

Title: Medication Therapy Management
in Pharmacy Practice (Declaratory Statement)

Policy No. I.A.19

Approved: 08-06-2014

Revised:

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Pursuant to a petition considered during its May 2014 meeting, the Board considered the principles and several applications of medication therapy management in the practice of pharmacy relative to the scope of practice of pharmacy in Louisiana. Following substantial discussion during their deliberations on August 6, 2014, Mr. McKay moved to approve the declaratory statement as amended. The motion was adopted after a unanimous vote in the affirmative. The full text of the declaratory statement approved by the Board follows:

In response to multiple requests for opinions as to whether a variety of medication management activities are within the scope of practice of pharmacy, the Board now issues a Declaratory Statement relative to medication therapy management.

The Louisiana Legislature has established a definition of the '*practice of pharmacy*' in the Louisiana Pharmacy Practice Act: it means and includes the compounding, filling, dispensing, exchanging, giving, offering for sale, or selling drugs, medicines, or poisons, pursuant to prescriptions or orders of physicians, dentists, veterinarians, or other licensed practitioners, or any other act, service operation or transaction incidental to or forming a part of any of the foregoing acts, requiring, involving or employing the science or art of any branch of the pharmacy profession, study, or training. [La. R.S. 37:1164(41)]

A review of the definition above reveals intentionally broad language to provide the latitude necessary for the Board to interpret its law and regulations to include contemporary practice standards which benefit the public's health, safety and welfare.

As the education and practice of pharmacy has evolved, the pharmacy profession sought consensus on a description of a collection of professional services that may or may not include the dispensing of a drug or device. The term ultimately selected was Medication Therapy Management (MTM). In July 2004, the Joint Commission of Pharmacy Practitioners issued *Medication Therapy Management – Core Elements of an MTM Service Model*. The commission issued its second version of that document in March 2008. Appendix A of that document contains a description and definition of MTM:

Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.

Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice. These services include but are not limited to the following, according to the individual needs of the patient:

- a. Performing or obtaining necessary assessments of the patient's health status*
- b. Formulating a medication treatment plan*
- c. Selecting, initiating, modifying, or administering medication therapy*
- d. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness*
- e. Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events*

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- f. Documenting the care delivered and communicating essential information to the patient's other primary care providers*
- g. Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications*
- h. Providing information, support services, and resources designed to enhance patient adherence with his/her therapeutic regimens*
- i. Coordinating and integrating medication therapy management services within the broader healthcare management services being provided to the patient*

It is important to note this service model is applicable in all sectors of pharmacy practice, and further, that such cognitive and non-dispensing services requires only a pharmacist license. No pharmacy permit is required. Evidence of this can be found in §525 of the Board's rules relative to cognitive services. Pharmacist office-based practices already exist in this state and elsewhere in the U.S. Of course, pharmacies may also offer these services in conjunction with medication dispensing services.

"Cognitive Services" – those acts and operations related to a patient's drug therapy that are judgmental in nature, based on knowledge, and derived from empirical factual information. Such services may include, but are not necessarily limited to, the following:

- a. Drug regimen review, drug use evaluation and drug information;
- b. Provision of advice and counsel on drug, the selection and use thereof (...) regarding the appropriateness, use, storage, handling, administration and disposal of drugs (...);
- c. Participation in the development of policies and procedures for drug therapy (...) including storage, handling, administration and disposing of drugs and devices;
- d. Assuring the compliance with all applicable laws, rules, and regulations;
- e. Provision of educational and drug information sources (...); and
- f. Accepting responsibility for the implementation and performance of review of quality-related or sentinel events.

[LAC 46:LIII.525.A]

It is also important to note that MTM services may be performed by a pharmacist without the necessity of a collaborative drug therapy management (CDTM) agreement with a physician; however, such an agreement may include MTM services and may actually facilitate or even improve the provision of such services.

"Collaborative Drug Therapy Management" – that practice in which a pharmacist voluntarily agrees with a physician to manage the disease specific drug therapy of one or more patients of such physician, within a predetermined range of medication selected by the physician and set forth in a patient specific written order set. Drug therapy management shall be limited to:

- a. Monitoring and modifying a disease specific drug therapy;
- b. Collecting and reviewing patient history;
- c. Obtaining and reviewing vital signs, including pulse, temperature, blood pressure, and respiration;

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- d. Ordering, evaluating, and applying the results of laboratory tests directly related to the disease specific drug therapy being managed under an order set, provided such tests do not require the pharmacist to interpret such testing or formulate a diagnosis; and
 - e. Providing disease or condition specific patient education and counseling.
- [LAC 46:LIII.523.A]

The performance of some MTM services may bring a pharmacist close to the line of demarcation that exists between the scopes of practice of medicine and pharmacy; indeed, those inquiries have prompted the issuance of this declaratory statement. In an effort to provide guidance to pharmacists and help them maintain compliance with the laws governing the practice of pharmacy, the following clarifications are offered.

- A. The pharmacist may interview a patient or his caregiver to collect a broad range of relevant information, including:
 - A current medication list and medication use history for prescription and nonprescription medications, herbal products, and other dietary supplements;
 - Relevant health data that may include medical history, health and wellness information, biometric test results, and physical assessment findings; and
 - Patient lifestyle habits, preferences and beliefs, health and functional goals, and socioeconomic factors that affect access to medications and other aspects of care.
- B. With respect to the solicitation or ordering of laboratory testing, a pharmacist may offer general health screenings for blood glucose, cholesterol, or other assessments which bear a CLIA (Clinical Laboratory Improvement Amendments of 1988) designation of either waived or moderately complex. However, a pharmacist may not order an assessment bearing a CLIA designation of highly complex.
 - An exception to the restriction on the solicitation of highly complex laboratory testing could exist within a properly constructed CDTM agreement wherein a physician delegates his authority to the pharmacist to order highly complex laboratory assessments.
 - Another exception to the restriction on the solicitation of highly complex laboratory testing could exist in a practice setting of a hospital or other organized health care setting wherein the medical staff has approved policies and procedures authorizing pharmacists to order such tests.
- C. With respect to the analysis or evaluation of results of laboratory testing, a pharmacist may perform such analysis and evaluation for the purpose of monitoring previously prescribed medication therapy; however, a pharmacist may not formally interpret such testing to establish a diagnosis.
- D. A pharmacist may develop a medication treatment plan and submit such plan to the patient's physician or other primary healthcare practitioner.