April 18, 2025

Dorothy Fink, M.D.
Acting Assistant Secretary for Health & Head of the United States Public Health Service Commissioned Corps
c/o Food and Drug Administration (FDA)
Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

RE: Nonprescription Drug Product With an Additional Condition for Nonprescription Use Final Rule and Delay of Effective Date [Docket No. FDA-2021-N-0862]

Dear Acting Assistant Secretary Fink,

The American Pharmacists Association (APhA) is writing to restate our concerns and urge a continuation of the delay in implementing the "Nonprescription Drug Product With an Additional Condition for Nonprescription Use" (ACNU), final rule. APhA shares FDA's efforts to revise drug paradigms that allow greater access to certain medications under conditions of safe use. However, APhA is concerned that the final rule in its current form will lead to confusion, limit access to care, and create patient safety concerns.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

The concurrent marketing of prescription and nonprescription versions of the same drug products will lead to patient confusion and patient safety issues. APhA believes pharmacists must play an integral role in assisting patients to determine whether a particular nonprescription drug product with an ACNU is appropriate for each patient's healthcare needs. For example, if a pharmacist is aware that the patient has an underlying condition or drug interaction, but the patient presents proof that they fulfilled the ACNU and attempts to purchase the product. Could the pharmacist withhold access, or would that then create a barrier to access that is reportable to the FDA? FDA did not address this question in the final rule,

which is necessary to prevent avoidable patient harm before moving forward with a final ACNU.

In addition, without the involvement of a pharmacist or another health care provider, patients will struggle to understand the difference between the two versions of the products and why they can access one under this framework and the other only with a prescription.

Further, FDA's final rule notes that nonprescription drug products with an ACNU will be sold similarly to all other nonprescription drugs in pharmacies, supermarkets, other retailers, and online.[1] Having nonprescription drug products with an ACNU at the same point of purchase as those nonprescription drugs without it will lead to confusion among patients, as they may be unfamiliar with the process of meeting qualifying criteria. Additionally, pharmacies and other sellers would need to make significant modifications to their point-of-sale systems to create a "stop" to ensure that the person selling the product confirms that the patient has appropriately completed the ACNU self-assessment. To avoid making this modification, pharmacies and sellers may move these products behind the counter to ensure that this additional step is satisfied. Once behind the counter, patients would have more limited access to reading the labeling and knowing that the product is available. Patient confusion about the difference between the prescription and nonprescription versions of the same drug product, along with the need to ensure patients have completed the appropriate self-selection condition and are eligible to use it safely, will likely force pharmacies and other sellers to put mechanisms in place to ensure customers cannot acquire these medications without going through the proper protocols.

The final rule states that the lack of uniformity in the operationalization of the ACNU is done intentionally by FDA to allow for flexibility.[2] However, this will only further exacerbate patient confusion. The logistical and operational issues associated with implementing this rule are what FDA should be concerned about regarding limiting access to care. To verify the patient's proof of fulfilling the ACNU for each drug product, pharmacists, pharmacies, and other sellers must learn each product's appropriate verification format (bar code, QR code, coupon, voucher, etc.). Learning all the intricacies of these separate programs will overburden pharmacists, pharmacies, and sellers of these products to the point that they may not stock all the available options, which limits patient access.

APhA strongly recommends consulting with a health care provider to ensure patient safety. However, this should not create another unfunded mandate on our nation's pharmacists. Requiring pharmacist intervention in accessing nonprescription drug products with an ACNU would improve patient experience and ensure patient safety while increasing access to these medications currently only available with a prescription. In its final rule, FDA notes that "requiring consultation with a healthcare professional (i.e., a pharmacist) … would undermine

[1] Nonprescription Drug Product With an Additional Condition for Nonprescription Use, 89 Fed. Reg. 105293 (Dec. 26, 2024). Available at: https://www.federalregister.gov/d/2024-30261/p-100.
[2] *Id.* at 105302. Available at: https://www.federalregister.gov/d/2024-30261/p-177.

the[] public health benefits of this rule."[3] This is simply not the case. Pharmacies and pharmacists are readily accessible. Almost 90% of Americans live within five miles of a pharmacy.[4] Additionally, most patients do not need an appointment to see their pharmacists, making pharmacists' medication expertise easily accessible to most Americans. As medication experts, pharmacists can perform assessments of the patient, ask pertinent questions to determine if the drug is appropriate for the patient, provide the patient with relevant information about the medication, and allow the patient to ask any questions they may have about the medication. Pharmacists can do all this without relying on the technology required for a patient to complete the self-selection process and the complicated logistical and operational processes outlined within this final rule. Pharmacists across the country are already able to initiate treatment independently, or under statewide protocols, for a host of drugs and conditions, including hormonal contraception, testing and treating certain infectious diseases (e.g., flu, strep, COVID-19) and uncomplicated minor ailments, tobacco cessation, HIV PEP/PrEP, opioid antagonists, and more depending on their state's laws and regulations.

APhA is also concerned about the liability that pharmacists and pharmacies may incur if drug products with an ACNU are sold without proper oversight and assessment. In its final rule, FDA notes that commenters asked about the "legal liability for pharmacists," but also failed to address the topic in its subsequent response.[5] APhA asks to clarify the responsibilities of pharmacists, pharmacies, or sellers in ensuring the ACNU is fulfilled and to reevaluate the final rule to ensure that an additional unfunded mandate is not imposed on our nation's pharmacists and that the product is safe and appropriate for the patient. At a minimum, patients using self-selection should assume full liability for safely using an ACNU product.

APhA appreciates FDA's attention to these concerns. Addressing these issues will maximize the number of patients who can access nonprescription drugs with an ACNU while prioritizing patient safety. If you have any questions, want to arrange a meeting with APhA, or need additional information, please contact Corey Whetzel, Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Government Affairs

cc: The Honorable Martin A Makary, M.D., M.P.H., Commissioner, FDA

---

[3] *Id.* at 105293. Available at: https://www.federalregister.gov/d/2024-30261/p-100

[4] Lucas Berenbrok, et al., *Access to Community Pharmacies: A Nation-Wide Geographic Information Systems Cross-Sectional Analysis*, 62 JAPhA 1816 (2022).

[5] Nonprescription Drug Product With an Additional Condition for Nonprescription Use, 89 Fed. Reg. 105293 (Dec. 26, 2024). Available at: https://www.federalregister.gov/d/2024-30261/p-99.