

RULE ANALYSIS

Introduction: THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS ADOPTED RULES

Short Title: Pharmacist to Technician Ratio

Rule Numbers: §§291.32, 291.53, and 291.153

Statutory Authority: Texas Pharmacy Act, Chapter 551-566 and 568-569, Occupations Code:

- (1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
- (2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The amendments, if adopted, change the ratio for Class A and Class B pharmacies from 1:3 to no ratio requirements; and for Class G pharmacies from 1:6 to no ratio requirements.

Background: The Board discussed the pharmacist to pharmacy technician ratio requirements at the February 5, 2013, May 7, 2013, and August 6, 2013 meetings. The Board directed staff to draft amendments to the rules changing the ratio requirements.

The Board reviewed and voted to propose the amendments during the August 6, 2013, meeting. The proposed amendments were published in the September 27, 2013, issue of the *Texas Register* at 38 TexReg 6504, 38 TexReg 6506, and 38 TexReg 6532.

1 **SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)**
2 **§291.32**

3 The Texas State Board of Pharmacy (TSBP) proposes amendments to §291.32, concerning
4 Personnel, and §291.33, concerning Operational Standards, and new §291.36, concerning
5 Pharmacies Compounding Sterile Preparations (Class A-S).

6 The proposed amendments to §291.32, if adopted, eliminate the pharmacist to technician ratio
7 for Class A pharmacies. The proposed amendments to §291.33, if adopted, clarify that Class A
8 pharmacies will no longer be able to compound sterile preparations after June 1, 2013, unless the
9 pharmacy obtains a Class A-S pharmacy license. Proposed new §291.36, if adopted, outlines the
10 requirements for pharmacies that compound sterile preparations, implements recommendations
11 of the TSBP appointment Task Force on Compounding Sterile Preparations (Task Force), and
12 implements Senate Bill 1100 passed by the 83rd Regular Session of the Texas Legislature
13 regarding compounding pharmacies.

14 The TSBP established the Task Force in December 2012 to review the current standards of
15 practice for pharmacy compounding and was charged with: (1) reviewing current federal and
16 state requirements for sterile compounding; and (2) making recommendations to the Board of
17 Pharmacy regarding standards for pharmacy compounding in Texas that provide necessary
18 compounded medications while protecting the health, safety, and welfare of the public. The Task
19 Force met three times and presented its recommendations to the Board at the August 6, 2013,
20 meeting. The Task Force was composed of representatives from the pharmacy community
21 appointed by the three major pharmacy associations in Texas and pharmacists primarily involved
22 in compounding.

23 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
24 period the proposed amendments and new rule are in effect, there will be no fiscal implications
25 for state or local government as a result of enforcing or administering the rules.

26 Ms. Dodson has determined that, for each year of the first five-year period the proposed
27 amendments and new rule will be in effect, the public benefit anticipated as a result of enforcing
28 the amendments to §291.32 will be allowing a pharmacist in a Class A pharmacy to determine
29 the appropriate number of pharmacy technicians to safely operate the pharmacy as well as
30 allowing the pharmacist to be more directly involved with the patient. The amendments to
31 §291.33 and new §291.36 will ensure pharmacies engaged in sterile compounding are
32 appropriately licensed and establish standards for the safe compounding of sterile preparations.

33 There may be an adverse economic effect on micro, small, and large businesses or to other
34 entities/persons who are required to comply with the proposed rules for pharmacies
35 compounding sterile preparations. Based on the significant variances in pharmacies' physical
36 structure and layout, it is difficult for TSBP to determine the actual cost to businesses required to
37 comply with these rules. These costs would involve bringing the sterile compounding area of
38 pharmacies into compliance with the new provisions. TSBP cannot precisely determine the
39 number of pharmacies affected because TSBP records do not provide complete information
40 about the details of the pharmacies' compounding operations. In addition, TSBP is unable to

41 reduce these costs because to do so would compromise the purposes of these rules which is
42 intended to protect the health and safety of the public.

43 A public hearing to receive comments on the proposed §§291.32, 291.33, and 291.36 will be
44 held at 1:00 p.m. on Monday, November 4, 2013, at the Health Professions Council Board
45 Room, 333 Guadalupe Street, Tower II, Room 225, Austin, Texas 78701. Persons planning to
46 present comments to the Board are asked to provide a written copy of their comments prior to the
47 hearing or to bring 20 copies to the hearing. Written comments on the amendments and new rule
48 may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State
49 Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-
50 8008. Comments must be received by 5:00 p.m., October 31, 2013.

51 The amendments and new rule are proposed under §§551.002, 551.003, 554.001, 554.051,
52 554.053, and 560.053 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 569, Texas
53 Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the
54 public through the effective control and regulation of the practice of pharmacy. The Board
55 interprets §551.003(9) as authorizing the agency to adopt rules concerning the compounding of
56 prescriptions. The Board interprets §551.003(33) as authorizing the agency to adopt rules
57 concerning the practice of pharmacy. The Board interprets §554.001(a) as authorizing the agency
58 to adopt rules to administer and enforce the Act and rules adopted under the Act as well as
59 enforce other laws relating to the practice of pharmacy. The Board interprets §554.051(a) as
60 authorizing the agency to adopt rules for the proper administration and enforcement of the Act.
61 The Board interprets §554.053 as authorizing the agency to determine the ratio of pharmacists to
62 pharmacy technicians in a pharmacy. The Board interprets §560.053 as authorizing the agency to
63 adopt rules establishing additional pharmacy classifications.

64 The statutes affected by the amendments and new rule: Texas Pharmacy Act, Chapters 551 - 566,
65 568 and 569, Texas Occupations Code.

66 **§291.32. Personnel.**

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

68 (d) Pharmacy Technicians and Pharmacy Technician Trainees.

69 (1) (No change.)

70 (2) Duties.

71 (A) - (B) (No change.)

72 (C) Pharmacy technicians and pharmacy technician trainees may perform only nonjudgmental
73 technical duties associated with the preparation and distribution of prescription drugs, as follows:

74 (i) initiating and receiving refill authorization requests;

- 75 (ii) entering prescription data into a data processing system;
- 76 (iii) selecting a stock container [~~taking a stock bottle~~] from the shelf for a prescription;
- 77 (iv) preparing and packaging prescription drug orders (i.e., counting tablets/capsules, measuring
78 liquids and placing them in the prescription container);
- 79 (v) affixing prescription labels and auxiliary labels to the prescription container;
- 80 (vi) reconstituting medications;
- 81 (vii) prepackaging and labeling prepackaged drugs;
- 82 (viii) loading bulk unlabeled drugs into an automated dispensing system provided a pharmacist
83 verifies that the system is properly loaded prior to use;
- 84 (ix) compounding non-sterile and sterile prescription drug orders; and
- 85 (x) compounding bulk preparations.

86 (3) Ratio of on-site pharmacist to pharmacy technicians and pharmacy technician trainees.

87 (A) Except as provided in subparagraph (B) of this paragraph, there is no ratio requirement for
88 Class A pharmacies. [~~the ratio of on-site pharmacists to pharmacy technicians and pharmacy~~
89 ~~technician trainees may be 1:3, provided the pharmacist is on-site and at least one of the three is~~
90 ~~a pharmacy technician. The ratio of pharmacists to pharmacy technician trainees may not exceed~~
91 ~~1:2.~~]

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

94 (i) the Class A pharmacy:

95 (I) dispenses no more than 20 different prescription drugs; and

96 (II) does not produce sterile preparations including intravenous or intramuscular drugs on-site;
97 and

98 (ii) the following conditions are met:

99 (I) at least four are pharmacy technicians and not pharmacy technician trainees; and

100 (II) The pharmacy has written policies and procedures regarding the supervision of pharmacy
101 technicians and pharmacy technician trainees, including requirements that the pharmacy
102 technicians and pharmacy technician trainees included in a 1:5 ratio may be involved only in one
103 process at a time. For example, a technician/trainee who is compounding non-sterile preparations

104 or who is involved in the preparation of prescription drug orders may not also call physicians for
105 authorization of refills.

106 (e) (No change.)

1 **SUBCHAPTER C. NUCLEAR PHARMACY (CLASS B)**
2 **§291.53**

3 The Texas State Board of Pharmacy (TSBP) proposes amendments to §291.53, concerning
4 Personnel, and §291.54, concerning Operational Standards, and new §291.56, concerning
5 Pharmacies Compounding Sterile Preparations (Class B-S).

6 The proposed amendments to §291.53, if adopted, eliminate the pharmacist to technician ratio
7 for Class B pharmacies. The proposed amendments to §291.54, if adopted, clarify that Class B
8 pharmacies will no longer be able to compound sterile preparations after June 1, 2014, unless the
9 pharmacy obtains a Class B-S pharmacy license. Proposed new §291.56, if adopted, outlines the
10 requirements for pharmacies that compound sterile preparations, implements recommendations
11 of the TSBP appointment Task Force on Compounding Sterile Preparations (Task Force), and
12 implements Senate Bill 1100 passed by the 83rd Regular Session of the Texas Legislature
13 regarding compounding pharmacies.

14 The TSBP established the Task Force in December 2012 to review the current standards of
15 practice for pharmacy compounding and was charged with: (1) reviewing current federal and
16 state requirements for sterile compounding; and (2) making recommendations to the Board of
17 Pharmacy regarding standards for pharmacy compounding in Texas that provide necessary
18 compounded medications while protecting the health, safety, and welfare of the public. The Task
19 Force met three times and presented its recommendations to the Board at the August 6, 2013,
20 meeting. The Task Force was composed of representatives from the pharmacy community
21 appointed by the three major pharmacy associations in Texas and pharmacists primarily involved
22 in compounding.

23 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
24 period the proposed amendments and new rule are in effect, there will be no fiscal implications
25 for state or local government as a result of enforcing or administering the rules.

26 Ms. Dodson has determined that, for each year of the first five-year period the proposed
27 amendments and new rule will be in effect, the public benefit anticipated as a result of enforcing
28 the amendments to §291.53 is allowing a pharmacist in a Class B pharmacy to determine the
29 appropriate number of pharmacy technicians needed to safely operate the pharmacy as well as
30 allowing the pharmacist to be more directly involved with the patient. The amendments to
31 §291.54 and new §291.56 will ensure pharmacies engaged in sterile compounding are
32 appropriately licensed and establish standards for the compounding of sterile preparations.

33 There may be an adverse economic effect on micro, small, and large businesses or to other
34 entities/persons who are required to comply with the proposed rules for pharmacies
35 compounding sterile preparations. Based on the significant variances in pharmacies' physical
36 structure and layout, it is difficult for TSBP to determine the actual cost to businesses required to
37 comply with these rules. These costs would involve bringing the sterile compounding area of
38 pharmacies into compliance with the new provisions. TSBP cannot precisely determine the
39 number of pharmacies affected because TSBP records do not provide complete information
40 about the details of the pharmacies' compounding operations. In addition, TSBP is unable to

41 reduce these costs because to do so would compromise the purposes of these rules which is
42 intended to protect the health and safety of the public.

43 A public hearing to receive comments on proposed §§291.53, 291.54, and 291.56 will be held at
44 1:00 p.m. on Monday, November 4, 2013, at the Health Professions Council Board Room, 333
45 Guadalupe Street, Tower II, Room 225, Austin, Texas 78701. Persons planning to present
46 comments to the Board are asked to provide a written copy of their comments prior to the
47 hearing or to bring 20 copies to the hearing. Written comments on the amendments and new rule
48 may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State
49 Board of Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-
50 8008. Comments must be received by 5:00 p.m., October 31, 2013.

51 The amendments and new rule are proposed under §§551.002, 551.003, 554.001, 554.051,
52 554.053, and 560.053 of the Texas Pharmacy Act (Chapters 551 - 566, 568 and 569, Texas
53 Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the
54 public through the effective control and regulation of the practice of pharmacy. The Board
55 interprets §551.003(9) as authorizing the agency to adopt rules concerning the compounding of
56 prescriptions. The Board interprets §551.003(33) as authorizing the agency to adopt rules
57 concerning the practice of pharmacy. The Board interprets §554.001(a) as authorizing the agency
58 to adopt rules to administer and enforce the Act and rules adopted under the Act as well as
59 enforce other laws relating to the practice of pharmacy. The Board interprets §554.051(a) as
60 authorizing the agency to adopt rules for the proper administration and enforcement of the Act.
61 The Board interprets §554.053 as authorizing the agency to determine the ratio of pharmacists to
62 pharmacy technicians in a pharmacy. The Board interprets §560.053 as authorizing the agency to
63 adopt rules establishing additional pharmacy classifications.

64 The statutes affected by the amendments and new rule: Texas Pharmacy Act, Chapters 551 - 566,
65 568 and 569, Texas Occupations Code.

66 **§291.53. Personnel.**

67 (a) Pharmacists-in-Charge.

68 (1) General.

69 (A) - (B) (No change.)

70 (C) Each Class B pharmacy shall have one pharmacist-in-charge who is employed on a full-time
71 basis, who may be the pharmacist-in-charge for only one such pharmacy; provided, however,
72 such pharmacist-in-charge may be the pharmacist-in-charge of:

73 (i) more than one Class B pharmacy, if the additional Class B pharmacies are not open to provide
74 pharmacy services simultaneously; or

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

78 (2) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum,
79 the following:

80 (A) - (K) (No change)

81 (L) legally operating [~~legal operation of~~] the pharmacy, including meeting all inspection and
82 other requirements of all state and federal laws or rules governing the practice of pharmacy.

83 (b) Owner. The owner of a Class B pharmacy shall have responsibility for all administrative and
84 operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on
85 administrative and operational concerns. The owner shall have responsibility for, at a minimum,
86 the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with
87 the pharmacist-in-charge or another Texas licensed pharmacist:

88 (1) establishing [~~establishment of~~] policies for procurement of prescription drugs and devices and
89 other products dispensed from the Class B pharmacy;

90 (2) establishing [~~establishment of~~] policies and procedures for the security of the prescription
91 department including the maintenance of effective controls against the theft or diversion of
92 prescription drugs;

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

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

98 (5) establishing [~~establishment of~~] policies and procedures regarding maintenance, storage, and
99 retrieval of records in a data processing system such that the system is in compliance with state
100 and federal requirements.

101 (c) Authorized nuclear pharmacists.

102 (1) General.

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

104 (D) Authorized nuclear pharmacists are solely responsible for the direct supervision of pharmacy
105 technicians and pharmacy technician trainees and for delegating nuclear pharmacy techniques
106 and additional duties, other than those listed in paragraph (2) of this subsection, to pharmacy
107 technicians and pharmacy technician trainees. Each authorized nuclear pharmacist shall:

108 (i) ~~shall~~ verify the accuracy of all acts, tasks, or functions performed by pharmacy technicians
109 and pharmacy technician trainees; and

110 (ii) ~~shall~~ be responsible for any delegated act performed by pharmacy technicians and
111 pharmacy technician trainees under his or her supervision.

112 (E) - (F) (No change.)

113 (2) (No change.)

114 (3) Duties. Duties which may only be performed by an authorized nuclear pharmacist are as
115 follows:

116 (A) receiving verbal therapeutic prescription drug orders and reducing these orders to writing,
117 either manually or electronically;

118 (B) receiving verbal, diagnostic prescription drug orders in instances where patient specificity is
119 required for patient safety (e.g., radiolabeled blood products, radiolabeled antibodies) and
120 reducing these orders to writing, either manually or electronically;

121 (C) interpreting and evaluating radioactive prescription drug orders;

122 (D) selecting ~~selection of~~ drug products; and

123 (E) performing the final check of the dispensed prescription before delivery to the patient to
124 ensure that the radioactive prescription drug order has been dispensed accurately as prescribed.

125 (d) Pharmacy Technicians and Pharmacy Technician Trainees.

126 (1) - (3) (No change.)

127 (4) Ratio of authorized nuclear pharmacist to pharmacy technicians and pharmacy technician
128 trainees. There is no ratio requirement for Class B pharmacies.

129 ~~{(A) The ratio of authorized nuclear pharmacists to pharmacy technicians and pharmacy
130 technician trainees may be 1:3, provided at least one of the three is a pharmacy technician and is
131 trained in the handling of radioactive materials.}~~

132 ~~{(B) The ratio of authorized nuclear pharmacists to pharmacy technician trainees may not exceed
133 1:2.}~~

134 (e) (No change.)

1 **SUBCHAPTER H. OTHER CLASSES OF PHARMACY**

2 **22 TAC §291.153**

3 The Texas State Board of Pharmacy proposes amendments to §291.153, concerning Central
4 Prescription Drug or Medication Order Processing Pharmacy (Class G). The proposed
5 amendments to §291.153, if adopted, eliminate the pharmacist to technician ratio for Class G
6 pharmacies.

7 Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year
8 period the amended rule is in effect, there will be no fiscal implications for state or local
9 government as a result of enforcing or administering the rule.

10 Ms. Dodson has determined that, for each year of the first five-year period the amended rule will
11 be in effect, the public benefit anticipated as a result of enforcing the amendments will be by
12 allowing a pharmacist in a Class G pharmacy to determine the appropriate number of pharmacy
13 technicians to safely operate the pharmacy and allow the pharmacist to be more directly involved
14 with the patient. There is no fiscal impact for individuals, small or large businesses, or to other
15 entities which are required to comply with this section.

16 A public hearing to receive comments on the proposed amendments to §291.153 will be held at
17 1:00 p.m. on Monday, November 4, 2013, at the Health Professions Council Board Room, 333
18 Guadalupe Street, Tower II, Room 225, Austin, Texas 78701. Persons planning to present
19 comments to the Board are asked to provide a written copy of their comments prior to the
20 hearing or to bring 20 copies to the hearing. Written comments on the amendments may be
21 submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, Texas State Board of
22 Pharmacy, 333 Guadalupe Street, Suite 3-600, Austin, Texas 78701, fax (512) 305-8008.
23 Comments must be received by 5:00 p.m., October 31, 2013.

24 The amendments are proposed under §§551.002, 554.051, and 554.053 of the Texas Pharmacy
25 Act (Chapters 551 - 566, 568 and 569, Texas Occupations Code). The Board interprets §551.002
26 as authorizing the agency to protect the public through the effective control and regulation of the
27 practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules
28 for the proper administration and enforcement of the Act. The Board interprets §554.053 as
29 authorizing the agency to determine the ratio of pharmacists to pharmacy technicians in a
30 pharmacy.

31 The statutes affected by the amendments: Texas Pharmacy Act, Chapters 551 - 566, 568 and 569,
32 Texas Occupations Code.

33 ***§291.153. Central Prescription Drug or Medication Order Processing Pharmacy (Class G).***

34 (a) - (b) (No change.)

35 (c) Personnel.

- 36 (1) - (2) (No change.)
- 37 (3) Pharmacists.
- 38 (A) (No change.)
- 39 (B) Duties. Duties which may only be performed by a pharmacist are as follows:
- 40 (i) receiving oral prescription drug or medication orders and reducing these orders to writing,
41 either manually or electronically;
- 42 (ii) interpreting prescription drug or medication orders;
- 43 (iii) selecting [~~selection of~~] drug products;
- 44 (iv) verifying the data entry of the prescription drug or medication order information at the time
45 of data entry prior to the release of the information to a Class A, Class C, or Class E pharmacy
46 for dispensing;
- 47 (v) communicating to the patient or patient's agent information about the prescription drug or
48 device which in the exercise of the pharmacist's professional judgment, the pharmacist deems
49 significant, as specified in §291.33(c) of this title (relating to Operational Standards);
- 50 (vi) communicating to the patient or the patient's agent on his or her request information
51 concerning any prescription drugs dispensed to the patient by the pharmacy;
- 52 (vii) assuring that a reasonable effort is made to obtain, record, and maintain patient medication
53 records;
- 54 (viii) interpreting patient medication records and performing drug regimen reviews; and
- 55 (ix) performing a specific act of drug therapy management for a patient delegated to a pharmacist
56 by a written protocol from a physician licensed in this state in compliance with the Medical
57 Practice Act.
- 58 (4) Pharmacy Technicians and Pharmacy Technician Trainees.
- 59 (A) - (B) (No change.)
- 60 (C) Ratio of on-site pharmacists to pharmacy technicians and pharmacy technician trainees.
61 There is no ratio requirement for Class G pharmacies provided [~~A Class G pharmacy may have a~~
62 ~~ratio of on-site pharmacists to pharmacy technicians/pharmacy technician trainees of 1:6~~
63 ~~provided;~~]
- 64 [~~(i) at least five are pharmacy technicians and not pharmacy technician trainees; and~~]

65 [~~(i)~~] the pharmacy has written policies and procedures regarding the supervision of pharmacy
66 technicians and pharmacy technician trainees.

67 (5) (No change.)

68 (d) - (e) (No change.)



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The Senate of the State of Texas

Jane Nelson
Senate District 12

Committees:

HEALTH AND HUMAN SERVICES, CHAIR
TEXAS LEGISLATIVE COUNCIL
GOVERNMENT ORGANIZATION
NOMINATIONS
FINANCE

October 1, 2013

Ms. Jeanne D. Waggener
President, Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-600
333 Guadalupe Street
Austin, Texas 78701

Dear President Waggener:

It has come to my attention that the Texas State Board of Pharmacy is considering a rule change that would allow pharmacists to supervise an unlimited number of pharmacy technicians in Class A pharmacies. This is a dramatic increase over the current 1:3 pharmacist to pharmacy technician ratio for these types of pharmacies.

Under the direct supervision of licensed pharmacists, pharmacy technicians play a critical role in ensuring patients receive prescriptions in a safe and timely manner. While I understand the desire to improve access to care and allow pharmacists to spend less time on technical duties, these efforts should not trump patient safety. The pharmacy technician ratio should reflect the number of pharmacy technicians that can be safely supervised by a pharmacist.

As you continue your work on this proposed rule change, I request that any modification to the current pharmacy technician ratio increase access to care while maintaining patient safety.

Very truly yours,

A handwritten signature in cursive script that reads "Jane Nelson".

Senator Jane Nelson

Cc: Ms. Gay Dodson, Executive Director of the Texas State Board of Pharmacy



CHARLES SCHWERTNER

STATE SENATOR
DISTRICT 5

October 2, 2013

Ms. Gay Dodson
Executive Director
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-8701

Dear Ms. Dodson,

In August, I learned that the Texas State Board of Pharmacy voted to propose rules that would eliminate the pharmacist to pharmacy technician supervision ratio. I have now been informed that the proposed rules were made public and published in the Texas Register last Friday, September 27.

I am deeply concerned that the Board has taken this bold action. If these rules are approved, there would not be a limit on the number of technicians that a pharmacist could supervise. This would establish a dangerous precedent, jeopardizing patient safety and placing the public at risk.

I understand that prescription volume is increasing and pharmacy workloads continue to grow as pharmacies provide a greater array of services. It would, however, be irresponsible to move from the current 1:3 ratio to a complete elimination of any ratio. That being said, I would support an increase in the supervision ratio to 1:4. At this time, any increase beyond a 1:4 ratio will compromise the safety and quality of care for Texans.

I strongly encourage the Board to reconsider the current proposal. If you have any questions or would like to visit with me about this issue and my concerns, I am happy to meet with you or any Board member.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Schwertner".

Charles Schwertner, M.D., R.Ph.
State Senator



The Senate of The State of Texas

Senator Leticia Van de Putte, R. Ph.

District 26

PRESIDENT PRO TEMPORE, 2013

October 17, 2013

Ms. Jeanne Waggener
Texas State Board of Pharmacy
President
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-8701

Dear Ms. Waggener:

Thank you for your service to our state as President of the Texas State Board of Pharmacy. I appreciate the time that you have taken to consider serious matters regarding patient safety within the delivery of pharmacy services. Currently before the Board is an issue of great importance, which would change the current pharmacist to pharmacy technician supervision ratio of 1:3 in certain pharmacies.

As a practicing pharmacist for over thirty-three years, I understand and appreciate the crucial role of pharmacy technicians. However, I am concerned that a complete elimination of this ratio would be a dramatic change that could have serious unforeseen consequences. Pharmacists should have the ability to focus more time on direct patient care, but adequate supervision of pharmacy technicians by trained pharmacists is absolutely crucial to guarantee our patient safety.

Over the last 30+ years, I have had the opportunity to work with many different technicians. Most of these pharmacy technicians were extremely competent, well trained, and required the appropriate level of supervision. In fact, I would have been within my professional jurisdiction to supervise four or even five technicians of this quality. However, I have also worked with pharmacy technicians who required so much individual attention that it became difficult to oversee even one technician's workload.

I respect the Board's authority to determine the rules most appropriate for the practice of pharmacy in Texas. Because patient safety is the most important aspect of our work, I would strongly encourage the board to look more closely at the rigorousness and depth of training required for pharmacy technicians before moving forward with any dramatic expansion of the supervision ratio. I understand the industry is developing a pharmacy technician task force to facilitate more thoughtful discussion on this issue, and I believe it would benefit everyone involved to postpone adoption on this potential rule change until the recommendations of this task force, or a task force created by the Board itself, have been completed.

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I am proud that the practice of pharmacy is evolving rapidly and making changes to meet new healthcare paradigms. In order to address these changes, I support the Board's original proposal to increase the ratio from 1:3 to 1:4. This reasonable increase will capture the benefits of granting pharmacists more staff members capable of handling technical tasks, without creating environments in which pharmacists become overburdened and unable to safely and sufficiently oversee the work done by pharmacy technicians.

Please know how much I appreciate your deliberation and concern in this matter, and I look forward to working with you as the board of pharmacy prepares for the sunset process next legislative session.

Sincerely,

A handwritten signature in cursive script that reads "Leticia Van de Putte, R.Ph." The signature is written in dark ink and is positioned below the word "Sincerely,".

Leticia Van de Putte, R.Ph.

TEXAS HOUSE OF REPRESENTATIVES



J.D. Sheffield District 59

October 24, 2013

Ms. Jeanne Waggener
President
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-8701

Dear Ms. Waggener;

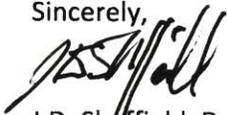
On November 4, 2013, the Texas State Board of Pharmacy is scheduled to consider a measure that would change the supervision ratio of pharmacists to pharmacy technicians, currently set at 1 to 3, in certain pharmacies. I am writing to express my concern over these changes as it impacts patients and customers of pharmacies in Texas.

As a family practice physician for almost 20 years; my first priority is the health and safety of Texans. Having worked closely with pharmacists, I understand that they have many responsibilities beyond supervision of the work of pharmacy technicians. I am concerned that a large increase in this ratio could result in safety concerns for customers and patients.

It is my understanding that the State Board of Pharmacy has previously considered a ratio of one pharmacist to four pharmacy technicians. This increase seems more manageable for pharmacists than a greater increase in the ratio or elimination of the ratio requirement altogether. I would still urge that any increase in the ratio be studied to provide for the highest level of patient safety possible.

I am looking forward to working with you, other members of the legislature, and pharmacists to develop the best healthcare policies for our state. Thank you for your concern and attention to this matter.

Sincerely,



J.D. Sheffield, D.O.



RECEIVED
2013 OCT 10 PM 2:15
TX STATE BD
OF PHARMACY

ALLIANCE of
Independent
Pharmacists
of TEXAS

October 9, 2013

Ms. Gay Dodson
Executive Director
Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701

Dear Ms. Dodson:

The Board of Directors and members of the Alliance of Independent Pharmacists of Texas are deeply concerned about the Texas State Board of Pharmacy's decision to eliminate the pharmacist to technician ratio in class A and B pharmacies.

In a survey taken of our members, out of 222 respondents, only 12% thought eliminating the ratio was a viable option. Thirty-seven percent voted to keep the current 3:1 ratio and 40% voted to increase the ratio to 4:1.

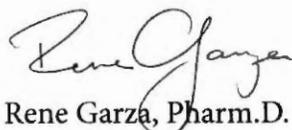
One pharmacist stated, "I am afraid unlimited ratios will force pharmacists to supervise more technicians than they feel comfortable. Some pharmacists may say "yes" to something they are not comfortable with in order to keep their jobs." Many Alliance members feel this decision would be taken out of the hands of pharmacists and delegated to staff more concerned about the bottom line than patient safety.

Another pharmacist commented on the survey, "Having an unlimited ratio opens pharmacies up to more errors. This would be a detriment to our patients and to the profession as a whole." In light of the national and state scrutiny of compounding pharmacies this decision does not align with the best interest of patient care and public safety.

The Alliance Board of Directors strongly encourages the Board to reconsider their initial proposal and take a more gradual approach by considering a 4:1 ratio. This aggressive move to eliminate the ratio should only be considered after additional technician training and further study.

The Alliance Board and staff will continue to monitor this issue and encourage members to speak against the proposal at the November 4 meeting in Austin. Please contact Alliance Executive Director Audra Conwell, CAE, at aconwell@aiptexas.org if you would like to see complete survey results and pharmacist comments.

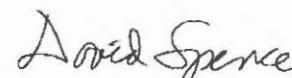
Sincerely,



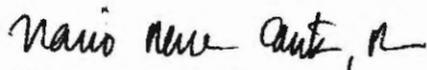
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President



Anjanette Wyatt, Pharm.D.
President-Elect



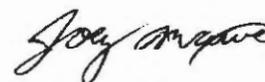
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Nario Cantu, R.Ph.
Director



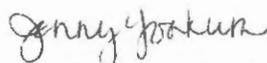
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Director



Joey Maxwell, R.Ph.
Director



Mark Peippo, R.Ph.
Director



Jenny Downing Yoakum, Pharm.D.
Director



TEXAS *Pharmacy Association*

Advancing, Protecting & Unifying the Profession of Pharmacy since 1875

October 29, 2013

Gay Dodson, R. Ph.
Executive Director/Secretary
Texas State Board of Pharmacy
William P. Hobby Building
Tower 3, Suite 600
333 Guadalupe St.
Austin, Texas 78701

RE: TSBP Proposed Rules regarding

- **Supervision Ratio for Pharmacy Technicians**
- **Sterile Compounding**
- **Pharmacists Certification Programs**

Dear Executive Director Dodson:

The Texas Pharmacy Association appreciates the opportunity to provide comments on the various proposed rules developed by the Texas State Board of Pharmacy and published in the September 27, 2013, issue of the *Texas Register* – **38 TexReg 6499-6535**. In this transmittal, TPA is focusing its comments only on the proposed rules noted above. Though important, TPA is not providing comments on the other proposed rules. A summary is included at the end of our comment letter.

Supervision Ratio for Pharmacy Technicians - Comments

Our Association must express strong **opposition to the elimination** of the Pharmacist- to-Technician supervision ratio of 1:3 in class A and B pharmacies as proposed in rules published Sept. 28 in the *Texas Register*. And asks that the **TSBP “pull-down” the proposed rules from further consideration**. Members of TPA strongly believe that more comprehensive information is needed before a supervision ratio is eliminated.

For more than a year, TPA has proposed and continues to support **a comprehensive study regarding the education and scope of practice for Pharmacy Technicians to gather timely, relevant data** to help determine what, if any, should be an appropriate supervision ratio. In recognition that such a study will take some time, TPA would **support an interim change** in the supervision ratio from 1:3 to 1:4 as a compromise.

TPA has a long-time position in support of regulations that cap the technician supervision ratio at 1:3. Legally, this supervision ratio pertains to pharmacy technicians; however, nearly all pharmacists in Texas also supervise many other pharmacy staff. At any one time, these additional individuals and employees could include other pharmacists and student pharmacists, along with a very wide range of staff that is not directly involved in the dispensing process, such as cash register staff, clerical staff, staff in the front part of the store, etc.

The Association’s position always has been based on the likelihood that high supervision requirements will impact patient safety unless appropriate education and work flow issues are addressed. And our position on protecting the current ratio was recently reaffirmed during months of discussion by the TPA Board of Directors along with strong membership feedback.

Less than two months ago, the Association conducted a statewide survey regarding the technician supervision ratio. Participation was overwhelming with nearly a **50% response rate** or **1408 respondents** in less than 48 hours. More than **89 percent of pharmacists and 75 percent of pharmacy technicians favored limiting the supervision ratio to 1:5 or less**. There also were 84 pages of additional verbatim comments from the respondents. Clearly, this continues to be a very important issue for many TPA members.

The information that follows provides a brief summary of the 1408 responses from pharmacists (89%) and pharmacy technicians (11%) as of the survey deadline.

TPA Poll results:

Pharmacists

All Pharmacists 1249 Total Respondents

41.6% 1:3
 20.0% 1:4
 13.8% 1:5
 21.0% Unlimited
 3.7% Other

Chain & Independent Pharmacists 800 Respondents

58% Male 42% Female
 37% 1:3
 29% 1:4
 15% 1:5
 18% Unlimited
 <1% Other (1:1, 1:2)

Chain Pharmacists – only 487 Respondents

50.5% Male 49.5% Female
 32% 1:3
 19% 1:4
 13% 1:5
 35% Unlimited
 <1% Other (1:1, 1:2)

Independent Pharmacists – only 313 Respondents

70% Male 30% Female
 44% 1:3
 24% 1:4
 19% 1:5
 12% Unlimited
 <1% Other (1:1, 1:2)

Clinical Pharmacists 120 Respondents

82% Limits
 18% Unlimited

Pharmacy Technicians

All Technicians 159 Total Respondents

29% Male 71% Female
 41% 1:3
 19% 1:4
 11% 1:5
 25% Unlimited
 4% Other (1:1, 1:2)

Chain Technicians 52 Respondents

76% Limits
 24% Unlimited

Independent Technicians 28 Respondents

71% Limits
 29% Unlimited

Compounding Technicians 11 Respondents

90% Limits
 10% Unlimited

Clinical Technicians 19 Respondents

75% Limits
 25% Unlimited

Though this survey was conducted purely as an opinion poll and is not statistically valid, the number and breadth of the respondents, the 84 pages of additional comments received and the quick turn-around timeframe of the responses clearly indicate the opposition by Texas pharmacists as well as the critical nature of the issue. These points strongly suggest that a change in the Agency’s proposal must be considered.

TPA believes that a patient’s health and safety is the primary responsibility of the pharmacist and should be everyone’s ultimate objective. Protecting the health and safety of the patient also is TSBP’s **only** charge. TSBP is **THE** state agency charged with protecting Texans’ health and safety relating to **ALL** matters involving prescription medication. The TSBP proposal to eliminate the pharmacy technician supervision ratio puts that critical goal at risk and is a step that must not be taken at this time.

Technician Study

Aside from the issue of ratios, TPA strongly believes that the initial educational requirements for technicians as well as their continuing education directives should be reviewed. The limits placed on their scope of duties also should be reconsidered as the pharmacy profession continues to change. Clearly, the demands on pharmacists have continued to increase. And consequently, the role of the pharmacy technician may warrant expansion to meet the needs in the various pharmacy settings.

Though the TSBP's current strategic plan includes conducting a comprehensive analysis and possible expansion of educational requirements for pharmacy technicians, the agency has informally discussed the possibility that such a study could be conducted by the pharmacy profession and their associations. Should that continue to be the case, the **Texas Pharmacy Association**, the **Texas Society of Health System Pharmacists** and the **Texas Federation of Drug Stores** have agreed to establish a broad-based **Pharmacy Technician Initiative Task Force** to review the current and possible future scope of practice for pharmacy technicians as well as their initial and ongoing educational requirements. Included among the issues the Task Force would be expected to discuss and consider are:

- minimum entry-level educational requirements for pharmacy tech candidates;
- establishment of different levels and modes of training for technicians;
- increased specificity of continuing education requirements; and
- a redefined, expanded and/or varying technician role to allow for different levels of responsibilities.

The *Pharmacy Technician Initiative Task Force* would issue a report with related recommendations to be submitted to the TSBP in early 2014.

The three organizations will have further planning discussions during the week of October 28 regarding the parameters of the study, the timeline and the needed process to involve the profession as well as other pharmacy-related organizations.

Please be aware that the study will **not** address or have official recommendations regarding the technician supervision ratio nor any regulatory alternatives that would allow pharmacists to determine how many technicians they can safely supervise. TPA likely will address such issues outside of the joint study efforts based on the conclusions and recommendations resulting from the study.

Sterile Compounding - Comments

TPA recognizes that much of what is included in the proposed rules *Concerning Personnel, Operational Standards and Compounding Sterile Preparations in Chapter 297* for Class A, B, C, E, and G pharmacies was the result of discussions and recommendations from the TSBP Task Force on Pharmacy Compounding.

With strong support from the agency's staff, this Task Force ably met their charge to review current regulations and the inspection process for compounding pharmacies. To date, the Association is not aware of any significant concerns with the rules as proposed pertaining to.

Please know that TPA appreciated the opportunity to have two representatives on the Task Force and commends the Agency for its handling of the issue.

Pharmacists Certification Programs - Comments

TPA supports the proposed rule changes in Chapter 295. PHARMACISTS 22 TAC §295.12 (TexReg 6533) concerning *Pharmacist Certification Programs and clarifying the requirements for the recognition/approval of pharmacist certification programs*. However, clarification may be needed regarding board approval, the process and additional criteria, if any, for "(c)(1)(D) any additional certifications as published on the board's website."

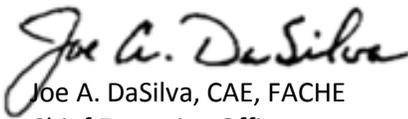
Included below is a summary that highlights the Association's positions on the various issues incorporated in the extensive set of proposed rules:

<u>Proposed Rule</u>	<u>Texas Register Page No.</u>
1 CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES SUBCHAPTER B. GENERAL PROCEDURES IN A CONTESTED CASE 22 TAC §281.22 <i>Concerning Informal Disposition of a Contested Case</i> No comments.	TexReg 6499
2 CHAPTER 281. ADMINISTRATIVE PRACTICE AND PROCEDURES SUBCHAPTER C. DISCIPLINARY GUIDELINES 22 TAC §281.68 <i>Concerning Remedial Plan</i> No comments.	TexReg 6501
3 CHAPTER 283. LICENSING REQUIREMENTS FOR PHARMACISTS 22 TAC §283.12 <i>Concerning Licenses for Military Spouses</i> No comments.	TexReg 6501
4 CHAPTER 291. PHARMACIES SUBCHAPTER A. ALL CLASSES OF PHARMACIES 22 TAC §291.17 <i>Concerning Inventory Requirements</i> No comments.	TexReg 6503
5 SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A) 22 TAC §§291.32, 291.33, 291.36 <i>Concerning Personnel, Operational Standards and Compounding Sterile Preparations (Class A-S)</i> <u>Comments noted above.</u>	TexReg 6504
6 SUBCHAPTER C. NUCLEAR PHARMACY (CLASS B) 22 TAC §§291.53, 291.54, 291.56 <i>Concerning Personnel, Operational Standards and Compounding Sterile Preparations (Class B-S)</i> <u>Comments noted above.</u>	TexReg 6506
7 SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C) 22 TAC §§291.74, 291.76, 291.77 <i>Concerning Operational Standards, Class C Pharmacies located in a Freestanding Ambulatory Surgical Center, and Pharmacies Compounding Sterile Preparations (Class C-S)</i> <u>Comments noted above.</u>	TexReg 6509
8 SUBCHAPTER F. NON-RESIDENT PHARMACY (CLASS E) 22 TAC §§291.104 - 291.106 <i>Concerning Operational Standards, Records, and Pharmacies Compounding Sterile Preparations (Class E-S)</i> <u>Comments noted above.</u>	TexReg 6512
9 SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES Repeal / addition of new §291.133 <i>Concerning Pharmacies Compounding Sterile Preparations.</i> <u>Comments noted above.</u>	TexReg 6514
10 SUBCHAPTER H. OTHER CLASSES OF PHARMACY 22 TAC §291.153 <i>Concerning Central Prescription Drug or Medication Order Processing Pharmacy (Class G)</i> <u>Comments noted above.</u>	TexReg 6532

- 11 CHAPTER 295. PHARMACISTS TexReg 6533
22 TAC §295.12
Concerning Pharmacist Certification Programs and clarifying the requirements for the recognition/approval of pharmacist certification programs.
Comments noted above.
- 12 CHAPTER 297. PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES TexReg 6534
22 TAC §297.10
Concerning expedited procedures for registration as a pharmacy technician for military spouses.
No comments.

Again, thank you for the opportunity to provide our comments. It is our hope and request that you consider the actions the Association has recommended on behalf of Texas patients and the pharmacists, pharmacy technicians and pharmacy support staff who serve them.

Sincerely,



Joe A. DaSilva, CAE, FACHE
Chief Executive Officer
Texas Pharmacy Association

cc: Members of the Board, Texas State Board of Pharmacy
Members, Board of Directors, Texas Pharmacy Association



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TPBC Board

Bruce Rogers,
Chairman, Victoria
Mike Muecke,
Vice-Chair, Bay City
Ray Carvajal,
San Antonio
Joe Ochoa, Edinburg

Executive Director

Michael J. Wright

September 30, 2013

Ms. Gay Dodson, R.Ph.
Executive Director
Texas State Board of Pharmacy
333 Guadalupe St., Suite 3-600
Austin, Texas 78701

I am taking this opportunity to address the proposed rules that would eliminate the Pharmacist to Technician supervision ratio of 1:3 in class A and B pharmacies. If these rules are approved, there would not be limitations on the number of technicians that could be supervised by a single pharmacist.

In the interest of public health and patient safety, this bold move toward unlimited supervision ratios needs further study and careful consideration.

As you are aware, the Texas Pharmacy Business Council represents the largest bloc of independent pharmacists in Texas in the legislative and regulatory arena. Our mission is ensuring access to quality pharmacy services and ensuring the economic viability of community pharmacy and protecting the profession of pharmacy. Public safety is a cornerstone of our concerns that clearly aligns with the Texas State Board of Pharmacy's mission.

The Texas Pharmacy Business Council Board of Directors and the American Pharmacies Board of Directors have taken a position to oppose elimination of the pharmacist to pharmacy technician supervision ratio and support a change in the supervision ration from 1:3 to 1:4 for Class A and Class B pharmacies.

Prescription volumes are rising and community pharmacists continue to provide increasing levels of patient care services. TPBC and American Pharmacies' Directors, who are all community pharmacists, believe that safety and quality of care for Texas patients could be compromised if a ratio beyond 1:4 were ultimately adopted.

TPBC will continue to give this matter our utmost attention by monitoring publication of these rules in the Texas Register and the subsequent 30-day period for public comment, as well as attending the public hearing on November 4 in Austin.

Thanks in advance for consideration of our position.

Best Regards

Michael W. Wright
Executive Director

Bruce Rogers, R.Ph.
Chairman, Board of Directors

Due to the large volume of comments received, additional comments have been posted on the TSBP website in the following two files:

Comments In Favor of Proposed Tech Ratio Rules

http://www.tsbp.state.tx.us/files_pdf/BN/Nov13/In_Favor_of_Proposed_Tech_Ratio_Rules.pdf

Comments Opposed to Proposed Tech Ratio Rules

http://www.tsbp.state.tx.us/files_pdf/BN/Nov13/Opposed_to_Proposed_Tech_Ratio_Rules.pdf