NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

May 7, 2026

Phong Pham
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., White Oak Building 22, Room 5134
Silver Spring, MD 20993

Submitted via regulations.gov

Re: Request for Comments; Increasing Availability of Nonprescription Drugs (Docket No. FDA-2025-N-4731)

Dear Mr. Pham:

The National Association of Chain Drug Stores (NACDS) thanks the Food and Drug Administration (FDA) for the opportunity to respond to the Request for Comments on *Increasing Availability of Nonprescription Drugs*. NACDS shares the Administration's goal of connecting Americans to affordable, accessible healthcare and we welcome the opportunity to work with FDA as the agency seeks to leverage OTC drug approval pathways in support of this aim. For decades, access to nonprescription medicines in pharmacies and other retail settings has helped connect Americans to simple, timely treatment for minor, self-diagnosed conditions. As FDA considers expanding the scope of over-the-counter (OTC) product availability, the growing number and types of nonprescription drugs have the potential to meaningfully shift how patients obtain care and could streamline access to certain preventive services and routine therapies. However, to ensure additional prescription to nonprescription switches improve real-world access and do not unintentionally create new barriers for any Americans, additional policy and operational factors must be addressed in tandem. Accordingly, NACDS recommends the following:

1. **For nonprescription drugs with additional conditions for nonprescription use (ACNU), FDA should convene a forum where stakeholders can identify and start to work through implementation issues for this new category of OTC products and encourage standardization of the mechanisms and processes that product sponsors deploy for consumers to demonstrate that they have satisfied a particular product's ACNU requirements at the point-of-sale.**
2. **FDA should coordinate with state policymakers, including state legislatures and boards of pharmacy, to encourage state policy alignment that supports Americans' access to nonprescription drugs – especially in instances where medications transition from prescription to nonprescription status, including:**
    a. Enacting state policies that support reimbursement to pharmacists for providing clinical services to individuals who seek additional counseling and care related to nonprescription products;
    b. Updating state pharmacy and health insurance laws to authorize pharmacists to issue prescriptions for nonprescription drugs where required for insurance coverage purposes; and
    c. Discouraging any state sales restrictions or pharmacy practice limits that would impede pharmacy and retail establishments' ability to sell nonprescription drugs.
3. **Because insurance coverage often equates to access, FDA should coordinate with Congress, the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury to encourage policy changes that require public and private payors to cover nonprescription products.** The transition of additional medications to nonprescription status, without insurance coverage, may inadvertently limit access for some Americans given out-of-pocket costs.

I. Standardization of the ACNU-Related Mechanisms and Processes

Once available, nonprescription drugs with ACNU have the potential to fundamentally change how Americans access care – particularly if medications that are currently prescription-only transition into this new OTC product category. FDA's final rule for these products outlines the parameters for product sponsors to demonstrate that nonprescription drugs with ACNU will ensure appropriate self-selection and appropriate use by consumers without the supervision of a health care provider, while providing significant flexibility to product sponsors for how the ACNU is operationalized for individual products. In practice, that flexibility means ACNU could be implemented in many different ways. A product's ACNU might involve a questionnaire completed at a retail kiosk, through a mobile app, by telephone, or via a website which produces a coupon, voucher, or barcode for the consumer to present at the point-of-sale to demonstrate that they have met the requirements and that the product is appropriate for them. Or the process could be implemented in an entirely different way.

From a retailer perspective, this variability presents real operational challenges. Implementing multiple, product specific systems and software, and training staff on different workflows at the point-of-sale, can be complex and costly. To the extent that ACNU-related processes can be simplified and standardized across products, the more feasible it will be for pharmacies and retailers to implement them and offer a broad range of these products for sale to consumers.

- **NACDS Recommendation:** FDA should convene a forum where product sponsors, pharmacies and retail establishments, and other stakeholders can identify and start to work through ACNU implementation issues, encouraging standardization of the mechanisms and processes that product sponsors deploy for consumers to demonstrate that they have satisfied a particular product's ACNU requirements at the point-of-sale.

II. State Regulatory Considerations that Impact Access to Medications Transitioning from Prescription to Nonprescription Status

Over the years, federal and state policymakers and other stakeholders have taken various actions to facilitate broader public availability of healthcare services at neighborhood pharmacies – including policies that enable pharmacists to order and dispense medications such as naloxone, hormonal contraceptives, tobacco cessation products, and pre- and post-exposure prophylaxis for HIV prevention. Many states have also adopted laws that require health plans to cover clinical services provided by pharmacists related to this care. As policymakers have acted in the past to strengthen access to care through pharmacies, additional actions will be necessary to effectively facilitate future transitions of prescription to nonprescription products. Without certain policy changes, as outlined below, FDA risks the unintended effect of complicating access to newly designated nonprescription drugs. To avoid this, where needed, states should update laws to ensure that Americans have sustained access to any product that transitions from prescription to nonprescription status.

Especially for medications that transition from prescription to nonprescription drug status, it is conceivable and likely that many individuals will seek guidance and direction from their trusted pharmacists before initiating therapy. To support access to counseling and other related wrap-around services that patients seek related to these products, federal and state policymakers should enact policies that require health plans and insurers to cover and reimburse pharmacists for counseling and delivering other clinical care that supports individuals' use of nonprescription drugs.

- **NACDS Recommendation:** FDA should coordinate with Congress and state legislatures to require health plans and insurers to reimburse pharmacists for counseling and related clinical services that are provided to patients who seek additional care at pharmacies related to nonprescription products.

Additionally, many health plans and insurers that provide coverage for nonprescription drugs do so only where the individual has received a prescription from a healthcare provider. To simplify access to care in these situations, states

should update their pharmacy practice and health insurance laws to expressly recognize pharmacists' authority to prescribe or order nonprescription drugs for health insurance coverage purposes. At the same time, states should look to identify and eliminate any practice or sales restrictions that might inadvertently impede access to newly approved nonprescription drugs. States should not impose any special requirements for nonprescription drugs that are inconsistent with FDA labeling.

- **NACDS Recommendation:** FDA should coordinate with state policymakers, including boards of pharmacy, to update pharmacy practice laws and state insurance code to recognize authority for pharmacists to issue prescriptions for nonprescription drugs where required for insurance coverage purposes.

- **NACDS Recommendation:** FDA should discourage states from imposing any pharmacy practice limits or sales restrictions or that would impede pharmacy and retail establishments' ability to sell nonprescription drugs.

III. Coverage of Nonprescription Drug Products and Related Supportive Clinical Care Provided by Pharmacists Is Critical to Making Healthcare More Accessible to Many Americans

History has shown that insurance coverage of various health services and products helps facilitate patient access to care. Traditionally, prescription drugs have been covered by payors, while nonprescription medications have not. It is therefore plausible that if the category of nonprescription drugs grows to include more medications that been previously been available by prescription only, this could result in both public and private payors ceasing to cover these products.

While many older nonprescription drugs remain generally affordable for most Americans, the more recently approved OTC products may be too costly for some Americans. For example, an internet search for the cost of a package of 200 mg ibuprofen – a product that has been available over the counter since 1984 – can typically cost consumers $2–$25 depending on package size and manufacturer. In contrast, recent products that have switched from prescription to nonprescription status like naloxone and oral contraceptives can range in cost from the manufacturer suggested retail price of $30–$50 and $20–$90 respectively, depending on package size. In many cases, the prices of newer nonprescription drugs exceed the typical (and often nominal) out-of-pocket costs that individuals pay for any prescription drugs covered by their health plans. Especially for Medicaid-covered individuals whose copays range from as low as $0-$3.00,[1] if plans follow historical trends and cease to cover products that have switched from prescription to nonprescription status, such a coverage change forcing new out-of-pocket costs could put high-cost nonprescription products out of reach entirely.

To support the accessibility of these products, it will be extremely important that public policy keeps pace with the switching of any medication from prescription to nonprescription status. While coverage issues are outside of FDA's purview, it is still a very relevant consideration that impacts access to care for most Americans. Thus, if more products are moved from prescription to nonprescription status, FDA should work with Congress and federal agencies with oversight authority of commercial and publicly funded health plans to support coverage of nonprescription drugs.

- **NACDS Recommendation:** To support access to nonprescription drugs – especially for medications that have previously been available as prescription drugs – FDA should coordinate with Congress, the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury to encourage policy changes that require public and private payors to cover nonprescription products.

[1] https://www.kff.org/state-health-policy-data/state-indicator/state-medicaid-pharmacy-copay-requirements/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

It is also important that health plans and insurers adopt a standardized approach to claims processing at the point-of-sale that both pharmacies and non-healthcare retail settings can implement, and that enables clear and consistent billing practices with minimal administrative burdens for different provider types.

Currently, pharmacy providers use the well-established and longstanding National Council for Prescription Drug Programs (NCPDP) pharmacy billing standards to facilitate the electronic claims submission processes between pharmacies and payors for covered drugs. The existing NCPDP standards have data fields to facilitate nonprescription drug coverage if/where covered by different payors. However, claims for nonprescription drugs commonly require the "prescriber" of the product to be identified in a field using the prescriber's national provider identifier (NPI) number. Claims without a prescriber will not be covered and those claims will be rejected. In other words, the existing standards are not designed to facilitate billing claims for nonprescription products without a prescriber/prescription.

We also recognize that some health plans/insurers may have already opted to cover certain nonprescription products without a prescription and may have worked with certain pharmacy providers to implement a claims processing workaround for the prescriber NPI number issue. However, it should be noted that these workarounds would have been established directly between the individual health plan/insurer and individual pharmacies, and there is not a uniform, standardized approach for how pharmacy providers should handle the prescriber NPI number issue when processing a claim without a prescriber/prescription. Moreover, the standards that facilitate claims processing are designed to integrate with pharmacy systems – not point-of-sale systems at registers at the front end of the store, which thereby excludes non-traditional provider establishments (e.g. non-healthcare retailers) from utilizing any existing/available systems to process claims for nonprescription drug items sought by covered individuals outside the pharmacy.

To simplify the consumer journey and support access to nonprescription drugs at the front end of pharmacy establishments and at other non-pharmacy retail locations (similar to how patients currently obtain most nonprescription medications,) a new data transaction standard would be needed to facilitate the real-time processing of these nonprescription claims outside of pharmacy systems. NCPDP's Work Group 19 has considered the possibility of developing of a new standard for this very purpose, but to date, has not moved forward with doing so. Notably, the NCPDP standards development process – which involves health plans/insurers, providers and other stakeholders coming together to create data transaction requirements and processes that are workable for all parties – is time-intensive. Historically, it can take 12-18 months (and sometimes longer) to develop and finalize a new NCPDP data transaction standard, and then another year or more to vet, test, and implement across different payor and provider systems. That being the case, any requirements for health plans/insurers to cover nonprescription drugs should take these timelines into consideration for implementation purposes.

- **NACDS Recommendation:** To support point-of-sale access to nonprescription drugs covered by insurance both in healthcare settings like pharmacies and in non-healthcare retail settings, FDA should coordinate with the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury to adopt NCPDP's standards (currently in development) to facilitate the real-time processing of nonprescription claims outside of the pharmacy system.

Given the time needed to develop and implement new NCPDP billing standards to facilitate claims processing through traditional retail point-of-sale systems, health plans/insurers should additionally provide beneficiaries with a WIC- or FSA-style credit or debit card that could be used to obtain covered nonprescription drugs from both in-network and out of network providers. Credit card processors are already familiar with setting up their credit and debit card products to be used only for limited types of items, so it would be feasible for these cards to be set up to cover only the purchase of covered nonprescription drugs. This approach could also be a preferred, simpler, permanent way of handling the coverage of nonprescription products and would have the added benefit of being less time- and cost-intensive to implement across different provider types, including in non-traditional retail provider establishments.

- **NACDS Recommendation:** FDA should coordinate with Congress, the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury to encourage health plans and insurers to provide covered beneficiaries with a WIC or FSA-style prepaid credit or debit card as a means of ensuring coverage of nonprescription products – this would be the preferred approach for supporting patient access to covered OTC products.

NACDS thanks the FDA for the opportunity to submit comments and for considering our recommendations. If we can provide any additional information, please contact Kayla McFeely, Vice President, Health and Wellness Strategy and Policy, at kmcfeely@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.