APhA
American Pharmacists Association

September 6, 2022

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA–2020–N–1663: National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers, Proposed Rule

Submitted via www.regulations.gov to Docket FDA-2020-N-1663

Dear Food and Drug Administration staff:

The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) are pleased to submit comments on the proposed rule entitled "National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers."

APhA is the only organization advancing the entire pharmacy profession. Our expert staff and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians find success and satisfaction in their work while advocating for changes that benefit them, their patients, and their communities.

NASPA is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

APhA and NASPA strongly support the purpose and goals of the Drug Supply Chain Security Act (DSCSA) to enhance the safety and security of the pharmaceutical distribution supply chain and agrees that uniform national standards for licensure of wholesale drug distributors is a critical component to achieve the goals. APhA and NASPA appreciates FDA's efforts in developing guidance, standards, and other information to assist pharmacists and pharmacies in complying with DSCSA's requirements.

APhA and NASPA members are particularly interested in these standards because if dispensers' activities and actions fall outside the activities excluded from the definition of wholesale distribution in section 503(e)(4) of the Food, Drug, and Cosmetic Act (FD&C Act), then they would be considered wholesale distributors and would need to be licensed as such. The comments below mainly focus on these exemptions.

1. **Minimal Quantities – 5% Rule**

Section 503(e)(4)(E) of the FD&C Act excludes from wholesale distribution ''the distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use.'' Proposed §205.3(h) defines "minimal quantities" as the "total annual dollar volume of prescription drugs sold by a retail pharmacy to licensed practitioners for office use does not exceed 5 percent of the total dollar volume of that retail pharmacy's annual prescription sales." As a result, any total dollar volume above 5% would be considered wholesale distribution and the pharmacy would need to be licensed as a wholesale distributor.

APhA and NASPA agree that a specific number should be codified so it is clear when activities would be considered wholesale distribution. Licensed practitioners often rely on pharmacies for prescription drugs for office use because they may not have the purchase volume or power to obtain the drug at an acceptable cost. Many state laws do include a "5% rule," so pharmacies in most states would be prepared to comply with this proposed standard. However, as FDA notes in the proposed rule at 87 FR 6714, several states have expanded the applicability of this exclusion to allow for distribution from pharmacies to other entities outside of licensed practitioners for office use.[1] While we recognize that distribution to other than licensed practitioners for office use is not permitted under the law, we urge FDA to work closely with the state boards, licensed dispensers, and pharmacy associations to educate dispensers and practitioners on these changes, well in advance of the compliance date. In some states this change will be significant. Continuity of care is essential, and it is important that licensed practitioners are ready with alternative sources of the prescription drugs that have been supplied by this means in states that have different standards.

2. **Emergency Medical Reasons**

Section 503(e)(4)(C) of the FD&C Act states that the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a federal public health emergency declaration, does not constitute wholesale distribution. The preamble to the proposed rule notes that in addition to distribution of a drug during a declared public health emergency, FDA

[1] For example, see Nebraska Revised Statute Section 71-7454.

considers the following circumstances to constitute emergency medical reasons and therefore would be excluded from the definition of wholesale distribution: (1) The distribution of a drug to a first responder or other authorized individual administering prescription drugs to acutely ill or injured persons in an emergency situation and outside a healthcare facility, and (2) a long-term care facility receiving an emergency kit containing drugs for use in emergency situations to treat acutely ill or injured persons during hours of the day when necessary drugs cannot be obtained from a dispenser. Pursuant to DSCSA, this exclusion from the definition of wholesale distribution does not include distributing a drug during a shortage unless such shortage was caused by a public health emergency.

APhA and NASPA appreciates FDA's identification in the preamble of specific emergency medical reasons, however, there are other situations that would fall under an emergency medical need. APhA and NASPA requests FDA to clarify that what is in the preamble is not an all-inclusive list. For example, an emergency medical reason could be as a result of a public health, security, or other emergency situation declared under state law, such as during a natural or man-made disaster or civil unrest. The exemption in 503(e)(4)(C) lists a public health emergency under section 319 of the Public Health Service Act as one situation, but the law uses the term "including," which implies that Congress intended it to be included, but not necessarily as the only situation.

Additionally, in the case of first responders, APhA and NASPA requests FDA please clarify that the distribution may occur to someone other than the first responder and it would be acceptable to sell or transfer to an entity acting on behalf of first responders, such as a police or fire departments or ambulance companies.

3. **Dispenser to Dispenser Sale/Transfer**

Section 503(e)(4) of the FD&C Act excludes distributions of a drug to a consumer or patient from the definition of wholesale distribution. The proposed rule discusses how the sale or transfer of a drug from one dispenser to another dispenser to fulfill a ''specific patient need,'' is outside of the definition of wholesale distribution because it is to a consumer or patient. The preamble further discusses how a dispenser who transfers or sells a drug to a trading partner other than another dispenser, or to another dispenser, where there is no specific patient need as evidenced by a prescription would be considered wholesale drug distribution. APhA and NASPA agree with FDA's assessment that dispenser to dispenser sales or transfers of prescription drugs for a specific patient need is outside the scope of wholesale distribution and appreciates this analysis.

However, APhA and NASPA are concerned with FDA's interpretation of "specific patient need," which describes a specific patient need as having "*evidence of a prescription*" [emphasis added]. "Specific patient need" is defined at section 581(19) of the FD&C Act as ''the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need." Nowhere in the statutory definition does it mention that "*evidence of a prescription*" is required. A pharmacy may want to purchase or borrow a prescription drug from another pharmacy knowing that a patient will be coming in with a prescription and have product available in anticipation of that prescription so a patient will not have to wait. This is not unusual for a pharmacy that knows their patients, particularly those with medications used for chronic medical conditions. This transfer or sale would be for an identified patient, but there may not be "evidence of a prescription" at the time of the transfer or sale. APhA and NASPA understand that the law's exclusion of replenishing stock in anticipation of a potential need means that a pharmacy may want to have this product on hand just in case of a *potential* need. If a pharmacy knows that there is a patient who will likely be coming in with a prescription, that is not anticipation of a potential need. Rather, that is in anticipation of a prescription for an identified patient. APhA requests that FDA please clarify this distinction.

4. **State vs. Federal licensure**

Section 503(e) of the FD&C Act, as amended by DSCSA, requires FDA to license wholesale distributors directly if the State in which it engages in wholesale distribution has not established a licensing requirement that follows the standards. In the preamble, FDA notes that they plan to make information available to clarify who is the appropriate licensing authority in the wholesale distributor's State.

APhA and NASPA urges FDA to create a system that clearly delineates whether a state program meets the requirements of the new 21 CFR Part 205 or if the licensee must get a license from FDA. As FDA knows, every state has its own licensing program. Some have aligned their laws and regulations with the exact language of new section 503(e) of the FD&C Act, but many have not.

FDA cannot take this lightly. Having a license in good standing is essential for an entity to do business and keep their doors open. There is no room for confusion or controversy over what specific license is needed to do business and be an authorized trading partner in a state. We strongly urge FDA to seek input from licensees, including dispensers that are also wholesale distributors, for feedback and input on practical aspects of which licensor prevails in each state,

as well as work closely with the National Association of Boards of Pharmacy (NABP) on any clarifications needed.

APhA and NASPA also have several additional concerns with state versus federal licensing that FDA should clarify and address in the final rule preamble, regulations, and/or guidance:

- State regulatory bodies may by default believe and act as if their program aligns with federal standards. A licensee may then get licensed by the state, but if FDA does not agree that the state requirements align, the licensee may be stuck in the middle. FDA cannot leave it up to a licensee to determine if they should be getting a state or federal license. FDA must be clear in how the agency will assess or consider whether a state program meets federal standards.
- FDA may determine that the state requirements do not align with federal requirements and require a federal license. However, if the state disagrees and requires a state license, the licensee is stuck between two regulatory bodies and cannot be expected to get licensed under state and federal programs. APhA and NASPA request clarity on how this will be handled and reconciled.
- A state may continue to have different requirements from federal standards that would make a dispenser a wholesale distributor for some activities. Although this is preempted by DSCSA, will FDA have an administrative process to address challenges related to preemption? Will FDA defend a licensee in a potential challenge with a state licensing body if the state takes action for not obtaining a state license?

5. <u>Preemption</u>

Section 585 of the FD&C Act, added by the DSCSA, establishes uniform licensure requirements for wholesale distributors and third-party logistics providers (3PLs) by preempting state licensure requirements that do not follow the applicable federal requirements. Specifically, section 585(b) preempts all state "standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under [the law]."

APhA and NASPA appreciates FDA's analysis and agrees with FDA's change in position regarding the scope of this preemption. It is essential that there is certainty and predictability across the country for licensees, which is the intent of this preemption. As stated above, APhA and NASPA are concerned that states may maintain in effect or establish requirements that would require dispensers to be licensed as wholesale

distributors for activities that otherwise would not be considered wholesale distribution under federal law. FDA's new position leaves no uncertainty regarding the requirements under state or federal law for licensing of wholesale distributors.

Conclusion

APhA and NASPA appreciates FDA's ongoing efforts in developing guidance, standards, and other information to assist pharmacists and pharmacies in complying with DSCSA's requirements. We look forward to continuing to support FDA's efforts and working to improve the safety and security of the drug supply chain. If you have any questions or require additional information, please contact Heather Boyd, APhA Director, Health Policy at hboyd@aphanet.org.

Sincerely,

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