



Texas State Board of Pharmacy M E M O R A N D U M

DATE: August 9, 2018

TO: Board Members
Staff
Interested Parties

FROM: Megan G. Holloway
Assistant General Counsel

SUBJECT: Rules adopted and proposed at the August 7, 2018 Board Meeting.

ADOPTED RULES

CHAPTER 291. PHARMACIES

SUBCHAPTER A – ALL CLASSES OF PHARMACIES

§291.1

The Texas State Board of Pharmacy adopted amendments to §291.1 concerning Pharmacy License Application. The amendments clarify that the applicant for a pharmacy license must provide any information requested on the application.

§291.3

The Texas State Board of Pharmacy adopted amendments to §291.3 concerning Required Notifications. The amendments add inspection requirements for sterile compounding pharmacies (Class A-S, C-S and E-S) and nuclear pharmacies (Class B) when the pharmacy changes location.

§291.19

The Texas State Board of Pharmacy adopted amendments to §291.19 concerning Administrative Actions as a Result of Compliance Inspection. The amendments update the response required to a written warning notice.

§291.29

The Texas State Board of Pharmacy adopted amendments to §291.29 concerning Professional Responsibility of Pharmacists. The amendments clarify the patterns (i.e., red flag factors) relevant to preventing non-therapeutic dispensing of controlled substances to be considered by a pharmacist by evaluating the totality of the circumstances before dispensing a controlled substance prescription.

SUBCHAPTER B – COMMUNITY PHARMACY (CLASS A)

§291.31

The Texas State Board of Pharmacy adopts amendments to §291.31 concerning Definitions. The amendments create a definition of electronic verification process and update the definition of prepackaging.

§291.32

The Texas State Board of Pharmacy adopts amendments to §291.32 concerning Personnel. The amendments allow pharmacy technicians and pharmacy technician trainees to load prepackaged containers previously verified by a pharmacist or manufacturer's unit of use packages into an automated dispensing system.

§291.33

The Texas State Board of Pharmacy adopts amendments to §291.33 concerning Operational Standards. The amendments update the requirements for use of automated storage and distribution devices by Class A pharmacies.

§291.34

The Texas State Board of Pharmacy adopted amendments to §291.34 concerning Records. The amendments clarify the responsibility of a pharmacy owner as provided in §562.112 of the Texas Pharmacy Act.

SUBCHAPTER D – INSTITUTIONAL PHARMACY (CLASS C)

§291.74

The Texas State Board of Pharmacy adopted amendments to §291.74 concerning Operational Standards. The amendments update the requirements for drug use review as authorized by §562.1011(i) of the Texas Pharmacy Act.

SUBCHAPTER G – SERVICES PROVIDED BY PHARMACIES

§291.133

The Texas State Board of Pharmacy adopted amendments to §291.133 concerning Pharmacies Compounding Sterile Preparations. The amendments update the media fill and aseptic procedures test requirements for all sterile compounding personnel in Class A-S, Class B, Class C-S and Class E-S pharmacies; clarify the testing requirements for compounding personnel working in multiple pharmacies under common ownership; clarify the environmental testing certification procedures; and correct grammatical and punctuation errors.

CHAPTER 295. PHARMACISTS

§295.9

The Texas State Board of Pharmacy adopted amendments to §295.9 concerning Inactive License. The amendments add a requirement of one hour of continuing education on opioid abuse for pharmacist license reactivation.

§295.11

The Texas State Board of Pharmacy adopted amendments to §295.11 concerning Notification to Consumers. The amendments update the requirement for pharmacies to post a sign notifying consumers of the Board's contact information for filing complaints regarding the practice of pharmacy, and permit a

pharmacy to utilize an electronic messaging system in lieu of such a sign.

CHAPTER 305. EDUCATIONAL REQUIREMENTS

§305.2

The Texas State Board of Pharmacy adopted amendments to §305.2 concerning Pharmacy Technician Training Programs. The amendments clarify the standard for Board-approved pharmacy technician training programs by recognizing that pharmacy technician training programs are jointly accredited by the American Society of Health-System Pharmacists and the Accreditation Council on Pharmacy Education.

PROPOSED RULES

CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES

SUBCHAPTER C – DISCIPLINARY GUIDELINES

§281.62

The Texas State Board of Pharmacy proposed amendments to §281.62 concerning Aggravating and Mitigating Factors. The amendments, if adopted, update the factors which may merit an increase or decrease in the severity of disciplinary action imposed by the Board.

§281.65

The Texas State Board of Pharmacy proposed amendments to §281.65 concerning Schedule of Administrative Penalties. The amendments, if adopted, update the administrative penalties the Board may assess in disciplinary matters.

CHAPTER 291. PHARMACIES

SUBCHAPTER A – ALL CLASSES OF PHARMACIES

§291.17

The Texas State Board of Pharmacy proposed amendments to §291.17 concerning Inventory Requirements. The amendments, if adopted, update the requirements for taking inventories upon change of ownership and closure of pharmacies, and correct grammatical errors.

§291.28

The Texas State Board of Pharmacy proposed amendments to §291.28 concerning Access to Confidential Records. The amendments, if adopted, update the requirements for responding to a request for a patient's confidential records, to be consistent with section 181.102 of the Health and Safety Code.

SUBCHAPTER B – COMMUNITY PHARMACY (CLASS A)

§291.33

The Texas State Board of Pharmacy proposed amendments to §291.33 concerning Operational Standards. The amendments, if adopted, clarify the pharmacist's patient counseling duties by expressly prohibiting a pharmacy's

computer system from asking questions of the patient intended to screen and/or limit interaction with the pharmacist.

§291.34

The Texas State Board of Pharmacy proposed amendments to §291.34 concerning Records. The amendments, if adopted, allow the utilization of and specify recordkeeping requirements for prescription drug orders dispensed for patients institutionalized in licensed health care institutions, as authorized in Title 40, Part 1, Chapter 19 of the Texas Administrative Code; allow a pharmacist to dispense less than the quantity prescribed at the request of the patient or patient's agent; clarify that a rubber stamp may not be used as the signature of a practitioner; and correct grammatical errors.

§291.74

The Texas State Board of Pharmacy proposed amendments to §291.74 concerning Drug Regimen Review. The amendments, if adopted, update the requirements for drug use review for facilities with a part-time or consultant pharmacist when a practitioner orders a drug for administration when the pharmacist is not on duty or the pharmacy is closed and for rural hospitals, as authorized by §562.1011(i) of the Texas Pharmacy Act.

SUBCHAPTER F – NON-RESIDENT PHARMACY (CLASS E)

§291.104

The Texas State Board of Pharmacy proposed amendments to §291.104 concerning Operational Standards. The amendments, if adopted, update the time period to report required prescription information from a Class E pharmacy to the Texas Prescription Monitoring Program, to be consistent with section 481.074(q) of the Texas Controlled Substances Act, and correct grammatical errors.

SUBCHAPTER G – SERVICES PROVIDED BY PHARMACIES

§291.129

The Texas State Board of Pharmacy proposed amendments to §291.129 concerning Satellite Pharmacy. The amendments, if adopted, update the application requirements for Class A and Class C pharmacies and correct grammatical errors.

CHAPTER 315. CONTROLLED SUBSTANCES

§315.6

The Texas State Board of Pharmacy proposed amendments to §315.6 concerning Pharmacy Responsibility- Electronic Reporting. The amendments, if adopted, update the time period to report required prescription information to the Texas Prescription Monitoring Program (PMP) to be consistent with section 481.074(q) of the Texas Controlled Substances Act, add a requirement to correct inaccurate data that was submitted to PMP, and correct grammatical errors.

§315.15 - New Rule

The Texas State Board of Pharmacy proposed a new rule §315.15 concerning Access Requirements. The new rule, if adopted, creates requirements for practitioners and pharmacists to consult the Texas Prescription Monitoring Program database and clarifies that PMP information may only be accessed as authorized in section 481.076 of the Texas Controlled Substances Act.

RULE REVIEW

The Texas State Board of Pharmacy adopted the review of Chapter 281 (§§281.1-281.13, 281.15, 281.17-281.23, 281.30-281.34, 281.60-281.68) concerning Administrative Practices and Procedures, pursuant to the Texas Government Code §2001.039, regarding Agency Review of Existing Rules.

The Texas State Board of Pharmacy adopted the review of Chapter 311 (§§311.1-311.2) concerning Code of Conduct, pursuant to the Texas Government Code §2001.039, regarding Agency Review of Existing Rules.