Submitted electronically to: www.regulations.gov

May 12, 2025

Kelsi Feltz
Office of Information and Regulatory Affairs
725 17th Street NW
Washington, D.C. 20503

Re: Request for Information: Deregulation

Ms. Feltz,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Office of Management and Budget to its docket: Request for information: Deregulation.

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care (LTC) services and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings. Together, our members employ 205,000 individuals, and provide an expanding set of health care services to millions of patients every day. Our members are small business owners who are among America's most accessible health care providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Reform the Inflation Reduction Act's Medicare Drug Price Negotiation Program. NCPA urges CMS to revise the Inflation Reduction Act's Medicare Drug Price Negotiation Program (MDPNP). CMS's unnecessarily bureaucratic approach requires pharmacies to float the costs associated with the IRA's negotiated drug pricing provisions as they are waiting for reimbursements from manufacturers, and leaves pharmacies vulnerable to underwater payments by pharmacy benefit managers (PBMs). This convoluted model is also at odds with President Trump's Executive Order "Lowering Drug Prices By Once Again Putting Americans First," which called for transparency of the MDPNP.

NCPA opposes CMS requiring pharmacies to float the MDPNP because this is a financially unviable solution. According to a study that NCPA recently commissioned, with MDPN drugs, the average pharmacy will float the program to the tune of $11,000 per week, with an estimated annual revenue loss of approximately $43,000 per pharmacy per year, which approximately equates to the salary of one full-time pharmacy technician.[1] These significant numbers are only for year one

[1] Unpacking the Financial Impacts of Medicare Drug Price Negotiation on Pharmacy Cash Flows. 3Axis Advisors January 2025.

of the MDPN Program and will grow larger and larger as more drugs are added each year, resulting in devastating, irreparable impact on pharmacies serving most vulnerable and at-risk patients, especially those serving long-term care facilities.

NCPA continues to be vocal about our concerns and has attached updated NCPA member survey results on the impact of the MDPN Program on our members. Our survey, conducted in January 2025, indicated that approximately 61 percent of independent pharmacists are strongly not considering stocking one or more drugs with prices negotiated under Medicare Part D, while an additional approximately 33 percent have already decided not to stock one or more of the drugs, which would all but guarantee that CMS' attempt to reduce prescription drug prices will fail.

Late manufacturer refund payments are unviable for pharmacy. Under the program, manufacturers will need to make pharmacies whole with a manufacturer refund by paying pharmacies the difference between wholesale acquisition cost (or another benchmark the manufacturer chooses) and the MFP. As it stands now, pharmacies will likely be waiting over 30 days for the manufacturer refund payments. The best-case scenario is 21 days, which is still unsustainable when pharmacies have to pay their wholesalers twice every month. NCPA has made our concerns regarding the impossibility of pharmacies implementing the MDPN clear, yet CMS did not address our concerns. Looking at our comments to CMS' draft guidance on the MDPN guidance in July 2024 versus CMS's final guidance in October 2024:

- NCPA opposed CMS requiring fair reimbursement for MPF drugs from PBMs, including dispensing fees to pharmacy under this program, yet CMS choses to continue to not require fair reimbursement and dispensing fees;
- NCPA asked for clarification from CMS regarding the Primary Manufacturer transmitting an MFP refund amount within 14 days of adjudication of the MFP drug, as opposed to ensuring the dispensing entity has received the MFP reimbursement within 14 days, to comply with the 14-day prompt MFP payment window, yet CMS did not clarify this;
- NCPA asked that CMS prefund the Medicare Transaction Facilitator (MTF) to expedite payment to pharmacies, yet CMS did not require a prefund from either CMS or manufacturers;
- NCPA asked that the standard default refund amount (SDRA) of WAC-maximum fair price (MFP) be required, yet CMS did not mandate this; and
- NCPA expressed concern that CMS has chosen to allow manufacturers to voluntarily effectuate the MFP via the MTF Payment Module (MTF PM), yet CMS made manufacturer participation in the MTF PM optional, causing pharmacies to worry that they will have to have multiple systems and software programs to reconcile these payments.

Further, CMS is unwilling to protect pharmacies from PBMs' underwater reimbursements due to CMS's unwillingness to "interfere" with PBM/pharmacy contracts. At the same time, CMS is interfering in PBM/pharmacy contracts when it dictates that any contract between the sponsor or its PBM and a pharmacy must include a provision requiring the pharmacy to be enrolled in the Medicare Transaction Facilitator Data Module (MTF DM). So, while CMS is willing to interfere with contracts concerning the data module, it is not willing to interfere in contracts that make certain pharmacies are paid fairly. For those reasons, NCPA thinks this program has a high

likelihood of failure and opens CMS up to potential legal claims that it can -- in fact -- interfere in PBM/pharmacy contracts but chooses not to do so.

To remedy these concerns, CMS must at the very least modify plan and manufacturer Maximum Fair Price (MFP) reimbursement policies under the MDPNP:

- Part D plans and PBMs must: 1) pay pharmacies no less than the MFP plus a commensurate dispensing fee when providing MFP drugs; and 2) not assess Direct and Indirect Renumeration (DIR) fees on MFP drugs.
- Manufacturers should be required to: 1) effectuate the MFP via the Medicare Transaction Facilitator Data Module (MTF DM) **and** the Medicare Transaction Facilitator Payment Module (MTF PM); 2) pay the pharmacy the refund amount WAC minus MFP (the Standard Default Refund Amount, or SDRA), and within 14 days of claim adjudication; and 3) submit to CMS their MFP effectuation plans sooner than September 1, 2025, as pharmacies need to make decisions on PBM/plan contracts earlier.

Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

NCPA advises CMS to strike the amendments to § 423.505 that it finalized in its CY 2026 Medicare Part D final rule,[2] where it added paragraph (q) to require that Part D sponsors' network contracts with pharmacies require such pharmacies to be enrolled in the MDPNP's Medicare Transaction Facilitator Data Module (''MTF DM''). **NCPA opposes mandatory participation in the MDPNP 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 MDPNP, and NCPA requests formal explanation as to why CMS believes it has such authority.**

FOOD AND DRUG ADMINISTRATION (FDA)

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.[3] 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."[4] **NCPA would support FDA suspending this MOU indefinitely, given our multiple concerns.**

[2] See Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. Fed Reg Vol 90, No 71, April 15, 2025.

[3] 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.

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

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.

Demonstrably Difficult to Compound Federal Register Notice

NCPA asks FDA to eliminate its proposed rule[5] 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

[5] 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.

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.

Therefore, NCPA urges the Administration 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)

NCPA asks FDA to 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[6] 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 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.**

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

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.

DRUG ENFORCEMENT ADMINISTRATION (DEA)

Limits on methadone prescribing and dispensing

NCPA asks the Department of Justice and the Drug Enforcement Administration to modify overly burdensome regulations that currently ban qualified prescribers from prescribing methadone for opioid use disorder and pharmacies from administering/dispensing it pursuant to a prescription. NCPA and other organizations submitted a letter to DOJ and DEA calling for such revisions back in April 2025.[7] Specifically, 21 C.F.R. § 1306.07(a) bans the dispensing by pharmacies of methadone as treatment for opioid use disorder (OUD), even though pharmacies can dispense the very same medication for treatment of pain. This conflicts with the plain reading of the underlying statute (21 U.S.C. 823(h)). However, the underlying statute (21 U.S.C. 823(h)) does not explicitly prohibit practitioners prescribing methadone for OUD or pharmacies from dispensing it under a prescription. Instead, the statutory language requires practitioners who "dispense" narcotic drugs for maintenance or detoxification to annually obtain a separate registration for that purpose. By DEA not incorporating a plain reading of the statute, patient harm results by the agency unnecessarily restricting patient choices and limiting the autonomy of qualified practitioners in addiction medicine.

Positive ID Requirement for telemedicine encounters for controlled substances

NCPA calls on DEA to strike the positive ID requirements established in 21 CRF 1306.51 (b)(4) and 42 CFR § 12.3 (b)(4) requiring that pharmacists verify identification of the patient when filling prescriptions for Schedule III-V medications for the treatment of opioid use disorder that were issued on the basis of a telemedicine encounter. Under regulation:

> 21 CFR § 1306.51(b)(4)
> *(4) Pharmacy identification requirement. The pharmacist shall verify the identity of the patient prior to filling a controlled substance prescription issued under the authority of this section. The pharmacist shall verify the identity of the patient with a state or Federal Government-issued photographic identification card or other form of identification. For the purposes of verifying the identity of the patient, the pharmacist may accept identification in the manner described herein from any*

[7] See Letter from American Society of Addiction Medicine (ASAM), R Street Institute (RSI), National Community Pharmacists Association (NCPA), American Society of Health-System Pharmacists (ASHP), and National Commission on Correctional Health Care (NCCHC) to DOJ and DEA. March 26, 2025.

qualifying "ultimate user" as defined in 21 U.S.C. 802(27) prior to filling the prescription.

42 CFR § 12.3(b)(4)
(4) Pharmacy identification requirement. The pharmacist shall verify the identity of the patient prior to filling a controlled medication prescription issued under the authority of this section. The pharmacist shall verify the identity of the patient with a state or Federal Government-issued photographic identification card or other form of identification. For the purposes of verifying the identity of the patient, the pharmacist may accept identification in the manner described herein from any qualifying "ultimate user" as defined in 21 U.S.C. 802(27) prior to filling the prescription.

Earlier this year, the Drug Enforcement Administration (DEA) and the Substance Abuse and Mental Health Service Administration (SAMHSA) jointly published final rules under 21 CFR § 1306.51 & 42 CFR § 12.3 to permanently authorize prescribers to issue prescriptions for schedule III, IV and V medications to treat opioid use disorder via a telemedicine encounter. When finalizing the rulemaking, DEA and SAMHSA added new language to the Final Rule requiring pharmacists verify the identity of the patient prior to filling a prescription for buprenorphine issued on the basis of a telemedicine encounter. This "positive ID" requirement will be burdensome, costly and unworkable for dispensing pharmacies to implement, and contradicts the purpose of the Final Rule to "increase patient access to legitimate medical treatment."[8] Additionally, DEA and SAMHSA did not give pharmacies an opportunity to comment on this policy before finalizing it.

CUSTOMS AND BORDER PROTECTION (CBP)

Country of origin (COO) ruling

NCPA asks CBP to strike its interpretive ruling regarding country of origin (COO) marking for prescription medication bottles that pharmacies dispense to patients, as well as the recently issued CBP Fact Sheet, both indicating that medication bottles that pharmacies dispense to patients must be marked with the COO on the packaging that the patient receives. NCPA believes that this ruling and fact sheet was not in line with the spirit of the law, and that CBP should revert to its previous interpretation that pharmacies and medical service providers are the ultimate purchasers of prescription medications. Such an interpretation would then negate the need for COO marking to be included on prescription bottles filled at a retail pharmacy and dispensed to patients.

CBP notes in the recently issued Fact Sheet:

> Marking is required by law (19 U.S.C. § 1304 and 19 C.F.R. § 134.11); however, there are exceptions to the rule. Certain commodities listed in 19 C.F.R. § 134.33

[8] Expansion of Buprenorphine Treatment via Telemedicine Encounter. Fed Reg Vol 90 No 11. Jan 17, 2025.

> are excepted from individual country of origin marking. This list is known as the J-List. "Chemicals, drugs, medicinal, and similar substances, when imported in capsules, pills, tablets, lozenges, or troches," are excepted articles set forth on the J-List. Articles on the J-List are exempt from having to be individually marked; however, the outermost container that ordinarily reaches the ultimate purchaser of a J-List article must be marked with the country of origin of the article.

However, in the Fact Sheet, CBP goes on to state:

> In situations where imported medication is repackaged in bottles by retail pharmacies and sold for individual use, **the customer at the retail pharmacy is the last person to receive the medication in the form in which the medication is imported, and thus, is 2 considered the ultimate purchaser for purposes of 19 U.S.C. § 1304**. (emphasis added).

We respectfully disagree. In these circumstances, the last person to receive the medication in the form in which it was imported is the retail pharmacy. Pharmacies do not merely repackage medications from larger bottles into smaller bottles. The dispensing of medications by a pharmacy is part of a suite of services that can only be provided by licensed pharmacists. Pharmacists provide related critical services, including ensuring that the patient receives correct quantities, strengths, indications, instructions, and warnings, as well as patient counseling.

Pharmacies are not mere "repackagers." Each container of prescription medication may only be dispensed pursuant to a legal and valid prescription order. It is notable that FDA exempts pharmacies from the requirements of repackagers when the medication is repackaged under the direct supervision of a licensed pharmacist and dispensed pursuant to a valid prescription for a specific patient. Moreover, the bottle and labeling the pharmacy provides does not include other carton or packaging information that would otherwise be required by FDA such as the National Drug Code (NDC).

In CBP's June 14, 2024 interpretive ruling, the agency states that "a retail customer's purchasing decision is not based on a particular service provided by the pharmacists, as such services are uniform from pharmacy to pharmacy. Instead, a retail customer as the ultimate purchaser is deciding whether or not to purchase medication from a pharmacy based on factors such as the medication's country of origin and/or manufacturer." We find this statement to be woefully misinformed. In fact, patients rarely base their decision on what prescription medication to purchase based on the medication's COO and/or manufacturer. First and foremost, patients are prescribed medication by their health care provider; patients do not independently choose which prescription medications to purchase. The prescriber makes prescription medication decisions based on their training and expertise. Second, patients choose their pharmacy based on their relationship with the pharmacist and pharmacy personnel, convenience, insurance coverage, and other factors that are completely unrelated to the country from which the prescription medication was imported. Patients do not purchase prescription medications off the shelf whereby they would plausibly look at the container label for COO before purchasing. Finally, FDA-

approved labeling and other information about prescription medication is available to patients who seek additional information before filling or picking up the prescription.

CBP's interpretative ruling is a stark departure from more than a century of standard pharmacy practice. Requiring pharmacies to now include the COO on prescription bottles would impose undue burdens on pharmacy practice. Since pharmacists presently do not provide this information on prescription bottles, pharmacy workflow would need to be reconfigured to allow pharmacists to view the COO and somehow mark that information on the prescription bottle. This would cause widespread disruption of pharmacy practice nationwide as pharmacy computer systems are not designed to capture this information. Every pharmacy computer system nationwide and its software would need to be redesigned and reconfigured to capture this information and mark it on the prescription bottle. This would cost millions of dollars in technology upgrades and could take years to accomplish.

In addition, we fear that this requirement would greatly exacerbate existing prescription drug shortages because pharmacies would be forced to dispense medications in manufacturer-provided stock bottles that are already marked with the COO. They would not be able to utilize larger stock bottles that are broken down into smaller quantities for dispensing. Hence, we fear that patients may have increasingly difficult experiences obtaining their life-saving prescription medications.

NCPA thanks the Office of Management and Budget 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,

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