



August 2, 2024

Via Email

Texas State Board of Pharmacy
Attention: Daniel R. Carroll, Executive Director/Secretary.
1801 Congress Avenue
Austin, TX 78701-1319
Email: Daniel.carroll@pharmacy.texas.gov

Re: Petition for Rule Change – 22 Tex. Admin. Code, *§291.32 Personnel*

Dear Mr. Carroll and Esteemed Members of the Board,

On behalf of Texas Federation of Drug Stores (TFDS), we thank the Board for its consideration of this request to amend the technician ratio language found within 22 Tex. Admin. Code, *§291.32 Personnel* as it applies to Class A Central Fill pharmacies.

Background:

The current community pharmacy model is struggling from lower prescription reimbursements and higher back-end fees, staffing pressures in many areas of the state and an increase in prescription orders. Central fill pharmacies have been shown for many years to be a safe and effective tool to provide accurate and timely medications to patients. We request the Board expand certain allowances within the staffing regulations to permit central fill pharmacies to be leveraged to their fullest potential.

We have found through our use of central fill pharmacies that they help to alleviate some pressures at the customer facing community pharmacies, improve efficiencies, minimize mistakes, and can increase access to medications not stocked at all locations. We share the Board's mission to protect the health, safety, and welfare of Texas citizens, and believe the staffing proposal we recommend is in line with the Board's mission while supporting advancements in the pharmacy industry.

TFDS finds central fill pharmacies are a vastly different model than a traditional Class A community pharmacy for several reasons, including:

- Central fill pharmacies employ enhanced technology to ensure accuracy and patient safety, including the use of barcode scanning and automation to remove the potential for human error to occur within the process. This can include such features as a system lock that will trigger if there is a deviation in the automation replenishment process by the technician, thereby minimizing the need for constant supervision by a pharmacist.
- We believe the ratio requirements included within 22 Tex. Admin. Code, *§291.32* were not intended for closed door pharmacies, such as those that exclusively perform centralized filling, but rather were designed for traditional community pharmacies.

- Pharmacy Technicians at central fill pharmacies perform VERY limited functions. The only technician tasks they perform are filling prescriptions, replenishing medication stocked in automation and performing inventory-related duties such as stocking and ordering.
- Technicians at central fill pharmacies do not perform any patient or prescriber facing functions, or complete data entry, patient phone calls, refill requests, third party billing, immunizations, assist in compounding, etc. Therefore, oversight of these duties and answering questions by technicians that would normally be asked in a traditional community pharmacy are not required by pharmacists at the central fill facility which translates into an increased capacity for pharmacist supervision.
- Pharmacists and technicians at central fill pharmacies do not engage with patients within the facility, therefore there are also fewer distractions for pharmacists and technicians.
- Pharmacists at central fill pharmacies are focused exclusively on checking filled prescriptions and supervising technicians and other support personnel. They do not perform data review, DUR (Drug Utilization Review) review, patient consultations, immunizations, answering phone calls, compounding, and the myriad of other requirements of a typical community pharmacist. Therefore, pharmacists in these facility settings are fully capable of properly supervising more technicians than in a traditional community pharmacy.

TFDS would like to recommend the following two options for amending 22 Tex. Admin. Code, §291.32 Personnel which will enable central fill pharmacies to be optimally utilized:

*(d)(3) Ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees.
(A) Except as provided in subparagraph (B) and (C) of this paragraph, the ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees may be 1:6, provided the pharmacist is on-site and a maximum of three of the six are pharmacy technician trainees. The ratio of pharmacists to pharmacy technician trainees may not exceed 1:3.*

Option #1:

(B) A Central Fill Pharmacy that has no patient facing contact shall be excluded from any ratio requirements if it meets the requirements set forth in §291.125.

OR

Option #2:

(B) The PIC of a pharmacy that provides only centralized prescription dispensing functions as outlined in §291.125 shall determine the appropriate technician ratio requirements for that facility.

~~(B)-(C)~~ As specified in §568.006 of the Act, a Class A pharmacy may have a ratio of on-site pharmacists to pharmacy technicians/pharmacy technician trainees of 1:5 provided:

(i) the Class A pharmacy:

(I) dispenses no more than 20 different prescription drugs; and (II) does not produce sterile preparations including intravenous or intramuscular drugs on-site; and

(ii) the following conditions are met:

(I) at least four 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, including requirements that the pharmacy technicians and pharmacy technician trainees included in a 1:5 ratio may be involved only in one process at a time. For example, a

technician/trainee who is compounding non-sterile preparations or who is involved in the preparation of prescription drug orders may not also call physicians for authorization of refills.

Rationale for change:

Complying with the current ratio requirements can create a substantial hardship for central fill pharmacies by requiring additional pharmacists to staff the facility to maintain the ratio even when the supervisory workload does not necessitate such ratios.

TFDS finds the current ratios applied to central fill pharmacies is a poor utilization of healthcare resources. Pharmacists are better utilized in traditional community pharmacies, engaging in direct patient care activities. Since central fill pharmacies employ pharmacy technicians that do not perform many functions that are normally performed in a traditional community setting, we maintain removing the ratio would be appropriate.

As a similar comparison, the Texas State Board of Pharmacy eliminated the mandatory ratio requirement for class G pharmacies. The Board recognized that pharmacists in Class G pharmacies who perform centralized functions may supervise more technicians than in a traditional community pharmacy model. We believe that pharmacists in central fill pharmacies should be treated in a similar manner to Class G pharmacies.

Conclusion:

The application of a technician-to-pharmacist ratio that was intended for a traditional community pharmacy setting should not be considered the standard for a central fill pharmacy that is not customer facing and which has limited functions and extensive automation and technology.

We respectfully ask the Board to permit pharmacists within a Class A central fill pharmacy to be held to the same standards as pharmacists working in a Class G pharmacy by removing technician ratio restrictions **or** empowering the supervising pharmacist of central fill pharmacies to determine how many technicians they are capable of supervising.

TFDS sincerely thanks the Board for the opportunity to recommend these changes to 22 Tex. Admin. Code, §291.32. If the Board would like additional information, please feel free to contact me.

Sincerely,



Doug Read, President
Texas Federation of Drug Stores
H-E-B, Director of Pharmacy Compliance

1 **TITLE 22 EXAMINING BOARDS**
2 **PART 15 TEXAS STATE BOARD OF PHARMACY**
3 **CHAPTER 291 PHARMACIES**
4 **SUBCHAPTER B COMMUNITY PHARMACY (CLASS A)**

5 **§291.32. Personnel.**

6 (a) Pharmacist-in-charge.

7 (1) General.

8 (A) Each Class A pharmacy shall have one pharmacist-in-charge who is employed on a full-
9 time basis and who may be the pharmacist-in-charge for only one such pharmacy; provided,
10 however, such pharmacist-in-charge may be the pharmacist-in-charge of:

11 (i) more than one Class A pharmacy, if the additional Class A pharmacies are not open to
12 provide pharmacy services simultaneously; or

13 (ii) during an emergency, up to two Class A pharmacies open simultaneously if the
14 pharmacist-in-charge works at least 10 hours per week in each pharmacy for no more than a
15 period of 30 consecutive days.

16 (B) The pharmacist-in-charge shall comply with the provisions of §291.17 of this title (relating
17 to Inventory Requirements).

18 (C) The pharmacist-in-charge of a Class A pharmacy may not serve as the pharmacist-in-
19 charge of a Class B pharmacy or a Class C pharmacy with 101 beds or more.

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

24 (A) educating and training of pharmacy technicians and pharmacy technician trainees;

25 (B) supervising a system to assure appropriate procurement of prescription drugs and
26 devices and other products dispensed from the Class A pharmacy;

27 (C) disposing of and distributing drugs from the Class A pharmacy;

28 (D) storing all materials, including drugs, chemicals, and biologicals;

29 (E) maintaining records of all transactions of the Class A pharmacy necessary to maintain
30 accurate control over and accountability for all pharmaceutical materials required by applicable
31 state and federal laws and sections;

32 (F) supervising a system to assure maintenance of effective controls against the theft or
33 diversion of prescription drugs, and records for such drugs;

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

37 (H) legally operating the pharmacy, including meeting all inspection and other requirements of
38 all state and federal laws or sections governing the practice of pharmacy; and

39 (I) if the pharmacy uses an automated pharmacy dispensing system, shall be responsible for
40 the following:

41 (i) consulting with the owner concerning and adherence to the policies and procedures for
42 system operation, safety, security, accuracy and access, patient confidentiality, prevention of
43 unauthorized access, and malfunction;

44 (ii) inspecting medications in the automated pharmacy dispensing system, at least monthly,
45 for expiration date, misbranding, physical integrity, security, and accountability;

46 (iii) assigning, discontinuing, or changing personnel access to the automated pharmacy
47 dispensing system;

48 (iv) ensuring that pharmacy technicians, pharmacy technician trainees, and licensed
49 healthcare professionals performing any services in connection with an automated pharmacy
50 dispensing system have been properly trained on the use of the system and can demonstrate
51 comprehensive knowledge of the written policies and procedures for operation of the system;
52 and

53 (v) ensuring that the automated pharmacy dispensing system is stocked accurately and an
54 accountability record is maintained in accordance with the written policies and procedures of
55 operation.

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

61 (1) establishing policies for procurement of prescription drugs and devices and other products
62 dispensed from the Class A pharmacy;

63 (2) establishing policies and procedures for the security of the prescription department
64 including the maintenance of effective controls against the theft or diversion of prescription
65 drugs;

66 (3) if the pharmacy uses an automated pharmacy dispensing system, reviewing and approving
67 all policies and procedures for system operation, safety, security, accuracy and access, patient
68 confidentiality, prevention of unauthorized access, and malfunction;

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

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

74 (c) Pharmacists.

75 (1) General.

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

79 (B) All pharmacists shall assist the pharmacist-in-charge in meeting his or her responsibilities
80 in ordering, dispensing, and accounting for prescription drugs.

81 (C) Pharmacists are solely responsible for the direct supervision of pharmacy technicians and
82 pharmacy technician trainees and for designating and delegating duties, other than those listed
83 in paragraph (2) of this subsection, to pharmacy technicians and pharmacy technician trainees.
84 Each pharmacist shall be responsible for any delegated act performed by pharmacy technicians
85 and pharmacy technician trainees under his or her supervision.

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

89 (i) Physically present supervision. A pharmacist shall be physically present to directly
90 supervise a pharmacy technician or pharmacy technician trainee who is entering prescription
91 data into the data processing system. Each prescription entered into the data processing
92 system shall be verified at the time of data entry. If the pharmacist is not physically present due
93 to a temporary absence as specified in §291.33(b)(3) of this title (relating to Operational
94 Standards), on return the pharmacist must:

95 (I) conduct a drug regimen review for the prescriptions data entered during this time period
96 as specified in §291.33(c)(2) of this title; and

97 (II) verify that prescription data entered during this time period was entered accurately.

98 (ii) Electronic supervision. A pharmacist may electronically supervise a pharmacy technician
99 or pharmacy technician trainee who is entering prescription data into the data processing
100 system provided the pharmacist:

101 (I) has the ability to immediately communicate directly with the technician/trainee;

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

106 (III) verifies the accuracy of the data entered information prior to the release of the
107 information to the system for storage and/or generation of the prescription label.

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

111 (I) the pharmacist has the ability to immediately communicate directly with the
112 technician/trainee;

113 (II) the pharmacist electronically conducting the verification is either a:

114 (-a-) Texas licensed pharmacist; or

- 115 (-b-) pharmacist employed by a Class E pharmacy that:
- 116 (-1-) has the same owner as the Class A pharmacy where the pharmacy
117 technicians/trainees are located; or
- 118 (-2-) has entered into a written contract or agreement with the Class A pharmacy which
119 outlines the services to be provided and the responsibilities and accountabilities of each
120 pharmacy in compliance with federal and state laws and regulations;
- 121 (III) the pharmacy establishes controls to protect the privacy and security of confidential
122 records; and
- 123 (IV) the pharmacy keeps permanent records of prescriptions electronically verified for a
124 period of two years.
- 125 (E) All pharmacists, while on duty, shall be responsible for the legal operation of the
126 pharmacy and for complying with all state and federal laws or rules governing the practice of
127 pharmacy.
- 128 (F) A dispensing pharmacist shall be responsible for and ensure that the drug is dispensed
129 and delivered safely and accurately as prescribed, unless the pharmacy's data processing
130 system can record the identity of each pharmacist involved in a specific portion of the
131 dispensing processing. If the system can track the identity of each pharmacist involved in the
132 dispensing process, each pharmacist involved in the dispensing process shall be responsible for
133 and ensure that the portion of the process the pharmacist is performing results in the safe and
134 accurate dispensing and delivery of the drug as prescribed. The dispensing process shall
135 include, but not be limited to, drug regimen review and verification of accurate prescription data
136 entry, including prescriptions placed on hold, packaging, preparation, compounding,
137 transferring, labeling, and performance of the final check of the dispensed prescription. An
138 intern has the same responsibilities described in this subparagraph as a pharmacist but must
139 perform his or her duties under the supervision of a pharmacist.
- 140 (2) Duties. Duties which may only be performed by a pharmacist are as follows:
- 141 (A) receiving oral prescription drug orders for controlled substances and reducing these
142 orders to writing, either manually or electronically;
- 143 (B) interpreting prescription drug orders;
- 144 (C) selecting drug products;
- 145 (D) performing the final check of the dispensed prescription before delivery to the patient to
146 ensure that the prescription has been dispensed accurately as prescribed;
- 147 (E) communicating to the patient or patient's agent information about the prescription drug or
148 device which in the exercise of the pharmacist's professional judgment, the pharmacist deems
149 significant, as specified in §291.33(c) of this title;
- 150 (F) communicating to the patient or the patient's agent on his or her request information
151 concerning any prescription drugs dispensed to the patient by the pharmacy;
- 152 (G) assuring that a reasonable effort is made to obtain, record, and maintain patient
153 medication records;

- 154 (H) interpreting patient medication records and performing drug regimen reviews;
- 155 (I) performing a specific act of drug therapy management for a patient delegated to a
156 pharmacist by a written protocol from a physician licensed in this state in compliance with the
157 Medical Practice Act;
- 158 (J) verifying that controlled substances listed on invoices are received by clearly recording
159 his/her initials and date of receipt of the controlled substances; and
- 160 (K) transferring or receiving a transfer of original prescription information for a controlled
161 substance on behalf of a patient.
- 162 (3) Special requirements for compounding. All pharmacists engaged in compounding non-
163 sterile preparations shall meet the training requirements specified in §291.131 of this title
164 (relating to Pharmacies Compounding Non-Sterile Preparations).
- 165 (d) Pharmacy Technicians and Pharmacy Technician Trainees.
- 166 (1) General.
- 167 (A) All pharmacy technicians and pharmacy technician trainees shall meet the training
168 requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy
169 Technician Trainee Training).
- 170 (B) Special requirements for compounding. All pharmacy technicians and pharmacy
171 technician trainees engaged in compounding non-sterile preparations shall meet the training
172 requirements specified in §291.131 of this title.
- 173 (2) Duties.
- 174 (A) Pharmacy technicians and pharmacy technician trainees may not perform any of the
175 duties listed in subsection (c)(2) of this section.
- 176 (B) A pharmacist may delegate to pharmacy technicians and pharmacy technician trainees
177 any nonjudgmental technical duty associated with the preparation and distribution of
178 prescription drugs provided:
- 179 (i) unless otherwise provided under §291.33 of this subchapter, a pharmacist verifies the
180 accuracy of all acts, tasks, and functions performed by pharmacy technicians and pharmacy
181 technician trainees;
- 182 (ii) pharmacy technicians and pharmacy technician trainees are under the direct supervision
183 of and responsible to a pharmacist; and
- 184 (iii) only pharmacy technicians and pharmacy technician trainees who have been properly
185 trained on the use of an automated pharmacy dispensing system and can demonstrate
186 comprehensive knowledge of the written policies and procedures for the operation of the system
187 may be allowed access to the system.
- 188 (C) Pharmacy technicians and pharmacy technician trainees may perform only
189 nonjudgmental technical duties associated with the preparation and distribution of prescription
190 drugs, as follows:
- 191 (i) initiating and receiving refill authorization requests;

- 192 (ii) entering prescription data into a data processing system;
- 193 (iii) taking a stock bottle from the shelf for a prescription;
- 194 (iv) preparing and packaging prescription drug orders (i.e., counting tablets/capsules,
195 measuring liquids and placing them in the prescription container);
- 196 (v) affixing prescription labels and auxiliary labels to the prescription container;
- 197 (vi) reconstituting medications;
- 198 (vii) prepackaging and labeling prepackaged drugs;
- 199 (viii) loading bulk unlabeled drugs into an automated dispensing system provided a
200 pharmacist verifies that the system is properly loaded prior to use;
- 201 (ix) loading prepackaged containers previously verified by a pharmacist or manufacturer's
202 unit of use packages into an automated dispensing system in accordance with
203 §291.33(i)(2)(D)(III) of this subchapter;
- 204 (x) compounding non-sterile prescription drug orders; and
- 205 (xi) compounding bulk non-sterile preparations.

206 (D) In addition to the duties listed above in subparagraph (C) of this paragraph, pharmacy
207 technicians may perform the following nonjudgmental technical duties associated with the
208 preparation and distribution of prescription drugs:

209 (i) receiving oral prescription drug orders for dangerous drugs and reducing these orders to
210 writing, either manually or electronically;

211 (ii) transferring or receiving a transfer of original prescription information for a dangerous
212 drug on behalf of a patient; and

213 (iii) contacting a prescriber for information regarding an existing prescription for a dangerous
214 drug.

215 (3) Ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees.

216 (A) Except as provided in **subparagraphs (B) and (C)**[subparagraph (B)] of this paragraph,
217 the ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees may
218 be 1:6, provided the pharmacist is on-site and a maximum of three of the six are pharmacy
219 technician trainees. The ratio of pharmacists to pharmacy technician trainees may not exceed
220 1:3.

221 **(B) Subparagraph (A) of this paragraph does not apply to a central fill pharmacy, as**
222 **defined in §291.125 of this title (relating to Centralized Prescription Dispensing), that has**
223 **no patient-facing contact. For purposes of this subparagraph, patient-facing contact**
224 **means any direct interaction between a pharmacy employee and a patient or patient's**
225 **agent.**

226 **(C)**[~~(B)~~] As specified in §568.006 of the Act, a Class A pharmacy may have a ratio of on-site
227 pharmacists to pharmacy technicians/pharmacy technician trainees of 1:5 provided:

- 228 (i) the Class A pharmacy:
- 229 (I) dispenses no more than 20 different prescription drugs; and
- 230 (II) does not produce sterile preparations including intravenous or intramuscular drugs on-
231 site; and
- 232 (ii) the following conditions are met:
- 233 (I) at least four are pharmacy technicians and not pharmacy technician trainees; and
- 234 (II) the pharmacy has written policies and procedures regarding the supervision of
235 pharmacy technicians and pharmacy technician trainees, including requirements that the
236 pharmacy technicians and pharmacy technician trainees included in a 1:5 ratio may be involved
237 only in one process at a time. For example, a technician/trainee who is compounding non-sterile
238 preparations or who is involved in the preparation of prescription drug orders may not also call
239 physicians for authorization of refills.
- 240 (e) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows.
- 241 (1) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge
242 that bears the person's name and identifies him or her as a pharmacy technician, or a certified
243 pharmacy technician, if the technician maintains current certification with the Pharmacy
244 Technician Certification Board or any other entity providing an examination approved by the
245 board.
- 246 (2) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification
247 tag or badge that bears the person's name and identifies him or her as a pharmacy technician
248 trainee.
- 249 (3) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that
250 bears the person's name and identifies him or her as a pharmacist intern.
- 251 (4) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the
252 person's name and identifies him or her as a pharmacist.