

May 8, 2026

[Submitted electronically to <http://www.regulations.gov>]

Grace R. Graham
Deputy Commissioner for Policy, Legislation, and International Affairs
Food and Drug Administration (FDA)
5630 Fishers Lane
Rockville, MD 20852

RE: [Docket No. FDA-2025-N-4731] Increasing Access to Nonprescription Drugs; Public Meeting; Request for Comments

Dear Deputy Commissioner Graham,

The American Pharmacists Association (APhA) and the National Community Pharmacists Association (NCPA) appreciate the opportunity to provide additional comments to the FDA's "Increasing Access to Nonprescription Drugs; Public Meeting; Request for Comments."

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.

NCPA represents America's community pharmacists, including 18,900 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 employ 205,000 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.

APhA and NCPA propose the following roadmap to FDA to ensure the ACNU framework successfully increases patient access while balancing safety concerns.

Unlocking the ACNU Pathway by Leveraging Our Nation’s Pharmacists to Increase Access to Medicines and Primary Care

Purpose of the ACNU

FDA finalized its “[Nonprescription Drug Product With an Additional Condition for Nonprescription Use](#)” (ACNU) rule, allowing certain products to be legally marketed without a prescription if additional conditions ensure appropriate self-selection or actual use. FDA intended to increase consumer access to safe and effective nonprescription drugs that, before this rule, would not have been available without a prescription due to requirements related to labeling being insufficient for the consumer to appropriately self-select and use the product without a health care provider licensed to administer the drug.

Recently, the Duke Margolis Institute for Health Policy and FDA held a hybrid meeting on Increasing Access to Nonprescription Drugs, on FDA’s recently announced [request for information](#) on this topic, with comments due on May 8, 2026.

Additionally, the well-documented and worsening shortage of primary care providers¹ in the United States necessitates innovative approaches to expanding consumer access to therapies that, with appropriate safeguards, could be more readily available for a range of acute and chronic conditions. Pharmacists, as medication experts and with twice as much contact with patients as other health care providers, are well-positioned to facilitate access to nonprescription drugs. The following policy recommendations focus on leveraging pharmacists and/or technology to provide safeguards and improve consumer access. We believe this approach can serve as a blueprint for implementation across the federal government to facilitate safe access to nonprescription therapeutics.

Implementation of the ACNU

The current ACNU final rule provides a broad interpretation of viable pathways for reclassifying prescription products to nonprescription with ACNU. We believe that, given the complexities of product access in the U.S., providing two well-defined pathways for prescription-to-nonprescription (Rx-to-OTC) conversion with ACNU would provide clarity, encourage manufacturers to move products from prescription to OTC more swiftly with ACNU, and result in less burdensome end-user (i.e., pharmacies and other outlets) tracking requirements.

¹ *Health Workforce Projections*, Health Resources & Services Administration. Available at: <https://bhw.hrsa.gov/data-research/projecting-health-workforce-supply-demand> (noting that the National Center for Health Workforce Analysis estimates an overall shortage of 141,160 physicians in 2038, including a shortage of 70,610 primary care physicians).

To maximize the impact of the ACNU framework, FDA should prioritize two pathways: (1) pharmacist-facilitated assessment and (2) technology-enabled self-evaluation. To illustrate these two pathways, we offer the following use-case scenarios:

Scenario A – Pharmacist-Facilitated Assessment. In this scenario, a pharmacist would utilize their medication expertise to review the patient’s responses to a drug-specific assessment and ask follow-up questions to determine eligibility and ensure patient safety. The role of the pharmacist in a patient’s health care journey continues to grow as states expand pharmacists’ scope of practice to capitalize on their advanced training and medication expertise, and to improve the accessibility of a patient’s community pharmacy to meet patient needs.² In every state and the District of Columbia, pharmacists can prescribe or initiate medications, whether through a collaborative agreement, standing order, or independent prescribing authority.³ Additionally, a majority of states authorize pharmacists to perform Clinical Laboratory Improvement Amendments (CLIA)-waived tests. Manufacturers may prefer pharmacist-facilitated assessments to satisfy the additional condition requirements, and choose to utilize such a framework when seeking Rx-to-OTC approval to address the critical issues of safety, including drug-drug or drug-disease interactions and potential for misuse/abuse, including consumer manipulation of digital assessments, labeling concerns, post-marketing safety, and insufficient self-selection study or real-world data.

As such, FDA should prioritize the pharmacist-facilitated pathway as the primary pathway to allow manufacturers to address FDA’s concerns, to promptly increase access to nonprescription drugs safely for patients until manufacturers provide self-selection studies to show the general public can appropriately use these medications without the intervention of a health care provider. As such, FDA should consider a primary category of medications for a certain number of years (e.g., 36 months) to allow adequate real-world patient-use evaluation, including data from pharmacists before offering other pathways.

An example of an ACNU framework that would work is utilizing a pharmacist conducting a CLIA-waived test, such as influenza A testing. In this case, antiviral therapy, such as oseltamivir, could be authorized as an OTC with ACNU, including a pharmacist-facilitated assessment. In this manner, consumers can receive an influenza test at a local pharmacy, and the pharmacist can document and provide appropriate therapy without a prescription. This removes barriers that may exist in some states where pharmacist prescribing is not yet permitted under state law. Additionally, with the policy recommendations outlined in this paper, coverage for the product and the test, along with a fee paid by manufacturers or public

² Lucas A. Berenbrok, et al., *Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis*, 62 *Journal of the American Pharmacists Association* 1816, 1816 (2022). Available at: <https://www.japha.org/action/showPdf?pii=S1544-3191%2822%2900233-3> (noting that nearly 90% of Americans live within 5 miles of a community pharmacy).

³ Marc Joffe & Jeffrey A. Singer, *Let Pharmacists Prescribe*, CATO Institute (Mar. 21, 2024). Available at: <https://www.cato.org/briefing-paper/let-pharmacists-prescribe>.

or private payors for the pharmacist's assessment and consultation, would improve access, reduce costs, and significantly shorten time to treatment, a critical factor in treating influenza.

A similar example concerns the treatment of a chronic or self-limiting condition. Minoxidil 10mg tablets are an inexpensive oral therapy. In topical form, the drug has been used safely for decades in OTC preparations. However, oral preparations can be contraindicated when certain underlying conditions are present and may have drug interactions. Yet dermatologists frequently prescribe oral minoxidil for male pattern baldness. An Rx-to-OTC switch with ACNU for minoxidil would allow the drug therapy expert, a pharmacist, to consult with the patient to ensure safety in the specific individual's case, provide the product, and document the care provided. A wider range of patients would have better access to this therapy, while also ensuring that the additional condition assessment is not manipulated to be used by patients who should not use the medication.

During the April 23, 2026, FDA Convening on Increasing Access to Nonprescription Drugs, panelists raised this concern, noting that patients who cannot access certain medications, including minoxidil, through their health care providers may rely on technology-enabled self-evaluations to obtain them. Pharmacists could help ensure that such medications, those with a high potential for patients to manipulate the additional condition for safe use assessment or to abuse, are provided to appropriate patients while still increasing access to them through pharmacist-facilitated assessments.

Scenario B – Technology-Enabled Self-Evaluation. In this scenario, only recommended after Scenario A and after allowing adequate real-world patient-use evaluation to “ensure appropriate self-selection or appropriate actual use, or both,” a patient could use online technology or an in-store kiosk to quickly self-assess their need for therapy. Following such an assessment, a QR code could then be digitally printed or saved on an electronic device, allowing the patient to purchase the product from a retail or online store. If these technologies are authorized to connect to the patient's electronic health record, with key access by the patient's personal pharmacist, the medication expert on the patient care team, and patient-selected therapies should be fully integrated into the health care encounter, enabling more optimal future care by pharmacists, who patients interact with the most, physicians, nurses, and other members of the patient's care team.

Stepwise Approach. We recommend FDA view these pathways in a tiered or stepwise strategy. For example, the pharmacist-facilitated assessment pathway is more appropriate for products that are generally safe but raise FDA safety concerns, noted above. The pharmacist-facilitated assessment pathway should also be used when the FDA has concerns that the newly created OTC product's Drug Facts label is not fully understood or is not being appropriately acted upon. For example, if the directions are too complex, there is a long list of warnings, and a patient may struggle with self-diagnosis, a pharmacist-facilitated assessment would be

beneficial, ensuring patient safety and increasing patient access.⁴ FDA and manufacturers could also use the pharmacist-facilitated pathway rather than the technology-enabled self-evaluation pathway when additional real-world evidence from these interactions is needed to support future engagement with FDA on potential progression to make the product available through a technology-enabled self-evaluation.

As noted throughout the panels at FDA’s convening on April 23, 2026, self-selection studies will be instrumental in confirming that patients can appropriately select and use these medications without a health care provider. For any switch applications for which FDA has concerns about the self-selection studies or other provided analyses and considerations, FDA should use the pharmacist-facilitated pathway in the interim to allow FDA to meet its goal of increasing access to these once-prescription-only medications while also protecting patients and providing manufacturers with additional time to acquire such data points. Only those products for which the additional condition will ensure appropriate self-selection or actual use by the average consumer, without the supervision of a health care practitioner, should be immediately available through a technology-enabled self-evaluation.

FDA and Manufacturer Self-Selection and Consumer Studies Favor a Pharmacist-Facilitated Pathway

FDA’s ACNU final rule requires adequate data that demonstrates that the “additional condition [] ensure[s] appropriate self-selection or appropriate actual use, or both.”⁵ FDA makes clear that consumer studies will often be necessary to meet the evidentiary standard. To satisfy this substantial evidentiary standard, FDA should use ACNU pathways with statistically significant self-selection and consumer-use data that appropriately mitigate risks that labeling alone cannot. The ACNU final rule recognizes that consumer misunderstanding or misuse presents a significant safety risk. As a result, FDA approval decisions must be based on evidence showing that the selected additional condition effectively supports appropriate self-selection and real-world use. A pharmacist-facilitated ACNU pathway is the most practical approach because it combines real-world evidence of consumer behavior with oversight by a health care professional at the point of access, addressing any safety concerns raised by FDA. Focusing on

⁴ Updating drug labeling is an essential step in any Rx-to-OTC switch. The standardization and requirements of the “Drug Facts” label on OTC products can make it difficult to switch some prescription medications to OTC products. Consumers must be able to comprehend the instructions and associated risks and warnings without needing a health care provider for a Rx-to-OTC switch to be successful. Accordingly, manufacturers and FDA must weigh the need to warn and educate consumers appropriately without causing confusion due to low health literacy or label fatigue. For medications with complex instructions, multiple medication- or disease-state warnings, or other misuse risks, an Rx-to-OTC with ACNU switch that relies solely on technology-enabled self-evaluation may not be sufficient to meet federal and state labeling requirements and keep patients safe. As such, FDA should prioritize the pharmacist-facilitated assessment pathway to promote patient access to these drugs that would fail the switch due to the inability to meet labeling requirements and standards.

⁵ Nonprescription Drug Product With an Additional Condition for Nonprescription Use, 89 Fed. Reg. 105288, 105288 (Dec. 26, 2024). Available at: <https://www.federalregister.gov/d/2024-30261/p-3>.

this model rather helps FDA align regulatory decisions with identified risks, while reducing speculation and promoting consistency across products.

Self-selection and consumer studies are the backbone of nonprescription drug applications once safety and efficacy are demonstrated, as FDA must know whether consumers can appropriately apply the information on the drug's label and make correct decisions regarding its use. While improvements to the process of switching a drug from prescription to OTC, including greater clarity and predictability regarding the overall process and FDA criteria used in decision-making, are warranted, self-selection studies remain necessary to preserve patient safety. Accordingly, FDA should not forgo safety requirements; rather, we strongly recommend FDA utilize the pharmacist-facilitated assessment pathway to increase access while these studies and the subsequent FDA review occur. This gives FDA the opportunity to meet President Trump's goal of increasing medication access and lowering health care costs, while granting manufacturers time to conduct these studies and FDA time to review the data to ensure patients can safely and appropriately use these drugs.

As noted throughout this proposal, there are risks associated with RX-to-OTC switches with ACNU, including drug-drug or drug-disease interactions and potential misuse or abuse, especially following consumer manipulation of digital assessments. Not only do self-selection and consumer studies assess whether consumers can make correct self-selection decisions based on their current conditions after reading the drug's label, but they also provide FDA with greater insight into why some make incorrect decisions. This type of information is critical for drugs that have contraindications, as patients with such contraindications who end up using the product have made an incorrect self-selection decision.⁶ Incorrect self-selection of OTC products can lead to adverse reactions, drug interactions, abuse, masking of more serious health conditions, and increased overall health care costs, as patients either are spending money on OTC products that do not work or now need to visit a health care provider or emergency room.⁷

While moving a prescription medication to OTC with ACNU may increase certain patients' access, especially if health care coverage can be maintained, FDA and other agencies tracking potential cost savings from such a switch should also consider the additional costs of suboptimal medication use in some of the situations listed above. It does not matter if FDA increases access if a drug is used incorrectly. For example, the United States spends over \$528 billion each year on treating non-optimized medication use.⁸ Comparing that to U.S. prescription expenditure of \$340 billion, for every \$1.00 spent on drug therapy, the United States spends an additional \$1.55 to address problems associated with non-optimized drug

⁶ *Guidance for Industry: Self-Selection Studies for Nonprescription Drug Products*, FDA (Apr. 2013). Available at: <https://www.fda.gov/media/81141/download>.

⁷ *Over-the-Counter Medication Misuse*, Defense Health Agency (June 15, 2020). Available at: <https://ph.health.mil/topics/healthyliving/asm/Pages/OverCounter.aspx> (noting that the misuse of OTC medications causes 178,000 hospitalizations per year).

⁸ Jonathan H. Watanabe, et al., *Cost of Prescription Drug-Related Morbidity and Mortality*, 52 *Annals of Pharmacology* 829 (2018). Available at: <https://pubmed.ncbi.nlm.nih.gov/29577766/>.

therapy. While FDA does not consider cost in its decision-making process, it is important to recognize that making prescription drugs available OTC does not automatically equate to increased access and cost savings for the overall health care system, and in fact, the opposite may also be true.

Consumer studies are also beneficial for understanding how patients will use these drugs. Given the fact that patients have never had access to these medications before without the assistance of a health care provider, it is essential that FDA know how patients will use the product, such as in the frequency of use, the willingness to use the product given its OTC status, and the intentional or accidental misuse of the product. These studies can also highlight what speakers raised at FDA's convening on April 23, 2026, regarding the benefit-risk analysis associated with switching a drug from prescription to OTC status, as the incremental benefits of the switch should outweigh the additional risks before FDA acts. Potential risks include: patients taking too much of the product or taking it too often, the likelihood of drug-disease or drug-drug interactions, which should remain top of mind for FDA. A pharmacist-facilitated assessment pathway could alleviate these concerns, as patients would still have quick access to medication with access to the medication expert, our nation's pharmacists, to address their concerns. As discussed above, this pathway could serve as the primary approach as companies compile the data needed to support the potential use of technology-enabled self-evaluations.

Consumer behavior studies may also shed light on whether consumers would manipulate self-evaluation assessments to obtain products that are not appropriate for them, given their medical conditions or medications. Products that patients may feel uncomfortable discussing with their providers but that carry additional warnings may be targets of this type of manipulation, including products intended for hair loss, sexual health, and erectile dysfunction. The pharmacist-facilitated assessment pathway would ensure these products become more accessible while mitigating the potentially serious patient safety risks associated with inappropriate use.

In addition to specific types of medications that may be prone to consumer manipulation of the assessments, there is also the potential for patients to misuse products that are available OTC with ACNU at low doses, but higher doses are prescription only. As part of the self-selection and consumer studies conducted during such a switch, FDA should document patients' behavior of taking multiple doses of the lower-dosed OTC with ACNU in place of seeing a health care provider and the corresponding adverse events and care associated with the higher-dosed version. The FDA would need to deter such misuse, as the higher-dose version could pose greater risks under the technology-enabled self-evaluation-only pathway. The pharmacist-facilitated assessment pathway would provide FDA with a way to curtail this misuse.

Recommended Federal Agency Actions

Consistency. FDA’s final rule intentionally promotes flexibility for manufacturers in operationalizing the ACNU. As such, FDA must clearly outline ACNU guidelines that promote consistency amongst the switching and implementation processes to ensure appropriate uptake by pharmacies and other vendors. Panelists at the FDA’s convening on April 23, 2026, stressed the same sentiment: without standardization, uptake will be too difficult for pharmacies and other vendors.

For ACNU products approved under a pharmacist-facilitated assessment pathway (Scenario A), the pharmacist must know the appropriate mechanisms for initiating, completing, and recording the assessment results. FDA should also coordinate with the Centers for Medicare & Medicaid Services (CMS) to provide coverage for any additional requirements and additions to pharmacists’ workflows (addressed further below).

For those approved under a technology-enabled self-evaluation pathway (Scenario B), all applicable vendors, including pharmacies, must know how to assess successful completion of the digital tool for dispensing the corresponding ACNU-approved product. Consistency in the rollout process and in the digital tools used to evaluate and render results will be instrumental to expanding access to these medications. Additionally, seamless integration with the patient’s electronic health record, accessible to the patient’s personal pharmacist, will ensure that documentation occurs under either Scenario A or Scenario B.

CMS. Because insurance plans and PBMs often discontinue drug coverage when a drug undergoes an Rx-to-OTC switch, CMS must also act to ensure that consumer access is not compromised following the shift of prescription medications to nonprescription drug products with an ACNU by preserving coverage for these medications post-transition. This is critical as there are concerns that the “simultaneous marketing” of prescription and nonprescription versions of the same drug lacks a legal basis and causes consumer confusion. Therefore, it is likely that these drugs, once they undergo this shift, will not be available as prescription drugs. Accordingly, CMS should promulgate rules and regulations requiring Medicare Advantage plans, Medicare Part D plans, and state Medicaid plans to cover ACNU-approved drugs in the same manner as they were covered when they were prescription drugs. Additionally, public and private payors should require payment for the pharmacist’s assessment of the consumer to determine eligibility for the nonprescription drug product approved under a pharmacist-facilitated assessment pathway. For Medicare, this payment can occur through regional Medicare suppliers for traditional Medicare, or through mandated coverage in MA and PDP plans, with pharmacies or pharmacists potentially credentialed as providers (such as through [Pharmacy Profiles, LLC](#)), like all other providers of health care services.

Recommended Action on Interoperability to Increase OTC ACNU Access

In conjunction with the Administration's focus on enhanced interoperability, FDA should work with CMS and the Office of the National Coordinator for Health Information Technology (ONC) to work with private entities to accelerate interoperability by promoting the bidirectional sharing of electronic health information with pharmacies and preventing information blocking of our nation's pharmacists to patients' electronic health information (EHI). This would include allowing pharmacists and pharmacies to add data to the electronic health record for care provided under an OTC with ACNU. Such an approach would increase access to care beyond ACNU products, as pharmacists are highly trained medication experts who can initiate therapies for numerous medical conditions. With nearly 90% of Americans living within 5 miles of a community pharmacy,⁹ pharmacies and pharmacists are key to improving Americans' health and reducing overall health care expenditures.

Joint Recommendations

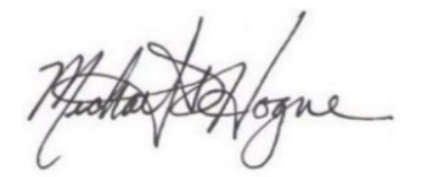
It is our position that the following action steps should be taken as a blueprint to facilitate the movement of more pharmaceuticals from prescription to OTC with ACNU:

- 1) **Step One:** FDA needs to clarify clear pathways for Rx-to-OTC switch with ACNU. We recommend: (1) the pharmacist-facilitated assessment pathway (Scenario A) and the technology-enabled self-evaluation pathway (Scenario B). The risk of drug-drug or drug-disease interactions, the potential for patient manipulation of technology-enabled assessments, and the other areas identified above should drive FDA's decision-making on these pathways.
- 2) **Step Two:** FDA should work with CMS to require Part D plan sponsors, state Medicaid agencies, Medicare Advantage plans, and others to cover any additional requirements and additions to pharmacists' workflows under Scenario A or B and establish mechanisms to reimburse patients for products purchased outside pharmacies under the technology-enabled self-evaluation pathway (Scenario B). FDA could also partner with manufacturers, distributors, and retailers to create novel solutions for product access under this pathway. CMS should provide similar guidance to ensure that an OTC drug product with ACNU continues to be covered by prescription drug insurance in the same way as prescription drugs.
- 3) **Step Three:** FDA should work with ONC to call upon HHS to leverage its influence of EHR systems to facilitate full integration of pharmacies and pharmacists wherever they exist in the health care system to ensure bi-directional (read/write) access to the patient's health care record.

⁹ Lucas A. Berenbrok, et al., *Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis*, 62 *Journal of the American Pharmacists Association* 1816, 1816 (2022). Available at: <https://www.japha.org/action/showPdf?pii=S1544-3191%2822%2900233-3>.

APhA and NCPA thank you for the opportunity to provide additional comments. Please contact Michael Baxter, APhA Vice President of Government Affairs, at mbaxter@aphanet.org and Ronna Hauser, NCPA Senior Vice President, Policy and Pharmacy Affairs, at ronna.hauser@ncpa.org to meet with APhA, NCPA, and our nation's community pharmacists.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael D. Hogue". The signature is fluid and cursive, with the first name "Michael" and last name "Hogue" clearly legible.

Michael D. Hogue, PharmD, FAPhA, FNAP, FFIP
APhA Executive Vice President and CEO

A handwritten signature in black ink, appearing to read "Ronna B. Hauser". The signature is written in a cursive style, with the first name "Ronna" and last name "Hauser" clearly legible.

Ronna B. Hauser, PharmD
NCPA Senior Vice President, Policy
and Pharmacy Affairs