The Sound Medication Therapy Management Programs, Version 2.0 With Validation Study is being published by the Academy of Managed Care Pharmacy based on a field study conducted by the National Committee for Quality Assurance (NCQA) to validate and assess version 1.0 of the document. On the basis of recommendations contained in the report, the Academy has revised the Sound Medication Therapy Management document. The revised document, version 2.0, is being published as part of this supplement.

Project Director
Marissa Schlaifer, RPh, MS
Pharmacy Affairs Director
Academy of Managed Care Pharmacy
100 North Pitt St., Suite 400
Alexandria, VA 22314
703.683.8416, x603
Fax: 703.683.8417
mschlaifer@amcp.org

Consultants
Ann F. Carson, MPH
Assistant Vice President
Product Development
National Committee for Quality Assurance

Anna Mangum, MPH, MSW
Consultant to NCQA

Linda K. Shelton, MA
Consultant to NCQA

About AMCP
The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by applying sound medication management principles and strategies to improve health care for all. The Academy’s 5,000 members develop and provide a diversified range of clinical, educational, and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. More news and information about AMCP can be obtained on its Web site at www.amcp.org.
Table of Contents

Sound Medication Therapy Management Programs, Version 2.0
With Validation Study

S2 Abstract
S3 Preface
S5 Executive Summary
S7 I. Introduction and Purpose
S9 II. Methods of Validation
S11 III. General Findings on the Definition of Medication Therapy Management
S12 IV. Findings of Phase One: Stakeholder Responses to the Document
S13 V. Findings of Phase Two: Elements from the Consensus Document in Existing MTM Programs
S22 VI. Conclusions and Recommendations
S23 Appendix A. Phase Two Survey Tables
S28 Appendix B. Phase One Interim Report
S34 Appendix C. Participants in Advisory Panel Meetings
S35 Appendix D. Participating Organizations
S36 Sound Medication Therapy Management Programs, Version 2.0
S43 Continuing Education*:
   CE Submission Instructions and Posttest Worksheet

Target Audience
Managed care and other pharmacists, physicians and other health care professionals

Learning Objectives
Upon completion of this activity, participants should be able to
1. describe features and operational aspects of sound medication therapy management (MTM) programs as described in the consensus document Sound Medication Therapy Management Programs;
2. explain the process that the Academy of Managed Care Pharmacy and the National Committee for Quality Assurance (NCQA) used to validate those features and operational aspects;
3. identify which features and operational aspects were included in selected MTM programs and to what degree; and
4. describe the recommendations made by NCQA for changes to version 2.0 of the Sound Medication Therapy Management Programs document.

This program was funded through a grant from Merck/Schering-Plough.

*A total of 0.10 CEU (1.0 contact hour) will be awarded for successful completion of this continuing education activity.
(ACPE Universal Program No. 233-000-07-064-H01-P)
ABSTRACT

BACKGROUND: The Academy of Managed Care Pharmacy (AMCP, the Academy) contracted with the National Committee for Quality Assurance (NCQA) to conduct a field study to validate and assess the 2006 Sound Medication Therapy Management Programs, Version 1.0 document. Version 1.0 posits several principles of sound medication therapy management (MTM) programs: they (1) recruit patients whose data show they may need assistance with managing medications; (2) have health professionals who intervene with patients and their physicians to improve medication regimens; and (3) measure their results. The validation study determined the extent to which the principles identified in version 1.0 are incorporated in MTM programs.

OBJECTIVE: The method was designed to determine to what extent the important features and operational elements of sound MTM programs as described in version 1.0 are (1) acceptable and seen as comprehensive to users, (2) incorporated into MTM programs in the field, (3) reflective of the consensus group’s intentions, and (4) in need of modification or updating.

SUMMARY: NCQA first conducted Phase One, in which NCQA gathered perspectives on the principles in the consensus document from a mixed group of stakeholders representing both providers and users of MTM programs. Phase Two involved a deeper analysis of existing programs related to the consensus document, in which NCQA conducted a Web-based survey of 20 varied MTM programs and conducted in-depth site visits with 5 programs. NCQA selected programs offered by a range of MTM-providing organizations—health plans, pharmacy benefit management companies, disease management organizations, and stand-alone MTM providers. NCQA analyzed the results of both phases. The Phase Two survey asked specific questions of the programs and found that some programs perform beyond the principles listed in version 1.0. NCQA found that none of the elements of the consensus document should be eliminated because programs cannot perform them, although NCQA suggested some areas where the document could be more expansive or more specific, given the state of MTM operations in the field. The important features and operational elements in the document were categorized into the following 3 overall categories, which NCQA used to structure the survey and conduct the site visits in Phase Two: (1) eligibility and enrollment, (2) operations, and (3) quality management.

CONCLUSIONS/RECOMMENDATIONS: NCQA found that the original consensus document was realistic in identifying the elements of sound MTM. In the current project, NCQA’s purpose was not to make judgments about the effectiveness of MTM programs in general or any individual program in particular. NCQA recommended that the consensus document could be made stronger and more specific in 3 areas: (1) specifically state that the Patient Identification and Recruitment section advocates use of various eligibility criteria that may include, but are not limited to, Medicare-defined MTM eligibility criteria; (2) reframe or remove the statement in Appendix A of the consensus document that the preferred modality for MTM is face-to-face interaction between patient and pharmacist, unless there are comparative data to support it as currently written; and (3) specifically recommend that programs measure performance across the entire populations in their plans in addition to measuring results for those patients selected into MTM. This will make benchmarking among programs possible and will lead to substantiated best practices in this growing field.

J Manag Care Pharm. 2008;14(1)(suppl S-b):S2-S42

Copyright© 2008, Academy of Managed Care Pharmacy. All rights reserved.
The Academy of Managed Care Pharmacy (AMCP, the Academy) recently completed a validation study of version 1.0 of the Sound Medication Therapy Management Programs document. This supplement includes the validation study of version 1.0 of the document and the resulting version 2.0.

In 2005, spurred by the Medicare Modernization Act’s (MMA) inclusion of the medication therapy management (MTM) requirement, AMCP and other organizations recognized a lack of clear definition of what specific elements would constitute a sound MTM program. To fill that gap, AMCP assembled a variety of stakeholder organizations that served as a working group to build a consensus document that would define those elements.

The Academy issued the consensus document Sound Medication Therapy Management Programs in April 2006.1 In late 2006, AMCP undertook a project to validate the content of the document in the marketplace. AMCP coordinated the project components and the work of the project’s advisory panel; the National Committee for Quality Assurance (NCQA) performed the project’s field work under contract to the Academy. AMCP received a restricted grant from Merck/Schering-Plough (MSP) for this initiative.

For the original consensus document (version 1.0), a 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 stakeholder group and for drafting and disseminating the document. This initiative also was funded through a restricted grant from MSP.

The stakeholder work group consisted of the following:

- AARP
- AMCP
- American Academy of Family Physicians
- American Geriatrics Society
- American Pharmacists Association
- American Society of Consultant Pharmacists
- Case Management Society of America
- U.S. 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. The individuals brought expertise in medication therapy improvement and served as a resource for the stakeholder group while the consensus paper was being developed. 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. The project began in September 2005; the draft document was completed by February 2006, with release of the final document in April 2006. The project was facilitated by Pete Penna, PharmD, an independent consultant.

The document identified 7 important overall features and 9 specific operational aspects of a quality MTM program.

**Important Features**

1. Patient-centered approach
2. Interdisciplinary, team-based approach
3. Communication
4. Population and individual patient perspective
5. Flexibility for broad applications
6. Evidence-based medicine
7. Promotion of MTM services

**Operational Aspects**

1. Patient identification and recruitment
2. Services to meet the needs of individual patients
3. Services tailored for setting, cultural differences
4. Coordination of care
5. Appropriate documentation and measurement
6. Quality assurance
7. Communications by the MTM program
8. Practitioners who can coordinate and provide MTM
9. Adoption of standardized documentation, billing and payment systems

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 and operational aspects 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 and operational aspects comprehensive and sufficient?
3. Do organizations purporting to offer MTM programs offer all the program features and operational aspects identified by the consensus document or, alternatively, different features and aspects?

The Academy identified a need to answer these questions through a project aimed at validating the consensus document.

---

which expanded on these questions and took the following steps to answer them:

1. The Academy convened a validation 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 and reviewed the results of the field work analysis and made recommendations on the final project report. The panel encompassed a variety of stakeholder perspectives to ensure that the project results are responsive to the needs of patients, pharmacists, other 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 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, consulted with a variety of stakeholders, both providers and users of MTM programs, to validate that the features and operational aspects described in version 1.0 were important to sound MTM programs.

3. The Academy, in conjunction with NCQA, then reviewed the MTM programs of a representative sample of health plans and PBMs to identify which of the features and operational aspects noted in version 1.0 were included in each program and to what degree. The project described the different ways that the chosen plans implement the features and operational aspects.

4. Additionally, following the development of the project report, the Academy shared the report with the project advisory panel and determined what changes to version 1.0 should be made. AMCP then coordinated the necessary revisions.

It is important to note that the consensus document acknowledged that its recommended features and operational aspects were not meant to be prescriptive requirements and were not likely to be found in all MTM programs. However, the validation process could determine whether and how the features and operational aspects are now present in MTM programs.

The Academy believes this medication therapy management project report will stimulate the public policy discussion, aid in the evolution of sound MTM programs, enhance patient care, and encourage the efficient use of health care resources dedicated to these programs. The validation project report will provide guidance to both those who develop health care resources dedicated to these programs. On the basis of recommendations contained in the report, the Academy revised the Sound Medication Therapy Management document. The revised document, version 2.0, is published as part of this supplement.
Sound Medication Therapy Management Programs Validation Study

Executive Summary

■ The Project

The Academy of Managed Care Pharmacy (AMCP) contracted with the National Committee for Quality Assurance (NCQA) to conduct a field study to validate and assess the 2006 Sound Medication Therapy Management Programs, Version 1.0 consensus document. The consensus document’s purpose was to define elements of sound medication therapy management (MTM) programs. The validation project compared those elements, expressed as features and operational aspects of sound programs, to a wide array of rapidly changing MTM programs.

The validation project established an advisory panel comprising a broad range of stakeholders representing the perspectives of both providers and users of medication therapy management programs.

■ Medication Therapy Management

MTM-type programs have been offered by pharmacy benefit management companies (PBMs), health plans, and other organizations to

• optimize therapeutic outcomes by improving the use of medications by patients with chronic conditions and multiple prescribed medications, and

• avoid adverse drug events and unnecessary costs.

The term “medication therapy management” was introduced in 2003 with the passage of the Medicare Modernization Act (MMA). The Act requires Part D prescription drug plans to operate MTM programs and establishes specific eligibility requirements. The linkage of the MTM terminology to the Medicare Part D program has created confusion over the use of the term. Many organizations use the term “MTM” to designate only programs offered to Medicare-defined eligible beneficiaries. However, both the original consensus document and this report use the term MTM to designate a broad range of programs that address appropriate use of medications covered under both public- and private-sector programs.

Version 1.0 posits several features and operational aspects of sound MTM programs, which NCQA grouped into 3 overall areas. Sound MTM programs (1) recruit patients whose data show they may need assistance with managing medications; (2) deploy health professionals to work with patients and their physicians to improve medication regimens; and (3) measure and learn from their results.

In conducting the validation project, NCQA used its experience with the early development of many new evaluation programs. The tasks in this project are similar to the step, prior to developing standards, in which NCQA assesses how statements of the ideal compare with programs offered by real-world organizations.

■ The Method and Programs Chosen

The method was designed to determine to what extent the features and operational aspects of sound programs as described in version 1.0 are

• acceptable and seen as comprehensive to users,

• incorporated into programs in the field,

• reflective of the consensus group’s intentions, and

• in need of modification or updating.

NCQA first conducted Phase One of the validation process, in which NCQA gathered perspectives on the features and operational aspects in the consensus document from a mixed group of stakeholders representing both providers and users of MTM programs. Phase Two involved a deeper analysis of programs related to the consensus document, in which NCQA conducted a Web-based survey of 20 varied MTM programs and conducted in-depth site visits with 5 of these. NCQA analyzed the results of both phases. The groups queried in both Phase One and Phase Two represent a purposive sample chosen to make sure that NCQA tested the document with a variety of programs, rather than a statistical sample.

■ Overall Assessment

MTM programs operated by all types of organizations represent a dynamic sector of health care, integrating the skills of pharmacists with other professionals and care management methods. All the sampled programs, to different degrees and in different ways, represent the features and operational aspects described in Sound Medication Therapy Management Programs, Version 1.0. There is great variety among MTM programs, which are evolving to produce better results based on their own unique strengths. The Sound Medication Therapy Management Programs document took the approach of general rather than prescriptive guidance, which is important to avoid stifling innovation in this early stage.

NCQA found the following:

1. All of the features and aspects were confirmed by stakeholders to be desirable, with some stakeholders advocating more specificity in some areas.

2. MTM programs use information technology in all aspects of their work. They build and operate their services using pharmacy claims data, a detailed and electronically accessible data set. Using pharmacy data, most programs extensively evaluate their own performance.

3. Some of the features and aspects are present in all the programs and therefore might be considered “floor requirements.”

4. Some programs implement the features and operational aspects in ways that go beyond the descriptions in version 1.0.
Executive Summary

5. The features and operational aspects, as described, are realistic and valuable as general direction for MTM programs at this time. The project found none that should be deleted and found some that the project recommends making more specific.

Following are findings grouped into 3 overall categories of features and operational aspects, categories which NCQA used for the purposes of structuring the survey and the site visits in Phase Two.

1. **Eligibility and enrollment.** Programs described their rules for choosing eligible patients in 2 parts: eligibility as defined by Medicare criteria, and broader eligibility. The latter corresponds to the aspect of patient identification and recruitment in the consensus document. Combining the 2 parts of each organization's MTM services showed that existing programs have the flexibility that the consensus document recommends.

   There is great variation in both the Medicare and the wider programs, and organizations described efforts to continue trying different approaches. For the reportable Medicare-eligible members, programs required enrollees to have between 2 and 5 chronic diseases, an average of 5.6 covered medications, and, as required by Medicare, the likelihood of $4,000 per year in drug costs. For the wider services for other Medicare patients, commercial patients, or Medicaid patients, programs had flexible eligibility criteria based on patient characteristics, such as medications prescribed by multiple physicians.

2. **Operations.** The 20 MTM programs NCQA surveyed showed wide variation in the complement of services they provide; however, they are alike in that these programs are delivered and managed primarily by pharmacists. Successful MTM improves treatment by changing the behavior of both patients and physicians. Reflecting the challenge of this task, programs commonly revise their approaches and continuously analyze and modify what they do.

   At least some of the 20 programs surveyed offer all of the services mentioned in the consensus document. Programs use a combination of modalities, including mail, personal interventions (both in person and by telephone), fax, the Web, and e-mail. In-house personnel offer most services, but about half of programs also contract with other organizations and involve community pharmacists. All programs focus on the patient by integrating data on medications from all prescribers and patient demographics, and all incorporate evidence-based medicine in guidelines for MTM providers. They coordinate care with other providers and programs to varying degrees. However, while most programs intervene with both patients and physicians, 2 of the programs that NCQA surveyed work just with patients and 2 others work primarily with prescribers.

3. **Quality management.** All 20 of the programs surveyed by NCQA extensively measure their performance, which is consistent with MTM programs' use of information technology and the presence of a rich data source. Programs commonly measure enrollment, participation, quantity of services, cost, and several dimensions of clinical quality. In this area, NCQA found that the activities in the field outdistanced the scope of activities mentioned in the consensus document.

   The great majority of programs also engage in quality assurance, using technology to both guide and monitor the performance of their staff members and subcontractors, such as pharmacies, on an ongoing basis.

**Recommendations**

NCQA found that the original consensus document was realistic in identifying the features and operational aspects of sound MTM programs. In the current project, NCQA's purpose was not to make judgments about the effectiveness of MTM programs in general or any individual program in particular. NCQA recommended that the consensus document be made stronger and more specific in 3 areas. AMCP accepted the following 3 recommendations and incorporated them into version 2.0 of the document.

1. Specifically state that the Patient Identification and Recruitment section advocates use of various eligibility criteria that may include, but are not limited to, Medicare-defined MTM eligibility criteria.

2. Restate or remove the statement in Appendix A of version 1.0 that the preferred modality for MTM is face-to-face interaction between patient and pharmacist, unless there are comparative data to support it as written.

3. Specifically recommend that programs measure performance for the entire populations in their plans, in addition to measuring results for only those patients selected into MTM. This will make benchmarking among programs possible and will lead to substantiated best practices in this growing field.
I. Introduction and Purpose

AMCP and NCQA undertook this project to assess the features and operational aspects described in the consensus document Sound Medication Therapy Management Programs, using systematic input from those most likely to use the document—operators and purchasers of MTM programs. The purpose of the project was to assess the consensus document—not to evaluate the quality or effectiveness of the MTM programs that participated in the study or to draw conclusions about the effectiveness of specific methods those programs employed.

MTM, as characterized in the consensus document, operates like the related functions of care management and disease management and can be part of those functions. These kinds of management represent a change from the traditional, visit-based organization of health care, which grew out of caring mainly for acute problems. MTM, care management, and disease management recognize the ongoing needs of patients with chronic conditions by

- using comprehensive data on each patient to identify patients with potential health-related issues that may benefit from MTM services;
- relying on multiple kinds of health care professionals coordinating care and services for a single patient; and
- making ongoing contact with the patient to offer support or services rather than depending on the patient to initiate a visit to a health professional.

There are now 3 sets of national quality standards for disease management, and there are national standards for care management in the physician practice (Physician Practice Connections). Those standards include helping to manage the patient’s medications.

The consensus document was developed to articulate features and operational elements for sound MTM programs and not to be the basis for specific standards such as would be used in certification or accreditation. The following 2 excerpts state the document’s purpose:

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

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 consensus document addresses that gap by outlining the critical elements for an MTM program to be considered high quality.

Following are the important features and operational aspects on which the consensus group agreed. All are stated flexibly and are not prescriptive, which allows MTM programs latitude to be innovative in how they implement them. Each is the subject of a section of this report, and each report section contains the complete consensus statement text.

1. Important Features of a Quality MTM Program—The following list comprises overall features, principles, and approaches to MTM that the consensus group believed should be present to some degree in a quality MTM program:
   a. Patient-centered approach
   b. Interdisciplinary, team-based approach
   c. Communication
   d. Population and individual patient perspective
   e. Flexibility for broad application
   f. Evidence-based medicine
   g. Promotion of MTM services

2. Operational Aspects of Quality MTM Programs—The following list consists of specific operational elements that the consensus group identified as components of quality MTM programs:
   a. Patient identification and recruitment
   b. Services to meet the needs of individual patients
   c. Services tailored for setting, cultural differences
   d. Coordination of care
   e. Appropriate documentation and measurement
   f. Quality assurance
   g. Communications by the MTM program
   h. Practitioners who can coordinate and provide MTM
   i. Adoption of standardized documentation, billing, and payment systems

NCQA’s process of validating the document expanded the 3 questions identified in the preface and obtained answers to the following 4, more detailed, questions.

1. To what extent does the consensus document represent attributes of MTM programs desired by stakeholders? In Phase One of the project, NCQA asked that question of many potential users of the document, both operators and potential purchasers of MTM programs.

2. To what extent in practice do we find those attributes desired by stakeholders in existing programs? In the first part of Phase Two, NCQA surveyed 20 organizations that operate programs to obtain data on these questions.

---

2 National quality standards for disease management and care management include NCQA’s 2006 Standards and Guidelines for Accreditation and Certification in Disease Management, NCQA’s 2006 Standards and Guidelines for Physician Practice Connections, URAC’s Disease Management Accreditation Program, Version 2.0, and The Joint Commission’s Disease-Specific Care Certification Programs, 2002-2007.
I. Introduction and Purpose

3. How do MTM services and the ways that programs operate incorporate and embody the principles in the document? In the second part of Phase Two, NCQA obtained supporting documentation from programs and conducted 5 in-depth site visits. This enabled NCQA to develop a detailed picture of how programs put the document's principles into operation, to confirm that the actual implementation is what the authors of the document intended.

4. Are there areas where the consensus document should be modified? Analysis of the Phase One and Phase Two findings, presented in this report, lead to NCQA’s recommendations on suggested changes to version 1.0.

This process of validation is similar to the process NCQA undertakes in testing concepts before developing quality standards, which are much more specific. At this early stage, NCQA first gathers data on what the desirable aspects are, as shown ideally in research evidence or, in the absence of evidence, in expert consensus. Second, as in this project, NCQA determines what actual programs are doing related to those aspects. Third, the subject matter is related to subjects NCQA has addressed through standards for managed care organizations, disease management organizations, and care management in the physician practice, such as NCQA’s Standards and Guidelines for the Accreditation of Health Plans, Standards and Guidelines for Accreditation and Certification in Disease Management, and Standards and Guidelines for Physician Practice Connections.
NCQA worked with AMCP throughout the 9-month project to select respondents for each phase that represented a range of types of MTM programs and stakeholders. NCQA also worked closely with AMCP to ensure that NCQA’s interpretations of the features and operational aspects, both in the document and in the existing programs, were consistent with the intent of the stakeholder group that developed the document.

AMCP 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 plan, interview guides, and Web-based survey instrument. The panel reviewed the results of the field work analyses and provided input on the final project report. The panel included a variety of stakeholder perspectives to ensure that the project results were responsive to the needs of patients, providers, and payers. See Appendix C for a list of advisory panel members.

II. Methods of Validation

- Phase One: Stakeholder Interviews

To test the desirability of the features and operational aspects in the consensus document, NCQA conducted structured key-informant interviews with 20 stakeholders from several types of organizations. To include both those who would use the document to shape their programs as well as those who would use it to evaluate programs, NCQA and AMCP chose respondents representing the following:

- Health plans
- PBMs
- Stand-alone MTM providers
- Disease management organizations
- Physicians
- Public and private purchasers
- Consumer groups
- Community pharmacies

Types of organizations were selected based on input from the advisory panel. Among the characteristics considered were the size of the organization, the location in the country, and the population served. Individual organizations were identified by NCQA, AMCP, or members of the advisory panel to meet the array of characteristics desired. If an organization declined to participate, NCQA replaced it in the survey with an organization similar in characteristics whenever possible.

The researchers developed a core outline for the interview and several variations of the protocol to reflect the various roles stakeholders had in MTM. For example, a question to an MTM provider might ask how it performed a function; the parallel question to a purchaser would seek expectations about how purchasers think the function should be performed. NCQA used the stakeholder input from Phase One participants to more precisely define program features to examine in the Phase Two tasks.

- Phase Two: Self-Assessment Survey and Site Visits

Self-Assessment Survey

To validate that the features and operational aspects in the consensus document are realistic in practice and to best describe how those features and aspects appear in existing programs, NCQA conducted a self-assessment survey of 20 MTM programs and in-depth site visits with 5 of these programs.

For the respondent group, NCQA selected programs offered by a range of MTM-providing organizations—health plans, PBMs, disease management organizations, and stand-alone MTM providers. NCQA selected some national and local organizations, MTM providers in different areas of the country, large and small programs, and providers of different programs for different clients. Some programs selected were Medicare Part D sponsors; some were NCQA-accredited health plans. The 20 organizations surveyed operate MTM programs, some for multiple clients, as follows:

- Thirteen operate Medicare Part D prescription drug plans (PDPs).
- Eighteen operate Medicare Advantage Part D programs (MA-PDs).
- Seven operate commercial MTM programs.
- Five operate Medicaid MTM programs.

NCQA included in the respondent sample the largest providers of MTM in the country, so that the findings represent programs offered in MA-PDs and PDPs that cover the majority of Medicare Part D enrollees.

The 20 organizations surveyed offered different combinations of MTM programs, as shown in the Table.

<table>
<thead>
<tr>
<th>TABLE</th>
<th>Number of Survey Respondents by MTM Program Sponsor Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor Type</td>
<td>No. of Survey Respondents</td>
</tr>
<tr>
<td>PDP only</td>
<td>1</td>
</tr>
<tr>
<td>MA-PD only</td>
<td>3</td>
</tr>
<tr>
<td>Commercial only</td>
<td>1</td>
</tr>
<tr>
<td>PDP + MA-PD</td>
<td>8</td>
</tr>
<tr>
<td>MA-PD + commercial</td>
<td>2</td>
</tr>
<tr>
<td>PDP + MA-PD + Medicaid</td>
<td>1</td>
</tr>
<tr>
<td>MA-PD + commercial + Medicaid</td>
<td>1</td>
</tr>
<tr>
<td>PDP + MA-PD + commercial + Medicaid</td>
<td>3</td>
</tr>
</tbody>
</table>

MA-PD=Medicare Advantage Part D (programs); MTM=medication therapy management; PDP=prescription drug plan.
II. Methods of Validation

The survey was mounted on a widely used Web-based survey program. NCQA designed the questions in concert with AMCP and sought input from the project’s advisory panel. The questions more precisely define and operationalize the elements in the consensus document. NCQA asked the respondents to assess their programs, responding to 65 questions covering MTM functions in 3 areas into which the “important features” and “operational aspects” had been grouped.

1. Eligibility and enrollment
2. Operations
3. Quality management

The Findings sections and Tables 1-6 in Appendix A summarize the data compiled from the survey.

All 20 respondents completed the survey. NCQA requested that respondents send supporting documents and received them from 6 programs, including the programs visited on the site visits. The documents included procedures used by the programs, samples of written communications to patients and prescribers, computer screen prints with algorithms used by health care professionals delivering MTM services, reports sent to the Centers for Medicare & Medicaid Services (CMS), and reports on quality measurement. Several organizations were not willing to share documents that they considered proprietary.

Site Visits

In collaboration with AMCP, NCQA identified a sample of organizations (n = 5) that also represented a diverse group of MTM programs and a variety of organizational characteristics. The site visits investigated what programs consider to be “best practices.” On the site visits, NCQA and AMCP delved into specific areas revealed through the organization’s responses to the data collection tool. Researchers also reviewed multiple program aspects, including the rationale, features, and infrastructure of the organization’s MTM program.

Before the site visit, NCQA provided each site with a comparison of its survey response to a summary of responses from other respondents. NCQA established a 5-hour agenda for each visit to obtain in-depth explanations not feasible in a survey, including a time for the site to describe its programs in detail. NCQA also received documents such as patient mailings, pharmacist directives, statistics on enrollment and patient contacts, and results of performance measures. One NCQA representative and 1 AMCP staff member conducted all 5 site visits. The sites involved between 3 and 10 staff people, asking staff members to respond to questions based on their expertise and responsibilities.

Benefits of the Methods Used

The combined activities of Phase One and Phase Two provided a broad-brush look and an in-depth look at MTM programs and the elements of the consensus document. Taken together, the telephone interviews, Web-based survey, and site visits provided a reinforcing picture of the field and how it is changing. In particular, the site visits afforded an opportunity to discuss the rationale for program decisions with program operators, to resolve questions, and to learn about changes or additions they are planning to make. The 5 organizations also gave us additional perspectives on the consensus document.

Limitations of the Methods Used

This was a descriptive, qualitative study. The purpose of the study was to validate a series of statements. Because the statements were based on a consensus of expert opinion, rather than research evidence, and were purposely written to accommodate a wide range of program sponsors and organizational styles, qualitative data are the most appropriate. NCQA also obtained quantitative results, as shown in the tables, for the purpose of showing trends rather than precise statistics. The groups queried in both Phase One and Phase Two represent a purposive sample chosen to make sure that NCQA tested the document with a variety of programs, rather than a statistical sample. Therefore, the quantitative results cannot describe the field as a whole.

The findings represent a snapshot of a point in time for a sampling of MTM programs, many of which are rapidly evolving. Some of the findings changed from Phase One to Phase Two, notably the greater development of telephone MTM services and the ability of programs to measure results. More aspects may change in the near future, since many programs are in an early stage of development.

A further limitation was the different definitions of MTM held by the programs. Several respondents initially answered the survey questions based only on their MTM program for Medicare-defined eligible beneficiaries, since they called their wider MTM services by a different name. NCQA alerted all respondents to the issue, and some revised their responses.
III. General Findings on the Definition of Medication Therapy Management

The original consensus document described MTM programs as those that implement effective MTM services to reduce improper medication use, prevent adverse drug events and other undesirable outcomes, and support achievement of therapeutic goals.

The MMA and its regulations governing MTM under Medicare Part D do not define what services an MTM program should include but do define eligibility for MTM programs. Patients eligible for Medicare-defined MTM must

- have multiple chronic diseases (number to be specified by the individual program);
- have multiple covered Part D drugs (number to be specified by the program); and
- be identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary of Health and Human Services ($4,000).²

To qualify under the MMA, programs must choose their eligibility rules well in advance of a calendar year and must later report to CMS only on those members who meet the Medicare eligibility criteria.

The restricted eligibility criteria under the Medicare Part D MTM programs and the reporting requirements attendant to those programs have led most organizations to separate their MTM services into 2 groups: (1) services for Medicare-defined eligible patients and (2) services for a broader group of patients. The 2 groups of services are often called by different names, with only the Medicare-defined services referred to as “MTM” or “official MTM.” Organizations in both phases of this validation project noted that the Medicare-defined eligibility criteria leave out many patients who would benefit from MTM, such as those on only 1 very expensive medication or those on multiple medications for only 1 chronic condition.

In this project, the division of MTM programs into these 2 groups led to confusion for our respondents. Most respondents initially answered questions about MTM programs by describing what was in place for their Medicare-eligible beneficiaries. Only after follow-up conversations did they provide information on both types of populations.

Responding to this challenge in definition, other organizations have developed alternate terminology for MTM such as “drug therapy management (DTM)” and “therapeutic drug management (TDM).” The consensus document maintains the use of the term MTM, with a broad definition. This field study makes a recommendation for the consensus document, shown in the Patient Identification and Recruitment section, to more thoroughly explain the confusion over the use of the MTM term and to clearly state that its principles apply broadly to an organization’s development of services and eligibility of patients for improving medication management.

IV. Findings of Phase One: Stakeholder Responses to the Document

The Table in Appendix B displays the views of the various stakeholders on the original consensus document. Differing recommendations reflect their differing viewpoints and perspectives. Further, differences between some of the findings in Phase One and Phase Two also reflect the difference in timing and the dynamic status of MTM. The Phase One interviews occurred in late 2006, when most MTM providers had not yet analyzed the first whole year’s experience with Medicare Part D.

Most of the recommendations from key informants were consistent with the consensus document and with Phase Two findings.

1. It is desirable for MTM programs to have flexible eligibility criteria, including using referrals from physicians and using data on all health services utilization, identifying cases of nonadherence, and targeting medications with a narrow therapeutic index. Using flexible eligibility criteria is in keeping with the consensus document; key informants expressed discomfort with the limitations of the Medicare eligibility criteria.

2. All informants mentioned that services are appropriate and are being provided.

3. Tailoring of the services for the individual patient is important.

On the other hand, 2 recommendations that were mentioned multiple times by different stakeholders could not be confirmed in the Phase Two review of programs. These statements appeared to be common perceptions not substantiated by data:

1. Available data are a barrier to quality measurement. In Phase Two, MTM programs demonstrated to NCQA a variety of quality measurements using available electronic data.

2. The best modality is face-to-face interaction; programs should not rely on just mail and telephone. Data are not yet available to support this perception; anecdotal evidence from MTM programs in Phase Two would seem to support the use of multiple modalities for delivering services.
The findings summarized below represent an analysis of the responses produced in the self-assessment surveys and the findings of the site visits. They follow the structure of the consensus document, showing the results grouped by “Important Features” and by “Operational Aspects.” In 3 of these sections, NCQA made recommendations for modifying the consensus document on the basis of research findings. These recommendations are detailed in Section VI.

NCQA’s role in the validation study was to describe to what extent the elements of the consensus document are, or are not, seen in MTM programs, and what additional elements are present and may be useful. These findings are not intended to evaluate existing MTM programs or to make a statement about the quality of those programs.

Findings on Important Features of a Quality MTM Program

The following are features of sound programs as listed in version 1.0. The features are stated in broad language designed to allow a degree of flexibility in how an MTM program might implement or demonstrate them. Following each feature excerpted from version 1.0, a description is included of how NCQA researchers saw the feature operationalized in the 20 programs. They then summarized findings from the self-assessment surveys and the site visits.

1. Feature: Patient-Centered Approach

Consensus Statement

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.

Field Findings: As Patient-Centered as the Program Structure Permits

Definition of patient-centered approach to care. Although 18 of 20 programs reported some tailoring of their MTM approach for the individual, the capability to offer a patient-centered approach is limited by the fact that MTM programs address only 1 component—medication therapy—of the patient’s health care. Ongoing work by the Commonwealth Fund and the Picker Institute\(^4\) use an expansive definition of patient-centered care that mainly applies to the patient’s primary care provider or medical home. It most often mentions education and shared knowledge; involvement of family and friends; collaboration and team management; sensitivity to nonmedical and spiritual dimensions of care; respect for patient needs and preferences; and free flow and accessibility of information. The Sound Medication Therapy Management Programs document addresses some of those components in other features and operational aspects. As written above, the consensus document’s more narrow definition of “patient-centered approach to care” focuses on the education and shared knowledge component through communication to provide self-management support. The questions asked in the self-assessment survey (see Table 3 in Appendix A) followed the description in the consensus document.

Data. All 20 programs use data, mainly pharmacy claims data, to form the most accurate picture possible of the medical status of the patient. The MTM program can provide combined data describing the patient’s medications from all prescribers, crucial information that other members of the patient’s team need, and a component of patient-centered care (free flow of information).

Written advice. Some programs use highly personalized monthly statements or personalized explanations of benefits (EOBs) to recommend to patients ways to improve their medication plan or save money. Others personalize less specifically by using written communications targeted only toward patients’ chronic conditions. In these programs, a person with diabetes and heart disease receives, for example, general newsletters on managing both conditions, which are not necessarily coordinated for the individual patient.

A majority of programs (13 out of 20) provide written materials in languages other than English, with Spanish as the predominant second language; 9 reported that they adjust written materials for low literacy levels, but not necessarily that different reading levels are provided for different patients.

Interaction with the patient. Sixteen of the 20 programs interact with some patients personally, either in person or by telephone. These interactions involve MTM-eligible patients who have opted in to the program. This fact, according to respondents, generally results in less than 3 percent of the total covered population receiving personal interaction. In these interactions, the MTM programs validate the accuracy of the claims data and consider additional aspects of the individual patient’s situation, such as environment, preferred language, and socioeconomic status. Twelve provide staff who speak languages other than English. Programs report learning directly from patients; for instance, that the patient has discontinued a medication that claims data show her taking, or that the patient needs help remembering when to take medications. Some programs conduct individualized ongoing counseling with callbacks as needed by the patient’s situation, usually for the “sickest of the sick.”

Patient’s choice. A minority of programs reported actually surveying patients for their preferences in communication or setting for MTM services: 8 surveyed for preferred language,

---

6 for preferred setting, and 7 for preferred modality, such as telephone or mail. Two programs reported no personalization.

Interaction with the prescriber. Two programs in the survey focus on the patient by communicating patient-centered information to the prescriber. These programs let the prescriber know all the medications that claims data indicate the patient is taking and make individualized recommendations that the prescriber consider changes based on practice guidelines and drug interaction information.

2. Features: Interdisciplinary, Team-Based Approach and Communication
Consensus Statements
Services offered by MTM programs should be delivered by an interdisciplinary MTM team led by a qualified pharmacist or other health care professional; 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 of the answers to all of these problems for all patients. Therefore, MTM programs may involve representatives of a variety of professions so that more effective programs can be delivered.

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.

Field Findings: Pharmacist-Prescriber Communication
Pharmacists in charge. The MTM programs in the study are managed and heavily staffed by pharmacists. The main interdisciplinary connections and communications are between the MTM programs’ pharmacists and the patients’ physicians. Nineteen of 20 programs reported having the program’s personnel, usually pharmacists, interact with the patients’ physicians, generally by phone or fax. Sixteen reported that MTM services include suggesting modifications to the patients’ regimens to the prescriber; 17 reported sending the physician complete medication lists for patients.

Teams. Ten of the 20 programs reported deploying MTM staff professionals as part of an interdisciplinary team. Ten also reported that nurses, as well as pharmacists, render MTM services, and 4 reported that physicians are employed by the MTM program. (See Coordination of Care section.)

One of the strongest examples of actual interdisciplinary teams is a program that actively coordinates between MTM programs and disease management programs, using electronic tools. The company holds regular meetings between pharmacist MTM providers and nurse case managers for disease management. Professionals working with the same patient share pharmacy data, other claims data, and clinical information on the patient electronically, including data gathered from the patient by all staff. When a telephone conversation with the patient leads to a need to consult the other professional—pharmacist or case manager—both can transfer the patient and stay on the phone. All data gathered from the patient—such as over-the-counter (OTC) medicines, samples obtained from the doctor, and laboratory test results—become part of the electronic record that informs subsequent drug utilization review and other functions of pharmacy benefit managers.

Other programs’ interdisciplinary teams involve a range of professionals in the development and review of educational materials. Sixteen MTM programs reported having physicians, pharmacists, and health writers develop materials.

3. Features: Population and Individual Patient Perspective, and Flexibility for Broad Application
Consensus Statements
MTM programs are developed for target patient populations so that services can be individually delivered to patients.

Programs can be designed and implemented to address the needs of additional at-risk patient populations.

Field Findings: Stratification With an Eye to Scalability
Data. All programs use population-level data to target actions for individual patients; most employ sophisticated algorithms to determine not only those patients eligible for MTM, but also those in need of the most intensive services or interventions. All 20 respondent programs used pharmacy claims plus enrollment data; the next most available data source was ambulatory claims; and Flexibility for Broad Application
Consensus Statements
MTM programs are developed for target patient populations so that services can be individually delivered to patients.

Programs can be designed and implemented to address the needs of additional at-risk patient populations.

Field Findings: Stratification With an Eye to Scalability
Data. All programs use population-level data to target actions for individual patients; most employ sophisticated algorithms to determine not only those patients eligible for MTM, but also those in need of the most intensive services or interventions. All 20 respondent programs used pharmacy claims plus enrollment data; the next most available data source was ambulatory claims, reported by 10 programs.

“I only have 24 patients now, so I can keep up with them all fairly often.”
—Pharmacist providing telephone MTM Services. To varying degrees, programs stratify their interventions based on patients’ needs and program resources, offering more general interventions (written information, for instance) to those patients with the least need and offering outreach for personal interaction to those whose data show the most immediate and significant potential problems. The programs also target specific messages and interventions based on practice guidelines and data that identify patients whose treatment is not consistent with those guidelines.

Future development. The programs NCQA visited reported continually improving their ability to target subpopulations, including patients with specific disease states and patients whose data indicate specific problems with medications. For example, one program designed an intervention specifically for patients with poor cholesterol control.
Scalability is an acknowledged issue: all the site-visited programs had engaged in planning for how they would accommodate additional populations of eligible patients. One program reported having made more than 200,000 outbound telephone calls to patients and serving a patient population of more than 600,000 with a staff of pharmacists and customer service representatives. The customer service representatives had only the responsibility of scheduling calls between the patients and pharmacists. At the other end of the scale, a regional program serves its active MTM population of 24 patients with 1 pharmacist, acknowledging that changes to the program may be necessary if it expands eligibility and significantly increases enrollment.

4. Feature: Evidence-Based Medicine
Consensus Statement
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.

Field Findings: Practiced Use of Medical Evidence
This is a strength of the programs surveyed: all the surveyed programs base their interventions on medical evidence. Eighteen of 20 programs disseminate clinical guidelines and up-to-date reference materials to staff providing services; 13 of 20 provide staff with online decision support based on evidence. One site-visited program conducts a complete annual review of all content, including each practice guideline and each piece of patient material, to make sure it reflects current evidence.

5. Feature: Promotion of MTM Services
Consensus Statement
Mutual promotion of MTM by health plans and health care professionals can help enhance adoption.

Field Findings: Increasing Promotion to Increase the Program’s Reach
Direct to patients. All the programs either invite eligible patients to elect to participate (to opt in), or automatically enroll eligible patients unless they opt out. Some of those that had reached only a small percentage of plan members through opt-in by promoting the programs in mailed literature have begun making outbound calls to promote more participation. Two programs reported reaching less than 1 percent of their members and were concerned that this was too small.

Mutual promotion. Some of the programs allow physicians, pharmacists, or patients themselves to make referrals into the MTM program. This is true for commercial patients for one fourth of the programs (5 of 20) and for Medicare patients for 3 programs. Nurses and case managers are referral sources for 3 programs. Phase One respondents specifically recommended having the capability for physicians to refer patients for consideration for MTM programs. Medicare criteria do not provide for this, so only the broader programs can accommodate referrals. (See Operational Aspect: Patient Identification and Recruitment section, below.)

B. Findings on Operational Aspects of Quality MTM Programs
The operational aspects described in the consensus document are more specific than the important features of a program and so lend themselves to more detailed analysis using data from the self-assessment phase and the site visits.

1. Operational Aspect: Patient Identification and Recruitment
Consensus Statement
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:

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

Field Findings: Medicare and More Inclusive MTM Programs
Separate programs. This aspect was the most difficult to assess because of the difference between its broad concept of patient recruitment and the strict limitations of Medicare-defined MTM eligibility criteria. All of the site-visited programs and some of the other respondents described their MTM programs in 2 parts: the Medicare-eligible patients for the Medicare-required program and the more inclusive eligibility rules for their broader services. They often had a different name for the latter, more inclusive programs, which incorporated the aspects above as described in Sound Medication Therapy Management Programs. The patients reportable to CMS are by regulation a much more limited group.

MTM program reportable to Medicare, eligibility criteria from 20 programs. Following are the averages from the 13 PDP and 18 MA-PD programs represented in the respondent group.

- Average number of chronic conditions: 2.6 (range is 2-5)
- Average number of medications: 5.6 (range is 2-12)
- Annual drug expenditures (all programs): ≥ $4,000
- Average percentage of all PDP and MA-PD members eligible for Medicare MTM: 11% (range is 3%-27%).

Some organizations, particularly those with the lowest number of conditions and medications required for Medicare MTM, further stratify patients to gear interventions to the patients’
needs. For example, within an eligible population of members with at least 2 chronic conditions, plans may further identify members with 3 or more conditions. The members with 2 chronic conditions, such as high blood pressure and hypercholesterolemia with no complications, might receive only mailed patient support material; those who also have diabetes might receive a mailed invitation for a consultation with a provider of MTM services. Those with multiple conditions and an irregular pattern of filling prescriptions might receive outbound telephone calls from the program to arrange a consultation.

**Broader MTM services eligibility criteria.** Most programs offer broader MTM services also—for instance, to all Medicare members, to a larger range of Medicare members, to commercial members, and/or to Medicaid members. They define this eligible group flexibly to better identify people who might benefit from MTM, as the consensus document suggests.

- Ten reported using patient-needs criteria, as listed in the consensus document; an average of 4 reported using any one of the patient-needs criteria.
- Four commercial programs, 2 PDPs, and 3 MA-PD programs reported considering financial barriers as a criterion for eligibility.
- Eleven allowed referrals into the MTM program by the patient or by providers, including physicians and case managers.
- One plan used hospital and long-term care discharge as an eligibility criterion.
- No commercial or Medicaid programs imposed a minimum expenditure criterion or a requirement for more than 1 chronic condition.
- The site-visited programs demonstrated how they provide some MTM services for which all patients were eligible, such as EOBs with medication recommendations or interventions for specific problems, such as the need for asthma controller medications.

The result of the range of criteria is that a wide range of percentage of total patients are touched by active intervention, as opposed to written materials, from MTM programs. Further, most MTM programs are undergoing change to reach the cohort of patients who would best benefit from intervention. A large percentage—8 of the 16 MA-PD program providers and 5 of the 13 PDP program providers—reported changing their eligibility criteria from 2006 to 2007. Some intend to decrease their pool of eligible patients and others intend to increase eligibility.

**In-person services, whether telephone or face to face, are opt-in by necessity:** the program invites the patient to participate and the patient must call to take advantage of it. Even when the programs make follow-up outbound calls to enroll patients—and some do—the patient must consent to participate in MTM telephone calls. Conversely, the services that rely mostly on mailed information to recipients are opt-out: the mailing continues unless the patient takes action to stop it.

In-person services, whether telephone or face to face, are opt-in by necessity: the program invites the patient to participate and the patient must call to take advantage of it. Even when the programs make follow-up outbound calls to enroll patients—and some do—the patient must consent to participate in MTM telephone calls. Conversely, the services that rely mostly on mailed information to recipients are opt-out: the mailing continues unless the patient takes action to stop it.

The resulting participation rates very widely: for opt-in services, programs reported an average participation level of 14% for PDP and 18% for MA-PD of eligible members opting in, with a range of <1% (2 programs) to >50%. This large range could reflect the following:

- The appeal of the invitation to participate—one program repeatedly tested its written materials with members and redesigned them to improve the response rate.
- The level of health care need of the eligible patients—programs with the most stringent criteria for eligibility may be reaching sicker patients, who may be more likely to enroll.
- The follow-up—the site-visited programs reported either making outbound calls to increase recruitment or planning to make them.

The opt-out method produces much higher percentages of enrollments (usually >95%, since few patients actively opt out).

**Recommendation for the consensus document.** To reflect what is happening in the field, NCQA recommended amending the consensus document to state explicitly how the Patient Identification and Recruitment section relates to both the Medicare-defined requirements for eligibility and the wider programs in operation.

---

**Data used for eligibility.** All 20 programs use pharmacy claims data to identify and target patients for both Medicare and wider MTM. Pharmacy data do not include medical diagnoses; however, where pharmacy data are the only data available, programs did infer the presence of chronic conditions from the medication pattern. Ten programs also use medical claims data, including hospital claims, ambulatory claims or both, where available.

The 5 site-visited programs provided examples of sophisticated algorithms for identifying eligible patients and stratifying them into levels of service. One program calculates a score for each patient, whether Medicare-defined eligible or not, using proprietary software; some programs identify patients eligible for specific evidence-based interventions, such as increasing persistence with beta-blocker treatment.

**Recruitment: Opt-in, opt-out, and follow-up.** NCQA asked programs about the extent to which they require patients to opt in (i.e., affirmatively agree to be part of MTM) or opt out (i.e., be included in MTM unless they affirmatively disenroll). Ten programs had both opt-in and opt-out features. 3 had opt-in only, and 7 had opt-out only. For programs reporting on their Medicare Part D program, data collected referred to their current (2007) program.

**“When we say we’re calling from your Medicare drug program, members take our calls. Doctors also.”**

—Pharmacist in a national program
V. Findings of Phase Two: Elements from the Consensus Document in Existing MTM Programs

Although the consensus document states that it applies broadly to MTM programs, not just to Medicare MTM programs, many programs NCQA included now use the term “MTM” to refer only to programs using Medicare eligibility criteria. They interpret the patient-needs criteria in the document as being recommended in addition to the 3 Medicare criteria. This interpretation is seen as further narrowing eligibility rather than as broadening the eligibility criteria, which is what the document intends.

As stated in version 1.0, the Patient Identification and Recruitment section describes a flexible set of guidelines for ensuring that a flexibly defined group of patients who can benefit from MTM are eligible for it. Many organizations consider their MTM program to apply only to Medicare and have a separate program with another name that includes eligibility criteria similar to that in the consensus document.

The stakeholders interviewed in Phase One recommended that the eligibility for MTM be expanded beyond the Medicare criteria to consider patient needs such as those in the consensus document, including the following:

- Types of medications, rather than just number, including those with a narrow therapeutic index or with high risk. A program visited by researchers gave the example of a patient on one very expensive, hard-to-manage medication. The patient does not meet Medicare requirements but is a good candidate for MTM.
- Patients with socioeconomic barriers to using medications effectively.
- Patients with transitions in care that can increase risk for medication-related problems. One program automatically includes in MTM Medicare patients who are discharged from a hospital or long-term care facility.

2. Operational Aspect: Services to Meet the Needs of Individual Patients

Consensus Statement

There are a number of potential activities that might be undertaken by quality MTM programs, targeted to the needs of individual patients. While not an all-inclusive list, there is a catalogue of nine service activities identified by a group of 11 national pharmacy organizations in a July 2004 consensus statement (see Appendix A [of version 1.0] for this report).5 This is not intended to be a definitive list, and it is not suggested that any given program must contain all of these elements. The items listed are offered as examples of the types of activities that quality 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.

Field Findings: Many Ways of Providing MTM

Large complement of services. The scope of services in MTM program operations vary widely. All programs employ personalized services to some degree, from providing the same disease-specific newsletters to all patients with each disease to discussing individual treatment steps and progress with the patient or caregiver, as needed.

Of the services identified by 11 pharmacy organizations in Appendix A of version 1.0 of the consensus document, plus others identified by AMCP and the project advisory committee,:

- 60% of the survey respondents develop a medication plan;
- most, but not all, provide each of the other services;
- all potential services were provided by some programs;
- all 20 programs provide education through information, support services and other resources; and
- the lowest occurrence of a service identified was that only 2 programs waive prescription copays for MTM participants.

Different services. Table 2 shows the number of organizations surveyed that provide, or do not provide, the suggested services—using either their own in-house staff or contracts with other organizations, usually pharmacies. Two programs send mailings to eligible patients but do personal outreach only to physicians. Two others work only with patients, but one is planning to initiate a physician outreach component.

Different settings. Table 3 shows the settings and modes of communications used—again, a great variety. Mail and telephone are by far the most-used media, followed by in-person services in pharmacies. Each site-visited program that uses the telephone took issue with the consensus document’s Appendix A, advocating “face-to-face interaction between the patient and the pharmacist as the preferred method of delivery.” They prefer telephone interaction as more scalable, more consistent, more convenient for the patient, and more effective.

Recommendation for the consensus document. To provide more balance and to reflect the range of programs in the field, researchers recommended that the authors of the consensus document could reconsider the statement of preference for face-to-face interactions. The statement above, from Appendix A of version 1.0, appears problematic, since many programs employ well-trained pharmacists to provide counseling by phone. (See Practitioners

V. Findings of Phase Two: Elements from the Consensus Document in Existing MTM Programs

Who Can Coordinate and Provide MTM.) As there are no comparative data to validate either stakeholder preference for face-to-face interaction or better outcomes for such interactions, NCQA recommended that the consensus document not refer to it as “preferred.”

3. Operational Aspect: Services Tailored for Setting, Cultural Differences

Consensus Statement

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.

Field Findings: Some Tailoring

Sixteen of 20 programs tailor services to some degree. The most common type of tailoring is to accommodate language differences, from translating disease-specific information into a few languages to accessing language-line services for live translation between pharmacist-advisor and patient. Regarding tailoring for low health literacy, 8 programs stated that they adjusted materials for low literacy, and 1 program specifically tested and retested its materials with patients to maximize their effectiveness (see Table 3 in Appendix A).

The setting, whether in person at the pharmacy or by telephone, seems to be determined most often by program design or availability of in-person services where patients live.

A minority of programs have in-person services available in senior centers (see Table 2 in Appendix A). The site-visited programs stated that tailoring MTM services for long-term care residents is problematic because the patients have the management of a consultant pharmacist available to them. They reported the potential for conflicting information. Given the health status of these patients, the MTM programs generally defer to the consultant pharmacist and do not initiate intensive dialogue with the patients.

Less than half of programs survey patients to determine their preferred method of communication or language.

4. Operational Aspect: Coordination of Care

Consensus Statement

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

- 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)
- maximizing the productivity of MTM providers through appropriate use of information technology as well as other communication tools
- 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.

Field Findings: Coordination With Physicians and Case Managers

“For money-saving changes like switching to generics or mail-order, we do best giving the information to the patient to take to the doctor. If the patient cares about saving money, the doctor will care.”

—National MTM program director

Growing understanding of how to coordinate. As noted under Interdisciplinary, Team-Based Approach and Communication in the Important Features of a Quality MTM Program section, all programs report that they initiate coordination of care, with 90% coordinating by contacting prescribing physicians. Although a broader assessment of health care would probably assign overall responsibility for coordination to the primary care physician, MTM programs do take responsibility for coordinating information with prescribers and making recommendations to them. Interestingly, 2 of the 20 programs include communication only with the patient and not with the prescribing physician, but 1 of those has plans to begin following up with physicians.

Table 4 in Appendix A shows the findings of the self-assessment survey pertaining to coordination of care. Following are some examples of coordination in the field.

- Eleven programs coordinate with disease management or Medicare Health Support, some of those by transferring patients’ calls between the case manager providing disease management in a Medicare Health Support program and the pharmacist providing MTM.
- Several programs ensure that nurses provide patient education and ask the patient’s health plan can access information regarding a patient’s medication use and status of MTM program activities.
- One program sends the patient a follow-up letter to reinforce points made in an MTM phone call with a pharmacist to assist in patient self-management.

Section 721 of the Medicare Modernization Act of 2003 (MMA) authorized development and testing of voluntary chronic care improvement programs, now called Medicare Health Support, to improve the quality of care and life for people living with multiple chronic illnesses. The programs are overseen by the CMS and are operated by health care organizations chosen through a competitive selection process. The first programs became operational in August 2005, and the eighth and final program became operational in January 2006. More information can be found at: www.cms.hhs.gov/CCIP/ Accessed November 30, 2007.
5. Operational Aspects: Appropriate Documentation and Measurement, and Quality Assurance

Consensus Statements

MTM programs will need to identify and perform a variety of measurements and document program results in order to determine overall program effectiveness and achievements. Examples include:

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

Field Findings for Both Aspects: Measurement of Many Aspects of Program Performance and Active, Ongoing Improvement

Combined emphasis on measurement. Researchers addressed these 2 operational aspects together because they overlap. In keeping with the fact that MTM programs heavily use information systems, all 20 programs reported thorough documentation and all measure multiple aspects of program performance at some level. About half of the programs listed measures that they are using, in addition to the options given in the survey. They use a variety of metrics from internal and external sources to measure their program components and the performance of their contracted providers, as shown in Tables 5 and 6 in Appendix A.

QA and QM. The research questions fell into 2 categories.

1. Quality assurance for individual MTM services, through ongoing support and monitoring of staff providing MTM.
2. Quality measurement and improvement, looking across all plan members. This category incorporates the ideas in the consensus statements on these topics.

QA—Support and monitoring of staff for quality assurance. As noted in the earlier section, Evidence-Based Medicine, 13 of the 20 programs use online decision support for their pharmacists and for others providing MTM to patients. This ensures consistency and use of the most up-to-date information.

To monitor the quality of work, 14 programs perform periodic checks or audits of practitioners providing MTM; 9 check the accuracy of information given to patients. Only 3 reported no checks or audits. Several reported monitoring quality through periodic reports, which they required of internal staff or contracted providers.

QM—Quality measurement and improvement. All programs report measurement across their operations, looking at all patients eligible for or enrolled in their MTM programs. Tables 5 and 6 show the kinds of externally and internally developed measurements that the programs use. Some programs also report that they measure more broadly across their entire populations. Ten programs reported using the Healthcare Effectiveness Data and Information Set (HEDIS)\(^7\) measures, and 1 reported that it uses measures of quality provided by quality improvement organizations (QIOs).

It should be noted that the survey instrument did not ask MTM programs to submit details on measure specifications as this was beyond the project scope; therefore the researchers were not able to confirm the extent of population-based measurement. This is important, because as MTM programs expand,

---

7 HEDIS is a registered trademark of the National Committee for Quality Assurance.
population-based measurement will be necessary to understand
the performance of 1 program relative to another.
1. All programs reported the process measures required by CMS
regarding the numbers of patients eligible and enrolled; some
reported clinical process measures such as HEDIS measures of
prescribing beta-blockers after a heart attack.
2. Twelve reported measures of cost-effectiveness.
3. More than half reported measuring patient satisfaction.
4. Two site-visited programs showed measurements across their
populations, including 1 that applied several QIO-sponsored
clinical process measures to its MTM populations, its non-
MTM population, and its total population. There were also
data from the QIO providing comparisons among Medicare
Part D MTM programs, which allowed a plan to see how it
performs and how its MTM patients compare on important
dimensions (e.g., beta-blocker persistence).
5. QI—Seventeen programs used the measurement results to
improve services: some to increase the numbers of patients
in MTM, some to decrease the numbers; some to do more,
or less, interaction with patients; some to improve written
communications. The site visits confirmed that most of these
programs incorporate the results of measurements to improve
program quality and are working toward improvement.

Recommendation for the consensus document. Quality measure-
ment to date is not consistent enough to enable comparisons of
MTM programs based on quality or to establish best practices
based on performance. NCQA recommended that the document
specifically state that organizations operating MTM programs
should measure performance across their entire enrolled popula-
tions in addition to those members who are either eligible for or
are participating in MTM programs.

The following theoretical example uses low-density lipopro-
tein (LDL) cholesterol levels in diabetic patients to illustrate the
value of population-based measurement:
1. Program A and program B have roughly the same size popula-
tions.
2. Program A sets eligibility rules resulting in 40% of its diabetic
patients qualifying for MTM services. Program B sets higher
eligibility thresholds so that only 10% of its diabetic patients
qualify for MTM services. Because program B requires more
medications or more comorbidities, patients with diabetes
who qualify for MTM services in program B may be consid-
ered sicker and harder to treat to LDL goal.
3. Because the patients with diabetes selected in program B may
be more challenging to treat than those in program A, when
only MTM-eligible members are used as the denominator,
the measured percentage of patients with diabetes with LDL
<100 may likely be lower in program B than in program A.
This lower percentage may be the result of the populations
represented in the denominators being different and cannot
support an inference that 1 program is better than the other.
4. However, when both programs measure by using as a denomi-

ator the population of all diabetic patients among their plan's
covered members, program A actually shows a lower percent-
age of diabetes patients with LDL <100 than does program
B. This difference demonstrates a population-based measure-
ment, and the difference is more likely to be due to the perfor-
mance of the programs.
5. Having comparable data helps the programs. Program A
might decide to reconsider either its eligibility rules or its
MTM methods to make a difference in its population-based
measurement; program B might decide to continue devoting
resources to the hard-to-treat patients to achieve smaller but
still-crucial improvements.

Plans can use comparative data to show whether their MTM
programs are achieving the desired outcomes and how they com-
pare with other plans. It may also be necessary to employ risk
adjustment to ensure that populations are comparable. NCQA's
HEDIS program risk-adjusts by separating populations according
to whether they are commercially insured, covered by Medicare,
or covered by Medicaid.

Several observations of existing quality measurement led
NCQA to this conclusion.
1. Some programs already measure across their populations.
QIO-sponsored measurements collect data from MTM pro-
grams based on their MTM population, their non-MTM popu-
lation, and all members (population based).
2. Data are available for many measures that require only age,
gender, and pharmacy claims data, such as the percentage of
members > 65 years taking drugs to be avoided in the elderly.
Thus, measurement programs can be highly automated.
3. Standardized measures are available from HEDIS and from
QIOs and are specified so that programs can measure compa-
rability.
4. Population-based measurement will allow comparison of pro-
gram results between plans, identify best practices, and allow
programs to benchmark themselves against data.

6. Operational Aspect: Communications by the MTM Program
Consensus Statement
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
• regular and ongoing;
• descriptive of the benefits and limitations, including opt-in and
  opt-out opportunities; and
• descriptive of how long patients remain enrolled once they enter
  the program.

Field Findings: Communications at Many Levels
Different uses for written information. The programs surveyed
placed varying emphasis and effort on written communication
with patients. Fourteen communicate by mail; the average fre-
quency is 4.5 contacts per year with patients, and there is a wide
range among plans. Other programs that communicate only by telephone or in person attempt regular and ongoing interactions with patients. Some include MTM-related advice in EOBs for all patients; some send written information monthly for all Medicare members; most limit MTM advice to MTM-eligible patients.

Some programs placed considerable emphasis on developing interesting communications that patients would read; others send standard form letters. Descriptions of what MTM can offer the patients and how long they remain enrolled were present in the materials that NCQA reviewed.

7. Operational Aspect: Practitioners Who Can Coordinate and Provide MTM

Consensus Statement

Programs may be delivered by and involve a variety of health care professionals. The list of potential providers might include

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

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

Field Findings: Well-Trained Pharmacists

Pharmacist prevalence. Most of the MTM programs surveyed were developed and operated by pharmacists. All 20 programs use pharmacists to deliver services to patients; 10 also use nurses; several use pharmacy technicians. This also applies to subcontracting organizations, usually associations or chains of community pharmacies, in which pharmacists and pharmacy technicians are the dominant employees.

Training. Regarding specific professional training, 16 programs require registered pharmacists and 9 require additional training. In Phase One interviews, some organizations noted that not all pharmacists are trained and prepared to render the proactive intervention with patients that is part of MTM. This type of relationship differs from the normal operational mode of most pharmacies and physicians, in which the patient initiates interactions. Some programs support their staff with templates

for interviews with patients; others leave the process to pharmacists and their professional knowledge. One program specifically trains its pharmacists to understand common difficulties faced by some senior citizens in communication about their medications.

New roles. MTM is an opportunity for community-based pharmacists to develop greater contact with patients than they have had in the past and use more of their patient care training. The programs visited had a variety of beliefs about providing MTM services in community pharmacies. One large national program said community pharmacies work well in MTM where it can enroll pharmacies but that it was disappointed in the number of pharmacies that wish to contract to provide MTM services: only about 11% of all the program’s MTM patients in the nation live near contracted pharmacies.

8. Operational Aspect: Adoption of Standardized Documentation, Billing, and Payment Systems

Consensus Statement

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

Field Findings: Some Adoption of Standardized Systems

Focus on payment. For reimbursing contracted pharmacists, 4 of the 20 programs reported using CPT® pharmacy codes; 1 uses National Council for Prescription Drug Programs transaction standards; and 1 uses a flat hourly rate. The majority of programs do not reimburse pharmacists directly by service, and standardized documentation or payment systems do not apply. Telephone-based programs use salaried pharmacists, and programs that contract for services from a network of pharmacies may pay on a capitated basis.

Documenting services. One program, trying to increase the number of contracted pharmacies in its network, stated that it will accept documentation that each pharmacy provides rather than imposing its own, standardized forms or rules. Documentation systems are an area of plan operations that is still evolving.
VI. Conclusions and Recommendations

Conclusions
Overall, the researchers found the consensus document (version 1.0) to be successful—to the point that it is already being used and quoted by organizations drafting new industry standards. It provides a good guide for developing programs. The project’s findings lead researchers to describe it as neither a best-practice document nor a “floor” for performance, but rather as a reasonable complement of features indicating what sound programs would include. Some programs embody only a few of the features; others embody most of them.

Purchasers could use elements of the consensus document to evaluate MTM programs, with the understanding that the features and operational aspects recommended are similar to standards for structure and process and are not to measures of outcomes. At this point, the researchers do not have data to indicate whether the features and operational aspects correlate with better outcomes. It is anticipated that the features and operational aspects will be further evaluated and specified as more is known about the results of MTM programs.

Although the researchers agree that the best course overall for the consensus document is to remain nonprescriptive, in 3 areas they found a need for greater specificity. Adopting the recommendations is not meant to discourage innovation and variety in MTM programs but rather to encourage program development that acknowledges the features and aspects recommended in the consensus document.

Recommendations
The researchers found 3 areas where the status of the programs leads them to recommend that the consensus document can be improved. AMCP has incorporated the recommended changes into the Sound Medication Therapy Management Programs, Version 2.0 document.

1. State how the document relates to Medicare-required MTM programs. Help address the larger issue of confusion around the definition of MTM; make it clear to users that the important features and operational aspects apply not just to MTM as a Medicare Part D benefit, but also to all MTM programs designed to improve medication therapy for patients with complex medication needs. These programs may be identified by terms other than MTM and may use eligibility criteria including but not limited to the Medicare-defined MTM eligibility criteria.

2. Remove the statement in Appendix A of version 1.0 or clarify to state that face-to-face interaction by pharmacists is the pharmacy profession’s preferred method for MTM and not a specific recommendation of the document. Appendix A of the consensus document (version 1.0) is the “Medication Therapy Management Services Definition and Program Criteria” approved in 2004 by 11 pharmacy organizations, which stated that programs shall include “face-to-face interaction between the patient and the pharmacist as the preferred method of delivery.” Most MTM programs visited as part of the research misinterpreted that statement in the consensus document’s Appendix A to be a recommendation of the consensus document, which it is not.

3. State that sound MTM programs use plan population-based measurement as they evaluate MTM programs. This recommendation means using measures that include in their denominator the entire relevant population of members in the plan, in addition to using measures that include only patients eligible for or enrolled in the plans’ MTM program. Measurements of just the members eligible for MTM programs allow internal evaluation of MTM within a plan. Because plans have different eligibility rules, population-based measurements are needed to allow consistent external comparison and benchmarking across plans. Comparable, externally available population-based analyses are necessary to spur competition and begin to identify best practices. In addition, the development and use of population-based measures will enable research on the kinds of programs that are successful.

---

Appendix A. Phase Two Survey Tables

The data in the following tables are taken from the responses of the 20 MTM programs to the self-assessment survey questions in Phase Two. These numerical data are included to illustrate similarities and differences among programs in the selected sample. These similarities and differences are discussed more thoroughly in the text.

The tables address the following aspects of the survey:

• Table 1 shows the different types of services provided by MTM programs to members.
• Table 2 shows the settings and modes of communication MTM programs use.
• Table 3 shows the methods used for tailoring services for the individual member.
• Table 4 shows the ways that MTM programs coordinate care across providers for an individual patient.
• Tables 5 and 6 show types of performance measures that the programs use. Table 5 covers measures used to evaluate the MTM program's performance overall; Table 6 shows measures for evaluating individual contracted pharmacies or providers. Both tables are divided into external and internal measures—measures from external sources and measures developed internally by the MTM programs.

Please note the following when reviewing these data:

1. The researchers used a purposive sample of MTM programs rather than a statistically valid or random sample. The goals in selecting the sample were to include a range of types of MTM programs and to include programs from Part D plans that cover the majority of Medicare Part D beneficiaries. The data may not fully represent MTM programs currently offered.
2. These tables represent responses to questions at a point in time, April through June 2007. Ensuing interviews show that MTM programs are changing aspects of their operation based on their own analyses of their performance.
3. The tables represent the questions asked in the survey that lend themselves to numerical representation. More than 40 additional questions and their responses are synthesized in the report. The questions and the answer options for each question were based on several sources:
   • Sound Medication Therapy Management Programs, Version 1.0, and appendices
   • AMCP and NCQA staff's knowledge of MTM programs
   • Validation project advisory council input
4. MTM programs differ in their use of in-house staff or contracted pharmacies to provide services. Some programs use both in-house staff and contracted pharmacies. In each table we have separated the responses on this basis to further illustrate the range of operations and measurement used by MTM programs.
### Table 1. Number of MTM Program Respondents Providing Identified MTM Services

**Survey question:** What services does your MTM program provide to members directly? Check below the services you provide either in-house (centrally, using your own employees) or by contract (such as using contracted pharmacies or pharmacists). This includes services provided by mail, telephone, or e-mail and in person in any setting.

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>In-House Only</th>
<th>By Contract Only</th>
<th>Both In-House and by Contract</th>
<th>Total Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment of the member’s health status through interview with member</td>
<td>10</td>
<td>2</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Assessment of the member’s health status through access to electronic health record (EHR) or other database of clinical data</td>
<td>9</td>
<td>1</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>Comprehensive review of all prescribed medications through interview with member</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Comprehensive review of all prescribed and OTC medications through interview with member</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Comprehensive review of all prescribed and OTC medications through access to EHR or other database</td>
<td>7</td>
<td>1</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Formulation of a medication treatment plan</td>
<td>9</td>
<td>2</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Modification of the member’s medications without contact with the prescriber (such as generic substitution)</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Modification of the member’s medication with contact with the prescriber</td>
<td>10</td>
<td>2</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>Documentation of all medications and communication with the member’s primary prescriber</td>
<td>11</td>
<td>2</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Provision of direct, verbal education and training to the member and/or caregivers</td>
<td>10</td>
<td>3</td>
<td>3</td>
<td>16</td>
</tr>
<tr>
<td>Provision of education through information, support services and resources</td>
<td>14</td>
<td>3</td>
<td>2</td>
<td>19</td>
</tr>
<tr>
<td>Waiver of copays for medications if member participates in MTM</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Continuing or periodic interaction on managing medications</td>
<td>10</td>
<td>3</td>
<td>3</td>
<td>16</td>
</tr>
<tr>
<td>Continuing or periodic interaction on managing chronic conditions</td>
<td>12</td>
<td>3</td>
<td>2</td>
<td>17</td>
</tr>
<tr>
<td>Continuing or periodic interaction on managing health</td>
<td>11</td>
<td>3</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td><strong>Organizations responding</strong></td>
<td>20</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MTM = medication therapy management; OTC = over the counter.

### Table 2. Number of MTM Respondents Using Service Settings and Modes of Communication

**Survey question:** What is the setting and mode of communication in which your program interacts with members? Check all that apply in any of your programs, including whether offered through in-house personnel or by contract.

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>In-House Only</th>
<th>By Contract Only</th>
<th>Both In-House and by Contract</th>
<th>Total Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy in person</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Home visit by health care practitioner</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Senior drop-in centers in person</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Long-term care centers in person, such as assisted living facilities</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Employer site in person</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Telephone, contact with live person</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Telephone, automated calling</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>E-mail, contact with live person</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>E-mail, automated distribution</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Web site, interactive</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Web site, static information only</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Mail</td>
<td>11</td>
<td>2</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>Fax</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td><strong>Organizations responding</strong></td>
<td>20</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MTM = medication therapy management.
### TABLE 3  Number of MTM Respondents Reporting Methods of Tailoring Services for Individuals

**Survey question:** How does your program personalize services for the member, accommodating cultural and linguistic differences, among other things? Choose from the following options.

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>In-House Only</th>
<th>By Contract Only</th>
<th>Both In-House and by Contract</th>
<th>Total Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveying members to determine preferred language</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Surveying members to determine preferred setting, among the settings you offer (above—may include home, pharmacy, drop-in center, long-term care facility)</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Surveying members to determine preferred mode of communication, among the types you offer (above—may include in-person, telephone, e-mail, mail)</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Assessing members’ literacy level</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Providing services in multiple settings as above</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Using multiple modes of communication as above</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Employing or contracting with staff who speak languages other than English. Note how many languages you cover in the box below.</td>
<td>8</td>
<td>3</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Providing written material in other languages</td>
<td>11</td>
<td>1</td>
<td>1</td>
<td>13</td>
</tr>
<tr>
<td>Providing written material adjusted for low literacy levels</td>
<td>8</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>Providing in-person services in multiple parts of the country to accommodate “snowbirds”</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>No personalization</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

Organizations responding 19

MTM=medication therapy management.

### TABLE 4  Number of MTM Respondents Reporting Methods of Coordinating Care

**Survey question:** In what ways does your MTM program include coordination of care among providers to ensure that the MTM program does not fragment care? Please check either in-house or by contract based on which professionals initiate the coordination.

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Initiated by In-House Staff Only</th>
<th>Initiated by Contracted Staff Only</th>
<th>Initiated by Both</th>
<th>Total Programs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deploying MTM staff professionals as part of an interdisciplinary team responsible for the member’s care</td>
<td>8</td>
<td>1</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Sending complete medication lists to health care providers, including physicians, on paper or electronically, so that each treating provider knows what others have prescribed</td>
<td>14</td>
<td>2</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>Sending complete medication lists to noncontracted pharmacists</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Consulting with prescribers on questions about and changes to members’ medication regimens</td>
<td>12</td>
<td>2</td>
<td>4</td>
<td>18</td>
</tr>
<tr>
<td>Giving treating providers the outcome of MTM encounters, by phone, on paper, or electronically</td>
<td>6</td>
<td>3</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Providing members with paper or electronic lists of medications and medication plans to take to providers</td>
<td>12</td>
<td>1</td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>Making recommendations to members and providers regarding monitoring needed, such as lab tests, blood pressure, weight, or blood sugar</td>
<td>14</td>
<td>2</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>Using information technology such as EHRs and e-prescribing systems to integrate pharmacy data and other health care data</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Coordinating MTM with Medicare Health Support (MHS) or a chronic care improvement program (CCIP) by sharing information between the MTM and MHS personnel responsible for the member (required by CMS)</td>
<td>11</td>
<td>0</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Integrating MTM with other care management services being provided to the member, such as by having the same provider manage all contact with a member</td>
<td>9</td>
<td>1</td>
<td>1</td>
<td>11</td>
</tr>
</tbody>
</table>

Organizations responding 20

CMS=Centers for Medicare & Medicaid Services; EHR=electronic health record; MTM=medication therapy management.
## TABLE 5  Number of MTM Respondents Reporting Measurements Used for Program as a Whole

Survey question: Performance measurement for the program(s) as a whole: Which of the following types of measures from external sources do you use for evaluation of performance?

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Response Percentage</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS-required reporting</td>
<td>89%</td>
<td>17</td>
</tr>
<tr>
<td>NCQA HEDIS</td>
<td>53%</td>
<td>10</td>
</tr>
<tr>
<td>JCAHO measures</td>
<td>11%</td>
<td>2</td>
</tr>
<tr>
<td>National Quality Forum Ambulatory Care Quality measures</td>
<td>5%</td>
<td>1</td>
</tr>
<tr>
<td>Measures from local collaborative(s)</td>
<td>16%</td>
<td>3</td>
</tr>
<tr>
<td>Measures required by employer contracts</td>
<td>16%</td>
<td>3</td>
</tr>
<tr>
<td>None</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Other (please specify). Respondents noted Pharmacy Quality Alliance and FMQAI measures.</td>
<td>11%</td>
<td>2</td>
</tr>
</tbody>
</table>

Organizations responding: 19

Survey question: Performance measurement for the program(s) as a whole: What kinds of internally created measures do you use?

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Response Percentage</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measures of enrollment</td>
<td>90%</td>
<td>18</td>
</tr>
<tr>
<td>Measures of adherence</td>
<td>55%</td>
<td>11</td>
</tr>
<tr>
<td>Measures of satisfaction</td>
<td>55%</td>
<td>11</td>
</tr>
<tr>
<td>Frequency of interaction</td>
<td>75%</td>
<td>15</td>
</tr>
<tr>
<td>Number of interactions with members by site</td>
<td>40%</td>
<td>8</td>
</tr>
<tr>
<td>Number of interactions with members by mode of communication</td>
<td>45%</td>
<td>9</td>
</tr>
<tr>
<td>Measures of quality process</td>
<td>60%</td>
<td>12</td>
</tr>
<tr>
<td>Measures of quality outcomes</td>
<td>55%</td>
<td>11</td>
</tr>
<tr>
<td>Measures of cost-effectiveness for medications</td>
<td>70%</td>
<td>14</td>
</tr>
<tr>
<td>Measures of cost-effectiveness for all health care services</td>
<td>45%</td>
<td>9</td>
</tr>
<tr>
<td>None</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>25%</td>
<td>5</td>
</tr>
</tbody>
</table>

Organizations responding: 20

CMS = Centers for Medicare & Medicaid Services; FMQAI = Florida QIO (quality improvement organization); HEDIS = Healthcare Effectiveness Data and Information Set; JCAHO = Joint Commission on Accreditation of Healthcare Organizations (recently changed to The Joint Commission); MTM = medication therapy management; NCQA = National Committee for Quality Assurance.
Appendix A. Phase Two Survey Tables

### TABLE 6 Number of MTM Respondents Reporting Measurements of Contracted Providers

**Survey question:** Performance measurement for contracted outside providers (if applicable): Which of the following types of measures from external sources do you use, for any program(s)?

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Response Percentage</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS-required reporting</td>
<td>30%</td>
<td>3</td>
</tr>
<tr>
<td>NCQA HEDIS</td>
<td>10%</td>
<td>1</td>
</tr>
<tr>
<td>JCAHO measures</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>National Quality Forum Ambulatory Care Quality measures</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Measures from local collaborative(s)</td>
<td>20%</td>
<td>2</td>
</tr>
<tr>
<td>Measures required by employer contracts</td>
<td>20%</td>
<td>2</td>
</tr>
<tr>
<td>None</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Not applicable (no contracted outside providers)</td>
<td>40%</td>
<td>4</td>
</tr>
<tr>
<td>Other (please specify). One response was nonspecific; I noted working with 33 QIOs on measurement</td>
<td>20%</td>
<td>2</td>
</tr>
</tbody>
</table>

*Organizations responding (others may not have contracted providers)* 10

**Survey question:** Performance measurement for contracted outside providers (if applicable): What kinds of internally generated measures do you use for any program(s)?

<table>
<thead>
<tr>
<th>Answer Options</th>
<th>Response Percentage</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measures of enrollment</td>
<td>27%</td>
<td>3</td>
</tr>
<tr>
<td>Measures of adherence</td>
<td>18%</td>
<td>2</td>
</tr>
<tr>
<td>Measures of satisfaction</td>
<td>36%</td>
<td>4</td>
</tr>
<tr>
<td>Frequency of interaction</td>
<td>45%</td>
<td>5</td>
</tr>
<tr>
<td>Number of interactions with members by site</td>
<td>36%</td>
<td>4</td>
</tr>
<tr>
<td>Number of interactions with members by mode of communication</td>
<td>27%</td>
<td>3</td>
</tr>
<tr>
<td>Measures of quality process</td>
<td>36%</td>
<td>4</td>
</tr>
<tr>
<td>Measures of quality outcomes</td>
<td>36%</td>
<td>4</td>
</tr>
<tr>
<td>Measures of cost-effectiveness for medications</td>
<td>36%</td>
<td>4</td>
</tr>
<tr>
<td>Measures of cost-effectiveness for all health care services</td>
<td>27%</td>
<td>3</td>
</tr>
<tr>
<td>None</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Not applicable (no contracted outside providers)</td>
<td>36%</td>
<td>4</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>9%</td>
<td>1</td>
</tr>
</tbody>
</table>

*Organizations responding (others may not have contracted providers)* 11

CMS=Centers for Medicare & Medicaid Services; FMQAI=Florida QIO; HEDIS=Healthcare Effectiveness Data and Information Set; JCAHO=Joint Commission on Accreditation of Healthcare Organizations (The Joint Commission); MTM=medication therapy management; NCQA=National Committee for Quality Assurance; QIO=quality improvement organization.
Appendix B. Phase One Interim Report

The following summarizes in tabular fashion NCQA’s findings from Phase One of the validation study. NCQA conducted structured interviews with a variety of stakeholders including MTM program providers, community pharmacy representatives, purchasers, consumer organizations, and practicing physicians.

The table shows summarized comments made by each stakeholder group (purchasers, consumers, and unions are grouped together). The content is grouped according to the 9 operational aspects described in the consensus document. Within each operational aspect are topics raised by the interviewer and responses of the interviewees.
# Appendix B. Phase One Interim Report

## Operational Aspects and Topics Addressed

### Phase One Interim Report

#### Operational Aspects and Topics Addressed

<table>
<thead>
<tr>
<th>A1</th>
<th>Criteria</th>
<th>MTM Program Providers</th>
<th>Community Pharmacy</th>
<th>Purchasers, Consumers, and Unions</th>
<th>Practicing Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>All MTM programs interviewed have a minimum $4,000 annual drug spend requirement (based on CMS).</td>
<td>MTM programs should use broader criteria including medical data; focus on certain types of medications, such as those with narrow therapeutic index (e.g., anticoagulants, antiseizure) or drugs with very expensive significant side effects (e.g., warfarin); consider all medical costs, not just medication; permit health care providers who know the patient to refer them to the program; and include those with conditions for which spending may increase significantly as the condition progresses (e.g., diabetes, congestive heart failure).</td>
<td>MTM programs should ensure the criteria are not too limited; consider types of medications, not just number of medications; include over-the-counter medications; include psychiatric conditions and obesity; focus on preventive approach; and better understand noncompliance and the multiple and varied reasons for it.</td>
<td>MTM programs should look at health service utilization (such as frequent hospitalizations); consider including neuropsychiatric and cardiovascular drugs, as these are the hardest for the elderly to effectively manage; address medication issues with transitions in care; include or target patients with low socioeconomic status; consider other factors besides the number of chronic conditions; better screen for nonadherence and drug-drug interactions; and realize that polypharmacy is a big issue because there are so many new, good medications, and guidelines are driving the use of drugs.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number of chronic conditions required ranges from 2 to 8.</td>
<td>All MTM program criteria require that the patient have 1 or more chronic diseases of specified types (e.g., asthma, diabetes, chronic obstructive pulmonary disorder, osteoarthritis, rheumatoid arthritis, osteoporosis, hypertension, hyperlipidemia, congestive heart failure, depression).</td>
<td>All MTM program criteria require that the patient have 1 or more chronic diseases of specified types (e.g., asthma, diabetes, chronic obstructive pulmonary disorder, osteoarthritis, rheumatoid arthritis, osteoporosis, hypertension, hyperlipidemia, congestive heart failure, depression).</td>
<td>All MTM program criteria require that the patient have 1 or more chronic diseases of specified types (e.g., asthma, diabetes, chronic obstructive pulmonary disorder, osteoarthritis, rheumatoid arthritis, osteoporosis, hypertension, hyperlipidemia, congestive heart failure, depression).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All MTM program criteria require that the patient have 1 or more chronic diseases of specified types (e.g., asthma, diabetes, chronic obstructive pulmonary disorder, osteoarthritis, rheumatoid arthritis, osteoporosis, hypertension, hyperlipidemia, congestive heart failure, depression).</td>
<td>Number of medications required ranges from 6 to 23.</td>
<td>Number of medications required ranges from 6 to 23.</td>
<td>Number of medications required ranges from 6 to 23.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>When making projections for 2006, the programs interviewed did not have data about Medicare Part D enrollees. They started with “conservative” approaches to test the waters.</td>
<td>Not sure.</td>
<td>Not sure.</td>
<td>Not sure.</td>
</tr>
<tr>
<td></td>
<td>A3</td>
<td>Data used</td>
<td>All programs but 1 use pharmacy claims data only.</td>
<td>Their MTM program clients use pharmacy claims data only.</td>
<td>MTM programs should use robust information, including pharmacy, medical claims, health fair screening results, and direct observation by physician or pharmacists.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>One uses pharmacy plus medical data, as well as results from a health assessment questionnaire completed by member.</td>
<td>Their MTM program clients use pharmacy claims data only.</td>
<td>MTM programs should use robust information, including pharmacy, medical claims, health fair screening results, and direct observation by physician or pharmacists.</td>
<td>MTM programs should use robust information, including pharmacy, medical claims, and utilization data.</td>
</tr>
<tr>
<td></td>
<td>A4</td>
<td>Frequency of review</td>
<td>All programs review criteria annually (per CMS). They may submit “enhancements” to criteria to CMS quarterly starting in 2007.</td>
<td>Their MTM program clients review criteria annually. Community pharmacy recommends quarterly review.</td>
<td>Prefer quarterly to annual review of criteria.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Their MTM program clients review criteria annually. Community pharmacy recommends quarterly review.</td>
<td>Their MTM program clients review criteria annually. Community pharmacy recommends quarterly review.</td>
<td>Prefer quarterly to annual review of criteria.</td>
<td>Annual review of criteria is acceptable.</td>
</tr>
<tr>
<td></td>
<td>A5</td>
<td>Barriers</td>
<td>Difficult to set criteria to capture the “right” patients, due in part to data quality.</td>
<td>None cited.</td>
<td>None cited.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pharmacy data may be inaccurate or incomplete. Criteria based on pharmacy data alone may not capture the “right” patients.</td>
<td>None cited.</td>
<td>None cited.</td>
<td>None cited.</td>
</tr>
</tbody>
</table>

### Phase One Interim Report

#### Services to Meet the Needs of Individual Patients

<table>
<thead>
<tr>
<th>B1</th>
<th>List of services (see consensus document)</th>
<th>MTM Program Providers</th>
<th>Community Pharmacy</th>
<th>Purchasers, Consumers, and Unions</th>
<th>Practicing Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Majority of programs interviewed provide all services listed in consensus document.</td>
<td>MTM programs provide all the services listed.</td>
<td>All look reasonable.</td>
<td>No specific comments.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No additional services cited.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Operational Aspects and Topics Addressed

<table>
<thead>
<tr>
<th>B2</th>
<th>Who delivers/why</th>
<th>MTM Program Providers</th>
<th>Community Pharmacy</th>
<th>Purchasers, Consumers, and Unions</th>
<th>Practicing Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Most programs use pharmacists only.  • Some also use nurses, especially for health education activities.  • Rationale for use of pharmacists: medication expertise, relationships with patients.</td>
<td>• Most programs provide medication expertise.  • Some also use nurses, especially for health education activities.  • Rationale for use of pharmacists: medication expertise, relationships with patients.</td>
<td>• Community pharmacies recommend pharmacists. They are best positioned in the community (i.e., accessible) and have the medication expertise.</td>
<td>• Pharmacists or nurses are both appropriate.</td>
<td>• Pharmacists are the best provider of this type of care.  • Such pharmacists need to be able to relate to the elderly.  • Pharmacists should do initial intake because they have expertise; follow-up by nurses okay.  • Physicians and other providers need to collaborate with pharmacists so they can encourage their patients to participate.  • Pharmacists should not diagnose or prepare treatment plans, even for over-the-counter drugs.</td>
</tr>
</tbody>
</table>

### Aspect C—Services Tailored for Setting, Cultural Differences

<table>
<thead>
<tr>
<th>C1</th>
<th>Tailoring approaches</th>
<th>MTM Program Providers</th>
<th>Community Pharmacy</th>
<th>Purchasers, Consumers, and Unions</th>
<th>Practicing Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Most programs interviewed do some form of tailoring.  • Focus for programs interviewed is on language instead of cultural differences.  • Some programs’ approaches are part of the overall health plan approach to these issues, not a separate approach.  • Approaches include TTY; translators (via phone services); bilingual materials; larger font.</td>
<td>• One pharmacy has labels available in 30 languages.  • Font sizes are larger for certain materials.  • Spanish education materials are available.</td>
<td>• Tailoring is very important as cultural differences can contribute to compliance issues.  • With the elderly, programs need to use repetition, have continuity, and have messages from a trusted source.</td>
<td>• MTM programs need to customize for cultural, religious, value differences.  • Programs also need to address differences in views of medication (e.g., some patients prefer herbal medications).</td>
<td>• MTM programs will need to pay pharmacists, which can be expensive.  • Lack of data.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C2</th>
<th>Effective or ineffective: examples</th>
<th>MTM Program Providers</th>
<th>Community Pharmacy</th>
<th>Purchasers, Consumers, and Unions</th>
<th>Practicing Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Phone calls do not work with many patients, especially if there are language barriers.  • Written materials may not work with patients with language or literacy issues.  • Face-to-face consultation is ideal for overcoming some of these barriers.</td>
<td>• Not sure.</td>
<td>• Multiple reinforcing approaches are best.  • Medication information sheets are too long and too technical.</td>
<td>• Spanish-language interpreters are effective at 1 physician’s site.</td>
<td>• Not sure.</td>
</tr>
</tbody>
</table>

### Aspect D—Coordination of Care

<table>
<thead>
<tr>
<th>D1</th>
<th>Approach</th>
<th>MTM Program Providers</th>
<th>Community Pharmacy</th>
<th>Purchasers, Consumers, and Unions</th>
<th>Practicing Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• All programs coordinate with physicians, usually via phone or fax.  • One program also coordinates with the health plan case manager.  • Most programs provide medication “profiles” to physicians of eligible patients.</td>
<td>• The pharmacist helps coordinate care, faxing a letter or calling the physician after consults.</td>
<td>• Physician should be an active part of the program so he/she can encourage participation.</td>
<td>• Would like to see electronic coordination with physicians and other providers, such as social workers, and with other settings, such as nursing homes.  • Need strong collaboration between plan, pharmacist, and physician; give the physician lists of eligible patients so he/she can encourage patients to participate.</td>
<td>• Not sure.</td>
</tr>
</tbody>
</table>
Appendix B. Phase One Interim Report

<table>
<thead>
<tr>
<th>Operational Aspects and Topics Addressed</th>
<th>MTM Program Providers</th>
<th>Community Pharmacy</th>
<th>Purchasers, Consumers, and Unions</th>
<th>Practicing Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>D2 Types of tools</td>
<td>• Medication profile with comprehensive medication information provided to patients, to take to providers. • Phone calls. • Fax. • Secure e-mail. • Integrated systems platform allows program to coordinate with participating pharmacies.</td>
<td>• Fax or phone call.</td>
<td>• Electronic systems preferred, especially if these systems can allow multiple providers to track progress and medication use.</td>
<td>• Not sure.</td>
</tr>
<tr>
<td>D3 Referrals</td>
<td>• Referrals not currently allowed from physicians, pharmacists, or other providers to MTM program.</td>
<td>• The pharmacist or physician must go through the health plan, prescription drug program, or pharmacy benefit manager that is paying for the MTM services.</td>
<td>• Physicians and pharmacists should be able to readily refer, as they know the patients best and are trusted sources.</td>
<td>• Would like to see more ability to refer from variety of community providers. • Should be able to have physician or pharmacist referral to these programs.</td>
</tr>
<tr>
<td>D4 Barriers</td>
<td>• Lack of relationships between MTM program with physicians and pharmacists. • Lack of relationships between physicians and pharmacists. • Lack of certain types of systems infrastructure.</td>
<td>• Providers may not know about MTM.</td>
<td>• None cited.</td>
<td>• Pharmacists and physicians do not usually know each other.</td>
</tr>
</tbody>
</table>

Aspect E—Appropriate Documentation and Measurement

| E1 Assessments done?                      | • Four programs have performed longitudinal assessments of program effectiveness and achievements. | • Their MTM program clients are conducting some longitudinal assessments of program effectiveness. | • Not sure. | • Not sure. |
| E2 Topics, methods, results               | • Patient satisfaction surveys. • Pharmacy costs. • Medical costs and cost savings. • Refill reminder program effectiveness. • Educational program effectiveness. | • Cost savings from reduced adverse medication events, increased compliance. • Compliance with medication protocols. | • Return on investment. • Cost/benefit analysis. | • Patient satisfaction. • Reduction in polypharmacy (although this does not work well because always have new comorbidities requiring more medications). • Want to see more health services utilization metrics (e.g., reduced emergency room visits). |
| E3 Communication                          | • Only communicated internally. | • Provided to pharmacies but not sure what else. | • None cited. | • Not sure. |
| E4 Barriers                               | • Cause-effect relationships are unclear. • Lack of good metrics. • Lack of data. | • None cited. | • None cited. | • Need to get MTM programs to understand concept of “transparency” to consumers and payers. • Regression to the mean. • Lack of accessible data. |

Aspect F—Quality Assurance

| F1 Program in place?                      | • Six programs had a quality measurement program in 2006. | • Not sure. | | |
| F2 Program components                     | • Interrater reliability/calibration. • Medication safety improvement metrics. • Adherence metrics (such as Medication Adherence Ratio). • Fraud. • Provider feedback. | • Recommend comparative longitudinal analyses of various services. • One of the community pharmacies interviewed have clinical software developed through state school of pharmacy to review patient cases monthly. The system helps ensure that each patient has an action plan and medication list. | • Adherence metrics. • Clinical outcomes, even if it means getting lab values. • Health services utilization (e.g., emergency room visits). • Concurrent or retrospective drug utilization review. | • See Aspect E, above. |

Continued on next page
## Appendix B. Phase One Interim Report

### Operational Aspects and Topics Addressed

**F3** Use of Evidence-Based Medicine

- Four programs have formal reference materials, such as implementation guides.
- Others assume pharmacists are following FDA or other guidelines.

**F4** Barriers

- Cost.
- Lack of control group.
- Lack of reliable, standardized metrics.
- Staff turnover.
- Lack of data infrastructure.

### Aspect G—Communications by the MTM Program

**G1** With members/caregivers

- Majority of programs use letters or phone calls as communication method, either for initial recruitment or for initial and ongoing contact.
- Several programs provide medication "profiles" that vary in level of detail.
- One program offers face-to-face consultation.

**G2** With providers

- Fax and phone calls are methods of choice.
- Several programs provide copies of medication profiles.
- One program has a quarterly magazine for providers.

**G3** Effective and ineffective: examples

- Face-to-face is cited as optimal approach by one program.
- One program cited a tested methodology for member materials.

**G4** Barriers

- Inaccurate contact information for some patients, especially low-income patients, exists.
- Lack of robust information about each patient exists.
- Pharmacists are still learning how to communicate with patients.

### MTM Program Providers

- POA, a pharmacy quality alliance, has guidelines pharmacists refer to, except those are only based on pharmacy data.

### Community Pharmacy

- None cited.

### Purchasers, Consumers, and Unions

- Patient satisfaction results can be misleading.
- Providers reluctant to provide results.
- Lack of time for measurement activities.
- Unclear cause-effect relationships.
- Confounding variables.
- Lack of adequate documentation by pharmacists and physicians.
- Lack of adequate information systems.

### Practicing Physicians

- None cited.

---

Continued on next page
### Appendix B. Phase One Interim Report

#### Operational Aspects and Topics Addressed

| Aspect H—Practitioners Who Can Coordinate and Provide MTM |
|---------------------------------|-----------------|-----------------|-----------------|
| **H1** Required credentials     | MTM Program Providers | Community Pharmacy | Purchasers, Consumers, and Unions | Practicing Physicians |
|                                 | • All require registered pharmacists; 1 permits pharmacy techs to deliver some services. | • Community pharmacies recommend that practitioners be registered pharmacists. | • Registered pharmacist or registered nurse. | • Registered pharmacist for main role, with follow-up by nurses okay. |
|                                 | • One program now requires certificate in geriatric pharmacy. | • One pharmacy interviewed requires attendance at 4-day training at state school of pharmacy, which is then followed by 3 months of ongoing development. | • Ensure pharmacists are trained in cultural sensitivity and in how to work effectively with patients. | • Training is desirable on different therapies, evidence, controversial medications, etc. |
|                                 | • One program employs pharmacist with pharmacotherapy specialty certification (but this is not required). | • Community pharmacies recommend additional training, but not too much as they don’t want to deter pharmacy participation. | | |
| **H2** Professional development | • Two programs cited specific training for pharmacists and nurses. | • Community pharmacies recommend continuing education on patient assessment, documentation, and how to meet the needs of various MTM program clients. | | |
|                                 | • One program requires pharmacists to attend annual seminar at the state school of pharmacy (continuing education). | • Community pharmacy noted that it is difficult to create a good staffing model as there are not many MTM patients. | | |
|                                 | • One program indicated that because of the shortage of participating pharmacies, the requirements must not be too onerous. | | | |

#### Aspect I—Adoption of Standardized Documentation, Billing and Payment Systems

<table>
<thead>
<tr>
<th>I1 Types of systems (list)</th>
<th>MTM Program Providers</th>
<th>Community Pharmacy</th>
<th>Purchasers, Consumers, and Unions</th>
<th>Practicing Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Varies from manual (3 programs) to proprietary, Web-based systems (3 programs).</td>
<td>• One pharmacy interviewed has a proprietary Web portal for all systems.</td>
<td>• Not sure.</td>
<td>• None cited.</td>
</tr>
<tr>
<td></td>
<td>• One program uses Access database but is looking for a Web-based system.</td>
<td>• One pharmacy interviewed said its client MTM programs require Web-based billing. This does not integrate with its pharmacy information system due to security issues so it has had to use laptops and manual documentation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NCPDP Version 5.1 cited.</td>
<td>• Community pharmacies recommend service billing through NCPDP Version 5.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• CPT codes for MTM cited.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• PPS codes cited.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I2 Barriers</th>
<th>MTM Program Providers</th>
<th>Community Pharmacy</th>
<th>Purchasers, Consumers, and Unions</th>
<th>Practicing Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Some pharmacies do not use the CPT codes and that is a barrier.</td>
<td>• Community pharmacies interviewed would like to have a single information system platform for all plans, pharmacy benefit managers, and prescription drug plans.</td>
<td>• None cited.</td>
<td>• None cited.</td>
</tr>
</tbody>
</table>

**CMS = Centers for Medicare & Medicaid Services; CPT = Current Procedure Terminology; MTM = medication therapy management; NCPDP = National Council for Prescription Drug Programs; PPS = Professional Pharmacy Services Codes; TTY = teletypewriter.**
Appendix C. Participants in Advisory Panel Meetings

Anne Burns  
American Pharmacists Association

Judith Cahill  
Academy of Managed Care Pharmacy

Chris Goff  
Employers Health Purchasing Corporation of Ohio

Jim Grant  
Physician Practice/Pharmacy Quality Improvement Organization Support Center (PPP QIOSC), FMQAI

Greg Johnson  
Pharmaceutical Care Management Association

Carmella Bocchino, Craig Miner, Bob Rehm  
America’s Health Insurance Plans

Terri Smith Moore  
National Quality Forum

Lee Rucker  
AARP

Gerald Shea  
American Federation of Labor and Congress of Industrial Organizations (AFL-CIO)

Jennifer Tija, MD  
American Geriatrics Society
Appendix D. Participating Organizations

Participants in the study were given the option of releasing their names. The following is a list of organizations that participated and agreed to have their names released.

Phase One Participants
American Federation of State, County and Municipal Employees
American Geriatric Society
Andersen Benson Consulting Services, LLC
Blue Cross Blue Shield of Massachusetts
Blue Cross Blue Shield of Michigan
Brigham & Women's Physicians Organization
Healthways
Humana, Inc.
Omnova Solutions, Inc.
Outcomes Pharmaceutical Health Care
Prescription Solutions/PacifiCare
Rite Aid Corporation
Supervalu Pharmacies, Inc.

Phase Two Participants
AveMed Health Plans
Blue Cross Blue Shield of Minnesota
Caremark
Catalyst Rx
Coventry Health Care, Inc.
Healthways
Humana, Inc.
Kaiser Permanente–California Region
McKesson Corporation
Medco Health Solutions of Columbus North, Ltd.
Member Health, Inc.
Outcomes Pharmaceutical Health Care
Perform Rx
PharmMD
Prescription Solutions/PacifiCare
SelectHealth/Intermountain Healthcare
Tufts Health Plan
Wellpoint, Inc.
# 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 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. 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 Department of Veterans Affairs hospitals and clinics, health plans, integrated health systems, hospitals, and community pharmacies. Examples include the following:

1. 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.

2. 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.

3. 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.

4. 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. 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. 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.

What is lacking today is a clear identification of what elements would constitute a sound medication therapy management program. From a programatic 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 services 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.
   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. **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.

4. **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)

5. **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.

REFERENCES

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 Part D 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.
Sound Medication Therapy Management Programs, Version 2.0
With Validation Study

The Academy of Managed Care Pharmacy is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. This activity will award 0.10 CEU (1.0 contact hour) of continuing pharmacy education credit. Statements of credit will be issued automatically online. ACPE Universal Program No. 233-000-07-064-H01-P. (Release date: January 2, 2008; Expiration date: January 2, 2009)

Continuing Education for this program is processed solely through the AMCP.org Online Learning Center site at www.amcp.org (Learning Center/Online CE). No mailed forms will be accepted.

The posttest worksheet (below) is provided to assist you in marking your answers prior to entering the online CE center for submission; these pages cannot be submitted for CE credits.

In order to receive CE credit for this program, you must complete the following forms online:

1. Posttest form for this program, “Sound Medication Therapy Management Programs, Version 2.0 With Validation Study” on the AMCP.org Online Learning Center site. To receive CE credit, you must receive a score of at least 70%. You will have 2 opportunities to pass the posttest.

2. Program Evaluation form.

Upon successful completion of this program, you will automatically receive your CE statement. Your CE credits will be automatically archived and tracked for you on the AMCP.org Online Learning Center site. All information is kept confidential. There is no cost for participating in this activity.

Posttest Worksheet: Sound Medication Therapy Management Programs, Version 2.0 With Validation Study

1. AMCP and NCQA undertook this project to
   a. draw conclusions about the effectiveness of specific methods that MTM programs employ.
   b. assess and validate the principles in the consensus document Sound Medication Therapy Management Programs.
   c. measure the outcomes of MTM services provided to Medicare Part D beneficiaries.
   d. evaluate the quality or effectiveness of the MTM programs that participated in the study.

2. MTM, care management, and disease management recognize the ongoing needs of patients with chronic conditions by
   a. using comprehensive information on each patient to identify patients with potential need for assistance.
   b. relying on health professionals representing various disciplines coordinating assistance for a single patient.
   c. making ongoing contact with the patient to offer assistance that does not require the patient’s decision to initiate a visit to a health professional.
   d. all of the above.
3. Which of the following is not one of the “important features of an MTM program” as identified in the Sound Medication Therapy Management Programs document?  
   a. Patient-centered approach  
   b. Communication  
   c. Evidence-based medicine  
   d. Enrollment criteria

4. For the self-assessment survey used in Phase Two of the project, AMCP and NCQA included  
   a. both large and small programs.  
   b. only programs that were NCQA-accredited.  
   c. primarily programs based operating within health plans.  
   d. only MTM programs associated with Part D providers.

5. Patients eligible for Medicare-defined MTM must have which of the following:  
   a. At least 4 chronic conditions  
   b. At least 8 prescribed medications  
   c. A likelihood of incurring costs for prescriptions above $4,000 in a calendar year  
   d. Be enrolled in a Medicare Advantage plan

6. In Phase One, key informants stated that  
   a. it is desirable for MTM programs to have flexible eligibility criteria.  
   b. eligibility criteria should be the same across all Medicare Part D plans.  
   c. MTM programs should have structured services across all populations.  
   d. the limitations of the Medicare eligibility criteria were appropriate.

7. Use of evidence-based medicine was found to  
   a. be a weakness of the programs surveyed.  
   b. be a basis for interventions in half of the programs.  
   c. include online decision support in all programs.  
   d. include clinical guideline dissemination in 18 of 20 programs.

8. To determine eligibility,  
   a. one half of the MTM programs surveyed used pharmacy claims data to identify and target patients.  
   b. some MTM programs inferred the presence of chronic conditions from the medication pattern.  
   c. 15 MTM programs used medical claims data.  
   d. all MTM programs had diagnoses data available.

9. In response to questions regarding the extent that MTM programs require plans to opt in or opt out, plans indicated that  
   a. most programs used opt-out exclusively.  
   b. most programs used opt-in exclusively.  
   c. in-person services are opt-in by necessity, as the patient must decide to take advantage of the service.  
   d. participation rates varied, with a range of 25% to 50%.

10. In response to questions about the types of practitioners who coordinate and provide MTM services,  
    a. most of the programs surveyed were created and operated by pharmacists.  
    b. only half of the programs use pharmacists to deliver services to patients.  
    c. no programs require additional training for pharmacists.  
    d. all programs use nurses to deliver services.