



August 28, 2023

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

RE: Docket No. FDA-2023-N-0917: In-Home Disposal Systems for Opioid Analgesics; Request for Information

Submitted electronically via www.regulations.gov to [Docket No. FDA-2023-N-0917](https://www.fda.gov/oc/foia/docket-no-0917)

Dear FDA Staff:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments on the Food and Drug Administration's (FDA) request for information titled "In-Home Disposal Systems for Opioid Analgesics." APhA is providing specific comments on the issues discussed during the National Academies of Sciences, Engineering and Medicine's (NASEM's) workshop, "Defining and Evaluating In-Home Disposal Systems for Opioid Analgesics" held in June 2023.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA's House of Delegates, which includes over 400 delegates from across the profession, passed the following policy on drug disposal programs in 2013:

Medication Take-Back/Disposal Programs

1. APhA encourages pharmacist involvement in the planning and coordination of medication take-back programs for the purpose of disposal.
2. APhA supports increasing public awareness regarding medication take-back programs for the purpose of disposal.

3. APhA urges public and private stakeholders, including local, state, and federal agencies, to coordinate and create uniform, standardized regulations, including issues related to liability and sustainable funding sources, for the proper and safe disposal of unused medications.
4. APhA recommends ongoing medication take-back and disposal programs.

APhA appreciates FDA assessing whether in-home disposal products will mitigate the risk of nonmedical use or overdose of opioid analgesics (OA) if drug manufacturers are required to make in-home disposal products available to patients under a risk evaluation and mitigation strategy (REMS). APhA also appreciates FDA's modifications to the OA REMS will also require manufacturers to develop educational materials for patients on the safe disposal of opioid analgesics and provide outpatient pharmacies and other dispensers the option to provide these materials to patients. APhA agrees with FDA that removing unused opioid analgesics from a home is an important public health goal.

In April 2023, FDA announced requirements for manufacturers to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers as an additional opioid analgesic disposal option for patients. APhA appreciates FDA's clarification that outpatient pharmacies and other dispensers will have "the option" to order prepaid mail-back envelopes from opioid analgesic manufacturers to provide patients prescribed opioid analgesics once this change is implemented in 2024.

Changes to OA REMS Should Remain Optional

APhA requests clarity from FDA that these changes to the OA REMS will remain optional for pharmacists to provide in outpatient settings. Requiring pharmacists to dispense mail-back envelopes and educate patients on the safe disposal with opioid analgesics could create operational and workflow issues for pharmacy staff. Although pharmacists do provide this type of counseling and education, it varies across pharmacies, depending on staffing and the patient's time and willingness to be informed. APhA does not support new uncompensated mandates on pharmacies/pharmacists.

In addition, APhA appreciates the inclusion of the 2020 article titled "[Prescription drug disposal: Products available for home use](#)" from the Journal of American Pharmacists Association in the RFI from the June workshop that concluded pharmacists and consumers must consider cost, effectiveness, and environmental impact when recommending and selecting products for medication disposal at home. APhA recommends FDA require manufacturers cover all costs for the prepaid mail-back envelopes and provide an easy method for pharmacies to reorder envelopes.

Consider Alternatives for Medication Disposal

APhA also requests FDA consider alternative methods for medication disposal. By mandating a specific method or system, like mail-back envelopes, FDA's goal of mitigating the risk of nonmedical use or overdose of opioids may not be met if patients accidentally discard or choose

not to use mail-back envelopes. APhA believes providing patients with access to multiple methods for medication disposal could help increase the likelihood patients will appropriately dispose of unused opioid medications.

APhA Recommends FDA Reference State Actions

APhA recommends FDA reference the Legislative Analysis and Public Policy Association's report, "[Drug Take-back and Disposal Programs: Summary of State Laws](#)," which examined state-level legislative and administrative responses to the public health risks posed by unused prescription medications. Thirty-one states have worked with the Drug Enforcement Administration to enact legislation or administrative regulations to authorize drug take-back programs where expired or unused pharmaceuticals can be collected by authorized individuals and disposed of safely.

APhA recommends FDA consider examples from successful state-take back programs as they finalize any changes to the OA REMS program. As of August 2022, twenty-seven states have enacted legislation to authorize a drug take-back program or provide program or provides mechanisms for the collection of prescription medication disposal. Additionally, four states have issued administrative regulations that authorize or establish a drug take-back program or provide mechanisms for the collection of prescription medication disposal. Six states including: California, Illinois, Maine, Oregon, Vermont, and Washington state require drug manufacturers to fund programs for the collection and disposal of unused or unwanted medications.

Lastly, APhA recommends FDA consider a widespread public service campaign for consumers that promotes the various methods of safe disposal of opioid analgesics, that includes educating and providing pharmacists with tools and resources to voluntarily use at their pharmacy or in their communities.

Conclusion

APhA appreciates the opportunity to provide feedback on FDA's RFI and request the changes to the OA REMS on requirements for mail-back envelopes remain optional for pharmacists to provide in outpatient settings. APhA agrees that removing unused opioid analgesics from a home is an important public health goal to reduce the potential for misuse of these medications. APhA supports providing patients with access to multiple methods for medication disposal, in addition to mail-back envelopes to increase the likelihood of patients disposing of unused opioid medications appropriately. If you have any questions or need any additional information please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Acting Head of Government Affairs