

EXPLORING OPTIONS FOR SAFE AND EFFECTIVE IN-HOME OPIOID DISPOSAL

INTRODUCTION

Prescription opioids remain a critical part of treatment regimens for patients with both acute and chronic pain conditions. However, misuse, abuse, and diversion of prescription opioids remains an ongoing crisis in the United States. In 2019 alone, [an estimated 9.7 million people](#) misused prescription pain relievers. During the Covid-19 pandemic, [opioid overdose deaths in the U.S. hit an all-time high](#).^{1,2}

Removing unused opioids from patients' homes can help prevent drug misuse and accidental overdose. To achieve this, it is important to have safe and effective opioid disposal options that patients can easily use and access. Providing consumers with multiple options to safely dispose of their opioids has become a priority component of local and state responses to the opioid crisis.

The range of disposal methods and programs available today form a patchwork of different approaches for patients which vary by location. In addition to providing opioid disposal programs to help keep patients and communities safe, it is important to understand why patients may be reluctant or unable to dispose of their medications, such as the inconvenience of disposal or an unwillingness to throw away medication for which they have paid. Understanding these two components

presents an opportunity for the FDA to use its authority to address the need for more comprehensive and patient-centered safe opioid disposal options on a federal level.

The passage of the [2018 SUPPORT for Patients and Communities Act](#) granted FDA the authority to require that drug manufacturers provide patients with a safe opioid disposal option when their prescription is dispensed. This specific new authority is part of FDA's broader authority to require drug manufacturers to implement [Risk Evaluation and Mitigation Strategies \(REMS\)](#) – drug safety programs for certain medications with serious safety concerns.

On June 28 and 29, 2021, the Duke-Margolis Center for Health Policy, under a cooperative agreement with the U.S. Food and Drug Administration (FDA), convened a private workshop with participants to explore different opioid disposal options available and consider the potential impact and benefits of FDA requiring manufacturers to provide a safe, in-home disposal option when opioids are dispensed. This document summarizes the workshop presentations and discussion to inform policymakers and public health professionals interested in safe and effective in-home opioid disposal.

The Current Landscape for In-Home Opioid Disposal?

Inappropriate prescribing of opioids has fueled the crisis in the U.S. Patients must have access to these drugs; however, health care systems and regulators must act to mitigate the substantial risks associated with these medications. While opioid prescribing has been declining, opioids are still inappropriately prescribed.^{3,4} Inappropriate opioid prescribing has led to many patients having unused tablets in their homes. Even when an opioid prescription is appropriate, patients are frequently

prescribed more tablets than needed, especially when the prescription is related to surgery or dentistry.⁴ When these unused tablets are not properly disposed of or securely stored, they may become available for misuse, abuse, and diversion. Proper opioid disposal is important in ensuring safe medication use. Safe, effective opioid disposal methods are an important component of a broader effort to address the opioid crisis in the United States.

Unused and improperly stored opioid analgesics can worsen the opioid crisis, leading to consequences such as overdose, death, and accidental ingestion by children (poisoning). [The CDC recommends](#) storing controlled substances, such as opioids, in their original packaging and in a locked cabinet or drawer. In an FDA literature review, most studies that analyzed unused opioid tablets reported that 50-70% of tablets went unused and 70-100% of patients stored opioids in unlocked locations.⁵ Even after widespread changes in prescribing practices, many patients still have unused tablets.

Partial solutions, such as “right-size” prescribing, safe storage, and child-resistant packaging, have not adequately addressed the large number of unused tablets already in patients’ homes. In Michigan, one researcher estimated that there are collectively 62 million unused tablets per year in patient homes from post-surgical prescriptions alone. Given this large number of unused pills, researchers have noted that even a small increase in disposal rates of leftover opioids could reduce the number of tablets that are available for inappropriate use, resulting in a large public health benefit. This meeting focused on access to opioid disposal options as one way to reduce abuse, misuse, and accidental ingestion of unused tablets.

Existing Opioid Disposal Efforts

Several opioid disposal options are already available to patients. These include kiosks available in retail and hospital pharmacies, health care centers, and police departments; drug take back events; flushing (for opioids on the FDA’s [“flush list”](#)); mixing with unpalatable substances and dumping in household waste; mail-back envelopes; and in-home disposal products that include commercially available disposal pouches, packets, and containers. Rather than an overarching national disposal program funded by drug manufacturers or the federal government, disposal solutions form a patchwork that vary by state and/or operating organization.

Chain Pharmacy Efforts in Safe Opioid Disposal

Some major chain pharmacies have started voluntarily offering disposal programs in response to the opioid crisis. Most chain pharmacies offer kiosks (monitored drop boxes in which patients can dispose of their unused medications) in some of their locations, and some also offer in-home disposal products. These in-home disposal products are typically either sealable pouches that contain chemicals

that neutralize medications or packets of chemical compounds that, when mixed with water and medications, sequester the medications. Kiosks may be especially useful for patients with large amounts of unused tablets. While not every chain pharmacy store has a kiosk, thousands are located across the country for patient use. Some chain pharmacies also partner with police departments for take back days.

There are variations in chain pharmacy disposal programs and how pharmacies dispense the in-home disposal products to patients. For some chain pharmacies, in-home products are dispensed with certain prescriptions, and in others, they are dispensed only upon request. Some chain pharmacies use algorithms to identify patients for in-home disposal product provision, such as opioid-naïve patients. In some pharmacies, when patients are dispensed an opioid prescription for the first time, they are offered a counseling session which includes education about the in-home disposal products. Aside from counseling sessions, chain pharmacies use different educational tools that are provided to patients for medication disposal, including instructions in a pamphlet or printed on the in-home disposal product itself. According to some chain pharmacy representatives at the meeting, patients seem to like in-home disposal products. Pharmacists are trained on safe drug disposal, and many see this interaction as an additional touchpoint in the clinician-patient relationship and opportunity for education.

State Legislation on Opioid Disposal

Several states have enacted laws that require manufacturers to fund drug disposal, including Washington, Oregon, Hawaii, California, New York, and Massachusetts. These laws typically include all drugs dispensed in the state, not just opioids. The drug disposal programs in these states typically focus on kiosks and are supplemented with mail-back envelopes, and they are often implemented by a consortium of manufacturers through a Pharmaceutical Product Stewardship Work Group (PPSWG).

In the meeting, participants took a closer look at Washington’s program – the first state-wide drug disposal program to be implemented. Washington’s drug take back law was passed in 2018 and was modeled on seven local county ordinances surrounding drug disposal. The program officially began in 2020. The law includes provisions for over-the-counter medicines, prescriptions, brands, generics, medications for household pets, medications in medical devices, and combination products.

Drug manufacturers fully fund the disposal programs, which are run by program operators. The Washington State Department of Health oversees program operators and approves proposals for new programs. Currently, the programs are using three different types of drug collection, including kiosks, take back days, and pre-paid, pre-addressed mail-back envelopes. In locations where program operators do not meet the kiosk convenience standard set by law, they must establish distribution centers where patients can access mail-back envelopes. Washington residents may also request a mail-back envelope and have it sent to their homes.

Washington's program is still new, and only preliminary data has been collected. Collected drugs are measured in pounds and are not separated by type, making it difficult to know how successful the programs are at collecting unused opioids specifically. In-home opioid disposal products are not currently covered under the state's law, though these products could supplement current disposal efforts.

In-Home Disposal Products

In-home disposal products typically take the form of pouches that contain chemical compounds that, when mixed with water, can neutralize or sequester medications and render them unusable. These products are available to patients in some clinical settings and pharmacies, but they are not yet widely used or supported by federal or statewide programs. In Texas, researchers at the University of Houston College of Pharmacy are trying to determine patient preferences and utilization rates of in-home opioid disposal products by assessing the use of single-use disposal systems for in-home drug disposal. Community prevention organizations (CPOs) in Texas are the main drivers of opioid disposal product distribution. This distribution is tracked via activity reporting sheets. However, it is not possible to track whether patients used the in-home disposal products and which medications they disposed of using the products because of United States Drug Enforcement Agency (DEA) regulations.

Some research does exist surrounding patient use of in-home disposal products. In one Michigan study comparing the effectiveness of providing an informational sheet about opioid disposal vs. an in-home disposal product, patients were more likely to dispose of their opioids with the in-home product. In addition, patients were less likely to participate in inappropriate disposal (such as through household trash) when provided with a disposal product.⁶

Other studies suggest that education combined with in-home product provision may further increase disposal rates.^{7,8}

Considerations for In-home Disposal Products

Based on a literature review, providing in-home disposal products to patients increased disposal rates, especially when clinicians provided enhanced patient education.⁵ However, in-home disposal products are relatively new, and there are limited studies that investigate how effective they are as an opioid disposal method. This leaves regulators and policymakers with many unanswered questions surrounding patient motivations and willingness to dispose of opioids, consumer preferences for safe disposal options, alignment of patient and provider preferences, and preferences of patients with chronic pain versus acute pain.

Addressing Patient Needs

Patients and caretakers have many different reasons for engaging in safe medication disposal, including disposing of unused pills post-surgery or after end-of-life care. One participant that works with patients offered their perspective on working with different patient needs, noting that it is important to provide patients and families with multiple options and to make disposal options as convenient as possible.

Meeting participants made a notable distinction between patients with chronic pain and acute pain (e.g., post-surgical patients), as these patient groups have different needs related to medication disposal.

In-home disposal options may serve as an accessible alternative to kiosks for patients with chronic pain, as many of these patients may have difficulty driving or leaving the house. However, chronic pain patients likely do not need a disposal option dispensed with each prescription as they are less likely to have unused pills. Acute pain patients, on the other hand, are more likely to have unused tablets and thus need a disposal option with each prescription. Addressing the difference in patient needs may help reduce waste from unused disposal products.

One speaker suggested that patients need to understand the "why" of opioid disposal, and pharmacists are in a prime position to educate patients about its importance.

Participants also offered solutions to encourage patient participation in opioid disposal, noting that text messages and emails could help remind patients to dispose of unused tablets. One speaker added that one state has a new system that flags patients with opioid prescriptions and calls them 10 days later, asking them how they have disposed of their medications and if they need additional resources. This model could help encourage disposal and meet patients' needs for an in-home disposal option.

Social and Behavioral Considerations

Social and behavioral considerations may play a role in forming strategies to encourage opioid disposal. Older individuals, according to public opinion polls, are less likely to dispose of their opioids. In many communities of color, the only disposal sites are in law enforcement buildings, which can be a barrier to access for individuals wishing to dispose via kiosks. Rural and underserved urban communities face a lack of access to disposal options, and patients in high-density urban centers may feel uncomfortable carrying medications to kiosks via public transit or in busy areas. Finally, patients may view opioids as a scarce resource that may be hard to access later. Declining prescribing rates may fuel this impulse to view unused tablets as a scarce resource and may lead to hoarding.

One participant is working to engage community health care workers in local health care facilities, which could increase in-home product distribution to those with low access to kiosks and take back days. Another participant noted that patient education in the home is often highly effective and that perhaps new solutions such as traveling vans that distribute these in-home products could be helpful in increasing patient convenience and disposal rates for older patients and patients with chronic pain.

Environmental Health and Safety

Some meeting participants expressed that in-home disposal products may pose safety concerns for patients. For example, one participant noted that most disposal products suspend medications in liquid solution without warnings about dermal exposures or guidance on how to clean up spills. In addition, waste material from in-home disposal products has not been proven to be non-hazardous or non-toxic because in-home disposal product manufacturers do not disclose product ingredients.

Meeting participants also expressed concerns about the environmental impact of in-home disposal products. While research suggests that some patients may feel reluctant to flush medications due to concerns about environmental pollution, there are additional environmental concerns associated with in-home disposal products being dumped in household waste and contributing to environmental pollution in landfills. Given that these products' chemical makeup is unclear, questions remain about the extent of in-home products' environmental risks. Waste management officials should be engaged to explore potential risks of large-scale in-home disposal product distribution.

Increasing Safe Disposal Using Any Method

Opioid disposal programs seek not only to provide patients with the means to dispose of their opioids, but also to encourage patients to do so. Little is known about which options patients prefer and which are most effective at encouraging patients to dispose of their medications. Participants discussed what is known about these preferences, as well as what factors make patients reluctant to use existing disposal options.

Incentivizing Behavior Changes

Several participants noted key motivators which may impact patients' willingness to dispose of their opioids. Stakeholders articulated that patients likely prefer convenience and asking individuals to undertake additional effort often reduces uptake of new interventions, despite apparent perceived benefits. In addition, patients might feel a sense of "thriftiness" leading them to be unwilling to throw away a product for which they have paid.

To achieve high disposal rates, a "one-size-fits-all" approach to disposal is insufficient. In addition to maintaining a variety of disposal solutions for patients, finding new approaches to encourage drug disposal could be beneficial in increasing disposal rates. One participant noted that patient motivations surrounding opioid disposal vary, so approaches for encouraging disposal should include emotional motivations, intellectual justifications, and financial incentives. Another participant added that working to instill a sense of "duty" in patients to return their opioids could create a shift in perspective that could lead to more disposal.

Applying Principles of Injury Prevention

The general principles of injury prevention can be applied to opioid disposal solutions. Education, engineering, and enforcement are key principles of injury prevention. Education helps patients understand the rationale for their behavior change, and this behavior change must be reinforced for sustained change over time. Engineering solutions are successfully implemented when the new technology is effective and reliable, as well as easily understood by key audiences. Enforcement strategies use policy or legislation to drive behavior change. These strategies must be widely known and understood, and there must be a cost to not participating in the desired behavior.

Additional injury prevention considerations may apply to opioid disposal. As one participant noted, one goal of injury prevention is making the safest behavior the easiest behavior. Interventions need to consider cultural issues, the needs of diverse communities, and they must be equitable.

Exploring Policy Options and Discussing Potential Implications of a REMS

Under SUPPORT Act Section 3032, FDA may require a drug to be dispensed to certain patients with safe disposal packaging or safe disposal system. Guiding principles for an FDA-required REMS for opioid disposal include considerations such as:

1. importance of an educational component of the REMS;
2. patient access to multiple disposal options depending on their needs;
3. the benefit of a REMS beyond current state and voluntary efforts; and
4. unintended consequences of a REMS mandate on patient access and existing opioid disposal programs.

In the meeting, experts weighed in on these points to inform FDA's decision-making process around the potential implementation of a REMS for opioid disposal.

Determining the Scope and Cost of a REMS

Meeting participants discussed the potential cost considerations and scope of a REMS for opioid disposal. Participants expressed concerns about who would be shouldering the cost of in-home products and their distribution, noting that this funding should be sustainable. Some participants noted that pharmacists are unable to bill payers for time spent educating and that overworked pharmacists should receive some sort of compensation for their additional responsibilities that would come with patient education about opioid disposal.

While costs are high for small quantities of in-home disposal products, at scale, the costs should decrease. However, participants added that cost-effectiveness studies should be conducted to assess in-home disposal product costs versus benefits at scale. Other disposal options also have high associated costs. One speaker highlighted that kiosk costs are high for voluntary disposal efforts and can be cost-prohibitive in some communities, as the transportation and security needs create financial obstacles.

Logistical Considerations

Participants contributed several perceived obstacles to the implementation of a REMS for opioid disposal. One participant noted that some pharmacies may have little storage space. Another noted that currently there are no publicly funded resources to help consumers locate kiosks and take back days, so a compiled website or another digital tool could be helpful to patients. Finally, patients are not always aware of the categories of drugs they are taking, so it could be important to find a drug disposal solution that will accommodate multiple types of drugs.

Distribution of the in-home disposal products is likely easier in large chain pharmacies than in community pharmacies, which have different sets of needs. However, it is important that community pharmacy needs to be taken into consideration so as not to leave out large groups of patients. For example, some states have very few or no chain pharmacies, such as North Dakota.

One speaker suggested that prepaid mail-back envelopes could present an eco-friendlier alternative to other commercially available in-home disposal products that are disposed of in household waste. One speaker mentioned that public opinion surveys show that individuals will use mail-back envelopes or packages and that the practice

is already regulated by the United States Postal Service and Drug Enforcement Administration. Multiple stakeholders mentioned in response that mail-back envelopes see low rates of return and that patients might prefer in-home disposal products. However, this could be due to a lack of patient education accompanying the mail-back envelopes.

Patient Education

Patient education would be a necessary component of a REMS program for opioid disposal. Educational approaches range from one-on-one patient education to mass media campaigns. For educational approaches to be successful, they must reach the target audience, the information must be appropriate, and the audience needs to understand and believe the information, as well as have the resources and skills to make the desired change. There is low general population awareness about opioid disposal programs or why it is important to dispose of unused opioids – for this reason, mass public education campaigns could be beneficial in increasing disposal rates.

In addition, it is important that patients receive the same message from all health care providers (prescribers, nurses, pharmacists, and other clinicians) at multiple touchpoints to reinforce education surrounding opioid disposal. One speaker noted that it is important that patient education be private to foster patient trust and confidentiality. Patients place a great degree of trust in their pharmacists and care providers, so leveraging these relationships in patient education could increase disposal rates. However, meeting participants stressed that opioid disposal education should be integrated into existing pharmacy workflows, and pharmacy practitioners should be compensated for their time spent on this education, documentation, and follow-up. Regulators should consider the time and resource burden on clinicians when considering a new REMS.

Evidentiary Needs

Meeting participants stressed that new policy enacted for drug disposal should be evidence-based rather than reactionary. One speaker noted that there is little data on current drug collection efforts, and the data that does exist is not standardized. Providing a framework for common metrics could help determine the efficacy of different opioid disposal options. Additionally, there is little known about what types of medications are included

in disposal efforts. DEA regulations prevent inventorying of medications collected in kiosks or mail-back envelopes and packages, therefore collecting data on the types of medication disposed or what percentage of collected drugs are opioids is difficult. Data that can be collected includes the total weight of the medication, but it is not separated by type of medication.

Currently, there seems to be no research comparing mail-back envelopes to in-home disposal products. Determining the rate of disposal with in-home disposal products is dependent on self-reporting, which could lead to bias; some participants suggested that introducing radio-frequency identification technology could help in tracking disposal rates via in-home products.

One participant suggested that there could be increased federal grant funding toward research in this area like the initiatives started after large tobacco settlements. Other participants noted that assessing the impact of a REMS through FDA-funded studies could be an important step in determining the public health value of in-home opioid disposal products. Assessment is an important component of a REMS, and participants added that surveys and quasi-experimental or experimental research are needed to determine the causal relationship between REMS and disposal rates.

Potential Unintended Consequences of a REMS

Meeting participants considered potential unintended consequences of a REMS for opioid disposal. Participants suggested that since individuals often hold onto pills for later use, it is possible that opioid prescribing could increase with increased disposal as patients would request new prescriptions with each episode of pain rather than taking unused pills from old prescriptions. In addition, in-home disposal products can be easily misplaced, thrown out, or left unused, generating waste amongst patients who do not utilize the products. Finally, a REMS for opioid disposal could create a sense of fear amongst patients who perceive the drugs as dangerous, potentially affecting their care if prescribed opioids for acute pain.

There may be system-level challenges associated with implementing a new REMS program for in-home opioid disposal that stem from coordinating the needs of regulators, manufacturers, vendors, and other stakeholders. The program would be a novel REMS using a new authority and would likely be a large

[shared system REMS](#). Furthermore, it could overlap with other approved shared system REMS for opioids, including the Opioid Analgesic REMS. Shared system

REMS come with their own set of challenges, such as determining governance structures and the time needed to coordinate such programs.

Conclusion

Disposal is an important component of safe medication use for the opioid drug class and could help prevent misuse or diversion of unused medication. Participants in this meeting discussed the different needs that patients have in disposing of unused medications, emphasizing that a **multi-faceted approach with a focus on patient education would likely be most successful in encouraging high rates of disposal**. A new REMS for opioid disposal, if implemented, should be done so in concert with state and local efforts in safe medication disposal and should consider the needs of different stakeholders in the health care system, including prescribers, pharmacists, and patients. While questions remain about the preference for in-home disposal products and the best way to incentivize their use, even a small increase in the disposal of opioid medications using this method, or the other methods described here, can have a large impact on public health.

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