



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."

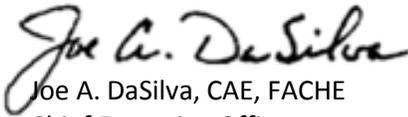
Included below is a summary that highlights the Association's positions on the various issues incorporated in the extensive set of proposed rules:

<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