

April 29, 2009

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

***RE: 22 TAC §291.33 and 22 TAC §291.34***

Dear Ms. Benz:

On behalf of the approximately 2,648 chain pharmacies operating in the state of Texas, the National Association of Chain Drug Stores (NACDS) thanks the Texas State Board of Pharmacy (“Board”) for considering our comments on the proposed revisions to 22 TAC §291.33 and 22 TAC §291.34.

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**22 TAC §291.33 -- Operational Standards**

NACDS commends the Board for promulgating rules to allow the use of automated storage and distribution devices in pharmacies. We believe that this technology can improve pharmacy efficiencies and assist pharmacy personnel in meeting patients’ increasing needs and growing demand for pharmacy services. Furthermore, permitting use of this technology will benefit patients on multiple levels: it will facilitate streamlined services by affording consumers who do not need or want to be counseled with added convenience; permit pharmacists to focus on patients who require counseling or disease management services; and enable pharmacies to expand the hours that they are able to serve patients who pick up prescriptions through automated storage and distribution devices.

In order to make this beneficial technology usable in a greater number of pharmacies, we ask the Board to consider the following additional revisions to the proposed rule:

***1. Clarification that the rule would permit use of an automated storage and distribution device both when a pharmacy is open and a pharmacist is on-site and when a pharmacy is closed.***

In the proposed rule preamble, the Board states its intention for the rule to permit automated storage and distribution devices to be used “during and after pharmacy hours.” However, the proposed rule only explicitly addresses one scenario in which such devices may be used; that is in instances when the pharmacist is temporarily off-site.<sup>1</sup> Presumably, under 22 TAC §291.33 (i)(5), the Board also means to permit use of automated storage and distribution devices when the pharmacy is open and a pharmacist is on-site, and when the pharmacy is otherwise closed. To clarify this, we ask the Board to revise the proposed rule as follows:

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<sup>1</sup> 22 TAC 291.33 (b)(3)(B)(iii)

- (i) (5) Automated storage and distribution device. A pharmacy may use an automated storage and distribution device to deliver a previously verified prescription to a patient or patient's agent **when the pharmacy is open and the supervising pharmacist is on-site, or when a pharmacy is closed,** provided:

**2. Delete language specifying the exact location wherein a pharmacy building that the automated storage and distribution device must be placed.**

Under 22 TAC §291.33 (i)(5)(J), the Board proposes to limit where inside of a pharmacy building an automated storage and distribution device may be placed. Considering the strict security provisions in the proposed rule, we do not believe that the placement limitation under item (J) is warranted. Item (K), which specifies that “the automated storage and distribution device... [be] secure from access and removal of prescription drug orders by unauthorized individuals”, effectively requires sufficient security to ensure that no unauthorized individual can access the device regardless of where it is located. Furthermore, item (L) would mandate that the “automated storage and distribution device... [have] adequate security system to prevent unauthorized access...” For this reason, we ask that item (J) be stricken in its entirety.

- (i) (5) ~~(J) the automated storage and distribution device is located within the pharmacy building whereby pharmacy staff has access to the device from within the prescription department and patients have access to the device from outside the prescription department. The device may not be located on an outside wall of the pharmacy and may not be accessible from a drive thru;~~

**3. Where means are employed to ensure that appropriate counseling is provided, permit pharmacies to deliver new prescriptions from automated storage and distribution devices.**

Under 22 TAC §291.33 (i)(5)(A), the Board is proposing to prohibit pharmacies from using automated storage and distribution devices to deliver new prescriptions to patients. We believe that this restriction is unnecessary and would inconvenience patients who would otherwise prefer to have their medications delivered in this manner. Furthermore, this would be particularly confusing for patients picking up both a new and refill prescriptions on the same visit; patients could receive one of their medications from the device (the refill), but not the other (the new prescription). We assume the proposed restriction is meant to ensure that patients who obtain new prescriptions are appropriately counseled. There are numerous other ways to accomplish this, similar to how pharmacists filling mail order prescriptions counsel patients. For example, a pharmacist could telephone patients receiving new prescriptions delivered via automated storage and distribution devices within a set number of hours to counsel and answer any questions the patient might have. We suggest the following revision to the proposed rules to permit delivery of new prescriptions where appropriate counseling provisions are made:

- (i) (5) **(A) the device is used to deliver refills of prescription drug orders and shall not be used to deliver new prescriptions as defined by §291.31(26) of the title (Relating to Definitions) unless means are employed to ensure that appropriate counseling is provided for new prescriptions;**

***4. Permit pharmacies to use automated storage and distribution devices to deliver schedule III-V controlled substances to patients.***

Under 22 TAC §291.33 (i)(5)(B), the Board proposes to prohibit pharmacies from using automated storage and distribution devices to deliver any controlled substance prescriptions. As noted in our earlier comments on why the Board should not prohibit pharmacies from using such devices to deliver new prescriptions, we have similar concerns with the proposed prohibition on delivery of controlled substances. Likewise, a limitation on delivery of controlled substance prescriptions would unnecessarily inconvenience and confuse patients. (Notably, many patients take maintenance scheduled III through V controlled substances, and would be impacted by this restriction.) If the Board's rationale for this proposed restriction pertains to maintaining security of controlled substance, we believe that the following requirements in the proposed rules would already effectively accomplish this: items (K) and (L) would ensure that only authorized persons have access to any drug stored in the device and maintain appropriate security; item (G) would ensure that drugs are accurately delivered to their intended recipient. Accordingly, we ask the Board to make the following revision to the proposed language:

- (i) (5) **(B) the automated storage and distribution device may not be used to deliver a *schedule II* controlled substance;**

***5. Delete language that would require pharmacies to provide the results of testing performed on automated storage and distribution devices to the Board upon request.***

Under 22 TAC §291.33 (i)(5)(G), the Board proposes to require pharmacies using automated storage and distribution devices to test that these devices dispense prescriptions accurately. The proposed rules would require that the results of such testing be made available to the Board upon request. Being that pharmacies will ultimately be held responsible and liable for how the equipment performs, regardless of what the device testing results indicate, requiring that pharmacies provide device testing results to the Board would serve no purpose. For this reason, we ask the Board to strike the proposed language that would require pharmacies to make device testing results available to the Board upon request:

- (i) (5) **(G) the automated storage and distribution device has been tested by the pharmacy and found to dispense prescriptions accurately. The pharmacy shall make the results of such testing available to the board upon request;**

**22 TAC §291.34 -- Records**

Under 22 TAC §291.34 (b)(5)(A), the Board is proposing to add language specifying that original prescriptions may be dispensed only in accordance with prescriber's authorization as

indicated on original prescription drug order. We have concerns with the language qualifying that the prescription be dispensed according to what is *indicated on the original prescription* [emphasis added]. This limitation would prevent pharmacists who have consulted with a prescriber following receipt of an order to deviate from what is indicated on the original order even after they have otherwise obtained consent to make a change from the prescriber. To address this issue, we suggest the following revision:

(b) (5) (A) Original prescriptions may be dispensed only in accordance with the prescriber's authorization ~~as indicated on the original prescription drug order.~~

We thank the Board for considering our comments, and welcome the opportunity to further discuss these issues or answer any questions. Please do not hesitate to contact us if we can further assist you.

Sincerely,



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Michelle Cope  
Manager, Legislative and Regulatory Affairs  
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April 28, 2009

Ms. 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 Ms. Benz:

I am writing to you to provide comments on the proposed amendments to §291.33 *Operational Standards*; specifically the sections dealing with automated storage and distribution devices. Our company, Asteres Inc, is the manufacturer of ScriptCenter™, an automated storage and distribution device, which would be covered by the proposed regulation.

After reviewing the proposed amendments I would request that the Board consider changes to three separate sections: Line 132 (B), Line 137 (E) and Line 151 (J).

1. **Line 132 (B)** does not allow for the delivery of a controlled substance. I would suggest that this section be changed to NOT allow for the delivery of a CII substance only. Many patients receive both controlled and non-controlled medications and if CIII-CV are permitted in automated storage and delivery devices, patients will not be required to pick-up their prescriptions from two locations. This type of technology is approved in various ways in 32 states with 29 allowing for the placement of non CII substances in the device. The three states that currently do not allow for any controlled substances require additional regulatory changes. These three states have indicated they are not opposed to making additional regulatory changes if requested to do so at some future time. Additionally, if the security of controlled substances is of concern the proposed regulation comprehensively covers security in Lines 156 (K) and 158 (L).

2. **Line 137 (E)** requires that the pharmacy have a phone available that "connects directly" to another pharmacy. I would suggest that the words "connect directly" be removed and in its place insert "by a telephone and telephone number available to reach another pharmacy." This has the same result, and allows for flexibility in where the calls are routed.

3. **Line 151 (J)** states in part "pharmacy staff has access to the device from within the prescription department." I would suggest this be changed to say "from within or adjacent to the prescription department." Many "prescription departments" do not have

APR 28, 2009 14:17 bhansen

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Page 2



the room to place a device through a wall so that it opens into the "prescription department." The proposed language keeps the unit in the pharmacy area, but allows for flexibility in placing the device.

Thank you for allowing me to submit comments. I will be attending the Board meeting on May 5th and will be happy to answer any questions the Board and/or staff may have.

Sincerely,

A handwritten signature in cursive script that reads "Bob Hansen".

Bob Hansen, PharmD  
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HEB Privacy office

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Dear Ms. Benz,

I would like to take this opportunity to thank the Texas State Board of Pharmacy for proposing rules to allow the use of automated storage and distribution devices. These systems have the capability for providing patients with an alternate means for receiving completed prescription drug refill orders without compromising patient safety. While H-E-B supports the proposed rules, we would ask the Board to consider a couple of amendments that would make this technology of greater value for a wider range of patients and minimize the impact on pharmacies wishing to utilize these devices.

Given the level of technology that is married with numerous checks and balances plus stringent audit trails identifying the pharmacy staff and the patient, there should be no limit to the prescriptions that can be delivered utilizing this technology. Security rules that address physical concerns have been proposed to prevent unauthorized access and exclude devices without adequate security measures. Eliminating barriers and access to timely professional service for patients is important. By not allowing the delivery of controlled substance prescriptions via an automated storage and distribution device, some patients will be excluded who might benefit from this technology. We would request that the Board consider language barring the distribution of only schedule II controlled substances and not those in schedules III- V via these machines as proposed below:

22 TAC§291.33 (i)(5) (B) the automated storage and distribution device may not be used to deliver a schedule II controlled substance;

We support the requirement for the machine to be placed inside the store without access from outside the building, but would ask the Board to consider less restrictive language on how the device may be stocked as each unit could have different loading capabilities based on the pharmacy's physical structure. The goal is for the pharmacy to have greater flexibility when selecting a device meeting their specific needs, possibly without requiring extensive remodeling. We would respectfully request that the Board consider the proposed language below:

22 TAC§291.33 (i)(5) (J) the automated storage and distribution device is located within the pharmacy building whereby pharmacy staff has access to the device from within or adjacent to the prescription department and patients have access to the device from outside the prescription department. The device may not be located on an outside wall of the pharmacy and may not be accessible from a drive-thru;

Thanks, again for your leadership in advancing the use of automation in Texas pharmacies.

Sincerely,

Jay Bueche, R.Ph  
Director of Pharmacy Compliance  
H-E-B  
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