Submitted electronically to: www.regulations.gov

July 14, 2025

Robert F. Kennedy, Jr.
Secretary
US Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again [Docket: AHRQ–2025–0001]

Secretary Kennedy,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the US Department of Health and Human Services' (HHS') Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again.

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. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

In this RFI, HHS seeks input on how to dramatically deregulate across all areas the Department touches. NCPA provides the following suggestions:

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

CMS should eliminate pharmacies' mandatory participation in the Medicare Drug Price Negotiation (MDPN) Program via PBM/plan contracts

To preserve the viability of Medicare Part D, access of beneficiaries to the pharmacy of their choice, and the viability of independent pharmacies, NCPA asks CMS to make the following reforms to Medicare Part D: Eliminate pharmacies' mandatory participation in the Medicare Drug Price Negotiation (MDPN) Program via PBM/plan contracts. CMS has required such participation in the recent Part D final rule by amending § 423.505 by adding paragraph (q) to require that Part D sponsors' network contracts with pharmacies require such pharmacies to be enrolled in the Medicare Drug Price Negotiation (MDPN) Program's Medicare Transaction Facilitator Data Module (''MTF DM''). NCPA opposes mandatory participation in the MDPN Program via

PBM/plan contracts via this mandatory requirement. NCPA does not believe that CMS has the authority to tie participation in Part D as a whole with participation in the MDPN Program.

CMS should rescind the Medicare Part B requirement for a beneficiary's signature on a reimbursement claim

CMS should rescind the Medicare Part B requirement for a beneficiary's signature on a reimbursement claim under 42 C.F.R. 424.32 and 42 C.F.R. 424.36 because it is outdated in today's era of electronic claim submission. Capturing a signature – both on paper and electronically – is administratively burdensome and not an effective deterrent for fraud and abuse.

42 C.F.R. 424.32 Basic requirements for all claims.
(a) A claim must meet the following requirements:
(3) A claim must be signed by the beneficiary or on behalf of the beneficiary (in accordance with § 424.36).

42 C.F.R. 424.36 Signature requirements.
(a) General rule. The beneficiary's own signature is required on the claim unless the beneficiary has died or the provisions of paragraphs (b), (c), or (d) of this section apply. For purposes of this section, "the claim" includes the actual claim form or such other form that contains adequate notice to the beneficiary or other authorized individual that the purpose of the signature is to authorize a provider or supplier to submit a claim to Medicare for specified services furnished to the beneficiary.

* * *

(c) Who may sign if the beneficiary was not present for the service. If a provider, nonparticipating hospital, or supplier files a claim for services that involved no personal contact between the provider, hospital, or supplier and the beneficiary (for example, a physician sent a blood sample to the provider for diagnostic tests), a representative of the provider, hospital, or supplier may sign the claim on the beneficiary's behalf.

We request that CMS rescind these regulations which require a beneficiary's signature on a reimbursement claim in the Medicare program. This requirement was more appropriate when pharmacies were more regularly submitting paper claims, but is no longer viable today as pharmacies engage predominantly in real-time, electronic claims submission. It is unclear what, if anything, these rules do to protect the Medicare program from fraud or abuse, but these rules do substantially add to administrative burden on pharmacies, and delays in patient care.

Specific administrative burdens of the existing regulation include lost time attempting to mail a form to the beneficiary requesting signature and repeatedly following up seeking a response.

CMS should revise its interpretation of 42 CFR 424.57(c)(12) - Signature for In Person Pickup of Items

42 CFR 424.57(c)(12) - Signature for In Person Pickup of Items
Must be responsible for the delivery of Medicare covered items to beneficiaries and maintain proof of delivery. (The supplier must document that it or another qualified party has at an appropriate time provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively)

CMS should revise its interpretation of this regulation, and instead interpret it to mean that a signature capture is not required for in person pickup. Requiring a signature for items that are picked up in person at a supplier is contrary to this regulation and unnecessarily burdensome.

The federal regulation does not specifically state that signature must be captured to document proof of delivery. A supplier can rely on receipt of delivery confirmation from the carrier.

Requiring a signature for items that are picked up in person at a supplier is contrary to this regulation and unnecessarily burdensome, especially since a signature is not required for home delivery. Moreover, it is unclear how the signature requirement protects against fraud or abuse in the Medicare program, as a supplier has other forms of documentation it can produce for items picked up in person (electronic documentation of sales transactions, use of/form of payment collected for copayments, etc.) to document proof of delivery, similar to a third-party carrier delivery confirmation.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA) / DRUG ENFORCEMENT ADMINISTRATION (DEA)

SAMHSA and DEA should rescind joint rules requiring pharmacists to verify the identity of patients filling prescriptions for buprenorphine to treat opioid use disorder (OUD) that were issued on the basis of a telemedicine encounter

42 CFR § 12.3 (b)(4) and 21 CFR § 1306.51 (b)(4) - Requirement for Pharmacists to Verify Identification of the Patient When Filling Prescriptions for Schedule III-V Medications

HHS should work with Substance Abuse and Mental Health Services Administration (SAMSHA) and the Drug Enforcement Administration (DEA) to rescind their joint rules requiring pharmacists to verify the identity of patients filling prescriptions for buprenorphine to treat opioid use disorder (OUD) that were issued on the basis of a telemedicine encounter – a requirement that perpetuates the stigma that individuals seeking OUD treatment can experience, thereby undermining the underlying purpose of the Final Rule to "increase patient access to legitimate medical treatment." Further, these requirements that impose burdensome, costly, and unworkable requirements on pharmacies were never properly noticed for public comment.

FOOD AND DRUG ADMINISTRATION

Any Future MOU

In 1997, Congress amended the Food, Drug, and Cosmetic Act to require FDA to develop a Memorandum of Understanding (MOU) with state boards of pharmacy. NCPA welcomed FDA's delay of implementation of the MOU on October 21, 2022 until the effective date of a final rule regarding certain distributions of compounded human drug products and publication of an updated standard MOU.[1] NCPA also supported FDA's past suspension of the October 2020 MOU, its plans to establish a new MOU through rulemaking, and its "plans to further extend the period during which FDA does not intend to enforce the statutory 5 percent limit during the rulemaking process."[2] **NCPA supports FDA suspending this MOU indefinitely, given our multiple concerns.**

NCPA hopes that any future MOU, if it were promulgated, will address our previously stated concerns. First, we hope that states are given sufficient time to assess any conflicts of law, and if they choose to sign, modify existing laws to comply with the MOU. Already, several state boards of pharmacy have raised issues about the potential conflicts between the old MOU and existing state laws regarding confidentiality of information – which conflicts with the reporting requirements of the old MOU. Some of these states have significant patient populations who use compounded drugs.

We also remain concerned about the consequences of not signing the MOU on patient access to essential compounded medications. Pharmacies in states that sign the MOU will be permitted to provide patients with personalized medications unimpeded. In states that choose not to sign, a five percent cap on interstate shipments would be imposed on pharmacies. NCPA is also concerned that patients who rely on compounded medications from pharmacies in states that cannot or do not sign the final MOU deadline will be penalized by disruption of care and inability to receive therapy from their pharmacy of choice.

NCPA also disapproves of the way FDA has structured the past MOU. NCPA continues to have issues with both the process and the content of the old MOU – we believe FDA conflates the definitions of "distribute" and "dispense" without Congressional authorization.

The statutory language in section 503A of the FDCA directing FDA to establish an MOU with states requiring reporting of interstate distributions of compounded drugs is now outdated and does not make sense in the context of the establishment of 503B outsourcing facilities under the DQSA. We hope that FDA will work with NCPA, NABP and other pharmacy stakeholders on consensus legislation to update this statute to require reporting by pharmacies of interstate dispensing and distributions of compounded drugs without the need for states to sign an MOU that may conflict with state laws and without the arbitrary and punitive 5% cap in the current law.

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[1] See Extension of the Period Before the Food and Drug Administration Intends To Begin Enforcing the Statutory 5 Percent Limit on Out-of-State Distribution of Compounded Human Drug Products. Fed Reg Vol 87 No 203. Oct 21, 2022.

[2] See Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs | FDA.

Demonstrably Difficult to Compound Federal Register Notice

FDA should eliminate its proposed rule[3] on demonstrable difficulties for compounding.

FDA's proposed rule to establish criteria for two lists of drug products or categories of drug products that present demonstrable difficulties for compounding (Demonstrable Difficulties for Compounding Lists or DDC Lists) under certain sections of the Federal Food, Drug, and Cosmetic Act. Drug products or categories of drug products that appear on the DDC Lists cannot qualify for certain statutory exemptions, and therefore may not be compounded under, either section 503A or section 503B, respectively. FDA is also proposing to establish criteria for evaluating drug products or categories of products for inclusion on one or both lists. For evaluating drug products or categories of drug products for inclusion on the DDC Lists, FDA is proposing to establish the following criteria: the formulation complexity, drug delivery mechanism complexity, dosage form complexity, complexity of achieving or assessing bioavailability, compounding process complexity, and complexity of physicochemical or analytical testing of the drug product or category of drug products. Additionally, FDA is proposing to identify the first three categories of drug products on both DDC Lists: (1) oral solid modified-release drug products that employ coated systems (MRCs), (2) liposome drug products (LDPs), and (3) drug products produced using hot melt extrusion (HMEs).

Both sections 503A and 503B of the Federal Food, Drug and Cosmetic Act give FDA authority to prohibit compounding of certain medications deemed "demonstrably difficult to compound in a manner that reasonably demonstrates an adverse effect on the safety or effectiveness" of the drug. But according to Congress, the authority is different in these sections:

- In 503A, FDA may bar specific drug products from compounding — a narrow authority focused on individual formulations.
- In 503B, FDA is authorized to restrict both drug products and categories of drugs — a broader power that reflects the scale and manufacturing practices of outsourcing facilities.

Despite this distinction, FDA's proposed regulations apply the broader category-based prohibition to 503A pharmacies — an approach not supported by the statute. In the March 2024 proposed rule, FDA proposed six vague criteria for evaluating whether a drug is "demonstrably difficult to compound," and stated that it may choose to use them to justify banning entire drug classes from 503A compounding.

This is not a permissible interpretation of the statute. Section 503A refers only to "drug products" — not categories — and makes no provision for banning entire classes of medications. By attempting to impose the 503B framework into 503A, FDA is acting beyond its authority.

[3] See Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act. Fed Reg Vol 89 No 55. March 20, 2024, 19776.

Therefore, NCPA urges HHS to:

- Prevent FDA from finalizing any rule that exceeds its statutory authority under Section 503A; and
- Ensure that only individual drug products — not entire categories — may be added to the 503A DDC list, consistent with congressional intent.

Veterinarian GFI #256

FDA should rescind its 2023 *Guidance for Industry #256* (GFI 256). FDA seeks to regulate veterinary compounding, despite having no clear congressional mandate to do so. One example of FDA's regulation of veterinary compounding is in its' GFI 256. GFI 256 imposes broad restrictions on the use of bulk drug substances in veterinary compounding which undermine the clinical judgment of veterinarians and unnecessarily restricts access of compounded drugs for animals.

If FDA insists on maintaining GFI 256, a much more revised GFI 256 would be appropriate – one which: respects veterinary practice, prescribing veterinarians, and the essential role of compounded medications in animal health, and one which streamlines the bulk substance nomination process, incorporating transparency in its evaluations.

Nonprescription Drug Products with Additional Conditions for Nonprescription Use (ACNU)

FDA should modify its Nonprescription Drug Products with Additional Conditions for Nonprescription Use (ACNU) final rule to standardize the ACNU process and incorporate the role of the pharmacist. In December 2024, FDA issued a final rule[4] establishing requirements for the approval, labeling and post-marketing reporting of Nonprescription Drug Products with Additional Conditions for Nonprescription Use ("ACNU"). FDA created ACNU drugs as a new category of over-the-counter drug products that can be sold at retail to consumers without a prescription if the product manufacturer implements an additional condition to ensure appropriate self-selection or appropriate actual use, or both, by consumers without a prescribing healthcare provider's supervision. Consumers must complete a self-assessment process designed by the product manufacturer to screen and determine whether that individual is eligible to purchase the product based on their health. NCPA believes this final rule creates operational burdens and costs at pharmacies, and proposes revisions to make the rule workable for pharmacies and patients alike.

Lack of Standardization. The Final Rule allows for different manufacturers to establish and deploy varying methods for consumers to complete the self-assessment process to determine their eligibility to purchase a particular ACNU drug. Therefore, each manufacturer may operationalize ACNU differently, resulting in significant administrative burden for pharmacies as they would need to operationalize and implement sales processes to accommodate myriad ACNU requirements, which would necessitate the training of sales clerks. **NCPA instead recommends**

[4] Nonprescription Drug Product With an Additional Condition for Nonprescription Use. Fed Reg Vol 89, No 247. Dec 26, 2024.

that FDA standardize the ACNU process such that there is a common way for patients to prove that they fulfilled the ACNU.

Costs and Time to Modify Point of Sale Systems. The ACNU final rule will require costly modifications for point-of-sale systems in pharmacy establishments to enter a "stop" in order to ask the patient to show their "proof" that they did the self-assessment, and the product is right for them. The POS systems will also have to add some type of documentation that the patient provided the self-assessment showing it was appropriate for that patient. This too would create great administrative burden, as pharmacies would be hesitant to modify their systems without knowing how manufacturers are going to approach the self-assessment. **This is why NCPA supports standardization of the ACNU self-assessment, as well as pharmacy input in the development of the systems.**

Patient concerns. Additionally, there will likely be significant patient confusion of the same product being available both for prescription and over-the counter. Insurance plans may also stop covering the prescription version of the drug, which will contribute to greater out-of-pocket costs to patients and possible medication adherence/access issues.

Ideally, the ACNU class of drugs should leverage the expertise of the pharmacist by being available only from state licensed pharmacies where pharmacists can assist with the necessary assessment processes for determining whether a particular medication is appropriate for the individual seeking the therapy.

NCPA thanks HHS for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

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