

Submitted electronically to: www.regulations.gov

June 20, 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20652

Re: Providing Mail-Back Envelopes and Education on Safe Disposal With Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments [Docket No. FDA-2022-N-0165]

To Whom it May Concern,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments on the FDA notice, establishment of a public docket, and request for comments on *Providing Mail-Back Envelopes and Education on Safe Disposal With Opioid Analgesics Dispensed in an Outpatient Setting*. 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 \$67 billion healthcare marketplace, employ 215,000 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.

To minimize burden on pharmacies, to avoid redundancies with existing programs, and to address our other concerns below, NCPA asks FDA to not move forward with the proposed changes to OA REMS, or at the very least make it a strictly voluntary 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 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.

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

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

patients for SUDs. Two CPESN[®] pharmacies in Missouri were featured in an article in the Standard Democrat through their use of Community Health Workers.²

NCPA provides comment to the following requests for information:

6. What key educational messages regarding secure storage and safe disposal should be included in any patient education component of the potential OA REMS requirement described in this notice, including educational messages to increase uptake and use of mail-back envelopes, as well as what form that education should take (e.g., handouts, pharmacist counseling of patients).

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.³ 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.

7. How a mail-back envelope requirement could be designed and implemented to help ensure that the disposal requirement minimizes burden on pharmacies while still providing the public health benefit. As discussed in the document, there is a tradeoff between the potential effectiveness of a mail-back envelope REMS requirement and the level of burden imposed on those pharmacies involved in implementing the requirement.

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

For any safe disposal or educational program, FDA must ensure that there is no cost to pharmacies regarding take-back or disposal materials, 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 mandate or uncompensated burden to pharmacies. FDA should ensure pharmacists are reimbursed for added time and resources spent on complying. Considerable time will be needed to educate the pharmacist 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.

² *Local Pharmacies are Including Community Health Workers in Staff*, The Standard Democrat (May 17, 2019), available at <https://standard-democrat.com/story/2609607.html>.

³ *Walking Through Opioid Management*, NCPA, available at <https://ncpa.org/opioid-resources>.

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:

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.

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

Prescription claims. As one solution, there could be a federal requirement for health plans to provide an add-on fee for mail-back envelopes. For reimbursement, coverage could be based on a NADAC-like benchmark plus a state Medicaid dispensing fee, plus an add-on fee for the mail-back envelope. Health plans covered by the Affordable Care Act could be required to report the percentage of plan members with a qualifying prescription that also paid for mail back envelopes.

Mail-back envelope provided by manufacturer or physician. FDA may find it challenging to establish a reference price for mail-back envelopes. To alleviate this concern, as suggested by FDA, manufacturers could provide these packets free of charge. Alternatively, prescribing physicians could provide mail-back envelopes to the pharmacies. And to reduce the burden on pharmacies, the manufacturer could provide the mail-back envelopes directly to the prescribing physicians, who in turn give them directly to their patients.

Plans reimburse pharmacies for mail-back envelopes. Alternatively, FDA could assign a NDC to a mail back envelope, and plans would reimburse pharmacies through the pharmacy benefit. The NDCs could then be listed in Medispan or First DataBank.

Any waste/unused medication should not go back to pharmacy

Any mail-back program should require the patient to directly mail the envelope 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.

8. Possible challenges, including technical and logistical challenges, with the potential REMS mandate described in this notice, and what factors could impact manufacturers' ability to provide

mail-back envelopes to pharmacies, or the ability of pharmacies to dispense mail-back envelopes and provide appropriate disposal education to consumers.

There are multiple factors that could impact the ability of pharmacies to dispense mail-back envelopes and provide appropriate disposal education to consumers. These are discussed below.

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. For example, Med-Project is an industry-funded product stewardship program to put DEA-compliant disposal systems in pharmacies.⁴ Additionally, 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 or have disposal bins bolted to the floor that are inspected regularly.

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 the mail back envelopes or education materials, or alternative ideas such as disposal kits, or disposal bins bolted to the floor. Many of our member pharmacists find that space is a premium in their pharmacies, and they are packed to capacity.

Drug diversion

FDA needs to create a way to ensure that any mail back program it initiates is safeguarded from risk of drug diversion by theft of mail. Often the efficacy of take-home packets are negated by patients wanting to keep remaining prescriptions “just in case.”

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,

⁴ <https://med-project.org/>.

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.⁵

Conclusion

NCPA appreciates the opportunity to comment on FDA's proposed revision to the OA REMS. That being said, community pharmacists already provide significant assistance in fighting the opioid pandemic. Therefore, NCPA asks FDA to not move forward with the proposed changes to OA REMS, or at the very least make it a strictly voluntary 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

⁵ 42 U.S.C. 1395w-4.