

SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §§291.72 - 291.74

The Texas State Board of Pharmacy proposes amendments to §291.72, concerning Definitions, §291.73, concerning Personnel, and §291.74, concerning Operational Standards. The proposed amendments to §291.72, if adopted, define physically present supervision and electronic supervision. The proposed amendments to §291.73, if adopted, require the pharmacy to document the identity of each pharmacist involved in a specific portion of the distribution process if the pharmacy's data processing system is capable of recording such information and outline the duties for pharmacy technicians and pharmacy technician trainees that must be performed under the physically present supervision of a pharmacist and duties that may be performed under the electronic supervision of a pharmacist. The proposed amendments to §291.74, if adopted, remove the storage of drugs requirements and locate the requirements in new §291.15 proposed elsewhere in this issue of the *Texas Register*, and replace the term substitute with the term interchange.

Gay Dodson, R.Ph., 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 rules.

Ms. Dodson has determined that, for each year of the first five-year period the rules will be in effect, the public benefit anticipated as a result of enforcing the rules will be to ensure pharmacy technicians and pharmacy technician trainees working in Class C pharmacies are appropriately supervised by a pharmacist, ensure the storage of drugs is consistent with other classes of pharmacy and USP guidelines, and clarify the rules regarding formularies in hospitals. There is no fiscal impact for individuals, small or large businesses or to other entities which are required to comply with the sections.

Comments on the proposed amendments may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, FAX (512) 305-8082. Comments must be received by 5:00 p.m., July 21, 2008.

The amendments are proposed under §551.002 and §554.051 of the Texas Pharmacy Act (Chapters 551 - 566 and 568 - 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 the amendments: Chapters 551 - 566 and 568 - 569, Texas Occupations Code.

§291.72. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) - (43) (No change.)

(44) Supervision--

(A) Physically present supervision--In a Class C pharmacy, a pharmacist shall be physically present to directly supervise pharmacy technicians or pharmacy technician trainees.

(B) Electronic supervision--In a Class C pharmacy in a facility licensed for 100 beds or less, a pharmacist licensed in Texas may electronically supervise pharmacy technicians or pharmacy technician trainees to perform the duties specified in §291.73(e)(2) of this title (relating to Personnel) provided:

(i) the pharmacy uses a system that monitors the data entry of medication orders and the filling of such orders by an electronic method that shall include the use of one or more the following types of technology:

(I) digital interactive video, audio, or data transmission;

(II) data transmission using computer imaging by way of still-image capture and store and forward; and

(III) other technology that facilitates access to pharmacy services;

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

(iii) the pharmacist responsible for the duties performed by a pharmacy technician or pharmacy technician trainee verifies:

(I) the data entry; and

(II) the accuracy of the filled orders prior to release of the order; and

(iv) the pharmacy keeps permanent digital records of duties electronically supervised and data transmissions associated with electronically supervised duties for a period of two years.

(C) If the conditions of subparagraph (B) of this paragraph are met, electronic supervision shall be considered the equivalent of direct supervision for the purposes of the Act.

(45) [(44)] Texas Controlled Substances Act--The Texas Controlled Substances Act, the Health and Safety Code, Chapter 481, as amended.

(46) [(45)] Unit-dose packaging--The ordered amount of drug in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.

(47) [(46)] Unusable drugs--Drugs or devices that are unusable for reasons, such as they are adulterated, misbranded, expired, defective, or recalled.

(48) [(47)] Written protocol--A physician's order, standing medical order, standing delegation order, or other order or protocol as defined by rule of the Texas Medical Board under the Texas Medical Practice Act Subtitle B, Chapter 157, Occupations Code.

§291.73. *Personnel.*

(a) - (c) (No change.)

(d) Pharmacists.

(1) General.

(A) - (D) (No change.)

(E) A distributing pharmacist shall be responsible for and ensure that the drug is prepared for distribution safely, and accurately as prescribed unless the pharmacy's data processing system can record the identity of each pharmacist involved in a specific portion of the preparation of medication orders for distribution, in which case each pharmacist involved in the preparation of medication orders shall be responsible for and ensure that the portion of the process the pharmacist is performing results in the safe and accurate distribution and delivery of the drug as ordered. [~~In addition, if multiple pharmacists participate in the preparation of medication orders for distribution, each pharmacist shall ensure the safety and accuracy of the portion of the process the pharmacist is performing.~~] The preparation and distribution process for medication orders shall include, but not be limited to, drug regimen review, and verification of accurate medication order data entry, preparation, and distribution, and performance of the final check of the prepared medication.

(2) - (3) (No change.)

(e) Pharmacy technicians and pharmacy technician trainees.

(1) 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).

(2) Duties. Duties may include, but need not be limited to, the following functions under the [~~direct~~] supervision of and responsible to a pharmacist:

(A) Facilities licensed for 101 beds or more. The following functions must be performed under the physically present supervision of a pharmacist:

(i) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-process and final checks and affixes his or her initials to the appropriate quality control records;

(iv) distributing routine orders for stock supplies to patient care areas;

(v) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order;

(vi) loading bulk unlabeled drugs into an automated compounding or counting device provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records;

(vii) accessing automated medication supply systems after proper training on the use of the automated medication supply system and demonstration of comprehensive knowledge of the written policies and procedures for its operation;

(viii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title; and

(ix) compounding sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:

(I) have completed the training specified in §291.133 of this title; and

(II) are supervised by a pharmacist who has completed the training specified in §291.133 of this title and who conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy.)

(B) Facilities licensed for 100 beds or less.

(i) Physically present supervision. The following functions must be performed under the physically present supervision of a pharmacist:

(I) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records;

(II) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-process and final checks and affixes his or her initials to the appropriate quality control records;

(III) loading bulk unlabeled drugs into an automated compounding or counting device provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records; and

(IV) compounding medium-risk and high-risk sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:

(-a-) have completed the training specified in §291.133 of this title; and

(-b-) are supervised by a pharmacist who has completed the training specified in §291.133 of this title, and who conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy.)

(ii) Electronic supervision or physically present supervision. The following functions may be performed under the electronic supervision or physically present supervision of a pharmacist:

(I) preparing, packaging, or labeling prescription drugs pursuant to medication orders, provided a pharmacist checks the preparation;

(II) distributing routine orders for stock supplies to patient care areas;

(III) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order;

(IV) accessing automated medication supply systems after proper training on the use of the automated medication supply system and demonstration of comprehensive knowledge of the written policies and procedures for its operation;

(V) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title; and

(VI) compounding low-risk sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees:

(-a-) have completed the training specified in §291.133 of this title; and

(-b-) are supervised by a pharmacist who has completed the training specified in §291.133 of this title, and who conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy.)

~~{(A) pre-packing and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records;}~~

~~{(B) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;}~~

~~[(C) bulk compounding or batch preparation provided a pharmacist supervises and conducts in-process and final checks and affixes his or her initials to the appropriate quality control records;]~~

~~[(D) distributing routine orders for stock supplies to patient care areas;]~~

~~[(E) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in §291.74(e) of this title (relating to Operational Standards);]~~

~~[(F) loading bulk unlabeled drugs into an automated compounding or counting device provided a pharmacist supervises, verifies that the system was properly loaded prior to use, and affixes his or her signature (first initial and last name or full signature) or electronic signature to the appropriate quality control records; and]~~

~~[(G) may be allowed access to automated medication supply systems after proper training on the use of the automated medication supply system and demonstration of comprehensive knowledge of the written policies and procedures for its operation.]~~

~~[(H) compounding sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees;]~~

~~[(i) have completed the training specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations); and]~~

~~[(ii) are supervised by a pharmacist who has completed the training specified in §291.133 of this title and who conducts in-process and final checks, and affixes his or her initials to the label or if batch prepared, to the appropriate quality control records. (The initials are not required on the label if it is maintained in a permanent record of the pharmacy.)]~~

~~[(3) Special requirements for compounding.]~~

~~[(A) Non-Sterile Preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.]~~

~~[(B) Sterile Preparations. Pharmacy technicians and pharmacy technician trainees engaged in compounding sterile preparations shall meet the training requirements specified in §291.133 of this title.]~~

(3) ~~[(4)]~~ Procedures.

(A) Pharmacy [~~pharmacy~~] technicians and pharmacy technician trainees shall handle medication orders in accordance with standard, written procedures and guidelines.

(B) Pharmacy [~~pharmacy~~] technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as those working in a Class A pharmacy.

(f) - (g) (No change.)

§291.74. Operational Standards.

(a) - (e) (No change.)

(f) Drugs.

(1) Procurement, preparation and storage.

(A) - (C) (No change.)

(D) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs) [by the following].

~~[(i) Cold—Any temperature not exceeding 8 degrees Centigrade (46 degrees Fahrenheit). A refrigerator is a cold place in which the temperature is maintained thermostatically between 2 and 8 degrees Centigrade (36 and 46 degrees Fahrenheit). A freezer is a cold place in which the temperature is maintained thermostatically between -20 and -10 degrees Centigrade (-4 and 14 degrees Fahrenheit).]~~

~~[(ii) Cool—Any temperature between 8 and 15 degrees Centigrade (46 and 59 degrees Fahrenheit). An article for which storage in a cool place is directed may, alternatively, be stored in a refrigerator unless otherwise specified in the labeling.]~~

~~[(iii) Room temperature—The temperature prevailing in a working area. Controlled room temperature is a temperature thermostatically between 15 and 30 degrees Centigrade (59 and 86 degrees Fahrenheit).]~~

~~[(iv) Warm—Any temperature between 30 and 40 degrees Centigrade (86 and 104 degrees Fahrenheit).]~~

~~[(v) Excessive heat—Any temperature above 40 degrees Centigrade (104 degrees Fahrenheit).]~~

~~[(vi) Protection from freezing where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to destructive alteration of the dosage form, the container label bears an appropriate instruction to protect the product from freezing.]~~

(E) Any drug bearing an expiration date may not be distributed beyond the expiration date of the drug.

(F) Outdated and other unusable drugs shall be removed from stock and shall be quarantined together until such drugs are disposed of properly.

(2) Formulary.

(A) A formulary shall be developed by the facility committee performing the pharmacy and therapeutics function for the facility. For the purpose of this section, a formulary is a compilation of pharmaceuticals that reflects the current clinical judgment of a facility's medical staff.

(B) The pharmacist-in-charge or pharmacist designated by the pharmacist-in-charge shall be a full voting member of the committee performing the pharmacy and therapeutics function for the facility, when such committee is performing the pharmacy and therapeutics function.

(C) A practitioner may grant approval for pharmacists at the facility to interchange [~~substitute~~], in accordance with the facility's formulary, for the prescribed drugs on the practitioner's medication orders provided:

(i) the pharmacy and therapeutics committee has developed a formulary;

(ii) the formulary has been approved by the medical staff committee of the facility;

(iii) there is a reasonable method for the practitioner to override any interchange [~~substitution~~];
and

(iv) the practitioner authorizes pharmacists in the facility to interchange [~~substitute~~] on his/her medication orders in accordance with the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility.

(3) - (5) (No change.)

(g) - (j) (No change.)

This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's legal authority to adopt.

Filed with the Office of the Secretary of State on June 9, 2008.

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Gay Dodson, R.Ph.

Executive Director/Secretary

Texas State Board of Pharmacy

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For further information, please call: (512) 305-8028