

## **Meeting Notice**

### **Missouri Board of Pharmacy and Missouri State Board of Registration for the Healing Arts Joint Rulemaking Subcommittee**

**Conference Call  
August 11, 2010 4:00 p.m.  
Professional Registration  
3605 Missouri Blvd  
Jefferson City, MO 65109**

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13) and (14) and under Section 324.001.8.

The Joint Committee may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

If any member of the public wishes to attend the open portion of the telephone conference call, s/he should be present at the Division of Professional Registration, Missouri Conference Room, 3605 Missouri Blvd, Jefferson City, Missouri, at 4:00 p.m. on August 11, 2010.

Please see attached tentative agenda for this meeting.

**TENTATIVE AGENDA  
August 11, 2010 4:00 p.m.**

**Missouri Board of Pharmacy  
and  
Missouri State Board of Registration for the Healing Arts  
Joint Rulemaking Subcommittee**

**Professional Registration  
3605 Missouri Blvd  
Jefferson City, MO 65109  
Conference Call**

**OPEN SESSION**

- 1 Call to Order
- 2 Roll Call
- 3 Discussion and Review of Proposed Medication Therapy Services Rules
- 4 The Joint Committee may go into closed session at any point during the meeting and all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (3), (5), (7), (13) and (14) and under Section 324.001.8. The Board will return to open session at the conclusion of discussion of closed session items.
- 5 Adjournment



## MISSOURI BOARD OF PHARMACY

3605 Missouri Boulevard ♦ P.O. Box 625

Jefferson City, MO 65102

(573) 751-0091- Phone ♦ (573) 526-3464- Fax

(800) 735-2966 TTY Relay Missouri ♦ (800) 735-2466 Voice Relay Missouri

**TO:** Tina Steinman, Executive Director  
Missouri Board of Registration For The Healing Arts

**FROM:** Kimberly Grinston, Executive Director  
Missouri Board of Pharmacy

**DATE:** August 5, 2010

**RE:** Pharmacist Medication Therapy Services Rules

---

In 2007, the Missouri General Assembly amended § 338.010, RSMo, to allow Missouri pharmacists to perform medication therapy services pursuant to rules jointly promulgated by the Missouri Board of Pharmacy and the Board of Healing Arts. Pharmacists performing medication therapy services are required to obtain a certificate of medication plan authority from the Board of Pharmacy and can only perform services under protocol with a Missouri licensed physician.

Representatives from both of our Boards met in 2007/2008, to discuss preliminary proposals. After considerable discussion, BOHA representatives asked the Board of Pharmacy to develop more definite qualification standards before the Boards jointly developed rules governing authorized practices.

In November 2009, the Board established a Working Group to gather suggestions for the proposed medication therapy services rules. The Working Group consisted of various government and industry representatives and included the following stakeholders/representatives:

- Missouri Pharmacy Association (Christian Tadrus)
- Missouri Society of Health-System Pharmacists (Greg Teale- Hospital Pharmacist)
- UMKC School of Pharmacy & St. Louis College of Pharmacy (STLCoP) Representatives
- Daniel Good, RPh. (Cox Health Systems)
- Bert McClary (Pharmacist, Missouri Department of Health and Senior Services)
- Steve Calloway, RPh. (MSHP)
- Carla Zeillman, RPh.
- Amy Dewein, RPh. (Independent Consulting Pharmacy Owner)
- Sandra Bollinger, RPh. (Past MPA President/Independent Consulting Pharmacy Owner)
- Peggy Kuehl, RPh. (UMKC)
- Doug Lang , RPh. (Former bd. member who participated in legislative drafting)
- Barb Bilek, RPh. (Bd. Member)
- Gary Sobocinski, RPh. (Former bd. member)
- Pam Marshall, RPh. (Bd. Member)

The Working Group submitted proposed suggestions to the Board for review. After review, the Board approved the attached proposed rules for submission to the Board of Healing Arts.

To assist in your review, I've provided the following information:

- TAB 1- Section 338.010, RSMo
- TAB 2- Medication Therapy Management In Pharmacy Practice Article (This document provides a good overall review of MTM services/history and is supported by the American Association of Colleges of Pharmacy, the American College of Apothecaries, American College of Clinical Pharmacy, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, National Alliance of State Pharmacy Associations and the National Community Pharmacists Association)
- TAB 3- Proposed Rule Suggestions
- TAB 4- ACPE Standards (Excerpts)
- TAB 5- Certificate Course Requirements
- TAB 6- Certification Information
- TAB 7- Sample MTM Protocols (from other states)

We look forward to our meeting on August 11<sup>th</sup>. Please let me know if you have any questions.

# *Missouri Revised Statutes*

## Chapter 338

### Pharmacists and Pharmacies

#### Section 338.010

August 28, 2009

#### **Practice of pharmacy defined--auxiliary personnel--written protocol required, when--nonprescription drugs--rulemaking authority--therapeutic plan requirements.**

338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his duties. This assistance in no way is intended to relieve the pharmacist from his responsibilities for compliance with this chapter and he will be responsible for the actions of the auxiliary personnel acting in his assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, podiatry, or veterinary medicine, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220, RSMo, in the compounding or dispensing of his own prescriptions.

2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written protocol from the physician who refers the patient for medication therapy services. The written protocol and the prescription order for a medication therapeutic plan shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, RSMo, or from a physician assistant engaged in a supervision agreement under section 334.735, RSMo.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376, RSMo, shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section 334.125, RSMo, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's prescription order.

(RSMo 1939 § 10005, A.L. 1951 p. 737, A.L. 1989 S.B. 39, A.L. 1990 H.B. 1287, A.L. 2007 S.B. 195, A.L. 2009 S.B. 296)

Prior revisions: 1929 § 13140; 1919 § 4712; 1909 § 5764

(2006) Definition of "practice of pharmacy" does not include retail sale of veterinary prescription drugs used for treating animals. *United Pharmacal Co. v. Missouri Board of Pharmacy*, 208 S.W.3d 907 (Mo.banc).

---

© Copyright



Missouri General Assembly

# Medication therapy management in pharmacy practice: Core elements of an MTM service model (version 2.0)

American Pharmacists Association and the  
National Association of Chain Drug Stores Foundation

---

## Abstract

---

**Objective:** To further develop the service model for medication therapy management (MTM) delivery by pharmacists in settings where patients or their caregivers can be actively involved in managing their medications.

**Data sources:** Peer-reviewed literature, structured discussions with pharmacy leaders from diverse patient care settings, input from pharmacists and pharmacy associations, recommendations on patient-centered documents (personal medication record and medication-related action plan) from experts in the field of health literacy, and incorporation of extensive feedback received during an extended public comment period open to all MTM stakeholders and interested parties.

**Summary:** Built on an MTM consensus definition adopted by 11 national pharmacy organizations in July 2004, Medication Therapy Management in Community Pharmacy Practice: Core Elements of an MTM Service (Version 1.0) described core elements of an MTM service model that can be provided by pharmacists across the spectrum of community pharmacy. Version 2.0 of that model, presented in this article, maintains the original five core elements of an MTM service: medication therapy review (MTR), a personal medication record (PMR), a medication-related action plan (MAP), intervention and referral, and documentation and follow-up. The MTR can be comprehensive or targeted, depending on the needs of the patient. In Version 2.0, the PMR and MAP have been redesigned with the assistance of a health literacy expert to be more "patient friendly," effective, and efficient for patients to use in medication self-management.

**Conclusion:** The developing service model presented in this article for use by pharmacists involved in providing MTM services in diverse patient care settings consists of five core elements. The service model provides a consistent and recognizable framework for MTM service delivery by pharmacists that enhances efficient delivery of the service and improves patient outcomes.

**Keywords:** Medication therapy management, Medicare, pharmaceutical care, medication self-management, coordination of care.

*J Am Pharm Assoc.* 2008;48:341-353.

doi: 10.1331/JAPhA.2008.08514

Developed through a joint initiative of the American Pharmacists Association and the National Association of Chain Drug Stores Foundation.

**Correspondence:** Anne Burns, BPharm, American Pharmacists Association, 1100 15th St., NW, Suite 400, Washington, DC 20005. Fax: 202-628-0443. E-mail: aburns@aphanet.org

**Disclosure:** The organizations declare no conflicts of interest regarding products or services discussed in this manuscript. The authors declare no conflicts of interest or financial interests in any product or service mentioned in this article, including grants, employment, gifts, stock holdings, or honoraria.

**Acknowledgments:** Individuals and organizations participating in the review of this document are listed in Appendices 1 and 2.

Copyright © 2008, American Pharmacists Association, Inc., and the National Association of Chain Drug Stores Foundation, Inc. All rights reserved.

Eleven national pharmacy organizations achieved consensus on a definition of medication therapy management (MTM) in July 2004 (Appendix 3). Building on the consensus definition, the American Pharmacists Association (APhA) and the National Association of Chain Drug Stores (NACDS) Foundation developed a model framework for implementing effective MTM services in a community pharmacy setting by publishing Medication Therapy Management in Community Pharmacy Practice: Core Elements of an MTM Service (version 1.0). The original Version 1.0 document described the foundational or core elements of MTM services that could be provided by pharmacists across the spectrum of community pharmacy.<sup>1</sup>

Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model (version 2.0) is an evolutionary document that focuses on the provision of MTM services in settings where patients<sup>a</sup> or their caregivers can be actively involved in managing their medications. This service model was developed with the input of an advisory panel of pharmacy leaders representing diverse pharmacy practice settings (listed in Appendix 1). While adoption of this model is voluntary, it is important to note that this model is crafted to maximize both effectiveness and efficiency of MTM service delivery across pharmacy practice settings in an effort to improve continuity of care and patient outcomes.<sup>b</sup>

### At a Glance

**Synopsis:** Working with an expert advisory panel, and with input from national pharmacy organizations and other stakeholders, the American Pharmacists Association and the National Association of Chain Drug Stores Foundation have refined version 1.0 of the core elements of a medication therapy management (MTM) service model. The resulting version 2.0 contains the five core elements from the version 1.0 model: medication therapy review (MTR), a personal medication record (PMR), a medication-related action plan (MAP), intervention and referral, and documentation and follow-up. The new version can be implemented in more diverse patient care settings and places a greater emphasis on patient transitions of care, health care provider collaboration, and documentation requirements.

**Analysis:** As reflected in environmental scans of providers and payers being published in this and the next issue of JAPhA, MTM is taking hold in cities and towns across the country. The adoption of these core elements by pharmacists when providing MTM will advance comprehension by prescribers and patients of what they can expect during and following MTM visits. The result will be widespread availability of a consistent MTM service that increases opportunities for pharmacists and improves care for patients.

Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model (Version 2.0) is designed to improve collaboration among pharmacists, physicians, and other health care professionals; enhance communication between patients and their health care team; and optimize medication use for improved patient outcomes. The MTM services described in this model empower patients to take an active role in managing their medications. The services are dependent on pharmacists working collaboratively with physicians and other health care professionals to optimize medication use in accordance with evidence-based guidelines.<sup>2,3</sup>

MTM services, as described in this model, are distinct from medication dispensing and focus on a patient-centered, rather than an individual product-centered, process of care.<sup>4,c</sup>

MTM services encompass the assessment and evaluation of the patient's complete medication therapy regimen, rather than focusing on an individual medication product. This model framework describes core elements of MTM service delivery in pharmacy practice and does not represent a specific minimum or maximum level of all services that could be delivered by pharmacists.<sup>5</sup>

Medication-related problems are a significant public health issue within the health care system. Incidence estimates suggest that more than 1.5 million preventable medication-related adverse events occur each year in the United States, accounting for an excess of \$177 billion in terms of medication-related morbidity and mortality.<sup>6,7</sup> The Institute of Medicine advocates that health care should be safe, effective, patient centered, timely, efficient, and effective to meet patients' needs and that patients should be active participants in the health care process to prevent medication-related problems.<sup>3,7</sup>

MTM services, as described in this service model, may help address the urgent public health need for the prevention of medication-related morbidity and mortality.<sup>3</sup> MTM services may contribute to medication error prevention, result in improved reliability of health care delivery, and enable patients to take an active role in medication and health care self-management.<sup>7</sup> The MTM services outlined in this model are aligned with the expectations of the Centers for Medicare & Medicaid Services, as stated in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, that MTM services will enhance patient understanding of appropriate drug use, increase adherence to medication therapy, and improve detection of adverse drug events.<sup>8</sup>

MTM programs are demonstrating positive clinical, economic, and humanistic outcomes across diverse patient populations in various patient care settings.<sup>9-15</sup> MTM services are currently being delivered in both the public and private sectors. In the public sector, some state Medicaid and Medicare Part D plans have focused on a comprehensive medication therapy review as the foundation of their MTM programs. Pharmacists participating in these programs often provide patients with an initial comprehensive assessment and ongoing follow-up assessments to identify and resolve medication-related problems.<sup>11,16-20</sup>

In the private sector, MTM programs are beginning to emerge nationwide, offering MTM services to traditional insured groups, managed-care populations, self-insured employers, and self-paying individual patients.<sup>9,10,12</sup>

Any patient who uses prescription and nonprescription medications, herbal products, or other dietary supplements could potentially benefit from the MTM core elements outlined in this model. As part of the effort to effectively address the urgent public health issue of medication-related morbidity and mortality, MTM services should be considered for any patient with actual or potential medication-related problems, regardless of the number of medications they use, their specific disease states, or their health plan coverage. Although MTM program structure and the needs of individual patients may vary, the use of a consistent and recognizable framework for core MTM services, as described in this model, will enhance their efficient delivery and effective quality measurement. As new opportunities arise, pharmacists in all practice settings must share a common vision for patient-centered MTM services that improve medication therapy outcomes and provide value within our nation's health care system.

### **Framework for pharmacist-provided MTM services**

This framework for MTM service delivery in pharmacy practice is designed to facilitate collaboration among the pharmacist, patient, physician, and other health care professionals to promote safe and effective medication use and achieve optimal patient outcomes. MTM services in all patient care settings should include structures supporting the establishment and maintenance of the patient-pharmacist relationship.

### **Providing MTM services in various patient care settings**

Patients with a potential need for MTM services can be identified by the pharmacist, physician, or other health care professionals; the health plan; or patients themselves when medication-related problems are suspected. Appendix 4 provides considerations for identification of patients who may benefit from MTM services. Patients may be especially vulnerable to medication-related problems during transitions of care, such as when their health care setting changes, when they change physicians, or when their payer status changes.<sup>4</sup>

These transitions of care often result in medication therapy changes that may be due to changes in the patient's needs or resources, the patient's health status or condition, or formulary requirements. It is important that systems be established so that pharmacist-provided MTM services can focus on reconciling the patient's medications and ensuring the provision of appropriate medication management during transitions of care.

For ambulatory patients, MTM services typically are offered by appointment but may be provided on a walk-in basis. MTM services should be delivered in a private or semiprivate area, as

required by the Health Insurance Portability and Accountability Act, by a pharmacist whose time can be devoted to the patient during this service.<sup>21</sup> In other patient care settings (e.g., acute care, long-term care, home care, managed care), the environment in which MTM services are delivered may differ because of variability in structure and facilities design. Even so, to the extent that MTM core elements are implemented, a consistent approach to their delivery should be maintained.

### **The delivery of MTM services by the pharmacist**

Within the MTM core elements service model, the patient receives an annual comprehensive medication therapy review and additional medication therapy reviews according to the patient's needs. The patient may require ongoing monitoring by the pharmacist to address new or recurring medication-related problems.

The total number of reviews required to successfully manage a patient's therapy will vary from patient to patient and will be ultimately determined by the complexity of the individual patient's medication-related problems. The extent of health plan benefits or other limitations imposed by the patient's payer may affect coverage for MTM services; however, this would not preclude additional services provided by the pharmacist for which the patient pays on a fee-for-service basis.

To perform the most comprehensive assessment of a patient, personal interaction with direct contact between a health care professional and a patient is optimal. A face-to-face interaction optimizes the pharmacist's ability to observe signs of and visual cues to the patient's health problems (e.g., adverse reactions to medications, lethargy, alopecia, extrapyramidal symptoms, jaundice, disorientation) and can enhance the patient-pharmacist relationship.<sup>22</sup> The pharmacist's observations may result in early detection of medication-related problems and thus have the potential to reduce inappropriate medication use, emergency department visits, and hospitalizations. It is recognized, however, that alternative methods of patient contact and interaction, such as telephonic, may be necessary for those patients for whom a face-to-face interaction is not possible or not desired (e.g., homebound patients) or in pharmacy practice settings in which the pharmacist serves in a consultative role on the health care team. Irrespective of whether the MTM service is provided by the pharmacist to the patient face to face or by alternative means, the service is intended to support the establishment and maintenance of the patient-pharmacist relationship.

### **Core elements of an MTM service model in pharmacy practice**

The MTM service model in pharmacy practice includes the following five core elements:

- Medication therapy review (MTR)
- Personal medication record (PMR)
- Medication-related action plan (MAP)

- Intervention and/or referral
- Documentation and follow-up

These five core elements form a framework for the delivery of MTM services in pharmacy practice. Every core element is integral to the provision of MTM; however, the sequence and delivery of the core elements may be modified to meet an individual patient's needs.

### Medication therapy review

The medication therapy review (MTR) is a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them.

An MTR is conducted between the patient and the pharmacist. Pharmacist-provided MTR and consultation in various settings has resulted in reductions in physician visits, emergency department visits, hospital days, and overall health care costs.<sup>9,10,12,14,20,23-25</sup> In addition, pharmacists have been shown to obtain accurate and efficient medication-related information from patients.<sup>10,26,27</sup> The MTR is designed to improve patients' knowledge of their medications, address problems or concerns that patients may have, and empower patients to self-manage their medications and their health condition(s).

The MTR can be comprehensive or targeted to an actual or potential medication-related problem. Regardless of whether the MTR is comprehensive or targeted, patients may be identified as requiring this service in a variety of ways. Commonly, patients may be referred to a pharmacist by their health plan, another pharmacist, physician, or other health care professionals. Patients may also request an MTR independent of any referral. Additional opportunities for providing an MTR include when a patient is experiencing a transition of care, when actual or potential medication-related problems are identified, or if the patient is suspected to be at higher risk for medication-related problems.

In a comprehensive MTR, ideally the patient presents all current medications to the pharmacist, including all prescription and nonprescription medications, herbal products, and other dietary supplements. The pharmacist then assesses the patient's medications for the presence of any medication-related problems, including adherence, and works with the patient, the physician, or other health care professionals to determine appropriate options for resolving identified problems. In addition, the pharmacist supplies the patient with education and information to improve the patient's self-management of his or her medications.

Targeted MTRs are used to address an actual or potential medication-related problem. Ideally, targeted MTRs are performed for patients who have received a comprehensive MTR. Whether for a new problem or subsequent monitoring, the pharmacist assesses the specific therapy problem in the context of the patient's complete medical and medication history. Follow-

ing assessment, the pharmacist intervenes and provides education and information to the patient, the physician or other health care professionals, or both, as appropriate. The MTR is tailored to the individual needs of the patient at each encounter.

Depending on its scope, the MTR may include the following:

- Interviewing the patient to gather data, including demographic information, general health and activity status, medical history, medication history, immunization history, and patients' thoughts or feelings about their conditions and medication use<sup>28</sup>
- Assessing, on the basis of all relevant clinical information available to the pharmacist, the patient's physical and overall health status, including current and previous diseases or conditions
- Assessing the patient's values, preferences, quality of life, and goals of therapy
- Assessing cultural issues, education level, language barriers, literacy level, and other characteristics of the patient's communication abilities that could affect outcomes
- Evaluating the patient to detect symptoms that could be attributed to adverse events caused by any of his or her current medications
- Interpreting, monitoring, and assessing the patient's laboratory results
- Assessing, identifying, and prioritizing medication-related problems related to
  - The clinical appropriateness of each medication being taken by the patient, including benefit versus risk
  - The appropriateness of the dose and dosing regimen of each medication, including consideration of indications, contraindications, potential adverse effects, and potential problems with concomitant medications
  - Therapeutic duplication or other unnecessary medications
  - Adherence to the therapy
  - Untreated diseases or conditions
  - Medication cost considerations
  - Health care/medication access considerations
- Developing a plan for resolving each medication-related problem identified
- Providing education and training on the appropriate use of medications and monitoring devices and the importance of medication adherence and understanding treatment goals
- Coaching patients to be empowered to manage their medications
- Monitoring and evaluating the patient's response to therapy, including safety and effectiveness
- Communicating appropriate information to the physician or other health care professionals, including consultation on the selection of medications, suggestions to address identified medication problems, updates on the patient's progress, and recommended follow-up care<sup>29</sup>

In this service model, a patient would receive an annual comprehensive MTR and additional targeted MTRs to address

new or ongoing medication-related problem(s). Significant events such as important changes in the patient's medication therapy, changes in the patient's needs or resources, changes in the patient's health status or condition, a hospital admission or discharge, an emergency department visit, or an admission or discharge from a long-term care or assisted-living facility could necessitate additional comprehensive MTRs.

### Personal medication record

The personal medication record (PMR) is a comprehensive record of the patient's medications (prescription and nonprescription medications, herbal products, and other dietary supplements).

Within the MTM core elements service model, the patient receives a comprehensive record of his or her medications (prescription and nonprescription medications, herbal products, and other dietary supplements) that has been completed either by the patient with the assistance of the pharmacist or by the pharmacist, or the patient's existing PMR is updated. Ideally, the patient's PMR would be generated electronically, but it also may be produced manually. Whether the pharmacist provides the PMR manually or electronically, the information should be written at a literacy level that is appropriate for and easily understood by the patient. In institutional settings, the PMR may be created at discharge from the medication administration record or patient chart for use by the patient in the outpatient setting. The PMR contains information to assist the patient in his or her overall medication therapy self-management. A sample PMR is shown in Figure 1.

The PMR, which is intended for use by the patient, may include the following information<sup>30</sup>:

- Patient name
- Patient birth date
- Patient telephone number
- Emergency contact information (name, relationship, and telephone number)
- Primary care physician (name and telephone number)
- Pharmacy/pharmacist (name and telephone number)
- Allergies (e.g., What allergies do I have? What happened when I had the allergy or reaction?)
- Other medication-related problems (e.g., What medication caused the problem? What was the problem I had?)
- Potential questions for patients to ask about their medications (e.g., When you are prescribed a new drug, ask your doctor or pharmacist...)
- Date last updated
- Date last reviewed by the pharmacist, physician, or other health care professional
- Patient's signature
- Health care provider's signature
- For each medication, inclusion of the following:
  - Medication (e.g., drug name and dose)
  - Indication (e.g., Take for...)

- Instructions for use (e.g., When do I take it?)
- Start date
- Stop date
- Ordering prescriber/contact information (e.g., doctor)
- Special instructions

The PMR is intended for patients to use in medication self-management. The maintenance of the PMR is a collaborative effort among the patient, pharmacist, physician, and other health care professionals. Patients should be encouraged to maintain and update this perpetual document. Patients should be educated to carry the PMR with them at all times and share it at all health care visits and at all admissions to or discharges from institutional settings to help ensure that all health care professionals are aware of their current medication regimen.

Each time the patient receives a new medication; has a current medication discontinued; has an instruction change; begins using a new prescription or nonprescription medication, herbal product, or other dietary supplement; or has any other changes to the medication regimen, the patient should update the PMR to help ensure a current and accurate record. Ideally, the pharmacist, physician, and other health care professionals can actively assist the patient with the PMR revision process.

Pharmacists may use the PMR to communicate and collaborate with physicians and other health care professionals to achieve optimal patient outcomes. Widespread use of the PMR will support uniformity of information provided to all health care professionals and enhance the continuity of care provided to patients while facilitating flexibility to account for pharmacy- or institution-specific variations.

### Medication-related action plan

The medication-related action plan (MAP) is a patient-centric document containing a list of actions for the patient to use in tracking progress for self-management.

A care plan is the health professional's course of action for helping a patient achieve specific health goals.<sup>31</sup> The care plan is an important component of the documentation core element outlined in this service model. In addition to the care plan, which is developed by the pharmacist and used in the collaborative care of the patient, the patient receives an individualized MAP for use in medication self-management. Completion of the MAP is a collaborative effort between the patient and the pharmacist. The patient MAP includes only items that the patient can act on that are within the pharmacist's scope of practice or that have been agreed to by relevant members of the health care team. The MAP should not include outstanding action items that still require physician or other health care professional review or approval. The patient can use the MAP as a simple guide to track his or her progress. The Institute of Medicine has advocated the need for a patient-centered model of health care.<sup>7</sup> The patient MAP, coupled with education, is an essential element for incorporating the patient-centered approach into the MTM service model. The MAP reinforces a sense of patient empowerment and



encourages the patient's active participation in his or her medication-adherence behavior and overall MTM. A sample MAP is shown in Figure 2.

The MAP, which is intended for use by the patient, may include the following information:

- Patient name
- Primary care physician (doctor's name and telephone number)
- Pharmacy/pharmacist (pharmacy/pharmacist name and telephone number)
- Date of MAP creation (date prepared)
- Action steps for the patient: "What I need to do..."
- Notes for the patient: "What I did and when I did it..."
- Appointment information for follow-up with pharmacist, if applicable

Specific items that require intervention and that have been approved by other members of the health care team and any new items within the pharmacist's scope of practice should be included on a MAP distributed to the patient on a follow-up visit. In institutional settings, the MAP could be established at the time the patient is discharged for use by the patient in medication self-management.

**Intervention and/or referral**

The pharmacist provides consultative services and intervenes to address medication-related problems; when necessary, the pharmacist refers the patient to a physician or other health care professional.

During the course of an MTM encounter, medication-related problems may be identified that require the pharmacist to intervene on the patient's behalf. Interventions may include collaborating with physicians or other health care professionals to resolve existing or potential medication-related problems or working with the patient directly. The communication of appropriate information to the physician or other health care professional, including consultation on the selection of medications, suggestions to address medication problems, and recommended follow-up care, is integral to the intervention component of the MTM service model.<sup>29</sup>

The positive impact of pharmacist interventions on outcomes related to medication-related problems has been demonstrated in numerous studies.<sup>32-37</sup> Appropriate resolution of medication-related problems involves collaboration and communication between the patient, the pharmacist, and the patient's physician or other health care professionals.

Some patients' medical conditions or medication therapy may be highly specialized or complex, and their needs may extend beyond the core elements of MTM service delivery. In such cases, pharmacists may provide additional services according to their expertise or refer the patient to a physician, another pharmacist, or other health care professional.

Examples of circumstances that may require referral include the following:

**Figure 2.** Sample medication-related action plan (for the patient). Patients, health care professionals, payers, and health information technology system vendors are encouraged to develop a format that meets individual and customer needs, collecting elements such as those included in this sample medication-related action plan.

APhA and the NACDS Foundation encourage the use of this document in a manner and form that serves the individual needs of practitioners. All reproductions, including modified forms, should include the following statement: "This form is based on forms developed by the American Pharmacists Association and the National Association of Chain Drug Stores Foundation. Reproduced with permission of APhA and the NACDS Foundation."

- A patient may exhibit potential problems discovered during the MTR that may necessitate referral for evaluation and diagnosis.
- A patient may require disease management education to help him or her manage chronic diseases such as diabetes.
- A patient may require monitoring for high-risk medications (e.g., warfarin, phenytoin, methotrexate).

The intent of intervention and/or referral is to optimize medication use, enhance continuity of care, and encourage patients to avail themselves of health care services to prevent future adverse outcomes.

**Documentation and follow-up**

MTM services are documented in a consistent manner, and a follow-up MTM visit is scheduled based on the patient's medication-related needs or the patient is transitioned from one care setting to another.

Documentation is an essential element of the MTM service model. The pharmacist documents services and intervention(s) performed in a manner appropriate for evaluating patient progress and sufficient for billing purposes. Proper documentation of MTM services may serve several purposes, including, but not limited to, the following:

- Facilitating communication between the pharmacist and the patient's other health care professionals regarding recommendations intended to resolve or monitor actual or potential medication-related problems
- Improving patient care and outcomes
- Enhancing the continuity of patient care among providers and care settings
- Ensuring compliance with laws and regulations for the maintenance of patient records
- Protecting against professional liability
- Capturing services provided for justification of billing or reimbursement (e.g., payer audits)
- Demonstrating the value of pharmacist-provided MTM services
- Demonstrating clinical, economic, and humanistic outcomes

MTM documentation includes creating and maintaining an ongoing patient-specific record that contains, in chronological order, a record of all provided care in an established standard

health care professional format (e.g., the SOAP [subjective observations, objective observations, assessment, and plan] note<sup>38</sup>).

Ideally, documentation will be completed electronically or, alternatively, on paper. The inclusion of resources such as a PMR, a MAP, and other practice-specific forms will assist the pharmacist in maintaining consistent professional documentation. The use of consistent documentation will help facilitate collaboration among members of the health care team while accommodating practitioner, facility, organizational, or regional variations.

Documentation elements for the patient record may include, but are not limited to, the items listed in Table 1.<sup>22,29,38-40</sup>

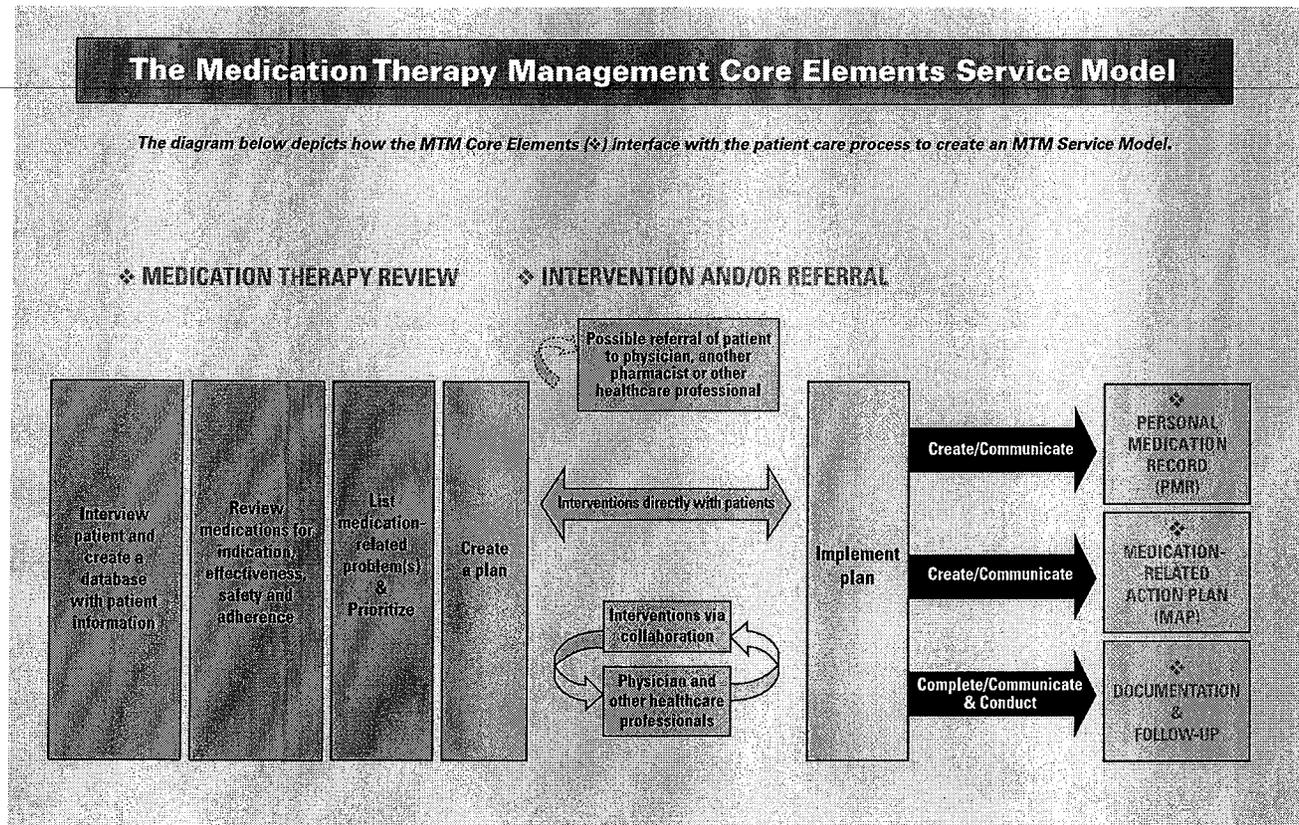
**External communication of MTM documentation**

Following documentation of the MTM encounter, appropriate external communication should be provided or sent to key audiences, including patients, physicians, and payers. Providing the patient with applicable documentation that he or she can easily understand is vital to facilitating active involvement in the care process. Documentation provided to the patient at the MTM encounter may include the PMR, MAP, and additional education materials. Documentation to physicians and other health care professionals may include a cover letter, the patient's PMR, the SOAP note, and the care plan. Communicating with payers and providing appropriate billing information may also be necessary and could include the name of the pharmacist or pharmacy and appropriate identifier, services provided, time spent on patient care, and appropriate billing codes.

**Table 1.** Examples of documentation elements for patient record

Patient demographics/basic information: Address, telephone number, e-mail address, gender, age, ethnicity, educational status, patient's special needs, health plan benefit/insurance coverage
Subjective observations: Pertinent patient-reported information: previous medical history, family history, social history, chief complaints, allergies, previous adverse drug reactions
Objective observations: Known allergies, diseases, conditions, laboratory results, vital signs, diagnostic signs, physical exam results, review of systems
Assessment: Problem list, assessment of medication-related problems
Plan: A care plan is the health care professional's course of action for helping a patient achieve specific health goals
Education: Goal setting and instruction provided to the patient with verification of understanding
Collaboration: Communication with other health care professionals: recommendations, referrals, and correspondence with other professionals (cover letter, SOAP note)
PMR: A record of all medications, including prescription and nonprescription medications, herbal products, and other dietary supplements
MAP: Patient-centric document containing a list of actions to use in tracking progress for self-management
Follow-up: Transition plan or scheduling of next follow-up visit
Billing: Amount of time spent on patient care, level of complexity, amount charged

Abbreviations used: MAP, medication-related action plan; PMR, personal medication record; SOAP, subjective observations, objective observations, assessment, and plan.



**Figure 3.** Flow chart of a medication therapy management service model

Abbreviation used: MTM, medication therapy management.

**Follow-up**

When a patient’s care setting changes (e.g., hospital admission, hospital to home, hospital to long-term care facility, home to long-term care facility), the pharmacist transitions the patient to another pharmacist in the patient’s new care setting to facilitate continued MTM services. In these situations, the initial pharmacist providing MTM services participates cooperatively with the patient’s new pharmacist provider to facilitate the coordinated transition of the patient, including the transfer of relevant medication and other health-related information.

If the patient will be remaining in the same care setting, the pharmacist should arrange for consistent follow-up MTM services in accordance with the patient’s unique medication-related needs. All follow-up evaluations and interactions with the patient and his or her other health care professional(s) should be included in MTM documentation.

**Conclusion**

The MTM core elements, as presented in this document, are intended to be applicable to patients in all care settings where the patients or their caregivers can be actively involved with managing their medication therapy, taking full advantage of the pharmacist’s role as the “medication therapy expert.” Figure 3 presents a flow chart of the core elements of an MTM service

model contained in this document. As the core elements service model continues to evolve to meet diverse patient needs, pharmacists are encouraged to make the most of the framework provided to improve patient outcomes and medication use.

<sup>a</sup>In this document, the term *patient* refers to the patient, caregiver, or other persons involved in the care of the patient.

<sup>b</sup>Notice: The materials in this service model are provided for general informational purposes only and do not constitute business or legal advice. The NACDS Foundation and APhA assume no responsibility for the accuracy or timeliness of any information provided herein. The reader should not under any circumstances solely rely on, or act on the basis of, the materials in this service model. These materials and information are not a substitute for obtaining business or legal advice in the appropriate jurisdiction or state.

The materials in this service model do not represent a standard of care or standard business practices. This service model may not be appropriate for all pharmacists or pharmacies. Service programs should be designed based on unique needs and circumstances, and model examples should be modified as appropriate.

Nothing contained in this service model shall be construed as an express or implicit invitation to engage in any illegal or anticompetitive activity. Nothing contained in this service model shall, or should be, construed as an endorsement of any particular method of treatment or pharmacy practice in general.

MTM services are built on the philosophy and process of pharmaceutical care that was first implemented in pharmacy practice in the early 1990s. As pharmacy education, training, and practice continue to evolve to a primarily clinical “patient-centered” focus, pharmacists are gaining recognition from other health care professionals and the public

as “medication therapy experts.” Recognizing the pharmacist’s role as the medication therapy expert, the pharmacy profession has developed a consensus definition for MTM and is increasingly using this term to describe the services provided by pharmacists to patients.

“Examples of transitions of care may include but are not limited

to changes in health care setting (e.g., hospital admission, hospital to home, hospital to long-term care facility, home to long-term care facility), changes in health care professionals and/or level of care (e.g., treatment by a specialist), or changes in payer status (e.g., change or loss of health plan benefits/insurance).

**Appendix 1. Medication therapy management model advisory panel**

Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model (Version 2.0) was developed with the input of an advisory panel of pharmacy leaders representing diverse pharmacy practice settings. The pharmacy practice setting areas represented by members of the advisory panel included ambulatory care, community, government technical support services, hospital, long-term care, managed care health systems, managed care organization plan administration, and outpatient clinics. Advisory panel members provided expert advice. The content of this document does not necessarily represent all of their opinions or those of their affiliated organizations.

Marialice S. Bennett, BPharm, FAPhA  
Ohio State University

Sandra Leal, PharmD, CDE  
El Rio Community Health Center

Winston Wong, PharmD  
CareFirst BCBS

Rebecca W. Chater, BPharm, MPH,  
FAPhA  
Kerr Drug, Inc.

Macary Weck Marciniak, PharmD, BCPS  
Albany College of Pharmacy

*Staff*  
Ben Bluml, BPharm  
American Pharmacists Association  
Foundation

Kimberly Sasser Croley, PharmD, CGP,  
FASCP  
Knox County Hospital

Randy P. McDonough, PharmD, MS, CGP,  
BCPS  
Towncrest and Medical Plaza  
Pharmacies

Anne Burns, BPharm  
American Pharmacists Association

Rachael Deck, PharmD  
Walgreen Co.

Melissa Somma McGivney, PharmD, CDE  
University of Pittsburgh School of  
Pharmacy

Ronna Hauser, PharmD  
National Association of Chain Drug  
Stores

Jeffrey C. Delafuente, MS, FCCP, FASCP  
Virginia Commonwealth University  
School of Pharmacy

Rick Mohall, PharmD  
Rite Aid Corporation

Crystal Lennartz, PharmD, MBA  
National Association of Chain Drug  
Stores

Susan L. Downard, BPharm  
Kaiser Permanente of the Mid-Atlantic  
States, Inc.

Anthony Provenzano, PharmD, CDE  
SUPERVALU Pharmacies, Inc.

James Owen, PharmD  
American Pharmacists Association

Margherita Giuliano, BPharm  
Connecticut Pharmacists Association

Michael Sherry, BPharm  
CVS Caremark

Afton Yurkon, PharmD  
National Association of Chain Drug  
Stores

Zandra Glenn, PharmD  
HRSA Pharmacy Services Support  
Center

Steven T. Simenson, BPharm, FAPhA  
Goodrich Pharmacies

Melinda C. Joyce, PharmD, FAPhA,  
FACHE  
The Medical Center

Donna S. Wall, BPharm, PharmD, BCPS,  
FASHP  
Clarian Healthcare Partners, Indiana  
University Hospital

Abbreviations used: BCBS, BlueCross BlueShield; HRSA, Health Resources and Services Administration.

**Appendix 2. Organizations contributing to medication therapy management model**

APhA and the NACDS Foundation respectfully acknowledge the contributions of all individuals and organizations that participated in the development of Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model (Version 2.0). This service model is supported by the following seven organizations:

- American Association of Colleges of Pharmacy
- American College of Apothecaries
- American College of Clinical Pharmacy
- American Society of Consultant Pharmacists
- American Society of Health-System Pharmacists
- National Alliance of State Pharmacy Associations
- National Community Pharmacists Association

**Appendix 3. Definition of medication therapy management<sup>a</sup>**

Medication therapy management (MTM) is a distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision of a medication product. MTM 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:

- 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 his/her medications
  - Providing information, support services, and resources designed to enhance patient adherence with his/her therapeutic regimens
  - Coordinating and integrating MTM services within the broader health care management services being provided to the patient
- A program that provides coverage for MTM services shall include the following:

- Patient-specific and individualized services or sets of services provided directly by a pharmacist to the patient.<sup>b</sup> 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
  - Face-to-face interaction between the patient<sup>b</sup> 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.
- MTM programs shall include structures supporting the establishment and maintenance of the patient<sup>b</sup>-pharmacist relationship
- Opportunities for pharmacists and other qualified health care providers to identify patients who should receive MTM services
  - Payment for MTM 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 CPT and RBRVS)
  - Processes to improve continuity of care, outcomes, and outcome measures

Approved July 27, 2004, by the Academy of Managed Care Pharmacy, the American Association of Colleges of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Society of Consultant Pharmacists, the American Pharmacists Association, the American Society of Health-System Pharmacists, the National Association of Boards of Pharmacy,<sup>c</sup> the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the National Council of State Pharmacy Association Executives (now the National Alliance of State Pharmacy Associations).

Abbreviations used: CPT, Current Procedural Terminology; MTM, medication therapy management; RBRVS, resource-based relative value scale.

<sup>a</sup>Bluml BM. Definition of medication therapy management: development of professionwide consensus. *J Am Pharm Assoc.* 2005;45:566-72.

<sup>b</sup>In some situations, MTM services may be provided to the caregiver or other persons involved in the care of the patient.

<sup>c</sup>Organization policy does not allow the National Association of Boards of Pharmacy to take a position on payment issues.

## Appendix 4. Considerations for identification of patients who may benefit from MTM services

Any patients using prescription and nonprescription medications, herbal products, and other dietary supplements could potentially benefit from the medication therapy management (MTM) services described in the core elements outlined in this service model, especially if medication-related problems or issues are discovered or suspected. Patients may be evaluated for MTM services regardless of the number of medications they use, their specific disease state(s), or their health plan coverage.

Opportunities for the identification of patients targeted for MTM services may result from many sources, including, but not limited to, pharmacist identification, physician referral, patient self-referral, and health plan or other payer referral. Pharmacists may wish to notify physicians or other health care professionals in their community or physicians within their facility, if applicable, of their MTM services, so that physicians may refer patients for MTM services.

To provide assistance in prioritizing who may benefit most from MTM services, pharmacists, health plans, physicians, other health care professionals, and health systems may consider using one or more of the following factors to target patients who are likely to benefit most from MTM services:

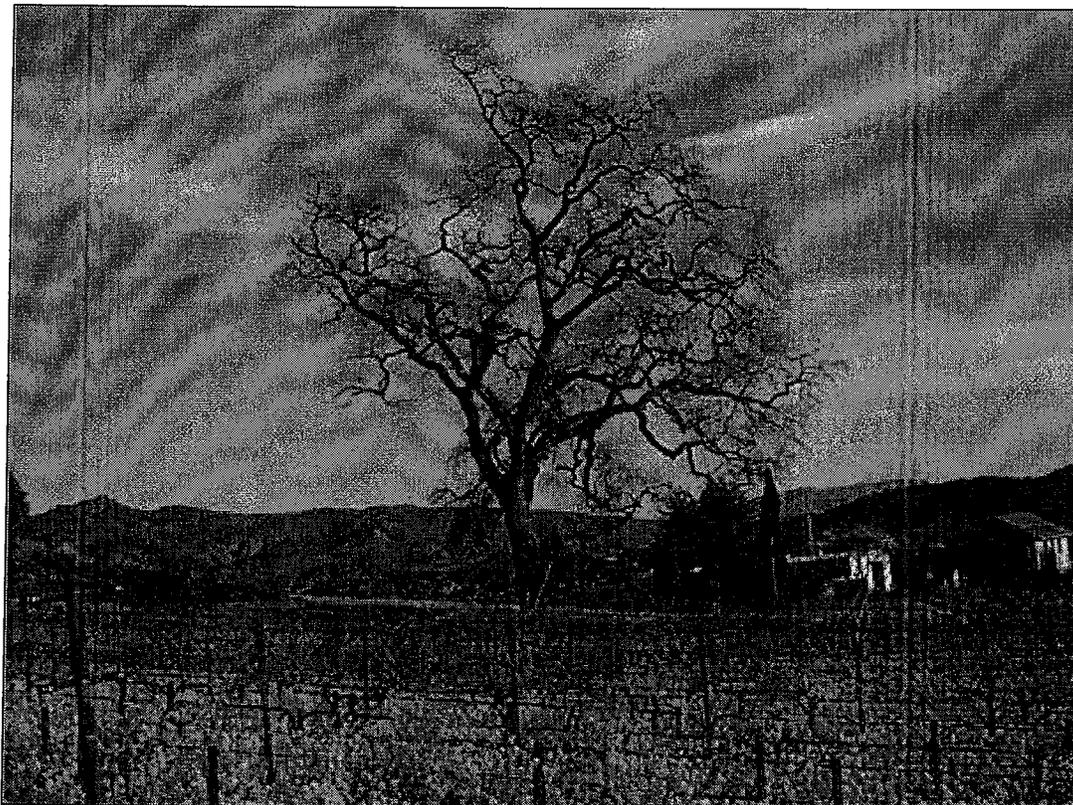
- Patient has experienced a transition of care, and his or her regimen has changed
- Patient is receiving care from more than one prescriber
- Patient is taking five or more chronic medications (including prescription and nonprescription medications, herbal products, and other dietary supplements)
- Patient has at least one chronic disease or chronic health condition (e.g., heart failure, diabetes, hypertension, hyperlipidemia, asthma, osteoporosis, depression, osteoarthritis, chronic obstructive pulmonary disease)
- Patient has laboratory values outside the normal range that could be caused by or may be improved with medication therapy
- Patient has demonstrated nonadherence (including underuse and overuse) to a medication regimen
- Patient has limited health literacy or cultural differences and therefore requires special communication strategies to optimize care
- Patient wants or needs to reduce out-of-pocket medication costs
- Patient has experienced a loss of or significant change in health plan benefit or insurance coverage
- Patient has recently experienced an adverse event (medication- or non-medication-related) while receiving care
- Patient is taking high-risk medication(s), including narrow therapeutic index drugs (e.g., warfarin, phenytoin, methotrexate)
- Patient self-identifies and presents with perceived need for MTM services

Abbreviation used: MTM, medication therapy management.

### References

1. American Pharmacists Association, National Association of Chain Drug Stores Foundation. Medication therapy management in community pharmacy practice: core elements of an MTM service (version 1.0). *J Am Pharm Assoc.* 2005;45:573-9.
2. Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? *Eff Clin Pract.* 1998;1(1):2-4.
3. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century. Washington, D.C.: Institute of Medicine; 2001.
4. Cipolle RJ, Strand LM, Morley PC. Pharmaceutical care practice: the clinician's guide. New York: McGraw Hill; 2004.
5. McGivney MS, Meyer SM, Duncan-Hewitt W, et al. Medication therapy management: its relationship to patient counseling, disease management, and pharmaceutical care. *J Am Pharm Assoc.* 2007;47:620-8.
6. Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. *J Am Pharm Assoc.* 2001;41:192-9.
7. Institute of Medicine. Report brief: preventing medication errors. Accessed at [www.iom.edu/Object.File/Master/35/943/medication%20errors%20new.pdf](http://www.iom.edu/Object.File/Master/35/943/medication%20errors%20new.pdf), September 1, 2007.
8. Centers for Medicare & Medicaid Services. Medicare Prescription Drug Benefit final rule: 42 CFR parts 400, 403, 411, 417, and 423 Medicare Program. *Federal Register.* 2005;70(18):January 28. Accessed at <http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-1321.pdf>, September 1, 2007.
9. Garrett D, Bluml B. Patient self-management program for diabetes: first-year clinical, humanistic, and economic outcomes. *J Am Pharm Assoc.* 2005;45:130-7.
10. 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.
11. 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.
12. Bunting BA, Cranor CW. The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. *J Am Pharm Assoc.* 2003;43:133-47.
13. Jameson J, VanNoord G, Vanderwoud K. The impact of a pharmacotherapy consultation on the cost and outcome of medical therapy. *J Fam Pract.* 1995;41:469-72.
14. Lipton HL, Bero LA, Bird JA, et al. The impact of clinical pharmacists' consultations on physicians' geriatric drug prescribing. *Med Care.* 1992;30:646-58.
15. Schumock GT, Butler MG, Meek PD, et al. Evidence of the economic benefit of clinical pharmacy services: 1996-2000. *Pharmacotherapy.* 2003;23:113-32.
16. Minnesota Department of Human Services. MHCP enrolled providers. Accessed at [www.dhs.state.mn.us/main/idcplg?IdcService=GET\\_DYNAMIC\\_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id\\_000090](http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=id_000090), February 5, 2007.
17. Traynor K. Wyoming program brings pharmacist consultations home. *Am J Health Syst Pharm.* 2004;61:760.
18. North Carolina Department of Health and Human Services. North Carolina Medicaid: medication therapy management program (MTMP). Accessed at [www.dhhs.state.nc.us/dma/Forms/mtmpinstructions.pdf](http://www.dhhs.state.nc.us/dma/Forms/mtmpinstructions.pdf), September 1, 2007.

19. Touchette DR, Burns AL, Bough MA, et al. Survey of medication therapy management programs under Medicare Part D. *J Am Pharm Assoc.* 2006;46:683-91.
20. Galt KA. Cost avoidance, acceptance, and outcomes associated with a pharmacotherapy consult clinic in a Veterans Affairs medical center. *Pharmacotherapy.* 1998;18:1103-11.
21. Rovers J, Currie J, Hagel H, et al. Re-engineering the pharmacy layout. In: *A practical guide to pharmaceutical care.* 2nd ed. Washington, D.C.: American Pharmacists Association; 2003:261-6.
22. Rovers J, Currie J, Hagel H, et al. Patient data collection. In: *A practical guide to pharmaceutical care.* 2nd ed. Washington, D.C.: American Pharmacists Association; 2003:26-51.
23. Borgsdorf LR, Miano JS, Knapp KK. Pharmacist-managed medication review in a managed care system. *Am J Hosp Pharm.* 1994;51:772-7.
24. Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacy staffing, and the total cost of care in the United States hospitals. *Pharmacotherapy.* 2000;20:609-21.
25. Christensen D, Trygstad T, Sullivan R, et al. A pharmacy management intervention for optimizing drug therapy for nursing home patients. *Am J Geriatr Pharmacother.* 2004;2:248-56.
26. Gurwich EL. Comparison of medication histories acquired by pharmacists and physicians. *Am J Hosp Pharm.* 1983;40:1541-2.
27. Nester TM, Hale LS. Effectiveness of a pharmacist-acquired medication history in promoting patient safety. *Am J Health Syst Pharm.* 2002;59:2221-5.
28. Rovers J, Currie J, Hagel H, et al. The case for pharmaceutical care. In: *A practical guide to pharmaceutical care.* 2nd ed. Washington, D.C.: American Pharmacists Association; 2003:3-4.
29. Berger BA. Interacting with physicians. In: *Communication skills for pharmacists.* 2nd ed. Washington, D.C.: American Pharmacists Association; 2005:131-9.
30. American Society of Health-System Pharmacists. Executive summary of the American Society of Health-System Pharmacists (ASHP) and ASHP Research and Education Foundation Continuity of Care in Medication Use Summit. *Am J Health Syst Pharm.* In press.
31. Rovers J, Currie J, Hagel H, et al. Patient care plan development. In: *A practical guide to pharmaceutical care.* 2nd ed. Washington, D.C.: American Pharmacists Association; 2003:69.
32. Rupp MT. Value of the community pharmacists' interventions to correct prescribing errors. *Ann Pharmacother.* 1992;26:1580-4.
33. McMullin ST, Hennenfent JA, Ritchie D, et al. A prospective randomized trial to assess the cost impact of pharmacist-initiated interventions. *Arch Intern Med.* 1999;159:2306-9.
34. Knapp KK, Katzman H, Hambricht JS, et al. Community pharmacist intervention in a capitated pharmacy benefit contract. *Am J Health Syst Pharm.* 1998;55:1141-5.
35. Dobie RL, Rascati KL. Documenting the value of pharmacist interventions. *Am Pharm.* 1994;NS34(5):50-4.
36. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm.* 1990;47:533-43.
37. Bootman JL, Harrison DL, Cox E. The healthcare cost of drug-related morbidity and mortality in nursing facilities. *Arch Intern Med.* 1997;157:2089-96.
38. Zierler-Brown S, Brown TR, Chen D, et al. Clinical documentation for patient care: models, concepts, and liability considerations for pharmacists. *Am J Health Syst Pharm.* 2007;64:1851-8.
39. Currie JD, Doucette WR, Kuhle J, et al. Identification of essential elements in documentation of pharmacist-provided care. *J Am Pharm Assoc.* 2003;43:41-9.
40. Culhane N, Brooks A, Cohen V, et al. Medication therapy management services: application of the core elements in ambulatory settings. Accessed at [www.accp.com/position/pos\\_AmCare.pdf](http://www.accp.com/position/pos_AmCare.pdf), September 1, 2007.



*Mustard Season* • Napa, Calif. • 2008 • George E. MacKinnon III, BPharm, FASHP

**DRAFT (6/10):**

*This draft is being circulated for discussions purposes only and has not been finally approved by the Missouri Board of Pharmacy.*

**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION**  
Division 2220—State Board of Pharmacy  
Chapter 6— Pharmaceutical Care Standards

**20 CSR 2220-6.060 General Provisions**

*PURPOSE: This rule establishes definitions for 20 CSR 2220-6.060 to 20 CSR 2220-6.080 governing medication therapy services by pharmacists.*

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080:

(A) “**Authorizing Physician(s)**”- The physician identified in the written protocol as authorizing the pharmacist to provide medication therapy services.

(B) “**Board**”- The Missouri State Board of Pharmacy.

(C) “**Board of Healing Arts**”- The Missouri Board of Registration for the Board of Healing Arts.

(D) “**Health Care Entity**”- For purposes of this rule, a health care entity shall be defined as any entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility or a habilitation center as defined by Chapter 630, and that is required to maintain patient medical records by state or federal law.

*The proposed suggestions include multiple record-keeping and notification requirements for documenting pharmacist provided medication therapy (MT) services. However, for patients of a licensed health care facility, this documentation is currently recorded in a patient medical record that the licensed facility is required to maintain under state/federal law. To avoid duplication, the proposed rules would allow the patient’s medical record to be the main source of documenting patient care in lieu of requiring the pharmacist to maintain a separate set of files.*

*To ensure proper documentation, the proposed exemption would only apply to pharmacists practicing in health care facilities that are required to maintain medical records by law. After discussions with Bert McClary from the Missouri Department of Health and Senior Services, these facilities are referred to in the proposed rules as a “health care entity.” As defined, the term would not apply to independent patient care facilities that are not licensed by the state or federal government as a health care facility.*

*The allowance for pharmacists practicing in a “health care entity” would only be applicable to record-keeping and notification requirements. Pharmacists practicing in health care entities would be required to comply with all other MT practice requirements.*

**DRAFT (6/10):**

*This draft is being circulated for discussions purposes only and has not been finally approved by the Missouri Board of Pharmacy.*

1  
2 (E) “**Prescription Order for A Medication Therapeutic Plan**”- A lawful order that is  
3 issued by an authorized prescriber within the scope of his professional practice for the provision  
4 of medication therapy services by a pharmacist for a specific patient, including, patients of a  
5 health care entity.

6 (F) “**Medication Therapy Services**”- The designing, initiating, implementing or  
7 monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to  
8 enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has  
9 authority to initiate or implement a modification of the patient’s medication therapy or device  
10 usage pursuant to a medication therapy protocol. For purposes of 20 CSR 2220-6.060 to 20 CSR  
11 2220-6.080, modification shall include selecting a new, different or additional medication or  
12 device, discontinuing a current medication or device, or selecting a new, different, or additional  
13 strength, dose, dosage form, dosage schedule or route of administration for a current medication  
14 or device, and implementing such selection(s). Medication therapy services shall not include the  
15 sole act of dispensing a drug or device pursuant to a valid prescription for the product or generic  
16 substitutions made pursuant to § 338.056, RSMo.  
17

*Medication therapy services include a wide array of activities, including, activities that are currently within the recognized scope of practice for pharmacists (i.e.- patient counseling/education, consulting with a physician). The Board agreed that the proposed rules should clearly identify when a certificate of medication plan authority is required and not restrict activities currently allowed under Chapter 338. In this regard, a certificate of medication plan authority would only be required if the pharmacist has authority to **initiate or implement a modification** to drug therapy/device usage. While other medication therapy services may be required for, or provided in conjunction with, a modification, the Board agreed that a pharmacist should only be required to obtain certification if he/she has authority to modify.*

18  
19 (G) “**Medication Therapy Protocol**” A written agreement between a physician and a  
20 pharmacist for the provision of medication therapy services. A medication therapy protocol shall  
21 comply with the provisions of this rule.

22 (H) “**Pharmacy Resident**”- A Missouri licensed pharmacist enrolled in a residency  
23 training program accredited by the American Society of Health-Systems Pharmacists or a  
24 residency training program with a valid application for accreditation pending with the American  
25 Society of Health-Systems Pharmacist;

26 (I) “**Protocol**”- A medication therapy protocol, as defined herein.  
27

28 (2) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 shall only be deemed  
29 applicable to persons/entities under the jurisdiction of the Board, as established by Chapter 338,  
30 RSMo.

**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION**  
Division 2220—State Board of Pharmacy  
Chapter 6— Pharmaceutical Care Standards

**20 CSR 2220-6.070 Certificate of Medication Therapeutic Plan Authority**

*PURPOSE: This rule establishes procedures for obtaining a certificate of medication therapeutic plan authority, as authorized by § 338.010, RSMo.*

(1) A pharmacist shall be authorized to provide medication therapy services if the pharmacist has obtained a certificate of medication therapeutic plan authority from the Board and has entered into a written protocol with a Missouri licensed physician that complies with the requirements 20 CSR 2220-6.080. A certificate of medication therapeutic plan authority shall only be required if the pharmacist who provides medication therapy services has been granted authority to initiate or implement a modification of the patient’s medication therapy or device usage pursuant to a medication therapy protocol.

*A protocol may authorize a pharmacist to manage several disease states. In lieu of establishing/tracking certification requirements for each disease state, the Board would issue a general certificate of medication therapeutic plan authority. To ensure a pharmacist is qualified to perform MT services, the authorizing physician would be responsible for ensuring that the MT services performed are within the skill, education, training and competence of the pharmacist and for ensuring that the activities authorized by the protocol are consistent with the pharmacist’s level of skill, education, training and competence. The suggestions also prohibit a pharmacist from providing any MT service beyond his/her “skill, education, training and competence.” [See 6.080(3)(B) and (4)(A)]*

(2) Applicants for certification shall hold an active Missouri pharmacist license that is not under discipline with the Board. Applications shall be submitted on forms provided by the Board and shall be accompanied by the certificate of medication therapeutic plan authority fee and proof the applicant:

(A) Holds a doctor of pharmacy (PharmD) degree earned from an ACPE accredited school, or;

(B) Has successfully completed a post-graduate medication therapy certificate course or program accredited or granted by the Accreditation Council for Pharmacy Education, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists or the American Pharmacists Association, or;

(C) Holds a current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators, or;

(D) Has completed a post graduate medication therapy certificate course that, at a minimum, included training in the following areas:

1. Assessing patient specific data and issues;

**DRAFT (6/10):**

*This draft is being circulated for discussions purposes only and has not been finally approved by the Missouri Board of Pharmacy.*

- 1           2. Establishing medication therapeutic goals or medication-related action plans for
- 2 identified medication conditions and medication related concerns;
- 3           3. Assessing and addressing adverse reactions and adverse drug events;
- 4           4. Modifying and monitoring medication regimens;
- 5           5. Improving patient care and outcomes through medication therapy services;
- 6           6. Evaluating treatment progress;
- 7           7. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in
- 8 medication regimen reviews;
- 9           8. Medication reconciliation;
- 10          9. Drug utilization review;
- 11          10. Applicable state or federal law;
- 12          11. Formulating and documenting personal medication records;
- 13          12. Documenting clinical outcomes;
- 14          13. Interpreting, monitoring, ordering and assessing patient test results, and;
- 15          14. Patient education and counseling.

*The Board and the Working Group extensively discussed qualifying training/experience for a certificate of medication plan authority.*

- *Except for limited reciprocity exceptions, the Board only licenses graduates of an ACPE accredited pharmacy school. As reflected in Tab-4, ACPE requires MTM training/education as a condition of accreditation. Accordingly, all recent PharmD graduates from an ACPE accredited school would have already completed MTM didactic and clinical training. After consulting with the colleges of pharmacy, the Board approved accepting a PharmD. as a qualifier. [SEE TAB 4- ACPE Standards]*
- *All of the certification programs listed above require/test medication therapy competence. [SEE TAB 6- Certification Info]*
- *See TAB 5 for examples of an MT certificate course.*

16  
17 (3) Certificate Renewal. A certificate of medication therapeutic plan authority shall be renewed  
18 biennially with the certificate holder's Missouri pharmacist license. For purposes of renewal, six  
19 (6) of the continuing education hours required for renewing the certificate holder's Missouri  
20 pharmacist license shall be earned in courses/programs related to medication therapy  
21 management. The continuing education required by this rule shall be governed by the rules of  
22 the Board governing pharmacist continuing education.

23  
24 (4) The Board may terminate a pharmacist's certificate of medication therapeutic plan authority  
25 if the Board determines that the pharmacist has violated the terms of a protocol, the requirements  
26 of the rules of the Board governing medication therapy services or any other state or federal drug  
27 law.  
28

**Title 20—DEPARTMENT OF  
INSURANCE, FINANCIAL  
INSTITUTIONS AND  
PROFESSIONAL REGISTRATION**  
Division 2220—State Board of Pharmacy  
Chapter 6— Pharmaceutical Care Standards

**20 CSR 2220-6.080 Medication Therapy Services By Protocol.**

*PURPOSE: This rule establishes procedures for the provision of medication therapy services by protocol, as authorized by § 338.010, RSMo.*

(1) Except as otherwise provided herein, a pharmacist who holds a certificate of medication therapeutic plan authority from the Board shall be authorized to provide medication therapy services in Missouri if the pharmacist:

(A) Holds a current Missouri pharmacist license that is not under discipline with the Board, and;

(B) Has entered into a written protocol with a Missouri licensed physician that complies with the requirements of 20 CSR 2220-6.080.

(2) **General Requirements.** A pharmacist providing medication therapy services pursuant to this rule shall comply with the following:

(A) Prior to providing medication therapy services, the authorizing physician shall issue a prescription order for a medication therapeutic plan for the specific patient which authorizes the pharmacist to perform medication therapy services. Except as otherwise provided in section (2)(B) of this section, the prescription order for a medication therapeutic plan shall be valid for one year and shall include:

1. The patient's name, address and date of birth;
2. The date the prescription order for a medication therapeutic plan is issued;
3. The clinical indication for medication therapy services;
4. The length of time for providing medication therapy services, if less than one year,

and;

5. The referring physician's name and address.

(B) A prescription order for a medication therapeutic plan may be transmitted orally, electronically, or in writing. If an oral prescription order for a medication therapeutic plan is issued, all information required under section (2)(A) of this rule shall be documented by the pharmacist and maintained in the patient's record in accordance with section (7) of this rule.

(C) The pharmacist shall review relevant prescription records, patient profiles, patient medical records or other medical information to determine the services to be rendered.

(D) Medication therapy decisions made by a pharmacist shall be made in the best interests of the patient.

(3) **Authorizing Physician Requirements.**

(A) The authorizing physician shall be actively engaged in the practice of medicine in the state of Missouri and shall hold a current Missouri physician license pursuant to Chapter 334, RSMo, that is not under discipline with the Board of Healing Arts.

**DRAFT (6/10):**

*This draft is being circulated for discussions purposes only and has not been finally approved by the Missouri Board of Pharmacy.*

1 (B) The authorizing physician shall be responsible for the oversight of, and accept the  
2 responsibility for, the medication therapy services provided by the pharmacist. The authorizing  
3 physician shall also consider the level of skill, education, training and competence of the  
4 pharmacist and ensure that the activities authorized by the protocol are consistent with the  
5 pharmacist's level of skill, education, training and competence.

6 (C) Review of Protocol. The written protocol shall be reviewed and signed by the pharmacist  
7 and the authorizing physician at least annually and revised as needed. The authorizing physician  
8 and pharmacist shall document the date of the annual review on the written protocol.

9 (D) Review of Services Provided. The authorizing physician shall review the pharmacist's  
10 medication therapy service activities at least once every six months. If the pharmacist is  
11 providing medication therapy services for or on behalf of a health care entity, the review  
12 requirements shall be satisfied if the participating pharmacist's work and services are reviewed  
13 every six months by a clinical care committee, pharmacy and therapeutics committee or a  
14 reviewing body/committee of the health care entity that includes a Missouri licensed physician.  
15 The review required by this subsection may be accomplished in person or by electronic means.

16 *(E) The practice location of the authorizing physician shall be no further than fifty (50)*  
17 *miles by road from the pharmacist identified in the written protocol.*

18 (F) An authorizing physician shall notify the Board of Healing Arts of a written protocol for  
19 medication therapy services entered with a pharmacist at each renewal.

20  
21 **(4) Protocol Requirements.**

22 (A) The medication therapy services performed by a pharmacist pursuant to the protocol  
23 shall be within the scope of practice of the physician and within the skill, education, training and  
24 competence of both the authorizing physician and the participating pharmacist.

25 (B) The written protocol between a physician and pharmacist shall, at a minimum, include  
26 the following:

- 27 1. The identity and signatures of the authorizing physician and pharmacist;
- 28 2. The effective dates of the protocol;
- 29 3. A statement of clinical conditions, diseases, drugs, or drug categories included in the  
30 written protocol and the type of medication therapy services allowed in each case;
- 31 4. A statement of the methods, procedures, decision criteria and plan the pharmacist is to  
32 follow when conducting medication therapy services;
- 33 5. Procedures for documenting medication therapy decisions made by the pharmacist and  
34 a plan for communication, feedback, and reporting to the authorizing physician concerning  
35 specific decisions made;
- 36 6. A mechanism and procedure that allows the authorizing physician to override, rescind,  
37 modify or otherwise amend the protocol. All modifications or amendments to the protocol shall  
38 be documented in writing and signed and dated by all involved parties prior to the  
39 implementation of such modification or amendment;

**DRAFT (6/10):**

*This draft is being circulated for discussions purposes only and has not been finally approved by the Missouri Board of Pharmacy.*

1           7. A statement that the pharmacist shall not delegate the provision of medication therapy  
2 services to another person. A Missouri licensed intern may perform medication therapy services  
3 under the direct supervision of a Missouri pharmacist certified to perform medication therapy  
4 management services by the Board, provided that any modification to drug therapy or device  
5 usage shall only be initiated by the supervising pharmacist.

6           8. A description of any authority granted to the pharmacist to administer any drug or  
7 medication including the identification of any such drug or medication or device;

8           9. A description of drug therapy related patient assessment procedures or testing that  
9 may be ordered or performed by the pharmacist, including, any authority to order or perform  
10 routine or other laboratory testing;

11          10. Provisions for allowing the pharmacist to access prescription records, patient  
12 profiles, patient medical records or other relevant medical information for purposes of providing  
13 medication therapy services;

14          11. A provision for providing the authorizing physician access to patient records for  
15 medication therapy services;

16          12. Provisions establishing a course of action the pharmacist is authorized to follow to  
17 address emergency situations, including, but not limited to, anaphylactic or other adverse  
18 medication reactions, adverse needle sticks or other adverse events;

19          13. Criteria for the timely communication between the pharmacist and authorizing  
20 physician, not inconsistent with the provisions of this rule;

21          14. The notification requirements required by section (5) of this rule, and;

22          15. The method for reviewing the pharmacist's medication therapy work or services by  
23 the authorizing physician, as required by 20 CSR 2220-6.080(3)(D).

24          (C) In addition to the requirements of this section, the written protocol shall also include a  
25 description of all medication therapy services the pharmacist is authorized to render or provide.  
26 Such services may include:

27           1. Assessing patient specific data and issues;

28           2. Establishing medication therapeutic goals or medication-related action plans for  
29 identified medical conditions and medication related concerns;

30           3. Assessing and addressing adverse reactions and adverse drug events;

31           4. Modifying and monitoring medication regimens;

32           5. Evaluating treatment progress;

33           7. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in  
34 medication regimen reviews;

35           8. Medication reconciliation;

36           9. Drug utilization review;

37           10. Applicable state or federal law;

38           11. Formulating and documenting personal medication records;

39           12. Documenting clinical outcomes;

40           13. Interpreting, monitoring and assessing patient test results, and;

41           14. Patient education and counseling.

**DRAFT (6/10):**

*This draft is being circulated for discussions purposes only and has not been finally approved by the Missouri Board of Pharmacy.*

*This listing is a modified version of accepted pharmacist MTM services/activities recognized by the American Association of Colleges of Pharmacy, the American College of Apothecaries, American College of Clinical Pharmacy, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, National Alliance of State Pharmacy Associations and the National Community Pharmacists Association. [SEE TAB I].*

(D) The protocol required by this section shall be signed and dated by the authorizing physician and the participating pharmacist. If the protocol includes multiple physicians or pharmacists, a separate protocol shall not be required for each physician or pharmacist if all authorizing physicians and participating pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol.

(E) Protocol Modifications. Any revisions, modifications or amendments to the protocol must be in writing. The physician shall promptly notify the pharmacist of any such revision, modification or amendment and shall maintain documentation of the notification, including, the date such notification was made. A physician may delegate the notification requirements of this subsection to an authorized designee, provided the physician shall be ultimately responsible for compliance with the notification requirements.

(F) A pharmacist shall not be authorized to adjust, change or modify any controlled substance prescribed for a patient, except as otherwise authorized by state or federal law.

(G) The protocol shall be maintained by the authorizing physician and the pharmacist for a minimum of eight (8) years after termination of the protocol. The protocol may be maintained electronically.

(H) A protocol shall automatically and immediately terminate if the pharmacist ceases to maintain an active Missouri pharmacist license, the authorizing physician is deceased or if the authorizing physician fails to maintain an active Missouri physician license.

(I) Pharmacy Residents. In lieu of an individual protocol, a pharmacy resident shall be authorized to perform medication therapy services under the written protocol of a Missouri pharmacist if:

a. The resident holds a certificate of medication therapeutic plan authority from the Board, and;

b. The resident is enrolled in a residency training program accredited by the American Society of Health Systems Pharmacist or a residency training program with a valid application for accreditation pending with the American Society of Health Systems Pharmacist;

c. The resident is providing medication therapy services under the supervision of a Missouri pharmacist certified to perform medication therapy services by the Board.

(J) The provisions of section (4)(I) shall only apply to medication therapy services provided by a pharmacist as part of his/her residency training.

**(5) Notification Requirements.** A pharmacist shall comply with the following notification requirements:

(A) Within twenty-four (24) hours after learning of an anaphylactic or other adverse medication reaction, adverse needle stick or other adverse event experienced by a patient, the pharmacist shall notify the patient's primary health care provider and, if different, the authorizing physician or an authorized designee of the authorizing physician;

**DRAFT (6/10):**

*This draft is being circulated for discussions purposes only and has not been finally approved by the Missouri Board of Pharmacy.*

1 (B) The pharmacist shall notify the authorizing physician or a designee approved by the  
2 physician in the written protocol of any modification of therapy within fourteen (14) days,  
3 provided the protocol may include more stringent notification requirements;

4 (C) A pharmacist shall be deemed in compliance with the notification requirements of this  
5 rule if the pharmacist is providing medication therapy services for or on behalf of a health care  
6 entity, as defined by this rule and documentation of the notifications required by this section is  
7 recorded in a patient medical record that is required to be maintained by the health care entity  
8 pursuant to state or federal law.

9 (D) Notifications required by this section shall be in writing unless otherwise authorized by  
10 the authorizing physician.

11  
12 **(6) Modifying Drug Therapy.** A pharmacist shall be authorized to modify a patient's non-  
13 controlled substance medication therapy, subject to the following:

14 (A) If the pharmacist modifies medication therapy and a medication or device is to be  
15 dispensed, the pharmacist shall create a prescription for the medication or device modified under  
16 the authorizing physician's name. Such prescription may be dispensed by a licensed pharmacy  
17 and shall be maintained in the prescription records of the dispensing pharmacy as provided by  
18 the rules of the Board.

19 (B) If the pharmacist modifies medication therapy or a device, the pharmacist shall  
20 document such modification according to section (6) of this rule. Pharmacists providing  
21 medication therapy services for patients of a health care entity shall be deemed in compliance  
22 with the provisions of this subsection if the modification is documented in a patient medical  
23 record that the health care entity is required to maintain under state or federal law.

24 (C) The pharmacist shall obtain a prescription order for a medication therapeutic plan  
25 from the authorizing physician or other prescriber for dispensing or modifying any controlled  
26 substance prescription.

27 (D) For purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080, modification of  
28 medication therapy shall include selecting a new, different or additional medication or device,  
29 discontinuing a current medication or device, or selecting a new, different, or additional strength,  
30 dose, dosage form, dosage schedule or route of administration for a current medication or device,  
31 and implementing such selection(s). Medication therapy services shall not include the sole act  
32 of dispensing a drug or device pursuant to a valid prescription for the product or generic  
33 substitutions made pursuant to § 338.056, RSMo.

34  
35 **(7) Recordkeeping.**

36 (A) A pharmacist shall document and maintain an adequate patient record of medication  
37 therapy services provided to each patient. The records may be maintained in an electronic  
38 format provided the records are capable of being printed for review by the state board of  
39 registration for the Board of Healing Arts and the board of pharmacy. An adequate and complete  
40 patient record shall include documentation of the following:

41 1. The identification of the patient, including, name, birthdate, address and telephone  
42 number;

43 2. The date or date(s) of any patient visit or consultation, including the reason for any  
44 such visit/consultation;

45 3. Any pertinent assessments, observations or findings;

46 4. Any diagnostic testing recommended or performed;

**DRAFT (6/10):**

*This draft is being circulated for discussions purposes only and has not been finally approved by the Missouri Board of Pharmacy.*

1           5. The name of any medication or device modified, and the strength, dose, dosage  
2 scheduled, dosage form and route of administration of any medication modified or administered,  
3 and;

4           6. Referrals to a treating physician or other health care provider;

5           7. Any contact with the authorizing physician concerning the patient's treatment or  
6 medication therapeutic plan;

7           8. Any informed consent for procedures, medications or devices, and;

8           9. Any consultation with any other treatment provider for the patient and the results of  
9 such consultation.

10           (B) Pharmacist Record Retention. Except as otherwise provided herein, records required  
11 to be maintained by a pharmacist pursuant to this rule shall be maintained securely and  
12 confidentially for a minimum of two (2) years after termination of the protocol unless different  
13 requirements are established for recordkeeping pursuant to state or federal law. All records  
14 required to be maintained by the pharmacist by this rule shall be maintained by the pharmacist at  
15 an address that shall be identified in the written protocol.

16           (C) Physician Record Retention. Except as otherwise provided herein, records required  
17 to be maintained by a physician pursuant to this rule shall be maintained securely and  
18 confidentially for a minimum of two (2) years after termination of the protocol unless more  
19 stringent requirements are established for recordkeeping pursuant to state or federal law.

20  
21           (8) **Production of Records.** Records maintained at a pharmacy must be produced during an  
22 inspection or investigation by the board of pharmacy or Board of Healing Arts, or their  
23 authorized representatives, as requested by the respective board or the board's designee.  
24 Records not maintained at a pharmacy shall be produced within three (3) business days after a  
25 request from the Board of Pharmacy and/or its authorized representative. Failure to maintain or  
26 produce records as provided by this rule shall constitute grounds for discipline.

27  
28           (9) Nothing in this rule shall be construed to permit medical diagnosis of any condition by a  
29 pharmacist or the independent issuing of a prescription order for a medication therapeutic plan  
30 by a pharmacist.

31  
32           (10) A pharmacist shall not violate or practice in a manner inconsistent with the provisions of  
33 this rule or a written protocol. Failure to abide by the requirements of this rule or the provisions  
34 of a written protocol shall be subject to disciplinary action pursuant to the provisions of Chapter  
35 338, RSMo.

36  
37           (11) The requirements of this rule shall not apply to the administration of vaccines pursuant to  
38 protocol as governed by 20 CSR 2220-6.050 or the administration of medication by protocol as  
39 governed by 20 CSR 2220-6.030.

40  
41           (12) The Missouri State Board of Registration for the Healing Arts and the Missouri Board of  
42 Pharmacy separately retain the right and duty to discipline their respective licensees for  
43 violations of any state or federal statutes, rules or regulations regardless of the licensee's  
44 participation in a protocol agreement.

**DRAFT (6/10):**

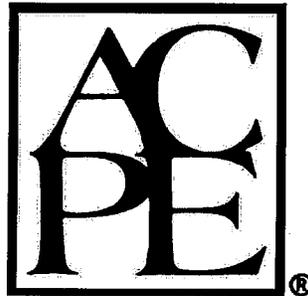
*This draft is being circulated for discussions purposes only and has not been finally approved by the Missouri Board of Pharmacy.*

- 1 (13) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 shall only be deemed
- 2 applicable to persons/entities under the jurisdiction of the Board, as established by Chapter 338,
- 3 RSMo.
- 4

**ACCREDITATION COUNCIL FOR PHARMACY EDUCATION**

**ACCREDITATION STANDARDS AND GUIDELINES FOR THE  
PROFESSIONAL PROGRAM IN PHARMACY LEADING TO  
THE DOCTOR OF PHARMACY DEGREE**

**ADOPTED: JANUARY 15, 2006  
RELEASED: FEBRUARY 17, 2006  
EFFECTIVE: JULY 1, 2007**



**Accreditation Council for Pharmacy Education  
Chicago, Illinois  
© 2006**

**ACCREDITATION STANDARDS AND GUIDELINES FOR THE  
PROFESSIONAL PROGRAM IN PHARMACY LEADING TO THE DOCTOR  
OF PHARMACY DEGREE  
ADOPTED: JANUARY 15, 2006**

**Standard No. 1: College or School Mission and Goals**

The college or school of pharmacy (*hereinafter "college or school"*) must have a published statement of its mission, its goals in the areas of education, research and other scholarly activities, service, and pharmacy practice, and its values. The statement must be compatible with the mission of the university in which the college or school operates.<sup>1</sup> These goals must include fundamental commitments of the college or school to the preparation of students who possess the competencies necessary for the provision of pharmacist-delivered patient care, including medication therapy management services, the advancement of the practice of pharmacy and its contributions to society, the pursuit of research and other scholarly activities, and the assessment and evaluation of desired outcomes.

**Standard No. 12: Professional Competencies and Outcome Expectations<sup>2</sup>**

Professional pharmacist competencies that must be achieved by graduates through the professional degree program curriculum are the ability to:

1. Provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social, cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social/behavioral/administrative, and clinical sciences that may impact therapeutic outcomes.
2. Manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
3. Promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an interprofessional team of health care providers.

**Guideline 12.1**

---

<sup>1</sup> The term "university" includes independent colleges and schools.

<sup>2</sup> American Association of Colleges of Pharmacy's, Center for the Advancement of Pharmaceutical Education (CAPE), Educational Outcomes, 2004 (with minor edits)

**ACCREDITATION STANDARDS AND GUIDELINES FOR THE  
PROFESSIONAL PROGRAM IN PHARMACY LEADING TO THE DOCTOR  
OF PHARMACY DEGREE  
ADOPTED: JANUARY 15, 2006**

Graduates must possess the basic knowledge, skills, attitudes, and values to practice pharmacy independently at the time of graduation. In this regard, the college or school must ensure that graduates are competent to:<sup>3</sup>

- *provide patient-centered care*, through the ability to:
  - design, implement, monitor, evaluate, and adjust pharmacy care plans that are patient-specific; address health literacy, cultural diversity, and behavioral psychosocial issues; and are evidence-based
  - manage a successful patient-centered practice (including establishing, marketing, and being compensated for medication therapy management and patient care services rendered)
- *provide population-based care*, through the ability to develop and implement population-specific, evidence-based disease management programs and protocols based upon analysis of epidemiologic and pharmaco-economic data, medication-use criteria, medication use review, and risk-reduction strategies
- *manage human, physical, medical, informational, and technological resources*, through the ability to ensure efficient, cost-effective use of these resources in the provision of patient care
- *manage medication use systems*, through the ability to apply patient- and population-specific data, quality improvement strategies, medication safety and error reduction programs, and research processes to minimize drug misadventures and optimize patient outcomes; to participate in the development of drug use and health policy; and to help design pharmacy benefits
- *promote the availability of effective health and disease prevention services and health policy* through the ability to apply population-specific data, quality improvement strategies, informatics, and research processes to identify and solve public health problems and to help develop health policy

To be capable of the above, pharmacy graduates also must be able to:

- communicate and collaborate with patients, care givers, physicians, nurses, other health care providers, policy makers, members of the community, and administrative and support personnel to engender a team approach to patient care
- retrieve, analyze, and interpret the professional, lay, and scientific literature to provide drug information and counseling to patients, their families or care givers, and other involved health care providers
- demonstrate expertise in informatics<sup>4</sup>

---

<sup>3</sup> Adapted from CAPE Educational Outcomes, 2004

<sup>4</sup> Competencies in informatics include basic terminology (data, information, knowledge, hardware, software, networks, information systems, information systems management); reasons for systematic processing of data, information and knowledge in health care; and the benefits and current constraints in using information and communication technology in health care. (*Adapted from recommendations of the International Medical Informatics Association*)

**ACCREDITATION STANDARDS AND GUIDELINES FOR THE  
PROFESSIONAL PROGRAM IN PHARMACY LEADING TO THE DOCTOR  
OF PHARMACY DEGREE  
ADOPTED: JANUARY 15, 2006**

- carry out duties in accordance with legal, ethical, social, economic, and professional guidelines
- maintain professional competence by identifying and analyzing emerging issues, products, and services

Guideline 14.5

The organization of the advanced pharmacy practice experiences should provide a balanced series of required (the majority) and elective experiences that cumulatively provide sustained experiences of adequate intensity, duration, and breadth (in terms of patients and disease states that pharmacists are likely to encounter when providing care) to enable achievement of stated competencies as demonstrated by assessment of outcome expectations. Generally, the required and elective experiences should be full-time, provide continuity of care, and be conducted under pharmacist-preceptor supervision and monitoring.

The required advanced pharmacy practice experiences in all program pathways must be conducted in the United States or its territories and possessions (including the District of Columbia, Guam, Puerto Rico, and U.S. Virgin Islands). Required experiences must include primary, acute, chronic, and preventive care among patients of all ages and develop pharmacist-delivered patient care competencies in the following settings:

- community pharmacy
- hospital or health-system pharmacy
- ambulatory care
- inpatient/acute care general medicine

The required advanced pharmacy practice experiences should emphasize the need for continuity of care throughout the health care delivery system, including the availability and sharing of information regarding a patient's condition, medications, and other therapies.

Elective advanced pharmacy practice experiences in other settings (such as research, management, drug information, education, managed care, long-term care, hospice, and home health care) should complement the required experiences and provide adequate and innovative opportunities for students to mature professionally and in accordance with their individual interests. The college or school may offer elective advanced pharmacy practice experiences outside the United States and its territories and possessions, provided that they support the development of the competencies required of the graduate, and the college or school implements policies and procedures to ensure the quality of the site(s) and preceptor(s).

Guideline 25.6

To contribute to the maintenance and enhancement of practice skills of faculty, and to develop such skills in students, pharmacy practice faculty who precept pharmacy practice

**ACCREDITATION STANDARDS AND GUIDELINES FOR THE  
PROFESSIONAL PROGRAM IN PHARMACY LEADING TO THE DOCTOR  
OF PHARMACY DEGREE  
ADOPTED: JANUARY 15, 2006**

experiences that involve direct patient care or provide instruction related to contemporary patient care should be engaged in patient medication therapy management.

Guideline 28.3

The college or school must identify a diverse mixture of sites for required and elective pharmacy practice experiences. In general, each site used for required pharmacy practice experiences should have the following characteristics:

- meets or exceeds all legal and professional standards required to provide patient care
- has a patient population that exhibits diversity in culture, medical conditions, gender, and age, where appropriate
- has an adequate patient population based on the learning objectives for the rotation
- has access to learning and information resources
- has a commitment to the education of pharmacy students
- has management that is supportive of professional staff involvement in the education of pharmacy students
- has a practice environment that nurtures and supports pharmacist and student interactions with patients
- provides daily contact with the preceptor or a qualified designee to ensure that students receive feedback and have opportunities to ask questions
- is adequately equipped with the technology needed to support student training and to reflect contemporary practice
- provides medication therapy management and patient care services for diverse populations
- has adequate professional staff and supportive technical and clerical staff to meet the learning objectives and to provide for optimum time for preceptor and student interaction
- provides educational workshops for patients and other health care providers
- serves as an accredited site for training of pharmacy residents
- has collaborative professional and/or training relationships with other health care providers

The college or school should ensure the availability of a broad array of quality-assured sites for elective pharmacy practice experiences (such as state or national pharmacy associations, state boards of pharmacy, pharmacy benefit managers, insurance companies, pharmaceutical manufacturers, drug information centers, and research laboratories) to support the achievement of curricular competencies and student interests.



## Delivering Medication Therapy Management Services in

### the Community

***Delivering Medication Therapy Management Services in the Community*** is an innovative and interactive certificate training program that explores the pharmacist's role in providing MTM services to patients. Pharmacists have a tremendous opportunity to receive reimbursement for monitoring and improving medication use in patients with complex medication regimens. This practice-based activity teaches pharmacists the essential skills necessary to become a successful MTM practitioner. The certificate training program will enhance pharmacists' clinical expertise in evaluating complicated medication regimens, identifying medication-related problems, and making recommendations to patients, caregivers, and health care professionals. ***Delivering Medication Therapy Management Services in the Community*** is conducted in three parts:

- Self-study activity and pre-seminar exercise
- Live interactive training seminar
- Post-seminar exercise
- Additional resources (password required; password included in printed course materials)

The goals of the certificate training program are to:

- Advance public health and patient care through improved medication use.
- Provide training to enhance pharmacists' ability to effectively provide MTM services.
- Motivate increased numbers of pharmacists to establish MTM services.
- Communicate benchmark practices for providing MTM services.

View a list of **upcoming open-enrollment sessions** hosted by APhA and ASCP or view a list of **Licensed Partners** that may be offering this certificate training program at a location near you.

### Self-Study Modules Description and Learning Objectives

The self-study learning activity is meant to ensure that all participants have a solid understanding of the role of pharmacists as medication therapy managers, the business aspects of setting up MTM services, and the core knowledge, skills, and processes needed for the provision of successful MTM services. As participants work through the self-study activity, they will learn more about the clinical and administrative aspects of providing MTM services.

#### *Module 1. MTM: A New Era for Pharmacy Practice*

After completing this module, pharmacists will be able to:

- Describe the economic and clinical outcomes that are affected when pharmacist-provided patient care services increase.
- State the definition of medication therapy management (MTM).
- Describe the Medicare Part D benefit and how it differs from Medicare Part B.

- Explain reimbursement opportunities provided by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.
- List additional opportunities for providing MTM services that do not involve Medicare Part D.
- Define the five core elements of the MTM services model.

#### *Module 2. Becoming an MTM Practitioner: A Plan for Success*

After completing this module, pharmacists will be able to:

- Describe the components of a business plan.
- Identify the strengths and weaknesses of current pharmacy operations and list potential services and barriers using a SWOT analysis and needs assessment.
- Write a mission statement and goals for providing MTM services.
- Describe appropriate activities for technicians, student pharmacists, and pharmacy practice residents involved with MTM services.
- Discuss reimbursement strategies to incorporate in the MTM business model.
- Outline the process and key considerations of making MTM services operational and integrated with existing services.
- Identify measures to track the economic, clinical, and humanistic outcomes of an MTM service.
- Project revenues and expenses to establish fees for MTM services.
- Review elements of a marketing plan for attracting patients, providers, employers, and payers to MTM services.
- List opportunities for professional and staff development to address any unmet learning needs.

#### *Module 3. Getting Ready for MTM Service Delivery: Knowledge and Skills*

After completing this module, pharmacists will be able to:

- Identify areas of therapeutic knowledge essential for providing MTM services.
- Describe strategies for, and limitations of, using clinical practice guidelines during MTM services.
- Explain pharmacodynamic and pharmacokinetic changes that are common in elderly adults.
- List other common health problems in elderly adults.
- Explain the risks of medication-related problems in elderly patients, and strategies for reducing their incidence.
- List patient assessment strategies that may be useful during MTM visits.
- Identify patients with low health literacy.
- Describe techniques that support open communication with patients, including the use of open-ended questions and active listening techniques.
- Describe a strategy for improving the cultural competence of pharmacists providing patient care during MTM visits.
- Identify the stages of behavior change in the transtheoretical model of change.
- Describe the communication process used in motivational interviewing.
- Adapt patient communication strategies for patients with functional impairments.
- Describe strategies for communicating effectively with prescribers.

#### *Module 4. Ready for Action: Conducting an MTM Encounter*

After completing this module, pharmacists will be able to:

- Define the responsibilities of the patient as it relates to the MTM process.
- Identify pertinent information needed from patients and other providers.
- Identify components of the personal medication record (PMR) and medication-related action plan (MAP).
- Describe how the patient might use the PMR and/or MAP.
- Describe the steps involved in completing an assessment of a patient's medication-related needs.
- List at least seven types of medication-related problems and possible solutions.
- Describe the primary responsibilities of the pharmacist in terms of identifying, prioritizing, resolving, and preventing medication therapy problems.
- Recognize opportunities for intervention and/or collaboration with (or referral to) other health care professionals to resolve medication-related problems.

- Explain information that should be included in a SOAP note.
- Describe how to document MTM services in a manner appropriate for evaluating patient progress, sufficient for billing purposes, and applicable for tracking clinical and financial outcomes of an MTM service.

### Pre-Seminar Exercise

After completion of the self-study portion of the certificate training program, participants must complete two pre-seminar patient cases. The pre-seminar exercises are intended to provide participants with initial experience in conducting a medication therapy review. Completing these exercises will give participants a baseline understanding of the process and allow them to identify questions and specific areas of difficulty to address during the live seminar. This activity is integral to a comprehensive learning experience and is useful for indentifying personal areas for additional practice and improvement. Participants should be prepared to use these patient cases during interactive portions of the live seminar.

### Live Seminar Description and Learning Objectives

The second part of the certificate training program is an active learning seminar focusing on pharmacy practice implementation; it is based on the experience of practitioners involved with the development and delivery of MTM services. The live seminar reinforces and expands on the self-study activity. Participants will practice a variety of communication techniques to elicit a patient's medication experience and identify medication-related problems. Participants also will gain experience in prioritizing medication-related problems, developing interventions, and documenting activities. Strategies for implementing an MTM service will be explored.

After completing the live seminar, participants will be able to:

- Explain how to overcome communication barriers and employ active listening when interviewing a patient.
- Conduct a thorough medication therapy review.
- Complete a personal medication record (PMR).
- Develop a medication-related action plan (MAP).
- Perform the following tasks, given a patient case including one or more medications:
  - Assess patient-specific data and issues, and interpret these findings to identify the patient's medication-related problems.
  - Account for pharmacokinetic and pharmacodynamic changes when reviewing an elderly person's medication regimen.
  - Develop a list of the patient's drug therapy problems.
  - Establish goals of therapy for each medical condition and medication-related problem identified.
  - Make recommendations for resolving situations in which a patient's medications are potentially inappropriate.
- Document services in a manner appropriate for evaluating patient progress, sufficient for billing purposes, and that facilitates tracking clinical and financial outcomes.
- Discuss the elements of an effective recommendation to another health care practitioner.
- Describe the medication use concerns and adverse drug events that affect senior patients.
- Explain how to bill for MTM services using the appropriate CPT code(s).

### Post-Seminar Exercise

Following the same format as the pre-seminar exercises and using cases from the pharmacist's practice, participants must perform and document a medication therapy review for three additional patient cases. For each case, participants will identify and prioritize the patient's medication-related problems, develop appropriate interventions, complete the appropriate documentation, and devise a plan for follow-up.

After completing the post-seminar, pharmacists will be able to:

- Conduct a thorough patient medication history for three patients.
- Complete a personal medication record (PMR) for three patients.
- Develop a medication-related action plan (MAP) for three patients.
- Given three patient cases:
  - Identify patient-specific data and issues and interpret these findings to assess the patient's medication-related needs.

- Apply the principles of pharmacokinetic and pharmacodynamic changes when reviewing an elderly persons medication regimen.
- Generate a list of medication-related problems for the patient.
- Establish goals of therapy for each identified medical condition and medication-related problem.
- Provide recommendations for modifying potentially inappropriate medication regimens.
- Document services provided to three patients in a manner appropriate for evaluating patient progress, sufficient for billing purposes, and applicable to tracking of clinical and financial outcomes.



The American Pharmacists Association and the American Society of Consultant Pharmacists are accredited by the Accreditation Council for Pharmacy Education as providers of continuing pharmacy education.

The self-study learning portion of the ***Delivering Medication Therapy Management Services in the Community*** certificate training program is approved for 10 hours (1.0 CEU) of continuing pharmacy education credit (UAN 202-999-09-006-H04-P). The live training seminar is approved for 8 hours (0.8 CEU) of continuing pharmacy education credit (UAN 202-999-09-005-L04-P). The post-seminar exercise is approved for 3 hours (0.3 CEU) of continuing pharmacy education credit (UAN 202-999-09-007-H04-P). CPN: 202-0012.

Initial Release Date: March 1, 2009; Expiration Date: March 1, 2012

Activity Type: Practice-based; Target Audience: Pharmacists in all practice settings

**Completion Information:** A Certificate of Achievement is awarded to participants who successfully complete all activity requirements, which include the self-study activity and pre-seminar exercises, the self-study examination, the live training seminar, and the post-seminar patient interviews. Successful completion is defined as a submission of the pre-work and post-work, a self-study examination score of 70% or better, and attendance at the live seminar.

For more information on the certificate training program curriculum or agenda, contact the APhA Certificate Training Department by e-mailing [ctp@aphanet.org](mailto:ctp@aphanet.org) or calling 202-429-7512.

If your company or organization is interested in offering this certificate training program to its pharmacists, please contact the APhA Certificate Training Department ([ctp@aphanet.org](mailto:ctp@aphanet.org); 202-429-7512).

***Delivering Medication Therapy Management Services in the Community***, developed by the American Pharmacists Association and the American Society of Consultant Pharmacists, was originally supported in part by independent educational grants from Boehringer Ingelheim Pharmaceuticals, Eisai Pharmaceuticals, Eli Lilly and Company, JanssenPharmaceuticals, Ortho-McNeil Janssen Pharmaceuticals, sanofi-aventis Pharmaceuticals, and Wyeth Pharmaceuticals.



## Commission for Certification in Geriatric Pharmacy

ccgp.org

← [Consumer Center](#)

[Industry Center](#)

[Pharmacist Center](#)

[About CCGP](#)

[Contact Us](#)

[CCGP Home](#)

[Search CCGP](#)

[Certification Facts](#)

A clinical FELLOWSHIP program is a directed, highly individualized postgraduate training program designed to prepare the participant to become an independent researcher.



### Pharmacist Center - Certification

[certification](#) | [recertification](#) | [pharmacists listserve](#)  
[geriatric practice award](#) | [exam offered in Australia](#) | [resources](#)  
[self assessment exam](#) | [test your geriatric IQ](#) | [CCGP white paper](#)

### Exam Content

[Exam History](#) | [Exam Fees & Requirements](#) | [FAQs](#) | [Exam General Information](#)  
[Test Center Locations & Dates](#) | [Exam Content](#) | [Request a Handbook](#)  
[Examination Administration](#) | [Register Online](#)

To begin your preparation in an informed and organized manner, you should know what to expect from the actual examination in terms of the content. The content outline will give you a general impression of the examination and can give you specific study direction by revealing the relative importance given to each category on the examination.

- [Patient Specific Activities](#)
- [Disease Specific Activities](#)
- [Population Specific Activities](#)

#### Patient Specific Activities (35%)

##### A. Collect and Evaluate Patient-Specific Information (21%)

1. Interpret and apply knowledge of the following to the provision of pharmaceutical care for older adults:
  - Incidence of disease, comorbidity, and disability
  - Patterns of medication use
  - Causes of morbidity and mortality
2. Assess and apply understanding of the following issues to the provision of pharmaceutical care for older adults:
  - Continuum of care
  - Wellness and health promotion
  - Loss of independence
  - End of life issues (advance directives, treatment issues, quality of life choices)
  - Ethical issues
3. Evaluate the social aspects of aging in the provision of pharmaceutical care for older adults related to the following:
  - Economic Issues
  - Availability of community-based services (referrals and triage)
  - isolation
  - losses
  - role of caregiver
4. Communicate with elderly patients, their caregivers and healthcare professionals:
  - recognize communication barriers including age-related sensory and cognitive impairments, illiteracy, and language and cultural differences
  - apply strategies to overcome communication barriers
  - apply privacy and confidentiality principles

- ensure patient understanding of prescribed therapy
- 5. Evaluate physiological changes that accompany aging (e.g., sensory, body composition, organ system function)
- 6. Interpret and monitor laboratory results and procedures for the older patient
- 7. Evaluate and apply results of standardized assessment tools (MMSE, GDS, etc.)
- 8. Recognize and assess altered disease state presentations in the elderly
- 9. Recognize and assess altered psychological status in the elderly
- 10. Identify and assess compliance/adherence issues affecting potential treatment plans (e.g., memory loss, sensory changes, hearing, cognition, patient beliefs, economics, and learning disabilities)
- 11. Obtain an accurate drug history including over-the-counter and alternative/complementary medications
- 12. Obtain and/or evaluate relevant physical assessment information
- 13. Apply principles of pharmacokinetic and pharmacodynamic changes associated with aging to the design of the pharmacotherapy regimen

**B. Identify, Resolve and Prevent Medication Therapy-Related Problems (31%)**

1. Untreated or under-treated conditions
2. Improper drug selection
3. Subtherapeutic or Supratherapeutic dosage
4. Compliance/adherence issues:
  - monitor patient's compliance/adherence with medications and apply strategies to educate the patient and/or caregiver, and encourage compliance/adherence with therapy
  - promote elder-appropriate drug labeling and packaging
5. Adverse drug reactions
6. Drug interactions
7. Drug use without indication
8. Treatment failures

**C. Determine Patient's Pharmaceutical and Related Health Care Needs and Integrate into Care Plan (6%)****D. Select Drug Therapy Goals Which Focus on Function and Quality of Life (6%)****E. Design and Implement a Therapeutic Regimen in Collaboration with the Patient and Other Health Care Professionals (13%)**

1. Apply concept of risk: benefit for each drug
2. Recommend non-prescription drugs
3. Educate patient on therapy options - generics, alternative therapies, non-drug therapies, formulary options, etc.
4. Educate patient on medication-related problems (e.g., side effects of medication, drug interactions)
5. Recognize need for referral to specialized healthcare provider for further evaluation/treatment

**F. Patient Monitoring Plan (23%)**

1. Design plan to monitor for safety, effectiveness, and achievement of therapeutic goals
2. Implement plan
3. Evaluate its effects on quality of life issues
4. Document steps and outcomes of pharmaceutical care plan

---

Promoting Excellence in Geriatric Health Care through Education and Certification.

1321 Duke Street | Suite 400 | Alexandria, VA 22314 | 703-535-3036



## Commission for Certification in Geriatric Pharmacy

ccgp.org

← [Consumer Center](#) | [Industry Center](#) | [Pharmacist Center](#) | [About CCGP](#) | [Contact Us](#)

[CCGP Home](#)

[Search CCGP](#)

[Certification Facts](#)

A PHARMACY TECHNICIAN is a category of supportive personnel that denotes a skilled worker who has been trained to assist the pharmacist in preparing and dispensing medications.



### Pharmacist Center - Certification

[certification](#) | [recertification](#) | [pharmacists listserve](#) | [geriatric practice award](#) | [exam offered in Australia](#) | [resources](#) | [self assessment exam](#) | [test your geriatric IQ](#) | [CCGP white paper](#)

### Exam Content

[Exam History](#) | [Exam Fees & Requirements](#) | [FAQs](#) | [Exam General Information](#) | [Test Center Locations & Dates](#) | [Exam Content](#) | [Request a Handbook](#) | [Examination Administration](#) | [Register Online](#)

To begin your preparation in an informed and organized manner, you should know what to expect from the actual examination in terms of the content. The content outline will give you a general impression of the examination and can give you specific study direction by revealing the relative importance given to each category on the examination.

- [Patient Specific Activities](#)
- [Disease Specific Activities](#)
- [Population Specific Activities](#)

#### Disease Specific Activities (53%)

The percent figures shown indicate the approximate question distribution within each of the content areas. The percent figures next to each content area show what percent of the disease-specific portion of the examination will be devoted to each disease area.

#### A. Cardiovascular Disorders - e.g., Hypertension, Heart Failure, Ischemic Heart Disease, Myocardial Infarction, Cardiac Arrhythmias, Hyperlipidemia, Peripheral Vascular Disease (11%)

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues, and recommend modifications in therapy as necessary

#### B. Dermatological Disorders - e.g., Pressure Ulcers, Drug-Induced Skin Disorders, Xerosis, Fungal Rashes, Other Common Skin Disorders (3%)

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors

4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues, and recommend modifications in therapy as necessary

**C. Endocrine and Exocrine Disorders - e.g., Thyroid Disorders, Diabetes Mellitus, SIADH, Disorders of the Adrenal Gland, Paget's Disease, Hormone Replacement Therapy (10%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues, and recommend modifications in therapy as necessary

**D. Gastrointestinal Disorders - e.g., Peptic Ulcer Disease, Gastro-Esophageal Reflux Disease, Diarrhea and Constipation, Irritable Bowel Syndrome, Inflammatory Bowel Disease, Hepatic Disorder (Cirrhosis), Pancreatitis, Cholelithiasis (7%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues, and recommend modifications in therapy as necessary

**E. Hematologic Disorders - e.g., Anemias, Disorders of Hemostasis, Thrombocytopenia, Disorders of White Blood Cells (5%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues, and recommend modifications in therapy as necessary

**F. Infectious Diseases - e.g., Pneumonia, Urinary Tract Infection, Tuberculosis, Herpes Zoster, Aids, Skin and Soft Tissue Infections, Hepatitis, Bone and Joint Infections, Genitourinary Tract Infection, Influenza, Ophthalmic Infections, Nosocomial Infections, Drug Resistance, Immunizations (9%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints,

quality of life issues, and recommend modifications in therapy as necessary

**G. Musculoskeletal Disorders - e.g., Osteoarthritis, Rheumatological Diseases, Osteoporosis, Gout, Acute and Chronic Pain, Foot Disorders (10%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary

**H. Neurological Disorders - e.g., Cerebrovascular Disease (Stroke, Transient Ischemic Attacks), Movement Disorders (Parkinson's Disease, Essential Tremor), Dementias (Alzheimer's Disease, Lewy Body Disease, Ischemic Vascular Dementia), Delirium, Seizure Disorders, Neuropathies, Acute and Chronic Pain Syndromes (11%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary

**I. Nutrition and Hydration Disorders - e.g., Malnutrition, Dehydration, Fluid and Electrolyte Disorders (5%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary

**J. Oncology - e.g., Breast Cancer, Skin Cancer, Prostate Cancer, Lung Cancer, Colorectal Cancer, Brain Tumors (3%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary

**K. Ophthalmology - e.g., Glaucoma, Dry Eyes, Blepharitis, Macular Degeneration, Cataracts (3%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary

**L. Psychiatric Disorders - e.g., Depression and Other Mood Disorders, Schizophrenia and Other Psychotic Disorders, Sleep Disturbances, Anxiety Disorders, Behavioral Disorders, Alcohol and Drug Abuse (11%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary

**M. Genitourinary Disorders - e.g., Urinary Incontinence, Benign Prostatic Hyperplasia, Sexual Dysfunction, Renal Failure (6%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary

**N. Respiratory Disorders - e.g., Chronic Obstructive Pulmonary Disease, Asthma (6%)**

1. Recognize common signs and symptoms
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmacoeconomics, quality of life, patient satisfaction)
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary

---

Promoting Excellence in Geriatric Health Care through Education and Certification.

1321 Duke Street | Suite 400 | Alexandria, VA 22314 | 703-535-3036



## Commission for Certification in Geriatric Pharmacy

ccgp.org

← Consumer Center

Industry Center

Pharmacist Center

About CCGP

Contact Us

CCGP Home

Search CCGP

Certification Facts

A clinical FELLOWSHIP program is a directed, highly individualized postgraduate training program designed to prepare the participant to become an independent researcher.



### Pharmacist Center - Certification

certification | recertification | pharmacists listserve  
geriatric practice award | exam offered in Australia | resources  
self assessment exam | test your geriatric IQ | CCGP white paper

### Exam Content

[Exam History](#) | [Exam Fees & Requirements](#) | [FAQs](#) | [Exam General Information](#)  
[Test Center Locations & Dates](#) | [Exam Content](#) | [Request a Handbook](#)  
[Examination Administration](#) | [Register Online](#)

To begin your preparation in an informed and organized manner, you should know what to expect from the actual examination in terms of the content. The content outline will give you a general impression of the examination and can give you specific study direction by revealing the relative importance given to each category on the examination.

- [Patient Specific Activities](#)
- [Disease Specific Activities](#)
- [Population Specific Activities](#)

#### Population Specific Activities (12%)

##### A. Research (33%)

1. Conduct drug use evaluations (DUE) and drug use review (DUR)
2. Apply DUE/DUR results to improve the quality of care
3. Evaluate and apply research pertinent to the elderly
4. Interpret and apply geriatric practice guidelines

##### B. Economics and Access (28%)

1. Develop and implement formulary management/protocols
2. Interpret pharmaco-economic data
3. Develop and implement practice guidelines
4. Evaluate costs/benefits issues that influence access to medications or therapy for specific patients

##### C. Health Policy (39%)

1. Communicate with healthcare professionals to improve quality of care
2. Ensure that privacy and confidentiality standards are maintained
3. Optimize the Continuum of Care process

Promoting Excellence in Geriatric Health Care through Education and Certification.

1321 Duke Street | Suite 400 | Alexandria, VA 22314 | 703-535-3036



# National Certification Board for Diabetes Educators

HANDBOOK

## 2010 Certification Examination for Diabetes Educators

### 2010 Examination Windows

May - June

November - December

### Application Windows

January 15 - March 15

July 15 - September 15



## 2010 Certification Examination for Diabetes Educators

GENERAL

### 2010 Initial Certification Requirements† Review

Please review before completing application.

NOTE: The Certification Examination for Diabetes Educators is designed and intended solely for health care professionals who have defined roles as diabetes educators, not for those who may perform some diabetes-related functions as part of or in the course of other usual and customary occupational duties.

†This review list represents a summary of requirements. See pages 5-6 for all details.

Yes      No

1. As a clinical psychologist, registered nurse, occupational therapist, optometrist, pharmacist, physical therapist, physician, podiatrist, registered clinical exercise physiologist (minimum of a master's degree), registered dietitian, or registered physician assistant, is your license or registration current, active and unrestricted?\*

**OR**

Do you hold a minimum of a qualifying master's degree from a United States college or university accredited by a nationally recognized regional accrediting body in social work?\*

2. Has your practice experience occurred within the United States or its territories?
3. Has all your practice experience occurred since you met requirement #1 above?
4. Do you have a minimum of 2 calendar years (to the day) of practice experience since you received the license, registration or advanced degree as outlined above (within the last 4 years)?
5. Have you accrued 1,000 hours of practice experience in diabetes self-management education (DSME) within the last 4 years?
6. Has a minimum of 40% (or 400 hours) of the 1,000 hours of DSME practice experience been accrued within the past year?
7. Have you completed a minimum of 15 hours of continuing education activities\*\*\* applicable to diabetes within the past 2 years?

**If the answer to any of the above questions is "no", you are not ready to apply for the Certification Examination for Diabetes Educators.**

**Before submitting an application, please refer to the application checklist on page 25 in the instruction section of the Handbook.**

\* See Eligibility Requirements for Initial Certification, page 5, 1. A. or B. for specific licensure/registration requirements.

\*\*See Eligibility Requirements for Initial Certification, page 5, 1. D. for note regarding advanced degrees in nutrition, public health or health education. Please review before completing application.

\*\*\* See Continuing Education Guidelines, page 19, for details.



## **Appendix III**

### **Examination Content Outline**

#### **I. Assessment (45)**

- A. Assess Learning/Self-Care Behaviors (15)
  - 1. Goals and learning needs
  - 2. Learning readiness (attitudes, developmental level, perceived learning needs, etc.)
  - 3. Learning style
  - 4. Barriers to learning (literacy level, language, cultural values, religious beliefs, health beliefs, psycho-socioeconomic, family dynamics, etc.)
  - 5. Physical capabilities/limitations (visual acuity, hearing, functional ability, etc.)
  - 6. Readiness to change behavior (confidence in ability to change, value in change, etc.)
- B. Assess Medical/Health/Psycho-Socioeconomic Status (10)
  - 1. Collect diabetes-specific health history (duration, symptoms, complications, adherence to standards of care, treatment, etc.)
  - 2. Collect general health history (family history, allergies, medical history, nutrition history, etc.)
  - 3. Assess previous and current medication regimen (prescription and nonprescription drugs, herbals, alternative remedies, adverse reactions, etc.)
  - 4. Assess treatment fears (hypoglycemia, hyperglycemia, needles, weight gain, etc.)
  - 5. Assess family/caregiver dynamics and social supports
  - 6. Assess substance use (alcohol, tobacco, caffeine, etc.)
  - 7. Assess psychosocial/ developmental/mental health status (adjustment to diagnosis, etc.)
  - 8. Identify specific barriers to diabetes self-care regimen (cognitive ability, language, cultural, psychosocial, physical, economic, etc.)
  - 9. Conduct diabetes-specific physical assessment (lower extremities, injection and blood glucose monitoring sites, blood pressure, weight, height, body mass index, acanthosis nigricans, etc.)
  - 10. Assess laboratory and patient collected data (blood glucose, A1C, lipid profile, renal/liver function, trends, meter, pump, sensor, etc.)
- C. Assess Current Knowledge and Practices Related to Diabetes Care (20)
  - 1. Diabetes knowledge and self-management skills
  - 2. Nutritional habits (food and beverage choices, portion sizes, timing of meals and snacks, eating environment, etc.)
  - 3. Exercise/physical activity history and/or level
  - 4. Monitoring techniques and equipment (blood glucose and ketones, etc.)
  - 5. Record keeping activities (blood glucose, food, activity, etc.)
  - 6. Medication administration (oral and injectable medications administration technique, use of delivery systems, timing and dosage of medication, adherence, etc.)
  - 7. Use of health care resources (health care professionals, insurance, etc.)

#### **II. Intervention (112)**

- A. Collaborate with Patient/Family/Caregiver/Healthcare Team to Develop: (14)
  - 1. Individualized diabetes education plan based on assessment (learning objectives, sequence of information, selection of content, communication, etc.)
  - 2. Instructional methods (discussion, demonstration, role playing, simulation, electronic media, etc.)
  - 3. Behavioral goals
- B. Teach/Counsel Regarding Principles of Diabetes Care (70)
  - 1. General issues
    - a) Classifications and diagnosis (ADA Guidelines)
    - b) Modifiable risk factors (lifestyle behaviors, etc.)
    - c) Pathophysiology (auto-immunity, MODY, insulin resistance, fuel metabolism, etc.)
    - d) Interaction of physical activity, food, medication, and stress
    - e) Treatment options (choices, availability, cost, risk/benefit, etc.)
    - f) Goals of treatment (blood glucose, A1C, blood pressure, lipids, quality of life, prevention, etc.)
    - g) Purpose of laboratory tests (A1C, lipids, kidney and liver function tests, etc.)
  - 2. Living with diabetes
    - a) Psychosocial adaptation (coping skills, depression, anxiety, etc.)
    - b) Role/responsibilities of care (patient, family members, team, etc.)
    - c) Decision making/behavior change skills
    - d) Safety (sharps disposal, medical ID, driving, etc.)
    - e) Hygiene (dental/skin/feet, etc.)
    - f) Social/Financial issues (employment, insurance, disability, etc.)
  - 3. Metabolic monitoring
    - a) Glucose (testing sites, meter selection, sensor, etc.)
    - b) A1C
    - c) Blood pressure
    - d) Regimen and record keeping (pattern management, etc.)
    - e) Lipids/cholesterol
    - f) Liver/Renal monitoring (liver function studies, microalbuminuria, creatinine, etc.)
  - 4. Nutrition principles and guidelines
    - a) American Diabetes Association nutrition recommendations (meal planning, macro/micronutrients, etc.)
    - b) Carbohydrates in blood glucose control (postprandial blood glucose, food source, sugar substitutes, fiber, carbohydrate counting, etc.)
    - c) Lipid management (total fat, saturated fat, monounsaturated fat, etc.)
    - d) Protein intake (renal disease, wound care, etc.)



## 2010 Certification Examination for Diabetes Educators

- e) Food and medication integration
  - f) Food label interpretation (nutrition facts, ingredients, health claims, etc.)
  - g) Alcohol
  - h) Principles of weight management
  - i) Changes in daily schedules (problem-solving)
  - j) Special considerations (gastroparesis, celiac, etc.)
  - 5. Physical activity
    - a) Benefits, barriers, and precautions
    - b) Exercise/activity plan
    - c) Post exercise delayed onset hypoglycemia
    - d) Food/medication/monitoring adjustment
  - 6. Pharmacologic management of diabetes
    - a) Medications (insulin, oral and injectable medication administration, side effects, etc.)
    - b) Delivery systems (pump therapy, devices, etc.)
    - c) Medication adjustment
    - d) Drug interactions
    - e) Non-prescription preparations (over the counter drugs, supplements, vitamins, minerals, herbals, etc.)
  - 7. Acute complications: prevention and treatment
    - a) Hypoglycemia (glucose tablets, glucagon, etc.)
    - b) Hyperglycemia (inpatient, outpatient, etc.)
    - c) Diabetic ketoacidosis (DKA)
    - d) Hyperglycemic hyperosmolar nonketotic syndrome (HHNS)
  - 8. Chronic complications: prevention and treatment
    - a) Screening and prevention of complications (smoking, hypertension, etc.)
    - b) Eye disease (retinopathy, cataracts, glaucoma, etc.)
    - c) Sexual dysfunction
    - d) Neuropathy (autonomic, peripheral, etc.)
    - e) Nephropathy
    - f) Vascular disease (cerebral, cardiovascular, peripheral, etc.)
    - g) Lower extremity problems (foot ulcers, Charcot foot, etc.)
  - 9. Special management issues
    - a) Honeymoon period, dawn phenomenon, Somogyi effect
    - b) Hypoglycemia unawareness
    - c) Sick days
    - d) Surgery and special procedures
    - e) Travel
    - f) Geriatrics populations
    - g) Pre-conception planning, pregnancy, and gestational diabetes
    - h) Co-morbidities (hypertension, depression, thyroid disease, celiac, obesity, etc.)
    - i) Dental and gum disease
    - j) Skin problems (wound care, yeast infection, ulcers, etc.)
    - k) Changes in usual schedules (shift, religious and cultural customs, etc.)
    - l) Assistive and adaptive devices (talking meter, magnifier, etc.)
    - m) Sleep apnea
  - 10. Interpret current diabetes research and translate findings into practical applications
  - C. Review, Evaluation, Revision, and Documentation (14)
    - 1. Interpret weight changes, blood glucose, food, medication, and physical activity records
    - 2. Evaluate effectiveness of teaching in the following:
      - a) Achievement of objectives
      - b) Progress towards behavioral goals
      - c) Self-management skills
      - d) Psychosocial adaptation
    - 3. Document results of assessment, intervention, and outcomes
    - 4. Establish an ongoing plan for achieving and evaluating objectives and behavioral goals
  - D. Follow-up and Referral Recommendations (14)
    - 1. Identify problems requiring intervention by other health care professionals
      - a) Medical nutrition therapy
      - b) Exercise prescription
      - c) Mental health
      - d) Medical care (foot care, dilated eye exam, pre-conception counseling, etc.)
      - e) Financial and social services
      - f) Risk reduction (smoking cessation, obesity, preventative services, etc.)
      - g) Medication consult
      - h) Discharge planning, home care, community resources (visual, hearing, language, etc.)
    - 2. Facilitate communication between patient, providers, and referral source to ensure health care and education needs are addressed
    - 3. Facilitate access for diabetes support: groups, camps, community resources, etc.
- ### III. Program Development and Administration (18)
- A. Diabetes Patient Education Program (8)
    - 1. Perform needs assessment (target population, etc.)
    - 2. Develop curriculum (identify program goals, content outline, lesson plan, teaching materials, etc.)
    - 3. Choose teaching methods and materials for target populations
    - 4. Market and promote diabetes patient education program
    - 5. Maintain patient information/demographic database
    - 6. Ensure patient confidentiality (HIPAA, etc.)
    - 7. Promote standards of care
    - 8. Implement infection control principles
  - B. Evaluate Outcomes and Quality (6)
    - 1. Program outcomes (number of people served, provider satisfaction, patient satisfaction, effectiveness of diabetes education materials, etc.)
    - 2. Patient outcomes (behavior changes, A1C, lipids, weight, quality of life, ER visits, decreased work absences, etc.)
    - 3. Continuous quality improvement activities
  - C. Promote Diabetes Advocacy (4)
    - 1. Health fairs
    - 2. Workplace (identify and eliminate discrimination)

EFFECTIVE DATE: 6/2005	<b>DEPARTMENT OF PHARMACY</b>  <b>POLICY &amp; PROCEDURE</b>	SECTION: Pharmacy & Therapeutics
REVIEW DATE:		Page 1 of 4
<b><u>PHARMACIST-MANAGED DRUG THERAPY PROTOCOL</u></b>		

**PROTOCOL:**

To optimize aminoglycoside and vancomycin therapy the pharmacist may order the drug dosage and related drug-levels and serum creatinine (SCr) for the purposes of monitoring a patient's therapy with aminoglycosides or vancomycin.

Prescribers may request on the Anti-Infective Order Form that pharmacists assist in managing aminoglycoside or vancomycin therapy as outlined in this protocol. This protocol is not a substitution for continued monitoring by physicians.

**PROCEDURE:**

I. Aminoglycoside Protocol: Prescribers may order therapy with aminoglycoside antibiotics using the Anti-Infective Order Form in one of two ways:

- Order the drug and dosage on the Anti-Infective Order Form and any serum levels to monitor the therapy him/herself.
- Order the drug on the Anti-Infective Order Form and request in the Monitoring Section that a pharmacist adjust the dosage and order laboratory values for the purposes of monitoring therapy per protocol.

A. Upon receipt of an aminoglycoside per protocol order, the pharmacist will assess the treatment indication and patient variables in order to determine the most appropriate dosage. The pharmacist will:

- a. Choose one of two dosing methodologies "extended interval dosing (EID)" or "traditional" dosing if dosing method is not specified.

The following patient types will be excluded from EID aminoglycoside therapy: Dosing in these patients will utilize traditional pharmacokinetic methods and peak/trough monitoring unless specifically ordered as EID by the physician.

1. Patients with predicted creatinine clearance less than 40ml/min
  2. Patients receiving aminoglycosides for synergy in the treatment of gram-positive microorganisms.
  3. Pediatrics
  4. Pregnant patients
  5. Cystic fibrosis patients
  6. Patients with ascites, extensive edema or any other condition where the volume status is unclear
- b. Base the dosage on an actual body weight or an adjusted weight [IBW + 0.4(TBW-IBW)] for patients >20% over ideal weight.
  - c. Calculate the appropriate mg/kg dose (EID) or dose based on pharmacokinetic calculations (traditional). Therapy may be initiated with an EID dose for gentamicin/tobramycin 7 mg/kg or amikacin 20mg/kg or a traditional dose for

EFFECTIVE DATE: 6/2005	<b>DEPARTMENT OF PHARMACY</b>	SECTION: Pharmacy & Therapeutics
REVIEW DATE:		Page 2 of 4
<b><u>PHARMACIST-MANAGED DRUG THERAPY PROTOCOL</u></b>		

gentamicin/tobramycin of 1.5-2 mg/kg or amikacin 7.5mg/kg. The maintenance regimen may be ordered as time allows, but always prior to the next anticipated dose (within 8-12 hours if using traditional dosing).

- d. Write the order or any changes to the order in the physician's orders in the patient chart after the regimen has been determined.
- e. Record a "Pharmacy Note" the physician progress notes section of the patient's chart that includes information similar to the following:

*Pharmacy Note: Gentamicin Extended Interval Dosing*

*S: Gentamicin initiated per protocol for (indication)*

*O: 65 y/o male, wt=74kg, ht=5'9", SCr=1.3, WBC, temp estimated CrCl, cultures pending, other pertinent labs*

*A: Patient meets protocol criteria for extended interval dosing at 7mg/kg.*

*P: Gentamicin 520 mg q 24 H. Will monitor clinical response, and renal function. Plan to reassess level in 3-5 days unless renal function changes; repeat level and refer to nomogram at that time.*

- B. The pharmacist will log the patient's name and appropriate information in the pharmacy monitoring notes. On a daily basis, a pharmacist checks the sheets for any protocol orders needing follow up, completes the follow up, and updates the patient chart and monitoring sheet. Follow-up and monitoring continues until the aminoglycoside therapy is discontinued.
- C. Provided therapy continues, levels will be obtained in the following manner:
  - a. EID: A drug level will be obtained 6 – 14 hours after the initial dose and the pharmacist will refer to the Hartford Nomogram published in the Antibiotic Use Guide to determine if dosing adjustments are required.
  - b. Traditional dosing: Peak and trough levels will be ordered after initiation of therapy prior to the third or fourth dose, or earlier at the discretion of the pharmacist and the physician
  - c. In cases of significant renal impairment, random troughs will be requested to determine timing of next dose.
- D. If therapy is continued, the pharmacist will assess the level and communicate his/her recommendation regarding further dosing.
  - a. An order will be written by the pharmacist if a dosing adjustment is needed.
  - b. A progress note that is appropriate to the levels and the patient's response will be recorded by the pharmacist:

*Pharmacy Note: Traditional Dosing*

*S: Gentamicin initiated per protocol for (indication)*

EFFECTIVE DATE: 6/2005	DEPARTMENT OF PHARMACY  POLICY & PROCEDURE	SECTION: Pharmacy & Therapeutics
REVIEW DATE:		Page 3 of 4
<b><u>PHARMACIST-MANAGED DRUG THERAPY PROTOCOL</u></b>		

*O: 65 y/o male, wt=74kg, ht=5'9", SCr=1.3, estimated CrCl, cultures pending, other pertinent labs, drug levels, WBC, temp  
A: Drug levels are within appropriate desired peak \_\_\_ and trough \_\_\_.  
P: Continue with gentamicin 120 mg q 8 H. Will monitor clinical response, and renal function. May need to reassess drug level if renal function changes.*

- c. The pharmacist may confer with the physician to determine the most appropriate adjustment to the dosage regimen.
- II. Vancomycin Protocol: Prescribers may order therapy with injectable vancomycin using the Anti-Infective Order Form in one of two ways:
- Order the drug and dosage on the Anti-Infective Order Form and any serum levels to monitor the therapy him/herself.
  - Order the drug on the Anti-Infective Order Form and request in the Monitoring Section that a pharmacist adjust the dosage and order laboratory values for the purposes of monitoring therapy per protocol.
- A. Upon receiving orders for vancomycin per protocol, the pharmacist will:
- a. Calculate the appropriate dosage. Therapy may be initiated with a dose of 15-20 mg/kg with the maintenance regimen ordered as time allows, but always within 12 hours of the initial dose.
  - b. Write the order in the physician's orders in the patient chart after the regimen has been determined.
  - c. Record a "Pharmacy Note" in the progress notes of the patient's chart that includes information similar to the following:  
  
*Pharmacy Note: Vancomycin Dosing  
S: Vancomycin Initiated per Protocol for (Indication)  
O: Culture results, patient's age, sex, height, weight, creatinine, estimated CrCl, and other pertinent labs, WBC, temp  
A: Calculated regimen of \_\_\_\_\_ is predicted to produce troughs within the desired range of 5-15 mcg/mL.  
P: Will monitor clinical response and renal function. A single trough level will be ordered (date/time). May need to reassess drug level if renal function changes.*
- B. The pharmacist will log the patient's name and appropriate information in the pharmacy monitoring notes. On a daily basis, a pharmacist checks the sheets for any protocol orders needing follow up, completes the follow up, and updates the patient chart and monitoring sheet. Follow-up and monitoring continues until the vancomycin therapy is discontinued.
- C. Provided therapy continues levels will be monitored in the following manner:

EFFECTIVE DATE: 6/2005	<u>DEPARTMENT OF PHARMACY</u>  POLICY & PROCEDURE	SECTION: Pharmacy & Therapeutics
REVIEW DATE:		Page 4 of 4
<b><u>PHARMACIST-MANAGED DRUG THERAPY PROTOCOL</u></b>		

- a. A trough level will be ordered after the patient has achieved steady state (approximately 48 hours after the initiation of therapy or prior to the 3<sup>rd</sup> dose - whichever is longer), or sooner if clinically indicated. This will be the usual, standard monitoring method.
  - b. In certain situations, a peak may be requested to facilitate monitoring.
  - c. In cases of significant renal impairment, random troughs will be requested to determine timing of next dose.
- D. If therapy is continued, the pharmacist will assess the level and communicate his/her recommendation regarding further dosing.
- a. An order will be written by the pharmacist if a dosing adjustment is needed.
  - b. A progress note that is appropriate to the levels and the patient's response will be recorded by the pharmacist:

*Pharmacy Note: Vancomycin Dosing*

*S: Vancomycin Initiated per Protocol for (Indication)*

*O: Currently receiving (dose) mg, trough level is reported as \_\_\_\_\_.*

*A: Trough level is higher/lower than desired. A(n) (increase/decrease) to (dose) would be anticipated to produce a desired trough of 5-15 mcg/mL.*

*P: Change dose to \_\_\_\_\_. Will continue to monitor renal function, response, and follow-up levels until therapy discontinued.*

- c. The pharmacist may confer with the physician to determine the most appropriate adjustment to the dosage regimen.

**REFERENCES:**

Nicolau, DP, Freeman, CD, Belliveau, PP, et al. Experience with a once-daily aminoglycoside program administered to 2,184 adult patients. *Antimicrobial Agents and Chemotherapy*. 1995; 39:650-655.

**RESPONSIBLE FOR REVIEW:** Pharmacy Clinical Coordinator, Antibiotic Subcommittee

\_\_\_\_\_  
DIRECTOR OF PHARMACY

\_\_\_\_\_  
DATE

\_\_\_\_\_  
CHAIR OF PHARMACY & THERAPEUTICS COMMITTEE

\_\_\_\_\_  
DATE

## Clinical Pharmacist Practitioner Protocol

**Supervising Physician: Racquel T. Tonuzi, MD**

**Clinical Pharmacist Practitioner: Amy H. Brian, PharmD, CGP, CPP**

The following protocol outlines the medication and laboratory prescribing privileges granted to Amy H. Brian, PharmD, CPP by Racquel T. Tonuzi, MD for patients referred to Cornerstone Health Care, High Point, NC 27262.

Patients who have been referred to Dr. Brian by Dr. Tonuzi with the following diagnoses may be seen and treated by Dr. Brian with medication therapies as outlined below:

<u>Diagnosis</u>	<u>ICD-9 Code</u>
Supraventricular tachycardia	427.0
Atrial fibrillation	427.31
Atrial flutter	427.32
Thromboembolism	451.19
Pulmonary embolus	415.1
Joint replacement	V43.60
Hip	V43.64
Knee	V43.65
Shoulder	V43.61
Anticoagulants	286.5
Vitamin K deficiency/Coumadin	286.7
Cerebrovascular accident	436
Transient ischemic attack	435.9
Heart valve replacement	V43.3
Coagulopathy	425.4
Coagulation disorder-unspecified	286.9
Neoplasm	199.1
Peripheral vascular disease	443.9
Metabolic syndrome	277.7
Diabetes	250.01, 250.03, 250.00, 250.02
Hyperlipidemia	272.4
Hypertension	401.1
Anemia	285.9
Chronic kidney disease	585.1, 585.2, 585.3, 585.4

Medications authorized by Dr. Tonuzi for written and telephone prescriptions by Clinical Pharmacist Practitioner: Amy H. Brian, PharmD, CPP are listed below. Authorized medications are grouped by therapeutic category. All medications listed in the latest edition of *Drug Facts and Comparisons* and *LexiComp Drug Information Handbook* are authorized for prescribing. *LexiComp Drug Information Handbook* is updated monthly via electronic device by Dr. Brian and will be maintained on site at all times while Dr. Brian is present.

Groups of medications included for prescribing include:

**Antiplatelet agents**  
**Anticoagulants**  
**Low molecular weight heparins**  
**Unfractionated heparin**

**Vitamin K**

**NOTE: Supervising MD initials required**

Iron supplements  
Erythropoietic agents

Non-steroidal anti-inflammatory agents  
Cox-2 inhibitors  
Hydrocodone/APAP combinations  
Propoxyphene/APAP combinations

Sulfonylureas  
Insulins  
Thiazolidinediones  
Biguanides  
Alpha-glucosidase inhibitors

HMG-CoA reductase inhibitors  
Fibric acid derivatives  
Niacin  
Bile acid sequestrants

Diuretics  
Antiadrenergics/sympatholytics  
ACE inhibitors  
Angiotensin II receptor antagonists  
Calcium channel blockers  
Vasodilators  
Beta Blockers

H2 antagonists  
Proton pump inhibitors  
Anti-spasmodics

Corticosteroids, inhalers or oral  
B agonist inhalers  
Anticholinergic inhalers

Product selection within the drug class will be permitted. Substitution of chemically dissimilar products is not permitted without physician authorization.

#### **Laboratory tests and monitoring**

The following tests that may be ordered as related to identified medication therapy include:

<b>Test</b>	<b>Medication</b>
Factor V Leiden	anticoagulants
Protein C (functional)	anticoagulants
Protein S (functional)	anticoagulants
Antithrombin III	anticoagulants
Antiphospholipid antibody	anticoagulants
Homocysteine	anticoagulants
Lupus anticoagulant	anticoagulants
PT/INR	anticoagulants
aPTT	anticoagulants/heparins
d-dimer	anticoagulants
Complete blood count	anticoagulants

**NOTE: Supervising MD initials required**

Liver function panel	anticoagulants/HMG CoA reductase inhibitors/sulfonylureas/thiazolidinediones
Complete/basic metabolic panel	anticoagulants/diuretics/ACE inhibitors
Urinalysis	anticoagulants
Fecal occult blood	anticoagulants
Hemoglobin A1C	antidiabetic agents
Lipid panel	antihyperlipidemic agents
Urine microalbumin	antidiabetic agents
C-peptide	antidiabetic agents
Islet cell antibodies	antidiabetic agents

**Plan for Emergencies**

In the event of an emergency, Dr. Tonuzi or her designee will be notified immediately. If the emergency is life-threatening, the patient will be transported to High Point Regional Hospital, 601 N. Elm St., High Point, NC.

**Weekly Plan for Quality Control, Review and Countersignature of all Orders**

Dr. Tonuzi and Dr. Brian will meet weekly (at minimum) at a mutually agreed upon time to review cases of patients seen in the preceding 7 days.

**Patient Notification**

Patients will be notified of the collaborative nature of their care when they are referred from their primary care physician or Dr. Tonuzi to Dr. Brian.

**Termination Provision**

This agreement will be terminated in the following situations:

1. At the written request of either Dr. Tonuzi or Dr. Brian.

\_\_\_\_\_  
Racquel T. Tonuzi, MD

\_\_\_\_\_  
Amy H. Brian, PharmD, CPP

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

This protocol also covers the following physicians within the same medical group practice:

\_\_\_\_\_  
Grace E. Terrell, MD

\_\_\_\_\_  
Richard L. Orr, MD

\_\_\_\_\_  
Robert A. Rostand, MD

**NOTE: Supervising MD initials required**