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January 13, 2023

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

Re: Safety and Effectiveness of Certain Naloxone Hydrochloride Drug Products for Nonprescription Use; Request for Comments [Docket No. FDA–2022–N–2673]

Dockets Management Staff,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide feedback on the Safety and Effectiveness of Certain Naloxone Hydrochloride Drug Products for Nonprescription Use; Request for Comments. NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

In its proposed rule, FDA stated:

It is our preliminary opinion at this time that naloxone nasal spray up to 4 milligrams (mg), and naloxone autoinjector for intramuscular (IM) or subcutaneous (SC) use up to 2 mg, have the potential to be safe and effective for use as directed in nonprescription drug labeling without the supervision of a healthcare practitioner….We welcome comments from the public on any potential consequences of a switch from prescription to nonprescription status for naloxone products.

Safety Concerns
The proposed rule states that the above naloxone products "have the potential to be safe and effective for use as directed in nonprescription drug labeling without the supervision of a healthcare provider." We believe pharmacists should not be excluded from dispensing naloxone. **Pharmacists are primary guardians of the public health and must retain their ability to supervise and consult with prescribers and patients within their scope of practice. A pharmacist's primary responsibility is to ensure appropriate medications for their patients.** Additionally, pharmacists are an important part of the comprehensive health care team, in this instance educating and counseling patients on how to use naloxone correctly and

safely. NCPA appreciates FDA's efforts to broaden access to naloxone. Considering the opioid crisis, we support ways in which FDA would improve access to naloxone by leveraging the expertise of the pharmacist.

Payment Concerns

Additionally, NCPA believes that switching naloxone to nonprescription status will create increased confusion for consumers surrounding payment. Once naloxone is nonprescription, payers and PBMs will likely cease any coverage, therefore shifting payment to the consumer. This may lead the increased consumer costs, which could hurt patient access. NCPA is also concerned that this additional class may face uncertain or lower reimbursement through FSA or HSA programs.

Regulatory Concerns

Pharmacists have varying authorities in states to dispense naloxone through: statewide protocol or prescriptive authority; statewide standing order, dispensing without a prescription, or another form of standing order.[1] Creating a new nonprescription class of naloxone may affect these existing state laws and policies. States may also react to the new nonprescription status of naloxone by establishing additional requirements for these over-the-counter sales, which may in turn hurt patient access.

Additionally, creating a new nonprescription class of naloxone may affect states' laws and policies requiring that naloxone products be reported to state prescription drug monitoring programs (PDMPs) or to other state public health data repositories for public health surveillance. Reporting to PDMPs involves reporting the NDC number for the dispensed naloxone, so reporting a nonprescription drug that lacks an NDC would be unworkable within the existing framework.

If FDA finalizes this proposal, FDA must work with state boards of pharmacy and other state public health authorities to reconcile the nonprescription naloxone switch with new state law and policy.

Liability Concerns

If the recommended naloxone products are switched to nonprescription use, it is essential that liability for the safety and effectiveness of these products is not passed down from manufacturers to retail pharmacists and pharmacies when these medications are dispensed in accordance with the approved product labeling for nonprescription sale.

[1] Pharmacist Prescribing: Naloxone. *National Alliance of State Pharmacy Associations.* Available at: https://naspa.us/resource/naloxone-access-community-pharmacies/.

Conclusion
NCPA thanks FDA for the opportunity to provide feedback, and we stand ready to work with FDA to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association