RULE ANALYSIS

Introduction: **THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE**

Short Title: Central Prescription Drug or Medication Order Processing Pharmacy (Class G)

Rule Numbers: §291.153

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, Occupations Code:

(1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
(2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, provide for the provision of medication therapy management services in Class G pharmacies and update a reference to pharmacy technician certification.

The Board reviewed and voted to propose the amendments during the November 6, 2018, meeting. The proposed amendments were published in the January 4, 2019, issue of the *Texas Register* at 44 TexReg 48-52.

TITLE 22 EXAMINING BOARDS
PART 15 TEXAS STATE BOARD OF PHARMACY
CHAPTER 291 PHARMACIES
SUBCHAPTER H OTHER CLASSES OF PHARMACY

§291.153. Central Prescription Drug or Medication Order Processing Pharmacy (Class G).

The Texas State Board of Pharmacy proposes amendments to §291.153, concerning Central Prescription Drug or Medication Order Processing Pharmacy (Class G). The amendments, if adopted, provide for the provision of medication therapy management services in Class G pharmacies and update a reference to pharmacy technician certification.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to allow Class G pharmacies to provide medication therapy management services to patients, which will increase patient access to comprehensive, patient-specific pharmaceutical care services. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendment will be in effect, Ms. Benz has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does not create a new regulation;

(6) The proposed rule expands an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule may positively affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Assistant General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., February 3, 2019.

The amendments are proposed under §§551.002, 554.051, and 562.1011 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.153.Central Prescription Drug or Medication Order Processing Pharmacy (Class G).

(a) Purpose.

(1) The purpose of this section is to provide standards for a centralized prescription drug or medication order processing pharmacy**, including a pharmacy that provides medication therapy management services in accordance with the requirements of this section**.

(2) Any facility established for the primary purpose of processing prescription drug or medication drug orders **or conducting medication therapy management services** shall be licensed as a Class G pharmacy under the Act. A Class G pharmacy shall not store bulk drugs, or dispense a prescription drug order. Nothing in this subsection shall prohibit an individual pharmacist employee who is licensed in Texas from remotely accessing the pharmacy's electronic data base from a location other than a licensed pharmacy in order to process prescription or medication drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records, and the Texas-licensed pharmacist does not engage in the receiving of written prescription or medication orders or the maintenance of prescription or medication drug orders at the non-licensed remote location.

(b) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the Act.

(1) Centralized prescription drug or medication order processing--The processing of a prescription drug or medication orders by a Class G pharmacy on behalf of another pharmacy, a health care provider, or a payor. Centralized prescription drug or medication order processing does not include the dispensing of a prescription drug but includes any of the following:

(A) receiving, interpreting, or clarifying prescription drug or medication drug orders;

(B) data entering and transferring of prescription drug or medication order information;

(C) performing drug regimen review;

(D) obtaining refill and substitution authorizations;

(E) verifying accurate prescription data entry;

(F) interpreting clinical data for prior authorization for dispensing;

(G) performing therapeutic interventions; and

(H) providing drug information concerning a patient's prescription.

(2) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or, if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(3) Medication Therapy Management (MTM) Services--Pharmaceutical care services that are independent of, but may occur in conjunction with, the dispensing of a drug or device, and are provided by a pharmacist to optimize therapeutic outcomes for individual patients. MTM services do not include drug therapy management under §295.13 of this title. MTM services include, but are not limited to, the following patient-specific activities delivered in an interaction between the patient and the pharmacist:

(A) identifying and resolving barriers regarding the patient's access to medication;

(B) identifying and resolving barriers regarding the patient's medication adherence;

(C) coordination of the patient's medication therapy to improve continuity of care, especially when prescribed multiple medications from multiple practitioners, or for multiple disease states or conditions, including effective communication with prescribers to develop a uniform plan of care;

(D) performing a comprehensive medication therapy review at each patient encounter to determine the effectiveness of the patient's medication and evaluate any drug-related problems or adverse drug events;

(E) providing education, counseling, or training to the patient or patient's caregiver to understanding of health conditions and appropriate medication use;

(F) formulating medication treatment plans for the patient;

(G) performing follow-up procedures to monitor and evaluate the patient's response to medication therapy, safety and effectiveness;

(H) documenting the patient's MTM session; and

(I) providing an individualized documentation of the MTM session to the patient or patient's caregiver.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each Class G pharmacy shall have one pharmacist-in-charge who is employed on a full-time basis, who may be the pharmacist-in-charge for only one such pharmacy.

(B) Responsibilities. The pharmacist-in-charge shall have responsibility for the practice of pharmacy at the pharmacy for which he or she is the pharmacist-in-charge. The pharmacist-in-charge may advise the owner on administrative or operational concerns. The pharmacist-in-charge shall have responsibility for, at a minimum, the following:

(i) educating and training pharmacy technicians and pharmacy technician trainees;

(ii) maintaining records of all transactions of the Class G pharmacy required by applicable state and federal laws and sections;

(iii) adhering to policies and procedures regarding the maintenance of records in a data processing system such that the data processing system is in compliance with Class G pharmacy requirements; and

(iv) legally operating the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy.

(2) Owner. The owner of a Class G pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(A) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(B) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by sufficient number of additional licensed pharmacists as may be required to operate the Class G pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities.

(iii) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and pharmacy technician trainees and for designating and delegating duties, other than those listed in subparagraph (B) of this paragraph, to pharmacy technicians and pharmacy technician trainees. Each pharmacist shall be responsible for any delegated act performed by pharmacy technicians and pharmacy technician trainees under his or her supervision.

(iv) Pharmacists shall directly supervise pharmacy technicians and pharmacy technician trainees who are entering prescription data into the pharmacy's data processing system by one of the following methods.

(I) Physically present supervision. A pharmacist shall be physically present to directly supervise a pharmacy technician or pharmacy technician trainee who is entering prescription order or medication order data into the data processing system. Each prescription or medication order entered into the data processing system shall be verified at the time of data entry.

(II) Electronic supervision. A pharmacist may electronically supervise a pharmacy technician or pharmacy technician trainee who is entering prescription order or medication order data into the data processing system provided the pharmacist:

(-a-) is on-site, in the pharmacy where the technician/trainee is located;

(-b-) has immediate access to any original document containing prescription or medication order information or other information related to the dispensing of the prescription or medication order. Such access may be through imaging technology provided the pharmacist has the ability to review the original, hardcopy documents if needed for clarification; and

(-c-) verifies the accuracy of the data entered information prior to the release of the information to the system for storage.

(III) Electronic verification of data entry by pharmacy technicians or pharmacy technician trainees. A pharmacist may electronically verify the data entry of prescription information into a data processing system provided:

(-a-) a pharmacist is on-site in the pharmacy where the pharmacy technicians/trainees are located;

(-b-) the pharmacist electronically conducting the verification is either a:

(-1-) Texas licensed pharmacist; or

(-2-) pharmacist employed by a Class E pharmacy that has the same owner as the Class G pharmacy where the pharmacy technicians/trainees are located or that has entered into a written contract or agreement with the Class G pharmacy, which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations;

(-c-) the pharmacy establishes controls to protect the privacy and security of confidential records; and

(-d-) the pharmacy keeps permanent records of prescriptions electronically verified for a period of two years.

(v) All pharmacists while on duty, shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties which may only be performed by a pharmacist are as follows:

(i) receiving oral prescription drug or medication orders and reducing these orders to writing, either manually or electronically;

(ii) interpreting prescription drug or medication orders;

(iii) selecting drug products;

(iv) verifying the data entry of the prescription drug or medication order information at the time of data entry prior to the release of the information to a Class A, Class C, or Class E pharmacy for dispensing;

(v) communicating to the patient or patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, as specified in §291.33(c) of this title (relating to Operational Standards);

(vi) communicating to the patient or the patient's agent on his or her request information concerning any prescription drugs dispensed to the patient by the pharmacy;

(vii) assuring that a reasonable effort is made to obtain, record, and maintain patient medication records; and

(viii) interpreting patient medication records and performing drug regimen reviews**, including the provision of medication therapy management services**.

(4) Pharmacy Technicians and Pharmacy Technician Trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties.

(i) Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection.

(ii) A pharmacist may delegate to pharmacy technicians and pharmacy technician trainees any nonjudgmental technical duty associated with the preparation and distribution of prescription drugs provided:

(I) a pharmacist verifies the accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy technician trainees;

(II) pharmacy technicians and pharmacy technician trainees are under the direct supervision of and responsible to a pharmacist; and

(iii) Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental technical duties associated with the preparation of prescription drugs, as follows:

(I) initiating and receiving refill authorization requests; and

(II) entering prescription or medication order data into a data processing system.

(C) Ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees. A Class G pharmacy may have a ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees of 1:8 provided:

(i) at least seven are pharmacy technicians and not pharmacy technician trainees; and

(ii) the pharmacy has written policies and procedures regarding the supervision of pharmacy technicians and pharmacy technician trainees.

(5) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician, or a certified pharmacy technician, if the technician maintains current certification **by an**[~~ with the Pharmacy~~

~~Technician Certification Board or any other~~] entity providing **a pharmacy technician certification**[~~an~~] examination approved by the board.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational Standards.

(1) General requirements.

(A) A Class A, Class C, or Class E Pharmacy may outsource prescription drug or medication order processing to a Class G pharmacy provided the pharmacies:

(i) have:

(I) the same owner; or

(II) entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(ii) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to perform a non-dispensing function.

(B) A Class G pharmacy shall comply with the provisions applicable to the class of pharmacy contained in either §§291.31 - 291.35 of this title (relating to Definitions, Personnel, Operational Standards, Records, and Official Prescription Requirements in Class A (Community) Pharmacies), or §§291.72 - 291.75 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class C (Institutional) Pharmacy), or §§291.102 - 291.105 of this title (relating to Definitions, Personnel, Operational Standards, and Records in a Class E (Non-Resident) Pharmacy) to the extent applicable for the specific processing activity and this section including:

(i) duties which must be performed by a pharmacist; and

(ii) supervision requirements for pharmacy technicians and pharmacy technician trainees.

(2) Licensing requirements.

(A) A Class G pharmacy shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) A Class G pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(C) A Class G pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) A Class G pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) A Class G pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance and renewal of a license and the issuance of an amended license.

(G) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(3) Environment.

(A) General requirements.

(i) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition.

(ii) The pharmacy shall be properly lighted and ventilated.

(B) Security.

(i) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drug records.

(ii) Pharmacies shall employ appropriate measures to ensure that security of prescription drug records is maintained at all times to prohibit unauthorized access.

(4) Policy and Procedures. A policy and procedure manual shall be maintained by the Class G pharmacy and be available for inspection. The manual shall:

(A) outline the responsibilities of each of the pharmacies;

(B) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription drug or medication order processing; and

(C) include policies and procedures for:

(i) protecting the confidentiality and integrity of patient information;

(ii) maintaining appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing;

(iii) complying with federal and state laws and regulations;

(iv) operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(v) annually reviewing the written policies and procedures and documenting such review.

(e) Records.

(1) every record required to be kept under the provisions of this section shall be:

(A) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(B) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(2) **A Class G pharmacy that processes prescription drug orders or medication drug orders**[~~The pharmacy~~] shall maintain appropriate records which identify, by prescription drug or medication order, the name(s), initials, or identification code(s) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs a processing function for a prescription drug or medication order. Such records may be maintained:

(A) separately by each pharmacy and pharmacist; or

(B) in a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy and pharmacist.

(3) In addition, the pharmacy shall comply with the record keeping requirements applicable to the class of pharmacy to the extent applicable for the specific processing activity and this section.

TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

January 24, 2019

Megan G. Holloway
Assistant General Counsel
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, Texas 78701

Via email to Megan.Holloway@pharmacy.texas.gov

Re: Comments on Proposed Rule 22 TAC §291.153

Dear Ms. Holloway:

The Texas Medical Association (TMA) writes to provide comments on rules proposed by the Texas State Board of Pharmacy (TSBP), as published in the Texas Register on January 4, 2019. TMA is a private, voluntary, nonprofit association founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health and represents over 51,000 Texas physicians and medical residents and students.

TSBP's proposed rules authorize pharmacists to provide medication therapy management (MTM) services in Class G pharmacies. TMA writes to express **strong opposition** to these proposed rules. As explained in greater detail below, TMA objects to the proposed rules because they: (1) are not based on express statutory authority or guidance; (2) contain broad and vague language regarding the scope of MTM services; and (3) authorize pharmacists to perform services that exceed the scope of pharmacy. Adopting the rules will lead to confusion on the part of pharmacists, physicians, and patients alike. TMA accordingly encourages the TSBP to withdraw the proposed rules.

I. General Comment: There are No Statutory Guidelines for a Pharmacist's Provision of MTM Services

TSBP's proposed rules authorize and provide for the provision of MTM services in Class G pharmacies. TMA first notes that there is no express statutory authorization or guidelines for MTM services, and so in order to more adequately understand what might be an appropriate scope for MTM services, TMA turned to more thoroughly explained Medicare guidance relating to those services. According to Medicare guidance, MTM services are intended to "promote coordinated care and improve medication use through services that engage the patient, their

physicians, and other healthcare providers."[1] MTM providers are to "work with physicians to deliver the best medication therapy to patients and to coordinate their medication therapy across multiple practitioners."[2]

TMA also notes that under Medicare, MTM programs are developed in accordance with clear, comprehensive regulatory guidelines that outline how MTM programs are to be structured and how services are to be provided, including stating by whom MTM services are provided, for whom MTM services are appropriate, and requiring that programs be developed in cooperation between physicians and pharmacists.[3]

In contrast, the TSBP's proposed MTM services rules contain very little of the structural elements found in Medicare rules. This is, at least in part, because there is no state law guidance for the TSBP's regulation of MTM services. TMA cannot find any statutory basis for the TSBP's rules relating to MTM services and asserts that, without such a basis, the rules regarding MTM services are unclear and blur the lines between what services are and are not within the scope of the practice of pharmacy as described by the Texas Legislature.

The Pharmacy Act defines the practice of pharmacy to include:

1. providing an act or service necessary to provide pharmaceutical care;
2. interpreting or evaluating a prescription drug order or medication order;
3. participating in drug or device selection as authorized by law, and participating in drug administration, drug regimen review, or drug or drug-related research;
4. providing patient counseling;
5. being responsible for:
    a. dispensing a prescription drug order or distributing a medication order;
    b. compounding or labeling a drug or device, other than labeling by a manufacturer, repackager, or distributor of a nonprescription drug or commercially packaged prescription drug or device;
    c. properly and safely storing a drug or device; or
    d. maintaining proper records for a drug or device;
6. performing for a patient a specific act of drug therapy management delegated to a pharmacist by a written protocol from a physician licensed in this state in compliance with Subtitle B; or
7. administering an immunization or vaccination under a physician's written protocol.[4]

The law's definition of the practice of pharmacy contains no mention of MTM services. In fact, nowhere else in the Pharmacy Act does the law even mention MTM services. TMA acknowledges that without a specific mention of MTM services, the legislature has still provided the TSBP with broad rulemaking authority as it relates to regulating the practice of pharmacy in Texas. But that authority must be consistent with limitations spelled out in the Pharmacy Act.

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[1] "A Physician's Guide to Medicare Part D Medication Therapy Management (MTM) Programs, Centers for Medicare & Medicaid Services (2017), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/A-Physician%E2%80%99s-Guide-to-Medicare-Part-D-Medication-Therapy-Management-MTM-Programs-08242017.pdf

[2] *Id*.

[3] 42 C.F.R. § 423.153

[4] Occ. Code §551.003(33)

The TSBP's rules on MTM services would thus have to rely on, and stay within the boundaries set by, the existing definition of the practice of pharmacy. But, as described in further detail below, many aspects of the MTM services described in the proposed rule either come close to or fall well outside the line for the practice of pharmacy established by state law.

Within the lines of the practice of pharmacy, according to state law, is the provision of patient counseling, so some parts of MTM services could be considered a part of patient counseling. But the extent to which MTM services may be considered a form of patient counseling is unclear, especially without further statutory clarification about MTM services. Further, as described by the proposed rules, some of what is proposed to be included in the TSBP's definition of MTM services certainly falls outside of mere "patient counseling."

Accordingly, TMA asserts that using rules to authorize pharmacists to perform services that are not mentioned in state law is putting the cart before the horse. TMA encourages TSBP to withdraw the rules until legislation is enacted that clearly defines the scope of and appropriate guidelines and limitations for MTM services in Texas. This is the surest way of ensuring that MTM services are provided in accordance with the state law's prescribed scope of the practice of pharmacy, and that pharmacists and physicians alike can more clearly understand the scope of the MTM services.[5]

While maintaining its objection to the rules generally and its insistence that these rules should be withdrawn, TMA also provides further comments regarding the substance of the rules below.

II. The Rule Does Not Clearly Define the Scope of the Provision of MTM Services

The preamble of the proposed rules state that the rule amendments would "provide for the provision of medication therapy management services in Class G pharmacies." While the stated intent may be straight forward, the actual text of the rules makes the intent of the proposal less clear.

1. Proposed §291.153(a)(1)

The amendment of the purpose section of the rules in Subsection (a)(1) would state that the purpose of the section is to "provide standards for a centralized prescription drug or medication order processing pharmacy, including a pharmacy that provides medication therapy management services in accordance with the requirements of this section."

This amendment is confusing and unclear because by using "including" following "a centralized prescription drug or medication order processing pharmacy," the amendment suggests that "a pharmacy that provides medication therapy management services" is a type of a "centralized prescription drug or medication order processing pharmacy." In other words, the amendment suggests that only centralized processing pharmacies will provide MTM services.

[5] In fact, the legislature has recently enacted legislation that fosters cooperation among physicians, pharmacists, and others. Legislation like H.B. 1296, 85th R.S. (2017), which requires a medication synchronization plan to be jointly approved by a prescribing physician, a pharmacist, and others, would be able to provide clearer guidance regarding the provision and scope of MTM services.

It is unclear to TMA whether this is actually what the TSBP intends. Other sources of information relating to MTM services like the Centers for Medicare and Medicaid Services do not mention that MTM services are provided only by pharmacists practicing in a processing pharmacy.[6]

There is further disconnect created by discrepancies between what a centralized processing pharmacy is described to do and what MTM services are defined to include. According to current rules, centralized prescription drug or medication order processing "does not include the dispensing of a prescription drug,"[7] and a Class G pharmacy "shall not . . . dispense a prescription drug order,"[8] but proposed amendments describe MTM services as services that "may occur in conjunction with the dispensing of a drug or device." This is inconsistent with the implication in Subsection (a)(1) that pharmacies that provide MTM services are included in centralized processing pharmacies.

Another inconsistency in the TSBP's rule proposal is the Board's stated statutory authority for proposing the rules. The TSBP states in the rule proposal that the "amendments are proposed under . . . 562.1011 of the Texas Pharmacy Act." Section 562.1011 of the Texas Pharmacy Act relates to the operation of Class C pharmacies in rural hospitals. This section does not appear to have any relation to Class G pharmacies or centralized processing pharmacies, but the fact that TSBP states that its authority for these rule amendments is based in law relating to Class C pharmacies may suggest that the TSBP's intent is not to have MTM services provided only in Class G pharmacies as the text of the rule proposal indicates.

The lack of clarity surrounding the fundamental question of where and by what class of pharmacy MTM services will be provided demands attention. TMA asserts that in order to properly address these questions, the TSBP should withdraw these rules and work more with stakeholders to ensure that proposed rules properly and adequately capture the intent of the Board.

2. Proposed §291.153(a)(2)

Amendments to Subsection (a)(2) further confuse the intended relationship between centralized prescription processing and MTM services. While Subsection (a)(1) suggests that a pharmacy that provides MTM services is included in the group of pharmacies providing centralized processing, Subsection (a)(2) suggests the pharmacy whose primary purpose is to perform centralized processing or MTM services should be a Class G pharmacy.

Further, the rule states that it provides standards for a pharmacy whose primary purpose is to provide MTM services, but it does not address pharmacies who do not have this primary purpose. In other words, does this rule authorize a pharmacist at a pharmacy whose primary purpose is *not* to provide MTM services to nevertheless provide ancillary MTM services? If

[6] See, for example, the resources on MTM services on CMS's website: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html
[7] 22 Tex. Admin. Code §291.153(b)(3)
[8] 22 Tex. Admin. Code §291.153(a)(2)

pharmacists at Class A or Class C pharmacies, for example, may provide MTM services, do these MTM regulations applying specifically to Class G pharmacies also apply to *any* provision of MTM services, regardless of the type of pharmacy at which the services are provided?

Again, without answers to these fundamental questions, there will be much confusion among pharmacists, physicians, and patients about the provision of MTM services. TMA asserts that these holes in the rules warrant further discussion and necessitate the TSBP's withdrawal of the rules.

3. Proposed §291.153(b)(3)

As described above, proposed Subsection (b)(3) contains discrepancies that makes it unclear how and by what class of pharmacy MTM services are provided. TMA notes the inconsistency in the statement in Subsection (b)(3) that MTM services may occur "in conjunction with" the dispensing of a drug or device, even though centralized processing pharmacies by rule "shall not . . . dispense a prescription drug order."[9]

TMA respectfully asserts that the discrepancies and internal inconsistencies in the TSBP's proposed rule reflect a rule that has not been thoroughly vetted and discussed. TMA expresses significant concern that failing to adopt rules that are internally consistent will breed confusion for all involved, including patients and those patients' physicians. Accordingly, if the TSBP does not withdraw these rules on the basis that there is no guiding statutory law, as TMA argued above, then TMA encourages the TSBP to still withdraw these rules in order to draft clearer regulations.

III. The Proposed Rules Authorize MTM Services That Are Outside the Scope of the Practice of Pharmacy

TMA's final comments regarding the proposed rules relate to the fact that the rules' definition of MTM services is so broad that it authorizes services that are outside the scope of pharmacy and does not restrict MTM services to be within that scope.

1. The Definition of MTM Services is So Broad It May Allow for Services Outside the Scope of Pharmacy

The proposed rules essentially define MTM services to be "pharmaceutical care services . . . provided by a pharmacist to optimize therapeutic outcomes for individual patients." What follows that broad statement is a non-exhaustive list of services that a pharmacist might provide as MTM services.

TMA strongly opposes such a broad definition, especially without clarification or requirement that any MTM services must be provided within the scope of the practice of pharmacy as defined by state statutory law. TMA acknowledges that it may be difficult to narrow down a type of service that is generally provided to help optimize therapeutic outcomes and may be altered on a patient-by-patient basis. But TMA expresses concern that without more specific guidance and

[9] 22 Tex. Admin. Code §291.153(a)(2)

articulation of limitations, pharmacists may be less certain about the boundaries they should follow in providing MTM services. For instance, TMA notes that the Medicare rule relating to MTM services more thoroughly defines those services by articulating the targeted patients, clarifying the desired outcome of MTM services, and more clearly stating the collaborative nature of MTM services.[10]

One thing that Medicare guidance makes particularly clear—but that is wholly absent from the TSBP's rules—is that MTM services are provided in collaboration with a patient's physician. MTM providers are to "work with physicians" in providing MTM services.[11] And importantly, Medicare guidance reiterates that, "as always, physicians make the final decisions about changes in drug therapy."[12]

The TSBP's definition of MTM services, on the other hand, appears to give pharmacists carte blanche with respect to MTM services with no mention of restrictions or limitations. The proposed rules do say that "MTM services do not include drug therapy management under §295.13." That section relates to drug therapy management *under a written protocol from a physician*. Stating that MTM services do not include drug therapy management under a written protocol under §295.13 is *not* the same thing as saying MTM services cannot include drug therapy management of any kind.

TMA encourages the TSBP to amend the proposed rules to more clearly narrow the scope of MTM services to ensure that those services stay within the bounds of the practice of pharmacy as defined by state statutory law. Further, the rules should clarify that MTM services are to be provided collaboratively with a patient's physician, and under no circumstance should a pharmacist modify a patient's drug therapy without specific authorization from a physician in accordance with state law or order procedures or take any other action outside the scope of the practice of pharmacy.

2. The Illustrative List of MTM Services Includes Services that Exceed the Scope of the Practice of Pharmacy

The vagueness of the proposed rule described above will lead to actions that exceed the scope of the practice of pharmacy, but TMA expresses concern that even some of the specifically listed activities will also have the same result. TMA raises questions and concern about the following activities listed in the rule:

- Proposed Subsection (b)(3)(A) and (B): These listed activities authorize a pharmacist to "resolve barriers" regarding patient access to medication or patient medication adherence. Some barriers may be resolved properly by a pharmacist's counseling or by coordinating with the patient's physician or other providers—properly within a

[10] 42 C.F.R. § 423.153
[11] "A Physician's Guide to Medicare Part D Medication Therapy Management (MTM) Programs, Centers for Medicare & Medicaid Services (2017), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/A-Physician%E2%80%99s-Guide-to-Medicare-Part-D-Medication-Therapy-Management-MTM-Programs-08242017.pdf
[12] *Id*.

pharmacist's scope—but other barriers might be resolved by issuing additional prescriptions or even administering drugs to a patient. The rule must clarify that a pharmacist's removal of barriers must be within the scope of the practice of pharmacy.

- Proposed Subsection (b)(3)(D): This activity authorizes a pharmacist to "perform a comprehensive medication therapy review at *each patient encounter*." Whether a medication therapy review is necessary should be a decision made in conjunction with the patient's physician.
- Proposed Subsection (b)(3)(F): This paragraph authorizes a pharmacist to "formulat[e] a medication treatment plan" for a patient. While a medication treatment plan that holistically reviews medication from a variety of physicians and other providers is beneficial to the patient, this again should be done in consultation with the patient's physicians.
- Proposed Subsection (b)(3)(G): This paragraph authorizes a pharmacist to perform follow-up procedures to monitor and evaluate a patient's response to medication therapy. TMA strongly opposes this language, as ordering or performing any follow-up procedures in reaction to a patient's response to medication should be performed, or at least overseen, by a physician.

IV. Proposed Amendments to the Proposed Rule

TMA again maintains that the most appropriate action for the TSBP to take is to withdraw the rules pending statutory direction from the legislature or, in the alternative, until the rules may be properly vetted with appropriate stakeholders. TMA nevertheless provides specific proposed amendments based on the foregoing comments.

First, the TSBP must clarify an appropriate scope for MTM services regarding which classes of pharmacies may provide MTM services. As stated above, it is not clear what TSBP's intent is, and TMA thus makes no recommendation regarding this language, only recommending that whatever the intended scope of MTM services is, those MTM services should be provided within the scope of the practice of pharmacy as defined by state statutory law.

As to the specific definition of MTM services, TMA offers the following suggested amendments:

> (3) Medication Therapy Management (MTM) Services--Pharmaceutical care services that are independent of, but may occur in conjunction with, the dispensing of a drug or device,[13] and are provided by a pharmacist in collaboration with a patient's physician to optimize therapeutic outcomes for individual patients. MTM services may [~~de~~] not include drug therapy management or modification of any kind. Drug therapy management by a pharmacist under a written protocol of a physician under §295.13 of this title is not considered MTM services. MTM services must be provided within the scope of the practice of pharmacy as defined by state statutory law, and include, but are

[13] TMA notes that whether the phrase "services that are independent of, but may occur in conjunction with, the dispensing of a drug or device" should be amended depends on whether the TSBP intends to authorize MTM services to be provided by centralized processing pharmacies only, or whether the authorization is broader.

not limited to, the following patient-specific activities delivered in an interaction between the patient and the pharmacist:

(A) identifying and resolving barriers, as appropriate and to the extent authorized by state statutory law, regarding the patient's access to medication;

(B) identifying and resolving barriers, as appropriate and to the extent authorized by state statutory law, regarding the patient's medication adherence;

(C) coordination of the patient's medication therapy to improve continuity of care, especially when prescribed multiple medications from multiple practitioners, or for multiple disease states or conditions, including effective communication with prescribers to develop a uniform plan of care;

(D) performing a comprehensive medication therapy review at [~~each~~] patient encounters as appropriate and as determined in collaboration with a patient's physician [~~encounter~~] to determine the effectiveness of the patient's medication and evaluate any drug-related problems or adverse drug events;

(E) providing education, counseling, or training to the patient or patient's caregiver to understanding of health conditions and appropriate medication use;

(F) in collaboration with a patient's physician, formulating medication treatment plans for the patient;

(G) [~~performing follow-up procedures to monitor and evaluate the patient's response to medication therapy, safety and effectiveness;~~]

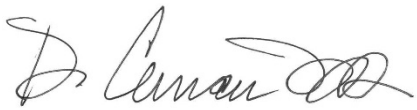
[~~(H)~~] documenting the patient's MTM session; and

(H) [~~(I)~~] providing an individualized documentation of the MTM session to the patient or patient's caregiver.

Conclusion

TMA again expresses appreciation for the opportunity to provide comment on these proposed rules. Should you have any questions regarding these comments, please contact Rocky Wilcox, Vice President and General Counsel, at rocky.wilcox@texmed.org; Kelly Walla, Associate Vice President and Deputy General Counsel, at kelly.walla@texmed.org; or Jared Livingston, Assistant General Counsel, at jared.livingston@texmed.org. You may also call TMA's toll free at 800-880-1300 and request to speak to these association staff members.

Sincerely,



Douglas W. Curran, MD
President
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