

Submitted electronically to: www.regulations.gov

August 28, 2023

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: In-Home Disposal Systems for Opioid Analgesics; Request for Information [[Docket No. FDA-2023-N-0917](#)]

To Whom it May Concern,

NCPA represents America's community pharmacists, including 19,400 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 represent a \$78.5 billion healthcare marketplace, employ 240,000 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.

FDA is seeking comment that will assist the Agency in assessing whether in-home disposal products can be expected to meet the public health goal of mitigating the risk of nonmedical use or overdose if the Agency were to require drug manufacturers to make in-home disposal products available to patients under a risk evaluation and mitigation strategy (REMS). To minimize burden on pharmacies, to avoid redundancies with existing programs, and to address our other concerns below, NCPA asks FDA to make any in-home disposal products program strictly voluntary, and to reimburse pharmacies for any goods and services that they may provide because of this program.

The NCPA Foundation operates a prescription disposal program, Dispose My Meds™, a program where community pharmacists can help their patients safely dispose of unused and expired medications.¹ There are currently 1,817 pharmacies nationwide that participate in Dispose My Meds™ through the NCPA Foundation, and the DEA publishes a list of all active pharmaceutical disposal locations.² NCPA members can buy discounted, DEA-compliant disposal systems and mail back envelopes. NCPA believes there is an increased opportunity for collaboration between the Drug Enforcement Administration (DEA) and community pharmacists with any expansion of DEA Take-Back Days.

¹ Dispose My Meds, NCPA. Available at: <https://ncpa.org/dispose-my-meds>.

² See apps.deadiversion.usdoj.gov/pubdisp/pub_disposal_sites.txt.

Additionally, NCPA supports CPESN USA, which is America's first clinically integrated network of pharmacy providers. More than 3,500 community pharmacies participating in 49 local networks in 44 states, it is pharmacy's fourth largest single contracting organization. CPESN has a Quality Assurance Standard that was recently updated by the Quality Committee and will take effect later this year. It states the following:

Pharmacy shall have a documented and active Opioid Stewardship Plan in place utilizing the [CPESN Opioid Stewardship Plan Example/Template](#) or equivalent.³ Pharmacy must submit an opioid waiver to CPESN USA if the pharmacy does not dispense opioid prescriptions.

Community health workers (CHW) are recognized public health professionals in almost all 50 states. They serve as liaisons between health and community services. Many pharmacy team members already adhere to many CHW practices and principles, including the role they play in conducting home visits and identifying social determinants of health to evaluate patients for SUDs. Two CPESN® pharmacies in Missouri were featured in an article in the *Standard Democrat* through their use of Community Health Workers.⁴

NCPA is active in educating our members regarding opioid use, abuse, and dispensing. In fact, we have an online series of opioid education for pharmacists and are actively publishing resources on our website to offer even more beneficial materials to aid pharmacists in understanding various issues surrounding the crisis.⁵ For example, we offer resources on background, the pharmacist's role, prevention, naloxone, treatment, as well as legislative updates to ensure our members are up to date on the practical and policy implications of this nationwide crisis. This area of our website offers links to various HHS tools and includes webinars we have hosted on opioid issues. In addition, NCPA supports increased healthcare provider education. The pharmacist's role is to provide continuity of education and monitoring.

NCPA offers the following governing principles for any in-home disposal products program that FDA would choose to implement.

Any program should be voluntary

To minimize burden on pharmacies and to avoid redundancies with existing programs, FDA should make any implementation of this potential requirement strictly voluntary.

Any program should include compensation for pharmacies

FDA must ensure that there is no cost to pharmacies regarding in-home disposal systems, education, or compliance with any of these provisions, and that this modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) does not result in an unfunded

³ All pharmacies have a grace period of 6 months from the effective date on their CPESN participation agreement to begin meeting quality-based metrics.

⁴ *Local Pharmacies are Including Community Health Workers in Staff*, The Standard Democrat (May 17, 2019), available at <https://standard-democrat.com/story/2609607.html>.

⁵ *Walking Through Opioid Management*, NCPA, available at <https://ncpa.org/opioid-resources>.

mandate or uncompensated burden to pharmacies. FDA should further ensure pharmacists are reimbursed for added time and resources spent on the provision of disposal education and resources. Considerable time will be needed to educate pharmacists and patients on any future requirements and scope of responsibilities, and pharmacists should be compensated for this time. There should be no additional financial burden to pharmacies or individual pharmacists because of this potential requirement.

FDA could work with state and local governments to fund this modification to the OA REMS, or state and local equivalents, through various opioid settlements.

Additional possible solutions for compensation of pharmacists in any voluntary program could include the following:

In-home disposal systems provided by manufacturer. FDA may find it challenging to establish a reference price for in-home disposal systems. To alleviate this concern, as suggested by FDA, manufacturers could provide these free of charge. And to reduce the burden on pharmacies, the manufacturer could provide the in-home disposal systems directly to the prescribing physicians, who in turn give them directly to their patients.

Transaction fee for education/training. FDA adoption of this requirement could be contingent on implementing a transaction fee that allows the pharmacy to bill for providing education and training to patients taking opioid analgesics. This fee would likely need to be tied to individual claims through NCPDP D.0 standards regulated by CMS or through manufacturer sponsored programs.

Inventory assessment fee. FDA adoption of this potential requirement could also be contingent on implementing an assessment. Pharmacies must have a mechanism to assess whether the patient has an adequate supply of in-home disposal systems so they can avoid wasteful dispensing of these systems. This claim would indicate that the pharmacy performed the assessment.

Any waste/unused medication should not go back to pharmacy

Any in-home disposal system should require the patient to directly mail the opioid analgesics to the site of disposal and should not involve the pharmacy. This will avoid practical concerns, including the limited amount of storage space in pharmacies, staffing availability concerns, and security concerns regarding placing opioid waste/unused medication at the pharmacy.

Redundancies with existing programs

Before implementation of this potential requirement, FDA should assess the current state of take-back, safe disposal, collection sites in the United States, on the federal, state and local level, and assess whether an additional program is necessary. Would an additional program be appropriate for certain localities, but redundant in others?

Pharmacists currently devote significant amounts of time, resources, or both to these programs. One of our members informed us that West Virginia has a pilot program with the West Virginia Drug Intervention Institute where pharmacists provide home disposal kits and are providing counseling on these scripts. Other members have stated they provide packets people can take home. Iowa Board of Pharmacy also provides grants for MedDrops and DisposeRx.

Space configuration

Given experience, our pharmacists have expressed concerns with finding space to place all the materials needed in any initiative by FDA, specifically regarding storing any in-home disposal systems.

Pharmacists as providers for opioid abuse services

Negative reimbursement pressure from insurers and pharmacy benefit managers and the inability of pharmacists to bill Medicare Part B as providers limits the positive impact pharmacists can provide to help combat the opioid crisis. Pharmacists are key players in counseling treatment for SUDs and provide many opioid abuse services, such as drug management and referral to counseling treatment.

Due to independent pharmacists' expertise in medication management and frequent interaction with their patients, they are equipped to educate patients about their use of controlled substances. Further, independent pharmacists can alert patients to possible consequences and, if needed, begin to motivate them to take steps to change their behavior. Patients currently choose to seek medication-related services from their community pharmacist for many reasons, as they have established relationships with their community pharmacists. Allowing the beneficiary to seek these services from their pharmacist increases the odds that medication adherence will occur. Therefore, we ask that FDA advise CMS to formally recognize pharmacists as providers eligible to furnish those opioid abuse reduction services in their scope of practice and claim reimbursement under Medicare Part B.⁶

⁶ 42 U.S.C. 1395w-4.

Conclusion

NCPA appreciates the opportunity to comment on FDA's request for information. To minimize burden on pharmacies, to avoid redundancies with existing programs, and to address our other concerns, NCPA asks FDA to make any in-home disposal products program strictly voluntary, and to reimburse pharmacies for any goods and services that they may provide because of this program. Please contact me with any additional questions or clarification at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a long horizontal stroke extending to the right.

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