



January 23, 2023

Marty Hendrick, Pharm. D., D.Ph.
Executive Director
Oklahoma State Board of Pharmacy
2920 N. Lincoln Blvd., Ste. A
Oklahoma City, OK 73105
EMAIL: pharmacy@pharmacy.ok.gov

SENT VIA EMAIL

Re: Oklahoma State Board of Pharmacy – Proposed Rule – Chapter 15 Draft Rules (Title 535 – Chapter 15. Pharmacies)

Dear Dr. Hendrick:

The Pharmaceutical Care Management Association (“PCMA”) appreciates the opportunity to comment on the Oklahoma State Board of Pharmacy (“Board”) Proposed Rule, specifically the Chapter 15 Draft Rules (“Proposed Rule”). The language of the Proposed Rule pertains to a “Qualified Packaging System,” which specifies the physical requirements for certain prescription drug packaging and shipping methods as conducted by non-resident pharmacies. The Proposed Rule was revised by the Board on November 15, 2022.

PCMA is the national trade association representing PBMs. PCMA’s member companies administer drug benefits for more than 266 million Americans, including most Oklahomans who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others.

Below are PCMA’s general concerns with the Proposed Rule. Also included are requests and recommendations regarding specific provisions in the Proposed Rule.

General Comments

Currently, the language of the Proposed Rule is not grounded in science and evidence. Rather, it appears to be based on speculation and an attempt to resolve a perceived issue. Because of this, the Rule Impact Statement for the Proposed Rule incorrectly positions these rules, without evidence, as necessary in order to prevent Oklahomans from receiving a deteriorated drug.

The Rule Impact Statement mischaracterizes the economic impact the Proposed Rule would have on non-resident pharmacies, all entities within the pharmaceutical supply chain, and ultimately, Oklahoma’s patients and consumers. For example, the Rule Impact Statement does not consider the economic impact of a prescription drug needing to be replaced, nor a break in a patient’s continuity of care.

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The focus of the Proposed Rule is only on a single moment of the pharmaceutical supply chain. It ignores the roles that pharmaceutical manufacturers, wholesaler distributors, and pharmacy services administrative organizations (PSAOs) play in the supply chain. Pharmacies are not the only entities who ship prescription drugs to Oklahomans. Pharmacies are shipping prescriptions to patients in the same or substantially similar manner that a pharmaceutical manufacturer, who performs stability studies, may also be directly shipping to Oklahomans.

535:15-3-9. Non-resident pharmacies

(j) Prescription shipping.

As is, this subsection of the Proposed Rule requires all prescription drugs, including ambient drugs, to be shipped in a “qualified packaging system” to maintain a specific temperature range for the duration of the shipping process and provide evidence of system meeting temperature range, if requested by the Board.

If enacted, this subsection would have a negative impact on Oklahomans. Packages would likely not be able to fit inside a standard mailbox, mail slot, or typical cluster box (understanding the shift in shipping supplier would likely not allow even if it fit).

Current prescription drug mail orders are generally shipped in convenient, space-efficient, light polybags. The language of this subsection would drive prescription drug medications towards requiring different packaging. It would be closer to current cold chain packaging, which is much larger and heavier.

(k) Prescription delivery.

Currently, the language of this subsection pertains to the same day delivery (24hrs) of prescription drugs. It requires passenger or cargo portions of delivery vehicles that contain prescriptions for delivery to maintain temperature requirements recommended by the pharmaceutical manufacturer or the United States Pharmacopeia (USP) for cargo portion of the vehicle the same as the driver – including heat and air conditioning.

If cargo portion is separate, when heating and/or air conditioning is not available, this subsection requires the adherence to guidelines for shipping in a “qualified packaging system,” as well as the pharmaceutical manufacturer’s labeled storage requirements. It does not allow for temperature excursion that exceeds temperature storage conditions outlined within the package insert or by the manufacturer of the drug product.

These processes are already used by non-resident and resident pharmacies. They ensure the integrity and stability of the prescription drug medications that are shipped to patients. The processes already used account for much of what the Board is trying to do with the language of the Proposed Rule. The processes used to ship temperature-sensitive medications are also validated by a third-party.

Non-resident and resident pharmacies undergo rigorous testing of materials and processes to validate the maintenance of the integrity and stability of medications. Patients already receive



multiple communications about their prescription delivery and can alert us in the event of an unforeseen issue. Moreover, federal Medicare law already requires shipment notifications to beneficiaries. This notification includes an approximate date of delivery.

Additionally, patients can already choose a variety of communication methods so they are updated about when their medications will be delivered. Generally, if a patient experiences an issue with a package, they can contact the pharmacy directly, which will work with them on a solution.

PCMA's Request

PCMA respectfully requests that the Board withdraw the Proposed Rule. We also respectfully request that the Board then conduct a proper and thoroughly complete Rule Impact Statement. Doing so would show an accurate economic impact analysis.

The Proposed Rule does not look at the entirety of the pharmaceutical supply chain. Instead, it has a very narrow focus. If the Board wants to act, we encourage it to do so in a way that holds *all* supply chain stakeholders to the same level of accountability. To achieve this goal, PCMA encourages the Board to also include pharmaceutical manufacturers, wholesale distributors, and PSAs as affected entities in the language of the Proposed Rule.

Moreover, the Proposed Rule would only apply "qualified packaging system" standards to pharmacies. Doing so would not guarantee end-to-end integrity. Applying these requirements to all entities of the pharmaceutical supply chain would create consistent expectations for all stakeholders, most importantly Oklahoma patients and consumers.

Lastly, PCMA and its member companies would like to thank the Board for its inclusion of pharmacy technician language in the Proposed Rule regarding administering immunizations and reinstatement requirements. This language would enable pharmacy technicians to work at the top of their licensure.

Again, we appreciate the opportunity to comment on the Board's Proposed Rule. We look forward to a continued dialogue with the Board regarding the Proposed Rule. Please feel free to contact us with any questions or for further discussion.

Sincerely,

A handwritten signature in black ink, appearing to read "Melodie Shrader".

Melodie Shrader
Vice President – State Affairs

A handwritten signature in black ink, appearing to read "Peter Fjelstad".

Peter Fjelstad
Director, State Regulatory & Legal Affairs

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