Texas Board of Pharmacy Meeting February 6, 2024



The Texas Board of Pharmacy (BoP) withdrew its rule from June, 2023, relating to the delivery of prescription drugs by mail. At its February, 2024, meeting, the BoP considered a new proposal. As discussed below, some of the changes requested by stakeholders in the first proposal were included in this proposal, but others were not. At the meeting, the rule was formally proposed with changes, but it has not yet been published in the Texas Register. TAHP is working with the agency to get a new draft of the rule with the changes made at the meeting.

BoP Staff Overview of Proposal Rule 291.12

- **(b) Delivery by Common Carrier.** This subsection allows delivery of drugs by common carrier "on request of the patient or the patient's agent." In the previous proposal, stakeholders raised concerns about requiring patients to request delivery. **BoP did not make changes based on this concern.**
 - (1) **Standards.** This subdivision requires the pharmacy to ensure that drugs are shipped according to nationally recognized standards, such as those of the manufacturer or of the United State Pharmacopoeia. **In the previous rulemaking, stakeholders asked for flexibility to use other nationally recognized standards, which the BoP has provided in this draft.**
 - (2) Packaging. This subdivision requires pharmacies to ensure drugs are delivered in commercially available tamper-proof packaging. This language was modified form the original proposal to include the "commercially available" language, as requested by stakeholders.
 - **(3) Temperature.** This subdivision requires pharmacies to ensure drugs delivered by common carriers maintain a temperature level appropriate for the drug. The original proposal would have only applied to drugs other than "room temperature" storage drugs, but this proposal removed that limitation based on stakeholder feedback.
- (c) Delivery by Pharmacy Employee or Same Day Courier Service.
 - (1) **Standards.** The original proposal required that the delivery be on a "continuous route" from the pharmacy to the patient. **That language was deleted based on stakeholder feedback**.



• **(2) Temperature.** The original proposal required maintaining the drug in the appropriate temperature range until delivery. The language was modified to clarify maintaining temperature was only required until "received by the patient or patient's agent" in response to stakeholder feedback.

(d) All deliveries.

- (1) Counseling information. This subdivision requires compliance with other counseling rules. Stakeholders opposed its inclusion, but the BoP did not remove the language.
- **(2) Notification of delivery.** Stakeholders opposed requiring pharmacies to notify patients of delivery and keeping record of such notices, but BoP staff kept the language in this proposal. **However, the BoP edited the language after a discussion (described below).**
- **(3) Required signature.** While there was a provision in the original rule requiring a patient to sign for certain drugs, **the provision was removed based on stakeholder feedback.**

Public Testimony

Debbie Garza, Texas Pharmacy Association

- Proposal still has many of the problematic provisions from the earlier proposal, which will ultimately reduce access to medications and pharmacy services.
- Recommend striking "same day," as some patients prefer to schedule their delivery days in advance.
- Standards for common carrier delivery are different from delivery by pharmacy, pharmacy delivery seems to place more responsibility on the pharmacist.
 Recommend aligning the two standards.
- Significant opposition to notification of delivery requirements in the rule. It will be very costly for pharmacies to implement a system that would satisfy the requirements. Recommend making that provision applicable to common carrier delivery only.
- Recordkeeping requirements are too burdensome, and requiring more records gives payors more opportunity to audit and reduce payments.

Jim Phillips, Walgreens



- Rather than creating new rule language, recommend using existing language for packaging, found in Rule 291.215.
- Notification requirements create unnecessary touch points when there are no concerns from patients.
- Records requirements are too burdensome.
- Unclear who determines when a prescription is compromised. Patient and pharmacist could disagree.

Board Member Questions and Discussion

- **Debbie Garza** was asked why there were so many concerns about the notification and recordkeeping requirements.
 - She responded that PBMs like to find any reason to not pay for drugs.
 - PBMs include rule provisions in contracts with pharmacies, and if all rules are not followed, they charge back
 - Strict notification requirements could result in denied payments

Formal Proposal

The BoP voted to formally propose the rule with some modifications:

- There were significant discussions related to the notice requirements, but it was unclear if any changes were made.
- Recordkeeping subsection shortened to remove the requirement to keep a record when a patient fails to receive a drug.
- Clarifies that it is up to the pharmacist (rather than the patient) to determine when a drug is compromised.

TAHP will be working with the agency to get an updated draft of the proposal.