



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

DATE: November 9, 2018

TO: Board Members
Staff
Interested Parties

FROM: Megan G. Holloway
Assistant General Counsel

SUBJECT: Rules adopted and proposed at the November 6, 2018 Board Meeting.

ADOPTED RULES

CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES

SUBCHAPTER C – DISCIPLINARY GUIDELINES

§281.62

The Texas State Board of Pharmacy adopted amendments to §281.62 concerning Aggravating and Mitigating Factors. The amendments 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 adopted amendments to §281.65 concerning Schedule of Administrative Penalties. The amendments update the administrative penalties the Board may assess in certain disciplinary matters.

CHAPTER 291. PHARMACIES

SUBCHAPTER A – ALL CLASSES OF PHARMACIES

§291.17

The Texas State Board of Pharmacy adopted amendments to §291.17 concerning Inventory Requirements. The amendments clarify 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 adopted amendments to §291.28 concerning Access to confidential Records. The amendments update the time

frame in which a pharmacy must respond to a request for confidential records and the format in which the records may be provided to be consistent with §181.102 of the Health and Safety Code.

SUBCHAPTER B – COMMUNITY PHARMACY (CLASS A)

§291.34

The Texas State Board of Pharmacy adopted amendments to §291.34 concerning Records. The amendments clarify that a rubber stamp may not be used as the signature of a practitioner on written prescription drug orders, 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 a quantity less than indicated on the original prescription at the request of the patient or patient's agent, and correct grammatical errors.

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 regimen review 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 adopted amendments to §291.104 concerning Operational Standards. The amendments update the time period to report required prescription information from a Class E pharmacy to the Texas Prescription Monitoring Program to not later than the next business day, to be consistent with §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 adopted amendments to §291.104 concerning Satellite Pharmacy. The amendments update the application requirements for Class A and Class C pharmacies to remove certain notarization requirements, and correct grammatical and punctuation errors.

CHAPTER 315. CONTROLLED SUBSTANCES

§315.6

The Texas State Board of Pharmacy adopted amendments to §315.6 concerning Pharmacy Responsibility – Electronic Reporting – Effective September 1, 2016. The amendments require pharmacies to report the dispensing of prescriptions for controlled substances to the Texas Prescription Monitoring Program not later than the next business day, in accordance with §481.074(q) of the Texas Controlled Substances Act, and to correct previously submitted data within seven days of identifying errors or omissions.

§315.15 – New Rule

The Texas State Board of Pharmacy adopted §315.15 concerning Access Requirements. The new rule specifies requirements for pharmacists to consult the Texas Prescription Monitoring Program (PMP) database to review a patient's controlled substance history before dispensing an opioid, benzodiazepine, barbiturate, or carisoprodol as provided in §§481.0764 and 481.0765 of the Texas Controlled Substances Act and clarify that PMP information may only be accessed as authorized in §481.076 of the Texas Controlled Substances Act.

PROPOSED RULES

CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES

SUBCHAPTER C – DISCIPLINARY GUIDELINES

§281.68

The Texas State Board of Pharmacy proposed amendments to §281.68 concerning Remedial Plan. The amendments, if adopted, clarify that the board shall remove all records of a completed remedial plan at the end of the fiscal year of the fifth anniversary of the date the board entered the remedial plan in accordance with §565.060 of the Act.

CHAPTER 283. LICENSING REQUIREMENTS FOR PHARMACISTS

§283.12

The Texas State Board of Pharmacy proposed amendments to §283.12 concerning Licenses for Military Service Members, Military Veterans, and Military Spouses. The amendments, if adopted, add provisions for a military service member, a military veteran, or a military spouse to place their pharmacist license on inactive status without paying a fee.

CHAPTER 291. PHARMACIES

SUBCHAPTER B – COMMUNITY PHARMACY (CLASS A)

§291.31

The Texas State Board of Pharmacy proposed amendments to §291.31 concerning Definitions. The amendments, if adopted, update the definitions of an automated counting device and automated pharmacy dispensing system, and correct grammatical errors.

§291.33

The Texas State Board of Pharmacy proposed amendments to §291.33 concerning Operational Standards. The amendments, if adopted, update the requirements for automated devices and systems in a Class A pharmacy, remove the provisions relating to automated storage and distribution devices, and correct grammatical errors

§291.35

The Texas State Board of Pharmacy proposed amendments to §291.35 concerning Official Prescription Requirements. The amendments, if adopted, update the citation references regarding the requirements for the use of official

prescription forms.

SUBCHAPTER D – INSTITUTIONAL PHARMACY (CLASS C)

§291.75

The Texas State Board of Pharmacy proposed amendments to §291.75 concerning Records. The amendments, if adopted, update the citation references regarding outpatient records, outpatient prescription forms, and official controlled substance forms, and correct grammatical errors.

SUBCHAPTER G – SERVICES PROVIDED BY PHARMACIES

§291.121

The Texas State Board of Pharmacy proposed amendments to §291.121 concerning Remote Pharmacy Services. The amendments, if adopted, add a subsection providing standards for the provision of remote pharmacy services through automated storage and delivery systems.

§291.131

The Texas State Board of Pharmacy proposed amendments to §291.131 concerning Pharmacies Compounding Non-Sterile Preparations. The amendments, if adopted, add definitions for active pharmaceutical ingredient, commercially available product, easily substitutable dosage strength, and essentially a copy of a commercially available product.

§291.133

The Texas State Board of Pharmacy proposed amendments to §291.133 concerning Pharmacies Compounding Sterile Preparations. The amendments, if adopted, add definitions for active pharmaceutical ingredient, commercially available product, easily substitutable dosage strength, and essentially a copy of commercially available product.

SUBCHAPTER H – OTHER CLASSES OF PHARMACY

§291.153

The Texas State Board of Pharmacy proposed amendments to §291.153 concerning Central Prescription Drug or medication Order Processing Pharmacy (Class G). The amendments, if adopted, provide standards for the provision of medication therapy management services in Class G pharmacies.

CHAPTER 315. CONTROLLED SUBSTANCES

§315.12

The Texas State Board of Pharmacy proposed amendments to §315.12 concerning Schedule III through V Prescription Forms. The amendments, if adopted, clarify that the United States Drug Enforcement Administration issues controlled substance registration numbers.

The Texas State Board of Pharmacy proposed the review of Chapter 291 (§§291.1 – 219.3, 291.5 – 291.11, 291.14 – 291.19, 291.22 – 291.24, 291.27 – 291.29) concerning Pharmacies, pursuant to the Texas Government Code §2001.039, regarding Agency Review of Existing Rules.