adoption and application of evidence-based medicine is a growing force in health care. There should be recognition that best practices predicated on rigorously applied evidence-based medicine should be incorporated into MTM programs.
7. *Promotion of MTM services.* Mutual promotion of MTM by health plans and health care professionals can help enhance adoption.

Operational Aspects Of Sound MTM Programs

The following list consists of specific operational elements that the consensus group identified as components of sound MTM programs. This list is not meant to be prescriptive.

1. Patient identification and recruitment. There should be a process to identify and then to enroll the pool of patients at risk for adverse events and those likely to suffer poor outcomes. Programs should identify both the process and accountability for identification of such patients. Lists of eligible patients should be updated frequently. Patients at risk could include those who

- a. are over- or under-utilizers of medications;
- b. visit multiple physicians;
- c. routinely are not adherent to or persistent with medication regimens;
- d. do not understand how to use their medications and do not have a support system/network in place to guide their utilization;
- e. have financial barriers to obtaining their prescriptions, including those who use very expensive medications or have very high total drug expenses; and
- f. need multiple medications to treat complex comorbidities.

Patients could be identified by an MTM program, a health plan or other health care entity, a provider, and/or patient self-referral.

A process for patient identification and recruitment should exist in all MTM programs. For some programs, such as MTM programs offered as a component of a Medicare Part D benefit, patient identification criteria may be dictated by program sponsors. In the Medicare Part D benefit, CMS has defined its MTM eligibility criteria. The CMS-defined MTM eligibility criteria are specific for services reported to CMS as part of the CMS-defined MTM benefit. The principles above apply to the factors that may be used in developing and defining identification criteria for any MTM program.

2. Services to meet the needs of individual patients. There are a number of potential activities that might be undertaken by MTM programs, targeted to the needs of individual patients. While not an all-inclusive list, presented below is a catalog of 9 service activities identified by a group of 11 national pharmacy organizations as part of a July 2004 consensus statement. This is not intended to be a definitive list, and it is not suggested that any given program must contain all of these elements.⁶

- a. Performing or obtaining necessary assessments of the patient's health status
- b. Formulating a medication treatment plan

- c. Selecting, initiating, modifying, or administering medication therapy
- d. Monitoring and evaluating the patient’s response to therapy, including safety and effectiveness
- e. Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events
- f. Documenting the care delivered and communicating essential information to the patient’s other primary care providers
- g. Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications
- h. Providing information, support services, and resources designed to enhance patient adherence with his/her therapeutic regimens
- i. Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient

These items are offered as examples of the types of activities that MTM programs might employ. In addition, it is recognized that interdisciplinary care should be encouraged, appropriately utilizing skill sets of different health care providers. Qualified pharmacists are in a unique position to manage MTM programs.

3. Services tailored for setting, cultural differences. Programs should use methods appropriate to meet the needs of the targeted patient population. Patient demographics and health conditions to be considered include such elements as the patient’s residence (institutional, multiple, undefined), cultural diversity, health literacy, and language barriers. Appropriate methods of delivering information to and communicating with patients should account for such factors in the design.

4. Coordination of care. An emphasis on coordination of care rather than on perpetuation of fragmented care can improve patient outcomes. This may be accomplished by:

- a. establishing processes that allow appropriate sharing and communication of patient information among health care providers who have a need to know (such processes should be able to identify those practitioners who need to have access to this information),
- b. maximizing the productivity of MTM providers through appropriate use of information technology as well as other communication tools, and
- c. providing a capability that allows one provider to refer patients to another.

It is noted that the technology of e-prescribing and electronic medical records may promote efforts to coordinate care.

5. Appropriate documentation and measurement. MTM programs will need to identify and perform a variety of measurements and document program results to determine overall program effectiveness and achievements. Examples include the following:

- a. Patient satisfaction
- b. Services that are provided and by whom (type of health care professional or other person)
- c. Desired treatment outcomes and results achieved (economic, clinical, or humanistic)

6. Quality assurance. Given concerns about the quality of health care, MTM programs will need to address the issue of quality assurance. Longitudinal assessment of program quality should be incorporated into program design to ensure that program goals are met. Specific areas that could be addressed include the following:

- a. Achievement of quality targets measured by both internal and external metrics
- b. Identification and appropriate use of best practices
- c. Application of evidence-based medicine, as appropriate

MTM programs should use population-based measurements in addition to measuring results focused on the patients enrolled in the MTM program. Comparable population-based data are necessary to spur competition and to begin to identify best practices. The development and use of population-based measures will enable research on the kinds of programs that are successful and will enable a second generation set of principles based on data. Both population-based measurement and MTM-enrolled measurement are valuable in evaluating program performance.

7. Communications by the MTM program. Effective communications with plan members and providers will be integral to the success of MTM programs. Considerations for such communications should include that they are

- a. regular and ongoing;
- b. descriptive of the benefits and limitations, including opt-in and opt-out opportunities; and
- c. descriptive of how long patients remain enrolled once they enter the program.

8. Practitioners who can coordinate and provide MTM. Programs may be delivered by and involve a variety of health care professionals. The list of potential providers might include the following:

- a. Pharmacists employed by a pharmacy, health plan, PBM, hospital, other health care entity or as an independent provider of care
- b. Other qualified health care professionals

Continuing education and training of MTM providers on services, access to care, and interventions will be necessary for success.

9. Adoption of standardized documentation, billing, and payment systems. Programs should include standardized documentation, billing, and payment systems for MTM services.

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Appendix A

Resource Group

Fifteen health plans, pharmacy benefit management companies, integrated health care systems, and medication therapy management programs, including the following:

Community Care Rx

Coventry Health Care, Inc.

Humana

Independent Health

Intermountain Health Care

Kaiser Permanente

Medicine Shoppe International

Outcomes Pharmaceutical Health Care

Ovations: Pharmacy Solutions, UnitedHealth Group

Premier Pharmacists Network

Prescription Solutions

Scott & White Health Plan

Walgreens Health Initiatives

Appendix B — Glossary

Access—A patient’s ability to obtain medical care determined by the availability of medical services, their acceptability to the patient, the location of health care facilities, transportation, hours of operation, and cost of care.

Adherent; adherence—Also referred to as compliant/compliance. The extent to which patients take medications as prescribed by their health care providers; a term applied to a patient taking the prescribed dose of medication at the prescribed frequency for the prescribed length of time.

Adverse drug event—Any injury resulting from administration of a drug.

Best practices—Actual practices in use by qualified providers following the latest treatment modalities that produce the best measurable results on a given dimension.

Case management—A collaborative process of assessment, planning, facilitation, and advocacy for options and services to meet an individual’s health needs through communication and available resources to promote quality cost-effective outcomes.

Centers for Medicare & Medicaid Services (CMS)—Formerly known as the Health Care Financing Administration (HCFA), the federal agency responsible for administering Medicare and overseeing states’ administration of Medicaid and the State Children’s Health Insurance Program.

Drug utilization review (DUR)—A system of drug use review that can detect potential adverse drug interactions, drug-pregnancy conflicts, therapeutic duplication, and drug-age conflicts. There are 3 forms of DUR: prospective (before dispensing), concurrent (at the time of prescription dispensing), and retrospective (after the therapy has been dispensed). Appropriate use of an integrated DUR program can reduce drug misuse and abuse and monitor quality of care. DUR can reduce hospitalization and other costs related to inappropriate drug use.

Medicare Advantage plans (MA-PDs)—Health plan coverage that is offered under a managed care policy or plan that has been approved by CMS and provides both prescription drug and comprehensive health care coverage.

Medicare Modernization Act (MMA)—The Medicare Prescription Drug Improvement and Modernization Act of 2003, referred to as the Medicare Modernization Act, was enacted in December 2003. Title I of MMA established a new Part D of Medicare, which provides an optional outpatient prescription drug benefit effective January 2006.

Prescription drug plan (PDP)—Medicare Part D prescription drug coverage that is offered under a policy or plan that has been approved by CMS and is offered by a PDP sponsor that has a contract with CMS.

Self-insured employers—Employers who choose to accept the financial risk for the health care costs of their employees. Typically, employers “hire” a health plan, PBM, third-party administrator, or insurance company to provide for the health care needs of their employees (and often their family members), and the employers accept the financial risk for the services provided. This allows employers to retain savings if the costs of health care provided are effectively managed.





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