Richie's
SPECIALTY PHARMACY

PCAB Accredited Pharmacy
Toll Free Phone 877.231.8386
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Richie@richiespharmacy.com

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

Via Facsimile (512) 305-8008
and Federal Express Delivery

Re: Proposed Amendments to 22 TAC 291.131 and 291.133

Dear Director Benz:

Richie's Specialty Pharmacy is a compounding pharmacy located in Conroe, Texas. I am writing to submit comments on the Texas Board of Pharmacy's proposed amendments to 22 TAC §291.131 and §291.133, which address pharmacy compounding.

As proposed, amended sections §291.131(d)(7)(I) and §291.131(10)(H) both read as follows:

A pharmacy may not compound a preparation that contains ingredients appearing on a federal or state agency [~~Food and Drug Administration~~] list of drug products withdrawn or removed from the market for safety reasons.

I believe that the federal and state agency responsible for publishing such a list should be specifically referenced in the rules. The FDA has currently published such a list, and a pharmacy should have the right to know which federal and state agency regulations need to be to monitored related to such lists. Additionally, failing to state the specific agency by name raises concerns about whether critical decisions as to which chemicals can or cannot be used by a pharmacist might be made by individuals without appropriate knowledge or qualifications, and whether there will be sufficient guidelines and processes in place for public review and comment regarding the drugs to be included on such a list.

As proposed, amended sections §291.131(g)(2) and §291.133(g)(2) both read as follows, respectively:

The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

There are many reasons why a patient could be harmed by a medication that are totally unrelated to the compound itself, and I do not believe that a pharmacy recall is appropriate in such situations. There may have been an error in administration (e.g., excessive application of a topical dosage form by the patient). There may be an adverse effect due to a patient allergy or intolerance to an active or inactive ingredient that was previously unknown to the patient, or previously undisclosed to the prescriber or pharmacist. Therefore, I recommend adding the phrase "due to the potency, sterility, or composition of the compound itself" to the end of each of these proposed sections. As revised, these sections would read as follows:

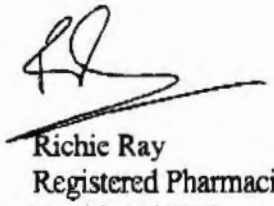
> §291.131(g)(2):
>
> The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient due to the potency, sterility, or composition of the compound itself.
>
> §291.133(g)(2):
>
> The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient due to the potency, sterility, or composition of the compound itself.

For these same reasons, I believe that proposed sections §291.131(g)(3) and §291.133(g)(3) should be revised as follows:

> ~~If the pharmacy identifies a potential or confirmed harm to a patient~~ In the event of a recall, the pharmacist-in-charge shall ensure that:

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 directly at (936) 588-5601 or by email at richie@richiespharmacy.com if you have any questions.

Sincerely,



Richie Ray
Registered Pharmacist
President / CEO

Fax Cover Sheet

David G. Miller, R.Ph., Executive Vice President & CEO
International Academy of Compounding Pharmacists
1321 Duke Street, Suite 200 – Alexandria, VA 22314
(215) 778-5128 *Direct*

To: Allison Benz, R.Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy

From: David G. Miller, R.Ph.

Fax: 512-305-8008

Date: 31 July 2012

Sent: Four (4) Pages Transmitted Including Cover Sheet

Re: Comments on Proposed Regulations
TAC §291.131 and 291.133

Ms. Benz,

On behalf of the members of the International Academy of Compounding Pharmacists, I am pleased to provide you and the Board with our comments on two proposed regulations pertaining to the practice of compounding.

Should the Board have any questions regarding our submission, please do not hesitate to contact our offices.

The documents accompanying this facsimile contain confidential information that may be legally privileged and protected by federal and state law. This information is intended for use only by the

July 23, 2012

Via Facsimile and First Class Mail

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

Dear Director Benz:

On behalf of the officers, directors and Texas members of the International Academy of Compounding Pharmacists (IACP), I am writing to submit comments on the proposed Texas Board of Pharmacy's amendments to 22 TAC §291.131 *Pharmacies Compounding Non-Sterile Preparations* and §291.133 ***Pharmacies Compounding Sterile Preparations.*** IACP very much values the opportunity to offer these observations to the Board as it crafts guidance for pharmacy practitioners that protects the citizens of Texas.

Our comments focus on ambiguities in the proposed language used in two sections of the amendments.

Undefined Use of the Phrase "state agency"

As proposed, amended sections §291.131(d)(7)(I) and §291.131(10)(H) both read as follows:

> *A pharmacy may not compound a preparation that contains ingredients appearing on a federal or state agency [~~Food and Drug Administration~~] list of drug products withdrawn or removed from the market for safety reasons.*

Currently, the Food and Drug Administration is responsible for and does publish a "negative" list of active pharmaceutical ingredients which pharmacists and others may not use in compounding [21CFR216.24]. While the intent to empower the state to also develop and publish such a list is understandable, IACP is concerned that there is no definition within existing Texas statute or regulations or within the proposed amendments themselves that specifically define which state agency would be involved in the identification and review process.

Without that definition or by stating a specific agency by name and leaving it entirely open-ended, we believe such critical decisions as to which chemicals shall or shall not be used by a pharmacist may be made by individuals without appropriate knowledge or qualifications. Additionally, without that definition or specificity, our Academy cannot ascertain whether there would be sufficient guidelines and processes in place for public review and comment.

Ambiguity of Language Pertaining to Recall Requirements

IACP strongly supports a robust recall procedure for all compounding pharmacies and has made available a comprehensive SOP and resource checklist to assist its members in issuing a recall for any preparation which they may dispense. Prompt and thorough communication is a core component of those materials.

We are, however, concerned with several areas of ambiguity within the amended regulations pertaining to the issuance of recalls of compounded medications.

As proposed, amended sections §291.131(g)(2) and §291.133(g)(2) both read as follows, respectively:

> *The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.*
>
> *The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.*

IACP believes that this language is unclear. There are many reasons why harm may come to a patient from a medication that is unrelated to the compound itself. There may have been an error in administration (e.g., excessive application of a topical dosage form by the patient). There may be an adverse effect due to an allergy or intolerance to an active or inactive ingredient that was heretofore unknown to the prescriber, the pharmacist or the patient.

IACP recommends the following substitute language for §291.131(g)(2) to read as:

> *The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient <u>due to the potency, sterility, or composition of the compound itself.</u>*

Although this section refers specifically to non-sterile compounds, there are instances where endotoxins or other contaminants may be present in a finished non-sterile preparation which can cause harm.

IACP recommends the following substitute language for §291.133(g)(2) to read as:

> *The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient <u>due to the potency, sterility, or composition of the compound itself.</u>*

As written, amended sections §291.131(g)(3) and §291.133(g)(3), which immediately follow the proposed language, provides for a qualifier that creates uncertainty.

> *If the pharmacy identifies a potential or confirmed harm to a patient, the pharmacist-in-charge shall ensure that:*

The previous section requires the immediate issuance of a recall if harm is identified as potential or confirmed. This section starts with the word "if" which introduces unnecessary ambiguity.

IACP recommends the following substitute language for both sections §291.131(g)(3) and §291.133(g)(3) as follows:

> *In the event of a recall, the pharmacist-in-charge shall ensure that:*

We believe this eliminates any ambiguity so that the previous requirement for a recall specified in §291.131(g)(2) and §291.133(g)(2) clearly requires an action by the pharmacist-in-charge.

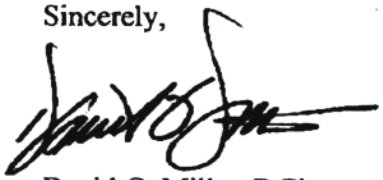
Lastly, there is further ambiguity in proposed amended sections §291.131(g)(4) and §291.133(g)(4) which read:

> (4) [~~(3)~~] *The board may require a pharmacy to initiate [~~institute~~] a recall if there is potential for [~~probable~~] or confirmed harm to a patient.*

As written, the language in this section again provides the unnecessary ambiguity of the qualifier of "may." IACP believes this section to be unnecessary in its entirety given that all preceding amended sections mandate a recall by the pharmacy once it becomes aware of a potential or confirmed harm. Whether that information is brought to their attention by the Board of Pharmacy or any other individual, agency or entity is immaterial. Presuming that the preceding sections are adopted as presented or with our recommendations, the pharmacy and the pharmacist-in-charge is *obligated* to initiate a recall once a patient risk has been identified.

We thank you, in advance, for your consideration of our comments on the proposed changes to §291.131 and §291.133. Our objective is to assure that our members providing compounded prescription and pharmacy services to the citizens of Texas are informed and compliant with all legal and professional requirements. We look forward to assisting you in communicating the new regulations to them.

Sincerely,



David G. Miller, R.Ph.
Executive Vice President & CEO

c: J. DaSilva, Texas Pharmacy Association