

Sound Medication Therapy Management Programs

2006 CONSENSUS DOCUMENT

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

- AARP
- Academy of Managed Care Pharmacy
- American College of Clinical Pharmacy
- American Geriatrics Society
- American Pharmacists Association
- American Society of Consultant Pharmacists
- Case Management Society of America
- College of Psychiatric and Neurologic Pharmacists
- Department of Veterans Affairs

Preface

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

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

The stakeholder work group consisted of:

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

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

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

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

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

Introduction

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

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

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

Background

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

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

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

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

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

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

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

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

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

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

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

Important Features of a Quality MTM Program

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

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

Operational Aspects of Quality MTM Programs

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

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

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

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

2. Services to meet the needs of individual patients. There are a number of potential activities that might be undertaken by quality MTM programs, targeted to the needs of individual patients. While not an all-inclusive list, there is a catalogue of nine service activities identified by a group of 11 national pharmacy organizations in a July 2004 consensus statement (see Appendix A for this report). This is not intended to be a definitive list, and it is not suggested that any given program must contain all of these elements. The items listed are offered as examples of the types of activities that quality MTM programs might employ. In addition, it is recognized that interdisciplinary care should be encouraged, appropriately utilizing skill sets of different health care providers. Qualified pharmacists are in a unique position to manage MTM programs.

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

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

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

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

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

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

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

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

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

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

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

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

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

9. Adoption of standardized documentation, billing and payment systems.

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

References

1. Cranor CW, Bunting BA, Christensen DB. The Asheville project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc.* 2003;43:173-90.
2. Chrischilles EA, Carter BL, Lund BC, et al . Evaluation of the Iowa Medicaid pharmaceutical case management program. *J Am Pharm Assoc.* 2004;44:337-49.
3. Bluml B. Definition of medication therapy management: development of profession-wide consensus. *J Am Pharm Assoc.* 2005;45:566-72.
4. American Pharmacists Association and National Association of Chain Drug Stores Foundation. Medication therapy management in community pharmacy services: core elements of an MTM service (I version 1.0). *Am Pharm Assoc.* 2005;45:573-79. Available at: <http://www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=3303>. Accessed July 5, 2005.
5. Summary of the executive sessions on medication therapy management programs, Bethesda, Maryland, June 14 and August 18, 2004. Medication therapy management programs: to optimize pharmacy outcomes [letter]. *J Manag Care Pharm.* 2004;11(2):179-86. Available at: <http://www.amcp.org/data/jmcp/Letters-179-186.pdf>. Accessed February 10, 2006.

Appendix A

Medication Therapy Management Services Definition and Program Criteria

Approved: July 27, 2004,

*by the Academy of Managed Care Pharmacy, American Association of Colleges of Pharmacy,
American College of Apothecaries, American College of Clinical Pharmacy,
American Society of Consultant Pharmacists, American Pharmacists Association,
American Society of Health-System Pharmacists, National Association of Boards of Pharmacy, **
National Association of Chain Drug Stores, National Community Pharmacists Association
and National Council of State Pharmacy Association Executives*

Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product. Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's, or other qualified health care provider's, scope of practice. These services include but are not limited to the following, according to the individual needs of the patient:

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

A program that provides coverage for Medication Therapy Management services shall include:

- a. Patient-specific and individualized services or sets of services provided directly by a pharmacist to the patient.* These services are distinct from formulary development and use, generalized patient education and information activities, and other population-focused quality assurance measures for medication use.
- b. Face-to-face interaction between the patient* and the pharmacist as the preferred method of delivery. When patient-specific barriers to face-to-face communication exist, patients shall have equal access to appropriate alternative delivery methods. Medication Therapy Management programs shall include structures supporting the establishment and maintenance of the patient*-pharmacist relationship.
- c. Opportunities for pharmacists and other qualified health care providers to identify patients who should receive Medication Therapy Management services.
- d. Payment for Medication Therapy Management services consistent with contemporary provider payment rates that are based on the time, clinical intensity, and resources required to provide services (e.g., Medicare Part A and/or Part B for Current Procedural Terminology [CPT] and Resource-Based Relative Value Scale [RBRVS]).
- e. Processes to improve continuity of care, outcomes, and outcome measures.

* *In some situations, Medication Therapy Management services may be provided to the caregiver or other persons involved in the care of the patient.*

** *Organizational policy does not allow NABP to take a position on payment issues.*

Appendix B

Evidence of the Pharmacists' Value: An Overview of Several Landmark Studies

Reprinted from:

**Medication Therapy Management Services:
A Critical Review**

Prepared for the American Pharmacists Association by
The Lewin Group
May 17, 2005

Note: The Executive Summary of this report is available at www.aphanet.org.

*To obtain a copy of the complete report,
contact the American Pharmacists Association at 202-429-7559.*

Appendix B: Evidence of the Pharmacists' Value

<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
<p>Garrett D, Bluml B. (2005). Patient self-management program for diabetes: First-year clinical, humanistic, and economic outcomes. <i>J Am Pharm Assoc</i>, 45: 130–137.</p>	<p>Quasi-experimental, pre-post cohort study</p>	<p>256 patients with diabetes covered by self-insured employers' health plans</p>	<p>Changes in glycosylated hemoglobin (A1c); low-density lipoprotein cholesterol (LDL-C); blood pressure; influenza vaccinations; foot examinations; eye examinations; patient goals for nutrition, exercise, and weight; patient satisfaction; and changes in medical and medication use and costs</p>	<p>Over the initial year of the program, participants' mean A1c decreased from 7.9% at initial visit to 7.1%, mean LDL-C decreased from 113.4 mg/dL to 104.5 mg/dL, and mean systolic blood pressured decreased from 136.2 mm Hg to 131.4 mm Hg. During this time, influenza vaccination rate increased from 52% to 77%, the eye examination rate increased from 46% to 82%, and the foot examination rate increased from 38% to 80%. Patient satisfaction with overall diabetes care improved from 57% of responses in the highest range at baseline to 87% at this level after 6 months, and 95.7% of patients reported being very satisfied or satisfied with the diabetes care provided by their pharmacists. Total mean health care costs per patient were \$918.00 lower than projections for the initial year of enrollment.</p>

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<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
<p>Bluml B, McKenney J, Cziraky M. (2000). Pharmaceutical care services and results in project ImPACT: Hyperlipidemia. J Am Pharm Assoc, 40: 157-165.</p>	<p>Observational</p>	<p>397 patients of 26 community-based ambulatory care pharmacies, including: independent, chain-professional, chain-grocery store, home health/home infusion, clinic, health maintenance organization/managed care pharmacies</p>	<p>Rates of patient persistence and compliance with medication therapy and achievement of target therapeutic goals</p>	<p>Over an average period of 24.6 months, observed rates for persistence and compliance with medication therapy were 93.6% and 90.1%, respectively, and 62.5% of patients had reached and were maintained at their NCEP lipid goal at the end of the project.</p>
<p>Jameson J, VanNoord G, Vanderwoud K. (Nov 1995). The impact of a pharmacy consultation on the cost and outcome of medical therapy. J Fam Pract, 1(5): 469-472.</p>	<p>Prospective randomized trial</p>	<p>56 hypertensive patients at risk for medication-related problems</p>	<p>Number of drugs, number of doses per day, 6-month drug costs, patient-reported adverse effects</p>	<p>Six months after intervention (single consultation by clinical pharmacist with high-risk patients and primary physicians), measured outcome variables. Found decreased number of drugs ($P < .004$), decreased number of doses ($P < .007$), and decreased 6-month drug costs ($P < .008$) for intervention group. Side effects score improved in intervention group ($P = NS$).</p>

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<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
Christensen D, Neil N, Fassett W, Smith D, Holmes G, Stergachis A. (2000). Frequency and characteristics of cognitive services provided in response to a financial incentive. <i>J Am Pharm Assoc</i> , 40: 609–617.	Prospective randomized trial	110 study pharmacies (financial intervention); 90 control pharmacies	Number of cognitive service (CS) interventions per 100 prescriptions over 20-month period	Study pharmacists documented an average of 1.59 CS interventions per 100 prescriptions versus controls documenting an average of 0.69 CS interventions per 100 prescriptions. The average self-reported time to perform CS was 7.5 minutes, with 75% lasting fewer than 6 minutes. Financial incentive associated with significantly more and different types of CS performed by pharmacists.
Manasse HR. (1989). Medication use in an imperfect world: Drug misadventuring as an issue of public policy. Part 1. <i>Am J Hosp Pharm</i> , 46: 929–944.	Review		Deaths and hospitalizations due to adverse drug reactions	Twelve thousand deaths and 15,000 hospitalizations were reported to the FDA, but the number of adverse drug reactions might be a small fraction—perhaps only 10% of the true number.
Bootman JL, Harrison DL, Cox E. (1997). The health care cost of drug-related morbidity and mortality in nursing facilities. <i>Arch Int Med</i> , 157: 2089–2096.	Decision analysis		Cost of drug-related morbidity in nursing facilities	Baseline estimates indicate that the cost of drug-related morbidity and mortality with the services of consultant pharmacists was \$4.0 billion versus \$7.6 billion without the services of consultant pharmacists.

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<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
<p>Johnston AM, Doane K, Phipps K, Bell A. (Jan 1996). Outcomes of pharmacists' cognitive services in the long-term care setting. <i>Cons Pharm</i>, 11(1): 41-50.</p>	<p>Chart review</p>	<p>10,207 resident chart reviews of drug regimens collected over 1-month period of 122 long-term care facilities; chart review over 3-month monitoring period</p>	<p>Number and type of interventions, change in drug therapy, change in medication cost, change in patient health</p>	<p>Pharmacists made 3,464 interventions. Response rate for interventions requesting a response was 85.7%, with a 68% acceptance rate. Accepted recommendations resulted in a total cost savings of \$15,111.38 for the 1-month period. Accepted recommendations resulted in favorable health outcomes 99.5% of the time.</p>
<p>McMullin ST, Hennenfent JA, Ritchie D, Huey WY, Lonergan T, Schaff R, Tonn M, Bailey TC. (1999). A prospective randomized trial to assess the cost impact of pharmacist-initiated interventions. <i>Arch Int Med</i>, 159: 2306-2309.</p>	<p>Prospective randomized controlled trial</p>	<p>1,226 interventions by six pharmacists at large university hospital</p>	<p>Drug costs</p>	<p>Cost-saving interventions involved streamlining therapy to less-expensive agents (39%), discontinuing an unnecessary medication (25%), and modifying route of administration (24%). Intervention group had drug costs 41% lower than control group ($P < .001$). Mean \$43.40 versus \$73.75.</p>

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<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
Schmader KE, Hanlon JT, Pieper CF, Sloane R, Ruby CM, Twersky J, Francis MA, Weinberger M, Feussner J, Cohen HJ. (2004). Effects of geriatric evaluation and management on adverse drug reactions and suboptimal prescribing in the frail elderly. <i>Am J Med</i> , 116: 394–401.	Randomized 2x2 factorial controlled study	834 patients in 11 VA hospitals over age 65 who met criteria for frail followed for 12 months—blinded physician-pharmacist pairs	Risk of serious adverse drug reactions, unnecessary and inappropriate drug use and underuse	Outpatient geriatric clinic care resulted in 35% reduction in the risk of serious drug reaction (adjusted relative risk, 0.65; 95% CI, 0.45–0.93). Inpatient geriatric unit care reduced unnecessary and inappropriate drug use and underuse significantly ($P < .05$). Outpatient geriatric care reduced the number of omitted drugs ($P < .05$).
Brooks JM, McDonough RP, Doucette WR. (Jun 2000). Cost analysis: Pharmacist reimbursement for pharmaceutical care services: Why insurers may flinch. <i>Drug Benefit Trends</i> , 45–62.	Economic cost analysis			Researchers developed complex economic model describing moral hazard, proving that enrolling high-risk patients into pharmaceutical care programs can be of value to insurers if the savings incurred is more than the program expense. Based on the model, authors conclude that reimbursing pharmacists to provide pharmaceutical care is optimal if a relatively inexpensive patient screening method is available that enables insurers to limit visits to those patients who offer cost savings to the insurer.

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<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
Christensen D, Trygstad T, Sullivan R, Garmise J, Wegner S. (Dec 2004). A pharmacy management intervention for optimizing drug therapy for nursing home patients. <i>Am J Geriatr Pharmacother</i> , 2(4): 248-256.	Before-after design	Documented DRR for 9,208 residents in 253 nursing homes receiving 18 or more prescription refills in 90 days	Number of prescriptions per month, drug costs	Baseline mean was 9.52 prescriptions per month, with mean drug cost of \$502.96 to North Carolina Medicaid program. After intervention, mean reduction of 0.21 occurred in number of prescriptions per month, with mean reduction in drug cost of \$30.33 per patient per month.
Lipton HL, Bero LA, Bird JA, McPhee SJ. (Jul 1992). The impact of clinical pharmacists' consultations on physicians' geriatric drug prescribing. <i>Med Care</i> , 30(7): 646-658.	Prospective randomized controlled trial	236 patients age 65+ with three + medications, 123 experimental, 113 controls from a 450-bed hospital	Drug therapy problems, regimen appropriateness	Experimentals were less likely to have one or more prescribing problems ($P < .05$); experimental drug regimens were more appropriate than those of controls ($P < .01$).
Cranor CW, Bunting BA, Christensen DB. (Mar/Apr 2003). The Asheville project: Long-term clinical and economic outcomes of a community pharmacy diabetes care program. <i>J Am Pharm Assoc</i> , 43(2): 173-190.	Quasi-experimental longitudinal pre-post cohort study	136 employees having diabetes followed for 5 years—intervention of education, consultations, clinical assessment, goal setting, collaborative drug therapy management with physicians	Changes in glycosylated hemoglobin (A1c) and serum lipid concentrations, changes in diabetes-related and total medical use, costs over time	Mean A1c decreased at all follow-ups, more than 50% of patients demonstrated improvements at each follow-up, number of patients with optimal A1c increased at each follow-up, and >50% improved in lipid levels. Costs shifted from inpatient and out-patient services from physicians <i>continued</i>

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<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
Cranor CW, Bunting BA, Christensen DB. (Mar/Apr 2003).				cians to prescriptions, mean direct medical costs decreased by \$1,200.00 to \$1,872.00 per patient per year, and sick days decreased for one employer group, with increases in productivity estimated at \$18,000.00 annually.
Walker S, Willey CW. (2004). Impact on drug costs and utilization of a clinical pharmacist in a multisite primary care medical group. <i>J Manag Care Pharm</i> , 10(4): 345–354.	Retrospective pretest posttest study	Independent, nonacademic, ambulatory, primary care medical practice of 65 physicians	Net medical group drug cost per enrolled member per year over 2-year period	Drug costs per patient per year increased 1.7% versus national increase of 31.2%. Prescriptions per patient per year increased 4% versus unchanged national rate. Cost per prescription decreased 2.1% versus national increase of 31.2%. Results due to increase in use of generics.
Weinberger M, Murray M, Marrero D, Brewer N, Lykens M, Harris LE, Seshadri R, Caffrey H, Roesner JF, Smith F, Newell AJ, Collins JC, McDonald CJ, Tierney WM. (2002). Effectiveness of pharmacist care for patients with reactive airways disease. <i>JAMA</i> , 288: 1594–1602.	Randomized controlled trial	1,113 participants with active COPD or asthma. Outcomes were assessed in 947 (85.1%) participants at 6 months and 898 (80.7%) at 12 months.	Peak expiratory flow rates, breathing-related ED or hospital visits, health-related quality of life (HRQOL), medication compliance, and patient satisfaction.	At 12 months, patients receiving pharmaceutical care had significantly higher peak flow rates than the usual care group (P = .02) but not than PEFR monitoring controls (P = .28). No significant between-group differences occurred in medication compliance, and patient satisfaction. <i>continued</i>

Appendix B: Evidence of the Pharmacists' Value

<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
<p>Weinberger M, Murray M, Marrero D, Brewer N, Lykens M, Harris LE, Seshadri R, Caffrey H, Roesner JF, Smith F, Newell AJ, Collins JC, McDonald CJ, Tierney WM. (2002).</p>				<p>ication compliance or HRQOL. Asthma patients receiving pharmaceutical care had significantly more breathing-related ED or hospital visits than the usual care group (OR, 2.16; 95% CI, 1.76-2.63; P < .001). Patients receiving pharmaceutical care were more satisfied with their pharmacist than the usual care group (P = .03) and the PEFR monitoring group (P = .001) and were more satisfied with their health care than the usual care group at 6 months only (P = .01). Despite ample opportunities to implement the program, pharmacists accessed patient-specific data only about half of the time and documented actions about half of the time that records were accessed.</p>

Appendix B: Evidence of the Pharmacists' Value

<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
<p>Goode JK, Swiger K, Bluml BM. (Mar/Apr 2004). Regional osteoporosis screening, referral, and monitoring program in community pharmacies: Findings from Project ImPACT: Osteoporosis. <i>J Am Pharm Assoc</i>, 44(2): 152–160.</p>	<p>Single cohort observational study</p>	<p>Consumers with one or more known risk factors for osteoporosis</p>	<p>Results of screenings, responses of patients and physicians to notifications, and long-term results during collaborative care</p>	<p>The pharmacists screened 532 patients and were able to contact 305 of these patients for follow-up interviews 3 months to 6 months later. The stratification for risk of fracture was 37%, high risk; 33%, moderate risk; and 30%, low risk. A total of 78% of patients indicated that they had no prior knowledge of their risk for future fracture. In the moderate- and high-risk categories, 37% of patients scheduled and completed a physician visit, 19% had a diagnostic scan, and 24% of those patients were initiated on osteoporosis therapy subsequent to the screening. Participating pharmacies received payment for both the osteoporosis screening and the collaborative health management services.</p>
<p>Hanlon JT, Artz MB, Pieper CF, Lindblad CI, Sloane RJ, Ruby CM, Schnader KE. (2004). Inappropriate medication use among frail elderly inpatients. <i>Ann Pharmacother</i>, 38(1): 9–14.</p>	<p>Observational</p>	<p>397 frail, elderly inpatients in eleven VA facilities</p>	<p>Prevalence of inappropriate prescribing for hospitalized frail, elderly patients</p>	<p>Three hundred sixty-five (91.9%) patients had =1 medication with =1 MAI criteria rated as inappropriate. The most common problems involved expensive drugs (70.0%), <i>continued</i></p>

Appendix B: Evidence of the Pharmacists' Value

<i>Citation</i>	<i>Study Type</i>	<i>Sample Population</i>	<i>Outcome Variables</i>	<i>Results (Conclusions)</i>
<p>Hanlon JT, Artz MB, Pieper CF, Lindblad CI, Sloane RJ, Ruby CM, Schnader KE. (2004).</p>				<p>impractical directions (55.2%), and incorrect dosages (50.9%). The most common drug classes with appropriateness problems were gastric (50.6%), cardiovascular (47.6%), and central nervous system (23.9%). The mean \pm SD MAI score per person was 8.9 \pm 7.6. Stepwise ordinal logistic regression analyses revealed that both the number of prescription (adjusted OR, 1.28; 95% CI, 1.21-1.36) and non-prescription drugs (adjusted OR, 1.17; 95% CI, 1.06-1.29) were related to higher MAI scores. Analyses excluding the number of drugs revealed that the Charlson index (adjusted OR, 1.62; 95% CI, 1.12-2.35) and fair/poor self-rated health (adjusted OR, 1.15; 95% CI, 1.05-1.26) were related to higher MAI scores.</p>
<p><i>CI = confidence interval; COPD = chronic obstructive pulmonary disease; DRR = drug regimen review; ED = emergency department; FDA = Food and Drug Administration; MAI = Medication Appropriateness Index; NCEP = National Cholesterol Education Program; OR = odds ratio; PEFR = peak expiratory flow rate.</i></p>				

Appendix C

Glossary

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

Adherent; adherence Also referred to as compliance. The ability of a patient to take a medication or follow a treatment protocol according to the directions for which it was prescribed; a patient taking the prescribed dose of medication at the prescribed frequency for the prescribed length of time.

Adverse event Any harm a patient suffers that is caused by factors other than the patient's underlying condition.

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

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

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

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

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

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

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

Self-insured employers Employers who choose to accept the financial risk for the health care costs of their employees. Typically, employers "hire" a health plan or insurance company to provide for the health care needs of their employees (and often their family members), and the employers accept the financial risk for the services provided. This allows employers to retain savings if the costs of health care provided are effectively managed. Self-insured employers will use a health plan or insurance company to provide administrative services such as claims processing. Self-insured employers commonly purchase stop-loss insurance to cover catastrophic cases.

Appendix D

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Resource Group:

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

Community Care Rx

Coventry Health Care, Inc.

Humana

Independent Health

Intermountain Health Care

Kaiser Permanente

Medicine Shoppe International

Outcomes Pharmaceutical Health Care

Ovations: Pharmacy Solutions, UnitedHealth Group

Premier Pharmacists Network

Prescription Solutions

Scott & White Health Plan

Walgreens Health Initiatives

Pharmacy Organizations Serving as Reviewers:

American Association of Colleges of Pharmacy

American Society of Health-System Pharmacists

College of Psychiatric and Neurologic Pharmacists

National Association of Chain Drug Stores



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