

## PRELIMINARY DRAFT RULE

The amendment could be made to Texas Administrative Code, Title 22, chapter 291, subchapter H (which includes Other Classes of Pharmacy).

### **PROPOSED §291.157 LIMITED PURPOSE AESTHETIC DRUG DELIVERY PHARMACY LICENSE (CLASS I)**

#### (a) PURPOSE.

(1) The purpose of this section is to establish a new classification of pharmacy license and establish standards to protect the public health, safety, and welfare of a Class I, pharmacy license.

(2) Any physician or therapeutic optometrist that dispenses aesthetic pharmaceuticals shall, in addition to being licensed as a physician or therapeutic optometrist, must also be licensed as a Class I pharmacy under this rule and comply with applicable provisions of the Act. A Class I pharmacy shall not dispense any other prescription drug order other than aesthetic pharmaceuticals or as otherwise permitted by law.

(3) A Class I pharmacy license holder may deliver dangerous drugs that are aesthetic pharmaceuticals. A Class I license holder may not deliver prescription drug orders for for controlled substances except as otherwise permitted by law.

(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) "Act" means the Texas Pharmacy Act, Chapters 551 - 566, Texas Occupations Code, as amended.

(2) "Aesthetic pharmaceutical" means:

(A) a drug that:

(i) is not a controlled substance;

(ii) requires a prescription for dispensation;

(iii) has been approved with the federal Food and Drug

Administration; and

(iv) is prescribed for the enhancement of an individual's appearance.

(3) "Consultant pharmacist" means a pharmacist retained by a Class I licensee on a routine basis to consult with the Class I license holder in areas that pertain to the practice of pharmacy.

(4) "Physician" means a person licensed to practice medicine under Subtitle B, Title 3, Occupations Code.

(5) "Therapeutic optometrist" means a person licensed to practice therapeutic optometry under Chapter 351, Occupations Code.

(c) PERSONNEL.

(1) Physician

(A) The physician must be licensed as required under the Texas Medical Practice Act, Occupations Code, Subtitle B, Title 3. A Class I pharmacy is not required to have a pharmacist-in-charge or pharmacy technician for the limited purpose of delivery of an aesthetic pharmaceutical.

(B) Responsibilities. In addition to any responsibilities as described in the Texas Medical Practice Act and administrative rules described in 28 Texas Administrative Code, Title 22, Part 9, the physician shall have responsibility for, at a minimum, the following:

(i) maintaining records of all transactions of the Class I pharmacy required by applicable state and federal laws;

(ii) adherence to policies and procedures regarding the maintenance of records; and

(iii) legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy.

(C) Duties. Duties include:

(i) delivery of previously verified prescription drug orders to a patient or patient's agent provided a record of prescriptions delivered is maintained;

(ii) maintaining through medical records or other appropriate records of aesthetic pharmaceuticals delivered; and

(iii) ensuring aesthetic pharmaceuticals are stored securely and at safe temperatures.

(2) Therapeutic Optometrist.

(A) A therapeutic optometrist must be licensed as required by Chapter 351, Occupations Code. A Class I pharmacy is not required to have a pharmacist-in-charge for the limited purpose aesthetic drug delivery by a therapeutic optometrist.

(B) Responsibilities. In addition to any responsibilities as described in Chapter 351, Occupations Code, the therapeutic optometrist shall have responsibility for, at a minimum, the following:

(i) maintaining records of all transactions of the Class I pharmacy required by applicable state and federal laws;

(ii) adherence to policies and procedures regarding the maintenance of records; and

(iii) legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or sections governing the practice of pharmacy.

(C) Duties. Duties include:

(i) delivery of previously verified prescription drug orders to a patient or patient's agent provided a record of prescriptions delivered is maintained;

(ii) maintaining through medical records or other appropriate records of aesthetic pharmaceuticals delivered; and

(iii) ensuring aesthetic pharmaceuticals are stored securely and at safe temperatures.

(3) Consultant Pharmacist.

(A) The consultant pharmacist shall be a licensed pharmacist.

(B) A written contract shall exist between the Class I pharmacy and any consultant pharmacist, and a copy of the written contract shall be made available upon request.

C) Duties. Duties include providing on site supervision or inspections at least twice per year for compliance with :

(i) the Class I pharmacy's delivery of previously verified prescription drug orders to a patient or patient's agent provided a record of prescriptions delivered is maintained;

(ii) maintaining through medical records or other appropriate records of aesthetic pharmaceuticals delivered; and

(iii) ensuring aesthetic pharmaceuticals are stored securely and at safe temperatures.

(d) OPERATIONAL STANDARDS.

(1) Licensing requirements.

(A) A Class I 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 I 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 I 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 I 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).

(E) 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. However, a pharmacy operated by the state or a political subdivision of the state that qualifies for a Class I license is not required to pay a fee to obtain a license.

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

(2) Environment.

(A) General requirements.

(i) The Class I pharmacy shall be arranged in an orderly fashion and kept clean ; and

(ii) Aesthetic pharmaceuticals shall be stored securely and at safe temperatures.

(B) Security.

(i) Only authorized personnel may have access to storage areas for aesthetic pharmaceuticals.

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

(iii) The Class I pharmacy shall be responsible for the security of all storage areas for aesthetic pharmaceuticals including provisions for adequate safeguards against theft or diversion of aesthetic pharmaceuticals, and records for such drugs.

(e) RECORDS.

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

(A) kept by the Class I 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 Class I 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) Records of drugs delivered to a patient or patient's agent shall include:

(A) patient name;

(B) name, signature, or electronic signature of the person who picks up the prescription drug;

(C) date delivered; and

(D) the name of the drug and quantity delivered.

(3) Ownership of pharmacy records. For the purposes of these sections, a Class I pharmacy licensed under the Act is the only entity which may legally own and maintain prescription drug records.