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Exploratory Research on Medication Therapy Management

Final Report

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Abt Associates Inc.
55 Wheeler Street
Cambridge, MA 02138-1168

Prepared for
Steven A. Blackwell
Centers for Medicare and Medicaid
Services (CMS)
7500 Security Boulevard
Mail Stop C3-20-17
Baltimore, MD 21244-1850

Prepared by
Andrea Hassol
Sarah J. Shoemaker

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Executive Summary

The Medicare Modernization Act of 2003 (MMA)¹ requires prescription drug plans (PDPs) and Medicare Advantage plans that offer prescription drug coverage (MA-PDs) to have a Medication Therapy Management Program (MTMP), to improve medication use and reduce adverse events for high-risk beneficiaries. CMS contracted with Abt Associates to explore the evolving field of Medication Therapy Management Programs. During 2007–2008 Abt researchers reviewed 59 publications about Medication Therapy Management (MTM), interviewed 60 individuals from 46 different organizations, and conducted four in-depth case studies.

Key Findings

MTM Organizational Practices and Models

The pharmacy industry associations² are converging on a definition of a Medication Therapy Management Program, with the following nine main elements (Bluml, 2005):

- Performing or obtaining necessary assessments of the patient’s health status.
- Formulating a medication treatment plan.
- Selecting, initiating, modifying, or administering medication therapy.
- Monitoring and evaluating the patient’s response to therapy, including safety and effectiveness.
- Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events.
- Documenting the care delivered and communicating essential information to the patient’s other primary care providers.
- Providing verbal education and training designed to enhance patient understanding and appropriate use of medications.
- Providing information, support services, and resources designed to enhance patients’ adherence with their therapeutic regimens.
- Coordinating and integrating medication therapy management services within the broader health care-management services being provided to the patient.

These elements do not offer guidance as to which patients are most likely to benefit from MTM, nor do they address enrollment mechanisms that optimize participation among eligible patients. This definition takes no stance on reimbursement mechanisms or amounts, but does broadly advocate the MTM services that should be provided to patients (e.g. Comprehensive Medication Reviews, patient education). Perhaps

¹ PL 108-173

² Academy of Managed Care Pharmacy (AMCP), American Association of Colleges of Pharmacy (AACCP), American College of Apothecaries, American College of Clinical Pharmacy (ACCP), American Society of Consultant Pharmacists (ASCP), American Pharmacists Association (APhA), American Society of Health-System Pharmacists (ASHP), National Association of Boards of Pharmacy (NABP), National Association of Chain Drug Stores (NACDS), National Community Pharmacists Association (NCPA), and National Council of State Pharmacy Association Executives (NCSPA).

most importantly, this consensus definition does not specify the outcomes MTMPs should be designed to achieve, or how to measure these outcomes.

There are a variety of practice models in the literature and in current MTMPs, each with different attributes. There does not yet appear to be an identifiable set of clearly defined models that are reasonably stable and mutually exclusive. The practice models vary on the following dimensions: primary focus, MTM service providers, intervention frequency, service delivery mode, reconciliation with prescribers, additional education and support, and disease state monitoring.

Targeted Patients, Eligibility Criteria and Enrollment Mechanisms

Medicare, Medicaid and employer MTMPs serve different populations and may have different objectives. For example, a leading employer MTMP aims to reduce absenteeism and improve productivity, which are not relevant objectives for Medicare. There is minimal research to indicate which Medicare patients are most likely to benefit from MTM, and as a result there is wide variability in the eligibility criteria currently in use. Several studies show promising (but inconsistent) results for patients with diabetes and hyperlipidemia, and many Medicare MTMPs include these two conditions among their eligibility criteria – along with other conditions for which there is less evidence in the literature.

There are differences between Medicare MTMPs and those from non-Medicare sectors, relative to eligibility criteria. Medicare statute requires that Medicare MTMPs use (at a minimum) the following three eligibility criteria:

- Have multiple chronic conditions, and
- Be taking multiple Part D drugs, and
- Are likely to incur annual costs of at least \$4000 for all covered Part D drugs

All Medicare MTMPs must include \$4,000 annual medication costs as an eligibility criterion. All Medicare MTMPs we interviewed also specify the number (and often the type) of chronic conditions that confer MTM eligibility; they all specify a minimum number of Part D medications that determine eligibility for MTM; and some require that the drugs being taken relate to the chronic conditions of concern. In contrast, it is uncommon for employer programs to specify numbers of medications or numbers of chronic conditions as eligibility criteria, and while some focus on “high cost” patients, none appear to use a specific drug cost threshold for MTMP eligibility.

MTMPs that require an affirmative “opt in” step have had varying success, with some enrolling less than 10% of eligible patients. Based on our case studies, it appears that MTMPs favoring an “opt out” or “automatic enrollment” approach achieve higher enrollment. An industry study similarly found that the “opt out” method produces much higher enrollment than an “opt in” approach.³ Some MTMPs rely on pharmacists to identify patients for MTM from among those who are eligible (or from among a plan’s entire population). In the state Medicaid MTM program we studied, this approach has been only marginally successful, in part due to low pharmacist participation. Similarly, an MTM vendor identifies eligible patients and sends the list of patients to the pharmacists who then offer MTM to the patients.

³ Academy of Managed Care Pharmacy. (2008). Sound Medication Therapy Management Programs, Version 2.0 with Validation Study. *Journal of Managed Care Pharmacy*, 14(1), S1-S44.

MTM Components and Services

Most MTMPs start with a comprehensive medication review (CMR), at entry to the program and (usually) annually thereafter. Most MTMPs also include reconciliation of drug therapy issues with prescribers; some include patient education and monitoring, laboratory tests to monitor progress, or other services. The evidence to-date does not allow us to determine whether annual CMRs with prescription reconciliation are sufficient to accomplish clinical goals, or whether other follow-up services are important contributors to clinical outcomes.

There is a divide in the industry between MTMPs that pursue face-to-face interventions, and those that rely largely on telephone or mail; we did not identify any research that rigorously tested different modes of service delivery. MTMPs that rely on face-to-face interactions may be better able to overcome language and literacy barriers by relying on accompanying family or friends to interpret for patients with these issues; this is not as easily accomplished by telephone. On the other hand, telephone interventions can reach patients in remote locations, those who are homebound or lack transportation to a pharmacy offering MTM, and those who choose to use mail-order pharmacies. Mail interactions are asynchronous and as a result are rather limited, and may at best be able to promote a conversation between patient and physician. Some MTMPs use multiple modes of intervention, flexibly tailoring their approach to meet patient needs. One industry organization's recent validation study recommended that face-to-face MTM no longer be emphasized (the previous industry position), recognizing that some MTMPs do not offer MTM face-to-face or perhaps implicitly acknowledging that other modes may be necessary to meet the needs of all patients.⁴

MTM Service Providers

We located only one MTMP that uses physicians as MTM providers; all others rely on pharmacists. A few MTMPs augment pharmacists with nurses at a call center, who phone patients to encourage and monitor medication adherence; others refer complex cases to nurse case-managers and/or multi-disciplinary teams.

Coordination of MTM with Disease/Care Management

Medicare beneficiaries served by MTMPs may also participate in chronic care or disease management (DM) programs. To the extent that these programs overlap, it is desirable to avoid duplication; coordination may produce optimal outcomes for patients served by both programs. In non-Medicare sectors, separate MTMPs are uncommon and it is unusual to have differing eligibility criteria for chronic care patients who can/cannot receive medication therapy management. Opportunities for MTM and DM coordination may be greatest in a managed care context where the plan is responsible for both programs and where all providers, including pharmacists, share an electronic health record. Opportunities for coordination between programs may be fewer when MTM is "carved out" to a separate vendor and implemented by community pharmacists. This may be due in part to data sharing issues, which are potentially easier to overcome with a shared record.

⁴ Academy of Managed Care Pharmacy, (2008), IDEM.

MTM for Nursing Home Patients

Part D plans are required to offer MTM services to eligible institutionalized patients, but there is overlap with the responsibilities of consultant pharmacists. Most Medicare MTMPs do not fully integrate MTM with nursing home care, or collaborate with nursing home consultant pharmacists, and none appear to interact directly with nursing home staff to improve medication therapy.

Reimbursement & Documentation

Most MTMPs appear to be using either a variant of fee-for-service reimbursement, or salaried in-house pharmacists. There is no research about the reimbursement approaches (e.g. per-case, fee-for-service), or the dollar amount needed to actively incentivize pharmacist engagement in MTM without inducing unnecessary service provision. We studied two MTMPs (one Medicaid MTMP and a national MTM vendor) that have somewhat similar fee schedules for pharmacist reimbursement, but very different rates of pharmacist participation. Reimbursement alone does not appear to be sufficient to motivate involvement in MTM, but other factors (e.g., training requirements, cost of documentation systems) are likely to be important.

Documentation systems vary and many are web-based, although at least one national pharmacy chain prohibits transmittal of patient-level information over the Internet. A few of the larger web-based MTM documentation systems are now accumulating substantial patient-level databases which could be used to address many MTMP design questions, and perhaps to evaluate patient outcomes as well.

Outcomes and Evaluations

There is minimal evaluative research as yet from Medicare MTMPs, which are in their third year of operation.

Costs are commonly measured in the MTM literature (although in different ways), including: prescription drug costs, total medical costs, return on investment, and estimated costs avoided. Findings are inconsistent and input costs (e.g. pharmacist reimbursement, program administration) are usually not included in these cost estimates.

A few clinical status measures appear frequently in the published MTM literature: Hemoglobin A1C (HbA1C) levels, LDL and total cholesterol levels, and blood pressure. Of all the research on MTM, the evidence appears to be strongest regarding the impact of MTM on a few clinical measures, notably HbA1C and LDL cholesterol, which can be considered intermediate outcomes. Removing drugs from the BEERS list, identifying over-use and under-use, reducing sick/absent days from work, and “avoiding” services like emergency department visits or hospitalizations, are also common outcomes in MTMP literature, but less so among Medicare MTMPs.

A few well-designed studies have demonstrated significant improvements in intermediate outcomes (e.g. lower cholesterol, blood pressure, blood glucose); even fewer have demonstrated effects on serious sequelae (hospitalizations, adverse drug events, mortality). Many of the studies and programs with significant findings were implemented in non-Medicare populations (e.g. working-aged people, Veterans) or concerned patients with only one chronic condition (e.g. diabetes), and thus are not directly relevant for the Medicare population as defined by statute.

Information Needed for Program Improvement

Targeting patients likely to benefit from MTM would be improved by more information regarding which patients are most likely to benefit from MTM – those for whom health status, cost, or other outcomes are most likely to improve following MTM.

MTM services could be more clearly specified with additional information regarding the degree of improvement that can be expected from a Comprehensive Medication Review alone, and how much additional improvement occurs when other MTM services are added (e.g. patient education, monitoring, or follow-up, prescriber consultation). It would be useful to know how frequently pharmacists must interact with patients to achieve desired outcomes, and what sort of maintenance schedule is needed to prevent the erosion of initial improvements. It would be equally useful to know what the differential impacts are between face-to-face MTM and telephonic MTM (in terms of health and/or cost), and whether either is significantly better than mailed MTM recommendations.

There is no information about the level of reimbursement (dollar amount) that will overcome pharmacists' opportunity costs and incentivize MTM participation. There have been no tests of differing reimbursement schemes, such as per-case versus fee-for-service reimbursement. More information is needed about both the amounts that may need to be paid, and the most effective methods for reimbursing pharmacists, which would galvanize participation without inducing provision of unnecessary services.

Many MTMPs have selected outcomes of interest to measure for their programs. These range from patient satisfaction, to detailed studies of changes in hospital and physician utilization and lab values, compared with non-MTM control groups. A number of Medicare MTMPs we interviewed are awaiting guidance from CMS, before developing data collection for outcomes measures.

Implications for Medicare

All Medicare MTMPs we studied are following CMS guidelines and targeting patients with multiple chronic conditions, multiple Part D drugs, and \$4,000+ per year of anticipated drug spending, but there is wide variability in specific eligibility criteria. Although there is no evidence of discriminatory exclusion criteria among Medicare MTMPs, some favor very strict eligibility criteria and an “opt in” enrollment approach that may limit beneficiary access to MTM services.

Beneficiaries who are eligible for, and participating in their drug plan's MTMP, will receive services in different ways, depending on the Medicare drug plan they enroll in. Services may be restricted to face-to-face interventions, may be offered by telephone or by mail, or a combination of all three modes. Given the diverse composition of the Medicare population, a multi-mode approach to service delivery may offer the greatest flexibility to meet beneficiaries' needs.

Coordination with disease management poses a challenge for some Medicare prescription drug plans, especially those that do not have operational responsibility for the disease management program (e.g. stand-alone prescription drug plans). Several health plans that serve both Medicare and non-Medicare populations do not offer a separate MTM *program* to their non-Medicare members; they incorporate MTM into their other care/disease management programs. They make the MTM-DM programmatic distinction for their Medicare population only, because the structure of their Medicare contracts requires distinctly separate programs.

Although a few MTMPs attempt to offer services to patients in nursing homes, most agree that there is an overlap – and potential conflict – between MTM services supported by a Part D drug plan, and drug regimen reviews conducted by nursing home consultant pharmacists. Some non-Medicare MTMPs do not support MTM for nursing home patients, because they consider it duplicative.

Each Medicare MTMP is collecting data on patient-level outcomes; virtually all are interested in drug costs, but there is little uniformity regarding other outcomes of interest. Some Medicare MTMPs are conducting careful research with strong methodological designs to learn from their early experiences, and others are rapidly accumulating large databases, all of which could be of benefit to CMS, in refining the Medicare MTM program.

1. Introduction and Background

The Medicare Modernization Act of 2003 (MMA)⁵ requires prescription drug plans (PDPs) and Medicare Advantage plans that offer prescription drug coverage (MA-PDs) to have a Medication Therapy Management Program (MTMP), in order to improve medication use and reduce adverse events for select beneficiaries. Section 1860D-4 identifies the following criteria for targeting eligible beneficiaries for MTMPs: having multiple chronic conditions, taking multiple Part D medications, and being likely to incur annual costs of at least \$4,000 per year (the Secretary's predetermined amount through CY2009).

Under section 423.153(d), a Medicare Part D sponsor must establish an MTMP that:

- Optimizes therapeutic outcomes for targeted beneficiaries through improved medication use.
- Reduces the risk of adverse events.
- Is developed in cooperation with licensed and practicing pharmacists and physicians.
- Describes the resources and time required to implement the program if outside personnel are being used, and establishes the fees for pharmacists or others.
- May be furnished by pharmacists or other qualified providers.
- May distinguish between services in the ambulatory and institutional setting.
- Is coordinated with any care management plan established for a targeted individual under a chronic care improvement program.

The MTMP initiatives undertaken by prescription drug plans and others may offer insights to inform testing of alternative payment and other regulatory strategies in the future. As a first step, CMS contracted with Abt Associates to conduct an exploratory study of Medication Therapy Management (MTM), to better understand the landscape of MTMPs, their components, and their outcomes.

The MMA sections cited above contain several principles that guided this investigation of MTMPs. We explored MTM models (in Medicare PDPs and elsewhere) that are designed by a pharmacist or physician and that, at a minimum, aim to optimize patient outcomes through use of medications, and to prevent adverse drug events. The focus was on MTM models that address medication issues for patients with multiple conditions, multiple drugs, and/or high costs. Also, for purposes of this project, we targeted MTM only, and distinguish it from disease management (DM) and drug utilization review.⁶

This exploratory study aims to address the following broad research questions:

1. Is there a working definition of MTMPs?
2. Which MTMPs or program features are effective, what criteria are used to evaluate effectiveness, and how strong is the evidence?

⁵ PL 108-173

⁶ By contrast, disease management programs generally strive to increase clinician and patient compliance/adherence with clinical practice guidelines, and virtually always include patient education for self-management, which may not be appropriate for all patients in an MTM program. Drug utilization review (DUR) focuses on drug interactions and avoiding adverse events, but may not specifically target patients with multiple conditions and high costs.

3. Are effective MTMP features from private and other public programs applicable to Medicare Part D? If not, why not – what barriers prevent effective features from being adopted by Part D plans?
4. How do MTMPs differ from disease management programs and/or other care management activities? Are MTM services provided as part of a broader disease management program, or specifically as an MTMP? What is the role of the pharmacy benefit management (PBM) firm? Is there integration between MTMP and other health care benefits and coverage?
5. How are MTMPs paid for? Are there any specific incentive arrangements that are applied? How are savings measured? Who benefits from the savings that result?
6. How are MTMP practice models, or components thereof, determined or defined?

Exhibit 1 displays the specific research domains and relevant research questions for this study:

We reviewed the literature and conducted interviews to answer these questions. Fifty-nine documents were reviewed for this Information Scan, and interviews were conducted with 60 representatives from 46 organizations (in some cases multiple interviews were conducted with staff from one program). In-depth case studies were also conducted with four MTMPs: one Medicaid MTMP, one MTM vendor, and two MA-PDs.

Throughout this report, MTMPs operated by Part D prescription drug plans are referred to as Medicare MTMPs, and those operated by other entities are referred to as non-Medicare MTMPs or by their sponsor type (e.g., Medicaid MTMPs).

The remainder of this report is organized as follows:

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|---------------|--|
| Chapter 2 | Methodology (also see Appendix A) |
| Chapter 3 | Brief summary of information collected from the literature, interviews and case studies (also see Appendix B) |
| Chapters 4-10 | Detailed findings about MTM operations (eligibility criteria, enrollment mechanisms, services, providers, reimbursement) |
| Chapter 11 | Outcomes and evaluations of MTMPs |
| Chapter 12 | Summary of key findings and implications for Medicare |

Exhibit 1: Research Domains and Research Questions

Research Domains	Research Questions
Organization	<p>What type of entity/organization administers the MTMP?</p> <p>What Part D plan(s) does the organization offer?</p> <p>How many beneficiaries does the organization serve?</p> <p>What is the role, if any, of the PBM?</p> <p>Does a third-party (outside) vendor administer the MTMP? What type of vendor (e.g., MTM, DM)?</p> <p>How long have the MTMPs been offered? Did they evolve from earlier programs? How have they changed over time?</p>
Targeted Patients and Eligibility Criteria	<p>What are the criteria for MTMP eligibility, including chronic conditions, drugs, and costs?</p> <p>How are beneficiaries identified and targeted to receive MTMS? How often are beneficiaries identified/targeted?</p> <p>Are beneficiaries identified from pharmacy claims or is additional information from health care providers needed?</p> <p>Are eligible beneficiaries referred? If so, how are they referred and by whom?</p> <p>How are beneficiaries recruited (e.g., opt-in versus opt-out)?</p>
MTM Components and Services (MTMS)	<p>What is the organization's operational definition of MTM?</p> <p>What services are provided by the MTMP (e.g., assessing patient health status, formulating prescription drug treatment plans, managing high-cost specialty medications, etc.)?</p> <p>What are the modes of service delivery (e.g., telephone, face-to-face)?</p> <p>How integrated and comprehensive are the MTM services?</p> <p>Are the MTM services individualized both in nature and frequency?</p> <p>What is the frequency of the services provided (e.g., follow-up)?</p> <p>What is the setting of the MTM service? Are services provided in house?</p> <p>What are the interventions? Who is the recipient of the intervention (e.g., provider, beneficiary, or both)?</p> <p>How have MTMPs and services evolved (e.g., since the initial implementation of Part D)?</p>
MTM Service Providers	<p>What provider type (e.g., pharmacist) is responsible for delivering MTM services?</p> <p>What professional degrees and licenses does the MTMS provider have? Is the MTMS provider certified or trained to provide MTMS? Is the MTMS provider <i>required</i> to be certified/trained to provide MTMS?</p> <p>To what extent are MTM services coordinated with efforts of a patient's other health care providers? How does the MTMS provider collaborate, if at all, with the beneficiary's physician? Are beneficiaries' physicians receptive to this service?</p>
Coordination with Disease Management (DM)	<p>What is the relationship between MTMPs and disease management (e.g., CCIP) or Medicare Health Support programs? How do they differ?</p> <p>Are MTMPs generally part of a broader disease management program, or are they a separate and unique feature of the insured product?</p> <p>Are individuals enrolled in both disease management programs and MTMPs, or are they mutually exclusive programs in terms of enrollment?</p> <p>If individuals are enrolled in both, how are interventions and advice coordinated?</p>

Exhibit 1: Research Domains and Research Questions

Research Domains	Research Questions
Special Populations	How are MTM services provided to individuals who receive their medications from mail- order pharmacies?
	How are MTM services provided to individuals who reside in institutional settings?
	How are MTM services tailored to patients with especially costly chronic diseases (e.g., HIV/AIDS)?
	How do MTMPs offered by SNP MA-PDs address the special needs of their enrollees (e.g., TTY, Braille, translations)?
Financial Arrangements & Reimbursement	How is the organization/entity administering the MTMP reimbursed?
	How are the MTMS providers reimbursed?
	What are the financial arrangements and incentives in the MTMP? What goals or targets are set in order to distribute incentives? What measures exist for this purpose?
	Do any of the arrangements include a pay-for-performance component?
Outcomes and Evaluation	How are savings measured? Who benefits from the savings that result?
	What are the anticipated outcomes of MTMPs, including measurable health outcomes?
	Is there any early evidence that the composition of MTMPs or specific components thereof, is particularly promising in terms of impact on health outcomes/costs?
	What documentation is maintained? Is it a specific documentation system? Can it be used to evaluate effectiveness?
	What types of analyses do Part D plans and other MTMPs routinely conduct to determine the effectiveness of MTM?
	What criteria and study designs are used to evaluate MTMPs (comparison groups, pre/post data)? What is the duration of MTM in evaluations to date, and how many patients have been involved? Are improved outcomes statistically significant?
Applicability to Medicare Part D	How are MTMPs assessed to determine if they reduce the risk of adverse events and if they optimize therapeutic outcomes for targeted beneficiaries? What actions are taken to adapt or revise MTMPs based on findings?
	What have been the successes and challenges of particular MTMPs?
	Which worthwhile MTMP features are applicable to Medicare Part D plans? Are these features common in Part D MTMPs? If not, why not?
	Which worthwhile MTMP features are not applicable to Medicare Part D? What barriers exist to implementing these features in Part D plans? How might these barriers be overcome?

2. Methodology: Literature, Interviews and Case Studies

This project involved a literature review, key informant interviews and in-depth case studies. A summary of these methods is provided below. See Appendix A for a more detailed description of the methodology.

2.1. Literature Review

To gain a full understanding of the current landscape of MTMPs, and to identify respondents for the key informant interviews, Abt Associates scanned both published and unpublished literature by searching several web-based information sources: the PubMed database; websites of pharmacy associations and organizations; the Google search engine for references to pharmaceutical companies, Pharmacy Benefit Managers (PBMs), Prescription Drug Plans (PDPs), Medicare Advantage Prescription Drug Plans (MA-PDs), Special Needs Plans (SNPs), and MTM vendors.

A PubMed search was conducted to locate recent literature on Medication Therapy Management. With a few exceptions, the search was limited to include literature that was in English, focused on adults (19 and older), and published between January 1, 2000 through July 15, 2007.⁷ The literature may not necessarily identify similar programs and services that aim to optimize therapeutic outcomes through improved medication use and reduced risk of adverse events for patients as “Medication Therapy Management”. Therefore, the PubMed search used the following keywords to capture literature that describes MTM and related programs by a different name:

- medication therapy management
- comprehensive medication therapy management
- pharmaceutical care
- drug regimen review
- cognitive pharmaceutical services
- cognitive pharmacy services
- medication management (not “administration”)
- drug utilization review (not “hospital”)⁸

These search terms and criteria returned 618 different articles. The titles and abstracts were further reviewed for relevance to our study objectives. We excluded very small studies, those focusing on a single drug or drug class (e.g., colestipol, antibiotics), those concerning drug regimen reviews

⁷ Several seminal pieces published prior to 2000 were included.

⁸ “Medication management” sometimes refers to the distribution of medications by nurses in a nursing home, and we excluded articles about administering medications. Articles focused on DUR in the hospital setting were excluded because the focus of this study was on the ambulatory and nursing home patients, not hospitalized patients.

conducted by nursing home consultant pharmacists, and those that simply describe the process of MTM. Publications concerning the rate of drug therapy problems in a population were also excluded, as were studies of the ability or willingness of pharmacists to provide cognitive services, unless the publication also described the results of MTM interventions. Some examples of articles deemed irrelevant include:

- Programs/services in a country outside the U.S.
- Medication use and utilization patterns (i.e., pharmacoepidemiology studies)
- Medication safety studies
- Prescribing studies (e.g., inappropriate prescribing, guidelines, prescriber education)
- Studies narrowly focused on adherence/compliance without mention of other medication therapy management
- Disease management programs without specific mention of MTM or similar services
- Community-based care management programs that do not address medication therapy management
- Pharmacist-physician collaborative practice descriptions that are not within an MTMP

The remaining publications were further limited to those that included more than 100 patients or study subjects.

We also searched the bibliographies of key peer-reviewed publications for seminal pieces from the 1990s. We included a few rigorous and important publications that concerned patients with a single chronic condition (e.g., reactive airway disease, heart failure) rather than limiting our report to studies about MTM for patients with multiple chronic conditions.

Websites from pharmacy organizations and associations, the pharmaceutical industry, pharmacy benefit managers, and MTM vendors were also explored, and a Google search was conducted to identify other relevant publications and documents (e.g., industry association position statements).

Appendix B contains a bibliography of the publications we reviewed, and detailed descriptions of many of the most salient publications containing evidence about MTM effectiveness.

2.2. Key Informant Interviews

The purpose of the key informant interviews was to understand MTMPs and the delivery and financing of MTMPs and services, from the vantage point of individuals involved in creating, managing, or evaluating these programs. We conducted 60 informal interviews with representatives from 46 organizations including: pharmacy associations and other organizations; Medicare prescription drug plans (PDPs), Medicare Advantage prescription drug plans (MA-PDs), Special Needs Plans (SNPs), employers, Medicaid programs, the Veterans Administration, pharmacy chains, long-term care facilities and LTC pharmacies, pharmacy benefit management firms (PBMs), MTM vendors, the DeCIDE MTM trial investigators (funded by AHRQ), and the Quality Improvement

Organization (QIO) Support Center.⁹ CMS approved an initial list of organizations, as well as the number of interviews that should be conducted with each type of stakeholder. Exhibit 2 shows the number of organizations interviewed, by type:

Exhibit 2: Organizations Interviewed

Organization Type	Number of Organizations Interviewed
Pharmacy Associations and Other Organizations	11
Employers	1
Pharmacies	3
LTC Facilities and Pharmacy Providers	3
Medicaid	3
MTM Vendors	3
PBMs	2
QIO	1
VA	1
AHRQ DeCIDE	1
SNPs	4
PDPs / MA-PDs	13
TOTAL	46

After selecting the organizations of interest we identified a senior representative from each organization with knowledge of the MTMP; in some cases two or more people from an organization participated. Appendix A describes the criteria for selecting specific organizations, and the process used to identify key informants within each organization type.

Interview protocols were created to collect descriptive information about MTMPs, and also to obtain perspectives on MTM’s successes and challenges. The protocols varied slightly across organization types since an MTM program administrator could offer different insights than a pharmacist.¹⁰ Interviews were conducted by telephone between July 1 and September 21, 2007.

2.3. Case Studies

Abt Associates staff conducted detailed case studies with four MTMPs to learn more about “what works” in MTM: how to target patients with the greatest opportunities for improved medication management, how to enroll these patients and provide MTM services, and what outcomes – both cost and quality – can be demonstrated for MTM. Additional topics of inquiry included pharmacist reimbursement, MTM documentation systems, MTM for patients in nursing facilities, and

⁹ Despite repeated attempts, we were not able to identify individuals at private fee-for-service plans who were knowledgeable about MTM.

¹⁰ These interview protocols are available in a separate volume.

coordination between MTM and disease management programs. The four MTMPs were selected for the following reasons:

- Different MTM modalities (telephone, mail, face-to-face);
- Different organizational structures (MA-PD, Medicaid program, MTM vendor);
- Different approaches to coordinating MTM with other disease management programs, and different approaches to serving institutionalized beneficiaries;
- MTMPs which were accumulating evidence about effectiveness, in terms of cost, health status, or other outcomes.

Brief descriptions of these four case studies appear in Chapter 3 and detailed descriptions of these four case studies appear in Appendix C.

3. Information Summary

This chapter contains summaries of the information collected from each of the three primary data sources: literature, key informant interviews and case studies. These three summaries provide background information and context for the remainder of the report, which focuses on key findings, the strength of the evidence about MTM effectiveness, applicability of this evidence for Medicare, and the implications for future research.

Exhibit 3 below illustrates which of the three data sources contained information relevant to each of the research domains. The Exhibit is followed by summaries of the information collected from each of the three data sources.

3.1. Summary of Information From the Literature

In total, fifty-nine (n=59) documents were reviewed for this report; Appendix B contains a bibliography of the literature and documents we reviewed, which included: peer-reviewed literature as well as other publicly-available publications and documents.

The industry, organization and non-research publications (n=33) contained organizational policy statements and descriptions of core MTM program elements, as well as consensus definitions of MTM. The research and evaluation studies (n=26) contributed to our understanding of research design, outcomes of interest in MTM, how these outcomes are measured, and the strength of evidence that currently exists about the impact of MTM. Most of the peer-reviewed literature studied the value of MTM services provided by pharmacists; fewer studies evaluated MTM *programs*. Moreover, some of the literature focused on non-Medicare populations (e.g. working-aged people) and may be less relevant for Medicare.

CMS is particularly interested in the strength of evidence about MTM outcomes. The following broad categories of measures and outcomes were frequently reported in the literature we reviewed:

- **Process Measures** in MTM studies included types of problems identified by pharmacists, pharmacist recommendations, utilization (counts of MTM interventions), etc.
- **Intermediate Outcomes** included the percent of pharmacist recommendations that were accepted by prescribers, patient compliance or adherence, reduction in number of medications, switching to less costly medications, and patient knowledge/understanding. Intermediate outcomes also include common clinical indicators for asthma, diabetes, blood pressure, and other chronic conditions.
- **Economic Analyses, ROI & Cost Savings** primarily included medication costs and savings, total medical/health care costs, estimated costs avoided through MTM and return on investment.
- **Other Measures** of interest in the MTM literature included performance measures, productivity, patient and prescriber satisfaction, and quality of life.

Exhibit 4 illustrates which of these five types of outcomes were addressed by the 26 publications which presented findings on 17 different MTMPs or MTM studies (e.g., findings on the Asheville project were presented in four publications we reviewed).

Exhibit 4: Summary of Outcome Measures Included in MTM Publications

Publication Title, Lead Author & Year	Process Measures	Intermediate Outcomes	Intermediate Clinical Outcomes ¹¹	Economic Outcomes, ROI & Cost Savings	Other Measures
Iowa Pharmaceutical Case Management Program. Becker et al. 2004; Carter et al. 2006; Doucette et al. 2005	X	X			
IMPROVE: A Study at Veteran's Administration Medical Centers Billups et al. 2000; Ellis, Billups, et al. 2000; Ellis, Carter, et al. 2000.	X	X	X		
Project IMPACT – community pharmacy-based demonstration. Bluml et al., 2000.	X	X	X		
The Asheville Project. Bunting & Cranor, 2006; Cranor et al., 2003; Cranor & Christensen, 2003a; Cranor & Christensen, 2003b.		X	X	X	X
North Carolina polypharmacy initiative. Christensen et al. 2004 Trygstad et al. 2005.	X	X		X	
Outcomes-based Pharmacist Reimbursement: Reimbursing Pharmacists for Cognitive Services. Farris et al. 2002.	X				
Pharmaceutical Care in an HMO. Fischer, et al. 2002.	X	X			
Evaluating Effectiveness of the Minnesota Medication Therapy Management Care Program. Isetts, 2007	X	X			X
Outcomes of Pharmacists' Cognitive services in the long-term care setting. Johnston et al.1996;		X			X
The Impact of Clinical pharmacists' Consultations on Physicians' Geriatric Drug Prescribing. Lipton et al. 1992.		X			
An Evaluation of Managing and Educating Patients on the Risk of Glucocorticoid-Induced Osteoporosis. McDonough et al. 2005.		X			
Medication adherence in heart failure patients Murray et al., 2002.		X			
Geriatric evaluation and prescription management for the Frail Elderly Schmader et al. 2004.		X			
Senior pharmacy assistance program, Durham NC. Smith, et al. 2004.		X		X	X
PRICE pharmacy clinic for low-income seniors Stebbins et al. 2003.	X				
Clinical pharmacist services in a multi-site primary care medical group. Walker & Willey, 2004.		X			
Hypertension Outcomes through BP Monitoring& Evaluation by Pharmacists (HOME Study) Zillich et al. 2005			X		

An accompanying table (Exhibit 12) can be found in Chapter 11, which describes the design of each of these studies, the outcomes measured in each, and whether the findings were statistically significant.

¹¹ Only statistically significant findings are presented for clinical outcomes, economic outcomes and cost savings.

3.2. Summary of Information From Key Informant Interviews

The purpose of the key informant interviews was to understand MTM and the delivery and financing of MTM programs and services, from the vantage point of individuals involved in creating, managing, or evaluating these programs. We interviewed 60 representatives from 46 organizations in the following sectors:

- Medicare Part D prescription drug plans
- Medicare Advantage plans and Special Need Plans
- Pharmacy benefit management firms and MTM vendors
- Employers operating MTM programs
- Medicaid MTM programs
- Pharmacy chains, long-term care pharmacies and long-term care facilities/chains
- Researchers and QIOs
- Veterans Administration MTM program staff
- Representatives from the pharmacy and pharmacist industries

The data collected from these interviews primarily focused on MTMP components, the MTM outcomes of interest, and the data being used to assess the effectiveness of MTMPs. A few of the key informants were also able to comment on MTM for special populations, such as long-term care patients.

The different key informant types varied in terms of which research domains they offered insights about (also illustrated in Exhibit 3 above).

- ***Eligibility Criteria and Enrollment:*** Information on MTM eligibility criteria was primarily obtained from the Medicare plans, PBMs, employers, Medicaid programs, and MTM vendors, who directly administer (or contract) MTMPs. Medicare MTMPs have the most elaborate eligibility criteria; those in other sectors may focus on specific conditions, but rarely include numbers of drugs or dollar thresholds as criteria for MTM entry. Insights about the enrollment of patients in MTMPs were offered by these same types of respondents, as well as pharmacies who often complete patient enrollment into MTMPs. “Opt out” approaches appear to facilitate enrollment better than “opt in” requirements.
- ***MTM Services & MTM Providers:*** All key informants contributed to the understanding of MTM services and providers. With a few exceptions, MTM is provided by pharmacists in all types of MTMPs. Services generally begin with a comprehensive medication review, but there is less uniformity regarding the other services covered/offered by MTMPs.
- ***Billing/Reimbursement & Documentation Systems:*** The pharmacy-related key informants (e.g., pharmacy associations, pharmacies) and those who administer MTMPs, provided input about the documentation, billing, and reimbursement for MTM services. Some MTMPs use salaried pharmacists to provide services and the rest use some variant of fee-for-service reimbursement; none appear to use per-case reimbursement mechanisms. Documentation system requirements range from straightforward bills to detailed patient-provided histories, to laboratory test results. Many documentation systems are now web-based.
- ***Coordination with Disease or Care Management:*** The informants involved with specific MTMPs (SNPs, MA plans, PDPs, etc.), as well as the V.A., provided insight on the coordination of MTM with disease/care management programs and services. Medicare MTMPs vary widely in the degree to which they coordinate MTM and DM; the opportunities

for coordination appear to be greatest when all providers (including pharmacists) share an electronic health record.

- ***MTM for Nursing Home Patients:*** Information on MTM for nursing home patients was obtained primarily from MTMPs, most of whom do not integrate MTM for institutionalized patients with the recommendations of nursing home consultant pharmacists. In addition, long term care facilities/chains, pharmacies and LTC pharmacies, and associations representing LTC consultant pharmacists, offered insights about provision of MTM in nursing homes.
- ***Outcomes Measured:*** Researchers, QIOs, MTM program directors, the VA, and industry representatives all offered opinions about appropriate outcomes of MTM and how best to measure these outcomes. Additionally, the MTM vendors specified which outcomes they focused on to demonstrate effectiveness to their clients. While most MTMPs measure drug costs, there is little consistency in terms of other outcomes measured.
- ***Evidence of Effectiveness:*** The evidence of effectiveness on MTM was not directly obtained from key informants, although some informants did reference evaluations previously conducted about their programs. Researchers from QIOs and the AHRQ DeCIDE MTM clinical trial advised about study design and early findings regarding evidence of MTM effectiveness.

3.3. Summary of Information From Case Studies

Case studies were conducted to obtain more in-depth examinations of four MTMPs to learn more about how MTMPs: target patients with the greatest opportunities for improved medication management, enroll these patients, provide and reimburse for MTM services, and what outcomes – both cost and quality are being measured. The four MTMPs were selected for the following reasons:

- Different MTM modalities (phone, mail, in-person);
- Different organizational structures (MA-PD, Medicaid program, MTM vendor);
- Different approaches to coordinating MTM with other disease management programs, and different approaches to serving institutionalized beneficiaries;
- Different ways of measuring effectiveness, in terms of cost, health status, or other outcomes.

These four programs should not be considered “best practices,” but rather examples of the range of MTMPs in existence. The following exhibit shows the salient characteristics of these four MTMPs. More detailed descriptions of each program can be found in Appendix C.

Exhibit 5. Cross Site MTM Program Features

Operational Features	Program A (Medicaid)	Program B (PDP and MA-PD)	Program C (Multi-state MA plan)	Program D (MTM Vendor)
Eligibility Criteria	4+ Rxs, 2+ chronic conditions, Not eligible for Part D, Not in a nursing home	9+ Rxs (formerly 12), 5+ chronic conditions, >\$4,000/year drug costs	2+ from list of 6 drugs, 2+ from list of 10 cardiovascular conditions, >\$4,000/year drug costs	Varies by client; many make every plan member eligible for MTM
Enrollment Mechanism	Referral by pharmacist or physician	Invitation letter	Invitation letter with telephone follow-up	Automatic enrollment, no Opt in or Opt out (services can be declined)
MTM Services Delivery Mode	Face-to-face MTM	Mailed MTM recommendations, referral to case managers	Telephone MTM	Face-to-face MTM (if not possible, telephone MTM)
MTM for Nursing Home Patients	No	Same letters	Yes, dedicated LTC case managers	Prescriber consultations only
Coordination with Disease Management/Chronic Care Management	No	MTM and DM refer cases to each other	Fully integrated	No

3.3.1. Program A - Medicaid MTM

MTM is defined in this state’s 2005 statute as “the provision of pharmaceutical care services by a licensed pharmacist to optimize therapeutic outcomes of the patient’s medications.” The state program (referred to here as Program A) requires that pharmacists be licensed in the state; have graduated since 1996 (the year that the state university graduated the first students exposed to the pharmaceutical care curriculum), or have completed a comprehensive MTM training program that has both clinical and didactic elements; be practicing in an ambulatory care setting as part of a multidisciplinary team; and use an electronic documentation system that meets state standards.

Pharmacists began enrolling in the state Medicaid MTM program in April 2006, and the first claims for MTM services provided to Medicaid recipients were paid in May 2006.

Eligibility and Enrollment

Medicaid recipients are eligible for Program A if they are taking four or more prescriptions to treat or prevent two or more chronic medical conditions, or are experiencing a drug therapy problem that is likely to result in significant non-drug program costs. Medicaid-sponsored MTM is provided only to recipients who are not eligible for Medicare Part D. Nursing home patients are not eligible for MTM because the state’s Department of Human Services (DHS) believes that this duplicates the services of nursing home consultant pharmacists. After Medicaid recipients are determined to be eligible for MTM services, they remain eligible as long as they have Medicaid coverage, regardless of changes in their health status, drug therapy, or number of prescriptions.

From April 2006 through December 2007, approximately 110 pharmacists applied and were approved by the state to provide MTM. DHS does not identify individuals who meet the MTM eligibility criteria, and Medicaid recipients do not “enroll” into the program. Instead, Medicaid recipients who could benefit from MTM are identified by their pharmacists, physicians, or other providers, and are referred to a participating MTM pharmacist – there is no separate step to “opt in” or enroll in the program.

MTM Services and Reimbursement

MTM services are covered if they are face-to-face encounters in an ambulatory care setting, including a pharmacy, hospital, or clinic. Services provided via telephone, e-mail, mail, or other modalities are not covered, nor are services provided in nursing homes or patient homes. All services must be documented using an electronic system, but only claims (not full documentation) are submitted to the state. DHS defines MTM services to include:

- Performing or obtaining necessary assessments of the patient’s health status.
- Formulating a medication treatment plan.
- Monitoring and evaluating the patient’s response to therapy, including safety and effectiveness.
- Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events.
- Documenting the care delivered and communicating essential information to the patient’s other primary care providers.
- Providing verbal education and training designed to enhance patient understanding and appropriate use of the patient’s medications.
- Providing information, support services, and resources designed to enhance patient adherence with the patient’s therapeutic regimens.
- Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient.

Program A uses a resource-based relative value scale (RBRVS) to reimburse pharmacists that reflects three patient criteria: the number of medications, number of medical conditions, and number of drug therapy problems (DTPs). The more complex the case (as measured by numbers of each), the greater the reimbursement. The program uses specific MTM CPT codes developed in collaboration between the CPT Editorial Panel and the Pharmacist Services Technical Advisory Coalition (PSTAC) for pharmacists to bill payers for MTM.¹²

Evidence of MTM effectiveness

The state university conducted an evaluation of Program A, with data from April 1, 2006 through March 31, 2007. During that 12 month period:

¹² The CPT codes were recently changed from temporary Category III codes to permanent Category I CPT codes. Further description of the codes can be found at www.PSTAC.org.

- 34 pharmacists provided MTM services to 259 recipients who had a total of 431 MTM encounters, for which the state paid approximately \$40,000 (program administration costs were not reported).
- Pharmacists identified and resolved 789 DTPs in the 259 MTM recipients, or approximately 3 DTPs per recipient.
- Medical record abstraction revealed that 36% of diabetics receiving MTM met all quality of care performance benchmarks (QCare standards¹³), compared with 6% of diabetics statewide.
- Analyses showed an 8% increase in total health expenditures from pre- to post-MTM intervention, comprised of decreases in the costs of various ambulatory services, and increases (approximately 25%) in prescription drug costs.

3.3.2. Program B – Medicare PDP and MA-PD

A health plan offering both MA-PD and PDP products, Program B covers over 4 million people in two states: 130,000 in stand-alone prescription drug plans and 230,000 in Medicare Advantage drug plans. The MTM program is the same for the MA-PD and PDP populations, but is not offered to commercial (employer) clients. Program B managers strive to offer the same MTM services, in the same way, to every drug plan member, regardless of their location. Due to their rural population, the plan relies on mailed information, with referral to telephone follow-up as needed, and this is identical for those who receive mail-order drugs, live in remote rural areas, or reside in institutions (e.g., nursing homes, assisted living).

Eligibility and Enrollment

Medicare plan members are eligible for MTM if they meet all three of the following criteria:

1. Prescriptions for nine or more drugs (reduced from 12 or more in 2006-07).
2. Five or more chronic conditions, at least two of which must be from the following: asthma/COPD, CHF, diabetes, hypertension, hyperlipidemia.¹⁴
3. Total drug costs estimated to exceed \$4,000 annually.

Eligible patients are sent an invitation letter and enrollment packet; those who wish to participate send back an enrollment form and a brief survey. Those who do not respond to this introductory mailing are sent a repeat invitation to “opt in” to the MTM program. In 2006 and 2007, approximately 6% of eligible Medicare drug plan enrollees who were invited to join the MTM program, enrolled. There were 539 members participating in the MTM program in 2006 and 741 in 2007.

¹³ The Minnesota Citizens Forum recommendation of coordinating existing state quality improvement efforts led to development of the Quality Care and Rewarding Excellence (“QCare”) initiative. The Minnesota QCare standards of care represent evidence-based best practice guidelines developed by various state stakeholders. The State of Minnesota 2006 QCare (Quality Care and Rewarding Excellence) benchmark standards for diabetics: (1) Hemoglobin A1C measurement below 8%; (2) LDL-cholesterol measurement below 130 mg/dL; (3) Blood pressure measurement below 130/85 mm Hg; (4) Daily aspirin use if over 41; and (5) No tobacco use.

¹⁴ In contrast to its Medicare plans, Program B focuses on very different conditions for its commercial clients (e.g., migraines).

MTM Services

Salaried staff pharmacists (six as of early 2008) review prescription claims of new MTM participants, looking for the following irregularities/opportunities:¹⁵

- Duplication of therapy
- Short-term drugs being used long-term
- Long-term drugs prescribed for short duration
- Overuse of medication – dose too high or refilled too often
- Underuse of medication – subclinical dose
- Drug-drug interaction (DDI)
- Drugs of concern for the elderly – BEERS list
- Adherence/compliance issues – refill gaps
- Congruence with clinical guidelines – e.g., patients with hyperlipidemia taking statins
- Potential cost saving issues for patient and for payer

When the pharmacist identifies medication issues, s/he uses the system to create paired letters: one for the patient that describes the issue and recommendation in lay terms, and one for the patient-designated primary care provider (PCP) using terminology that is more clinically precise. In addition to sending letters, pharmacists can refer cases that require telephonic communication either to a nurse-advice line available to all plan members, or to nurse case managers. Cases that require mainly patient education and prevention counseling are referred to the nurse-advice line. Cases that involve complex clinical issues, drug-disease issues, high health service utilization, or other indications of poorly-controlled chronic disease are referred to nurse case-managers. Neither of these nurse-support services is formally part of the MTM program.

There is a separate, large DM program for health plan members, directed by the nurse case managers. DM is offered to both Medicare and commercial clients, but the MTM program is currently offered only to Medicare drug plan members. If a Medicare patient is in both programs (MTM and DM), the MTM pharmacist will explain any medication issues to the nurse case managers.

Evidence of MTM Effectiveness

The MTM mailings sent to primary care physicians (PCPs) contain both the pharmacist's recommendations and a follow-up survey for the PCP to complete and mail/fax back. The follow-up survey asks the PCP to indicate whether s/he:

- Agrees with the MTM recommendation and will comply.
- Agrees with the MTM recommendation but will take no action at this time (and why).
- Disagrees with the recommendation and will take no action at this time (and why).

¹⁵ MTM staff are currently programming their system to identify the number and percent of medication issues in each category that the MTM pharmacists identify.

Approximately 25% of mailed MTM recommendations yield a return survey from the PCP; of these, about 80% of these respondents agree with the MTM recommendations they received, and state that they intend to comply. Patients also receive a follow-up survey 30-60 days after the MTM mailing. Approximately 40% of mailed MTM recommendations yield a completed feedback survey from patients; 80% of these respondents report that the MTM recommendations were helpful.

3.3.3. Program C – Multi-state Medicare Advantage Plan

This multi-state MA plan is organized in semi-autonomous regions, of which one was studied for this project. The MA plan operates many other programs that may have a pharmacy component, including registries of patients with specific conditions (e.g., cancer, renal failure), chronic disease management, and a cost-efficacy drug utilization program. One objective of the MTM program is to integrate these multiple initiatives. MTM is available only to Medicare plan members (not commercial – employer – members).

Program C’s MTM physicians and pharmacists are salaried employees and the majority of outpatient prescriptions are filled “in house” at the plan’s pharmacies. Many pharmacists in the MA plan have collaborative practice agreements with plan physicians and follow agreed-upon care protocols to change or reconcile prescriptions when necessary, without obtaining approval from the physician for every change. Some of physician practices use a primary care team model, where the pharmacist is part of the team and contributes to care decisions, including medication management.

Eligibility and Enrollment

Among patients with \$4,000 or more in annual drug costs, those with two or more medications from the following list are identified:

- Anticoagulants
- Hematopoietic Agents
- Antihyperlipidemics
- Insulin
- Antihypertensives
- Oral Hypoglycemics

Those who also have two or more of the following chronic conditions (based on ICD-9 diagnostic codes in the EHR) are eligible for MTM:

- Diabetes
- Coronary Artery Disease
- Cerebrovascular Accident
- Deep Vein Thromboembolism
- Dyslipidemia
- Pulmonary Embolism
- Atrial Fibrillation
- Hypertension
- Peripheral Artery Disease
- Mechanical Heart Valve

As these criteria indicate, Program C focuses on cardiovascular disease treatment and prevention, and common co-morbid conditions such as diabetes and stroke. In 2006, approximately 15,000 Medicare plan members were eligible for MTM; in 2007 this number increased to approximately 25,000. Eligible patients are sent an invitation to participate in MTM; they can “opt in” by telephone or mail and if they fail to enroll they are contacted by telephone. In 2006, approximately 10,000 Medicare beneficiaries (69% of eligibles) enrolled in Program C; in 2007, approximately 14,000 Medicare beneficiaries (57% of a much larger group of eligibles) enrolled.¹⁶

¹⁶ 2007 enrollment numbers are estimates.

MTM Services

After conducting a comprehensive medication review, the MTM pharmacist contacts the patient by telephone to discuss any opportunities to improve drug therapy, identify adherence barriers, and answer any questions or concerns. When necessary, the MTM pharmacist will advise and consult with the patient's physician and/or work under approved protocols to adjust medication therapy and order medication-specific laboratory tests or procedures. The MTM pharmacist designs individualized medication monitoring schedules and follow-up plans, and may refer the patient to specialty services (e.g., anticoagulation, oncology, asthma, etc.) or to disease management services or disease registries. The average MTM patient has two MTM encounters per year, and the range is from 1 to 10. In 2006, the 10,228 enrolled patients had 24,631 MTM interventions.

Patients in custodial care settings (nursing homes) who meet the eligibility criteria are automatically enrolled in the MTM program (no "opt in" step). An MTM pharmacist conducts a CMR for each eligible nursing home resident, and conveys these recommendations to the patient's continuing care physician. MTM program managers acknowledge that this activity overlaps substantially with the functions of nursing home consultant pharmacists, but the review conducted by the MTM pharmacist is more oriented to cost efficacy, elimination of therapeutic duplication, and medication issues for cardiovascular patients in particular (the targeted MTM population). Communication between the MTM pharmacist and nursing facility staff is limited – mainly to obtaining patient records/information – and the MTM pharmacist's recommendations are not entered into the patient charts maintained at each nursing home.

Evidence of MTM Effectiveness

Program C conducted a study of the effectiveness of MTM in achieving LDL-C (<100mg/dL) and HbA1C (<7%) goals among hyperlipidemic, diabetic, and coronary artery disease patients in their MTM program.¹⁷ A quasi-experimental design was used and all patients had lab values recorded six months before and six months after an index date (the date they enrolled). There were no significant differences in the pre/post changes in glycemic control between the MTM and control groups, but lipid control improved in the MTM group more than in the control groups. (unpublished data.)

A patient satisfaction survey was mailed to 1,000 randomly selected patients in the MTM group during program year 2006. Forty-four percent responded to the survey and rated all aspects of the MTM program quite highly.

3.3.4. Program D – National MTM Vendor

Program D is an MTM vendor that contracts with Medicare drug plans, Medicaid and state health programs, employer groups, pharmacy benefit management companies (PBMs), and pharmaceutical manufacturers, to deliver MTM. Program D offers its client-payers: a nationwide pharmacy network (over 12,000 pharmacies in early 2008), a software platform and documentation system, a pharmacist reimbursement system, and a capitated pricing arrangement. Since Part D began, Program D has become the MTM vendor for several PDPs including a multi-state Special Needs Plan for dual eligible

¹⁷ Jeong, Gallagher, Fredriks, Chan and Ostini; Impact of a Pharmacist-Managed Medication Therapy Management Program: Experience in an Integrated Healthcare Delivery System. *ASHP Poster Presentation*, December 2007.

beneficiaries, and a nationwide Part D plan. Program D is also beginning to offer MTM to individual consumers for an annual premium. Across client-payers, over two million individuals are now eligible to receive MTM services from Program D.

Eligibility and Enrollment

Program D's client-payers identify MTM eligible patients based on each payer's eligibility criteria.

While many commercial payers offer Program D services to all their employees (i.e. no eligibility criteria), Medicare Part D plans offer MTM to only a subset of their enrollees – those who meet the three criteria of having multiple drugs, multiple chronic conditions, and drug costs exceeding \$4,000 – and most plans further refine this by including only patients with specific chronic conditions and drugs. Some Medicare Part D plans that use Program D allow all their members to make use of MTM, but report to CMS only on the subset who meet the three Medicare eligibility criteria.

After Program D identifies a client's eligible patients, their system notifies dispensing pharmacies in the network that serve each patient, and the pharmacists are encouraged to offer these patients comprehensive medication reviews. Patients are free to decline each time an MTM service is offered, but very few do. Patients are never disenrolled from the MTM program. For patients who receive their prescriptions via mail order, Program D will send an invitation explaining MTM services, and offer the options of receiving MTM from network pharmacies in their area or via a phone call with a consultant pharmacist.¹⁸ Program D has specific policies for MTM services provided to nursing home patients: a pharmacist cannot bill for a CMR because this is part of the LTC consultant pharmacist's drug regimen review, nor for patient compliance interventions because the patients in a nursing home do not self-medicate; but pharmacists can bill for prescriber consultations.

MTM Services and Reimbursement

Pharmacists complete a one-hour on-line training program prior to joining the Program D network, and can then offer the four covered MTM services:

- Comprehensive Medication Review (face-to-face)
- Prescriber Consultation (telephone call with the prescriber to discuss drug therapy problems)
- Patient Compliance Consultation (usually face-to-face)
- Patient Education and Monitoring (education is face-to-face, monitoring can be via telephone)

More than one service can take place during a single encounter, to address all of a patient's medication-related needs. Contracted pharmacies and pharmacists are reimbursed for the covered services they provide, as follows:

¹⁸ Plan D allows mail order pharmacies to bill for the identification and resolution of drug therapy problems but not for CMRs; no mail order pharmacies have yet submitted claims for MTM. Patients who prefer mail order can receive MTM services face-to-face at any network pharmacy. Program D does not track the number of mail-order customers who receive MTM services in-person.

Exhibit 6: Program D Pharmacist Reimbursement

Covered Service	Outcome of Service (Result)	Reimbursement (\$)
Comprehensive Medication Review	CMR with or without Encounter	\$50.00
Prescriber Consultation	Initiation of Cost-Effective Drug	\$20.00
	Drug Therapy Problem (DTP) Resolved	\$20.00
	Prescriber Refusal – DTP or Cost Efficacy	\$ 2.00
Patient Consultation	Altered Compliance or Admin Technique	\$20.00
	Patient Refusal – Compliance or Cost Efficacy Management	\$ 0.00
Education & Monitoring	Therapeutic Success (or Failure)	\$10.00
	Patient Refusal	\$ 0.00

Complex patients with many drug therapy problems require multiple services; this greater complexity is recognized by reimbursement for additional services. Pharmacists submit claims using an Encounter Worksheet where they chart what was done in the encounter; all billing is done electronically. On each claim and for each service, the pharmacist indicates the *reason* for the encounter, the *action* or professional service rendered, and the *result* or outcome of the service. The documentation and billing system is web-based and free to network pharmacists. Each time a claim is submitted the pharmacist selects one reason, one corresponding action, and one corresponding result, and all have unique codes. Each patient’s record in the system can also capture laboratory values obtained directly from patients (self-report), from a printout from the clinic that the patient brings in, or from the prescriber or clinic staff.

The Program D web-based system allows pharmacists to create a printable MTM profile for patients – a written guide of the medications they are currently taking. Program D’s client-payers have access to real-time reports, which they can generate themselves. Program D also operates a targeted intervention program based on retrospective drug utilization reviews, to identify specific interventions that pharmacists can make for individual patients. These patient-specific “alerts” are sent to pharmacists via fax, mail, private email, or their system email.

Estimated Cost Avoidance

In addition to the documentation for reimbursement described above, each submitted claim must include an Estimated Cost Avoided (ECA). The ECA is what the pharmacist believes was potentially avoided because of the MTM intervention – what might have happened had she/he not intervened. There are seven levels of estimated cost avoidance:

- Level 1: Improved Quality of Care
- Level 2: Drug Product Costs avoided
- Level 3: Additional Physician Visit avoided
- Level 4: Additional Prescription Order avoided
- Level 5: Emergency Room Visit avoided
- Level 6: Hospital Admission avoided
- Level 7: Life Threatening Situation avoided

At a minimum, each MTM service encounter is a Level 1 and all education and monitoring claims are Level 1. Level 2, Drug Product Costs Avoided, is common for patient and prescriber consultations related to cost efficacy (e.g. generic substitutions).

Quality Assurance and Client-Payer Accountability

Program D staff (pharmacists) review all Level 2 ECA claims and a subset of Level 1 ECA claims. Program D contracts with a third-party quality assurance entity (a former division of a Quality Improvement Organization) to ensure that claims are documented in accordance with the vendor's Policy and Procedures Guide. The QA entity reviews claims with an ECA Level 3 or higher. Program D also identifies pharmacist "outliers" whose claims are not in accordance with usual patterns (e.g. high rate of CMRs without subsequent interventions). Program D also issues pharmacy report cards featuring a composite performance score for each pharmacy that allow pharmacy managers to compare their ratings with their peers.

Program D's client-payers pay a capitated rate per member per month (PMPM) based on whether the MTM program is being offered to all plan members or only to a selected subset. The per capita price is higher if only a subset is eligible for MTM, because these are likely to be the sickest patients and most in need of MTM services. Alternatively, Program D offers fee-for-service pricing in which a client-payer is charged an administrative fee plus actual pharmacist fees, or "platform-only" pricing, in which the company's administrative responsibilities are limited to system technical support. Program D offers client-payers a price guarantee that their payments/fees will be lower than the Estimated Costs Avoided.

Evidence of MTM Effectiveness

The most common types of MTM interventions delivered by contracted pharmacies/pharmacists, and the subsequent impact on drug product costs are:

- cost efficacy medication changes recommended (28%), which usually reduces drug costs
- additional medication therapy recommended (19%), which increases drug costs
- administration/technique counseling (11%), which usually has little effect on drug costs
- compliance/underuse counseling (10%), which increases drug costs

One way Program D calculates return on investment (ROI) is ECA/payments to pharmacists. The ECA per claim has trended upward over time, and by 2006, every dollar paid to a pharmacist for MTM services yielded approximately \$45 in ECA. The total ECA resulting from 1,736 CMRs that took place from 2003 through 2006 was \$1,275,469, and the ROI per CMR was \$735. Most of the ECA stemming from CMRs was due to a few CMRs where an emergency department visit or hospitalization may have been avoided – rare but costly events that add considerably to ECA. Just 10% of the CMRs were responsible for 75% of avoided costs, largely from avoiding use of hospital services.

Program D staff and other researchers have used their data to evaluate the effectiveness of MTM. An Exhibit summarizing the evidence of effectiveness on this program is provided in the detailed description in Appendix C.

Chapters 4–10 of this report present findings from these case studies, the literature and the telephone interviews.

4. MTMP Organizational Definitions and Practice Models

4.1. Working Definition of Medication Therapy Management Programs

The term Medication Therapy Management (MTM) was introduced with the Medicare Prescription Drug, Improvement and Modernization Act (MMA), which described a Medication Therapy Management Program (MTMP) as: “a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries...that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.” Previous programs with similar objectives of optimizing therapeutic outcomes and reducing the risk of adverse events were known by other names (e.g., pharmaceutical care,¹⁹ medication management, drug utilization review²⁰). All of these efforts stem from the expansion of pharmacists’ roles over the past few decades, to encompass professional responsibility for the outcomes of drug therapy (Smith & Clancy, 2006).

There have been efforts over the past several years to define MTM and come to agreement on a definition of MTM, but consensus has not yet been achieved. Other related efforts have provided a list of possible elements of an MTM program, or highlighted features of a quality MTM program. All of these efforts have been outlined in key position papers and other supporting documentation. Exhibit 7 lists the key documents defining MTM, the pseudonyms used for the documents in this chapter, the supporting organizations, and the year the document was published.

In 2004, 11 national pharmacy organizations developed a position statement on a working definition of MTMPs in a document titled, “MTM Service Definitions and Program Criteria” (“Consensus Definition”). These 11 organizations agreed that MTM is “a distinct service or group of services that optimize therapeutic outcomes for individual patients,” and that MTM services “are independent of, but can occur in conjunction with, the provision of a medication product” (Bluml, 2005).

¹⁹ Cipolle R, Strand LM, & Morley PC (1998) define pharmaceutical care as “a patient-centered practice in which the practitioner assumes responsibility for a patient’s drug therapy needs and is held accountable for this commitment,” in *Pharmaceutical Care Practice*. New York: McGraw Hill.

²⁰ Prospective drug utilization review (DUR) “involves reviewing each prescription for an individual patient before it is dispensed to identify drug-related problems such as drug-drug interactions or drug-disease contraindications, therapeutic duplication, or other potential adverse drug events” (Fulda et al. 2004. *Journal of Managed Care Pharmacy*). Retrospective DUR “involves a review of pharmacy claims data to identify inappropriate patterns of patient drug use and physician prescribing.” (Sleath et al., 2000 *Journal of Managed Care Pharmacy*).

Exhibit 7: Key Documents Defining MTM

Title & Date	Supporting Organizations	
<p>Title: “Medication Therapy Management Services Definition and Program Criteria” (Consensus Definition)</p> <p>Publication Date: 2004</p>	<ul style="list-style-type: none"> • Academy of Managed Care Pharmacy (AMCP) • American Association of Colleges of Pharmacy (AACP) • American College of Apothecaries • American College of Clinical Pharmacy (ACCP) • American Society of Consultant Pharmacists (ASCP) • American Pharmacists Association (APhA) • American Society of Health-System Pharmacists (ASHP) • National Association of Boards of Pharmacy (NABP)²¹ • National Association of Chain Drug Stores (NACDS) • National Community Pharmacists Association (NCPA) • National Council of State Pharmacy Association Executives (NCSPA) 	
<p>Title: “Summary of the Executive Sessions on Medication Therapy Management Programs” (Executive Sessions)</p> <p>Publication Date: 2004</p>	<ul style="list-style-type: none"> • AMCP • ASHP • Aetna Inc. • AACP • ACCP • AHQA • APhA • ASCP • Anthem Prescription Management, LLC • Caremark Inc. • Catalyst Rx 	<ul style="list-style-type: none"> • Express Scripts, Inc. • Harborview Medical Center • Humana Inc. • Iowa Pharmacy Association • Medco Health Solutions, Inc. • MedImpact Healthcare Systems Inc. • Prescription Solutions • Prime Therapeutics • UnitedHealth Group²² • Walgreens Health Initiatives • WellPoint Pharmacy Management
<p>Title: “Medication therapy management in community pharmacy practice: core elements of an MTM service” (Core Elements)</p> <p>Versions: Version 1.0 (2005) & Version 2.0²³ (2008)</p>	<ul style="list-style-type: none"> • APhA • NACDS Foundation <p>Version 2.0 is supported by AACP, ACCP, ASCP, ASHP, NASPA, NCPA, and American College of Apothecaries</p>	
<p>Title: “Sound Medication Therapy Management Programs” (Sound MTM)</p> <p>Versions: Consensus Document (2006) & Version 2.0 with Validation Study (2008)</p>	<ul style="list-style-type: none"> • AMCP • AARP • AMCP • ACCP • APhA • American Geriatrics Society 	<ul style="list-style-type: none"> • ASCP • Case Management Society of America • College of Psychiatric & Neurologic Pharmacists • Department of Veterans Affairs

²¹ Organization policy does not allow NABP to take a position on payment issues.

²² UnitedHealth Group participated in the August 18 session only.

²³ Version 2.0 is titled, “Medication Therapy Management in Pharmacy Practice: Core elements of an MTM service model.

The “Consensus Definition” identified MTM services to include, but not be limited to, the following (according to the individual needs of the patient) (Bluml, 2005):

- Performing or obtaining necessary assessments of the patient’s health status.
- Formulating a medication treatment plan.
- Selecting, initiating, modifying, or administering medication therapy.
- Monitoring and evaluating the patient’s response to therapy, including safety and effectiveness.
- Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events.
- Documenting the care delivered and communicating essential information to the patient’s other primary care providers.
- Providing verbal education and training designed to enhance patient understanding and appropriate use of medications.
- Providing information, support services, and resources designed to enhance patients’ adherence with their therapeutic regimens.
- Coordinating and integrating medication therapy management services within the broader health care-management services being provided to the patient.

Thereafter, many of the same organizations convened to further specify the program elements needed to effectively deliver MTM and ensure quality. To this end, in 2004 the Academy of Managed Care Pharmacy and the American Society of Health-System Pharmacists published the results of two executive sessions held to discuss MTM (“Executive Sessions”). Thereafter, the American Pharmacists Association and the National Association of Chain Drug Stores Foundation published “Core Elements,” a guide for community pharmacists to deliver MTM effectively. Finally in 2006, AMCP published “Sound MTM” to guide designers of MTMPs, highlighting the critical elements of an effective, quality MTM program. Each of the documents published deferred to the “Consensus Definition” document as the working definition of MTMP. Recently APhA and NACDS released version 2.0 of the “Core Elements” document²⁴ and AMCP completed a validation study of the “Sound MTM” version 1.0 document.²⁵ These initiatives illustrate the continued effort to refine working definitions as the MTM environment evolves.

The various efforts to define and specify the elements of an MTM program shared many features but there were also some differences. Seven services specified in the MMA also appeared in the “Consensus Definition” document. Two additional services mentioned in the “Consensus Definition” included: selecting, initiating, modifying, or administering medication therapy; and performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events.

The “Core Elements” document went further and offered a model framework with five core elements for community pharmacies in version 1.0, and for all patient care settings in version 2.0. Three of the

²⁴ American Pharmacists Association and National Association of Chain Drugstores Foundation. Medication therapy management in pharmacy practice: core elements of an MTM service model. Version 2.0. (2008).

²⁵ Academy of Managed Care Pharmacy. (2008). Sound Medication Therapy Management Programs, Version 2.0 with Validation Study. *Journal of Managed Care Pharmacy*, 14(1), S1-S44.

elements overlap with the services listed in the MMA and “Consensus Definition” including: medication therapy review, medication action plan, and documentation and follow-up. The two new core elements that do not overlap with the MMA are: a personal medication record for patients, and intervention and/or referral as needed to address medication-related problems.

The “Consensus Definition” and “Core Elements” documents specified that the preferred mode for MTM is a face-to-face interaction, whereas the “Sound MTM” document did not specify whether face-to-face interactions are the preferred method. Moreover, the “Sound MTM” version 2.0 validation study included a recommendation to reframe or remove the statement in the “consensus definition” that the preferred method is face-to-face “unless there are comparative data to support it.” All of the documents specified coordinating care with a patients’ other health care providers, but only the “Sound MTM” document included an explicit recommendation for an interdisciplinary, team-based approach.

It should be noted that the AMA asserts that a physician must be involved in any treatment plan or medication changes,²⁶ and that the primary care physician should take the lead in managing patient care, including medication therapy. The AMA position is that funds should be allocated to pharmacists for MTM services only if there is solid evidence that pharmacist-led MTM improves patient outcomes and is cost-effective. The AMA further believes that physicians should be fully informed when their patients are in an MTM program, and should be kept apprised at every step if a pharmacist recommends any medication changes, or is counseling a patient about anything beyond adherence. Finally, an AMA representative pointed out that it is important to defer to state laws regarding collaborative practice agreements (i.e., between physicians and pharmacists, or other allied health professionals). These agreements generally do not contemplate that pharmacists will be acting independently of physicians to alter medication therapy. The AMA believes these laws serve an important patient protection purpose. In 2002 the American College of Physicians-American Society of Internal Medicine issued a position paper on pharmacist scope of practice, opposing independent pharmacist prescriptive privileges and initiation of drug therapy.²⁷

The Medicare MTMPs we interviewed all deferred to the MMA final rule as their MTM definition, and each has more-detailed operational definitions. Most MTMPs specify pharmacists as the providers of MTM services (with a few exceptions); some specify face-to-face interventions, while others emphasize telephonic interactions and one relies on mailed communications with patients and physicians. Interviewees from state Medicaid MTMPs referenced the relevant State legislation requiring MTM as the source for operating definitions.

MTMPs continue to refine their operational definitions, in terms of services, targeted patients, and other aspects of their programs. There does not yet appear to be sufficient convergence in the field to formulate one standard definition of an MTMP.

²⁶ Based on an American Medical Association (AMA) letter to CMS’s Dr. McClellan, dated October 4, 2004, providing comment on the Medicare Prescription Drug Benefit proposed rule.

²⁷ American College of Physicians-American Society of Internal Medicine (2002). Pharmacist scope of practice. *Annals of Internal Medicine*;136:79-85.

4.2. Differing Goals and Objectives of MTMPs

The objectives of an MTMP contribute to decisions about program structure, services, providers, patients, and reimbursement. The objectives are primarily driven by the interests of the sponsoring organization, and these interests vary considerably – although all share a focus on enhancing therapeutic outcomes and avoiding adverse events. For purposes of understanding underlying objectives, there are six sectors active in MTMPs:

- Employers (and their health insurers)
- Medicaid programs
- State and municipal pharmacy assistance programs (PAPs) and AIDS drug assistance programs (ADAPs)
- Department of Veterans Affairs (VA)
- Medicare Special Needs Plans
- Other Medicare Part D drug plans

The Medicare Modernization Act (MMA) stated that Medication Therapy Management Programs “may include elements that promote (i) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means; (ii) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and (iii) detection of adverse drug events and patterns of overuse and underuse of prescription drugs.”²⁸ These objectives are evident in almost all MTMPs we explored, in all sectors.

Some MTMP objectives are sector-specific. For example, employer-sponsored MTMPs aim to improve employee health and productivity, and reduce absenteeism. The intensive MTM that the Asheville (employer-based) project offers is one example, where reduced absenteeism more than offsets the costs of the program. Several State and Municipal pharmacy assistance programs have a central concern with prescription insurance coverage and reducing out-of-pocket costs for low-income persons. The VA uses very structured, evidence-based guidelines to meet specific clinical objectives, but reducing absenteeism and patient out-of-pocket costs are not among the VA’s MTMP objectives. Some sectors focus on reducing prescription drug costs, while others expect to reduce total medical costs (recognizing that drug costs may increase with MTM, but overall medical costs may decrease through reduced hospitalizations and ED visits).

Exhibit 8 below provides an overview of the common MTMPs’ objectives across the various sectors.

²⁸ MMA Section 1860D-4 (c) COST AND UTILIZATION MANAGEMENT; QUALITY ASSURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM- (2)(B)

Exhibit 8: Objectives of MTMPs by Sector

MTMP Objectives	Employer-Sponsored MTMPs	Medicaid	PAPs & ADAPs	VA	Chronic Disease SNPs	Other Medicare Drug Plan MTMPs
Enhance patient understanding	x	x	x	x	x	x
Increase patient adherence	x	x	ADAP	x	x	x
Detect adverse events and patterns of overuse/ underuse	x	x		x	x	x
Improve therapeutic outcomes/meet clinical objectives	x	x	ADAP	x	x	x
Prevent ADEs or DTPs	x	x		x	x	x
Reduce other health care utilization (e.g., ED visits, office visits, hospitalizations) and associated costs	x	x		x	x	some
Reduce medical or drug costs	Focus more on total medical costs	Focus more on total medical costs	x		Focus more on total medical costs	Some focus on drug costs, others on total costs
Improve worker productivity and reduce absenteeism	x					
Reduce patient out-of-pocket costs			x			x

With this recognition of the differing objectives of MTMPs, the next section explores the MTM practice models evident in the literature and in key informant interviews.

4.3. MTM Practice Models

There are a variety of practice models in the literature and in current MTMPs, each with different attributes. There does not yet appear to be an identifiable set of clearly defined models that are reasonably stable and mutually exclusive; the following dimensions are currently used in various MTM practice models:

- **Primary Focus:** The primary focus of the program may be medication therapy, disease management, or a combination of both. Our work concentrated on programs focused primarily on medication therapy, and on those that combine medication therapy with other elements of disease management.
- **MTM Service Providers:** MTM practice models involve different providers delivering MTM services. In most models the MTM provider is a pharmacist, but there are models with other professionals providing MTM services. Two Medicaid programs have employed a model where pharmacists and physicians must work collaboratively and provide MTM services together (e.g., Mississippi and Iowa). Also, in some MTM practice models, nurses in a case manager role provide some elements of MTM – patient education, for example (e.g., one MTM vendor).
- **Reconciliation with Prescribers:** Many MTMPs require that pharmacists and prescribers communicate to resolve or reconcile prescription issues like therapeutic duplication or potential drug-drug interactions. Some MTMPs, however, do not require direct

communication; the MTM pharmacist notifies the prescriber about an issue (via telephone, email, fax, or letter) but there is no requirement that the two communicate to resolve issues. At least a few MTMPs do not explicitly require pharmacist-prescriber communication; the entire MTM focus is the pharmacist-patient interaction, and communication with the prescriber is merely encouraged – for example, programs that focus on adherence may not need a prescriber involved to resolve the drug therapy problem (Weinberger et al., 2002).

- Intervention Frequency: Some programs determine frequency of intervention based on patient needs (usually determined by the pharmacist), while others impose a specific or maximum frequency regardless of patient complexity. For example, many MTMPs cover quarterly service visits if a patient has a new prescription or requires follow-up, while others are limited to an annual service (e.g., one MTM vendor, some Part D plans).
- Service Delivery Mode: Some MTMPs rely exclusively on telephone interactions between the MTM provider and the patient, with calls typically being placed from a call center located in-house or maintained by a third party vendor. (e.g., some Medicare MTMPs). Other MTMPs rely exclusively on face-to-face interactions between pharmacist and patient, and have no telephone services (e.g., Minnesota Medicaid). Most MTMPs use a combination of telephone and face-to-face services, and some include direct mailings to patients as well (reminders, educational material).
- Additional Patient Education and Support: Although most MTMPs include the provision of adherence counseling or education, some MTMPs develop/disseminate additional patient education materials (e.g., adherence). Additionally, some MTMPs offer additional patient supports such as support groups, medication reminder “aides,” or medication “organizers” (e.g., Senior PHARMAssist in NC) as part of their services.
- Disease State Monitoring: Many MTMPs monitor therapeutic response to medications through laboratory test results (e.g., HbA1C, blood pressure, lipids). In some models, the pharmacist retrieves the lab test result data from an electronic health record or other lab reporting system. Alternatively, tests are performed at the clinic where the MTM provider also works, so that lab results are available at the time of or prior to the service visit, for the pharmacist to use in assessing therapeutic response. (e.g., many chronic disease SNPs and the VA). And in one model the pharmacist performs simple lab tests in the community pharmacy prior to refilling prescriptions, exercising direct clinical oversight (e.g., Project ImPACT²⁹).

The Physician Practice Pharmacy Quality Improvement Support Center (QIOSC)³⁰ posted an MTM resource on its website titled, “Medication Therapy Management Program Directory Version 1.5,” which proposes an MTM taxonomy (Krantzberg, 2007). This taxonomy has eight dimensions: setting, practitioner, mode of communication, elements of MTM, participant identification, selection criteria, single-level or multi-level program, and outcome evaluation. The taxonomy dimensions align closely with the reporting elements in CMS’s MTMP Submission Template.

Exhibit 9 displays several models of MTM practices that we observed in the literature or during interviews. As Exhibit 9 shows, the various MTM practice models combine these elements in different ways (practice models form the rows in the Exhibit below). Some of these practice models are distinguished by the providers who deliver MTM services; others are distinguished by the types of

²⁹ ImPACT is an acronym for Improve Persistence and Compliance with Therapy.

³⁰ The Medicare Quality Improvement Organizations are collaborating with Medicare prescription drug plans to assess their MTMPs. See Appendix C for an overview of the QIOs’ MTM projects.

services delivered or the mode of service delivery. Although the defining characteristics/dimensions vary, and these models are not entirely mutually exclusive, they demonstrate the rapidly evolving environment.³¹

- Hybrid MTM and Disease Management (DM) model: Comprehensive medication therapy oversight and management is combined with other interventions from disease management to achieve therapeutic outcomes (e.g., patient education, support for lifestyle change, patient self-monitoring). Many of the employer programs, including those with the most detailed research literature, employ this practice model (e.g., Asheville, United Mine Workers). MTM services are typically delivered by pharmacists during face-to-face sessions with patients, and through consultation between pharmacists and prescribers. There is sometimes an additional patient education element (by telephone or in-person).
- Care Teams: Primary care teams, sometimes enhanced by multi-service case managers, address myriad patient needs including medication therapy management. Like the hybrid MTM-DM model above, these care teams often incorporate DM features such as patient education and self-monitoring. Patients' other social services needs may be addressed as well (e.g., housing, insurance assistance). Examples of this model include the VA, where MTM is delivered by pharmacists who are members of primary care teams, and some chronic disease SNPs. The distinguishing feature of these programs is the use of multi-specialty care teams.
- Required Collaboration: At least two MTMPs specify the relationship between pharmacist and prescriber. Mississippi Medicaid requires the pharmacist and physician to enter into an explicit collaborative practice agreement³² and Iowa Medicaid requires that pharmacist and prescriber collaborate and agree upon the MTM action plan. This model is in contrast with many other MTMPs that infer that communication takes place between pharmacist and prescriber in order to resolve the medication problems identified.
- Multi-Mode, Comprehensive MTM: This practice model focuses on MTM and does not include other DM services/interventions. MTM is usually pharmacist-led, with an annual comprehensive medication review and regular/ongoing follow-up. MTM services are face-to-face, although a telephone call may be placed to follow up with patients, or patients may have access to a call center when questions arise. If data on lab test results are available,

³¹ The Quality Improvement Organization Support Center (QIOSC) report arrived at a somewhat different set of MTM Practice models:

- PBM/Mail Order Pharmacy Review
- Disease Management Enhancement to Include Medication Review
- Drug Plan Referral to Physician or Pharmacist
- Community-Based Brown Bag Program
- Staff Model HMO with Integrated Electronic Health Record
- Retail Pharmacy Based Program
- Community Health System Program
- Multi-level MTM Program in a Drug Plan

³² "A collaborative practice agreement is a voluntary, written agreement between a pharmacist and a prescriber that permits expanded authority for the pharmacist, such as the ability to initiate or modify drug therapy and order laboratory tests." Retrieved from ASCP Statement on Collaborative Practice at: <http://www.ascp.com/resources/policy/upload/Sta97-Collaborative%20Pract.pdf>

monitoring of therapeutic response may be incorporated into these programs. Often direct mailings to patients are added to reinforce adherence counseling.³³

- Telephonic MTM: This model is like the one above but relies entirely on telephone interactions for MTM, both between patient and pharmacist (or other MTM providers), and between pharmacist and prescriber. Calls are placed from call centers, staffed by pharmacists (and sometimes nurses). This model is most commonly seen in large national or regional health/drug plans.
- Pharmacy-Based Disease Monitoring: While many MTMPs use laboratory test data to monitor therapeutic response to medications, one practice model goes further and involves the pharmacist in a direct clinical care role. The pharmacist uses a point-of-care testing device to perform simple lab tests (e.g., lipid profile) in the pharmacy, then undertakes MTM (with patients and prescribers) to alter medications/doses and improve patient adherence. An example of this model is Project ImPACT.
- MRR in Nursing Homes: Nursing homes are required by law to arrange for the services of consultant pharmacists, who perform monthly medication regimen reviews (MRR) for all residents. MRR and MTM are mandated by separate federal regulations.³⁴ Nursing home patients may also be eligible for or enrolled in an MTMP operated by their Medicare Part D plan, and since MTM and MRR are distinct processes that share common goals, there is the potential for inconsistency between the consultant pharmacist's recommendations and an external MTMPs pharmacist's recommendations.

³³ Note: some equally-robust MTMPs rely exclusively on telephonic interactions —these appear as a distinct practice model in the chart because of that service delivery mode. This is not intended to imply that telephonic service delivery is less “comprehensive” or effective than in-person or mixed-mode service delivery

³⁴ MRR is newly defined, recently updated, and expanded in Appendix PP of the State Operations Manual (SOM) under “Guidance to Surveyors of Long Term Care Facilities.” Changes to Appendix PP were effective December 18, 2006.

Exhibit 9: Practice Model Components/Dimensions

MTM Practice Models	Primary Focus	MTM Providers	Intervention Frequency	Telephone Calls To/from patient homes	Face-to-face sessions w/patients	Mailings to Patients	Additional patient education & support	Rx Reconciliation with prescribers	Disease State monitoring (e.g. lab results)
Hybrid MTM-DM	MTM as one element; also lifestyle change & other DM	Pharmacists	Monthly or per-refill or as needed	No Call Centers. Some make refill reminder calls.	Yes	Yes – educational materials	Yes	Yes	Yes Lab tests available to MTM providers at clinics or in charts
Care teams	MTM as one element; also lifestyle change & other DM	Pharmacists collaborating with physicians & nurse teams	Monthly or per-refill or as needed	No Call Centers. V.A. mails refills—no reminders needed. Some others make refill reminder calls.	Yes	V.A. no; some others mail educational materials.	Yes – group support, education, case management	Yes	Yes Lab tests available to MTM providers at clinics or in charts
Required Collaboration	Medication Therapy Management only	Collaboration required between pharmacists and physicians	Driven by patient need (usually monthly or quarterly)	No Call Centers. May make telephone follow-up calls.	Yes	No	No	Yes	Lab tests may be available to MTM providers
Multi-Mode, Comprehensive MTM	Medication Therapy Management only	Pharmacists	Driven by patient need (usually monthly or quarterly)	Some have Call Centers. Others use telephone only for brief follow-up.	Yes	Some (Medicare Part D plans)	Some	Yes	Some health plans monitor lab results and revise prescriptions
Pharmacy-based Disease Monitoring	Medication Therapy Management with lab monitoring (usually single disease focus)	Pharmacists	Monthly or quarterly	Use telephone for brief follow-up.	Yes	No	Yes	Yes	Yes – pharmacists perform tests (e.g., lipids, HbA1C)
Telephonic MTM	Medication Therapy Management only	Pharmacists, nurses for some patient-education & reminder functions	Some annual, Some more frequent	All MTM conducted by phone, usually from call centers	No	Most do not; a few send educational materials	No	Some yes, some no	Some health plan MTMPs monitor lab results and revise prescriptions
MRR for nursing home patients	Medication Regimen Review (MRR)	Consultant pharmacists	Monthly	No	N/A	N/A	N/A	Notes in charts with recommendations for prescribers	Yes

5. Targeted Patients, Eligibility Criteria and Enrollment Mechanisms

5.1. Eligibility Criteria

Medicare statute requires that Medicare MTMPs use (at a minimum) the following three eligibility criteria:

- Have multiple chronic conditions, and
- Be taking multiple Part D drugs, and
- Are likely to incur annual costs of at least \$4000 for all covered Part D drugs

It is uncommon for non-Medicare MTMPs to specify numbers of medications or numbers of chronic conditions as eligibility criteria, and while some focus on “high cost” patients, none appear to use a specific drug cost threshold for MTMP eligibility. Some non-Medicare MTMPs (e.g., VA, Florida Medicaid, a national MTM vendor) have no explicit MTMP eligibility criteria at all; MTM services are/were offered to any patient whom clinicians or pharmacists believe would benefit.

Several non-Medicare MTMPs focus on patients with *specific* chronic conditions or types of diseases. ADAP programs are designed for people with HIV or AIDS, for example, and the Asheville program was aimed at people with diabetes, asthma, hypertension, or hyperlipidemia. Many MTMPs also focus on conditions consistent with HEDIS (e.g., inhaler use for asthmatics) for which data definitions and reporting are already in place at most health plans.

By contrast, Medicare MTMPs are required to specify the chronic conditions and the number of drugs that define eligibility.

Exhibit 10 displays the eligibility criteria used by the 15 Medicare Part D plans’ MTMPs interviewed for this project (the last two were case study programs).

All Medicare MTMPs include \$4,000 annual medication costs as an eligibility criterion. All Medicare MTMPs we interviewed also specify the number (and often the type) of chronic conditions that confer MTM eligibility. They all specify a minimum number of Part D medications that determine eligibility for MTM, and some require that the drugs being taken relate to the chronic conditions of concern. A survey of Medicare MTMPs by Touchette et al. (2006) similarly found that 90.5% of MTMPs restricted their enrollment based on number of disease states, with a median of 3 (range 2-5); 57.1% of MTMPs restricted enrollment based on the type of chronic condition; and 95.2% of MTMPs had requirements for the number of medications necessary for enrollment in the program, with a median of 6 (range 2-24) medications necessary. Similarly, AMCP’s validation study of “Sound MTM” found that the eligibility criteria for 13 PDP and 18 MA-PD programs were, on average, 2.6 chronic conditions and 5.6 medications (AMCP, 2008).

Generally speaking, the Medicare MTMPs are more structured and restrictive in how they determine eligibility than are non-Medicare MTMPs. There is, however, considerable diversity among the Medicare MTMPs. For example, one Medicare MTMP bases eligibility on two or more drugs used to

treat two of three specific chronic conditions, another Medicare MTMP bases eligibility on 12 or more drugs to treat at least 4 of 11 specific chronic conditions, and a third simply specifies two or more chronic conditions and at least five chronic medications. Some Medicare MTMPs match conditions of concern and the drugs used to treat them, others do not require that a patient's drugs correspond to specific medical conditions.

Exhibit 10: Medicare Prescription Drug Plans Interviewed: MTM eligibility criteria

	#/Type of conditions	#/Type of medications
Large, national PDP and its PBM	<i>At least 5 conditions with 2 being:</i> - Diabetes - CHF - Hypertension - Asthma - COPD - Dyslipidemia (Soon will decrease to 2 or more of these conditions)	Any 6+ Part D drugs
Plan with 1 PDP in 4 states	<i>2 or more of 3 conditions:</i> - Diabetes - Asthma - Dyslipidemia	2+ Part D Drugs related to specified chronic conditions
Large, national PDP	<i>2 or more of 6 conditions:</i> - Diabetes - Heart Failure - Dyslipidemia - Hypertension - Atrial Fibrillation - Rheumatoid Arthritis	6+ Part D Drugs related to chronic disease
Plan with 1 PDP, over 1 million enrollees	<i>4 or more of 5 chronic conditions:</i> - Diabetes - Hypertension - Dyslipidemia - Asthma - Chronic Pain	Any 10+ Part D drugs
Single State MA-PDP	<i>2 or more of 5 conditions:</i> - Diabetes - Heart Failure - Asthma - COPD - CAD	Any 7+ Part D drugs
Plan with 1 MA-PD	<i>Both of:</i> - Heart Failure - COPD	4 of: ACE inhibitors, beta-blockers or nebulizer; and oxygen in home
Regional MA-PDP	<i>3 or more of most chronic conditions including:</i> - Diabetes - Heart Failure - Hypertension - Asthma - COPD - Dyslipidemia	Any 5+ Part D drugs
Plan with 2 PDPs and 2 MA-PDs	<i>All of the following:</i> - Diabetes - Hypertension - Dyslipidemia	3+ drugs for treatment of 3 identified chronic conditions
Plan with 1 PDP and 1 MA-PD	<i>5 or more chronic conditions, at least 2 from:</i> - Diabetes - Heart Failure - Hypertension - Asthma - COPD - Dyslipidemia	12+ Part D drugs related to chronic disease
Plan with 1 PDP and 2 MA-PDs	<i>2 or more of 6 conditions:</i> - Diabetes - Heart Failure - Hypertension - Asthma - COPD - Dyslipidemia	Any 5+ Part D drugs related to chronic disease
Plan with 1 PDP and 6 MA-PDs	<i>4 or more of the following:</i> - Chronic pain - Angina - Migraine headaches - Diabetes - CAD - Anticoagulation - Dyslipidemia - COPD - Rheumatoid Arthritis - Asthma - Hypothyroidism	12+ Part D drugs
Large, national MA-PDP	<i>2 or more chronic medical conditions</i>	5+ Part D drugs related to chronic disease
Large, national PDP	<i>4 out of 10 diagnoses:</i> - Asthma - COPD - Angina/arrhythmia - Diabetes - ESRD - Rheumatoid Arthritis - Heart failure - Dyslipidemia - Hypertension - Alzheimer's disease/dementia	Any 10+ Part D drugs
Large, multi-state MA-PD (Case Study)	<i>2 or more from:</i> - Diabetes - Dyslipidemia - Hypertension - Coronary Artery Disease - Atrial Fibrillation - Pulmonary Embolism - Peripheral Artery Disease - Cerebrovascular Accident - Mechanical Heart Valve - Deep Vein Thromboembolism	2 or more medications from: Anticoagulants, Antihyperlipidemics, Antihypertensives, Hematopoietic Agents, Insulin, Oral Hypoglycemics
Small 2-state MA-PD (Case Study)	<i>5 or more chronic conditions, at least 2 from:</i> - Asthma/COPD - CHF - Diabetes - Hypertension - Hyperlipidemia	Any 9+ Part D drugs

5.2. Enrollment Mechanisms

In 5 of the 15 Medicare MTMPs interviewed, members are “auto-enrolled” and may opt out if they choose. Five others ask patients to “opt in,” and five allow both “opt in and opt out.” In general, it appears that those using an “opt out” approach have higher enrollment of their MTM eligible population, because the default state is inclusion. There are exceptions however: an MA plan we studied uses an aggressive “opt in” approach, including mailed invitations and telephone outreach, and enrolls a high percentage of eligible plan members into the MTM program. AMCP (2008) found in their validation study of the “Sound MTM” program components, that opt-in approaches resulted in <1% to >50% participation rates, whereas opt-out approaches produced much higher percentages of enrollment.

Some MTMPs rely on pharmacists to select patients for MTM from among those who are eligible (or from among a plan’s entire population). In the state Medicaid MTM program we studied, this approach has been only marginally successful, in part due to low pharmacist participation. The national MTM vendor we studied sends lists of eligible patients to the pharmacies in their network and encourages the pharmacists to offer MTM (no information was available on the number or percent of eligible patients who receive MTM services).

6. MTMP Components and Services

6.1. Services

In a few MTMPs (e.g., Florida Medicaid, Minnesota Medicaid, VA, a large national PDP), the first professional service that pharmacists or other clinicians undertake is to review patient data and identify those who could benefit from MTM. In most MTMPs, however, patients with indications for MTM are first identified by the program staff or vendor (using claims or other data) not by pharmacists.

Some health plans and MTM vendors operate both Medicare and non-Medicare MTMPs, and while they may use different eligibility criteria for Medicare and non-Medicare patients, the same array of services are offered; they do not operate different service models for different payers' populations. (As mentioned previously, some MA plans combine MTM and DM for non-Medicare populations, but feel required to separate the two programs for Medicare.)

Virtually all MTM patients receive a comprehensive medication review (CMR) as a starting point when they enroll in an MTMP. In most plans the CMR is conducted by a pharmacist, although this initial thorough medication review may be conducted by a physician (e.g., one Medicare MTMP). Medication reviews are similar to what were sometimes called “brown bag” reviews in the past. The terminology originates from patients literally bringing all of their medication bottles in a brown bag for a pharmacist to review; some more-recent programs still refer to the medication review as a “brown bag” review (for example, the Iowa Priority Brown Bag Review, described in Farris et al., 2004).

MTMPs offer some combination of services, following the CMR:

- Management of costs related to affordable alternatives (generic substitution, trials of other lower cost alternatives).
- Evaluation and monitoring of drugs (to reduce therapeutic duplication, avoid ADEs, etc.).
- Patient adherence counseling and aids.
- Coordination and prescription reconciliation with prescribers.³⁵

In addition, most MTMPs offer customized services to meet individual patient needs, such as:

- Laboratory testing in the pharmacy to monitor Coumadin, cholesterol, blood glucose, bone density, or other disease state markers.
- Personalized telephone or mailed reminders to reinforce patient adherence.³⁶
- Education materials, newsletters, and seminars for patients with specific chronic conditions.

³⁵ In some states (e.g., New Mexico, North Carolina) and the VA, pharmacists with special training and collaborative practice agreements have scopes of practice that allow them to alter prescriptions, rather than seeking prescription changes from prescribers.

³⁶ The V.A. does not use mailed reminders because the agency has seen no evidence of effectiveness for this outreach modality.

We observed no pattern of non-Medicare MTMPs differing from Medicare MTMPs in the array of services offered/covered. Both across sectors and among Medicare MTMPs, there is considerable diversity of services, and many MTMPs are still refining the services they offer. Touchette et al.'s (2006) survey of MTMPs operated by Medicare Part D plans similarly found a very diverse array of services. (The authors note the absence of definitive evidence supporting the effectiveness of the most common services.) AMCP's (2008) validation study also found that MTM services vary widely across MA-PD and PDP plans.

Three of the MTMPs we studied in-depth have demonstrated some clinical impact of MTM (e.g. improved blood glucose or LDL levels), but the evidence does not allow us to determine whether annual CMRs with prescription reconciliation is sufficient to accomplish clinical goals, or whether other follow-up services delivered by MTM pharmacists are an important contributor to clinical outcomes.

6.2. Frequency of Services

The frequency of services varies considerably across MTMPs. The most common approach is to begin with a comprehensive medication review (CMR) requiring 30-90 minutes depending on the complexity of the case, during which the pharmacist identifies medication issues and establishes a medication therapy plan. If prescription changes are necessary the pharmacist interacts with the prescriber (usually by telephone, sometimes by mail) to effect these changes. After this first (or annual) CMR, most MTMPs offer monthly or quarterly follow-up visits between patient and pharmacist, but there are variations. For example, interviewees reported that some Medicare MTMPs cover only an annual comprehensive medication review, without ongoing follow-up. Most non-Medicare MTMPs do not limit services to an annual CMR, other than a few instances of a one-time "brown bag" review which is similar to a CMR. At the other extreme, Project ImPACT included a CMR and periodic cholesterol testing in the pharmacy followed by interactions between patient and pharmacist prior to prescription refills, and the Asheville Project covered monthly follow-up visits and additional education supports for diabetic patients. The Minnesota Medicaid program allows pharmacists to provide MTM follow-up services, and in some Medicare and non-Medicare MTMPs, members are free to contact a pharmacist at any time. Similarly, one MTM vendor's contracted pharmacists can provide MTM services as frequently as needed to meet an individual patient's needs.

Though some interviewees expressed doubt that a one-time (annual) CMR could have a significant impact on outcomes, we found no evidence in the research literature indicating greater effectiveness of different intervention frequencies or periodicity, and minimal information about the frequency/type of services needed to prevent erosion of initial improvements. Interviewees commented that an MTM program should tailor the frequency of intervention to patient needs, rather than adopting a single/rigid schedule for all patients.

6.3. Service Delivery Mode: Telephonic versus Face-to-Face MTM

Most non-Medicare MTMPs include an annual face-to-face interaction between patient and pharmacist; many also include periodic in-person follow-up visits. These programs may use the telephone for periodic reminders or follow-up calls, and may triage some stable patients to telephone-only interactions while patients with greater needs receive repeated face-to-face interventions. Most non-Medicare MTMPs have the option for some patients to receive face-to-face interventions. Some of the largest national MTMPs deliver in-person services through community-pharmacies. And several non-Medicare

MTMPs do not specifically include reimbursement for telephonic interactions at all (e.g., VA, Minnesota Medicaid, United Mine Workers' West Virginia diabetes initiative).

Several MTMPs operated by large national managed care plans serving Medicare and non-Medicare members take a different approach and offer services exclusively by telephone—from the initial CMR through patient adherence counseling and prescription reconciliation with prescribers. (A few of these telephonic MTMPs also mail documentation of recommended prescription changes to patients and prescribers.) AMCP's (2008) study found that mail and telephone were the most common media, followed by in-person services. An advantage cited for telephonic MTM is that services are provided in the privacy of the patient's home, and can be offered to patients who do not reside near a community pharmacy where MTM services are available. A few MTMPs in the literature use a combination of face-to-face and telephonic MTM, tailoring interventions to patient needs and accessibility. One industry organization's recent validation study recommended that face-to-face MTM no longer be emphasized (the previous industry position), implicitly acknowledging that other modes may be necessary to meet the needs of all patients.

One Medicare MTMP is concerned about offering identical services to every patient and relies almost exclusively on MTM pharmacists sending their recommendations by mail to patients and their physicians. Similarly, AMCP's study participants who provided MTM via telephone preferred this interaction because it was more scalable, consistent, and convenient for the patient.

7. MTM Service Providers

Almost all MTMPs rely on pharmacists for CMRs, and for most other services as well. A few exceptions were found: one Medicare MTMP we interviewed uses nurses to deliver telephone adherence reminder calls to patients, another has physicians (rather than pharmacists) conducting MTM, and a third uses pharmacists for CMRs and refers complex care management needs to nurse case-managers. Many MTMPs use call centers for telephone interactions, and these too are staffed almost exclusively by pharmacists. We saw no differences between Medicare and non-Medicare MTMPs in the types of providers furnishing MTM services – almost all involve pharmacists.

Two Medicare MA-PDs we studied use salaried pharmacists to provide MTM services. One has its pharmacists conduct a CMR and mail recommendations to patients and physicians, and the other has its pharmacists interact with patients and physicians telephonically. Most other MTMPs either use call centers for telephonic MTM, or reimburse pharmacists at community pharmacies.

A Medicaid MTMP with whom we conducted a case study does not sign a contract with pharmacies, but does require that any pharmacy/pharmacist seeking reimbursement for MTM services to Medicaid recipients must:

- Be licensed in the state;
- Have graduated from an accredited college of pharmacy on or after May 1996 (the year that the state university graduated the first students exposed to a new pharmaceutical care curriculum), or have completed a comprehensive MTM training program that has both clinical and didactic elements;
- Be practicing in an ambulatory care setting as part of a multidisciplinary team; and
- Use an electronic documentation system that meets state standards (although the state receives only claims for services and not the data collected in such a documentation system).

Provider Networks

One national MTM vendor with whom we conducted a case study, contracts with pharmacies and pharmacists to provide MTM and expands this network as needed to serve its clients' populations. Within a pharmacy, not every pharmacist may be interested in MTM; those that are interested complete a free one-hour online training and receive login information to use the vendor's online system and submit claims. When contracting with a pharmacy, this vendor requires that the pharmacy "maintain a sufficient number of Approved Pharmacists on duty at each Approved Location, along with sufficient facilities, equipment, and support personnel in order to provide MTM to members in a timely and appropriate manner." Some PBMs and other MTM vendors similarly establish pharmacy networks at which patients can receive MTM services.

8. Financial Arrangements, Reimbursement and Documentation

8.1. MTMP Program Funding

Medicare Part D prescription drug plans are required to provide MTMPs to targeted beneficiaries and therefore administer their programs as part of their CMS contracts without additional reimbursement. Similarly, state pharmacy assistance programs and Medicaid MTMPs are funded through their respective state budgets. Employer-sponsored programs' MTMP costs are absorbed by the employers, and any savings accrue to the employer. Nursing homes are required to employ or contract with consultant pharmacists and savings accrue to the patients' insurers. The VA's pharmacists are salaried employees, as are MTM pharmacists in some Medicare MA plans.

Some programs receive financial support from outside sources including pharmacy association foundations (e.g., APhA Foundation support of Project ImPACT), provider networks (e.g., NC Polypharmacy Initiative), and consortia from within the pharmaceutical industry (e.g., the Pharmaceutical Care Consortium, consisting of pharmaceutical manufacturers). Many studies and evaluations of MTMPs we reviewed were funded by research grants or institutional support.

Many entities contract with third parties to partially or fully administer their programs (e.g., PBM or MTM vendors). Some also contract with third parties to operate telephone call centers for their MTMPs or provide MTM services in community pharmacies. The PBMs and MTM vendors we interviewed are paid a capitated rate by their clients (employers, Medicare drug plans), based in part on the characteristics of the client's population. Some MTM vendors offer a performance guarantee, for example one vendor guarantees to clients that a targeted return on investment (ROI) will be achieved.

We did not encounter any MTMPs that charge patients for MTM services, although some vendors and community pharmacies offer MTM services for purchase by individual patients. (The Asheville project eliminated prescription copays to encourage participation.)

8.2. Provider Reimbursement

The most common pharmacist reimbursement mechanisms we identified are summarized below.³⁷

8.2.1. Fee Schedules

Fee-for service (FFS) is a payment mechanism in which a provider is paid for each individual service provided to a patient. The majority of MTMPs that reimburse pharmacists for face-to-face MTM services use FFS payment, with pre-established rates (i.e. a fee schedule) for different services. For example, two MTM vendors set rates of \$50-\$60 for a Comprehensive Medication Review (CMR); one of the two also reimburses for prescriber consultation (\$20), patient compliance consultation (\$20), and education and

³⁷ Many studies did not describe provider reimbursement mechanisms, focusing instead on the services and outcomes of MTM.

monitoring (\$10). One of the MTM vendors stated that one client geographically adjusts the fee schedule for a CMR; while the other MTM vendor does not adjust the rates.

The employer-sponsored MTMPs that described their payment mechanism (in the literature, during interviews, or during case studies) all use FFS reimbursement with fee schedules.

The Medicare MTMPs that cover face-to-face MTM services either use salaried pharmacists in plan-operated clinics, or reimburse community pharmacists on a FFS basis. Medicare MTMPs vary in terms of the limits on the number of services they cover per year: some pay for only one service visit per year, but others cover quarterly or monthly visits. One of the MTM vendors contracts with pharmacists to provide services on an as needed basis to address an individual patient's needs. The reimbursement approach sometimes includes time increments, such that if the MTM service (e.g., CMR) requires more than 30 minutes for a complicated case, the pharmacist can bill in additional 15-minute increments. The few SNPs we interviewed primarily used in-house staff to provide MTM; however, a representative from one SNP that reimburses community pharmacists stated that pharmacists could bill up to \$100 an hour per month, per enrollee.

Three Medicaid programs reimburse pharmacists using an FFS fee schedule: one program reimburses pharmacists per visit (up to 12 per year) at \$20 per visit and had the following schedule and limits:

- Initial assessment - \$75 (1/patient)
- Problem follow-up assessment - \$40 (4/patient/year)
- New problem assessment \$40 (2/patient/12months)
- Preventive follow-up assessment - \$25 (1/patient/6months)

8.2.2. Resource-based Relative Value Scale (RBRVS) and CPT Codes

In an RBRVS, services are ranked based on the relative costs of the resources required to provide them. RBRVS as a reimbursement approach for pharmacists consists of five levels of case complexity, based on the following three components (Cipolle et al., 1998 and 2004):

- Number of medical conditions being managed with pharmacotherapy
- Number of drug therapy problems³⁸ identified and resolved
- Number of medications involved

The Minnesota Medicaid MTM Program was the only program we identified that uses a RBRVS. Exhibit 11 below illustrates the RBRVS used in the Minnesota Medicaid MTM Program. The Minnesota Medicaid MTM program also uses MTM Service CPT Codes for billing.

The Current Procedural Terminology (CPT) codes are descriptive terms for procedures and services used to report to public and private insurance programs and for claims processing. The Pharmacist Services Technical Advisory Coalition (PSTAC), formed in 2002 and composed of national pharmacy

³⁸ A drug therapy problem is defined as “any undesirable event experienced by a patient which involves, or is suspected to involve, drug therapy and that interferes with achieving the desired goals of therapy” (Cipolle et al., 2004, pp. 370).

organizations,³⁹ was established “to improve the coding infrastructure necessary to support billing for pharmacists' professional services.”⁴⁰ According to the PSTAC payer survey published on December 21, 2006, payers reported early adoption of the MTM CPT codes to pay claims for face-to-face encounters provided by pharmacists to covered beneficiaries.⁴¹

The MTM Service temporary Category III CPT codes were published in October 2005. The PSTAC applied to change the MTMS CPT code status from temporary (Category III) to the permanent classification (Category I); Category I status was officially granted by the CPT Editorial Panel at its February 2007 meeting. The new, permanent codes became effective January 1, 2008. The following is the PSTAC description of the Code Model, including a description of MTM and the relevant services included in the model.

“Medication Therapy Management Service(s) (MTMS) describes face-to-face patient assessment and intervention as appropriate, by a pharmacist. MTMS is provided to optimize the response to medications or to manage treatment-related medication interactions or complications. MTMS includes the following documented elements: review of the pertinent patient history, medication profile (prescription and non-prescription), and recommendations for improving health outcomes and treatment compliance. These codes are not to be used to describe the provision of product-specific information at the point of dispensing or any other routine dispensing-related activities.

- 99605: Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment, and intervention if provided; initial 15 minutes, new patient
- 99606: initial 15 minutes, established patient
- 99607: each additional 15 minutes (List separately in addition to code for the primary service.
- (Use 99607 in conjunction with 99605, 99606)⁴⁰

In Minnesota, pharmacists bill Medicaid using these CPT Codes with the following reimbursement amounts:

- 99605: A first encounter service performed face-to-face with a patient in a time increment of up to 15 minutes (rate = \$52.00)⁴²
- 99606: Follow-up encounter with the same patient in a time increment of up to 15 minutes for a subsequent encounter (rate = \$34.00)
- 99607: Additional increments of 15 minutes of time for 99605 or 99606 (rate = \$24.00)

³⁹ AMCP, ACCP, APhA, ASCP, ASHP, NACDS, and NCPA.

⁴⁰ Retrieved from PSTAC website at: <http://www.pstac.org/index.html>

⁴¹ “Provider and Payer Survey of Medication Therapy Management Services.” Report of the Pharmacist Services Technical Advisory Coalition. December 21, 2006. Retrieved from PSTAC website at: <http://www.pstac.org/index.html>

⁴² These rates are not adjusted for inflation on an annual basis, for example. The rates have not been updated since they were created in 2006.

The following Exhibit from the Minnesota Health Care Plan provider manual⁴³ identifies the CPT codes for pharmacists to use based on the corresponding assessments, drug therapy issues, and care plans (RBRVS).

Exhibit 11: Minnesota Medicaid MTM Codes and Payments

Patient Need Level	Assessment of Drug-related Needs (number of medications)	Identification of Drug Therapy Problems (number of drug therapy problems)	Complexity of Care Planning and Follow-Up Evaluation (number and complexity of medical conditions)	Approx. Service Time	CPT Code	Units	Rate: 1 st encounter vs. follow-up
1	Problem-focused – at least 1 medication	Problem-focused – 0 drug therapy problems	Straightforward – 1 medical condition	15 minutes	99605 or 99606	1 unit	\$52 or \$34
2	Expanded problem – at least 2 medications	Expanded problem – at least 1 drug therapy problem	Straightforward – 1 medical condition	16-30 minutes	99605 or 99606 and 99607	1 unit 1 unit	\$76 or \$58
3	Detailed – at least 3-5 medications	Detailed – at least 2 drug therapy problems	Low complexity – at least 2 medical conditions	31-45 minutes	99605 or 99606 and 99607	1 unit 2 units	\$100 or \$82
4	Expanded detailed – at least 6 medications	Expanded detailed – at least 3 drug therapy problems	Moderate complexity – at least 3 medical conditions	46-60 minutes	99605 or 99606 and 99607	1 unit 3 units	\$124 or \$106
5	Comprehensive – ≥ 9 medications	Comprehensive – ≥ 4 drug therapy problems	High complexity - ≥ 4 medical conditions	60+ minutes	99605 or 99606 and 99607	1 unit <u>4 units</u>	\$148 or \$130

Source: Minnesota DHS Health Care Provider Manual

For example: a patient with 9 medications and 4 medical conditions, but 0 drug therapy problems, is Level 1 – the lowest level that meets *all three criteria*. If this is the patient’s first MTM encounter, the pharmacist bills 99605 and is reimbursed \$52; if it is a follow-up encounter, the pharmacist bills 99606 and is reimbursed \$34.

The following limitations are placed on the number of MTM claims that can be submitted for each Medicaid recipient:

- One CPT 99605 (first encounter) per pharmacist, per recipient in a 365-day period
- Up to seven CPT 99606 (follow-up encounters) per recipient in a 365-day period

⁴³ Minnesota Health Care Program (MHCP) Provider Manual - Medication Therapy Management Services (MTMS) (Chapter 22A). Retrieved from <http://www.dhs.state.mn.us>.

- Up to four CPT 99607 (additional time increments) per recipient per date-of-service

MTM pharmacists may request prior authorization to bill the state for additional follow-up consultations (CPT 99606 only). MTM pharmacists file claims for MTM services using a CMS 1500 Form or through the MN-ITS 837P via an on-line billing system for submission of medical claims to DHS.

The Minnesota Medicaid MTM reimbursement model is unique; we found no other MTMP that reimburses pharmacists in this manner.

8.2.3. Other Reimbursement Issues

The vast majority of MTMPs and third party vendors we encountered have no explicit incentive component (e.g., pay-for-performance) in their pharmacist reimbursement arrangements. However, Farris et al. (2002) described an MTM vendor's introduction of pharmacy performance scores to demonstrate to payers that the providers bear some risk and have an incentive to achieve performance goals. Pharmacies that were rated poorly were subjected to a one dollar dispensing fee reduction. The introduction of the performance scores appeared to affect ROI, especially after the one dollar reduction in dispensing fee was implemented.

There are, however, implicit incentives and disincentives in some reimbursement systems. Pharmacy association representatives told us that most MTMPs offer no payment differential for simple vs. complex patients; this could lead pharmacists to avoid more-complex MTM cases. For example, the programs that pay a flat fee for a specific service, and fail to include a time variable for additional time needed to provide a service, create a disincentive for pharmacists to provide MTM to more-complex patients.

Pharmacy associations have argued that reimbursement is an important motivator for pharmacist participation in MTM. Several pharmacy association representatives noted a need for more-concrete evidence to determine an appropriate fee structure for MTM that incorporates the time required for various MTM services.

Two of the MTMPs we studied in-depth use similar fee schedules for pharmacist reimbursement, but have experienced very different pharmacist participation. One has thousands of pharmacists engaged and providing services to tens of thousands of patients, the other has just over 100 pharmacists serving a handful of patients each. Reimbursement alone does not appear to be a sufficient incentive to motivate pharmacists to provide MTM, and other factors (e.g., training requirements, cost and ease of documentation systems, competing priorities in retail pharmacies) are probably important. Pharmacists' opportunity costs are also a factor, as several pharmacy stakeholders reported that dispensing pharmacists are "too busy" to provide MTM.

8.3. Documentation Systems

The documentation systems used by MTMPs and their vendors facilitate interaction and data exchange between the vendor and pharmacies, but may also pose barriers to provision of MTM by community pharmacists.

One major MTM vendor we studied uses a web-based documentation platform that network pharmacists access using a login identification and password. The platform includes an electronic patient chart

containing a current medication list, allergies, etc. The medication list is not auto-populated from the pharmacy dispensing system; however, the medication history section of the system is populated every 30 days with prescription claim data provided by the client-payers, and is available for pharmacists to review. A pharmacist can also add to the patient record, to include patient-reports (or lab printouts) of laboratory test results. The electronic patient chart also includes a SOAP⁴⁴ note-like field for pharmacists to more fully describe the encounter and services, and necessary follow-up. The system allows pharmacists to create a printable MTM profile for patients. The profile is based on the APhA and NACDS guidelines for creating a printable Medication Action Plan⁴⁵ so that patients have a written guide of the medications they are currently taking. The system does not, at this time, have the ability to print an MTM profile in a calendar format to create an individualized schedule for a patient. With this system pharmacists can also submit MTM claims and send/receive messages. The system has a “report card” function that rates each pharmacy based on specific benchmarks for each of seven categories.⁴⁶ The pharmacy report card also includes a composite performance score for each pharmacy, which uses an algorithm to combine the seven categorical scores. The score can be used at the chain or administrator level to assess the performance of individual pharmacies or entire pharmacy chains.

Another MTM vendor has a system that is accessed by pharmacists via a secure web link. Each pharmacy or chain of pharmacies has access to only its own data, to assure patient confidentiality. The system is a comprehensive electronic documentation and billing system designed to help pharmacists provide MTM and includes patient demographics, medical conditions, medications, laboratory results, and drug therapy problems. The system facilitates the MTM care process for pharmacists by allowing them to: document MTM services, track medication reconciliation interventions, identify and resolve drug therapy problems, create care plans, document and report therapeutic goals, schedule appointments, create claims automatically, and submit invoices electronically to any payer (including those that use a CMS 1500 form). The system also facilitates data collection and reporting to support patient care and practice management activities, and to demonstrate the clinical and economic outcomes of MTM (there are over 250 discreet data variables in the system). This vendor’s system can generate reports for patients (medication summaries), practice management reports, clinical outcomes reports and financial reports for clients.

Both of these vendor systems and others are web-based. We interviewed a large national community pharmacy chain that refuses to use web-based systems like those created by most vendors, for data security reasons. This pharmacy chain is concerned about sending patient data over the Internet and allows no web-based applications in any of its thousands of drugstores. This corporate policy means that the chain cannot serve patients whose MTMPs contract with the two vendors we interviewed, which both use web-based documentation systems.

⁴⁴ SOAP stands for subjective, objective, assessment and plan and is a standard documentation format for health care professionals.

⁴⁵ American Pharmacists Association and National Association of Chain Drugstores Foundation (2005). Medication therapy management in community pharmacy practice: core elements of an MTM service (version 1.0). *Journal of the American Pharmacists Association*;45:573-79.

⁴⁶ The seven categories include comprehensive medication review claims; cost efficacy management claims; patient education/monitoring claims; indications, efficacy, and safety claims; patient compliance; consultation claims; estimated cost avoidance; and total claims

Many pharmacy chains centralize claims submission and adjudication; other pharmacies do not have a centralized process for adjudicating claims. MTM electronic systems that are intended to both support patient care and transmit claims from MTM providers pose a barrier to pharmacy chains that centralize claims submission. MTM documentation systems that separate patient care functions and data (e.g., lab results, allergies, medication histories) from billing functions may be more adaptable to different settings.

Because each MTMP has different policies for reimbursing pharmacists who provide MTM services, each requires different documentation. Some community pharmacies find it difficult to operate more than a few disparate billing and documentation systems.

All of these documentation issues may pose barriers to the provision of MTM through community pharmacies, and may also pose barriers for telephonic MTM delivered through call centers. Some, but not all, of these issues would be addressed if MTMPs moved toward more standardized documentation requirements. Over time, many pharmacy dispensing systems adopted standardized documentation and adjudication procedures; similar standardization may evolve for MTM.

Documentation systems capture varying levels of detail in terms of patient clinical data, drug therapy problems, pharmacist documentation assessment and care plans, and prescriber concurrence with MTM recommendations. The two largest documentation systems we studied, one of which is widely used in a Medicaid MTMP, are very similar and each is accumulating a large database of patient-level information on thousands of patients (each company reports thousands of encounters/claims in its system). There are probably other similar databases managed by other firms/vendors/plans that are similarly accumulating data on thousands of patients. Analysis of such data could be useful for answering a variety of important questions related to MTM. It might, for example, be possible to identify types of patients (e.g., diagnoses, drugs, age) most likely to have drug therapy problems or adherence problems, and for whom MTM has the greatest potential impact. This could allow CMS and other payers to more precisely specify the types of patients that should be included in MTMPs. These data sources are as yet largely untapped for such analytic and policy purposes.

9. MTM and Coordination with Disease Management/Care Management Programs

The Disease Management Association of America defines disease management as, “A system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant.” It says further that:

“Disease management:

- Supports the physician or practitioner/patient relationship and plan of care;
- Emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies; and
- Evaluates clinical, humanistic, and economic outcomes on an on-going basis with the goal of improving overall health.

Disease management components include:

- Population identification processes;
- Evidence-based practice guidelines;
- Collaborative practice models to include physician and support-service providers;
- Patient self-management education (may include primary prevention, behavior modification programs, and compliance/surveillance);
- Process and outcomes measurement, evaluation, and management;
- Routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling). ”

The National Pharmaceutical Council defines disease management as:

“A strategy of delivery health care services using interdisciplinary clinical teams, continuous analysis of relevant data, and cost-effective technology to improve the health outcomes of patients with specific diseases. Disease management programs enhance communication between practitioners and patients, facilitate feedback necessary for behavior modification (which may prevent or delay disease progression), and measure the effectiveness of interventions. When properly structured, disease management involves an integrated, comprehensive approach to patient care that extends beyond a focus on the drug line item. Disease management:

- Improves health outcomes and better measures the ‘value’ of provided services.
- Takes a patient-centered approach to providing care by addressing psychological aspects, caregiver issues, and treatment of multiple diseases using nationally recognized standards of care.
- May lower costs by reducing the use of unnecessary or redundant services or avoiding costs associated with poor outcomes.”⁴⁷

⁴⁷ Retrieved from: <http://www.npcnow.org/diseasemanagement/definition.asp>. Accessed on October 25, 2007.

In 2004 the Congressional Budget Office advised Congress that “Disease management programs vary widely in the specific techniques and tools that they use, but they share several common components that are designed to address those shortcomings. One component is to educate patients about their disease and how they can better manage it. The goal is to encourage patients to use medication properly, to understand and monitor their symptoms more effectively and possibly to change their behavior. A second component is to actively monitor patients' clinical symptoms and treatment plans, following evidence-based guidelines. A third component is to coordinate care for the disease among all providers, including physicians, hospitals, laboratories, and pharmacies” (Congressional Budget Office, 2004).

As these three examples demonstrate, there is no single definition of a DM program, just as there is no single definition of an MTM program. We did not explore the disease management literature, as our focus was on medication therapy management. We did, however, discuss with interviewees and case study programs whether and how the two types of programs are coordinated, and we note the following general distinctions between DM programs and MTMPs (all of which have exceptions):

- Many DM programs include medication therapy management as a component, and DM and MTM are combined in many different configurations. Some of the most often-cited MTMPs have DM features and might be considered hybrid MTM-DM programs (e.g., Asheville,⁴⁸ V.A.).
- DM programs often use multi-disciplinary teams of providers – combinations of social workers, nurses, physicians, therapists, and (sometimes) pharmacists. Although some MTMPs also use a team approach, and this is included in some of the MTMP definitions (see Chapter 4), most Medicare MTMPs rely on pharmacists.
- DM programs tend to focus on many types of medical care, and some include non-medical social services as well. Disease and Care Management programs may coordinate care among many types of providers, from hospitals to physicians to home health. By contrast, MTMPs focus on medication therapy and coordination among pharmacists and prescribers; few MTMPs, especially in Medicare, extend interventions to include other primary or tertiary care.
- The V.A., chronic care SNPs, and most other non-Medicare MTMPs make no formal distinction between their DM efforts and their MTM activities – all are combined in a single program aimed at improving patient health and reducing costs. V.A. providers believe that it would be counter-productive to separate MTM from other DM components, as this would cause discontinuities in care and confusion for patients. This is consistent with some of the features of MTMPs, such as coordinating medication management with other disease management services and providers.

Many non-Medicare MTMPs combine or integrate DM with MTM, but most Medicare Advantage plans we interviewed that operate both DM and MTMPs believe that their contracts require them to operate these programs separately. They do not combine DM and MTM into one program, in part because they would have difficulty separately reporting enrollment, expenditures, or outcomes for each program. In some Medicare Advantage plans, MTM and DM programs share patient rosters so that each program is aware of patients who are enrolled in both, but this is not universally the case; some MTMPs refer their patients to DM when indicated, or vice versa. Most of the Medicare MTMPs we interviewed do not

⁴⁸ The Asheville Project is a combined DM-MTM program sponsored by the City of Asheville, NC for employees and retirees of the City and their dependents, having a diagnosis of diabetes, asthma, hypertension, or hyperlipidemia. Services include monthly face-to-face interactions with a pharmacist for clinical assessment, education, patient monitoring, follow-up, and referral.

explicitly coordinate to ensure consistency in educational messages for patients, to combine monthly interventions, or to otherwise coordinate contacts/interventions for patients enrolled in both programs.

We conducted a case study with a large Medicare MA-PD that separates DM from MTM for their Medicare contracts because they believe this is necessary to meet CMS requirements; the plan does not separate the two programs for their commercial populations because they prefer to fully-integrate all chronic care services including medication management. The plan's salaried pharmacists have access to the same electronic health record used by physicians, so all providers involved in a patient's care share information about medications. The MTM vendor we studied uses community pharmacists and does not directly coordinate MTM interventions with any other care management programs, although their payer-clients can download data with which to coordinate MTM and DM programs. The Medicaid MTMP we studied uses community pharmacists and does not integrate MTM with other Medicaid programs; however, they plan to include MTM as one part of a Medical Home initiative in the future. The V.A., on the other hand, does not operate separate MTM and DM programs; salaried pharmacists are part of primary care teams that share a common electronic health record. The programs that utilize community pharmacists to provide MTM (e.g., Medicaid, MTM vendors) encourage coordination of care with patients' physicians, and some drug therapy problems require that pharmacists communicate with prescribers in order to resolve the issue.

Based on this evidence, it appears that opportunities for MTM and DM coordination may be greater in a managed care context, especially when services are provided by in-house staff using a shared EHR. Opportunities for coordinating MTM and DM may be less when MTM is "carved out" to a separate vendor and/or conducted by community pharmacists. One barrier may be data sharing, as DM programs and MTMPs are unlikely to share the same patient-level data systems unless they are operated by the same entity (e.g., an MA plan or the V.A.).

10. Special Populations

10.1. Nursing Home Patients

Nursing home patients are of particular concern for CMS, and Part D drug plans are required to offer MTM services to eligible institutionalized patients. Nursing home consultant pharmacists conduct (monthly) drug regimen reviews (DRRs) for every patient as well. This usually involves a chart or medication administration record review and not direct patient contact. There is thus overlap between MTMPs and the responsibilities of nursing home consultant pharmacists.

Each of the four MTMPs we studied in-depth takes a different approach to MTM for nursing home patients. One uses in-house/salaried pharmacists to conduct MTM and refers nursing home patients with medication management issues to dedicated LTC case managers. MTM program managers agree that the CMR review somewhat duplicates the work of nursing home consultant pharmacists. The Medicaid MTMP we studied does not serve patients in nursing homes or home settings because the state believes that this duplicates the work of nursing home consultant pharmacists. An MA plan mails the same letters to all prescribers and patients regardless of whether or not the patient resides at home, but conducts no further follow-up. The national MTM vendor we studied does not reimburse for CMRs for institutionalized patients because this duplicates the work of nursing home consulting pharmacists, and does not reimburse for direct patient services such as consultations, education, and monitoring. It does, however reimburse for prescriber consultation – although it would be unusual for an MTM pharmacist to deliver this service since these pharmacists are not reimbursed for the CMR that would lead to the identification of the need to consult with a prescriber. None of these four programs collaborate with nursing home consultant pharmacists, and none interact directly with nursing home staff (who actually control patient medication use) to improve medication therapy.

We interviewed representatives from three long-term care (LTC) pharmacies: one owns nursing facilities and the other two serve nursing home chains. None of the three organizations is directly involved with the implementation of an MTM program. Two of the three interviewees noted the overlap between MTMPs and CMS requirements that nursing homes employ consultant pharmacists to provide monthly medication reviews. One organization mentioned that duplicate payments might result if nursing homes' consultant pharmacists perform both a drug regimen review and a billable MTM service.

All three LTC pharmacy representatives believe that Medicare Part D MTMPs are intended for community-dwelling beneficiaries, not those living in nursing homes. They pointed out that letters and telephone calls to MTM enrollees, and meetings with pharmacists, are not useful for nursing home patients who may be cognitively impaired and who do not self-medicate. And they advised that nursing homes' consultant pharmacists conduct monthly medication chart reviews and interact with facility staff to improve adherence to guidelines, prevent therapeutic duplication, identify side effects, and review patient medications – all functions that duplicate the responsibilities of MTMPs.

One interviewee noted that on occasion, nursing home staff will call the LTC pharmacy when they receive a letter from an MTMP and are confused because the recommendations conflict with what the nursing home's consultant pharmacist has recommended. Often the MTMP's recommendations are based on claims/prescription data that could have a time lag of weeks to months; the nursing home's consultant

pharmacist has access to current patient charts and often has already addressed problems identified by the MTMP.

We interviewed three Special Needs Plans that serve LTC-eligible patients (the fourth SNP we interviewed focuses on HIV/AIDS). One of the LTC SNPs offers the same services to institutionalized patients as to others. The second SNP explained that although the plan offers MTM services to nursing home residents, LTC regulations require that the facility's consultant pharmacist review each patient's medications, and there can be inconsistencies between MTMP and consultant pharmacist recommendations. The third LTC SNP (which as yet has very few MTMP enrollees) plans to send nurses into LTC facilities, just as it does to private homes, to conduct initial assessments.

All four case study MTMPs, and many of the other Medicare drug plan MTMP representatives we interviewed, pointed to the same barriers and structural issues that LTC pharmacies described:

- Institutionalized patients are often cognitively impaired and hence unable to benefit from a conversation/meeting with an MTMP pharmacist.
- Institutionalized patients do not self-medicate.
- LTC consultant pharmacists conduct monthly medication reviews and suggest medication therapy changes; any conflict between MTM recommendations by consultant pharmacists and MTMP pharmacists will be resolved in favor of the consultant pharmacist's recommendations.

Long-term care pharmacies and institutions, as well as several Medicare MTMPs, advise that MTM practices may need to be altered for patients in nursing homes. Direct mailings to inform patients about compliance/adherence issues are ineffective for nursing home patients who are cognitively impaired and do not self-administer their medications. Telephonic interventions, or those that require a patient visit to a community pharmacy, are ineffective for most institutionalized patients. In addition, nursing home staff may not know how to reconcile inconsistent advice coming from the two sources, and generally defer to their consultant pharmacists.

10.2. Special Needs Plans

We interviewed representatives from four SNPs:

1. An SNP that contracts with Medicare and Medicaid to provide primary and acute healthcare services and comprehensive long-term care for approximately 1,200 frail elderly and physically disabled adults who have chronic conditions, who meet the nursing home level of care requirements, but who are living in the community,
2. An SNP designed specifically for people with HIV/AIDS,
3. An SNP offered by a county health authority for low-income families and persons with disabilities,
4. An SNP that offers services to dually eligible individuals living in services areas in three states.

Three of the four SNPs' MTMPs are run by interdisciplinary teams of an RN or nurse practitioner, social worker, pharmacist, and primary care physician. One MTM team includes case managers (nurses),

pharmacists, and physicians; another uses teams anchored by RNs, with contributing pharmacists and physicians. The fourth SNP's MTMP is primarily pharmacist-run.

Each of these four SNPs has DM as well as MTM elements in its program. Two representatives equated disease management with case management. One explained that she sees the MTM program at a macro level – generating data to show which patients need more oversight – while case management functions at a more “granular” or patient/individual level. Another noted that the MTM program looks at medication outcomes, while disease management tends to be more focused on disease awareness. In one program, disease management is not medication-focused, but is rather about helping members navigate the system (e.g., get a referral with a specialist); their members can be enrolled in both MTM and disease management, and the two programs share lists of enrollees.

The national MTM vendor has a client that is a multi-state Special Needs Plan (SNP) for dual-eligible beneficiaries. This SNP's MTM program was previously run by a PBM, which used an “opt-in” enrollment approach with a mailed invitation and had zero enrollment. A majority of that SNP's patients are illiterate, and they speak over two dozen different languages, which may be why a mailed invitation was unsuccessful. The vendor is expanding its network of pharmacies in the SNP's coverage area, and the program will be available to all patients. Dispensing pharmacies will be notified about their eligible patients, and encouraged to offer them MTM services. Retail pharmacies deal with language issues on a daily basis, and are accustomed to working through family members and other interpreters when necessary; the vendor believes that these same in-person translation strategies are the most effective way to overcome language barriers for MTM.

All four SNPs are still collecting data and none had completed analyses at the time of our interviews. We found no publications related to SNP MTMPs, and therefore have no evidence about the effectiveness of these programs in meeting the needs of special populations.

10.3. Literacy Issues

MTM services should ideally be delivered in a patient's spoken and/or written language; literacy and fluency in English should not be required in order to enroll in an MTM program and receive services. Community pharmacists deal with spoken language issues on a daily basis, using other staff, patients' family members and others as interpreters. Using this model, in-person (and perhaps telephonic) MTM conducted from community pharmacies may be the best way to overcome language barriers.

We found little mention of literacy issues in the published MTM literature but did explore this issue during case studies; the four MTMPs we studied deal with literacy and language issues in different ways. One MA plan sends enrollment invitation letters to eligible plan members, without telephone follow-up. This plan delivers all its MTM services via letters as well, in English. It is likely that persons who do not read English, and who have no English-literate “assistant” to help them, are unable to enroll and receive MTM services from this plan.

The other MA plan we studied also mails invitation letters, but follows-up with telephone invitations. These follow-up calls may be able to overcome literacy and language barriers, if the staff placing follow-up calls are able to communicate well in each patient's spoken language. Most MTM services are delivered telephonically in this MTMP, with the same potential barrier.

The Medicaid MTMP we studied relies on community pharmacists to identify patients who could benefit from MTMP, and provide services to them. The national MTM vendor sends community pharmacies lists of eligible patients, and the pharmacies provide direct patient services. Both of these programs assume that community pharmacists will use the same communication solutions that they employ for all patient interactions with non-English-speaking customers. Both programs believe that pharmacists who see patients in-person are better able to identify and overcome literacy and language barriers, than can pharmacists communicating with patients by telephone or especially by mail.

11. Outcomes and Evaluation

11.1. Outcomes Measured in Research/Evaluations

Some published MTMP assessments, and those conducted by many MTMPs in their first years of operation, focus on *process measures* including:

- Percent of enrolled MTM patients who received MTM services
- Number of MTM interventions provided (CMRs, patient sessions, etc.)
- Completeness of Patient Care Plans

Intermediate outcome measures are common in the research literature, and include:

- Patient adherence to drug regimen
- Patient knowledge/understanding of drug regimen
- Type and frequency of drug therapy problems identified
- Number of prescription changes recommended by pharmacists
- Percent of pharmacist recommendations “accepted” by prescribers
- Total number of prescriptions (studies are inconsistent as to whether an increase in number of prescriptions is considered “better” or “worse”)

Intermediate outcomes also include common clinical measures such as:

- Clinical indicators (e.g., HbA1c, LDL cholesterol, peak expiratory flow)
- Number of drug therapy problems resolved (over-use, under-use, therapeutic duplication, BEERs list drugs, drug-drug interactions, etc.)
- Number of potential adverse drug events (ADEs) identified (and avoided)

MTMP *financial/economic outcomes* include:

- Total prescription costs
- Patient out-of-pocket prescription costs (copays, non-formulary drugs)
- Total costs for all medical care (not limited to prescription costs)
- “Avoided” ED visits, physician visits, and/or hospitalizations, and associated costs; based on either actual claims or Estimated Costs Avoided
- Return on investment (for the MTMP), usually measured as the ratio (in dollars) of total savings to pharmacist reimbursement, or total savings to total programmatic costs.

And other *miscellaneous outcomes* include:

- Number of sick days or non-productive days (for employer MTMPs)
- Patient satisfaction with pharmacy/MTM services
- Prescriber satisfaction with MTM services

Some of these outcomes are measured at the patient level, for example, before/after changes in each participant's blood glucose level. Other outcomes are measured at the program level, for example, reduction in sick/unproductive days for an entire intervention group. Occasionally programmatic impact is expressed as Return on Investment – for example, \$4 savings for every \$1 spent⁴⁹ on the Asheville project (Bunting, 2007). And in some studies patient-level outcomes suggest a causal link between MTM services and program-level changes. For example, the causal relationship suggested by evaluators of the Asheville project is that MTM interventions helped to improve patient-level blood glucose or lung capacity, which in turn reduced sick days and other health care costs.

Several Medicare MTMPs we interviewed have not conducted evaluations, and thus far are focusing on process measures and some intermediate outcomes (e.g., patient adherence). They are, however, interested in the “business case” and whether their MTMP saves at least as much as it costs. They derive a rough approximation of savings by calculating Estimated Cost Avoidance. Pharmacists (or MTMP staff) estimate health care utilization that would have taken place in the absence of MTM. That is, they credit MTM with avoiding an ADE, an ED visit, or a hospitalization. Some programs have guidelines for crediting MTM with an avoided service; in other programs these decisions are ad hoc and subjective, and probably not consistent across pharmacists. MTM vendors review claims, rejects claims if inappropriate levels of cost or health care services avoided are attributed to MTM services. Program managers use average costs for “avoided” services (e.g., average cost of a hospital stay), to arrive at the total estimated costs avoided by the MTMP.

11.2. Evaluations: Strength of the Evidence

Appendix B contains detailed descriptions of published MTM studies and program evaluations. Many studies address the efficacy of MTM – whether pharmacist involvement can reduce costs and/or improve quality of care. Few studies, however, concern the best way to promote MTM in a structured *program*. And there is little published research as yet about Medicare Part D MTMPs (which are in their third year of operations). We discovered no clear evidence – published or unpublished – on the following topics:

- The most appropriate or “best” eligibility criteria for MTM, which would target the patients most likely to benefit from MTM
- The most effective MTM services, combination and frequency of MTM services for achieving optimal outcomes, or the best mode with which to deliver these services (i.e. mail, phone or face-to-face)
- Which pharmacist reimbursement mechanisms would incentivize pharmacists to deliver the most effective and efficient combination of MTM services
- Optimal approaches to coordinating MTM and DM programs
- Optimal approaches to provide MTM to Medicare beneficiaries in nursing homes and integrating MTM with nursing home consultant pharmacist services

We did, however, explore evaluations with relevance for the Medicare Part D program (See Exhibit 12).

⁴⁹ Mentioned in Bunting (2007) presentation titled “Community-Based Case Management Of High Risk Populations Decreases Healthcare Costs.” The ROI of 4 to 1 was calculated by the employer.

Exhibit 12: Study Designs of the Relevant Program Evaluations

Study Title, Lead Author & Year	Study Design ⁵⁰
Iowa Pharmaceutical Case Management Program	<i>Design:</i> Retrospective review of pharmacist services <i>Setting:</i> Community pharmacies in Iowa n=203 Medicaid patients (150 received MTM; 53 withdrew)
Becker et al. 2004; Carter et al. 2003; Doucette et al. 2005	<i>Limitations:</i> No random assignment, no comparison, no intent-to-treat analysis; cost and outcomes not assessed
IMPROVE: A Study at Veteran's Administration Medical Centers Billups et al. 2000; Ellis, Billups, et al 2000; Ellis, Carter, et al. 2000; Malone et al. 2000.	<i>Design:</i> Randomized control trial; pharmaceutical care vs. usual care. <i>Setting:</i> 9 V.A. medical centers n=523 patients intervention n=531 control n=208 patients with hyperlipidemia (intervention group); n= 229 controls <i>Duration:</i> 12 months <i>Limitations:</i> Patients self-selected to phone vs. in-person MTM
Pharmaceutical Care Services & Results in Project IMPACT: Hyperlipidemia Bluml et al., 2000.	<i>Design:</i> Pre/post study with a comparison group <i>Setting:</i> 26 community-based pharmacies in 12 states n=397 patients (345 lipid med & lifestyle; 52 exercise & diet lifestyle) <i>Duration:</i> Patients followed for average of 24.6 months. <i>Limitations:</i> No random assignment, no intention-to-treat analysis
The Asheville Project Bunting & Cranor, 2006; Cranor et al., 2003; Cranor & Christensen, 2003a; Cranor & Christensen, 2003b.	<i>Design:</i> Quasi-experimental, longitudinal pre/post cohort study <i>Setting:</i> 12 community pharmacies in Asheville, NC <i>Sample:</i> City of Asheville employees, dependents, & retirees. Analyses focused on asthma & diabetes (sample varies by analysis). <i>Duration:</i> 5 years <i>Limitations:</i> No random assignment
Pharmacist Response to Alerts Generated From Medicaid Pharmacy Claims, in a Long-term Care Setting: Results from the North Carolina Polypharmacy Initiative Christensen et al. 2004 Trygstad et al. 2005.	<i>Design:</i> Pre/post comparison of patients in nursing homes that volunteered, versus those in whose nursing homes did not. <i>Setting:</i> Nursing homes n=6,344 nursing home patients (intervention); n=2,202 control <i>Intervention:</i> Added drug therapy alerts to usual-care DRR provided by consultant pharmacists <i>Limitations:</i> No random assignment, potential selection bias stemming from "non-responder" nursing homes as comparison group
Outcomes-based Pharmacist Reimbursement: Reimbursing Pharmacists for Cognitive Services Farris et al. (2002). Pharmaceutical Care and Health Care Utilization in an HMO Fischer, et al. 2002.	<i>Design:</i> Cross-sectional descriptive analysis <i>Setting:</i> Approximately 90 pharmacies n=11,326 enrollees <i>Duration:</i> one year <i>Design:</i> Pre/post with comparison group <i>Setting:</i> 6 intervention pharmacies & 143 control pharmacies n=231 MTM participants at 6 intervention pharmacies; n=444 controls <i>Duration:</i> One year <i>Limitations:</i> - No random assignment, program costs not included; comparison group pharmacies and patients very different from intervention.
Evaluating Effectiveness of the Minnesota Medication Therapy Management Care Program Isetts, 2007.	<i>Design:</i> Pre/post study of MTM impact re: QCare standards, drug costs and total health care expenditures. n=259 recipients, of which: Economic analyses n=77; QCare standards n=114; Therapeutic goals n=167. <i>Duration:</i> One year. <i>Limitations:</i> - No random assignment, no comparison group, small sample size and missing data for some analyses
Outcomes of Pharmacists' Cognitive Services in the Long-term Care Setting Johnston et al.1996;	<i>Design:</i> Drug regimen review and follow-up. <i>Setting:</i> 122 nursing homes and 4 LTC pharmacies in 2 states N=10,207 residents of 122 nursing homes (98% SNFs). <i>Limitations:</i> No random assignment, no comparison group; health status assessed by pharmacist conducting DRRs from nursing notes and medical chart data; program costs not included.
The Impact of Clinical Pharmacists' Consultations on Physicians' Geriatric	<i>Design:</i> Prospective, randomized controlled trial. Patients randomly assigned at hospital discharge to intervention vs. usual care

⁵⁰ The intervention is specified when the intervention is not a standard MTM service. Some larger studies were presented in many articles. The study designs are summarized, with unique design elements described as appropriate (e.g., different samples for the subset of patients described in one publication versus another).

Exhibit 12: Study Designs of the Relevant Program Evaluations	
Study Title, Lead Author & Year	Study Design⁵⁰
Drug Prescribing. Lipton et al. 1992.	n=274 patients but only 123 intervention & 113 controls completed the study. <i>Duration:</i> Patients followed for 3 months. <i>Limitations:</i> No intention-to-treat analysis, accuracy of patient self-reported post-discharge prescriptions not measured, prescriber acceptance of pharmacist recommendations not measured, patient health outcomes and costs not measured.
An Evaluation of Managing and Educating Patients on the Risk of Glucocorticoid-Induced Osteoporosis McDonough et al. 2005.	<i>Design:</i> Randomized control design <i>Setting:</i> 8 treatment pharmacies & 7 control pharmacies n=80 patients: 61 treatment & 19 control <i>Duration:</i> 9 months <i>Limitations:</i> All pharmacies had participated in other research & were trained to deliver MTM; small control group
Medication adherence in heart failure patients Murray et al., 2002.	<i>Design:</i> Randomized trial of intervention vs. usual care. n=122 intervention patients n=92 control <i>Duration:</i> Intervention for 9 months, followed 3 months post intervention. <i>Limitations:</i> Unclear if analysis included patients who discontinued participation; one pharmacist provided the intervention (results may not be generalizable).
Effects of Geriatric Evaluation and Management on Adverse Drug Reactions and Suboptimal Prescribing in the Frail Elderly. Schmader et al. 2004	<i>Design:</i> Randomized 2 X 2 factorial controlled design. Inpatients randomly assigned to intervention that continued after discharge vs. usual care <i>Setting:</i> 11 V.A. hospitals 834 frail elderly patients (mostly male) <i>Duration:</i> 1-year post-discharge <i>Limitations:</i> Patient health outcomes and costs not measured.
Effect on health outcomes of a community-based medication therapy management program for seniors with limited incomes. Smith, et al. 2004.	<i>Design:</i> Pre/post cohort study of impact of pharmacist services in reducing prescription costs n=794 patients referred to PAP (Durham, NC community residents 65+) <i>Duration:</i> 2 years <i>Limitations:</i> No random assignment, no comparison group; service utilization self-reported; accuracy not measured. Attribution questionable: in addition to MTM, participants received prescription coverage and a variety of other programs and services.
The PRICE Clinic for Low-Income Elderly: A Managed Care Model for Implementing Pharmacist-Directed Services Stebbins et al. 2003.	<i>Design:</i> Non-controlled, retrospective review assessed impact of pharmacist services in reducing prescription costs, compared with national benchmark data <i>Setting:</i> California pharmacist-directed multi-disciplinary model n=520 low-income seniors (68% female) <i>Limitations:</i> No random assignment, no comparison group; participants self-reported income and OOP costs (saved receipts); patient health outcomes and utilization not measured
Impact on Drugs Costs and Utilization of a Clinical Pharmacist in a Multi-site Primary Care Medical Group Walker & Willey, 2004.	<i>Design:</i> Retrospective pre/post analysis of intervention group, compared with national benchmark data <i>Sample:</i> Patients of a multi-site primary care medical group. <i>Intervention Target:</i> physicians <i>Limitations:</i> -No random assignment, no comparison group; other health outcomes and total costs not measured.
Hypertension Outcomes through BP Monitoring & Evaluation by Pharmacists (HOME Study) Zillich et al. (2005)	<i>Design:</i> Randomized design <i>Setting:</i> 6 High Intensity Pharmacies & 6 Low Intensity n=125 patients (64 HI ; 61 Low) <i>Duration:</i> 3 months <i>Limitations:</i> Small study size, short duration, control pharmacies not 'usual care', likely selection bias for pharmacies and patients.

11.2.1. Research on Outpatient Populations

Most of the published literature concerns MTMPs for outpatient/ambulatory populations. Several of these program served non-Medicare populations, and several explored outcomes that are not directly applicable to Medicare (e.g. absenteeism), but a number of studies focused on drug costs, total costs and/or patient health status – all measures of relevance for Medicare (see Exhibit 13 and the descriptions that follow).

Exhibit 13: Summary of Findings from Relevant MTM Studies and Program Evaluations					
Study Title, Lead Author & Year	Process Measures	Intermediate Outcomes	Significant Clinical Intermediate Outcomes ⁵¹	Significant Economic Outcomes, ROI & Cost Savings	Other Outcomes Measured (performance measures, QOL, satisfaction)
Iowa Pharmaceutical Case Management Program Becker et al. 2004; Carter et al. 2003; Doucette et al. 2005	Pharmacist RX Recommendations Average of 3.8 pharmacist recommendations per patient	Pharmacist Recs Accepted 47% of pharmacist-recommended changes resulted in changed prescription Drug Therapy Problems (DTPs) 2.6 problems detected per patient			
IMPROVE: A Study at Veteran's Administration Medical Centers Billups et al. 2000; Ellis, Billups, et al 2000; Ellis, Carter, et al. 2000; Malone et al. 2000.	Length of Contact and DTPs Lengthier contacts between patient & pharmacist led to more DTPs identified and resolved. In-person versus telephone Pharmacists identified and resolve more drug problems when patient contact was in-person (patients self-selected mode).	Drug Therapy Problems (DTPs) 57% of DTPs resolved Serum Lipid Analysis Significantly more intervention patients had lipid analysis (87%) compared with control (78%).	Total Cholesterol & LDL A greater absolute reduction in total cholesterol and low-density lipoprotein (LDL) in the intervention group, but no more likely to achieve lipid goals.	<i>No significant difference in costs between intervention and control.</i>	<i>No difference in health-related QOL.</i>
Pharmaceutical Care Services & Results in Project IMPACT: Hyperlipidemia Bluml et al., 2000.	Pharmacist Rx Recommendations 346 recommendations	Pharmacist Recs Accepted 77% of recommendations accepted by physicians Persistence Rate: 94% Compliance Rate: 90%	Total Cholesterol & LDL Mean reductions > 30 points for patients completed study NCEP⁵² Goals Attained & Sustained 63% of patients		

⁵¹ Clinical outcome or economic analyses that do not specify significance of the finding are listed in italics.

⁵² National Cholesterol Education Program (NCEP) Adult Treatment Panel II (ATPII) guidelines recommend the following: LDL < 160mg/dL goal if < 2 risk factors; LDL ≤ 130mg/dL goal if > 2 risk factors; and LDL ≤ 100mg/dL goal if coronary artery disease (CAD) history.

Exhibit 13: Summary of Findings from Relevant MTM Studies and Program Evaluations					
Study Title, Lead Author & Year	Process Measures	Intermediate Outcomes	Significant Clinical Intermediate Outcomes ⁵¹	Significant Economic Outcomes, ROI & Cost Savings	Other Outcomes Measured (performance measures, QOL, satisfaction)
<p>The Asheville Project</p> <p>Bunting & Cranor, 2006; Cranor et al., 2003; Cranor & Christensen, 2003a; Cranor & Christensen, 2003b.</p>		<p>Health Care Utilization Asthma participants 6 times less likely to have an ED/hospitalization event.</p>	<p>Asthma Control Measures All measures of asthma control improved & sustained for 5 years.</p> <p>Hemoglobin A, c Diabetic patients achieved improved HbA1c values,</p> <p>Diabetic Clinical Measures Diabetic patients' clinical measures continued to improve every f/u visit.</p>	<p>Medication & Medical Costs Over 5 years diabetic patients' medication costs increased, but total mean direct medical costs PPPY decreased every year compared with baseline.</p> <p>Return-on-Investment (ROI) <i>4 to 1 for Asheville</i>⁴⁹</p>	<p>Productivity Sick days decreased for both diabetic and asthma patients and productivity increased for diabetic patients.</p> <p>Satisfaction Diabetic patients reported improved satisfaction with their care.</p>
<p>Pharmacist Response to Alerts Generated From Medicaid Pharmacy Claims, in a Long-term Care Setting: Results from the North Carolina Polypharmacy Initiative</p> <p>Christensen et al. 2004 Trygstad et al. 2005.</p>	<p>Pharmacist Rx Recommendations Average of 1.58 Rx recommendations made to prescribers.</p>	<p>Number of Medications Average number of medications per patient declined.</p> <p>Pharmacist Recs Accepted Prescribers concurred with 60% of recommendations.</p> <p>Drug Therapy Problems Significant reduction in potential DTP occurrence in all alert categories (e.g., BEERS list). 2 of 5 alert categories had significant reductions in alert persistence.</p>		<p>Cost Savings – Medications Cost reduction of \$57.12 per patient in 3-month f/u period, or \$19.04 PPPM</p> <p>Drug savings greatest in the subgroup for which drug therapy changes occurred (\$61.68 per patient).</p>	
<p>Outcomes-based Pharmacist Reimbursement: Reimbursing Pharmacists for Cognitive Services Farris et al. (2002).</p>	<p>MTM Interventions - 74% of patients received MTM - 90% interventions were education & monitoring - intervention rate 0.69 per 100 prescriptions</p>				
<p>Pharmaceutical Care and Health Care Utilization in an HMO</p> <p>Fischer, et al. 2002.</p>	<p>MTM Interventions MTM interventions provided for 87% of patients.</p>	<p>Drug Therapy Problems (DTPs) 69% of MTM participants had at least one DTP identified</p> <p>Number of Medications⁵³ Total number of medications increased more than for usual care group.</p>		<p><i>No statistically significant difference between MTM and usual care in total charges.</i></p>	

⁵³ After adjustment for gender, age, comorbidities, disease category, and baseline number of medications.

Exhibit 13: Summary of Findings from Relevant MTM Studies and Program Evaluations					
Study Title, Lead Author & Year	Process Measures	Intermediate Outcomes	Significant Clinical Intermediate Outcomes ⁵¹	Significant Economic Outcomes, ROI & Cost Savings	Other Outcomes Measured (performance measures, QOL, satisfaction)
Evaluating Effectiveness of the Minnesota Medication Therapy Management Care Program Isetts, 2007.	MTM Encounters 431 MTM encounters over one year period	Drug Therapy Problems 789 DTPs identified & resolved in the 259 MTM recipients; 3.1 DTPs per recipient.	Hemoglobin A_{1c} 77% of diabetic patients (88 of 114) achieved the QCare 2006 HgA _{1c} benchmark goal (< 8). [Significance not specified]	Total Costs An 8% increase in total health expenditures from pre- to post-MTM intervention. Change included both ambulatory services, and increases (~25%) in prescription drug costs. [Significance not specified]	Performance Measures QCare standards ⁵⁴ achieved for diabetic patients higher than the State average: 36% (41 of 114 patients) whereas the state average 6%.
Outcomes of Pharmacists' Cognitive Services in the Long-term Care Setting Johnston et al.1996;		Pharmacist Recs Accepted 68% of pharmacist recommendations resulted in medication changes.		Medication costs and total savings were conducted but significance was not analyzed. ⁵⁵	Health Status Patient health judged to have improved in 95% of cases when Rx recommendations accepted.
The Impact of Clinical Pharmacists' Consultations on Physicians' Geriatric Drug Prescribing. Lipton et al. 1992.		Drug Therapy Problems (DTPs) 88% of patients had 1+ clinically significant DTP identified by an expert panel after the three-month post-discharge study period; rate was higher in control group (93%) than intervention group (82%). Prescribing Intervention patients were less likely to have one or more prescribing problems in any category. The overall appropriateness of prescribing was significantly better for the intervention group than the control group, but the many intervention patients also had prescribing problems as identified by the panel, despite the intervention.			

⁵⁴ Minnesota Quality Care and Rewarding Excellence (“QCare”) standards of care were introduced in 2006 and represent evidence-based best practice. QCare standards for diabetes include: HgA_{1c} < 8%; LDL < 130mg/dL; blood pressure < 130/85 mmHg; daily aspirin use if over 41 yoa; and no tobacco use.

⁵⁵ Medication Costs: 97% of changed drug regimens resulted in cost reductions and Cost Savings – Total: There was a total annualized cost savings of \$125,248 per year across all patients.

Exhibit 13: Summary of Findings from Relevant MTM Studies and Program Evaluations					
Study Title, Lead Author & Year	Process Measures	Intermediate Outcomes	Significant Clinical Intermediate Outcomes ⁵¹	Significant Economic Outcomes, ROI & Cost Savings	Other Outcomes Measured (performance measures, QOL, satisfaction)
An Evaluation of Managing and Educating Patients on the Risk of Glucocorticoid-Induced Osteoporosis McDonough et al. 2005.		Presence of Calcium Supplement Comparing the changes in frequency between treatment and control group was significant for presence of calcium supplement.			
Medication adherence in heart failure patients Murray et al., 2002.		Medication Adherence Medication adherence was higher in the intervention group at the end of the 9 months, but dissipated in the 3 month follow-up period. Medication-taking Behavior Medications were more likely to be taken on schedule in the intervention group. Health Care Utilization ED visits and hospitalizations were lower in the intervention group.		<i>No costs comparisons between groups were statistically significant.</i> ⁵⁶	
Effects of Geriatric Evaluation and Management on Adverse Drug Reactions and Suboptimal Prescribing in the Frail Elderly. Schmader et al. 2004		Adverse Drug Events (ADEs) Outpatient geriatric clinic care resulted in 35% reduction in risk of a serious ADE when compared with usual care. Outpatient geriatric clinic care also reduced the incidence of patients with conditions for which indicated drugs were omitted.			
Effect on health outcomes of a community-based medication therapy management program for seniors with limited incomes. Smith, et al. 2004.		Medication Adherence The number of medications and adherence remained stable during the study period. Patient Knowledge & Understanding The proportion of patients who understood the purpose of their medications increased during the first 6 months, no further gains over the remainder of follow-up. Health Care Utilization Patient-reported hospitalizations and ED visits decreased.		Medication Costs – Formulary Percent of medications on-formulary increased significantly from 68% at baseline to 82% after 2 years.	Health Status Self-reported rating of health improved.

⁵⁶ Total Costs – Direct: Annual direct health care costs were lower in the intervention group.

Exhibit 13: Summary of Findings from Relevant MTM Studies and Program Evaluations					
Study Title, Lead Author & Year	Process Measures	Intermediate Outcomes	Significant Clinical Intermediate Outcomes ⁵¹	Significant Economic Outcomes, ROI & Cost Savings	Other Outcomes Measured (performance measures, QOL, satisfaction)
The PRICE Clinic for Low-Income Elderly: A Managed Care Model for Implementing Pharmacist-Directed Services Stebbins et al. 2003.	<p>MTM Interventions Clinic conducted 1,297 interventions; average of 2.5 per patient.</p> <p>Generic Use & Other Measures -Use of generics increased over 2-year period -Patients restarted drugs they'd previously discontinued b/c cost -On-formulary drug use increased</p>				<i>Out-of-pocket costs were measured but significance was not analyzed.⁵⁷</i>
Impact on Drugs Costs and Utilization of a Clinical Pharmacist in a Multi-site Primary Care Medical Group Walker & Willey, 2004.		Number of Medications The number of prescriptions increased more than it did for nationwide plans.			<i>Medication costs were measured but significance was not analyzed.⁵⁸</i>
Hypertension Outcomes through BP Monitoring & Evaluation by Pharmacists (HOME Study) Zillich et al. (2005)			Blood Pressure – DBP The high-intensity (HI) intervention patients achieved a lower DBP than the low-intensity (LI) intervention group.		

⁵⁷ Out-of-pocket costs decreased. Per-patient prescription costs were lower than in the “benchmark” populations from MEPS and the statewide PAP.

⁵⁸ PMPY drug costs increased (1.7%) during the two years following the intervention but much less than among health plans nationwide (31.2%). Average cost per prescription declined while nationwide cost per prescription increased. Results varied by therapeutic area. Improvements were largely due to a shift to on-formulary and generic drugs.

- A series of publications by Cranor, Bunting and colleagues described *the Asheville Project*, which was operated by the City of Asheville for its employees, dependents, and retirees, and which combined disease management and medication management interventions. One evaluation covered a five-year evaluation period – the longest MTM study period among those we reviewed – and used a non-randomized pre/post design to compare patients having a diagnosis of diabetes, asthma, hypertension, or hyperlipidemia, with similar employees of a large health care provider group who did not have access to MTM/DM. Monthly face-to-face interactions with a pharmacist were provided at one of 12 community pharmacies and diabetes patients also received self-monitoring training with blood glucose meters. The City of Asheville calculated a savings of \$4 for every \$1 spent on the program.⁴⁹ Evaluators found that over the course of five years, medication costs increased, but total direct medical costs per patient year decreased. Sick days decreased by 50% and productivity increased. Program participants were six times less likely to have an emergency department visit or hospitalization. All measures of asthma control improved and were sustained, diabetic patients achieved improved HbA1c values, and clinical measures continued to improve at every follow-up visit. Diabetic patients also reported improved satisfaction with their care.
- In an MTM program operated by an HMO (Fischer et al., 2002), 231 MTM participants with heart or lung disease filled prescriptions at six intervention pharmacies, and were compared with 444 controls who filled prescriptions at any of 143 comparison pharmacies in the community. MTM participants brought all their prescription and over-the-counter medications to an intervention pharmacy for a 20-30 minute interview and medication review; additional MTM services were provided to patients each time they filled a prescription. After one year, 69% of the intervention MTM patients had at least one pharmacist-identified drug therapy problem, and MTM interventions were provided for 87% of these patients to resolve problems. MTM was associated with increased prescription medications and possibly outpatient clinic visits, but no statistically significant difference was found between MTM and usual care in total charges (other cost reductions offset the increase in prescription costs).
- A study of MTM in community pharmacies (Bluml et al., 2000) included 26 carefully selected pharmacies in 12 states which offered MTM services to promote compliance and persistence with dyslipidemia therapy. Three hundred and ninety-seven non-randomized patients were followed for an average of 24.6 months and compared with similar patients who did not receive MTM services; 345 of these patients began a regimen of lipid-lowering medication and lifestyle modification at the start of the study and the remaining 52 patients chose exercise and diet-related lifestyle modifications to work toward their goals. Pharmacists provided a total of 346 recommendations to physicians to optimize drug therapy; physicians accepted 77% of these recommendations. The rate of patient persistence with medication was 94% and compliance was 90%; 63% of patients attained and sustained their NCEP lipid goals. Mean reductions in total cholesterol and LDL-C exceeded 30 points for those patients that completed the study protocol.
- The Veterans Administration has a system-wide MTM program; earlier published studies conducted in the V.A. were reviewed (Billups et al., 2000; Ellis, Billups, et al., 2000; Ellis, Carter, et al., 2000). One key study used a randomized and controlled, multi-center trial to determine whether outpatient pharmacists could affect resource utilization and outcomes among veterans at risk for medication-related problems. Veterans were included who used one of the nine Veteran's Administration Medical Center (VAMC) study sites and were diagnosed with at least three chronic conditions, took at least five medications, with a total of at least 12 doses each day, had a history of non-adherence, and had medication changes at least three times in the previous year. There were 523 participants (502 men; 21 women) in the intervention arm and 531 participants (511 men and 20 women) in the control group. Intervention patients had at least three contacts with pharmacists over the course of the 12-month study period. After controlling for age, gender, site cluster, and site cluster/treatment interaction, researchers found that: lengthier

contacts between patient and pharmacist were associated with the identification and resolution of more drug-related problem; pharmacists identified and resolved more drug problems when patient contact was in-person rather than by telephone (patients self-selected whether to interact in-person or by phone); approximately 57% of drug problems were resolved through pharmacist intervention; There was no significant difference in total cost for the intervention group as compared to the control group and no difference in health-related quality of life.

- When Iowa Medicaid instituted MTM (Becker et al., 2004; Carter et al., 2006; Doucette et al., 2005), the state required pharmacists and physicians to explicitly agree to collaborate on MTM; pharmacists also had to be certified to participate and bill Medicaid for cognitive services. A retrospective review was conducted to identify appropriate patients and 203 Medicaid beneficiaries with multiple drugs and chronic conditions, and at very high risk for adverse medication events, were identified; 150 received MTM services while the remaining 53 patients (26%) withdrew for various reasons and were excluded from analysis. Pharmacists detected an average of 2.6 medication-related problems per patient and made an average of 3.8 recommendations per patient; 47% of pharmacists' recommendations resulted in a physician making prescription changes.
- A primary care medical group implemented a pharmacist-led educational program focusing on 10 drug classes and aiming to alter physician-prescriber behavior to reduce drug costs and utilization (Walker & Willey, 2004). A retrospective pre/post analysis examined patient records before and after the MTM intervention, and compared results with national "benchmark" data on drug costs and utilization. Per-member-per-year drug costs increased during the two years following the intervention but much less than among health plans nationwide. The number of prescriptions increased more than it did for nationwide plans, but the average cost per prescription declined while nationwide cost per prescription increased. Improvements were largely due to a shift to on-formulary and generic drugs.
- Murray et al. (2002) examined whether pharmacist intervention could improve medication adherence, and consequent health outcomes, among low-income patients with heart failure. Patients were randomly assigned and 122 intervention patients were compared with 192 receiving usual care. All had a diagnosis of heart failure and were being managed medically and monitored for clinical exacerbations; a single pharmacist provided services aimed at improving adherence. Medication adherence was higher in the intervention group at the end of the nine-month intervention period, but dissipated during the following three months. Medications were more likely to be taken on schedule in the intervention group, and emergency department visits and hospitalizations were lower in the intervention group, as were direct health care costs.
- McDonough et al. (2005) assessed the impact of risk management activities on patient risk of glucocorticoid-induced osteoporosis using a randomized control design in eight intervention pharmacies and seven control pharmacies. Pharmacists participating in the study received education on the pathophysiology and management of glucocorticoid-induced osteoporosis and were given several articles for independent study. Patients were identified using prescription dispensing records and were recruited by the pharmacists who mailed a letter inviting them to participate. Patients in the control group received usual and customary pharmacy care, while patients in the treatment group received education by pharmacists, an educational pamphlet about the risks of glucocorticoid-induced osteoporosis, and MTM services. The treatment group had a significant increase in the presence of bisphosphonate and estrogen therapy⁵⁹, and a significant decrease in the frequency of patients reporting a low calcium diet. Patients in both treatment and control groups had more discussions over time with pharmacists about osteoporosis risk management and bone mineral density tests, and these tests were more frequent in both groups at

⁵⁹ The addition of estrogen therapy for the prevention of osteoporosis in post-menopausal women was considered a positive outcome in this study, which was likely conducted prior to a study in 2004 that raised the concern about the risks of estrogen therapy.

nine-month follow-up. The only significant contrast was that the treatment group had a greater increase in calcium supplementation than the control group.

- Zillich et al. (2005) evaluated the effectiveness of a community pharmacy-based initiative to improve home blood pressure monitoring, using a randomized design in community pharmacies. One-hundred twenty-five patients enrolled in the study (64 patients in the HI group and 61 in the LI group). Pharmacists in the HI pharmacies met face-to-face with patients four times over three months to measure blood pressure, provide education, make recommendations, contact physicians about medication therapy, and give patients a blood pressure self-monitoring tool to use at home. Pharmacists in the LI pharmacies met face-to-face with patients three times over three months to measure blood pressure, and to recommend they see their physician if it was above normal. The high-intensity intervention patients achieved a lower DBP than the low-intensity intervention group, demonstrating that pharmacist intervention can improve patient clinical status.

Three of the four MTMPs we studied in depth have conducted some sort of evaluation focusing on clinical and/or cost outcomes:

- The Medicaid MTM was evaluated by researchers at the state university. They found that pharmacists identified approximately three drug therapy problems among Medicaid recipients to whom MTM services were provided. Diabetic MTM patients were more likely to achieve all of the state's evidence-based quality of care performance standards than were diabetic patients statewide. There was a slight increase in total health care expenditures among MTM patients, which was comprised of decreases in the cost of various ambulatory services and increases in prescription drug costs.⁶⁰
- The multi-state MA plan evaluated its MTM program's effectiveness using a quasi-experimental, non-randomized design with two control groups, and focused on achieving lipid and cholesterol levels among hyperlipidemic, diabetic and coronary artery disease patients in their MTM program. There were no significant differences in the pre/post changes in glycemic control for intervention and control groups of diabetic patients. The percent of patients "at goal" for lipid control before and after MTM intervention, improved more among MTM patients than either control group. (Unpublished data.)
- The MTM vendor program uses an Estimated Cost Avoidance (ECA) methodology to measure cost impact of MTM and found that in 2006 every dollar paid to a pharmacist for MTM yielded approximately \$45 in ECA (program administration costs were not included in this analysis). Two QIOs conducted studies using this vendor's MTM system and data. One QIO used a pre/post non-randomized design and found no decrease in the incidence of potentially inappropriate medications in the elderly, but a consistent decline in the incidence of drug-drug interactions over the one year study period. The other QIO used a similar research design and found improved medication adherence, much improved glycemic control for diabetic patients, much improved lipid control among those with hyperlipidemia, and an increase in per-person total healthcare costs. (Unpublished data.)

The literature and case studies that examined lipid control generally found improvements due to MTM, and most that studied glycemic control among diabetics also attributed improvements to MTM. A few studies noted increased costs for prescription drugs, while others found that drug costs decreased due to generic substitution or other cost containment strategies. Total medical costs decreased in two studies,

⁶⁰ http://www.dhs.state.mn.us/main/groups/business_partners/documents/pub/dhs16_140283.pdf

increased in one, and were unchanged in two others. The differences in study design, populations studied, duration of MTM and follow-up periods may have contributed to these inconsistent findings.

11.2.2. Research on Recently Discharged Hospital Patients

A number of published studies evaluated MTM for inpatients, and a few focused on recently discharged hospital patients; the latter are of potential applicability for Medicare and are reviewed here.

- Schmader et al. (2004) evaluated geriatric management to reduce adverse drug reactions and suboptimal prescribing in the frail elderly. This was not a medication therapy management program per se, but the geriatricians were responsible for managing all medical care including medications. Eight hundred and thirty-four inpatients (mostly male) from 11 V.A. medical centers were randomized to either usual care or to be followed before and after discharge by specialists in geriatric management. Pairs of physicians and pharmacists, blinded to subjects' study arm, reviewed the care provided to identify adverse drug reactions and determine causality. Study subjects were followed for one year post-discharge. The goal was to determine whether care management by geriatric specialists would reduce adverse drug events. There were no inpatient geriatric unit effects, but outpatient geriatric clinic care resulted in reduced risk of a serious ADE when compared with usual care. Outpatient geriatric clinic care also reduced the incidence of patients with conditions for which indicated drugs were omitted.
- Lipton et al (1992) studied whether pharmacist educational interventions with physicians could affect drug prescribing patterns. Elderly patients recently discharged from a community hospital, and taking three or more medications, were randomly assigned to receive usual care or periodic pharmacist-physician consultation to review medication appropriateness. Two hundred and seventy-four patients were selected for randomization (123 intervention and 113 controls), and 236 completed the study. Pharmacists reviewed records and consulted with intervention patients' prescribers about any medication issues. An expert panel reviewed records of all patients to identify clinically significant drug problems. 88% of patients had one or more drug problems identified after the three-month post-discharge study period; the rate was higher in the control group (93%) than in the intervention group (82%). The overall appropriateness of prescribing was significantly better for the intervention group than the control group, but the great majority of intervention patients also had prescribing problems as identified by the panel, despite the intervention.

The appropriateness of prescriptions, and rate of adverse drug events, improved following MTM, but no other outcomes were measured so it is unclear whether these improvements resulted in better patient health status, reduced costs, or other beneficial changes.

11.2.3. Research on Nursing Home Patients

Three publications in recent years, about two different MTM initiatives, focus at least in part on nursing home patients.

- The North Carolina Polypharmacy Initiative (Christensen et al., 2004; Trygstad et al., 2005) aimed to improve the quality of pharmaceutical care available to patients of nursing facilities, and decrease aggregate costs. Using a non-randomized pre/post study design, researchers compared patients from nursing homes that agreed to MTM with similar patients from nursing homes that did not respond to an invitation to participate. Patients were dually-eligible for Medicare and Medicaid and had at least 18 prescription fills during the 90 days before the study commenced. Services included medication therapy review, intervention/referral, and follow-up. Pharmacists who were members of the North Carolina

LTC Pharmacy Alliance, and were already servicing nursing homes, collaborated with prescribing physicians to identify and correct: 1) unnecessary drug therapies, 2) more cost-effective drugs available, 3) wrong dose/delivery, 4) potential for adverse drug reaction, 5) additional drug therapy needs, 6) other problems. Alert criteria included: a drug on the BEERS Drug list (drugs to be avoided among the elderly), a drug on the NC Prescription Advantage List (encourages substitution of less expensive drug within same therapeutic class), or drugs (from among 16) on a "Clinical Initiatives" list (developed by consultant pharmacists participating in the NCPP Initiative).⁶¹

The greatest improvements were found in switching from drugs on the BEERS List, reduced therapeutic duplication, change in drug strength/dosage, change to a more cost-effective drug, and overall number of computer-generated drug therapy alerts. All other types of prescription problems were also reduced in the intervention population more than in the comparison group. Seventy-two percent of pharmacist recommendations were accepted/implemented by prescribers and the average number of medications per patient declined. Per patient monthly costs to the Medicaid program were \$57 lower in the intervention group.

- The second program offered Pharmacists' Cognitive Services in the Long-term Care Setting (Johnston et al., 1996) and concerned drug utilization review (DUR) conducted by consultant pharmacists (not part of an MTM program) in 122 nursing homes, most of which were skilled nursing facilities. DRR was conducted by consultant pharmacists and both prescriber actions and costs were documented. Sixty-eight percent of pharmacist recommendations resulted in medication changes and 97% of these changed drug regimens resulted in cost reductions. Patient health was judged to have improved in 95% of cases where pharmacist recommendations were accepted. There was a total annualized savings of \$125,248 per year across all patients, of which 41% was related to discontinuing unused/unnecessary medications.

These studies demonstrate the potential for MTM to improve patient health status and reduce costs for nursing home patients. Neither of these programs was instituted by a Part D prescription drug plan as part of an MTM program, however, and our interviews and case-studies with Part D MTMPs indicate that few provide comprehensive MTM to nursing home patients.

11.2.4. Research focusing on MTM Enhanced by Prescription Coverage/Financial Support

A number of early MTMPs were instituted by State Pharmacy Assistance Programs (prior to the MMA); these programs assisted seniors and low-income people with prescription drug coverage and had an interest in cost-effective medication management.

- The Senior PharmAssist Program in Durham County, NC is one such program, studied by Smith et al. (2004). This program combined MTM services with financial support for prescription drugs for low-income residents of Durham who lacked adequate prescription drug insurance; it included financial assistance for medications and referrals to community and governmental programs, as well as MTM services. A total of 794 patients (or their caregivers) were referred to this pharmacy assistance program over a six-year period and 515 were available for study six years later. The population was mostly female and half were African American; on average they had six medical conditions and were taking five

⁶¹ The specific drugs on the "clinical initiatives" list were not listed in the study publications.

medications. Participants or their caregivers met with a pharmacist at entry to the program, and three more times over a two-year period. Pharmacists reviewed medications and made recommendations to prescribers, and referred patients to other community services. The number of medications and adherence remained unchanged during the study period, the percent of medications on-formulary increased, and patient-reported hospitalizations and emergency department (ED) visits decreased while self-reported rating of health improved over time.

- A similar program was the PRICE Clinic for Low-Income Elderly (Stebbins et al., 2003), which combined MTM services with financial support for prescription drugs. Five hundred and twenty low-income elderly patients with multiple chronic conditions and multiple medications received pharmacist services and financial support for prescription drugs. The goal was to reduce patient co-payments and out-of-pocket costs. Data from a statewide Pharmacy Assistance Program (PAP) were used as a comparison or “benchmark,” as was the Medical Expenditure Panel Survey (MEPS). Patients took an average of six medications to treat four chronic conditions; 86% had generic-only coverage from a Medicare Advantage plan. Use of generic drugs increased over the two-year period of clinic participation, use of on-formulary drugs increased, out-of-pocket costs decreased, patients restarted drugs they had previously discontinued for cost reasons and per-patient prescription costs were lower than in the “benchmark” populations from MEPS and the statewide PAP.

Because both these programs included both improved prescription drug coverage and MTM, it is not possible to attribute improvements to MTM alone.

11.3. Research Design Issues and Limitations of MTM Evaluations

Several studies of MTMPs employed random assignment of patients to MTM versus usual care – a strong research design that minimizes bias (see for example Ellis et al., 2000; Lipton et al., 1992; Malone et al., 2000; Murray et al., 2007). In several other non-randomized pre/post studies with comparison groups, changes over time in an MTM intervention group were compared with changes in a similar group that did not receive MTM services (see, for example, Asheville project publications by Cranor, Bunting and colleagues; Fischer et al., 2002; Trygstad et al., 2005). We also reviewed MTMP evaluations that prospectively studied a single cohort of patients and measured changes before and after MTM. Like these latter studies, most of the Medicare MTMPs we interviewed are using (or plan to use) pre/post assessments of their MTM participants, without a comparison group, to evaluate their programs. A few published studies used retrospective record review to measure the impact of pharmacist interventions – a weaker study design for this type of research. The following sections raise several research design issues we observed in the MTMP literature.

11.3.1. Intervention and Comparison Groups

A few of the studies we reviewed intentionally excluded patients who previously had a comprehensive medication review (CMR) or “brown bag” consultation – i.e. had already experienced an MTM-like service (e.g., Ellis et al., 2000; Malone et al., 2000); however, most did not. Studies that retain such patients risk misattributing to an MTMP results that actually resulted from earlier exposure to similar services.

A number of studies were careful to retain patients who discontinued MTM services in the analysis – an intention-to-treat approach that reduces bias (e.g., Malone et al., 2000; Weinberger et al., 2002; Ellis et al., 2000; Cranor et al., 2003). In some studies, however, patients who discontinued MTM (e.g., switched

pharmacies, declined follow-up telephone interventions or surveys) were excluded from analysis (e.g., Fischer et al., 2000; Trygstad et al., 2005). If those who discontinued MTM were not a random subset of those who began, failure to include these patients in analysis of the intervention group could misestimate the impact of MTM.

A few studies used persons (or pharmacies or nursing homes) who declined to participate, as a comparison group against which to measure impact of MTM (e.g., Fischer et al., 2002; Trygstad et al., 2005). Again, if those who refused to participate differed from those who agreed, this type of comparison could yield biased results.

11.3.2. Intervention Sites and Site Effects

Some MTMPs were implemented in pharmacies with carefully chosen characteristics, compared with other community pharmacies. The intervention pharmacies were unlike their peers in selected ways, which reduces generalizability of study results. For example, pharmacies in one study (Bluml et al., 2000) were selected because they had a private or semi-private area for patient consultation, technician support, a documentation system for patient care interventions, experience with disease management programs, and the ability to do lipid tests in the pharmacy. It is not clear whether the results obtained in these pharmacies could be replicated at pharmacies that do not share these attributes.

Some studies used multiple pharmacy study sites that were treated as if they were all identical contributors to the intervention effect; evaluators did not attempt to discern (or control for) site effects, often because the small number of MTM program participants at each pharmacy prevented analysis at the site level. We located only one study – conducted in a V.A. setting – that carefully controlled for site effects and also used randomization to minimize selection bias (Malone et al., 2000)

11.3.3. Follow-up Periods and Temporal Trends

Many studies we reviewed collected data for one year or less (e.g., Fischer et al., 2002; Johnston et al., 1996; Lipton et al., 1992; Malone et al 2000; Murray et al., 2007; Schmader et al., 2004; Trygstad et al., 2005). It is unclear from such studies whether early gains attributed to MTM are sustained in subsequent years. A few studies used longer follow-up periods, and the Asheville publications notably described outcomes at multiple intervals to explore the sustainability of program impacts. Murray et al (2007) found that improvements in patient adherence dissipated soon after the MTM intervention ceased. Research to-date has not adequately addressed whether some optimal level of ongoing MTM (monthly, quarterly, annual) is needed to sustain early improvements in patient outcomes.

The Physician Practice Pharmacy Quality Improvement Organization Support Center (PPP QIOSC) has issued guidance about evaluating MTMPs, which points out that “MTM is more likely to increase the costs related to health care at the beginning of the program. More than likely there will be an increase in medication costs as members become more compliant with taking medications, and lab costs will increase” (Krantzberg et al., 2007). Many studies do not explicitly document/acknowledge such patterns, and may thus inaccurately quantify the “steady state” of MTM program impact.

11.3.4. Size and Statistical Power

We limited our literature review to studies with more than 100 MTM participants and searched for those with reasonably large study populations. Authors acknowledged sample size limitations in some smaller studies (e.g., Jameson et al., 2005). Future research should include study populations of sufficient size to detect differences with statistical confidence.

11.3.5. Prescriber Acceptance

Several studies explored the degree to which pharmacist recommendations led prescribers to alter prescriptions – referred to as “prescriber acceptance”. Among the studies we reviewed, prescribers failed to accept 23-53% of pharmacist recommendations (e.g., Bluml et al., 2000; Christensen et al., 2004; Doucette et al., 2005; Johnston et al., 1996). This lack of acceptance by prescribers is documented in studies of institutionalized patients as well as those using community pharmacies. Some evaluations define MTM effectiveness largely in terms of whether or not pharmacist recommendations are accepted by prescribers (e.g., Doucette et al., 2005; Walker & Willey, 2004;) regardless of whether patients’ health improves, costs decline, or other desirable outcomes occur. While prescriber acceptance is necessary for MTM to succeed, and could be considered an intermediate outcome, it is not sufficient to guarantee other successful outcomes and should not be the main end-point of MTM evaluations.

11.3.6. Cost-Effectiveness

In their review of the literature on clinical pharmacy services from 1996 to 2000, Schumock et al. (2003) found that most studies did not include the cost of providing MTM as part of the economic program evaluations. They advise that “Inclusion of input costs is required to determine the true net benefit of a clinical service.” In another review of the literature through 1999, Beney et al., (2007) “did not locate any studies that compared both the costs and outcomes of interventions delivered by pharmacists...” We noted the same weakness in a number of recent evaluations that measured the impact of MTM on prescription costs, total medical costs, sick days, etc. but did not include the costs of operating the MTM program and reimbursing pharmacists (e.g., Becker et al., 2004; Fischer et al., 2002; Murray et al., 2007; Stebbins et al., 2005). We also noted several evaluations that did include these cost inputs (e.g., Christensen et al., 2004; Ellis et al., 2000; Malone et al., 2000; Simpson et al., 2001). Cost-effectiveness evaluations in the future should include both savings attributable to MTM and input costs.

An Estimated Cost Avoidance (ECA) methodology is used by the large national MTM vendor we studied, and other programs as well. We did not, however, locate any studies that systematically validated the estimated costs that were avoided, and therefore do not know how accurate this methodology may be. If ECA is to be a common metric in the industry, research is needed to determine its accuracy, variability, and inter-rater reliability.

11.3.7. Future Research Design

To summarize, the field would benefit from large, well-designed studies with the following attributes:

- Randomized assignment of patients to MTM vs. usual care. It would be advisable to exclude patients who have recently undergone a comprehensive medication review or other MTM service, as their medication issues may have already been addressed. If randomization is not possible, and a well-matched comparison group can be identified, a difference-in-differences approach would be the next strongest design, wherein changes over time in the comparison group (i.e., not related to MTM) would be compared with changes over time in the MTM

group. We note that patients who refuse MTM should not be used as a comparison group against which to measure those who consent to MTM, as this could introduce selection bias.

- Inclusion of “dropouts” in the analysis (intention to treat) to avoid biased estimates of impact based on only those who chose to continue (i.e., those likely to be the most engaged/satisfied).
- Program implementation in ordinary sites of care, not unique/unusual settings, to enhance generalizability.
- Sufficient size to reject the null hypothesis with statistical confidence. Research-to-date has demonstrated MTM effect sizes of zero to several thousands of dollars in savings per patient per year, so a rather large study population may be necessary to estimate, with confidence, the effect of MTM on savings.
- Consistent patient-level and program-level outcomes (including economic outcomes), not just process measures.
- Inclusion of MTM input costs (program costs and pharmacist reimbursement), in addition to patient-level costs such as medication costs, medical care costs, absenteeism, etc. to estimate cost effectiveness for MTMPs.
- Validation of estimated avoided costs.
- Repeated measurements over time, to determine initial impact as well as any patterns of escalating or diminishing impact.

The effects of MTM may vary based on patient characteristics and circumstances. For example, homebound and less mobile patients, or those in isolated areas, may receive their prescriptions through the mail because they have difficulty traveling to community pharmacies; people in this circumstance may reject face-to-face MTM. Among the definitions of MTMP features presented in Chapter 3, there is disagreement in the industry about a few elements, especially whether MTM should be conducted face-to-face in every case. With many MTMPs now in operation that favor telephonic interactions, for some or all patients, the field would benefit from rigorous and well-designed evaluations that assess the impact of each mode of communication, for different types of patients.⁶²

11.4. Research Underway

During our interviews and case studies we learned about a few studies that are currently underway, which should address some of the outstanding questions about MTMP.

11.4.1. Evaluation of a Medication Therapy Management Clinical Trial Regarding Patient Safety for Medicare Beneficiaries at High Risk of Adverse Drug Events

The DeCIDE multi-site clinical trial has many methodological strengths. Starting in late 2007, this one-year study will randomize elderly patients with multiple conditions and multiple drugs to three arms: 1) usual care, 2) MTM based on prescription history alone, and 3) MTM based on additional/enhanced clinical information from medical records (diagnoses, allergies, recent hospitalizations, etc.). The goal is to understand whether richer clinical information contributes to more-effective MTM. Face-to-face MTM services will be offered in selected pharmacies in three health care delivery systems in different states.

⁶² One of the current QIO projects being conducted by the Michigan QIO is assessing the effectiveness of different modes of providing MTM (see Appendix C).

The study will exclude patients who self-report having undergone a comprehensive medication review in the previous year, and will use an “intent to treat” analytic approach. Outcomes to be evaluated include:

- Patient safety as indicated by ADEs, ED visits, and hospitalizations and office visits, documented using claims data.
- Process of care as reported by pharmacists and primary care practitioners and improvement between Arm 2 and Arm 3, in terms of more/less drug problems and different types of problems identified and corrected.
- PCP acceptance of pharmacist recommendations.
- Patient satisfaction measured via survey.

While methodologically stronger than many previous studies, the size of this trial may be insufficient to assess site effects (200 subjects in each arm of the study, across the three study sites combined; 67 per arm, per site).

11.4.2. Quality Improvement Organization (QIO) Studies

QIOs are private organizations with a variety of public and private customers, including the Medicare program. Medicare enters into contracts with QIOs to evaluate providers’ and professionals’ ability to reliably provide high-quality care, and assists them in doing so. Under their contracts, the QIOs have worked with prescription drug plans, pharmacy associations, schools and colleges of pharmacy, chain pharmacies, and medical societies. A recent supplement in the *Journal of Managed Care Pharmacy* (JMCP) describes the QIOs’ drug therapy improvement activities and partnerships with Medicare Part D plans, many of which focus on MTM (Schulke et al., 2007). The QIO projects related to MTM are quality improvement projects, and include assessing the quality of MTMPs with Medicare prescription drug plans using the plans’ data; studying specific interventions; and promoting MTM services and programs. Unfortunately, limited information about the QIO projects’ research designs is provided in the supplement.

The Florida Medicare Quality Improvement Organization (FMQAI), as the QIO support center (QIOSC) to all QIOs, has led various efforts to facilitate collaboration between the QIOs and Medicare prescription drug plans, and has participated in national MTM initiatives. One such effort focused special attention on coordinating with national prescription drug plans to obtain MTM data organized by state, which can then be forwarded to each QIO for use in state-level improvement activities. The QIOSC determined that working with the national plans would maximize data availability and be a better use of finite resources than trying to obtain data from dozens of state/regional PDPs. The QIOSC offers guidance related to MTM on their website, including two documents reviewed for this report: “Medication Therapy Management Program Directory Version 1.5” and “Medication Therapy Management Program Evaluation Methodologies Including Return on Investment (ROI) Version 1.1.”

As described in the supplement to the July 2007 issue of the *Journal of Managed Care Pharmacy* the QIOs organized MTM projects with drug plans in 25 states, including:

- Improving treatment of patients with anemia, asthma, coronary artery disease, heart failure, diabetes, dyslipidemia, hypertension, post myocardial infarction
- Replicating the Asheville Project to improve diabetic patient self-management
- Reducing use of potentially inappropriate medications for the elderly

- Reducing drug-drug interactions and adverse drug events
- Evaluating, giving feedback, and assisting plans regarding MTM program performance
- Studying the impact of face-to-face pharmacist MTM services
- Studying the impact of provider and patient education on MTM enrollment and retention
- Improving medication adherence and persistence” (Schulke, et al., 2007).”

We interviewed the QIOSC Project Manager, who indicated that it is too early to determine the cost savings from Medicare MTMPs. The results of the QIO MTMPs will be presented to the Part D plans, and it is not clear whether they will in turn make these findings public. An overview of the MTM projects being conducted by the QIOs appears in Appendix D.

11.4.3. Other Studies

America’s Health Insurance Plans (AHIP) intends to undertake an MTM evaluation, and will be working with their member plans to collect comparable data from numerous programs. The design of this evaluation is not yet available; results are expected in 2008.

12. Summary and Implications

12.1. Summary of key findings

This section briefly summarizes the key findings related to the main research domains.

12.1.1. MTM Organizational Practices and Models

The pharmacy industry associations are converging on a definition of a Medication Therapy Management Program, and the main elements of an MTMP have been articulated as:

- Performing or obtaining necessary assessments of the patient's health status.
- Formulating a medication treatment plan.
- Selecting, initiating, modifying, or administering medication therapy.
- Monitoring and evaluating the patient's response to therapy, including safety and effectiveness.
- Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events.
- Documenting the care delivered and communicating essential information to the patient's other primary care providers.
- Providing verbal education and training designed to enhance patient understanding and appropriate use of medications.
- Providing information, support services, and resources designed to enhance patients' adherence with their therapeutic regimens.
- Coordinating and integrating medication therapy management services within the broader health care-management services being provided to the patient. (Bluml, 2005).

This definition does not offer guidance as to which patients are most likely to benefit from MTM, and it does not address enrollment mechanisms that optimize participation among eligible patients. Most of the industry concurred with at least some these elements. This definition takes no stance on reimbursement mechanisms/approaches or amounts, but does broadly advocate the MTM services that should be provided to patients (e.g. Comprehensive Medicare Reviews, patient education). Perhaps most importantly, this consensus definition does not specify the outcomes MTMPs should be designed to achieve, or how to measure these outcomes.

There are a variety of practice models in the literature and in current MTMPs, each with different attributes. There does not yet appear to be an identifiable set of clearly defined models that are reasonably stable and mutually exclusive. The practice models vary on the following dimensions: primary focus, MTM service providers, reconciliation with prescribers, intervention frequency, service delivery mode, additional education and support, and disease state monitoring. We have identified what appear to be seven distinct MTM practice models based on the aforementioned dimensions. The descriptive labels for these practice models are: 1) Hybrid MTM-DM; 2) Care teams; 3) Required Collaboration; 4) Multi-Mode, Comprehensive MTM; 5) Pharmacy-based Disease Monitoring; 6) Telephonic MTM; and 7) MRR for nursing home patients. Exhibit 9 in section 4.3 of this report displays the features of MTMPs and how they are arrayed in varying practice models. There are a great many variations among MTMPs – even

among Medicare Part D MTMPs – and limited evidence as yet about which features are more likely to achieve optimal results for patients and/or payers.

12.1.2. Targeted Patients, Eligibility Criteria and Enrollment Mechanisms

Medicare, Medicaid and commercial/employer MTMPs serve different populations and may have different objectives. For example, the leading employer MTMPs aim to reduce absenteeism and improve productivity, which are not relevant objectives for Medicare.

Focusing more narrowly, Medicare Part D MTMPs exhibit a wide range of eligibility criteria, even though they serve very similar populations. For example, one Medicare MTMP bases eligibility on two or more drugs used to treat two of three specific chronic conditions, while another Medicare MTMP bases eligibility on nine or more drugs to treat at least four of eleven specific chronic conditions (the latter stringent criteria result in a very small MTM program).

All Medicare MTMPs include \$4,000 annual medication costs as an eligibility criterion. All Medicare MTMPs we interviewed also specify the number (and often the type) of chronic conditions that confer MTM eligibility; they all specify a minimum number of Part D medications that determine eligibility for MTM and some require that the drugs being taken relate to the chronic conditions of concern. It is uncommon for non-Medicare MTMPs to specify numbers of medications or numbers of chronic conditions as eligibility criteria, and while some focus on “high cost” patients, none appear to use a specific drug cost threshold for MTMP eligibility. Some non-Medicare MTMPs have no explicit MTMP eligibility criteria at all; MTM services are/were offered to any patient whom clinicians or pharmacists believe would benefit.

There is limited research to indicate which Medicare patients are most likely to benefit from MTM. Several studies show promising (but inconsistent) results for patients with diabetes and hyperlipidemia, and many Medicare MTMPs include these two conditions among their eligibility criteria – along with others for which there is less evidence in the literature.

MTMPs that require an affirmative “opt in” step have had varying success, with some enrolling less than 10% of eligible patients. Based on our case studies, it appears that MTMPs favoring an “opt out” or “automatic enrollment” approach achieve higher enrollment. Similarly, an industry study found that the opt-out method produces much higher enrollment (usually >95% compared with <1% to >50% with opt-in; AMCP, 2008). Some MTMPs rely on pharmacists to identify patients for MTM from among those who are eligible (or from among a plan’s entire population). In the state Medicaid MTM program we studied, this approach has been only marginally successful, in part due to low pharmacist participation.

Some MTMPs rely on pharmacists to select patients for MTM, from among those who are eligible (or from among a plan’s entire population). In the state Medicaid MTM program we studied, this approach has been only marginally successful, in part due to low pharmacist participation. There is no information about the success of this approach in other MTMPs.

12.1.3. MTM Components and Services

Most MTMPs start with a comprehensive medication review (CMR), at entry to the program and (usually) annually thereafter. A few MTMPs offer no other services; patients and physician-prescribers are simply informed of the CMR findings and recommendations, with no follow-up. Most MTMPs,

however, include reconciliation of drug therapy issues with prescribers, some include patient education and monitoring, laboratory tests to monitor progress, or other services. Three of the programs we studied in-depth have conducted research that demonstrates some clinical impact of MTM; the evidence does not allow us to determine whether annual CMRs with prescription reconciliation is sufficient to accomplish clinical goals, or whether other follow-up services delivered by MTM pharmacists are an important contributor to clinical outcomes.

We located no research that rigorously tested face-to-face vs. telephone or mail interventions.⁶³ There is a fundamental divide in the industry between MTMPs that pursue face-to-face interventions, and those that rely largely on telephone or mail. Both face-to-face and telephone services are real-time and interactive – pharmacists can ask patients questions, tailor recommendations based on the patients’ answers, and address patient concerns as they arise. MTMPs that rely on face-to-face interactions may also be better able to overcome language and literacy barriers by relying on accompanying family/friends to interpret for patients with these issues; this is not as easily accomplished by telephone. On the other hand, telephone interventions (provided by in-house pharmacists or those working in call centers or community pharmacies) can reach patients in remote locations, those who are homebound or lack transportation to a pharmacy offering MTM, and those who choose to use mail-order pharmacies – all people who would have difficulty with face-to-face MTM. Mail interactions are asynchronous and as a result are rather limited, and may at best be able to promote a conversation between patient and physician. Moreover, mail-only MTMPs are not likely to effectively address language and literacy issues. Some MTMPs use any/all modes of intervention, flexibly tailoring their approach to meet patient needs.

12.1.4. MTM Service Providers

We located only one MTMP that uses physicians as MTM providers; all others rely on pharmacists. A few MTMPs augment pharmacists with nurses at a call center, who phone patients to encourage and monitor medication adherence; a few others (including the two MA plans we studied) refer complex cases to nurse case-managers and/or multi-disciplinary teams.

12.1.5. Coordination of MTM with Disease/Care Management (DM)

Medicare beneficiaries served by MTMPs may also participate in chronic care or DM programs. To the extent that these programs overlap, it is desirable to avoid duplication; coordination may produce optimal outcomes for patients served by both programs. Based on the four MTMPs we studied, it appears that opportunities for MTM and DM coordination are greater in a managed care context, and less when MTM is “carved out” to a separate vendor. This may be due in part to data sharing issues, which are potentially easier to overcome with a shared record.

In most other sectors (employer programs, the V.A., Medicaid, managed care plans) separate MTMPs are uncommon. V.A. clinicians explain that separating MTM from other care management would be counter-productive because it would cause discontinuities in care and confusion for patients. In many non-Medicare sectors the emphasis is instead on primary care teams and case management with pharmacists as team members; it is especially uncommon to have differing eligibility criteria for chronic care patients who can/cannot receive medication therapy management by a pharmacist.

⁶³ One study allowed patients to self-select whether to receive services in-person or via telephone.

12.1.6. Special Populations

Nursing home patients are of particular concern for CMS, and Part D plans are required to offer MTM services to eligible institutionalized patients. Nursing home consultant pharmacists conduct (monthly) drug regimen reviews (DRRs) for every patient as well. There is thus overlap between MTMPs and the responsibilities of consultant pharmacists. None of the four MTMPs we studied in-depth fully integrate MTM with nursing home care or collaborate with nursing home consultant pharmacists, and none interact directly with nursing home staff to improve medication therapy.

MTM services should ideally be delivered in a patient's spoken and/or written language; literacy and fluency in English should not be required in order to enroll in an MTM program and receive services. Community pharmacists deal with spoken language issues on a daily basis, using other staff, patients' family members and others as interpreters. Using this model, in-person (and perhaps telephonic) MTM conducted by community pharmacists may have the greatest potential for overcoming language barriers, while mailed information may be least able to overcome these barriers.

12.1.7. Reimbursement & Documentation

Most MTMPs appear to be using some variant of fee-for-service reimbursement, or use salaried in-house pharmacists to conduct MTM. Other mechanisms such as capitated or per-case reimbursement are not in use, based on the published literature and the MTMPs we interviewed. There is no research assessing the impact of various reimbursement approaches – or dollar amounts – to actively incentivize pharmacist engagement in MTM without inducing unnecessary services.

Industry representatives have argued that reimbursement is an important motivator for pharmacist participation in MTM. We studied two MTMPs (one Medicaid MTMP and a national MTM vendor) that have developed somewhat similar fee schedules for pharmacist reimbursement, but have experienced very different rates of pharmacist participation. Reimbursement alone does not appear to be sufficient to motivate involvement in MTM, and other factors (e.g., training requirements, cost of documentation systems) are probably important.

Some MTMPs require pharmacists to document the services they deliver, based on different rules and service payments, and some of these include documentation of whether the prescriber followed through and altered the prescription as recommended by the MTM pharmacist. A few systems assist pharmacists in tracking patient adherence (using the “possession ratio”). Some MTMPs operated by MA plans document MTM services in patient electronic health records, which are difficult to “roll up” for the entire population served by the program and which do not facilitate evaluation of program outcomes.

We interviewed a large national pharmacy chain that does not permit Internet access in its branches and will not transmit patient information over the Internet, due to data security concerns. Some other pharmacies may agree, but most do not appear to share this prohibition, and permit the use of web-based systems. An important issue for pharmacies is the need to operate many separate documentation/billing systems for MTM. Web-based systems – while not identical – may reduce this barrier because they do not require software installation.

A few of the larger web-based documentation systems are now accumulating substantial patient-level databases which could be used to address many MTM Program design questions, and perhaps to evaluate patient outcomes as well.

12.1.8. Outcomes and Evaluations

Costs are commonly measured in the MTM literature (although in different ways), including: prescription drug costs, total medical costs, return on investment, and estimated costs avoided. Findings are inconsistent – some studies find increased drug costs, others find decreased drug costs or no change; total medical costs decrease in some studies and are unchanged in others. Input costs (e.g. pharmacist reimbursement, program administration) are usually not included in these cost estimates and there are few complete cost-effectiveness studies in the MTM literature.

A few clinical status measures appear frequently in the published MTM literature: Hemoglobin A1C levels, LDL and total cholesterol levels, and blood pressure. Of all the research on MTM, the evidence appears to be strongest regarding the impact of MTM on a few intermediate clinical outcomes, notably HbA1C and LDL cholesterol.

Removing drugs from the BEERS list, identifying over-use and under-use, reducing sick/absent days from work, and “avoiding” services like emergency department visits or hospitalizations are also common outcomes in MTMP literature, but less so among Part D MTMPs (most of which are in their second or third year of operation and have not completed such analyses). Patient satisfaction is reported by two of the four MTMPs we studied in-depth, and appears in a few published studies; satisfaction (among patients or prescribers) is generally treated as being of less importance than clinical measures or cost.

Many MTMP studies report on process measures and intermediate outcomes such as: percent of eligible patients enrolled in MTM, number of interventions provided, number and type of drug therapy problems identified, adverse events avoided, and prescriber concurrence with MTM recommendations. While some Medicare MTMPs plan to eventually measure some of the outcomes mentioned above, others state that they are waiting for CMS guidance regarding which outcomes to measure before designing data capture mechanisms and rigorous analyses.

12.2. Applicability for Medicare of MTM Research in Other Sectors

The Medicare population is 56% female, 74% are aged 65-84 years, and 10% are 85+.⁶⁴ Studies of MTM conducted among younger, working people, and studies limited to men (e.g., Asheville Project, V.A. studies), may not be directly applicable to Medicare.

Nearly one-third of the Medicare population has cognitive or physical impairments, or both.⁶⁵ Studies that exclude patients with cognitive or physical impairments (e.g., Ellis et al., 2000; Schmader et al., 2004) are less relevant for Medicare than those that are more inclusive.

Nearly 80% of Medicare beneficiaries have Part D coverage or creditable coverage from other sources. At the same time, 46% of Medicare beneficiaries are low-income (below 200% of the Federal Poverty

⁶⁴ Kaiser Family Foundation – Health Facts, as of January 16, 2007. Accessed on 11/13/07 at: <http://www.statehealthfacts.org/comparetable.jsp?cat=6&ind=307>

⁶⁵ Moon M and Storeygard M. One-Third at Risk: the Special Circumstances of Medicare Beneficiaries with Health Problems. The Commonwealth Fund 1997. Accessed on 11/13/07 at: http://www.urban.org/uploadedpdf/410352_one-third-at-risk.pdf

Level)⁶⁶. While studies focusing on low-income seniors are applicable to Medicare, those that focus entirely on seniors without prescription insurance (e.g., Smith et al., 2004) are less directly applicable. Fifteen percent of beneficiaries get their drug coverage through Medicare Advantage plans, and studies from managed care settings (e.g., Fischer et al., 2002) are relevant for this population.

The populations of most concern for Medicare MTM are elderly and disabled beneficiaries who take many prescription medications to treat multiple chronic conditions, and have high drug costs. Studies conducted among patients with a single chronic condition (e.g., Bluml et al., 2000; Murray et al. 2007) may suggest the potential of MTM, but are not as directly relevant as studies of persons with multiple chronic conditions (e.g., Ellis et al., 2000; Malone et al., 2000; Stebbins et al. 2005).

Nearly one-fourth of elderly Medicare beneficiaries live in rural areas,⁶⁷ others travel regularly, and some are homebound due to infirmity; beneficiaries in all of these circumstances— and others— may receive their prescription drugs through the mail. MTMPs that require patients to visit selected pharmacies for face-to-face services may be relevant for Medicare beneficiaries who are able to easily reach such a pharmacy, but less so for those who cannot.

Considering such factors, some of the leading MTM evaluations have more relevance for Medicare than others. For example, the VA's IMPROVE trial used a rigorous, randomized study design that tested the impact of MTM services for V.A. patients with hyperlipidemia. This study has partial relevance for Medicare, as it concerned an aging population (though largely male), receiving face-to-face MTM services. The services and systems, however, were unique to the VA: pharmacists were an integral part of multi-disciplinary primary care teams, all team members shared a comprehensive electronic health record, and the pharmacists' scope of practice included altering prescriptions— circumstances that are uncommon in non-V.A. settings. Even with these structural advantages, this study found no improvement in the intervention group in terms of total cost, quality of life, or success in achieving lipid goals.

Three other randomized trials with mixed results have varying relevance for Medicare. In a study of elderly patients with heart failure, Murray et al. (2007) found that medication adherence improved during the intervention but dissipated soon after the intervention ended; total costs, ED use, and hospitalizations were lower for the intervention group during the (brief) follow-up period. Schmader et al. (2004) studied recently discharged V.A. patients and found that those who received geriatric evaluation and management, including pharmaceutical care, had a reduced risk of serious ADEs. Lipton et al. (1992) studied elderly patients recently discharged from a community hospital and found that even after pharmacist intervention, over 80% of the study group had prescription problems.

A number of other studies used non-randomized pre/post designs with comparison groups; among these, the strongest study designs also generated mixed findings of varying relevance for Medicare. Fischer et al. (2002) studied a managed care population that included non-elderly patients as well as seniors. They found that MTM resulted in an overall increase in health care utilization, no difference in total cost, and an increase in the number of medications used by study participants. Bunting and Cranor (2006), Cranor

⁶⁶ IBID

⁶⁷ Brangan M and Caplan C. Prescription Drug Spending and Coverage Among Rural Medicare Beneficiaries in 2003. AARP Policy Brief, accessed on 11/13/07 at: http://www.aarp.org/research/medicare/outofpocket/prescription_drug_spending_and_coverage_among_rura.html

et al. (2003), Cranor and Christensen (2003a) and Cranor and Christensen (2003b) studied the Asheville Project population over a five-year period and found substantial improvements in patient health, costs, and productivity resulting from a program that combined disease management and MTM. The Asheville population was not directly relevant to Medicare; however, as it involved public sector employees, retirees, and dependents, most of whom were non-elderly and currently employed (and possibly more cognitively intact and more affluent than the Medicare population).

12.3. Information Needed for Program Improvement

Eligibility Criteria: As discussed above, little research has been conducted to identify the patients most likely to benefit from MTM – those for whom health status, cost or other outcomes are most likely to improve following MTM. Diabetics and patients with hyperlipidemia may experience improved glycemic or cholesterol control, but there is little additional evidence regarding the combination of chronic conditions and medications that could be used to best target MTMPs. Despite this lack of guidance in the research literature, there are many different combinations of conditions and medications being used as eligibility criteria by Medicare MTMPs. It is possible that some of the electronic MTM documentation systems (i.e., those maintained by MTM vendors) have now assembled large and sufficiently detailed databases to identify which patients improve most following MTM. We did not identify any research studies that are taking advantage of these databases for such a purpose, but this may be a fruitful avenue to pursue.

MTM Services and mode of service delivery: MTM services could be more clearly specified with additional information regarding the degree of improvement that can be expected from a Comprehensive Medication Review (CMR) alone, and how much additional improvement occurs when other MTM services are added (e.g. patient education and monitoring, prescriber consultation). It would be useful to know if there is an optimal frequency of MTM services – how frequently pharmacists must interact with patients to improve adherence, for example, and what sort of maintenance schedule is needed to prevent the erosion of initial improvements. It would be equally useful to know whether face-to-face MTM yields better outcomes (in terms of health and/or cost) than telephonic MTM, and whether either is significantly better than mailed MTM recommendations.

Reimbursement/incentives: There is no information about the level of reimbursement (dollar amount) that will overcome pharmacists' opportunity costs and incentivize MTM participation. We located no evaluations of differing reimbursement schemes, such as per-case versus fee-for-service reimbursement. More information is needed about both the amounts that may need to be paid, and the impact of different reimbursement approaches, to galvanize pharmacist participation without inducing provision of unnecessary services.

Outcomes: Many MTMPs have selected outcomes of interest to measure for their programs. These range from patient satisfaction (and little else in the case of one MTMP), to detailed studies of changes in hospital and physician utilization and lab values compared with non-MTM control groups. Although appropriate outcomes vary for different populations, many Medicare Part D MTMPs serve the same types of aged and disabled enrollees; some standardized outcomes against which all/most Medicare MTMPs will be measured would be helpful. Indeed, a number of Medicare MTMPs we interviewed are awaiting guidance from CMS, rather than developing data collection for outcomes measures.

12.4. Implications for Medicare

All Medicare MTMPs we interviewed/studied are following CMS guidelines and targeting patients with multiple chronic conditions, multiple Part D drugs, and \$4,000+ per year of anticipated drug spending, but there is wide variability in specific eligibility criteria. Although there is no evidence of discriminatory exclusion criteria among Medicare MTMPs, some favor very strict eligibility criteria that may limit beneficiary access to MTM services. MTMPs whose eligibility criteria are in the upper range (e.g., 10+ chronic conditions, 10+ medications) are not providing the same level of access to MTM as those that include patients with just two chronic conditions and a few medications. We note that some Medicare prescription drug plans offer MTM services to all drug plan members, but only report on those that meet CMS' minimum criteria. Medicare MTMPs that use an "opt out" approach facilitate participation and access to MTM more than those that use an "opt-in" approach. The least accessible Medicare MTMPs are those that combine strict eligibility criteria and an "opt in" invitation letter, without further outreach.

MTMPs that rely on face-to-face service delivery may often be able to overcome language, literacy, and educational barriers because pharmacists use family, friends or other pharmacy staff as interpreters – just as they do when filling prescriptions – but these strategies may not be available when MTM services are delivered by telephone or mail. On the other hand, MTMPs that support only face-to-face interventions may have difficulty reaching beneficiaries who live in remote locations, are homebound or in institutions, cannot easily travel to a pharmacy that provides MTM services, or use mail-order pharmacies. Given the diverse composition of the Medicare population, a multi-mode approach to service delivery may offer the greatest flexibility to meet beneficiaries' needs.

Coordination with disease management poses a challenge for some Medicare prescription drug plans, especially those that do not have operational responsibility for the disease management program (e.g. stand-alone drug plans). Plans that "carve out" either MTM or DM – or both – to vendors, may also face difficulty coordinating the two programs. Medicare Advantage plans that provide MTM, DM and other health care services using in-house staff (rather than community pharmacists) may face the fewest coordination challenges, especially if their staffs share an electronic health record. This is not to say that care coordination is impossible in other program models, just that the challenges are greater.

A Medical Home model is increasingly common in Medicaid, as are primary care teams in the V.A. and case managers in many managed care plans; all aim to prevent discontinuities by encouraging central clinical oversight and coordination of services. Accordingly, managers from several health plans that also serve Medicare populations, as well as V.A. staff, told us they prefer not to separate MTM from DM because they believe this to be confusing for patients and disruptive of care continuity. These health plans do not offer an MTM program to their non-Medicare members, but rather incorporate MTM into their other care/disease management programs. In non-Medicare sectors it is especially uncommon to have explicit criteria regarding which chronic care patients can/cannot receive medication therapy management. Some of the MA plan managers we interviewed reported that they make the MTM-DM programmatic distinction for their Medicare population only, because the structure of their Medicare contracts requires distinctly separate programs.

Although a few MTMPs attempt to offer services to patients in nursing homes, most agree that there is an overlap – and potential conflict – between MTM services supported by a Part D drug plan, and drug regimen reviews conducted by nursing home consultant pharmacists. Unlike nursing home consultant pharmacists, MTM pharmacists rarely (if ever) have direct contact with nursing home staff who

administer medications, or with institutionalized patients. Few Medicare MTMPs have identified effective ways to integrate MTM with nursing home consultant pharmacist services. It is worth noting that some non-Medicare MTMPs do not support MTM for nursing home patients because they see this as duplicative.

Each Medicare MTMP is collecting data on patient-level outcomes. There is as yet limited published information about Medicare MTMPs, as they are in just their third year of operation, but we learned that several MTMPs have presented preliminary findings at national meetings and have research manuscripts in preparation. With no sector-specific or industry-wide convergence on outcomes (i.e. no HEDIS-like measures), each Medicare MTMP has developed their own set of outcomes to focus on. Virtually all are interested in drug costs, but there is inconsistency regarding other outcomes of interest. Some Medicare MTMPs are conducting careful research with strong methodological designs to learn from their early experiences, and others are rapidly accumulating large databases that could be of benefit to CMS, in refining the Medicare MTM program.

Appendix A:

Detailed Methodology

Methodology: Literature Review, Key Informant Interviews and Case Studies

CMS contracted with Abt Associates to conduct exploratory research about Medication Therapy Management (MTM) programs. This project involved a literature review, key informant interviews and in-depth case studies.

Fifty-nine articles were reviewed, with a focus on the strength of the evidence they presented about MTM; interviews were conducted with 46 organizations (MTM programs and vendors, industry representatives, etc.) to learn about recent innovation, and explore how MTM *programs* (as distinct from research projects) are being implemented. A major focus was on understanding how MTM programs in non-Medicare sectors (Medicaid, commercial, Veterans Health Administration, etc.) can inform improvements in the Medicare MTM program going forward.

Abt Associates staff conducted detailed case studies with four MTM programs. The purpose of these case studies was to learn more about “what works” in MTM: how to target patients with the greatest opportunities for improved medication management, how to enroll these patients and provide MTM services, and what outcomes – both cost and quality – can be demonstrated for MTM. Additional topics of inquiry included pharmacist reimbursement, MTM documentation systems, MTM for patients in nursing facilities, and coordination between MTM and disease management programs. A summary of these methods is provided below.

Document and Literature Review

To gain a full understanding of the current landscape of MTMPs, and to identify respondents for the key informant interviews, Abt Associates analysts scanned both published and unpublished literature by searching several web-based information sources:

- PubMed database of biomedical and life sciences literature
- Websites of pharmacy associations and organizations
- Google search engine for references to pharmaceutical companies; Pharmacy Benefit Managers (PBMs); Prescription Drug Plans (PDPs), Medicare Advantage Prescription Drug Plan (MA-PD), and Special Needs Plans (SNP); and MTM vendors.

The specific search strategies used for each of these information sources is described in the following sections.

PubMed

A PubMed search was conducted to locate recent literature on Medication Therapy Management. Prior to providing search terms (described below), the search of the database was limited to include literature according to the following parameters:

- Publication Date Range: 1/1/00 thru 7/15/07 (a few additional documents were added in early 2008)

- Language: English
- Ages: All Adult 19+

Terminology for programs and services that aim to optimize therapeutic outcomes through improved medication use and reduced risk of adverse events for patients may not necessarily be identified as “Medication Therapy Management” in the literature. Literature that describes MTM programs, and programs and services that are similar but are not labeled as such, were captured in the PubMed search by using the keywords listed in the Exhibit below. The Exhibit also provides the total number of references returned in PubMed for each keyword.

Keyword search term	# of publications returned
medication therapy management	13
comprehensive medication therapy management	2
pharmaceutical care	146
drug regimen review	6
cognitive pharmaceutical services	0
cognitive pharmacy services	13
medication management (not “administration”)	97
drug utilization review (not “hospital”)	358

The eight searches were combined (with Boolean term “or”) to ensure articles were not duplicated in the list. This resulted in 618 potentially relevant articles. The 618 titles and abstracts were initially examined for relevance. Abt excluded very small studies, those focusing on a single drug or drug class (e.g., colestipol, antibiotics), those concerning drug regimen reviews conducted by nursing home consultant pharmacists, and those that simply describe the process of MTM. Publications concerning the rate of drug therapy problems in a population were also excluded, as were studies of the ability or willingness of pharmacists to provide cognitive services, unless the publication also described the results of MTM interventions. Some examples of articles deemed irrelevant include:

- Programs/services in a country outside the U.S.
- Single drug class or drug-specific programs (e.g., focus limited to Coumadin clinics).
- Drug spending and utilization studies (e.g., Medicaid drug spending).
- Medication use and utilization patterns (i.e., pharmacoepidemiology studies).
- Medication safety studies.
- Limited focus on patient satisfaction or pharmacist/physician perceptions.
- Studies about drug-related problems (e.g., studies of drugs that increase risk for falls among the elderly).
- Prescribing studies (e.g., inappropriate prescribing, guidelines, prescriber education).
- Studies narrowly focused on adherence/compliance without mention of other medication therapy management.
- Disease management programs without specific mention of MTM or similar services (because DM programs are being studied under a separate CMS project).

- Community-based care management programs that do not address medication therapy management.
- Pharmacist-physician collaborative practice descriptions that are not within an MTMP.
- Methodological studies that do not report on an actual MTM program (e.g., how to measure satisfaction with pharmacist care).

The MTMPs described in the remaining publications were further limited to those that described MTM models and programs that aim to improve patient outcomes through use of medications and included more than 100 patients or study subjects. There are numerous articles on MTM services provided in one pharmacy or a few pharmacies, and others focused on pharmacists' provision of services and the services pharmacists provided, but many fewer articles on MTM programs.

We also reviewed the bibliographies of key publications (e.g., Sound Medication Therapy Management Programs) to search for seminal pieces from the 1990s. We included a few rigorous and important publications that concerned patients with a single chronic condition (e.g., reactive airway disease, heart failure) rather than limiting our report to studies about MTM for patients with multiple chronic conditions.

Internet Search

Pharmacy Organization Websites

Websites of the following pharmacy associations & organizations were systematically searched for relevant information on MTMPs:

- American Pharmacists Association (APhA)
- American Society of Health-Systems Pharmacists (ASHP)
- American Society of Consultant Pharmacists (ASCP)
- American College of Clinical Pharmacy (ACCP)
- American Association of Colleges of Pharmacy (AACCP)
- Academy of Managed Care Pharmacy (AMCP)
- National Association of Chain Drug Stores (NACDS)
- National Community Pharmacists Association (NCPA)

A uniform set of strategies was used to locate any MTMP-related information on each website. The following keyword terms were used to scan the site using any “search” engine on each site:

- Medicare
- Medicaid
- Prescription drug plans (PDP)
- Medicare Advantage plans
- Medicare drug plans
- Special needs plans PDPs (SNPs)
- Medicare prescription drug program
- Medicare Part D
- MTM
- medication therapy management

- comprehensive medication therapy management
- pharmaceutical care
- medication management
- drug utilization review
- drug regimen review
- cognitive pharmacy services

Examination of these pharmacy association websites yielded many relevant MTM documents; however, some overlapped across organizations (e.g., position statements on MTM). These documents included primarily position statements, CMS’s MTM documents (e.g., MTMP application), MMA regulation, and articles on MTM.

Pharmaceutical Industry

A list of pharmaceutical companies was identified from the Pharmaceutical Research and Manufacturers of America (PhRMA) website. The following strategy was then used to identify the involvement of a pharmaceutical manufacturer in an MTM program.

The Google search engine was used to search the web for information about these companies’ involvement in MTMPs as follows:

- 2 Company Name AND “Medication Therapy Management”
- 3 Company Name AND “MTM”
- 4 Company Name AND “Medicare Part D”

The results of these searches generally returned news articles in which the company name was listed separately from documents referencing MTM (i.e., a link referenced both search terms on the same page but in different articles). Alternatively, results linked to conferences or educational opportunities held by NCPA or APhA and sponsored by the pharmaceutical company.

The search described above primarily yielded documents that were already identified from the pharmacy association websites: congressional testimony regarding the MMA as well as pharmaceutical manufacturer-sponsored continuing education, conferences related to MTM, and a website on Medicare Part D. Lastly, one disease-focused, manufacturer-sponsored MTM program was identified using this strategy.

Pharmacy Benefit Managers (PBM)

A list of PBMs was identified from the Pharmacy Benefit Management Institute, LP website, and Google. The Google search engine was used to search the web for information about these companies’ involvement in or provision of MTM programs as part of their pharmacy benefit services. The PBM name and terms MTM or medication therapy management were used to identify potential programs. The search yielded the identification of MTM programs for a few of the PBMs.

MTM Vendors

The websites of three major MTM vendors were searched, including: Outcomes Pharmaceutical Health Care at www.getoutcomes.com, CommunityMTM (rebranded as Mirixa) at www.communitymtm.com, and PharmMD at www.pharmmd.com. The search was conducted to

better understand the suite of MTM services they provide, the MTM programs they administer, and to understand the different clients they each have from both the public and private sector.

Google Keyword Search

An internet search using Google was conducted using the terms “Medication Therapy Management” and relevant synonyms described above to identify MTMPs. The Google search yielded documents, publications, and websites identified from the above-mentioned focused web searches and the PubMed search.

Synthesis of the Literature and Documents

In total, 59 documents from the literature, internet search, and other sources were deemed relevant and were reviewed for this information scan. Each of these documents was reviewed and information abstracted related to the research domains and questions (Exhibit 1 in the body of this report). Information was systematically reviewed and was abstracted onto a formatted data collection form to ensure consistency. The form organized the data by the research domains, and information was coded to support synthesis. For example, the targeted MTM patient population discussed in each document was coded. The coded categories of information contained sufficiently detailed descriptions of the MTM programs in the literature and other documents to identify trends.

Key Informant Interviews

Selection of Interviewees

The purpose of the key informant interviews was to further understand MTM programs and the delivery and financing of MTM programs and services, from the vantage point of individuals involved in creating, managing, or evaluating these programs. We initially aimed to conduct 50–60 informal interviews with representatives from various organizations including: pharmacy associations and other organizations; PDPs, MA-PDs, and SNPS; employers; Medicaid programs; VA; other health plans; pharmacies; LTC facilities and pharmacies; PBMs; MTM vendors; AHRQ DeCIDE network; and QIO support center.¹ An initial list of organizations was approved by CMS and interviews were conducted with key informants from 46 organizations. The Exhibit below displays the number of interviews by organization type and the respective organization names (or descriptive information²):

¹ We were unable to identify individuals at other health plans (e.g. Private Fee-For-Service plans) who were knowledgeable about MTM.

² Organization descriptors instead of names are provided for some organization types.

Organization Type	Number of Organizations Interviewed
Pharmacy Associations and Other Industry Organizations <ul style="list-style-type: none"> • American Society of Consultant Pharmacists • American College of Clinical Pharmacy • American Society of Health Systems Pharmacists • American Medical Association • Academy of Managed Care Pharmacy • America's Health Insurance Plans • National Association of Chain Drug Stores • Pharmacy Quality Alliance • National Community Pharmacists Association • American Pharmacists Association • National Alliance of State Pharmacy Associations 	11
Employers <ul style="list-style-type: none"> • United Mine Workers 	1
Pharmacies <ul style="list-style-type: none"> • Large, national pharmacy chain • Regional pharmacy chain • Large county hospital 	3
LTC Facilities and Pharmacies <ul style="list-style-type: none"> • National organization owns 350 nursing homes and provides LTC pharmacy services • National LTC pharmacy provider • Two-state LTC pharmacy provider 	3
Medicaid Programs <ul style="list-style-type: none"> • Florida • Iowa • Minnesota 	3
MTM Vendors <ul style="list-style-type: none"> • Mirixa • Outcomes Pharmaceutical Health Care • PharmMD 	3
PBMs <ul style="list-style-type: none"> • Prime Therapeutics • Medco 	2
QIO Support Center	1
Veteran's Administration (VA)	1
PI of AHRQ DeCIDE MTM clinical trial	1
SNPs <ul style="list-style-type: none"> • Community Health Partnership • OneCare • Positive Healthcare Partners • Senior Whole Health 	4
PDPs / MA-PDs <ul style="list-style-type: none"> • Large, national PDP with PBM • Plan with 1 PDP in 4 states • Large, national PDP • Plan with 1 PDP, over 1 million enrollees • Single-state MA-PD • Plan with 1 MA-PD • Regional MA-PD • Plan with 2 PDPs & 2 MA-PDs • Plan with 1 PDP & 1 MA-PD • Plan with 1 PDP & 2 MA-PDs • Plan with 1 PDP & 6 MA-PDs • Large, national MA-PD • Large, national PDP 	13
TOTAL	46

After selecting the organizations of interest we identified a senior staff person with knowledge of the MTM program. When we interviewed someone from a professional pharmacy association we also asked for recommendations of individuals who are particularly knowledgeable about MTM. And Lawrence Brown from the University of Tennessee Center for Medication Therapy Management, helped to identify MTMPs experts from among his extensive network of industry contacts. When we did not have a contact name at an organization we asked for individuals with titles of Pharmacy Service Director, MTM Program Manager, or Director of Government Policy.

For some organizations we interviewed two or more individuals, either as a group or in separate conversations. For example, two separate conversations were held with a total of six V.A. representatives. Across the 46 organizations, more than 60 individuals provided input. In addition, some MTM vendors, PBMs, and drug plan managers are responsible for multiple MTM programs and could discuss differences among these programs. For example, the 13 PDPs and MA-PDPs together offer more than 20 Medicare drug plans (separate Medicare contracts), MTM vendors and PBMs offer more than one type of MTM program to their many clients, and Medicaid programs have more than one MTM effort underway.

The reasons for selecting specific organizations, and the process used to identify key informants within each organization type, were as follows.

Pharmacy Associations and Other Organizational Representatives (n=11)

We sought input from representatives of many different national associations to understand the landscape of MTM in Medicare and other sectors. We wished to include insights from various constituencies in the field including community pharmacists in chain and individual retail setting, hospitals and clinics, long-term care, and managed care, as well as physicians' perspectives. Key informants from the following organizations were recruited and participated in this study:

- Academy of Managed Care Pharmacy (AMCP)
- American College of Clinical Pharmacy (ACCP)
- American Medical Association (AMA)
- American Pharmacists Association (APhA)
- American Society of Consultant Pharmacists (ASCP)
- American Society of Health-Systems Pharmacists (ASHP)
- America's Health Insurance Plans (AHIP)
- National Alliance of State Pharmacy Associations
- National Association of Chain Drug Stores (NACDS)
- National Community Pharmacists Association (NCPA)
- Pharmacy Quality Alliance (PQA)

Key informants from each organization were identified from the literature, from organizational websites, from Dr. Brown's contact list, and when necessary by asking for the association's Director of government affairs or public policy.

Stand alone Prescription Drug Plans and Medicare Advantage Prescription Drug Plans (n=13)

The Part D Plan sponsors are required to submit information to CMS regarding their MTM programs. CMS's Medicare Drug Benefit Group has conducted an analysis of the 613 MTMP submissions from

Part D sponsors that includes relevant summary information about the MTMPs, and shared some of these data with us.³ Abt reviewed de-identified plan level (e.g., PDP level) data to determine whether it could be used to select PDPs and MA-PDPs for interviews. The de-identified MTM program application data CMS forwarded to us did not contain several important characteristics. We could not determine from the data, for example, whether a plan is a PDP, MA-PD, or SNP; its total enrollment; or whether it is regional or national in scope. The data we received from CMS did indicate the plans' MTM criteria, and these were sorted into the following groups:

- **Group 1 “Few Drugs & Conditions”:** Plans with eligibility criteria of 2-3 drugs and 2-3 chronic conditions;
- **Group 2 “Face-to-Face”:** Plans with eligibility criteria of 5+ drugs and 5+ chronic conditions and face-to-face intervention;
- **Group 3 “Meds Review”:** Plans with eligibility criteria of 5+ drugs and 5+ specific chronic conditions and also listing medication review as an intervention;
- **Group 4 “Meds Review Any Chronic”:** Plans with eligibility criteria of 5+ drugs and 5+ chronic conditions (any chronic conditions, not from a specified list) and also listing medication review as an intervention;
- **Group 5 “All Others”:** Plans with eligibility criteria of 5+ drugs and 5+ specific chronic conditions, and indicating neither “face-to-face interaction” nor “medication review” interventions;
- **Group 6 “All Others Any Chronic”:** Plans with eligibility criteria of 5+ drugs and 5+ chronic conditions (any chronic conditions, not from a specified list), and indicating neither “face-to-face interaction” nor “medication review” interventions.

For each of the six groups CMS identified two PDPs (one large, one smaller) and two MA-PDs (one large, one smaller). Large plans were generally those with more than 300,000 enrollees; smaller plans were those with 50,000-300,000 enrollees. If no plans met these size criteria, CMS selected the largest and smallest plans within each group. This process resulted in 4-5 plans that CMS identified in each of the six groups above – a total of 25 drug plans. Two other plans were added to bring the total to 27: one because it is a very large, national plan active in MTM, and the other because several pharmacy association representatives mentioned it as a leading proponent of face-to-face MTM.

Each of these 27 drug plans was contacted via email and telephone multiple times to request participation in this study. Interviews were completed with representatives from 13 of these 27 plans. These included Part D plans from Groups 1, 2, 3, and 5 (there were only a few plans in groups 4 and 6, and none agreed to be interviewed). Interviews were also completed with the two plans deliberately selected as being especially important MTM innovators. Some of the plans whose representatives were interviewed have just a single Medicare contract; several others have multiple Medicare contracts – a few operate both stand-alone PDPs and MA-PDPs.

³ “The Evolution of Medication Therapy Management Programs in Part D: 2006 to 2007” Michelle B. Ketcham, PharmD, MBA. Division of Clinical and Economic Performance, Medicare Drug Benefit Group. Presentation at the Pharmacy Quality Alliance meeting on May1, 2007.

State Medicaid Programs (n=4)

To better understand the MTMPs offered under various Medicaid programs we interviewed representatives from the National Association of State Medicaid Directors (NASMD) and from the Medicaid programs in Iowa, Minnesota, and Florida. (The latter also included an interview with the Florida Pharmacy Association, which at one time operated an MTM initiative for Florida Medicaid.) These three states were chosen because they were identified by pharmacy association interviewees as having MTM programs, or because the literature indicated that these states had particularly innovative approaches to MTM.

LTC Facilities and Pharmacies (n=3)

Long-term care facilities and the pharmacists who serve them offer a unique and important perspective on MTM programs for patients in nursing homes and other facilities. To better understand the MTM challenges for these Medicare beneficiaries and their providers, we interviewed three representatives from LTC pharmacies, one of which owns LTC facilities and two that serve nursing home chains. One serves a two-state region and the others are national. These three were selected to reflect the different MTM programs and experiences of the LTC sector.

Special Needs PDPs (n=4)

CMS is interested in MTMPs that focus on special needs populations. These range from programs serving persons with specific chronic conditions (e.g., HIV/AIDS), to those serving institutionalized beneficiaries, or those who are dually eligible for Medicare and Medicaid. Many PDPs also operate special needs plans (SNPs). We identified SNPs from CMS contacts and from a list of SNPs from another CMS evaluation. An initial list of SNPs was developed that included national, regional, and single-state SNPs; SNPs focused on chronic diseases; and SNPs for institutionalized persons. Representatives from these organizations were contacted via email and telephone multiple times. Representatives from four SNPs participated in interviews.

MTM Program Vendors (n=3)

Representatives from three MTM vendors were interviewed to explore the MTM services and programs they offer for Medicare Part D plans and other public and private sector clients. Two of the vendors were selected because they were identified by pharmacy associations as administering MTMPs for Medicare PDPs; the third vendor was identified by CMS and other pharmacy stakeholders.

PBMs (n=2)

Four PBMs were initially selected and recruited to participate, but the key informants from two were not available for interviews during our data collection period; representatives from the other two were interviewed.

Outpatient Hospital and Community Pharmacies/Pharmacy chains (n=3)

We were interested in MTM from the perspective of pharmacists working in different settings, including national pharmacy chains and independent pharmacies as well as hospital outpatient pharmacies. We completed three interviews: one with a small drugstore chain in the southeast region of the United States that is actively involved with MTM, one with a large national pharmacy chain, and a brief interview with the pharmacy director at a large county hospital.

Self-insured employers' MTMPs (n=1)

We expected the document/literature scan to identify information about self-insured employers' MTMPs. Several of the programs that are well documented in the literature either no longer exist or have essentially merged. Two of the major employers that pioneered MTM were approached for interviews; one referred us to its MTM vendor (whom we had already interviewed) and the other (United Mine Workers) was interviewed.

Performance Improvement QIO Support Center (n=1)

The Performance Improvement Support Center for Quality Improvement Organizations (QIOs) is addressing several CMS priorities for quality improvement projects related to Medicare Part D, in 25 states. Several of these projects involve MTM. The Project Manager for the QIO Support Center (QIOSC) at the Florida Medicare Quality Improvement Organization (FMQAI) was interviewed, to learn about QIO involvement in MTM.

Veteran's Administration

Across two different interviews, six individuals from Veterans Affairs were interviewed, including the Director of the V.A.'s Pharmacy Benefit Management Health Services Group, and four senior pharmacy staff from that group.

AHRQ DeCIDE Network⁴

The Principal Investigator for the AHRQ DeCIDE network's MTM clinical trial was interviewed.

Interview Protocols

Interview protocols were created to collect descriptive information about MTM, and also to obtain perspectives on successes and challenges of MTM. The protocols varied slightly across organization types since interviews with an MTM program administrator are different from interviews with pharmacists who provide MTM services. When applicable, information identified from the literature and document scan were provided to the interviewer in advance, as background information and to facilitate the discussion. The interview protocol is available in a separate volume.

Contacting and Conducting Interviews

Abt senior staff members and experienced qualitative researchers were each assigned a set of key informants to interview. Each interviewer "specialized" in a sector. For example, one interviewer was assigned the Medicaid MTM program key informants while another was assigned the LTC facilities and chains. An Abt Associates senior team member contacted each key informant either by telephone or email (or both) to introduce the project, solicit interest, and schedule a time for the interview. A standard email invitation was used along with a one-page project description that was attached.

The interviews were conducted via telephone between July 1 and September 21, 2007. The interviews lasted from 15 to 60 minutes. The interviews were not tape-recorded; rather the

⁴ AHRQ's Developing Evidence to Inform Decisions about Effectiveness (DeCIDE) network is designing and conducting a trial of MTM aimed to improve patient safety among Medicare beneficiaries.

interviewers took notes during each interview and then wrote up these notes into an interview summary.

The procedures for recruiting interviewees, assurances of confidentiality, verbal informed consent processes, and informal interview protocols were reviewed and approved by Abt Associates' Institutional Review Board (IRB). Because we promised confidentiality, key informants' names are not revealed in this report; when especially proprietary information was shared, even the name of an organization is undisclosed.

Synthesis and Analysis

Each interview summary addresses the relevant research domains and questions, including at a minimum: the MTM intervention and services; target populations served in an MTMP and how/when they are identified; the providers of MTM services; the settings in which MTM services are provided (in-person at pharmacies, via telephone, by mail); reimbursement and billing procedures; anticipated/measurable outcomes; and any additional insights from the key informants' experiences. Program components were compared and contrasted to provide a fuller understanding of the landscape of MTM programs and consistency/diversity within the various sectors. In several cases, interviewees shared insights about the applicability of a non-Medicare program (e.g., VA, Medicaid) to the Part D program.

Case Studies

Case Study Goals and Objectives

After completing the literature and key informant interviews, Abt Associates staff conducted detailed case studies with four MTM programs. The purpose of these case studies was to learn more about “what works” in MTM: how best to target patients with the greatest opportunities for improved medication management, how best to enroll these patients and provide MTM services, and what outcomes – both cost and quality – can be demonstrated for MTM. Additional topics of inquiry included pharmacist reimbursement, MTM documentation systems, MTM for patients in nursing facilities, and coordination between MTM and disease management programs.

Case Selection and Methodology

Through the literature review we learned that many MTM (or pharmaceutical care) programs in the literature were one-time studies rather than ongoing programs, or have been discontinued (in the case of some Medicaid programs). Many other MTM programs are quite new and have not yet collected and analyzed data about MTM outcomes. And several MTM programs serve working people – often government employees – and are not directly relevant to the Medicare population. As a result, CMS and the study team decided to conduct just four case studies; the four MTM programs were selected for the following reasons:

- Different MTM modalities (phone, mail, in-person);
- Different organizational structures (stand-alone PDP, MA-PD, Medicaid program, MTM vendor);

- Different approaches to coordinating MTM with other disease management programs, and different approaches to serving institutionalized beneficiaries;
- Some accumulating evidence about effectiveness, in terms of cost, health status, or other outcomes.

Abt Associates staff conducted all interviews. Participants from the four MTM programs gave signed consent for the interviews (as approved by the Abt Institutional Review Board) and consented to tape-recording of the interviews. Recordings were used to complete this report and were then destroyed. Participants from the four programs reviewed the detailed descriptions of their programs that appear below, to ensure accuracy. Conclusions about each program, and the cross-site synthesis, were written by Abt researchers and not reviewed by the four programs.

Appendix B:

Bibliography of Publications Reviewed and Detailed Descriptions of Selected, Published MTM Studies and Evaluations

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Studies Focusing on Outpatient Populations

The Asheville Project (Bunting & Cranor, 2006; Cranor et al., 2003; Cranor & Christensen, 2003a; Cranor & Christensen, 2003b)

A series of publications by Cranor, Bunting and colleagues described the Asheville Project, which was operated by the City of Asheville for its employees, dependents, and retirees, and which included both disease management and medication management interventions. The publication reviewed here covered the entire five-year evaluation period – the longest MTM study period among those we reviewed.

- **Study Design:** This DM-MTM program was evaluated using a non-randomized pre/post design with a comparison group. Patients who discontinued services were included in the intention-to-treat analysis. Data were collected at several intervals during the five-year study period.
- **Patient Population:** Employees and retirees of the City of Asheville and their dependents, having a diagnosis of diabetes, asthma, hypertension, or hyperlipidemia, were compared with the employees of a large health care provider group. (The latter eventually had access to the same services.)
- **Services and Providers:** Monthly face-to-face interactions with a pharmacist at one of 12 community pharmacies included clinical assessment, education, patient monitoring, follow-up, and referral. Diabetes patients also receive training on self-monitoring blood glucose meters.
- **Results:**
 - The city of Asheville saved \$4 for every \$1 spent on the program: over the course of five years, medication costs increased, but total average direct medical costs per patient year decreased.
 - Sick days decreased by 50% and productivity increased.
 - Program participants had decreased emergency department (ED) visits and hospitalizations (intervention patients were six times less likely to have an ED/hospitalization event).
 - All measures of asthma control improved and were sustained for as long as five years, diabetic patients achieved improved HbA1c values, and clinical measures continued to improve at every follow-up visit.
 - Diabetic patients reported improved satisfaction with their care.
- **Study Limitations:** This was not a randomized trial, and it is possible that the comparison group from a large health care provider differed from the intervention group in unmeasured ways.

Pharmaceutical Care Project in an HMO (Fischer et al., 2002)

A large HMO selected six pharmacies to implement a one-year MTM program, and compared the results with those of over 140 other community pharmacies serving HMO members.

- **Study Design:** This was a non-randomized pre/post study with a comparison group. MTM participants (all HMO members) served by six intervention pharmacies were compared with “usual care” HMO members who filled prescriptions at comparison pharmacies. Outcomes were measured for all study subjects, including MTM participants who chose not to continue receiving MTM services, in an intention-to-treat analysis.
- **Patient Population:** 231 MTM participants with heart or lung disease, who filled prescriptions at six intervention pharmacies, were compared with 444 controls who filled prescriptions at any of 143 comparison pharmacies in the community.
- **Services and Providers:** MTM participants brought all their prescription and over-the-counter medications to an intervention pharmacy for a 20–30 minute interview and medication review. Pharmacists communicated with the patients’ physicians about any identified drug therapy problems. Additional MTM services were provided to patients each time they filled a prescription.
- **Results:**
 - 69% of the intervention MTM patients had at least one pharmacist-identified drug therapy problem, and MTM interventions were provided for 87% of these patients to resolve problems.
 - MTM was associated with an increase in health care utilization (specifically prescription medications and possibly outpatient clinic visits) among intervention patients.
 - No statistically significant difference was found between MTM and usual care in total charges. Program costs were not included in the analysis.
 - After adjustment for gender, age, comorbidities, disease category, and baseline number of medications, the number of medications for patients in the intervention group increased more than in the usual care group.
- **Study Limitations:** This was not a randomized trial, and it is possible that comparison group pharmacies and the patients they served differed from the intervention pharmacies and their patients, in unmeasured ways.

Project ImPACT – a community pharmacy-based demonstration project (Bluml et al., 2000)
Hyperlipidemia

Twenty-six carefully selected pharmacies in 12 states offered MTM services to promote compliance and persistence with dyslipidemia therapy, because previous literature indicated that more than half of patients discontinued lipid-lowering medications within one year. (Note: Although this study included patients with just one chronic condition, it is included here because it exemplifies an MTM approach with an expanded clinical role for pharmacists.)

- **Study Design:** a non-randomized pre/post study with a comparison group.
- **Patient Population:** Project participants were enrolled in the project through referrals from local healthcare providers, by the project pharmacists, or by self-referral. A total of 397 patients were followed for an average of 24.6 months; 345 of these patients began a regimen of lipid-lowering medication and lifestyle modification at the start of the study and the

remaining 52 patients chose exercise and diet-related lifestyle modifications to work toward their goals.

- **Services and Providers:** Participating pharmacies were selected through a competitive application process and were not a random or representative subset of pharmacies in the 12 states. Selected pharmacies had a private or semi-private area for patient consultation, technician support, a documentation system for patient care interventions, experience with disease management programs, communication skills, and ability to use point-of-care testing technologies. Patients met with pharmacists who collected information to create a risk profile for coronary artery disease (CAD), reviewed medications, and took a blood sample to obtain a fasting lipid profile. Patients made follow-up visits every month for the first three months, and then quarterly thereafter for the two years of the project. Patients and their physicians were kept apprised of cholesterol test results, overall condition of health, CAD risk, and achievement of NCEP goals.
- **Results:**
 - Pharmacists provided a total of 346 recommendations to physicians to optimize drug therapy; physicians accepted 77%, of these recommendations.
 - The rate of persistence with medication was 94% and compliance was 90%.
 - 63% of patients attained and sustained their NCEP lipid goals. Mean reductions in total cholesterol and LDL-C exceeded 30 points for those patients that completed the study protocol.
- **Study Limitations:** This was not a randomized trial; because the intervention pharmacies were carefully selected and unlike their peers in many respects, results may not be widely generalizable. In addition, the 31% of patients who did not complete the study were analyzed separately rather than being included in an intention-to-treat analysis.

IMPROVE: A Study at Veteran's Administration Medical Centers (Billups et al., 2000; Ellis, Billups, et al., 2000; Ellis, Carter, et al., 2000)

The Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers (IMPROVE) study was a randomized controlled, multi-center trial to determine whether outpatient pharmacists could affect resource utilization and outcomes among veterans at risk for drug-related problems. (Multiple articles have been published about this intervention.)

- **Study Design:** Study subjects randomly assigned to intervention and control (usual care) groups. Patients who had participated in pharmacist-managed clinics within the previous year were excluded from the study. An intention-to-treat analysis was conducted.
- **Patient Population:** Veterans who used one of the nine Veteran's Administration Medical Center (VAMC) study sites; they also were expected to use the same VAMC site for the 12-month study, were diagnosed with at least three chronic conditions, took at least five medications, with a total of at least 12 doses each day, had a history of non-adherence, and had had medication changes at least three times in the previous year. There were 523 participants at high risk for adverse drug events (502 men; 21 women) in the intervention arm and 531 participants (511 men and 20 women) in the control group.

- **Services and Providers:** Pharmacists interacted with patients, usually in person, and made adjustments to patients' drug regimens. Pharmacists identified the following types of drug-related problems: 1) needs a drug but not receiving it; 2) taking the wrong drug; 3) taking too little of the correct drug; 4) taking too much of the correct drug; 5) experiencing an adverse drug event; 6) drug-drug or drug-food interaction; 7) not taking the drug as prescribed; 8) taking a non-formulary drug, and; 9) requires drug therapy education. Intervention patients had at least three contacts with pharmacists (each contact averaging 15–30 minutes) over the course of the 12-month study period.
- **Results:** After controlling for age, gender, site cluster, and site cluster/treatment interaction, researchers found:
 - Lengthier contacts between patient and pharmacist were associated with the identification and resolution of more drug-related problem.,
 - Pharmacists were able to identify and resolve more drug problems when patient contact was in-person rather than by telephone (patients self-selected whether to interact in-person or by phone).
 - Approximately 57% of drug problems were resolved through pharmacist intervention.
 - There was no significant difference in total cost for the intervention group as compared to the control group.
 - There was no difference in health-related quality of life.
 - A greater absolute change in total cholesterol and low-density lipoprotein (LDL) occurred in the intervention group, although these patients were no more likely to achieve lipid goals.
- **Study Limitations:** This was one of the few studies reporting on MTM conducted in-person versus telephonic however, patients were not randomly assigned to mode of communication. Rather, patients were randomized to receive pharmaceutical care or not, and those in the intervention group then self-selected the mode of communication they preferred. Thus the findings related to mode of communication are not as reliable as the findings related to the impact of pharmaceutical care.

Iowa Pharmaceutical Case Management Program (Becker et al., 2004; Carter et al., 2006; Doucette et al., 2005)

This program was operated by Iowa Medicaid and required pharmacists and physicians to explicitly agree to collaborate on MTM; pharmacists also had to be certified to participate and bill Medicaid for cognitive services. (Several articles have been published about this program.)

- **Study Design:** A retrospective review was conducted to identify appropriate patients. Pharmacist recommendations were documented, as were corresponding prescriber decisions to alter medications. Patients who withdrew were not included in the analysis.
- **Patient Population:** 203 Medicaid beneficiaries with multiple drugs and chronic conditions, and at very high risk for adverse medication events, were identified; 150 received MTM services while the remaining 53 patients (26%) withdrew for various reasons and were excluded from analysis.

- **Providers and Services:** Program staff identified candidate patients and informed their pharmacists and physicians. After an initial pharmacist assessment, patients received MTM at follow-up visits. Pharmacists met with patients, reviewed their medication regimens, and recommended changes to physicians. Documentation included the types of recommendations made by pharmacists, and whether physicians concurred with the recommended medication changes.
- **Results:**
 - Pharmacists detected an average of 2.6 medication-related problems per patient and made an average of 3.8 recommendations per patient.
 - 47% of pharmacists' recommendations resulted in a physician making prescription changes.
- **Study Limitations:** Only pharmacists and physicians who explicitly agreed to conduct MTM together participated in the program, and were reimbursed; these were probably not a random selection of pharmacists and physicians in the state. Patients were not randomly assigned to receive MTM and there was no comparison group. Patients who discontinued (including those who refused to participate) were not included in analyses, potentially biasing results. The impact of prescription changes on costs, patient health, or other outcomes was not assessed.

Impact on Drug Costs and Utilization of a Clinical Pharmacist in a Multi-site Primary Care Medical Group (Walker & Willey, 2004)

A primary care medical group implemented a pharmacist-led educational program for physician-prescribers, focusing on 10 drug classes and aiming to alter prescriber behavior to reduce drug costs and utilization. The medical group had a global “risk” contract with a health plan, and controlling drug costs was an important element of cost containment.

- **Study Design:** A retrospective pre/post analysis looked back at patient records before and after the intervention, and compared results with national “benchmark” data on drug cost and utilization.
- **Study Population:** Patients of a multi-site primary care medical group and their physician-prescribers. The intervention targeted physicians, not patients.
- **Providers and Services:** A pharmacist designed and implemented an educational intervention after reviewing prescribing practices. The intervention involved care algorithms for eight therapeutic areas (10 drug classes).
- **Results:**
 - Per-member-per-year drug costs increased during the two years following the intervention but much less than among health plans nationwide.
 - The number of prescriptions increased more than it did for nationwide plans, but the average cost per prescription declined while nationwide cost per prescription increased.
 - Results varied by therapeutic area.
 - Improvements were largely due to a shift to on-formulary and generic drugs.

- Study Limitations: This was not a randomized trial and did not have a matched comparison group; rather, nationwide data were used as a “benchmark” against which to measure changing patterns in prescription utilization and cost. The study did not assess other outcomes that might be associated with reduced prescription utilization (e.g., clinical outcomes, total healthcare costs), and it is not possible to determine whether the altered number and cost of prescriptions had positive or negative effects on patient health.

Improving Medication Adherence in Heart Failure Patients (Murray et al., 2002)

This study examined whether pharmacist intervention could improve medication adherence, and consequent health outcomes, among low-income patients with heart failure. (Note: Although this study concerned patients with one specific medical condition, it is included here because it explored whether early gains are sustained after the intervention ends.)

- Study Design: Patients were randomly assigned to intervention or control (usual care) groups. Intervention patients received services for nine months and were followed for three months after the intervention concluded.
- Patient Population: 122 intervention patients and 192 control patients were recruited from an academic primary care group practice and from affiliated specialty care clinics. All had a diagnosis of heart failure and were being managed medically and monitored for clinical exacerbations.
- Providers and Services: A single pharmacist provided services aimed at improving adherence. Medications were dispensed in bottles with special computerized lids that recorded the time/date each time the bottles were opened and closed. Adherence was measured by regularly scheduled openings/closings of pill bottles. The pharmacist also provided verbal and written instructions, monitored patients, and communicated with clinicians involved in the care of study subjects.
- Results:
 - Medication adherence was higher in the intervention group at the end of the nine-month intervention period, but dissipated during the following three-month follow-up period.
 - Medications were more likely to be taken on schedule in the intervention group, but this gain
 - Emergency department visits and hospitalizations were lower in the intervention group, as were direct health care costs.
- Study Limitations: It is not clear whether the analysis included patients who discontinued participation. A single pharmacist provided the intervention and the results he achieved may not be generalizable.

An Evaluation of Managing and Educating Patients on the Risk of Glucocorticoid-Induced Osteoporosis⁵

McDonough et al. (2005) assessed the impact of risk management activities on patient risk of glucocorticoid-induced osteoporosis using a randomized control design of eight intervention pharmacies and seven control pharmacies from the Outcomes® pharmacy network. Ninety-six patients were enrolled; 80 patients completed the study, including 61 patients in the treatment group and 19 in the control group.

Pharmacists participating in the study received four hours of classroom education on the pathophysiology and management of glucocorticoid-induced osteoporosis and were provided a packet of articles for independent study. Eligible patients were 18 years of age or older who had been on the equivalent of at least 7.5 mg of prednisone for at least six months. Patients were identified using prescription dispensing records. They were recruited by the pharmacists who mailed a letter inviting them to participate. Patients in the control group received usual and customary pharmacy care, while the patients in the treatment pharmacies received education, an educational pamphlet about the risks of glucocorticoid-induced osteoporosis, and MTM services. Patients in the control group and treatment group reported similar frequencies for the osteoporosis risk factors (e.g., small frame, low calcium diet, tobacco use, and history of fracture).

The pre-post frequencies in each group were taken at baseline and nine months later.

- The treatment group had a significant increase in the presence of bisphosphonate and estrogen therapy⁶, and a significant decrease in the frequency of patients reporting a low calcium diet.
- Patients in both treatment and control groups had more discussions over time with pharmacists about osteoporosis risk management and bone mineral density tests, and these tests were more frequent in both groups at nine-month follow-up.

Using an intent-to-treat approach the two groups were compared at baseline and nine months later. The only significant contrast was that the treatment group had a greater increase in calcium supplementation than the control group.

Although a randomized design was used, all of the pharmacies had participated in other research projects and were trained to deliver MTM since all were part of the Outcomes® network; this may have contributed to the minimal difference between the treatment and control groups on several measures. The small number of control patients limited the statistical strength of findings.

⁵ McDonough RP, Doucette WR, Kumbera P, & Klepser DG (2005). An Evaluation of Managing and Educating Patients on the Risk of Glucocorticoid-Induced Osteoporosis. *Value in Health*, 8(1):24-31.

⁶ The addition of estrogen therapy for the prevention of osteoporosis in post-menopausal women was considered a positive outcome in this study which was likely conducted prior to the study in 2004 that raised the concern about the risks of estrogen therapy.

Hypertension Outcomes through Blood Pressure Monitoring and Evaluation by Pharmacists (HOME Study)⁷

Zillich et al. (2005) evaluated the effectiveness of a community pharmacy-based initiative to improve home blood pressure monitoring, using a randomized design in 12 Outcomes® network pharmacies. The 12 pharmacies were recruited based on willingness to participate; they were randomized into six high-intensity (HI) and six low-intensity (LI) pharmacies. Pharmacists in all 12 pharmacies received training on proper blood pressure measurement using an automated home monitoring device. The HI pharmacists also received an educational program that reviewed evidence-based guidelines regarding both patient and physician education about management and treatment of hypertension.

One-hundred twenty-five patients enrolled in the study (64 patients in the HI group and 61 in the LI group). Pharmacists in the HI pharmacies met face-to-face with patients four times over three months to measure blood pressure, provide education, make recommendations, contact physicians about medication therapy, and give patients a blood pressure self-monitoring tool to use at home. Pharmacists in the LI pharmacies met face-to-face with patients three times over three months to measure blood pressure, and to recommend they see their physician if it was above normal. A nested design was used to compare the change in systolic blood pressure (SBP) and diastolic blood pressure (DBP) between the two groups, controlling for baseline BP, age, gender, and cardiovascular comorbidities. The difference in BP was modeled using multivariate regression. Medication adherence was analyzed using logistic regression models controlling for covariates.

The high-intensity intervention patients achieved a lower DBP than the low-intensity intervention group, demonstrating that pharmacist intervention can improve patient clinical status.

The study size was small and made it difficult to detect any difference between the groups in systolic blood pressure. The study also had a short duration of only three months. The LI pharmacies were not a “usual and customary” care control group, since they had monthly contact with pharmacists and BP measurement. The study also had unmeasured but likely selection bias for both the pharmacies and patients, because all were voluntary, and pharmacies who volunteered may be different than those that did not participate; and because pharmacists might have recruited patients whom they thought would be the best participants for the intervention.

Studies Focusing on Recently Discharged Hospital Patients

Geriatric Evaluation and Management to Reduce Adverse Drug Reactions and Suboptimal Prescribing in the Frail Elderly (Schmader et al., 2004)

This study evaluated geriatric care management that involved collaboration between inpatient and outpatient geriatricians. This was not a medication therapy management program per se, but the geriatricians were responsible for managing all medical care including medications.

⁷ Zillich AJ, Sutherland JM, Kumbera PA., & Carter BL. (2005). Hypertension Outcomes Through Blood Pressure Monitoring and Evaluation by Pharmacists (HOME Study). *Journal of General Internal Medicine*, 20:1–6.

- Study Design: Inpatients were randomized to either usual care or to be followed before and after discharge by specialists in geriatric management. Pairs of physicians and pharmacists, blinded to subjects' study arm, reviewed the care provided to identify adverse drug reactions and determine causality. Study subjects were followed for one year post-discharge. The goal was to determine whether care management by geriatric specialists would reduce adverse drug events.
- Patient Population: 834 frail elderly patients (mostly male) in 11 VA medical centers.
- Services and Providers: Geriatric inpatient unit teams and outpatient clinic teams managed patient care. Independent experts identified adverse drug events and determined causality.
- Results: There were no inpatient geriatric unit effects, but outpatient geriatric clinic care resulted in reduced risk of a serious ADE when compared with usual care. Outpatient geriatric clinic care also reduced the incidence of patients with conditions for which indicated drugs were omitted.
- Study Limitations: The study focus was over-use and under-use of prescription drugs; health and cost outcomes (other than ADEs) were not studied. (Note: The applicability of this study may be somewhat limited for MTM programs serving non-hospitalized patients with multiple chronic conditions.)

The Impact of Clinical Pharmacists' Consultations on Physicians' Geriatric Drug Prescribing (Lipton et al., 1992)

Patients recently discharged from a community hospital, and taking three or more medications, received periodic pharmacist consultation to review medication appropriateness.

- Study Design: At hospital discharge, patients were randomly assigned to intervention and control (usual care) groups, and followed for three months.
- Patient Population: Patients were eligible if they were 65 or older and had Medicare coverage, left the hospital with prescriptions for three or more medications to treat chronic conditions, and were not discharged to nursing homes or hospice care. 274 patients were selected for randomization (123 intervention and 113 controls), but only 236 completed the study. Those who refused to participate or did not complete the study were removed from the analysis.
- Providers and Services: All patients were interviewed at intake (hospital discharge) and were given booklets to record information about their medications. Pharmacists reviewed hospital records and patient self-reports of post-discharge prescriptions, to assess the appropriateness of prescribing, and conducted periodic consultations with patients for three months post-discharge to discuss medications and potential problems. Pharmacists consulted with intervention patients' prescribers about any medication issues. An expert panel reviewed records of all patients to identify clinically significant drug problems.
- Results:
 - 88% of patients had one or more clinically significant drug problems identified by an expert panel after the three-month post-discharge study period; the rate was higher in the control group (93%) than in the intervention group (82%).

- The overall appropriateness of prescribing was significantly better for the intervention group than the control group, but the great majority of intervention patients also had prescribing problems as identified by the panel, despite the intervention.
- Study Limitations: An intention-to-treat design was not used. Patient self-reports about post-discharge prescriptions may have been incomplete or inaccurate. The degree to which prescribers accepted/acted upon pharmacist recommendations was not measured. Patient health outcomes and costs were not measured.

Studies Focusing on Nursing Home Patients

North Carolina Polypharmacy Initiative (Christensen et al., 2004; Trygstad et al., 2005)

This was a demonstration project administered by AccessCare, as part of the Community Care of NC (CCNC) program. The aims of the North Carolina Polypharmacy Initiative (NCPPI) Initiative were to improve the quality of pharmaceutical care available to patients of nursing facilities, and decrease aggregate costs.

- Study Design: Non-randomized pre/post study comparing patients from nursing homes that agreed to MTM with similar patients from nursing homes that did not respond to an invitation to participate.
- Population: The demonstration provided MTM services to 6,244 nursing home patients residing in 253 participating nursing homes. Participants were Medicaid-eligible with at least 18 prescription fills in the 90-day period prior to the start of study. Similar nursing home residents whose institutions did not respond to the invitation for the program served as a comparison group. The two patient groups differed at baseline with respect to race. There was a three-month follow-up period.
- MTM Services and Providers: The demonstration's services included medication therapy review, intervention/referral, and follow-up. Pharmacists who were members of the NC LTC Pharmacy Alliance, and were already servicing nursing homes, collaborated with prescribing physicians to identify drug therapy problems and adjust medication therapy. Pharmacists had access to patient drug profiles, computer-generated from Medicaid pharmacy claims, which displayed flags (described below) for patients and suggestions for modifications of drugs/drug classes. DRR categories of drug therapy flags were: 1) unnecessary drug therapy, 2) more cost-effective drug available, 3) wrong dose/delivery, 4) potential for adverse drug reaction, 5) needs additional therapy, 6) other problem. Alert criteria included: a drug on the Beers Drug list (drugs to be avoided among the elderly), a drug on the NC Prescription Advantage List (encourages substitution of less expensive drug within same therapeutic class), or drugs (from among 16) on a "Clinical Initiatives" list (developed by consultant pharmacists participating in the NCPPI Initiative).⁸
- Results: The addition of drug therapy alerts to usual-care drug regimen review, as routinely provided by consultant pharmacists in all study nursing homes, was associated with changes in drug therapy, primarily:

⁸ The specific drugs on the "clinical initiatives" list were not listed in the study publications.

- The greatest improvements were found in switching from drugs on the Beers List, reduced therapeutic duplication, change in drug strength/dosage, change to a more cost-effective drug, and overall number of computer-generated drug therapy alerts. All other types of prescription problems were also reduced in the intervention population more than in the comparison group.
 - Average number of medications per patient declined.
 - An average of 1.58 prescription changes were suggested to prescribers, of which 72% were implemented; most of these involved a change to a lower cost drug. Prescribers accepted 60% of recommended changes based on the Clinical Initiatives list.
 - Medicaid claims were used to measure drug savings. The intervention group's per patient per month cost was \$57.12 lower than the comparison group's, during the three month follow-up. Drug savings were greatest in the subgroup for whom drug therapy changes were recommended by pharmacists and "accepted" by prescribers (\$61.68 per patient month).
- Study Limitations: This was not a randomized trial, and the use of patients from "non-responder" nursing homes as the comparison group could have introduced selection bias if these two groups of nursing homes (and their patients) differed in unmeasured ways.

Outcomes of Pharmacists' Cognitive Services in the Long-term Care Setting (Johnston et al., 1996)

This study concerned drug utilization review conducted by consultant pharmacists (not part of an MTM program) in 122 nursing homes, most of which were skilled nursing facilities. (Note: Although this study was not part of an MTM initiative, it is presented here because it indicates the potential savings that can be achieved by pharmacist review of patients' medications, in intermediate-care facilities.)

- Study Design: Routine drug regimen review (DRR) was conducted by consultant pharmacists from four LTC pharmacies in two states. Pharmacist interventions, and interactions with prescribers, were documented for one month. Pharmacists checked physician comments in the patient charts for three months after the intervention. Medication costs were documented. Assessment results and other data from charts were used to determine changes in patient health (positive, negative, or no change).
- Patient Population: 10,207 residents of 122 nursing homes (98% skilled nursing facilities and 1.6% residential-care facilities).
- Providers and Services: LTC consultant pharmacists conducted standard DRR and noted changes in prescriptions and patient health status during a three-month follow-up review of patient medical charts.
- Results:
 - 68% of pharmacist recommendations resulted in medication changes directly related to the intervention.
 - 97% of these changed drug regimens resulted in cost reductions.
 - Patient health was judged to have improved in 95% of cases where pharmacist recommendations were accepted.

- There was a total annualized cost savings of \$125,248 per year across all patients, of which 41% was related to discontinuing unused/unnecessary medications.
- Study Limitations: This was not a randomized trial and there was no comparison group. Patient health status was subjectively judged by the consulting pharmacists—who were conducting the DRR—based on nursing notes and other data in the medical chart. The cost of operating the program was not calculated.

Studies Focusing on MTM Enhanced by Prescription Coverage/Financial Support

Senior PHARMAssist Program, Durham County, North Carolina (Smith et al., 2004)

This program combined MTM services with financial support for prescription drugs. Low-income residents of Durham, NC who lacked adequate prescription drug insurance were eligible to participate in this program, which included financial assistance for medications and referrals to community and governmental programs, as well as MTM services.

- Study Design: Recruitment for the study is not described; it appears that 794 patients (or their caregivers) were referred to this pharmacy assistance program (PAP) over a six-year period. Patients were assessed at baseline, including self-reports of health status, and again after two years in the program. Records were reviewed for hospitalizations and other health events.
- Patient Population: The population was mostly female and half were African American; on average they had six medical conditions and were taking five medications. At follow-up, 515 were available; those who discontinued were not included in the analysis.
- Providers and Services: Participants or their caregivers met with a pharmacist and other program staff at entry, and three more times over a two-year period. At each visit, data were collected on medication knowledge, adherence, use of services, and functional status. Participants received a drug card/coverage and were referred to other financial support programs. Pharmacists reviewed medications and made recommendations to prescribers.
- Results:
 - The proportion of patients who understood the purpose of their medications increased.
 - The number of medications and adherence remained unchanged during the study period.
 - The percent of medications on-formulary increased.
 - Patient-reported hospitalizations and ED visits decreased, and self-reported rating of health improved over time.
- Study Limitations: This was not a randomized study and there was no comparison group. All data about use of services were self-reported and subject to recall error. It is not possible to attribute outcomes to MTM alone, since participants also received prescription coverage that they previously lacked, and gained access to a variety of other programs and services.

PRICE Clinic for Low-Income Elderly (Stebbins et al., 2003)

This program too combined MTM services with financial support for prescription drugs. Low-income elderly patients with multiple chronic conditions and multiple medications received pharmacist services and financial support for prescription drugs. (Note: This study concerned the impact of pharmacists in reducing patient co-payments and out-of-pocket costs; it did not measure patient health outcomes or use of other medical services. It is presented here because it demonstrates pharmacists' ability to lower patient out-of-pocket costs. This is an element of MTM of particular importance for low-income patients.

- **Study Design:** Eligible elderly patients were seen in the PRICE clinic in 2002. Researchers documented the number and type of interventions performed by pharmacists and assessed changes in drug use through review of records. Data from a statewide Pharmacy Assistance Program (PAP) were used as a comparison or “benchmark,” as was the Medical Expenditure Panel Survey (MEPS). Patients were interviewed about their ability to pay for prescription drugs, and discontinuing drugs due to cost, and patients were asked to save their receipts from drug purchases.
- **Patient Population:** 520 low-income seniors (68% female) with Medicare participated; each had multiple chronic conditions, multiple medications, and high drug costs. Patients took an average of six medications to treat four chronic conditions; 86% had generic-only coverage from a Medicare Advantage plan.
- **Providers and Services:** Pharmacists determined out-of-pocket costs for drugs during the first clinic visit. Pharmacists enrolled eligible patients in state PAP and recommended generic substitutions and therapeutic interchange to less costly (on-formulary) drugs.
- **Results:**
 - Use of generic drugs increased over the two-year period of clinic participation.
 - Use of on-formulary drugs increased.
 - Out-of-pocket costs decreased.
 - Patients restarted drugs they had previously discontinued for cost reasons.
 - Per-patient prescription costs were lower than in the “benchmark” populations from MEPS and the statewide PAP.
- **Study Limitations:** This was not a randomized study and there was no comparison group. Data about income and out-of-pocket costs were based on participant self-report and saved receipts, which may have been incomplete or inaccurate. Patient health outcomes and use of other medical services were not measured. (Note: with the introduction of Medicare Part D, many seniors served by the PRICE clinic now have improved drug coverage and no longer qualify for the PAP, which was an important part of the intervention described above.)

Appendix C:

Case Studies

1.1. Program A – Medicaid

1.1.1. Background

Program A is a Medicaid MTM program that was enacted under a law in 2005. The legislative initiative was supported by favorable outcomes (clinical, economic, and humanistic) in other state MTM programs, in addition to the local university data on MTM described in the bill's fiscal note. MTM is defined as "the provision of pharmaceutical care services by a licensed pharmacist to optimize therapeutic outcomes of the patient's medications." Pharmacists began enrolling in the program on April 1, 2006.

Program A requires that pharmacists meet the following four criteria:

- Be licensed in the state.
- Have graduated from an accredited college of pharmacy on or after May 1996 (the year that local university graduated the first students exposed to the MTM-related curriculum), or have completed a comprehensive MTM training program that has both clinical and didactic elements.
- Be practicing in an ambulatory care setting as part of a multidisciplinary team.
- Use an electronic documentation system that meets state standards.

1.1.2. Program Description

Eligibility and Coverage Criteria

Under Program A, Medicaid recipients, both fee-for-service and managed care, are eligible for MTM if they are taking four or more prescriptions to treat or prevent two or more chronic medical conditions, or are experiencing a drug therapy problem that is likely to result in significant nondrug program costs. Medicaid-sponsored MTM is provided only to recipients who are not eligible for Medicare Part D. Nursing home patients are not eligible for MTM because that could duplicate the services of nursing home consultant pharmacists who are providing drug regimen review.

After Program A recipients are determined to be eligible for MTM services, they remain eligible as long as they have Medicaid coverage, regardless of changes in their health status, drug therapy, or number of prescriptions. If/when Medicaid recipients also become eligible for Medicare, they no longer receive prescription coverage through Medicaid and are no longer eligible for the MTM program.

Enrollment

Pharmacists must be approved to provide MTM services and receive reimbursement under Program A. They qualify by completing a provider application and agreement, and providing the state with a copy of their diploma and pharmacy license. From April 1, 2006 through December 31, 2007, approximately 110 pharmacists applied and were approved by the state to provide MTM.

The state has approximately 600,000 Medicaid recipients, of whom 240,000 are fee-for-service (FFS); the remainder are in managed care plans. Approximately half of the FFS Medicaid recipients are eligible for MTM. The state’s department of human services (DHS) does not identify individuals who meet the MTM eligibility criteria, and Medicaid recipients do not “enroll” into the program. Instead Medicaid recipients who could benefit from MTM are identified by their pharmacists, physicians, or other providers, and are referred to a participating MTM pharmacist—there is no separate step to “opt in” or enroll in the program. Participating pharmacists use their own judgment to decide which Medicaid recipients (among those who meet the broad criteria of having four or more prescriptions to treat two or more chronic conditions) should be offered MTM.

During the first two calendar years of the program, MTM pharmacists provided services to 493 Medicaid recipients, with a total of 792 MTM encounters, resulting in \$75,015 in paid MTM claims (this figure does not include DHS administrative costs). The table below shows the yearly breakdown of patients, encounters, and expenditures for the program for this two-year period.

Exhibit 1: Program A Activity

Period	Patients with One or More MTM Encounters	MTM Encounters	Reimbursement to Pharmacists
2006	222	329	\$30,136
2007	303*	463	\$44,879

Source: The State’s Department of Human Services, unpublished data.

* Many patients receiving MTM services in 2007 may have also received services in 2006.

The somewhat passive “referral” process for offering MTM to eligible Medicaid recipients may partially explain the relatively slow growth in the program. DHS has a new initiative underway to increase referrals of Medicaid recipients for MTM by improving awareness of the program among physicians. As part of their annual retrospective drug utilization review (RDUR) process, DHS staff are identifying eligible high-risk, fee-for-service Medicaid recipients, listing them by physician, and sending physicians lists of their MTM-eligible patients. Physicians will also receive lists of nearby approved MTM pharmacists who can serve their patients. The DHS targeting algorithm uses claims data to identify chronic conditions likely to benefit from MTM, based on the Core Elements of an MTM Service⁹ (e.g., asthma, diabetes, heart failure, hyperlipidemia, hypertension, osteoarthritis, and osteoporosis). The algorithm also includes four additional mental health conditions prevalent in the Medicaid population: ADHD, bipolar disorder, PTSD, and schizophrenia.

MTM Interventions and Services

MTM services are covered if they are face-to-face encounters in an ambulatory care setting including a pharmacy, hospital, or clinic. Services provided via telephone, e-mail, mail, or other modalities are not covered, nor are services provided in nursing homes or patient homes. Program A does not require the explicit involvement of physicians, but does require that pharmacists consult, coordinate,

⁹ From the list of chronic conditions in Medication Therapy Management in Community Pharmacy Practice: Core Elements of an MTM Service (version 1.0). *Journal of the American Pharmacists Association*; 45:573-79.

and collaborate with patients' prescribers in order to meet treatment goals and resolve drug therapy problems.

Program A defines MTM services to include:

- Performing or obtaining necessary assessments of the patient's health status.
- Formulating a medication treatment plan.
- Monitoring and evaluating the patient's response to therapy, including safety and effectiveness.
- Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events.
- Documenting the care delivered and communicating essential information to the patient's other primary care providers.
- Providing verbal education and training designed to enhance patient understanding and appropriate use of the patient's medications.
- Providing information, support services, and resources designed to enhance patient adherence with the patient's therapeutic regimens.
- Coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient.

Documentation

Program A requires that pharmacists document each patient encounter using an electronic system that is designed to improve therapeutic outcomes. The documentation must include, at a minimum, the following information:

- **Patient information:** recipient's full, legal name; address and telephone number; gender; date of birth; current medical conditions; resolved medical conditions; allergies; and primary physician and contact information.
- **Other information:** date of encounter; date of documentation; time spent with patient; list of all prescription and nonprescription drugs with their indications; list of drug doses, directions and intended use; list of all relevant medical devices; list of all dietary supplements, herbal products; alcohol and tobacco use history; list of environmental factors that impact the patient; assessment of drug problems identified; evaluating effectiveness and safety of current drug therapy; written plan including goals and actions needed to resolve issues of current drug therapy; evaluation of success in meeting goals of medication treatment plan; information, instructions, and resources delivered to the patient; and content of pharmacist's communications to patient's other health care providers.

While the State does not mandate a particular documentation system, one of the commercially available systems is used by approximately 80% of pharmacists participating in the MTM program. The system is accessed by pharmacists via a secure web link. The data are maintained on a server and each pharmacy or chain of pharmacies has access to only its own data, to assure patient confidentiality. The system is a comprehensive electronic documentation and billing system designed

to help pharmacists provide medication therapy management services by combining patient demographics, medical conditions, medications, laboratory results, and drug therapy problems. The system facilitates the MTM care process for pharmacists by allowing them to:

- Build a patient Electronic Therapeutic Record™
- Track medication reconciliation interventions
- Identify, track, and resolve drug therapy problems
- Create custom patient care plans
- Document and report therapeutic goals for a patient
- Schedule appointments
- Create claims automatically
- Submit invoices electronically to any payer, including those that use the CMS 1500 form.

The system also facilitates data collection and reporting to support patient care and practice management activities, and to demonstrate the clinical and economic outcomes of MTM. There are over 250 discreet data variables in the system. The following are brief descriptions of the available reports that the system can generate:

1. Reports for patients (medication summaries, personal medication diaries, and personal pharmaceutical care plans).
2. Practice management reports for physicians (number of patients served, number of encounters, distribution of patients by demographic variables or complexity—drug therapy problems, medical conditions, or medications). These reports could be used to demonstrate to physicians their own patients' common drug therapy problems.
3. Clinical outcome reports for physicians, and for clients such as Program A (change in clinical status over time measured against the established goal of therapy, or clinical outcomes of a subset of patients).
4. Economic outcome reports for clients (drug savings resulting from services provided, or pharmacist estimates of the number of hospitalizations, emergency department visits, or physician visits avoided).

Reimbursement and Billing for MTM

The reimbursement model for the Program A centers on a resource-based relative value scale (RBRVS) that reflects three criteria: the number of medications being taken by the patient, his/her number of medical conditions, and the number of drug therapy problems. The more complex the case, the greater the reimbursement.

The RBRVS structure calculates reimbursement for MTM services based on the lowest of five patient need levels (see Exhibit 2). The program uses specific MTM CPT codes developed in collaboration between the CPT Editorial Panel and the Pharmacist Services Technical Advisory Coalition (PSTAC) for pharmacists to bill payers for MTM.¹⁰ The RBRVS code structure reflects the estimated level of

¹⁰ The CPT codes were recently changed from temporary Category III codes to permanent Category I CPT codes. Further description of the codes can be found at www.PSTAC.org.

practitioner pre-, intra-, and post-service work, practice expenses, and time to conduct the service, as follows:

- 99605: A first encounter service performed face-to-face with a patient in a time increment of up to 15 minutes (rate = \$52.00)¹¹
- 99606: Follow-up encounter with the same patient in a time increment of up to 15 minutes for a subsequent encounter (rate = \$34.00)
- 99607: Additional increments of 15 minutes of time for 99605 or 99606 (rate = \$24.00)

The Program A RBRVS code structure is further delineated in the following table:

Exhibit 2: Program A MTM Codes and Payments

Patient Need Level	Assessment of Drug-related Needs (number of medications)	Identification of Drug Therapy Problems (number of drug therapy problems)	Complexity of Care Planning and Follow-Up Evaluation (number and complexity of medical conditions)	Approx. Service Time	CPT Code	Units	Rate
1	Problem-focused – at least 1 medication	Problem-focused – 0 drug therapy problems	Straightforward – 1 medical condition	15 minutes	99605 or 99606	1 unit	\$52 or \$34
2	Expanded problem – at least 2 medications	Expanded problem – at least 1 drug therapy problem	Straightforward – 1 medical condition	16-30 minutes	99605 or 99606 and	1 unit	\$76 or \$58
					99607	1 unit	
3	Detailed – at least 3-5 medications	Detailed – at least 2 drug therapy problems	Low complexity – at least 2 medical conditions	31-45 minutes	99605 or 99606 and	1 unit	\$100 or \$82
					99607	2 units	
4	Expanded detailed – at least 6 medications	Expanded detailed – at least 3 drug therapy problems	Moderate complexity – at least 3 medical conditions	46-60 minutes	99605 or 99606 and	1 unit	\$124 or \$106
					99607	3 units	
5	Comprehensive – \geq 9 medications	Comprehensive – \geq 4 drug therapy problems	High complexity – \geq 4 medical conditions	60+ minutes	99605 or 99606 and	1 unit	\$148 or \$130
					99607	4 units	

Source: DHS Health Care Provider Manual

¹¹ These rates are not adjusted for inflation on an annual basis, for example. The rates have not been updated since they were created in 2006.

For example: a patient with 9 medications and 4 medical conditions, but 0 drug therapy problems, is Level 1—the lowest level that meets *all three criteria*. If this is the patient’s first MTM encounter, the pharmacist bills 99605 and is reimbursed \$52; if it is a follow-up encounter, the pharmacist bills 99606 and is reimbursed \$34.

The following limitations are placed on the number of MTM claims that can be submitted for each Medicaid recipient:

- One CPT 99605 (first encounter) per pharmacist, per recipient in a 365-day period
- Up to seven CPT 99606 (follow-up encounters) per recipient in a 365-day period
- Up to four CPT 99607 (additional time increments) per recipient per date-of-service

MTM pharmacists may request prior authorization to bill for additional follow-up consultations (CPT 99606 only).

Program A MTM pharmacists file claims for MTM services using a CMS 1500 Form or through the state’s on-line billing system for submission of medical claims to DHS.

The Program A evaluators reviewed medical records for 48% (126 of 259) of MTM recipient records and found that 60% of MTM claims were submitted at the correct RBRVS level, consistent with evidence in the patient charts. However 30% of medical records contained documentation that supported billing at a *higher* RBRVS level, and 10% contained documentation indicating that a *lower* level should have been billed. The following is the percentage of claims across the five RBRVS levels, as corrected based on medical record review:

RBRVS Level	1	2	3	4	5
Number and percentage of claims	15 (6.4%)	54 (22.9%)	66 (28%)	56 (23.7%)	45 (19%)

1.1.3. Evidence of Program A Effectiveness

As stated in the amended statute, the Medicaid commissioner was to have the program evaluated, therefore DHS contracted with a local university to conduct the mandated evaluation, and explored the following research questions:

- 1) Does the provision of MTM services improve patient care?
- 2) Does the provision of MTM affect quality of care?
- 3) Does MTM have an impact on health expenditures?
- 4) What program improvements and enhancements are needed to support the MTM program’s continued application?

Evaluation Conducted by the Local University

The evaluation spanned a one-year period from April 1, 2006 through March 31, 2007. During this 12 month period, 34 pharmacists provided MTM services to 259 recipients who had a total of 431

MTM encounters. This represents roughly half of the encounters in the first two full calendar years of the MTM program. The reimbursement to pharmacies for these services was approximately \$40,000. The 259 recipients served during the study year ranged in age from 12 to 91 years (median age 52); 97% (250/259) of patients were under the age of 65.

The parameters assessed as part of this evaluation included:

- Clinical care, by evaluating drug therapy problems (DTPs) identified and resolved, goals of therapy achieved, and performance-based benchmark (QCare¹²) standards achieved for recipients with diabetes.
- Economic outcomes, by comparing total health care expenditures for recipients before and after receiving MTM services. In addition, savings were calculated for diabetic MTM patients who met all QCare standards.
- Program implementation, including assessing provider satisfaction with the program and with implementation of the program.
- Program improvement, evaluated through comparison with a model of continuous quality improvement.

There were several different quantitative analyses conducted; complete data were not available for each of the 259 recipients. The following study populations were used for the various analyses:

- Claims and related documentation (259 MTM recipients)
- Achievement of therapeutic goals (167 MTM recipients whose care was documented using the most commercial system)
- Quality care benchmark standards met (114 diabetic patients whose medical charts were reviewed/abstracted)
- Economic analyses for (77 recipients who had at least six months pre- and post-MTM continuous Medicaid coverage)

The 167 recipients whose care was documented in the commercial system had an average of 6.3 medical conditions and were taking an average of 14.1 drugs (10.5 prescription and 3.6 non-prescription).¹³

With respect to drug therapy problems, during the evaluation period pharmacists identified and resolved 789 DTPs in the 259 MTM recipients, or approximately 3 DTPs per recipient.

¹² The State's 2006 QCare (Quality Care and Rewarding Excellence) benchmark standards for diabetics:
(1) Hemoglobin A1C measurement below 8%,
(2) LDL-cholesterol measurement below 130 mg/dL,
(3) Blood pressure measurement below 130/85 mm Hg,
(4) Daily aspirin use if over 41, and
(5) No tobacco use.

¹³ We do not have information about whether MTM recipients whose pharmacists use the commercial system differ from those served by pharmacists using other documentation systems.

Medical record abstraction covered the period from one month prior to the first MTM service, through mid-2007. This analysis revealed that quality of care performance benchmarks (QCare standards) achieved by MTM for patients with diabetes was higher than the State average: 36% (41 of 114) of diabetic patients receiving MTM services achieved all QCare performance standards, compared with the statewide average of 6% of diabetics. Additionally, 77% of MTM patients with diabetes (88 of 114) achieved the QCare 2006 HgA_{1c} benchmark goal (statewide data not available).¹⁴¹⁵

Economic analyses were based on claims for MTM recipients who had at least six months' pre- and post-MTM continuous Medicaid coverage (n=77). These analyses showed an 8% increase in total health expenditures from pre- to post-MTM intervention. This change included both decreases in the costs of various ambulatory services, and increases (approximately 25%) in prescription drug costs. This finding is consistent with the fact that inadequate drug therapy (and the need for additional medication) was responsible for nearly two-thirds of the DTPs in the MTM population under study.¹⁶

The Department of Health had previously estimated that \$403.30 would be saved for each diabetic Medicaid recipient who met all QCare standards. The evaluators multiplied the number of recipients who received MTM and met all diabetes QCare standards by this pre-established estimated savings, to quantify total savings due to improved quality of care. A total savings of \$15,325 was estimated for 38 diabetic Medicaid recipients who met all QCare standards after receiving MTM services.

The evaluators concluded that DHS effectively implemented MTM by developing tools, procedures, and communication processes that were not previously available in other states' Medicaid programs. DHS facilitated the program's implementation by using a Help Desk Phone Line, verifying recipient eligibility through the state's on-line system, and communicating MTM program requirements on the DHS web site. The evaluators found that cooperation among the state professional association, academia, private industry, and the State was essential to program implementation, and they found that pharmacists who established collaborative relationships with physicians and other primary care providers were more successful in providing MTM services. Finally, the evaluators noted that ideally, MTMS software programs would be fully integrated into existing electronic medical record systems (which is not true of the commercial system) in order to eliminate the need for double entry and improve efficiency.

Researchers advised that the program could be strengthened, and offered several recommendations:

- enhancing provider awareness of the program (including both pharmacists and physicians),
- proactively identifying potentially eligible patients,

¹⁴ The pre-MTM period against which change was measured was brief (one month) and the number of diabetic MTM recipients was small, limiting the ability to determine causality.

¹⁵ There were not enough MTM patients with coronary heart disease to conduct a similar analysis of quality benchmarks.

¹⁶ The increase in total health expenditures for MTM participants was anticipated in the fiscal note that was submitted to the legislature in 2005. The fiscal note also anticipated that total health expenditures for MTM participants would decline (primarily due to a decline in inpatient costs) over the longer term (up to five years from program implementation).

- removing barriers to program participation by increasing pharmacists' use of health literacy tools for non-English-speaking patients,
- providing coverage for MTM services in patient's homes, and
- enhancing state-reimbursed patient transportation to MTM appointments to help minimize the "no-show rate."

A major challenge the evaluators identified was physicians' lack of awareness of the program, and pharmacists' relatively low participation in it. Enrollment of pharmacists into the program has been slow, and the pharmacist participation rate has been relatively low compared to the total number of pharmacists in the State. Data from the State Board of Pharmacy indicated that as of March 15, 2006, there were approximately 6,300 active pharmacists in the State, of whom at least 1,200 had graduated from the local university since 1996 and could therefore be approved to provide MTM services (in addition to pharmacists who were trained in other programs). At the end of 2007, only 110 pharmacists were providing MTM services in the Program A. It is the State's belief that many Medicaid recipients are not being reached and provided with the opportunity for MTM because not enough pharmacists are participating. A second training program meeting the requirement of having both a didactic and clinical component has recently been approved by the State's DHS for pharmacists graduating before 1996, which may help to increase the number of pharmacists participating in Program A's MTM program.

1.2. Program B – Medicare Prescription Drug Plan

Program B is a Medicare prescription drug plan. In 2008, Program B has approximately 130,000 members in its Medicare prescription drug plans (PDPs) and 230,000 members in its Medicare Advantage drug plans (MA-PDs). The MTM program is the same for the MA-PD and PDP populations. The MTM program is currently offered only to Medicare beneficiaries, not to Program B's commercial (employer) clients.

Program B's MTM program managers describe the initial goals of the MTM program as being "to touch a small number of people who can most benefit, with intensive services, to bring about meaningful change." MTM program managers believe that pharmacists can be most successful in managing medication therapy if they communicate the same information and recommendations to both patients and physician-prescribers at the same time, as this is the best way to foster dialog about medication management.

CMS requires MTM programs to "safeguard against discrimination based on the nature of MTM interventions." Program B's MTM program managers operate with the philosophy that the same services must be offered, in the same way, to every member in the drug plan's MTM program. That is, an MTM program featuring face-to-face interactions between pharmacists and patients ideally should deliver that service to every eligible plan member, regardless of location. Program B has a sizeable rural membership in two states, and judged face-to-face MTM to be impractical for this portion of their population. The MTM program instead relies on mailed information, with referral to telephone follow-up as needed. The identical mailed intervention is delivered to every MTM program participant including those who receive mail-order drugs, live in remote rural areas, or reside

in institutions (e.g., nursing homes, assisted living), and the program is the same for PDP and MA-PD members.

1.2.1. Program B MTM Program Description

Eligibility

Program B's plan managers deliberately began with a small and carefully defined high-risk population, in order to understand the population's MTM needs before broadening eligibility to a larger number of beneficiaries. Eligibility criteria were relaxed somewhat for 2008, reflecting the program's experience in 2006-07. Medicare plan members are eligible for MTM if they meet all three of the following criteria:

1. Prescriptions for nine or more drugs (reduced from 12 or more in 2006-07).
2. Five or more chronic conditions, at least two of which must include the following: asthma/COPD, CHF, diabetes, hypertension, hyperlipidemia.¹⁷
3. Total drug costs estimated to exceed \$4,000 annually.

Program B uses an automated process to identify eligible patients for MTM. Each month the system runs a program that searches prescription claims to identify patients with nine or more unique prescriptions within the contract year. The program then "infers" the chronic conditions associated with those drugs (e.g., insulin = diabetes) to determine which patients have five or more conditions, including two from the list above. For patients who meet the first two criteria, the program applies drug cost algorithms to identify those likely to have \$4,000/year in prescription drug costs.

Enrollment

Eligible patients are sent an invitation letter and enrollment packet containing a brief survey. Those who wish to participate in the MTM program send back the enrollment form and survey. The survey asks patients to designate their primary care provider, whether they smoke (and their desire to quit), and their use of dietary supplements and over-the-counter medications. The survey also asks about drug allergies, chronic conditions, and whether the patient has trouble paying for prescription drugs, and it asks if the patient would like to speak with a health care professional about medication issues. Those who do not respond to this introductory mailing are sent a repeat invitation to "opt in" to the MTM program.

In 2006 and 2007, approximately 6% of eligible Medicare drug plan enrollees who were invited to join the MTM program, enrolled in the program. There were 539 members participating in the MTM program in 2006 and 741 in 2007. Most of those who participated in 2006 continued to participate in 2007.

¹⁷ In contrast to its Medicare plans, Program B focuses on very different conditions for its commercial clients (e.g., migraines).

Exhibit 3: Program B's Plan and MTM Program Enrollment

2006	2007
Total Part D Enrollment ~300,000	Total Part D Enrollment ~360,000
9,337 Eligible Plan Members (3.1%)	11,424 Eligible Plan Members (3.2%)
MTM Enrollment 539 (5.8% of eligibles)	MTM Enrollment 741* (6.5% of eligibles)

Source: Program B, unpublished data

* Many people enrolled in the MTM program in 2007 may also have been enrolled in 2006.

In 2008 the number of prescription medications needed to qualify for the Medicare MTM program was reduced from 12 to 9, and plan managers expect 500-1,000 additional members to enroll in the MTM program following this change in eligibility criteria.

MTM Interventions and Services

Salaried staff pharmacists (six as of early 2008) review prescription claims of new MTM participants, looking for the following irregularities/opportunities:¹⁸

- Duplication of therapy
- Short-term drugs being used long-term
- Long-term drugs prescribed for short duration
- Overuse of medication – dose too high or refilled too often
- Underuse of medication – subclinical dose
- Drug-drug interaction (DDI)
- Drugs of concern for the elderly – Beers list
- Adherence/compliance issues – refill gaps
- Congruence with clinical guidelines – e.g., patients with hyperlipidemia taking statins
- Potential cost saving issues for patient and for payer

The pharmacists also consider information from the patient enrollment survey. For example, patients who report having asthma but have no prescriptions for inhalers or other relevant medications would receive an intervention recommending treatment for asthma.

In 2006 and 2007, 20% of new MTM enrollees who sent back a survey said that they had trouble remembering to take medications; in 2006 45% had difficulty paying for medications, as did 36% in 2007. For patients who reported having trouble paying for prescriptions, pharmacists will identify generic substitutions and other alternative medications with lower copayments. For patients who reported having trouble remembering to take their medications, pharmacists will recommend methods to increase their medication compliance, such as setting up a medication routine around daily events or through the use of a pill box.

If the pharmacist identifies medication issues, s/he uses the system to create paired letters: one for the patient that describes the issue and recommendation in lay terms, and one for the patient-designated

¹⁸ MTM staff are currently programming their system to identify the number and percent of medication issues in each category that the MTM pharmacists identify.

primary care provider (PCP). The latter uses terminology that is more clinically precise, and provides justification for the recommended change. If a pharmacist were to identify a patient with an acute, immediate risk (for example, critical drug-drug interactions); then immediate calls would be placed to the prescriber and community pharmacist.¹⁹ Otherwise, the MTM intervention is in the form of the paired letters sent to patients and PCPs. When a patient has prescriptions written by more than one prescriber, the MTM letter goes to the designated PCP, the assumption being that the PCP will contact other prescribers, as necessary, to align the patient's prescriptions.²⁰

MTM pharmacists can place telephone calls to prescribers when a particular situation warrants urgent attention, but this is extremely rare. Approximately 100 instances of drug-drug interactions have been identified by MTM pharmacists thus far, but none have been of sufficient urgency or severity to require telephone calls to prescribers.

MTM pharmacists have the ability to review monthly prescription claims for specific patients, to determine whether MTM recommendations result in prescription changes. However, claims are not systematically used to verify whether prescriptions change in accordance with MTM recommendations. (See description of follow-up surveys below.)

A case may be reviewed again each year, or any time during the year if the case warrants further intervention. If a review identifies new issues another pair of letters is sent. If the same issue is continuing at re-review, the MTM pharmacist assumes that the prescriber has considered the MTM recommendation and decided not to comply, and no repeat mailings are sent.

Referrals

In addition to sending letters, pharmacists can refer cases that require telephonic communication either to a nurse-advice line available to all Program B members, or to nurse case managers. Cases that require mainly patient education and prevention counseling are referred to the nurse-advice line. Cases that involve complex clinical issues, drug-disease issues, high health service utilization, or other indications of poorly-controlled chronic disease are referred to nurse case-managers employed by Program B. If a patient indicated in the enrollment survey that s/he wanted to speak with a health care professional about medication issues, the referral is made to nurse case managers as well. Neither the nurse-advice line nor the nurse case managers are funded as part of the MTM program, although they are available to MTM patients—these are additional services Program B offers. The MTM pharmacists identify patients who need more-direct assistance, and make the referrals to improve care and reduce costs.

In 2006 there were 141 referrals to other programs (26% of MTM cases), of which 82% were to the nurse-advice line and 18% to nurse case managers. MTM program managers realized that pharmacists were making many referrals to the nurse-advice line, who in turn referred patients to the nurse case-managers. In 2007 they began referring more cases directly to the nurse case managers, resulting in 150 referrals (20% of MTM cases) of which 65% were to the nurse-advice line and 35% to nurse case managers.

¹⁹ There have been no such events thus far.

²⁰ The MTM program does not supply PCPs with lists of their patients who are in the program, although managers are considering this communication/outreach effort.

Relationship between MTM and Disease Management (DM)

There is a separate, large DM program for health plan members, directed by the nurse case managers. DM is offered to both Medicare and commercial clients, but the MTM program is currently offered only to Medicare drug plan members. If a Medicare patient is in both programs (MTM and DM), the MTM pharmacist will explain any medication issues to the nurse case managers. On the other hand, a nurse case manager with a DM case might ask the pharmacist for advice, even if the patient is not MTM-eligible. Since both DM and MTM programs are staffed by in-house (salaried) Program B employees, the two programs are able to take advantage of each other's expertise at no additional cost.

MTM for Patients in Long-Term-Care Settings

Program B has a small number of MTM patients in nursing homes. The paired MTM letters are sent to the PCP and to the patient—or to someone else the patient designated as a caretaker (e.g., a family member with power of attorney). The MTM program does not communicate directly with nursing home staff, and assumes that nursing homes use consultant pharmacists for monthly drug regimen reviews. MTM program managers believe that the opportunities for MTM are fewer in the nursing home setting. Medications are managed by consultant pharmacists, and compliance is not an issue because nurses are responsible for administering drugs. If, however, an MTM pharmacist does identify a medication management issue, a patient can be referred to a dedicated Program B LTC nurse case manager.

Documentation

The in-house documentation system (not a commercial product) has three open-text comment sections: one to document letters that are sent to patients and referrals that were made; one to document letters (or calls) with prescribers; and one for the pharmacist to record additional comments to improve pharmacist continuity of care over time. Pharmacists enter this latter type of comment in two situations: 1) if the pharmacist intends to re-review and possibly send another set of letters, or 2) if the pharmacist comes across a really egregious case (e.g., expensive drug prescribed at a clinically ineffective dose, or drugs that should never be combined) and despite a telephone call cannot convince the PCP to change the prescription.

1.2.2. Evidence of MTM Effectiveness

Physician Satisfaction and Compliance with Recommendations

The MTM mailings sent to PCPs contain both the pharmacist's recommendations and a follow-up survey for the PCP to complete and mail/fax back. The follow-up survey asks the PCP to indicate whether s/he:

- Agrees with the MTM recommendation and will comply.
- Agrees with the MTM recommendation but will take no action at this time (and why).
- Disagrees with the recommendation and will take no action at this time (and why).

The follow-up survey also asks the PCP whether the MTM program has value for patients.

Approximately 25% of mailed MTM recommendations yield a return survey from the PCP. About 80% of these respondents agree with the MTM recommendations they received, and state that they intend to comply. (There is no systematic validation of these survey responses to determine whether the prescription did in fact change to conform to the MTM pharmacist's recommendation. This has thus far been accomplished via a manual process.) In addition, 82% of responding PCPs agree that the MTM program has value for patients.

MTM program managers have not examined response bias in this survey. They do not know whether certain types of PCPs are more likely to send back a follow-up survey, or whether certain kinds of MTM cases/recommendations are more likely to result in the PCP's sending back a follow-up survey. And they have not explored whether responding physicians are more or less likely to comply with certain kinds of recommendations (e.g., DDIs) than with others (e.g., generic substitutions).

Patient Satisfaction

Patients also receive a follow-up survey 30–60 days after the MTM recommendation mailing. This interval allows time for the patient to confer with his/her physicians and obtain new prescriptions. The survey asks whether the patient has discussed the MTM recommendation with his/her doctor or pharmacist, and whether the MTM recommendations were helpful. It also asks whether the patient is feeling better since enrolling in the MTM program, understands his/her medications better, and understands his/her medical conditions better. Finally, the survey asks a satisfaction question about the overall prescription drug plan.

Approximately 40% of mailed MTM recommendations yield a completed feedback survey from patients. Each year approximately 80% of patients who respond to the survey report that the MTM recommendations were helpful. In addition, about 98% of patient-respondents reported that they feel “better or the same.”

The patient survey asks about satisfaction with the overall drug plan. Drug plan managers examine retention rates from year to year, and the same could be done for the subset of patients participating in MTM, although this analysis has not yet been performed.

MTM program managers have not examined response bias in this patient follow-up survey. They do not know whether certain types of patients, or those with certain conditions or medication issues, are more likely to send back a survey. And they have not explored whether certain types of MTM recommendations are more likely to yield a follow-up response from patients.

Cost Outcomes

Program B's MTM program managers are planning a cost evaluation in the second quarter of 2008 focusing on brand-to-generic switches. They also intend to examine drug costs before/after for patients continuously enrolled during the first two years of the program, to explore total drug costs, out-of-pocket costs, and whether MTM cost efficacy interventions prevent some patients from entering the uncovered Part D “donut hole.”

In the future they are considering comparing MA-PD patients in the MTM program with those who are not in the MTM program, to see whether hospital and emergency department utilization differ.

This analysis would require age and risk adjustment because the two populations are probably quite different.²¹

Other Outcomes

In 2008 program managers plan to document the frequency of drug-drug interactions (DDIs) in the MTM population and whether DDIs decline over time (for patients continuously enrolled over a two-year period). MTM program managers are also interested in patient compliance, as measured by the medication possession ratio²², and whether MTM interventions improve compliance. They will examine the possession ratio across their entire population, not only the subset in the MTM program, to identify opportunities to improve.

The MTM program analysts do not extract data from medical claims or patient medical records to examine whether clinical markers (e.g., HbA_{1c}, LDL cholesterol) improve after MTM. Although MTM pharmacists try to identify prescriptions that are not in accordance with clinical guidelines, program analysts do not examine data to determine whether MTM is improving compliance with clinical guidelines. The data with which to perform such analyses would come from claims (for MTM patients in the MA-PD plan), but MTM managers use only pharmacy claims, not medical claims, because they believe that medical claims are generally delayed so long as to not be useful in achieving timely interventions and results. For example, an MTM pharmacist might recommend a prescription change to improve LDL cholesterol, but it could be three months or more before a claim for an office visit containing laboratory cholesterol values comes through the system. By then, the prescriber may have made additional medication changes. Moreover, it is extremely difficult to piece together a chain of events to determine whether MTM is affecting lab values. Program managers feel that the value of this analysis is difficult to determine, as many confounding variables influence patient outcomes.

1.3. Program C – Multi-State MA Plan

1.3.1. Background

Program C is a Medicare Advantage plan, organized in semi-autonomous regions; MTM is not conducted in exactly the same way in each region. This case study is specific to one of the regions.

When the MMA created the Part D benefit, with the requirement for Medication Therapy Management, the literature provided little initial guidance for structuring Program C's MTM program. Program C historically had clinical ambulatory care pharmacists managing various populations of patients; the MTM program was modeled after those programs where ambulatory care pharmacists established collaborative practice agreements with physicians to initiate, adjust, and manage drug therapy.

²¹ This analysis will likely be suggestive rather than conclusive, due to the small size of this MTM program.

²² The medication possession ratio is defined as the prescribed days supply of medication divided by the days between refills. A possession ratio of less than 1 may indicate that patients are not taking all their medication on time.

Program C operates many other programs that may have a pharmacy component, including registries of patients with specific conditions (e.g., cancer, renal failure), chronic disease management, and a cost-efficacy drug utilization program to convert patients to lower-cost drugs using evidence-based standard protocols. One objective of Program C's MTM program was to leverage the contributions of these multiple initiatives, with all clinicians aiming for the same outcomes – especially for patients with chronic conditions. These programs are available to all Program C patients, while the MTM program is thus far available to eligible Medicare patients only.

1.3.2. MTM Program Description

Program C pharmacists are salaried employees and the majority of outpatient prescriptions are filled “in house” at Program C pharmacies. MTM services are provided by clinical pharmacists, not dispensing pharmacists, and these clinical pharmacists can refer patients to even more highly specialized colleagues, such as oncology pharmacists. Program C is increasingly separating the dispensing function from clinical pharmacy services, seeking to automate dispensing and freeing pharmacists for MTM and other medication management or oversight efforts. All pharmacists, whether dispensing medication or providing MTM, have access to the same patient electronic health record (EHR).

In Program C, many clinical ambulatory care pharmacists have collaborative practice agreements with physicians and follow agreed-upon care protocols to change or reconcile prescriptions when necessary, without obtaining approval from the physician for every change. Some of the Program C medical practices use a primary care team model, where the pharmacist is part of the team and contributes to care decisions, including medication management. Some physicians may opt not to participate in collaborative practice agreements with pharmacists. In these instances the MTM pharmacist follows a more traditional approach and makes recommendations to the physician, who decides whether or not to alter medication therapy.

Eligibility

The Program C MTM program is for eligible Medicare patients only. Using a management information system that assembled MTM -relevant information (described below), the MTM program calculates medication costs over a rolling 12-month period. Twice each year program staff identify patients with drug costs exceeding \$4,000.

Among patients with \$4,000 or more in annual drug costs, those with two or more medications from the following list are identified:

- Anticoagulants
- Antihyperlipidemics
- Antihypertensives
- Hematopoietic Agents
- Insulin
- Oral Hypoglycemics

Those who also have two or more of the following chronic conditions (based on ICD-9 diagnostic codes in the EHR) are eligible for MTM:

- Diabetes
- Dyslipidemia
- Hypertension
- Coronary Artery Disease
- Pulmonary Embolism
- Peripheral Artery Disease
- Cerebrovascular Accident
- Atrial Fibrillation
- Mechanical Heart Valve
- Deep Vein Thromboembolism

As these criteria indicate, the MTM program focuses on cardiovascular disease treatment and prevention, and common co-morbid conditions such as diabetes and stroke. In 2006, approximately 15,000 Program C Medicare beneficiaries were eligible for MTM; in 2007 this number increased to approximately 25,000.

Enrollment

Eligible patients are sent a letter explaining the MTM program and inviting them to participate. This introductory letter includes a questionnaire regarding prescription and medical history. Eligible patients “opt in” by telephone or mail; if they call to enroll but fail to send back the questionnaire, MTM program staff contact them to obtain the necessary information. Patients who do not respond to the initial mailing, and who are at especially high risk and could benefit from MTM, may receive a telephone invitation. (Such cases include, for example, those with LDL-C not at goal, or those missing LDL-C within a specified time period.) After enrolling, patients may “opt out” at any time. Institutionalized patients (long-term-care nursing home residents) who meet the program criteria are automatically enrolled, and can opt out if they do not wish to have their medications reviewed by an MTM pharmacist. Thus both opt-in and opt-out enrollment mechanisms are employed. Patients enrolled in the MTMP in the previous year who continue to meet the MTMP enrollment requirements the next year are invited to re-enroll.

In 2006, approximately 10,000 Medicare beneficiaries (69% of eligibles) enrolled in the MTM program; in 2007, approximately 14,000 Medicare beneficiaries (57% of a much larger group of eligibles) enrolled.²³

MTM Interventions and Services

MTM pharmacists use patient histories, prescription profiles, laboratory test results, medical care utilization histories, and other information to conduct a comprehensive medication review (CMR), which is repeated annually. After reviewing medications, the MTM pharmacist contacts the patient by telephone to discuss any opportunities to improve drug therapy, identify adherence barriers, and answer any questions or concerns. The action plan may focus on therapeutic guideline concordance, duplicative therapy, drug-drug interactions, excessive/insufficient doses, adverse events, compliance issues, or identification of cost-effective alternative medications. When necessary, the MTM

²³ 2007 enrollment numbers are estimates.

pharmacist will advise and consult with the patient’s physician and/or work under approved protocols to adjust medication therapy and order medication-specific laboratory tests or procedures. The MTM pharmacist designs individualized medication monitoring schedules and follow-up plans, and may refer the patient to specialty services (e.g., anticoagulation, oncology, asthma, etc.) or to disease management services or disease registries. Follow-up with the patient is individualized to address specific issues, and may include telephone or office visits with an MTM pharmacist. Follow-up may include customized treatment plans, review of laboratory tests, evaluation of side effects, and patient education.

The average MTM patient has two MTM encounters per year, and the range is from 1 to 10. In 2006, the 10,228 enrolled patients had 24,631 MTM interventions recorded, as follows:

Exhibit 4: PROGRAM C MTM Encounters

Percent of MTM Encounters	Type of MTM Encounter												
14%	Non-drug therapy (e.g., patient education on disease states, referrals, recommended tests)												
1%	Preventive health (e.g., vaccination recommendations, smoking cessation counseling)												
85%	MTM drug therapy interventions, with the following breakdown: <table style="margin-left: 20px; border: none;"> <tr> <td>Optimizing dosing and monitoring</td> <td style="text-align: right;">48%</td> </tr> <tr> <td>Facilitating guideline concordant therapy</td> <td style="text-align: right;">15%</td> </tr> <tr> <td>Clarifying the prescription profile</td> <td style="text-align: right;">15%</td> </tr> <tr> <td>Supporting patient self-management and adherence</td> <td style="text-align: right;">12%</td> </tr> <tr> <td>Initiating new drug therapy when appropriate</td> <td style="text-align: right;">5%</td> </tr> <tr> <td>Facilitating cost effective medication management</td> <td style="text-align: right;">5%</td> </tr> </table>	Optimizing dosing and monitoring	48%	Facilitating guideline concordant therapy	15%	Clarifying the prescription profile	15%	Supporting patient self-management and adherence	12%	Initiating new drug therapy when appropriate	5%	Facilitating cost effective medication management	5%
Optimizing dosing and monitoring	48%												
Facilitating guideline concordant therapy	15%												
Clarifying the prescription profile	15%												
Supporting patient self-management and adherence	12%												
Initiating new drug therapy when appropriate	5%												
Facilitating cost effective medication management	5%												

Virtually all prescriptions are filled at Program C pharmacies. It is likely that dispensing pharmacists also provide some MTM-like services (e.g., compliance counseling, patient education, checking for drug allergies) at the point of sale. Some dispensing pharmacists may have access to the EHR and could document patient interactions there, but due to time pressures in the dispensing setting this rarely occurs. Dispensing pharmacists do not, however, have access to the MTM database, so these encounters are not documented in that system and cannot be readily tabulated or reported.

Patient Records and MTM Documentation

Like other EHRs, the one that Program C uses is intended for patient care and is not designed to manage or report on population health. It is not possible, for example, to identify MTM-eligible patients using the EHR, or to analyze the care patterns and processes for MTM patients as a group; EHRs do not support analysis at this level. To implement its MTM program, the Program C pharmacy operations group created a separate database that assembles relevant data from many sources (prescriptions, laboratory values, diagnosis, etc.) with which to identify eligible patients. After patients are identified and enrolled in the MTM program, chart documentation occurs in the patient’s EHR so that care providers are aware that the patient is receiving MTM. All interactions between the patient and MTM pharmacist, or between the pharmacist and prescriber, are documented in the pharmacy MTM database.

The separate MTM database is used to document and aggregate MTM services and generate reports for CMS. The same approach—creating an offline system for population management and reporting—is employed for many other programs (disease registries, chronic care management, etc.). Procedures for moving data from this system to the EHR, or vice versa, are “work-arounds” and not entirely seamless.

Relationship between MTM and Other Care Management Programs

Program C conducts cost-efficacy drug reviews for all plan members, aimed at switching to the most appropriate cost-effective medication whenever possible. For patients in the MTM program, medication review is more involved and addresses not only cost issues but therapeutic issues as well.

Program C has a variety of chronic care improvement programs available to all members in both Medicare and commercial plans. These programs range from disease registries to chronic care management and address many chronic conditions—including some of those selected as MTM eligibility criteria. Many of the Medicare patients in these other programs may also be eligible for MTM. Program C deliberately tries to integrate multiple chronic care improvement efforts, rather than operating entirely autonomous “programs” —patients are engaged in whichever clinical services may be beneficial.

The EHR platform is used by all programs for individual patient care but, as described above, the EHR is not able to manage/report on care processes and outcomes for a population of patients. Because CMS requires reporting on MTM and Medicare Health Support programs separately, two different management information systems/databases are used to capture and report data. Program C’s commercial plans do not have these distinct reporting requirements and there is no need to categorize a patient as being in one program or another (or both), or to report on the programs as separate entities.

MTM for Patients in Long-Term-Care Settings

Program C provides MTM services to patients in custodial nursing home settings. Patients in custodial care settings who meet the eligibility criteria and reside in a nursing home are automatically enrolled in the MTM program; patients (or their appointed surrogates) can “opt out” if they wish. An MTM pharmacist conducts a CMR for each eligible nursing home resident, using any information already available or provided by the nursing home, to identify cost efficacy and therapeutic opportunities and convey these recommendations to the patient’s continuing care physician. MTM program managers acknowledge that this activity overlaps substantially with the functions of nursing home consultant pharmacists, but the review conducted by the MTM pharmacist is more oriented to cost efficacy, elimination of therapeutic duplication, and medication issues for cardiovascular patients in particular (the targeted MTM population). Communication between the MTM pharmacist and nursing facility staff is limited – mainly to obtaining patient records/information – and the MTM pharmacist’s recommendations are not entered into the patient charts maintained at each nursing facility.

1.3.3. Evidence of MTM Effectiveness

Clinical Outcomes

The Program C MTM group conducted a study of the effectiveness of MTM in achieving LDL-C (<100mg/dL) and HbA_{1c} (<7%) goals among hyperlipidemic, diabetic, and coronary artery disease patients in their MTM program (presented at a national pharmacy association meeting). A quasi-experimental design was used with pre/post measurement and two control groups. The experimental group was composed of Medicare MTM patients with one or more of these chronic conditions and at least six months of active MTM follow-up (n=3,927). One control group was composed of patients with one or more of these chronic conditions and who were eligible for MTM but declined to enroll in the program (n=4,154); the other control group contained patients with these conditions who met all MTM criteria but did not have Medicare Part D coverage (n=2,854).²⁴ All patients had lab values recorded six months before and six months after an index date (the date they enrolled, or declined to enroll, in the MTM program).

Controls were demographically quite similar to experimental (MTM) patients, except that the non-Part D controls were somewhat older than the two Medicare groups, and somewhat less likely to have diabetes.

There were no significant differences in the pre/post changes in glycemic control between the MTM and control groups. The percent of patients “at goal” for lipid control, before and after the index date (MTM intervention), were as follows:

Exhibit 5: Change in Lipid Control Following MTM*

Lipid Control	MTM Patients n=1,481	Controls (declined MTM) n=1,357	Controls (non-Part D) n=899
Percent at goal before	62%	62%	67%
Percent at goal after	73%	67%	69%

*All differences between MTM and control patients are significant at the .0001 level.
Source: Program C's Presentation at a national pharmacy association meeting, 2007

Cost Outcomes

As described above, many MTM patients are concurrently participating in other disease management and chronic care programs at Program C, and all patients in the plan undergo a cost-efficacy drug utilization review that is not part of the MTM program. Program C pharmacy program staff have information from non-Medicare populations indicating that the cost-efficacy drug utilization review reduces drug costs, while chronic care management programs tend to increase drug costs. It is likely that MTM reduces drug costs for some patients and increases drug costs for others, but it is not possible to separate these effects from the other cost influences.

²⁴ The experimental group was self-selected and contained patients who opted to enroll in the MTM program; one control group was similarly self-selected and contained those who declined MTM. The second control group contained elderly people without Medicare Part D coverage; they either had other drug insurance or chose not to purchase drug coverage.

Program C is not an indemnity insurer and as such does not receive/process claims for medical services (emergency department visits, hospitalizations, etc.). Each patient’s utilization can be extracted from his/her EHR and may be analyzed to understand whether utilization is changing. This is cumbersome for the reasons discussed above, and it would not be possible to attribute all of the observed changes to MTM alone. Analysts are, however, in the process of extracting and assembling the necessary data to conduct analyses of this sort.

Patient Satisfaction

As part of the study, a patient satisfaction survey was mailed to 1,000 randomly selected patients in the experimental MTM group during program year 2006. Forty-four percent responded to the survey and answered eight questions on a Likert scale where 5 = Strongly Agree and 1 = Strongly Disagree:

Exhibit 6: Patient Satisfaction Survey

Survey Questions	Average Score
Q1: The pharmacist provided easy to understand instructions about my medicines and/or other health problems or concerns	4.3
Q2: The pharmacist effectively explained the possible side effects of my treatment	4.2
Q3: After speaking to the pharmacist, I feel that I understand my medicines better and I am able to make better decisions about my medicines	4.2
Q4: After speaking to the pharmacist, I am more likely to take my medicines as prescribed.	4.2
Q5: The pharmacist effectively answered any questions I had.	4.3
Q6: The time the pharmacist spent with me was adequate.	4.3
Q7: The MTM staff was courteous and professional.	4.5
Q8: Overall rating of the quality of the service provided.	4.4

Source: Program C unpublished 2006 data

This survey reassured MTM program managers that the program is being well-received by patients.

Other Outcomes

The Program C pharmacy group is embarking on an effort to assemble utilization data for other medical (non-drug) services, to study patterns among MTM patients. They are interested in whether MTM and other care management efforts are reducing utilization (and costs) for non-drug services.

Program C pharmacy program staff are also interested in identifying cases of poor medication outcomes and comparing these with similar cases that have better outcomes. They want to understand how to target or direct MTM to high-risk situations where there is the most risk – and therefore the most opportunity to improve outcomes. They plan to explore many sorts of indicators that would help to identify patients for whom a poor outcome could be prevented, including: patient medication adherence scores, CMR recommendations, patient compliance in getting lab tests done, and other “missed” opportunities to intervene along a poor trajectory. This exploratory work is just

beginning and is intended to improve all of their chronic care and MTM programs, rather than to evaluate the impact of MTM as a discreet service.

1.4. Program D – MTM Vendor

1.4.1. Background

Program D is a Medication Therapy Management company or vendor offering a nationwide network of pharmacists that deliver MTM services to covered members for Medicare drug plans, Medicaid and state health programs, employer groups, pharmacy benefit management companies (PBMs), and pharmaceutical manufacturer programs.

Unlike the three MTM programs described above, the Program D case study encompasses an entire system for administering MTM programs: a nationwide pharmacy network, serving patients covered by dozens of payers across the country, a software platform and documentation system, a pharmacist reimbursement system, and a capitated pricing arrangement. As a result, this case study is lengthier and more complex than the three previous cases. In addition, The Program D was founded in 1999 and several studies have been conducted using the system and/or its data; these studies are described below.

Clients

Program D began with self-insured employers because these entities are at risk for all health care costs of their employees, not just prescription-related costs. The initial group of self-insured employers included school systems, union funds, and municipalities.

In July 2003, Program D launched a state Medicaid program, which is available to ambulatory, fee-for-service Medicaid patients. The program was one of the state's value-add programs²⁵ funded by a major pharmaceutical manufacturer. The program started in four counties and after nine months was expanded statewide to nearly one million Medicaid recipients. The state legislature discontinued all other value-add programs shortly after this expansion, because another value-add program's evaluation did not demonstrate the anticipated savings to the state. The program with which Program D was involved was the only value-add program that was grandfathered and is still continuing.

Since Part D began, Program D has seen increased interest from Part D plans, and currently contracts with several plans including a multi-state Special Needs Plan for dual eligible beneficiaries and a nationwide Part D plan. Program D also recently launched an MTM program in a state modeled previously successful MTM programs in the state and emphasizes face-to-face MTM conducted by community pharmacists. It is available to all seniors statewide; more than 650,000 seniors qualify and thus far approximately 4,000 have received MTM services. The program is part of an effort to “wrap around” Part D and was implemented because the Trust Fund staff had anecdotal evidence that

²⁵ Drug companies routinely give rebates on their drugs to payers, including Medicaid programs, in return for having their drugs included in the formulary. The rebate is usually in cash; however, the Medicaid program developed a mechanism in which a drug company divides the traditional cash rebate into a smaller cash rebate and a “value-add” program such as nurse case management or MTM, to improve services for Medicaid recipients.

many seniors were receiving inadequate MTM (or none at all) from their Part D plans. Program D and the program sponsor recognize that this program could overlap with the MTM programs offered by Part D prescription drug plans. This is a two year pilot project intended to gather information about the gaps in Part D MTM; the sponsor staff plan to evaluate the program and share this information with CMS.

Program D also administers programs on behalf of pharmaceutical companies. These programs have included compliance or persistence programs tied to a specific manufacturer's drug, or a full MTM program centered on a specific drug or a drug class. Program D will not provide "switch-only" programs for pharmaceutical manufacturers or other clients, but will create programs to foster compliance/adherence for patients already using a particular drug. They have recently partnered with another company to offer a standardized medication adherence program to interested pharmaceutical manufacturers.

Finally, Program D offers a program for individual consumers to directly purchase MTM services for a \$120 annual premium. This program began when an early employer-sponsored MTM program was discontinued and the patients who had received the service for two years expressed interest in continuing to receive the service at their own cost. To meet this need, Program D created a personal pharmacist program. Patients sign up with Program D, pay the annual premium, and use one of the pharmacies in the network; Program D reimburses pharmacists for the services provided. Program D believes this option will be attractive to patients (both working and retired) who use health savings accounts.

The patients served by Program D MTM programs are identified by clients based on each plan's eligibility criteria. In 2003 Program D covered 12,000 to 15,000 lives, primarily in one state; now their MTM programs cover over 2 million patients nationwide.

1.4.2. Program Description

Eligibility Criteria

The employer-sponsored MTM programs operated by Program D are typically available to all employees, not a select high-risk subset. The state Medicaid program described above is available to all ambulatory, fee-for-service Medicaid recipients. The recently launched state program is available to all Medicare Part D patients aged 65 and older, in one state.

Most Part D plans offer MTM to only a subset of their enrollees – those who meet the three criteria of having multiple drugs, multiple chronic conditions, and drug costs exceeding \$4,000 – and most plans further refine this by including only patients with specific chronic conditions and drugs. Some Part D plans Program D works with allow all enrollees to make use of MTM, but reports to CMS only on the subset who meet the three criteria. As part of their service to clients, Program D will scan a client's data to identify eligible patients, based on the plan's unique eligibility criteria.

Recruiting Patients

Once Program D identifies a client's eligible patients, the system notifies dispensing pharmacies in the Program D network that serve each patient. Pharmacists are encouraged to offer these patients

comprehensive medication reviews (CMR). If a dispensing pharmacy for an eligible patient is not part of the Program D pharmacy network, the pharmacy is invited to join the network. (A free one-hour online training is required as well as a network contract.) If the pharmacist is not interested, Program D will look for a contract pharmacy or pharmacist nearby, and then call the patient to explain MTM and suggest s/he visit a participating pharmacy/pharmacist for the service. If no participating pharmacy is nearby, the patient will be invited to confer with a consulting pharmacist by telephone.

Patients are free to decline each time an MTM service is offered, but very few do. Patients are never disenrolled from the MTM program altogether, since circumstances change and they might wish to make use of MTM in the future.

Special Populations

Program D works with clients to meet the needs of special populations including patients who receive medications via mail order, patients in the nursing home, and patients enrolled in special-needs prescription drug plans. For patients who receive their prescriptions via mail order, Program D will send an invitation explaining MTM services, and offer the options of receiving MTM from network pharmacies in their area or via a phone call with a consultant pharmacist.²⁶ This entirely separates drug dispensing (mail order) from the MTM service, and is viewed by Program D as the best way to offer services to these patients.

Program D maintains specific policies and procedures for MTM services provided to nursing home patients. A pharmacist cannot bill for a CMR because this is part of the LTC consultant pharmacist's drug regimen review (DRR), nor for patient compliance interventions because the patients in a nursing home do not self-medicate. However, pharmacists can bill for prescriber consultations. This approach could be applied for other health/drug plan clients with patients in nursing homes.

Program D recently signed a contract with a multi-state Special Needs Plan (SNP) for dual-eligible beneficiaries. This SNP's MTM program was previously run by a PBM, which used an opt-in enrollment approach with a mailed invitation and had zero enrollment. A majority of the plan's patients are illiterate, and they speak over two dozen different languages, which may be why a mailed invitation was unsuccessful. The Program D® is expanding its network of pharmacies in the SNP's coverage area, and the program will be available to all patients. Dispensing pharmacies will be notified about their eligible patients, and encouraged to offer MTM services. Retail pharmacies deal with language issues on a daily basis, and are accustomed to working through family members and other interpreters when necessary; The Program D® believes that these same in-person translation strategies are the most effective way to overcome language barriers for MTM.

²⁶ Program D allows mail order pharmacies to bill for the identification and resolution of drug therapy problems but not for CMRs; no mail order pharmacies have yet submitted invoices for MTM. Patients who prefer mail order can receive MTM services face-to-face at any network pharmacy. Program D does not track the number of mail-order customers who receive MTM services in-person.

1.4.3. MTM System Components

Pharmacy Network

There are over 60,000 pharmacies in the United States; Program D's pharmacy network consists of approximately 12,000 pharmacies nationwide (in 50 states and Puerto Rico). Program D signs contracts with both pharmacies (e.g., independents, chains, clinics, health systems) and individual consultant pharmacists. Within a pharmacy, not every pharmacist may be interested in MTM; those that are interested complete a free one-hour online training and receive login information to use the Program D web-based system and submit claims. When contracting with a pharmacy, Program D requires that the pharmacy "maintain a sufficient number of Approved Pharmacists on duty at each Approved Location, along with sufficient facilities, equipment, and support personnel in order to provide MTM to members in a timely and appropriate manner."

When Program D contracts with clients whose patients are located in a region that is not yet well represented in their network, Program D recruits additional pharmacies and pharmacists. Thus as the Program D client base expands, so does the pharmacy network. For example, in 2006 Program D contracted with a county and recruited pharmacists in the area to serve this population.

Pharmacist Training

Program D staff originally provided in-person training for new pharmacy network members. When their contract with the state Medicaid value-add program expanded from four counties to the entire state, in-person training was infeasible and they created an interactive on-line training program. The training is a requirement for pharmacists to contract with Program D and receive reimbursement for providing MTM as part of their network. Pharmacists receive login information to use the system when they complete the training. There is no cost to pharmacists for this training, which is a web-based, interactive program with six modules. Pharmacists can complete one module at a time, returning to the training as time permits.²⁷

MTM Interventions and Services

Program D offers four MTM services within its covered services menu; the same four services are offered to all clients regardless of payer type, with a few exceptions (e.g., nursing home patients). These four covered services include:

- **Comprehensive Medication Review.** This is a face-to-face encounter between a contracted pharmacist and an eligible patient during which the pharmacist reviews the patients' medications and identifies problems as well as savings opportunities.²⁸ Only one CMR is reimbursed per year, unless the pharmacist believes it is clinically necessary. For example, patients may be discharged from the hospital with an entirely new drug regimen; in this case

²⁷ Originally the training was accredited for ACPE credit (2 hours). The training is not available for continuing education units because it is not approved by ACPE (the pharmacy education accrediting body), due to more stringent, non-proprietary requirements for ACPE accreditation.

²⁸ A CMR or patient education session can be conducted via telephone for a patient who is homebound or in a location not served by any network pharmacists.

the pharmacist could conduct a new CMR. During a CMR, patients are asked to rank the importance – to them – of the following factors: cost, comfort (avoiding medicine side effects, reducing/managing symptoms), or convenience (organizing medications, simplifying daily dosing schedule).

- **Prescriber Consultation.** This is an interaction between a pharmacist and a prescribing clinician regarding a more cost-effective drug therapy option or an identified drug therapy problem.
- **Patient Compliance Consultation.** This is an interaction between a pharmacist and a patient to encourage compliance with the prescribed drug regimen, and may not require prescriber involvement (e.g., patient under or over use of a medication).
- **Patient Education & Monitoring.** This service involves a pharmacist educating a patient about a medication when a new medication is initiated, a medication is changed, or an over-the-counter medication is recommended. After an initial education session, the pharmacist must also follow up (monitor) to determine if the patient is experiencing any medication-related problems and is experiencing improvement in his or her condition (e.g., symptom improvement within three days of initiating an antibiotic for a sinus infection). The pharmacist must provide education face-to-face whenever possible, though monitoring can be by telephone. Education and monitoring is the service most commonly provided.

These four services need not be mutually exclusive, separate events – more than one service can take place during a single encounter, to address all of a patient’s medication-related needs. For example, a CMR may reveal the need to consult with a prescriber, which results in the initiation of a new medication, which in turn necessitates patient education and monitoring. This example would yield three separate claims and three separate payments, reflecting the complexity of the encounter.

Program D believes the best results come from all four services, and that pharmacists should be reimbursed for all of them. They will not contract to provide only a CMR, as is the case in some other MTM programs, because they do not believe MTM can achieve optimal results with a CMR alone. In one instance, a client decided to discontinue reimbursement for education and monitoring; when reimbursement for this service ended, many pharmacists lost interest in MTM because their reimbursable interactions with patients were very limited. Program D finds that its standardized package of services achieves the best results and is the most efficient to administer.

MTM services can be provided by any pharmacy/pharmacist that has an MTM network contract, and by any pharmacist who has completed the training program. Patients who cannot travel to a pharmacy for in-person services, or who have no nearby network pharmacy or consultant pharmacist, can receive services via telephone.²⁹ Fewer than 10% of CMRs have been conducted via telephone, and Program D has given permission, on a case-by-case basis, for other patient interactions and follow-up to take place by telephone. Program D contracts with organizations (e.g., pharmacist provider groups or call centers) that can provide telephonic MTM services if needed, and tries to assure that a pharmacist providing MTM via telephone is located in the same state as the patient..

²⁹ Program D interprets CMS’s guidelines as requiring the same services, but not necessarily provided in an identical mode, for every patient. They emphasize in-person services but will cover telephone interactions when necessary.

Reimbursement & Billing

Contracted pharmacies and pharmacists are reimbursed for the covered services they provide. The following exhibit outlines the reimbursement level for each of the covered services and the expected result of each service.

Exhibit 7: Pharmacist Reimbursement Schedule - Program D

Covered Service	Outcome of Service (Result)	Reimbursement (\$)
Comprehensive Medication Review	CMR with or without Encounter	\$50.00
Prescriber Consultation	Initiation of Cost-Effective Drug	\$20.00
	Drug Therapy Problem (DTP) Resolved	\$20.00
	Prescriber Refusal – DTP or Cost Efficacy	\$ 2.00
Patient Consultation	Altered Compliance or Admin Technique	\$20.00
	Patient Refusal – Compliance or Cost Efficacy Management	\$ 0.00
Education & Monitoring	Therapeutic Success (or Failure)	\$10.00
	Patient Refusal	\$ 0.00

Source: Program D

A pharmacist is paid \$50 for a CMR whether or not it necessitates additional encounters.

A pharmacist is paid \$20 for a prescriber consultation, whether the consultation is related to a drug therapy problem or a cost efficacy issue. However, if the prescriber disagrees or does not accept the recommendation, the pharmacist is reimbursed only \$2. This small payment recognizes the pharmacist’s effort without encouraging inappropriate calls to prescribers.

A pharmacist is paid \$20 for a patient compliance consultation that could result in either improved compliance or improved administration/technique. A pharmacist is not reimbursed for patient consultations regarding cost efficacy management, because it is presumed that the prescriber must be involved for that issue to be resolved. That is, a consultation about switching to a lower-cost drug would be reimbursed as a prescriber consultation rather than as a patient consultation. A pharmacist is not compensated for a consultation that a patient refuses or is not interested in receiving.

A pharmacist is paid \$10 for patient education and monitoring, unless the patient refuses this service (the pharmacist should not file a claim if a patient refuses MTM, as there is no “result” for the interaction).

Complex patients with more drug therapy problems require multiple services; this greater complexity is recognized by reimbursement for additional services. A pharmacist can bill only one payer for an MTM service. For example, a beneficiary could receive MTM under a prescription drug plan’s MTM program administered by Program D or under a state program also administered by Program D, but not both.

Pharmacists document claims for the covered services described above on an encounter worksheet, where they chart what was done in the encounter; all billing is done electronically. On each claim

and for each service, the pharmacist indicates the *reason* for the encounter, the *action* or professional service rendered, and the *result* or outcome of the service.

In addition to processing claims for services provided to patients of Program D' clients, the Program D system can generate a CMS 1500 form for other MTM programs, so pharmacists can use this single system and generate claims that meet the requirements of other payers. Program D has mapped its proprietary codes to the CPT codes developed for MTM services, but still requires its pharmacists to document services in accordance with Program D procedures. Program D can also set up its system to accommodate other reimbursement structures (e.g., flat fee, RBRVS) that its clients (or its pharmacists' other payers) might prefer.

Electronic Charting Platform

Program D documentation and billing system is web-based and free to network pharmacists. Contracted pharmacists log on to the system using their pharmacist identification number and password and then see a dashboard screen that includes:

- a section summarizing the number of patients
- pending Targeted Interventions (see below)
- claims by status (e.g., pending, review/resubmit, rejected)
- pharmacy rating
- a mailbox (e.g., with a Targeted Intervention Program alert)
- a calendar to help with scheduling CMRs or follow-up monitoring calls with patients

The platform includes an electronic patient chart with each patient's medication list, allergies, etc. The medication list is not auto-populated from the pharmacy dispensing system (Program D is exploring this functionality); however, the medication history section of the system is populated based on information provided (a prescription claim file) by the company's clients, and is available for the pharmacist to review and modify. The prescription drug claims data are updated every 30 days. For some patients, the pharmacist will not have access to the prescription claims and must build the entire medication list based on the prescriptions the patient brings in. The chart also includes a SOAP³⁰ note-like field for pharmacists to more fully describe issues.

Each time a claim is submitted the pharmacist selects one reason, one corresponding action, and one corresponding result, and all have unique codes. For example, a pharmacist may determine that a prescription is unnecessary, may consult with the prescriber to discuss this, and may discontinue the prescription. In the encounter notes, the pharmacist would also describe the patient-reported symptoms or clinical situation that made the medication unnecessary, the specific recommendation made to the prescriber, and his/her reply. Pharmacists cannot see documentation about MTM services entered in a patient's record by other pharmacists. That is, if a patient moves, his or her new pharmacist cannot see detailed documentation about MTM provided by the previous pharmacist. Summary information may be viewed (e.g., last date of CMR, but not the CMR content; or that three MTM claims had been completed, but not the detail). All prescription information and claims are visible to pharmacists treating a patient, but MTM documentation and clinical notes are not.

³⁰ SOAP stands for subjective, objective, assessment and plan and is a standard documentation format for health care professionals.

Each patient's record in the system can also capture laboratory values obtained directly from patients (self-report), from a printout from the clinic that the patient brings in, or from the prescriber or clinic staff. Currently, the pharmacist populates the laboratory data; Program D would be willing to interface its system with clients' lab systems, but the clients have not requested this.

The Program D system allows pharmacists to create a printable MTM profile for patients. The profile is based on the APhA and NACDS guidelines for creating a printable Medication Action Plan³¹ so that patients have a written guide of the medications they are currently taking. The system does not, at this time, have the ability to print an MTM profile in a calendar format to create an individualized schedule for a patient.

The company's clients have access to real-time reports, which they can generate themselves. For example, Program D can set up access levels that meet client needs, specifying that certain data or reports be rolled up at the corporate level, district level, etc. The information a district manager has access to may differ from the data available to executive officers.

Program D is striving to reduce barriers to MTM by designing its platform and documentation system to support other MTM programs and payers.

Outreach and Communications

Program D operates an outreach center and distributes various communications to its pharmacy network. An important element of outreach to pharmacists is an intervention program.

Intervention program

Program D conducts retrospective drug utilization reviews (RDURs) of its clients' prescription claims and other information, to identify specific interventions that pharmacists can make for individual patients. The RDUR is based on standard guidelines and each client plan's formulary. The intervention alerts are patient-specific and sometimes include a reference or supporting document for the pharmacist. Intervention alerts are sent to pharmacists via fax, mail, private email, or their system email. After the pharmacist uses the information from the intervention alert to improve medication therapy, he or she can sign the intervention alert sheet and fax, mail, or email it back, which automatically generates a claim. (The pharmacist does not need to fill in a separate claim form when acting on an intervention alert.) In addition, pharmacists may access an "intervention alert Queue" in the Program D online system, which allows pharmacists to complete electronic billing of interventions themselves. Intervention alerts are intended to alert pharmacists to MTM interventions that should be undertaken for specific patients.

Intervention alert examples include clinical guidelines (e.g., presence of long-term steroid inhaler in addition to an albuterol inhaler), formulary management, compliance enhancement, product discontinuation (e.g., changing from CFC to HFA inhalers), tablet splitting, quality interventions (e.g., HEDIS measures), and many more. Program D will also create intervention alerts requested by clients. For example they used intervention alerts to encourage immunizations for an SNP plan. The

³¹ American Pharmacists Association and National Association of Chain Drugstores Foundation (2005). Medication therapy management in community pharmacy practice: core elements of an MTM service (version 1.0). *Journal of the American Pharmacists Association*;45:573-79.

intervention alerts were sent to pharmacists asking them to contact Program D if they were interested in providing influenza or pneumococcal immunizations (which pharmacists can legally provide in some states). Program D helped interested pharmacists to identify their patients who were eligible for immunization. For other clients Program D is exploring generating intervention alerts for newly discharged patients, to alert pharmacists that a new CMR may be needed to reconcile pre-admission and post-discharge prescription regimens.

Program D tracks how many intervention alerts are sent out and how many are responded to – how many generate a matching MTM claim. If a pharmacist does not comply with a patient-specific intervention alert, the Program D outreach center will contact the pharmacist to ask if the intervention alert was received, and encourage the pharmacist to provide the service indicated in the intervention alert.

Program D sends some intervention alerts to the entire dispensing network of pharmacies, not just to those pharmacists who are trained to use the system, so that other pharmacists can see how easy it is to be an MTM provider. In this sense intervention alerts are a marketing tool to build the pharmacy network.

Outreach Center

Program D outreach center staff make outbound calls to pharmacists in the network to follow up on unfulfilled intervention alerts, and to provide education as needed. Outreach staff also call pharmacists who are “outliers.” For example, if a pharmacist is repeatedly submitting CMR claims without additional encounters for other follow-on services, the outreach staff will call the pharmacist to ensure that s/he understands the other services that could be provided, and is billing for any services being provided. The Program D outreach center also makes outbound calls to non-network pharmacists and pharmacies in a new region to enroll them in the network when expansion is needed to meet a new client’s needs.

Communications

Program D sends four different types of communications to the pharmacy network; others who wish to receive these publications can do so, even if they are not in the Program D pharmacy network. These include news briefs about medication issues, recent reports about medication safety, press releases or announcements from Program D, and snapshots of MTM activities in each of the 26 Medicare Advantage regions.

1.4.4. Estimated Cost Avoidance

In addition to the documentation for reimbursement described above, each submitted claim must include an Estimated Cost Avoidance (ECA). The ECA is what the pharmacist believes was potentially avoided because of the MTM intervention —what might have happened had she/he not intervened. During the online training, and in the Policies and Procedures manual, pharmacists receive guidance as to level of ECA to assign for different situations. There are seven levels of estimated cost avoidance:

- Level 1: Improved Quality of Care
- Level 2: Drug Product Costs avoided
- Level 3: Additional Physician Visit avoided

Level 4: Additional Prescription Order avoided

Level 5: Emergency Room Visit avoided

Level 6: Hospital Admission avoided

Level 7: Life Threatening Situation avoided

At a minimum, each MTM service encounter is a Level 1. All education and monitoring claims have to be a Level 1 because this is a “floor” or minimum level of service – any education and monitoring session that does not at least improve quality of care should not be undertaken. Level 2, Drug Product Costs Avoided, is common for patient and prescriber consultations related to cost efficacy. The following example illustrates an encounter that could have resulted in a Level 4 or a Level 7 ECA.

A patient comes into the pharmacy with a new amoxicillin prescription. The pharmacist notices a penicillin allergy in the patient profile. The pharmacist asks the patient what type of reaction he had in the past. If the previous allergic reaction was a rash, the pharmacist would select a *Level 4 ECA (Additional Prescription Order avoided)* because had the patient taken the amoxicillin and had another rash, he would have returned to the pharmacy and the pharmacist would have called the physician to get a different prescription antibiotic. If the patient’s previous allergic reaction was anaphylaxis, the pharmacist would indicate a *Level 7 ECA (Life Threatening Situation avoided)*.

The pharmacist must describe the rationale for the ECA level claimed. An online advice screen provides guidance to the pharmacist on what information should be provided to justify the claimed ECA level. The ECA levels are reviewed as part of the quality assurance process (described below).

1.4.5. Quality Assurance (QA)

Program D clinical staff review all Level 2 ECA claims and a subset of Level 1 ECA claims. Program D contracts with a third-party quality assurance entity (a former division of a Quality Improvement Organization) to ensure that claims are documented in accordance with the Program D MTM Policy and Procedures Guide available on the website. The QA entity reviews claims with an ECA Level 3 and higher (more serious medication issues and hence more costly services avoided), and examines the medications involved, drug therapy problems, concordance across reason-action-result, and the associated notes. The QA entity also pre-approves protocols for intervention alerts so that if pharmacists follow through on an intervention, the QA reviewers do not have to quality-check the claim when it is submitted.

Program D staff run reports to identify outliers or pharmacists whose claims are not in accordance with usual patterns. Examples of outliers include:

- An inordinate number of CMRs without subsequent interventions.
- An inordinate number of education and monitoring claims without subsequent interventions.
- Unusually high prescriber refusal rates (refusal to make an MTM-recommended medication change). This could indicate that the pharmacist is finding problems that do not warrant physician attention, or that the pharmacist is not interacting well with prescribers.

When an outlier is identified, Program D assumes that the pharmacist needs additional training, and support and outreach center staff contact the pharmacist. Outlier checking also identifies pharmacists who are trying to “game” the system, or those who provide only services with higher reimbursement (e.g., neglecting services like education and monitoring that could improve results). Program D staff will work with pharmacists to help them understand and provide the full array of MTM services. To date, the most common outliers have been pharmacists submitting too few claims, not too many.

Pharmacy Report Cards

Program D creates pharmacy report cards or performance ratings in the following categories:

- Comprehensive medication review claims
- Cost efficacy management claims
- Patient education/monitoring claims
- Indications, efficacy, and safety claims
- Patient compliance consultation claims
- Estimated cost avoidance (aggregate – see below)³²
- Total claims

The performance ratings are based on specific benchmarks or thresholds for each category. The pharmacy report card also includes a composite performance score for each pharmacy, which uses an algorithm to combine the seven categorical scores. The ratings are depicted using *Consumer Reports*-style circles, where the more completely shaded the circle, the better the performance. All network pharmacists have access to the report cards.

Pharmacy managers can compare their ratings with their peers’ in the categories above, and chain pharmacies can use the ratings to compare their outlets. Patients visiting the Program D website will see an indication of which pharmacies have received the highest overall rating.

1.4.6. Pricing

Program D clients pay a capitated rate per member per month (PMPM) based on whether the MTM program is being offered to all plan members or only to a selected subset. The per capita price is higher if only a subset is eligible for MTM, because these are likely to be the sickest patients and most in need of MTM services. For example, the capitated price could be less than a dollar PMPM for the entire population, and several times higher for a very high-risk subset.³³ Most non-Medicare clients choose to include all plan members in the MTM program rather than just a subset, and Part D plans are increasingly doing the same (although they report to CMS only on patients who satisfy the three Medicare MTM eligibility criteria). The Program D capitated rate is not geographically adjusted to reflect varying costs of care or practice patterns in different parts of the country.

³² Although the ECA is a factor in the pharmacy score, it is not associated with pharmacist reimbursement.

³³ Program D considers actual client fees to be proprietary information.

Alternatively, Program D also offers fee-for-service pricing—in which a client is charged an administrative fee plus actual provider fees—as well as platform-only pricing, in which the company’s administrative responsibilities are limited to system technical support.

Performance Guarantees

Program D offers clients a price guarantee, and recently clients have begun requesting a “patients touched” guarantee as well.

Price Guarantee

Program D guarantees that for every dollar a client pays in the capitated rate, at least one dollar of “estimated” cost will be avoided. For example, if a client pays \$300,000 for its MTM program, at the end of the year Program D must demonstrate at least \$300,000 of ECA. If at the end of a year the ECA equaled only \$200,000, leading to a \$100,000 shortfall, the \$100,000 shortfall would be returned to the payer in a refund.

Annual reports to clients include the total ECA and also the ECA by each of the seven levels (the price guarantee is based on the total ECA). Typically the Level 2 ECA: Drug Product Costs is responsible for half of the estimated cost avoided. Reports can be generated on demand with real-time reporting through administrative, web-based access. These reports help clients understand the impact of MTM on drug costs and other medical care costs.

Program D calculates the ECA using a model based on the cost-of-illness work of Johnson and Bootman (1995).³⁴ For each ECA level, The Program D® applies a dollar value based on national estimates, updated annually for inflation using the CPI. For example, for every emergency department visit avoided, the national average cost of an ED visit is applied.

The Program D® assigns zero dollars to a Level 1 ECA because the company considers it a “floor” of service. Level 1 is primarily associated with education and monitoring encounters and comprehensive medication reviews, which do not necessarily save money. For Level 2 ECA, Program D calculates drug costs using Average Wholesale Price (AWP), annualizing the costs for chronic medications. The ECA is not based on a client’s actual drug costs.³⁵

Program D is aware of one client who compared the ECA with actual medical and drug utilization to determine the accuracy of the ECA. This employer group used medical and pharmacy claims, and found annual savings to be \$600,000 – better than Program D ECA of \$470,000. Another client analyzed medical and pharmacy claims and was satisfied that it had saved itself more than the MTM program cost.

³⁴ Johnson JA, Bootman JL. Drug-related morbidity and mortality: a cost-of-illness model. *Arch Int Med.* 1995;155:1949-56.

³⁵ The ECA does not address patient out-of-pocket costs, although Program D is considering adding comparisons of patient out-of-pocket costs to the Explanation of Benefits sent to individuals who enroll in the personal pharmacist program.

“Patients Touched” Guarantee

More recently, Program D clients (especially Part D plans) have begun to request a “patients touched” guarantee because they want to know what percentage of their patients are actually receiving MTM services. The guarantee is typically that 5% of a plan’s patients receive at least one MTM service per year (usually a CMR). This guarantee has been used in place of the price guarantee, or in combination with it.

1.4.7. Evidence of Effectiveness

Program D staff and other researchers have used their data to evaluate the effectiveness of MTM. Research has also been conducted using the Program D’s network of pharmacies to evaluate specific MTM interventions. A summary of research that has been conducted using Program D data, their pharmacy network, or their service package is provided below. A table summarizing the evidence of effectiveness on the Program D MTM program is provided at the end of this section.

MTM Program Trends

Program D staff explored program trends from 2000 to 2006 (approximately 75,000 claims) to understand changes in their covered patient population and use of MTM services. In this dataset there were on average 3.2 MTM claims per patient per year. The patients represented in these MTM claims were 39% male and on average 44 years of age. The average patient age in 2000 was 30 and increased to nearly 58 years in 2006, illustrating the expansion from employer groups in 2000 to Medicare Part D plans in 2006.

In 2000, 2002, and 2004 education and monitoring accounted for more than 80% of claims, which declined to 45% of claims in 2006; the percentage of claims for prescriber consultations and patient consultations increased concordantly. Program D staff believe that better documentation and billing by pharmacists is likely responsible for most of this change, along with the introduction of the targeted intervention program in 2005, which alerts pharmacists to specific, actionable interventions they could provide. The higher average age of MTM patients in 2006 may also have been accompanied by more-complex medication regimens, requiring more consultation by MTM pharmacists.

Over the period 2000 to 2006, there was a marked increase in the Estimated Cost Avoidance (ECA) per claim: in 2000 and 2002 the average ECA per claim was less than \$50, which increased to \$100 in 2004 and nearly \$450 in 2006. This increase in ECA is consistent with the reduction in (zero ECA) education and monitoring claims, and the increase in claims for other services. The higher ECA per claim may also be due to the population in 2006 being more elderly and more heavily weighted toward Part D enrollees with multiple chronic conditions and multiple prescriptions – more-complex cases where lack of MTM could have costly consequences.

One way Program D calculates return on investment (ROI) is ECA/payments to pharmacists. As the ECA per claim trended upward over time, the ROI also increased. By 2006, every dollar paid to a pharmacist for MTM covered services yielded approximately \$45 in ECA.

Program D staff are particularly interested in CMRs – the most complete MTM service with the highest reimbursement. The patients who received CMRs from 2003 through 2006 were 70% female

with an average age of 73 years. Patients receiving CMRs were much older than the overall population served from 2000 to 2006 because the CMR became available only in 2003 and the prescription drug benefit began in 2006.

From 2003 through 2006, 45% of CMRs led to other interventions – patient consultations, prescriber consultations, or education and monitoring. Ninety percent of the subsequent interventions were approved by the prescriber or patients; in 10% of cases the patient refused the consultation or the prescriber refused to accept the MTM recommendation.

The most common types of MTM interventions delivered by Program D contracted pharmacies/pharmacists, and the subsequent impact on drug product costs are:

- cost efficacy medication changes recommended (28%), which usually reduces drug costs.
- additional medication therapy recommended (19%), which increases drug costs.
- administration/technique counseling (11%), which usually has little effect on drug costs.
- compliance/underuse counseling (10%), which increases drug costs.

This pattern is consistent with the finding by Program D that fully 50% of ECA is due to reduced drug costs, and may be due to the emphasis Program D and its clients place on reducing drug costs through cost-efficacy management.

The total ECA resulting from 1,736 CMRs that took place from 2003 through 2006 was \$1,275,469, and the ROI per CMR was \$735. Most of the ECA stemming from CMRs was due to a few CMRs where an emergency department visit or hospitalization may have been avoided – rare but costly events that add considerably to ECA. Just 10% of the CMRs were responsible for 75% of avoided costs, largely from avoiding use of hospital services.

QIO Projects with Program D Clients

As part of the case study for Program D we interviewed two QIOs' research staff regarding their MTM projects with Part D drug plans whose MTM programs are administered by Program D. The QIOs are referred to as QIO One and QIO Two in the following descriptions.

QIO One's Project

QIO One's MTM project aimed to reduce drug-drug interactions (DDIs) and the incidence of prescribing potentially inappropriate medications (PIMs) by providing MTM in community pharmacies for Medicare beneficiaries enrolled in Part D prescription drug plans in the region. The project was a collaboration between the foundation, a prescription drug plan, and two schools of pharmacy.

The drug plan sent an informational letter to all enrollees at the start of the project and conducted an outreach program for community pharmacists to explain MTM. In the fall of 2006, in conjunction with the Schools of Pharmacy, the QIO held a gathering for pharmacists to learn about MTM with Program D and the Part D plan. After that meeting two pharmacy chains became involved.

An evaluation of the project used a pre/post design. The baseline period was six months, from January to June 2006, and the follow-up period was from July 2006 to June 2007. The objectives were to reduce the incidence of potentially inappropriate medications in the elderly and DDIs. The

study also included four process measures: utilization, education, patient consultation, and education & monitoring. The study did not examine cost data.

The project director reported high-level, summary findings from the evaluation:

- There was no demonstrated decrease in the incidence of potentially inappropriate medications in the elderly.
- There was a consistent decline in the incidence of drug-drug interactions over the study period.
- The number of patients receiving MTM services (and with MTM claims) increased dramatically over the study period.

QIO Two's Project

QIO Two conducted a one year study to improve diabetic patient self-management through pharmacist face-to-face MTM services. They partnered with two Medicare Advantage plans that provided their utilization data and laboratory results; these were combined with Program D data. All MA plan members were eligible for MTM in this project, not only those with multiple drugs, multiple conditions, and drug costs exceeding \$4,000/year. The study used a pre/post design: the pre-intervention period was January-June 2006, and the post-intervention period was January-June 2007.

The MA plans had 2,217 diabetic patients and the QIO had complete data on 95 of these patients, who received MTM services from various pharmacies in the southern part of their state. The study had access to data regarding hospitalizations, emergency department and physician office visits, and laboratory data. Information provided by Program D included the number of pharmacies participating, and number and type of MTM interventions. Quality indicators included:

- Overall health care costs (all medical and drug costs)
- Total number of medications
- Hemoglobin A_{1c} < 9%
- Total cholesterol < 200
- Medication compliance > 80%

The following table provides the measure for each quality measure at baseline and re-measurement.

Exhibit 8: QIO Two's MTM Study Results

Quality Indicator	Baseline	Final	Chi_sq value	Chi_sq_Prob
Medication adherence greater than 80%	38%	45%	0.7306	Not significant
Percentage of beneficiaries with HgA _{1c} < 9	20%	74%	44.55	<0.0001
Percentage of beneficiaries with total cholesterol <200	14%	62%	36.78	<0.0001
Number of prescribed medications per beneficiary	10.4	10.1	0.0044	Not significant
Average costs associated with total health care	\$3167	\$3452*	12.29	0.0005

* Intervention period costs were deflated by 5.1% to account for the changing costs of care over the study interval (based on the medical care component of the consumer price index).

Source: QIO Two, unpublished data

Improvement in medication adherence and the number of prescribed medications was small and not statistically significant, while improvements in clinical outcomes (H_gA_{1c} and total cholesterol) were significant. In addition, total health care costs increased and this increase was statistically significant.

Peer-Reviewed Articles

The Program D data and pharmacy network have been the subject of three different MTM-focused studies published in peer-reviewed journals.

An Evaluation of Managing and Educating Patients on the Risk of Glucocorticoid-Induced Osteoporosis³⁶

McDonough et al. (2005) assessed the impact of risk management activities on patient risk of glucocorticoid-induced osteoporosis using a randomized control design of eight intervention pharmacies and seven control pharmacies from the Program D pharmacy network. Ninety-six patients were enrolled; 80 patients completed the study, including 61 patients in the treatment group and 19 in the control group.

Pharmacists participating in the study received four hours of classroom education on the pathophysiology and management of glucocorticoid-induced osteoporosis and were provided a packet of articles for independent study. Eligible patients were 18 years of age or older who had been on the equivalent of at least 7.5 mg of prednisone for at least six months. Patients were identified using prescription dispensing records. They were recruited by the pharmacists who mailed a letter inviting them to participate. Patients in the control group received usual and customary pharmacy care, while the patients in the treatment pharmacies received education, an educational pamphlet about the risks of glucocorticoid-induced osteoporosis, and MTM services. Patients in the control group and treatment group reported similar frequencies for the osteoporosis risk factors (e.g. small frame, low calcium diet, tobacco use, and history of fracture).

The pre-post frequencies in each group were taken at baseline and nine months later.

- The treatment group had a significant increase in the presence of bisphosphonate and estrogen therapy³⁷, and a significant decrease in the frequency of patients reporting a low calcium diet.
- Patients in both treatment and control groups had more discussions over time with pharmacists about osteoporosis risk management and bone mineral density tests, and these tests were more frequent in both groups at nine-month follow-up.

Using an intent-to-treat approach the two groups were compared at baseline and nine months later. The only significant contrast was that the treatment group had a greater increase in calcium supplementation than the control group.

³⁶ McDonough RP, Doucette WR, Kumbera P, & Klepser DG (2005). An Evaluation of Managing and Educating Patients on the Risk of Glucocorticoid-Induced Osteoporosis. *Value in Health*, 8(1):24-31.

³⁷ The addition of estrogen therapy for the prevention of osteoporosis in post-menopausal women was considered a positive outcome in this study which was likely conducted prior to the study in 2004 that raised the concern about the risks of estrogen therapy.

Although a randomized design was used, all of the pharmacies had participated in other research projects and were trained to deliver MTM since all were part of the Program D network; this may have contributed to the minimal difference between the treatment and control groups on several measures. The small number of control patients limited the statistical strength of findings.

Hypertension Outcomes through Blood Pressure Monitoring and Evaluation by Pharmacists (HOME Study)³⁸

Zillich et al. (2005) evaluated the effectiveness of a community pharmacy-based initiative to improve home blood pressure monitoring, using a randomized design in 12 Program D network pharmacies. The 12 pharmacies were recruited based on willingness to participate; they were randomized into six high-intensity (HI) and six low-intensity (LI) pharmacies. Pharmacists in all 12 pharmacies received training on proper blood pressure measurement using an automated home monitoring device. The HI pharmacists also received an educational program that reviewed evidence-based guidelines regarding both patient and physician education about management and treatment of hypertension.

One-hundred twenty-five patients enrolled in the study (64 patients in the HI group and 61 in the LI group). Pharmacists in the HI pharmacies met face-to-face with patients four times over three months to measure blood pressure, provide education, make recommendations, contact physicians about medication therapy, and give patients a blood pressure self-monitoring tool to use at home. Pharmacists in the LI pharmacies met face-to-face with patients three times over three months to measure blood pressure, and to recommend they see their physician if it was above normal. A nested design was used to compare the change in systolic blood pressure (SBP) and diastolic blood pressure (DBP) between the two groups, controlling for baseline BP, age, gender, and cardiovascular co-morbidities. The difference in BP was modeled using multivariate regression. Medication adherence was analyzed using logistic regression models controlling for covariates.

The high-intensity intervention patients achieved a lower DBP than the low-intensity intervention group, demonstrating that pharmacist intervention can improve patient clinical status.

The study size was small and made it difficult to detect any difference between the groups in systolic blood pressure. The study also had a short duration of only three months. The LI pharmacies were not a “usual and customary” care control group, since they had monthly contact with pharmacists and BP measurement. The study also had unmeasured but likely selection bias for both the pharmacies and patients, because all were voluntary, and pharmacies who volunteered may be different than those that did not participate; and because pharmacists might have recruited patients whom they thought would be the best participants for the intervention.

Outcomes-based Pharmacist Reimbursement: Reimbursing Pharmacists for Cognitive Services³⁹

Farris et al. (2002) conducted a cross-sectional descriptive study using claims data to summarize findings from the first year of operations of the Program D MTM program. The 90 (approximately) pharmacies providing MTM in the first year of the program were all located in one state. The claims

³⁸ Zillich AJ, Sutherland JM, Kumbera PA., & Carter BL. (2005). Hypertension Outcomes Through Blood Pressure Monitoring and Evaluation by Pharmacists (HOME Study). *Journal of General Internal Medicine*, 20:1-6.

³⁹ Farris KB, Kumbera PA, Halterman T, & Fang G. (2002). Outcomes-based Pharmacist Reimbursement: Reimbursing Pharmacists for Cognitive Services. *Journal of Managed Care Pharmacy*, 8(5):383-393.

for the first full year of operations from July 1, 2000 to June 30, 2001 were analyzed: 11,326 enrollees obtained 124,768 prescriptions; the average age of MTM enrollees was 35 and 46% were male. Seventy-four percent (n=8,335) of patients received an MTM intervention in the first year and 99% of interventions were for patient education and monitoring. The remaining 869 interventions for 124,768 prescriptions indicate an intervention rate of 0.69 per 100 prescriptions. For each of the 285 drug-related problems identified, pharmacists most commonly claimed to have avoided an additional prescription order and an additional physician office visit. An avoided emergency department visit was claimed for 11 drug-related problems resolved.

In January 2001, Program D introduced pharmacy performance scores (report cards) to demonstrate to payers that the providers bear some risk and have an incentive to achieve performance goals. Pharmacies that were rated poor were subject to a one dollar dispensing fee withhold. The introduction of the performance scores appeared to affect ROI, especially after the one dollar reduction in dispensing fee withhold was implemented in April 2001. The return-on-investment for the program remained on target after the one dollar dispensing fee withhold policy was implemented, all except for one month.

Summary of the Evidence Related to Program D

The following table provides a summary of the evidence of MTM effectiveness from the different projects and studies described above.

Exhibit 10: Summary of the Evidence Regarding Program D

Study Authors and Title	Design	Pharmacies	Sample Size	Study Duration	Results (Significant)
McDonough et al. (2005). Patients on the Risk of Glucocorticoid-Induced Osteoporosis.	Randomized control design	8 treatment pharmacies 7 control pharmacies	n=80 patients 61 treatment 19 control	9 months	Contrasts comparing the change in frequencies between the treatment and control group were significant for the presence of calcium supplement only.
Farris et al. (2002). Outcomes-based Pharmacist Reimbursement	Cross-sectional descriptive analysis	~ 90 pharmacies	n = 11,326 enrollees	7/1/00 – 6/30/01	<ul style="list-style-type: none"> • Obtained 124,768 prescriptions. • 74% of patients received an intervention. • 90% of interventions were for education & monitoring. • Intervention rate was 0.69 per 100 prescriptions (including E&M).
Zillich et al. (2005). Hypertension Outcomes Through Evaluation by Pharmacists	Randomized block design	6 HI pharmacies 6 LI pharmacies	n=125 patients 64 HI group 61 LI group	3 months	The high-intensity intervention achieved a lower DBP than the low-intensity intervention.
Florida QIO Project	Pre/Post design		n = 95 patients	7-8 months	<ul style="list-style-type: none"> • Medication adherence > 80% changed from 38% to 45%. • % of benef. with HgA1c < 9 changed from 20% to 74%. • % of benef. with total cholesterol <200 changed from 14% to 62%. • # of Rx meds per benef. changed from 10.4 to 10.1. • Avg costs associated with total health care changed from \$3,167 to \$3,452.
Delmarva Foundation Project	Pre/Post design	Unavailable (?)	Unavailable (?)	Baseline: Jan – June 2006 Post-measurement: July 2006 to June 2007	<ul style="list-style-type: none"> • The findings did not consistently demonstrate a decrease in the incidence of potentially inappropriate medications in the elderly. Instead, the incidence was “jumping” up and down. • The study showed a consistent decline in the incidence of drug-drug interactions over the study period. • For the process measures, the number of patients receiving MTM services and who had MTM claims increased dramatically over the study period.
MTM Trends	Retrospective analysis	Unavailable	~75,000 claims	2000 - 2006	<ul style="list-style-type: none"> • Avg. 3.2 claims per patient per year. • E&M accounted for > 80% claims in 2000-2004 and ~ 45% in 2006. • In 2000 & 2002 the avg ECA per claim was < \$50, whereas in 2004 it was ~ \$100 and in 2006 ~\$450. • For every dollar paid to a pharmacist yielded ~\$45 in ECA in 2006. • 45% of CMRs led to other interventions, of which 90% were approved by the prescriber. • Most common types of encounters are cost efficacy (28%), needs therapy (19%), administration/technique (11%), and compliance – underuse (10%). • The total ECA resulting from 1,736 CMRs was \$1,275,469. • There is a \$735 ROI per CMR that resulted in additional interventions. • 10% of encounters may have prevented an ER visit or worse, which accounted for 75% of the total ECA.

Appendix D:

Overview of QIO MTM Projects

A few QIO projects aim to increase awareness and promote MTM services and patients' knowledge of medications. For example, the Hawaii QIO is working with prescription drug plans' provider networks to promote a consistent message about MTM services and evaluate patient satisfaction and medication therapy understanding. Similarly the Iowa, Minnesota, Montana, Wyoming Nebraska North Dakota, and South Dakota QIOs' MTM project had had as one of their aims to increase visibility and patients' understanding of MTM services. The Kansas (Kansas Foundation for Medical Care), Illinois (Illinois Foundation for Quality Health Care), and Missouri (Primaris) QIOs have an pre-intervention and post-intervention study design to evaluate the effectiveness of interventions to: increase awareness of the MTM benefit by practitioners and consumers, identify barriers to MTM implementation, and share lessons learned and performance data among participating plans. The QIOs will measure utilization in each plan type by eligible plan members' participation in MTM, and analyze medication possession ratio⁴⁰ data and prescription costs based on MTM access and delivery program characteristics.

Other QIO projects have patient and pharmacist acceptance or enrollment as outcomes of interest, including the Washington, DC & Maryland MTM project, which aimed to increase the use and enrollment of pharmacists providing MTM as measures of pharmacist and patient acceptance. In a related project, the Tennessee QIO (Center for Healthcare Quality: QSource) is attempting to increase patient knowledge about MTM services and increase patient participation with Medicare Part D plans. The primary desired outcome of the project is to improve patients' understanding of medication therapy and its potential side effects. A secondary outcome is to maximize the number of beneficiaries eligible for MTM services who are offered those services. The QIO will assist with systematic review of targeted beneficiary profiles through retrospective claims analysis and review of beneficiary profiles.

The Florida, Georgia, and Massachusetts QIOs' projects aimed to improve diabetic patients' self-management through the provision of MTM. The Florida QIO (FMQAI) is analyzing Avmed and Humana's clinical and pharmacy claims data reporting on specific quality indicators including: compliance to medication regimen, costs associated with care, change in the number of distinct medications prescribed, hemoglobin A1c, and total cholesterol level. The primary outcome measures include: decrease in overall health care costs at re-measurement factoring in an expected increase in health care costs; reduced number of medications at re-measurement; decreased hemoglobin A1c and total cholesterol; and increased medication compliance.

The Massachusetts QIO (MassPRO) is working with Part D plans to determine if incorporating principles and interventions for disease self-management into MTM services can impact patient quality process measures and outcomes focusing on hospitalizations and emergency department visits. MassPRO will assess each plan for improvement in indicators including: percentage of enrollees with claims for lipid-modifying drugs, and ACE inhibitors or angiotensin receptor blockers, percentage of enrollees who are hospitalized or visit an ED, and percentage of enrollees who are

⁴⁰ "The Medication Possession Ratio (MPR) is a formula used to determine compliance measured from the first to the last prescription, with the denominator being the duration from index to the exhaustion of the last prescription and the numerator being the days supplied over that period from first to last prescription." (Dezii C, *Managed Care*, February 2001).

hospitalized during the enrollment period with CVD, stroke, and or DM. The indicators will be collected at baseline and on a quarterly basis for the intervention period.

The Georgia QIO (Georgia Medical Care Foundation) designed a project based on the Asheville Project involving 100 patients (50 control; 50 intervention) within 10 independent community pharmacist service areas, with equal representation from rural and urban settings. The intervention is face-to-face MTM with a 12-month intervention period. The project aims to improve patient self-management and therapeutic outcomes of diabetic patients using pharmacist-directed MTM. The outcomes of interest include reduction in hemoglobin A1c, improvements in patient self-awareness and self-management, satisfaction with MTM, and reduction in health care costs.

A number of the QIOs' MTM projects are evaluating specific interventions or models of MTM. The projects are using key clinical outcome measures (e.g., hemoglobin A1c), process measures, measures of quality of life, satisfaction, and health care utilization (e.g., hospitalizations). For example, the Idaho, Washington (Qualis Health [ID/WA]), Nevada, Utah (HealthInsight [NV/UT]), and Oregon (Acumentra Health) QIOs are evaluating the effectiveness of an audit and feedback-style MTM intervention.⁴¹ The evaluation includes quality indicators based on prescription drug utilization data (e.g., prevalence of drug-drug interactions, adherence to antidepressants) measured at baseline and at 3-month intervals.

The Iowa (Iowa Foundation for Medical Care), Minnesota (Stratis Health), Montana, Wyoming (Mountain-Pacific Quality Health Foundation [MT/WY]), Nebraska (CIMRO), North Dakota (North Dakota Health Care Review), and South Dakota (South Dakota Foundation for Medical Care) QIOs are using plans' prescription claims data to calculate clinical quality indicators by analyzing the prescription drug event data as well as collect member survey data. The project includes a member survey to evaluate satisfaction with MTM services whether the beneficiary enrolled or disenrolled; performance indicators of medication possession ratio⁴⁰ for branded SSRIs versus generic SSRIs; and percentage of MTM-enrolled heart failure patients taking an ACE inhibitor or angiotensin-receptor blockers. This project may demonstrate differences across two different plans and between states when provided by the same plan.

The Virginia QIO (Virginia Health Quality Center) has a project evaluating the effectiveness of a patient's warfarin therapy being managed by a pharmacist in collaboration with a physician versus a physician alone. The outcome measures include International Normalized Ratio (INR) levels, dosing adjustments, emergency department visits, hospitalizations, bleeding episodes, transfusions, and thrombotic events. This project is small in scope, focusing on only one drug with approximately 85 patients who can self-select to participate in the intervention group (i.e., selection bias).

The New Mexico QIO (New Mexico Medical Review Association) created a coalition of 60 organizations focused on implementing e-prescribing solutions and MTM services. Although the MTM project design and details are unclear, the clinical outcome measures of the project include clinical measures (i.e., hemoglobin A1c, fasting blood glucose, blood pressure, low-density

⁴¹ In this type of program "plans receive data comparing the performance of their MTM services population, and their population as a whole with blinded data from the other plans participating in the project" (p. S18).

lipoprotein cholesterol and weight), measures of health related quality of life, and patient satisfaction. All of these will be collected at baseline, 6-month and 1-year intervals. Additionally, disease-specific resources utilization, including emergency department visits, hospitalizations, clinic visits, medication adherence, will be assessed for enrolled patients.

The Washington, DC and Maryland QIO (Delmarva Foundation) are conducting a project with a PDP to decrease the incidence of potentially inappropriate medications (PIMs) and drug-drug interactions (DDIs) by using MTM services, as well as to increase the use and enrollment of pharmacists providing MTM services as measures of pharmacist and patient acceptance of MTM services. The study includes a multifaceted intervention including the following activities: an informational letter to PDP enrollees, developing a pharmacist assessment of MTM services tool, seminars on MTM services, and monthly MTM services communications to participating pharmacists and colleges of pharmacy encouraging community pharmacists' participation in the project and adoption of MTM services. The study includes measures of PIM and DDI, but also process measures including: recruitment numbers for both pharmacists and enrollees to track members' acceptance and perceptions of value of the MTM services program; number of beneficiaries that receive medication review, consultation, and education and monitoring; and perceptions and satisfaction measurement of participating pharmacists to include premeasurement and postmeasurement of their awareness of MTM services.

The Michigan QIO (MPRO) is conducting a unique project to assess the effectiveness of different models of MTM. The QIO is collaborating with Priority Health and Humana Inc., both of which offer three MTM models (telephone-based, pharmacy-based, and educational mailings), to assess the effectiveness of different models of medication therapy management (MTM) services for patients with chronic conditions, including diabetes, hypertension, coronary artery disease (CAD), and/or heart failure. The primary outcomes include: financial savings from reduced hospital admissions, increased medication compliance, and improved patient safety (indicators include drug-drug interactions, potentially inappropriate medications, and disease-specific medication compliance).