

Sent: Wednesday, October 30, 2013 5:55 PM

To: 'allison.benz@tsbp.tsbp.state.tx.us'; 'Ben Santana'

Subject: comment on Sterile compounding revision, hazardous drugs and new USP chapter on compounding for investigational studies

Hello,

Concerning the Sterile compounding proposed revisions.

I am whole heartedly for all of the proposed revisions, I would suggest that a implementation timeline be determined and published.

I am especially hopeful that each of the following sections are passed in their entirety and/or will be enforced much more stringently :

1. (iii) A pharmacist shall review all compounding records for accuracy **and conduct in-process** and final checks and verification of calculations to ensure that errors have not occurred in the compounding process.
 - a. I know that in-process checking is already in the current law, but it seems that it is not focused on like it should. Also I believe that there might should be some wording for the use of State approved IV medication management systems that allow remote checking that the state finds acceptable (i.e. possible I.V. Soft, DoseEdge, or ScriptPro) as a electronic alternative to hands on in-process checking at the hood.
2. I have heard that there has been requests that the following education section be clarified as "either", For pharmacist training, I am hoping that you all will ***Please, please, clarify that IV pharmacist will be required to do **"BOTH" 20 hours of a National ACPE certified IV training course AND 20 hours in-house training. Having graduated in 1997, I realized that with the advent of USP 797 in 2004 and all the other pertinent USP chapters and all the facility variables, negative pressure with hazardous meds, environmental testing variables, etc., etc. that the pharmacy school and in-house training back then was sorely lacking for what knowledge is needed today, and that I needed substantial additional education and training, so please require both of these sections for pharmacists and techs that make sterile compounds so that even baseline education:**
 - a. (i) All pharmacists who compound sterile preparations or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall comply with the following:
 - (I) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider which provides 20 hours of instruction and experience in the areas listed in paragraph (4)(D);
 - (II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides 20 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program;
 - b. And the same for technicians;

- (I) All pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall comply with the following:
 - (I) complete through completion of a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection;
 - (II) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program;
3. I am whole heartedly for the 2 hours CE for low and medium risk involved personnel and 4 hours CE for personnel that do high risk both pharmacists and technicians for each license renewal. But, TSBP needs to have a method in place to make sure that the personnel that need to be doing this “are” doing it. Like maybe require C-S pharmacies to list those personnel that perform or check low, medium, or high risk preparations.
4. ****On the didactic and media-fill challenge section, please clarify that “BOTH”** didactic and media-fill challenge. Along with glove-tip testing, and surface sampling be required “every” 6 months for high risk preparations and every 12 months for low and medium. Currently it seems that only media fill is required each 6 months for high risk and the lack of a didactic examination each 6 months has led to a lot of forgetfulness.
5. Please re-iterate the hands free entry into the cleanroom.
6. I am for the use of sterile 70% isopropyl alcohol and from Trissel's studies the use of sterile gloves, even though some nay Sayers say that sterile gloves are cost prohibitive.
7. Re-iteration of visual inspection.
8. Inspection of all compounding pharmacies, please do it, the pharmacies that have spent a lot of time and money making their facility USP and TSBP 291.133 compliant are very proud and happy to demonstrate their accomplishment, those that haven't should be reprimanded and given a timeline to comply or close.
9. Request that TSBP clarify that Tech-check-Tech cannot be used for sterile compounding, that a pharmacist must ultimately at least check sterile compounds.

On a 2nd topic, I would like to mention that it has been a sad realization from interacting with several home healthcare facilities, that they are sorely lacking in the proper handling of hazardous medications and are sorely lacking in having the proper facilities of hazardous medications. An example would be when a patient discharges to them for home care and the patient is on a oral chemo that needs to be compounded into a oral solution, they continue to do this without a chemo hood. So I would suggest inspection of such facilities to check on their safe handling of hazardous medications.

And the last topic I would like to mention is the upcoming new USP chapter on investigational studies (see attached):

I am hoping that USP and TSBP will clarify that facilities that will be preparing Biosafety Level studies, such as Biosafety Level-2 studies, or investigational studies that hazard level is unknown, in the pharmacy, will be required to follow the most stringent equipment, facility, PPE, and cleaning requirements that USP has for hazardous drugs. It seems quite logical to me that at least to err on the

side of precaution that such studies should at least be performed in hoods and facilities designed with the most stringent requirements for hazardous drugs. That is using either a BSC-IIb, BSC-III or negative pressure CACI isolator, that vent 100% to outside air, with negative pressure storage area requirements, and that the hood must be contained in a negative pressure ISO Class 7 cleanroom that is monitored, that is fed clean air from a ISO Class 7 anteroom that is positive pressure. It also seems logical that the proper education/training to safely perform such studies should also be required.

Thank you,

Chas W. Gray, R.Ph.

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TEXAS SOCIETY OF HEALTH-SYSTEM PHARMACISTS

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October 30, 2013

Allison Benz, R.Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy
333 Guadalupe Street
Suite 3-600
Austin, TX 78701

Re: 22 TAC 291.33, Pharmacies Compounding Sterile Preparations

Dear Ms. Benz:

I am writing on behalf of TSHP, the statewide professional society of pharmacists, pharmacy technicians, students and residents, who practice in Texas hospitals and other organized health-systems to offer our comments on the proposed regulations in Section 291.133 as published in the September 27, 2013 issue of the *Texas Register*.

We recognize the significant public health challenges that led to the Board's establishment of a Task Force to review its rules and procedures, and commend the Board on its leadership and progressive approach to continuing its important public health protection role. We were honored to have members of our organization serve on the Task Force, and value the opportunity to communicate with the Board and staff over the years concerning issues relating to compounding within and for Texas hospitals.

We generally support the rules as proposed, but have three specific concerns to mention and request clarification for:

- The change proposed in 291.133 (c) Personnel (2) Pharmacists (B) Initial training and continuing education (i) (I) and (II) relating to completion of a training program and completion of a structured on-the-job didactic program were originally connected with the word "or," indicating that a pharmacist could complete a 20 hour didactic program or an OTJ program. [The same wording exists and previously existed for (3) Pharmacy technicians and pharmacy technician trainees in Section (B)(ii)(I) and (II).] We hope that this omission is an oversight. We believe that leaving this word out of the rules would lead to significant cost and time problems, especially for those currently in practice who may have not completed an ACPE-approved program as well as finding temporary or relief pharmacists or techs or fully qualified pharmacists or technicians transferring from one hospital to another. A total of 20 hours for pharmacists or 40 for technicians should be sufficient to assure quality control, especially given that most pharmacy students graduate today holding appropriate certification in sterile product preparation. We do not believe that data exists to document that the additional 20 hours of training provides any greater assurance of good sterile compounding practice than the basic course. We would request that the word "or" be reinserted between the 2 paragraphs. We are also assuming the rules as proposed will grandfather anyone currently in practice and that the board is not expecting all pharmacists who have previously completed acceptable training and who are today compounding sterile products to repeat an educational

program, and would request clarification of that in the final rules.

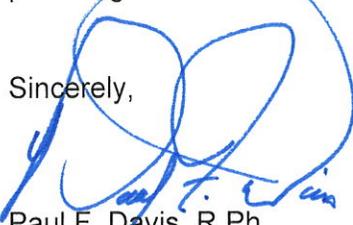
- The continuing education requirements may need to be clarified in terms of inspections and enforcement. Traditionally, individuals who participate in continuing pharmacy education (CPE) programs maintain their own records which are used for re-licensure purposes. Those documents may or may not be at their place of practice, or, in the case of an individual who practices in multiple locations, almost certainly won't be 'on-site' for inspection. Placing the burden on the PIC or facility for this type of recordkeeping is unnecessary. It is ultimately the responsibility of each individual practitioner. However, with the development of the NABP/ACPE MyCPE Monitor program, accredited CPE providers are no longer permitted to issue 'paper copies' of CPE statements, and all records must be uploaded to the MyCPE monitor for electronic access. Consequently, not even the individual pharmacist or technician will have any hard copy documentation of what program they have participated in, as only the UAN assigned by the provider will be recoverable electronically. While we commend the Board for attempting to see that individuals participate in CPE activities relating to sterile compounding, we honestly believe that the previous experience with relicensure requirements and the current status of recordkeeping will only present significant problems to pharmacists, technicians, health-systems, PICs and the Board. Additionally, the proposed rules require that individuals engaged in sterile compounding complete annual didactic reviews, pass written and media fill testing every 6 to 12 months depending on the level of compounding risk in which they are engaged. This requirement seems more important than sitting in a seminar on the latest injectable drug product.

For these reasons, we would urge that the CPE requirement be removed. Failing that, clarification of how the rule will be enforced seems almost essential.

- Finally, we do have a concern about the profession's and Board's ability to meet these standards within essentially 6 months. To have all pharmacies, technicians and pharmacists in full compliance, and have the Board's staff capable of inspecting all new Class S pharmacies prior to June 1 seems a Herculean task. As currently written, if these are not accomplished in all settings, any sterile compounding in that setting will need to be discontinued. We understand and support the need for deadlines, we simply believe that this may be setting us up for failure or non-compliance, and would recommend that a 'no fault' or transition period be incorporated into the rules in the event that TSBP is unable to complete the inspections.

Thank you for taking these comments into consideration. We will look forward to working with the Board to assure a prompt and through roll-out of the new rules when they are finalized and providing assistance so that our members will be in position to comply fully.

Sincerely,



Paul F. Davis, R.Ph.
Executive Director



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October 22, 2013

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Director of Professional Services
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Via Facsimile (512) 305-8008, Email, and Federal Express

Re: Proposed amendments to 22 TAC 291.32, 291.33, 291.36, and 291.133

Dear Director Benz:

Richie's Specialty Pharmacy is a specialty compounding pharmacy located in Conroe, Texas. I am writing to submit comments on the Texas State Board of Pharmacy's proposed regulations and amendments cited above, which address Class A pharmacy operations and pharmacy compounding.

I support the designation of a separate class of sterile compounding pharmacy for each existing class of pharmacies.

I support the amendments proposed to 22 TAC 291.32.

My only concern about the proposed amendments to 22 TAC 291.33 is whether the Texas State Board of Pharmacy will actually be able to inspect and issue Class A-S pharmacy licenses to all applicant pharmacies prior to June 1, 2014. If there is a reasonable doubt as to whether the TSBOP can timely inspect and process all such applications by June 1, 2014, I suggest that an applicant pharmacy currently compounding sterile preparations be allowed to continue to do so until such inspection occurs and the pharmacy passes inspection and receives its Class A-S license. If the inspection reveals deficiencies and the pharmacy applicant fails to pass the inspection, then the pharmacy can be ordered to cease compounding sterile products until it receives a Class A-S license. Further, if the pharmacy has never provided compounded sterile medications within the state of Texas, I support the prohibition of such provision until such time as the inspection and issuance of a Class A-S pharmacy license occurs.

Regarding the proposed 22 TAC 291.36, and based on the proposed language in 22 TAC 291.33, it is not clear when there is a change in ownership whether the new owner of a Class A-S pharmacy can continue to operate and compound sterile preparations prior to a new Class A-S license is issued, or whether the new owner must obtain such a license before being able to compound sterile preparations. This should be addressed and resolved in a manner that protects patients but does not result in an arbitrary break in pharmacy services.

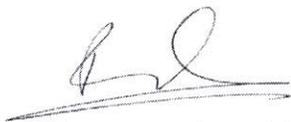
I suggest the following revisions to the proposed 22 TAC 291.133:

1. In the definition of Terminal Sterilization, the reference to "10-6" should be 10ⁿ where "n" is -6.

2. In subsections (c)(2)(B)(iii) (I) and (II), the reference to “clause (i)(II) of this subparagraph” should be changed to “paragraph 4(D) of this subsection”.
3. In subsection (c)(3)(B)(ii) the phrase “for administration to patients” should be stricken.
4. In subsection (c)(3)(B)(iii)(II), the reference to “paragraph (2)(C)” should instead reference “paragraph (2)(B).
5. In subsections (c)(3)(B)(v) (I) and (II), the reference to “clause (ii)(III) of this subparagraph” should be changed to “paragraph 4(D) of this subsection”.
6. In subsection (c)(4)(B), the phrase “preparing sterile preparations” should be added after the phrase “All pharmacy personnel”.
7. In subsection (c)(4)(F), the phrase “media fill tests test indicates” should be changed to “media fill tests indicate”.
8. In subsection (d)(6)(E)(vii), the phrase “ant-area” should be changed to “ante-area”.
9. In subsection (f)(3)(D)(i), the phrase “Class S pharmacy” should be changed to “institutional pharmacy”.

I appreciate both the opportunity to submit comments on these proposed rules and your consideration of our suggested revisions. Please feel free to contact me at 936-588-5601 or by email at richie@richiespharmacy.com if you have any questions.

Sincerely,



Richie Ray, Registered Pharmacist
Pharmacist-In-Charge
President / CEO



TEXAS *Pharmacy Association*

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October 29, 2013

Gay Dodson, R. Ph.
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Texas State Board of Pharmacy
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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