



September 2019

PRESCRIPTION OPIOIDS

Patient Options for Safe and Effective Disposal of Unused Opioids

Why GAO Did This Study

In 2017, an estimated 11.1 million Americans misused a prescription pain reliever, which included opioids. This misuse contributes to opioid abuse and death, which has quintupled from 1999 to 2017; about 17,000 people died from prescription opioid overdoses in 2017. Government agencies and stakeholders have attempted to address the potential for misuse and abuse by facilitating safe disposal of unused prescription opioids and other drugs.

The SUPPORT for Patients and Communities Act enacted in 2018 included a provision for GAO to review patient disposal of unused opioids, among other things. This report examines (1) federally recommended and other available methods patients may use to dispose of unused prescription opioids, and (2) what is known about patients' use of these methods.

To do this work, GAO examined peer-reviewed, academic literature on outcomes for prescription opioid disposal; reviewed federal agency documentation; interviewed federal agency officials, independent researchers, and stakeholder group representatives—such as those from the American Medical Association; and analyzed DEA data as of April 2019 on permanent drug collection sites. GAO also interviewed representatives of three companies that manufacture commercial in-home disposal products and reviewed publicly available documents about these products.

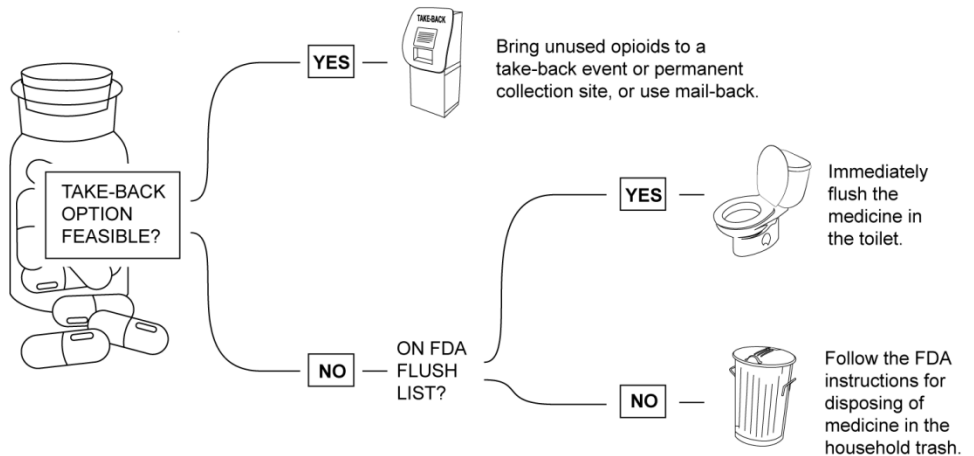
PRESCRIPTION OPIOIDS

Patient Options for Safe and Effective Disposal of Unused Opioids

What GAO Found

The Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), and Environmental Protection Agency (EPA) recommend that patients dispose of unused prescription opioids by bringing them to DEA-registered collection sites or a DEA take-back event, or using mail-back programs. As of April 2019, 70 percent of the U.S. population lived less than 5 miles from permanent collection sites, which are often located at pharmacies. If collection sites, take-back events, or mail-back programs are not feasible, FDA recommends quickly and permanently removing the most dangerous prescription opioids, such as hydrocodone and fentanyl, from the home by flushing them down the toilet. For all other prescription opioids, the agencies recommend disposal in the trash after mixing them with unpalatable substances, such as cat litter. Commercial products to facilitate in-home disposal also exist, and FDA is aware that patients may opt to use these products for disposal in the trash.

FDA Recommendations for Disposal of Unused Prescription Opioids



Source: GAO analysis of Food and Drug Administration (FDA) documents. | GAO-19-650

Available studies suggest that many patients are unaware of federally recommended disposal methods or choose not to dispose of unused prescription opioids. For example, five studies found that between one-quarter and three-quarters of patients stored unused opioids for future use or had misplaced their unused opioids. Further, federal data indicate that 85 percent of intentional misuse occurs with the patient's knowledge—for example, when a patient sells or gives away unused prescription opioids. To educate and motivate patients to dispose of unused opioids, FDA launched a public awareness campaign called "Remove the Risk" in April 2019. Also, FDA and other stakeholders have created educational materials for patients and providers on safe opioid disposal.

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Abbreviations

AMA	American Medical Association
CDC	Centers for Disease Control and Prevention
DEA	Drug Enforcement Administration
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
REMS	risk evaluation and mitigation strategy
RCRA	Resource Conservation and Recovery Act
SAMHSA	Substance Abuse and Mental Health Services Administration
SUPPORT Act	SUPPORT for Patients and Communities Act

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September 3, 2019

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Frank Pallone Jr.
Chairman
The Honorable Greg Walden
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Substance Abuse and Mental Health Services Administration (SAMHSA) estimates that in 2017, 11.1 million people aged 12 or older used a prescription pain reliever, which includes opioids, in a way not intended by the prescriber.¹ Health care providers prescribe opioids to treat chronic pain and after an acute medical event, such as a surgery, to help patients manage pain while they heal.² Because patients may not take all of the opioids that their providers prescribe, many possess excess opioids that could be misused by the patient or someone else. This misuse contributes to opioid abuse and can lead to overdoses. Overdoses involving prescription opioids—hereafter referred to as

¹SAMHSA. *Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health*, (2018). Misuse of prescription opioids includes taking opioids in a manner or dose other than prescribed or taking opioids for non-medical use. Abuse often starts as misuse of prescription opioids.

²For the purposes of this report, we use the term opioids to refer to prescription opioid pain relievers, such as hydrocodone or oxycodone, rather than illicit substances, such as heroin. SAMHSA reports that in 2017, 97.2 percent of an estimated 11.4 million people age 12 or older who misused opioids in the past year misused prescription opioids, and 2.8 percent of these people misused heroin only. Health care providers include physicians, dentists, and mid-level practitioners (e.g., nurse practitioners or physician assistants) who can be licensed, registered, or otherwise permitted to prescribe a controlled substance.

opioids—were five times higher in 2017 than in 1999, accounting for about 17,000 deaths in 2017.³

Federal, state and local government agencies, drug manufacturers, communities, and others have attempted to address the potential for misuse and abuse by identifying or providing safe, secure, and convenient methods for disposing of unused, unneeded, or expired opioids. However, there is no federal law or regulation imposing requirements for how patients are to dispose of unused opioids.

The SUPPORT for Patients and Communities Act (SUPPORT Act) included a provision for us to review options for patients to dispose of unused opioids, including products intended to facilitate in-home disposal.⁴ In this report we describe:

1. The federally recommended and other available methods patients may use to dispose of unused opioids, and
2. What is known about patients' use of these methods to dispose of unused opioids and examples of efforts to educate patients and providers about opioid disposal.

To describe the methods that federal agencies recommend patients use to dispose of unused opioids, we reviewed documentation and interviewed officials from the three federal agencies that have authorities related to the disposal of opioids—the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). We analyzed data from DEA as of April 2019 indicating the locations of permanent drug take-back collection sites in conjunction with data from the U.S. Census Bureau's population estimates through 2017. We used these data to estimate the percentage of the U.S. population living within varying distances of a permanent

³Centers for Disease Control and Prevention (CDC), *Prescription Opioid Data*, accessed June 13, 2019, <https://www.cdc.gov/drugoverdose/data/prescribing.html>.

⁴Pub. L. No. 115-271, § 3032(d), 132 Stat. 3894 (2018).

collection site.⁵ For all data used in these analyses, we reviewed related documentation and conducted electronic testing and, based on these steps, determined that the data were sufficiently reliable for our purposes. To describe other disposal methods, we reviewed documents and studies from vendors of three commercial in-home disposal products that patients can use to help them dispose of prescription and nonprescription medication in their home trash. We identified these products and documents through stakeholder interviews, a related study, a patent search using Google Patents, and a review of product websites.⁶ Additionally, we conducted interviews with other stakeholders—including researchers, a representative from the AmerisourceBergen Foundation, and representatives from three companies that manufacture in-home drug disposal products.⁷ We asked these stakeholders about the effectiveness of these other disposal methods at preventing misuse of opioids.⁸

To describe what is known about which methods patients use to dispose of unused opioids, we conducted interviews with stakeholders, such as the Association for Accessible Medicines and the American Medical Association (AMA), and reviewed results of SAMHSA’s 2017 National

⁵We analyzed the most recent DEA and U.S. Census Bureau data available at the time of our analysis. The U.S. Census Bureau’s American Community Survey 5-year estimates are updated annually and are based on data collected continuously from a sample of households during the entire 60-month period. We used the 5-year estimates rather than 1-year estimates because they are based on larger sample sizes and thus are more reliable. To conduct this analysis, we calculated the distance between the central point of each zip code and the nearest DEA-registered permanent collection site. For some zip codes, depending upon whether their central point is located just within the distance threshold or just beyond it, a portion of their population may be unintentionally included in or excluded from the population subtotal and total, thus introducing a small degree of error in the percentage calculation. The radius of each distance category was not limited by state boundaries, and we chose these distance thresholds based on a review of available information on convenient distances for accessing pharmacies.

⁶Community Environmental Health Strategies LLC, *Medicine Disposal Products: An Overview of Products and Performance Questions*, (2019). Community Environmental Health Strategies is a consulting firm that prepared this report for the San Francisco Department of the Environment.

⁷We selected manufacturers of two products that are distributed in retail outlets and one newer product that has not been broadly distributed.

⁸The AmerisourceBergen Foundation is an independent not-for-profit charitable giving organization established by the AmerisourceBergen Corporation to support health-related causes that enrich the global community, including by supporting distribution of in-home drug disposal products to communities.

Survey on Drug Use and Health.⁹ We also conducted a literature review. Specifically, we performed a structured search of research databases—such as Scopus, ProQuest, ProQuest Dialog, and Harvard Think Tank—to identify literature published from January 1, 2009 through February 2019. In our search, we used a combination of terms such as “controlled substance,” “disposal,” “drug,” and “prescription.” These searches retrieved 846 results, of which 191 studies were selected by a librarian based on general relevancy for further review. We selected 25 studies based on the following criteria: if the study was published after January 1, 2014 and (1) presented findings that assessed the effectiveness of certain methods for disposing of opioids and other medications, (2) documented the quantity of unused opioids in the community, (3) examined how patients disposed of unused opioids, or (4) evaluated patient attitudes toward opioid disposal.¹⁰ The findings from each individual study are limited by the studies’ overall lack of national representation and small patient populations; however, taken together, we found that the methods and conclusions were sufficient for our purposes. To describe examples of efforts to educate patients and providers about opioid disposal, we interviewed officials from FDA and the AMA and reviewed relevant documentation from each.

We conducted this performance audit from December 2018 to September 2019 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Opioids, such as hydrocodone and oxycodone, can be prescribed to treat both acute and chronic pain. Opioids can pose serious risks when they are misused. These risks include addiction, overdose, and death. As a

⁹The National Survey on Drug Use and Health collects data through interviews with U.S. civilians who are not institutionalized. In the survey, respondents are asked about their drug use, among other things. Based on these responses, SAMHSA estimates results for the U.S. population. Results from the 2017 survey were the most recent data available at the time of our analysis.

¹⁰We selected studies published after January 1, 2014 because DEA’s final rule governing disposal of controlled substances was released in 2014. See 79 Fed. Reg. 53,520, 53,548 (Sept. 9, 2014).

result, opioids are classified as controlled substances, which means that their use and disposal are subject to additional oversight by DEA.¹¹

Some studies suggest that the majority of patients who received prescriptions for opioids often do not use a large portion of the drugs dispensed. A study that surveyed U.S. adults who had received opioids found that approximately 60 percent of patients who were no longer using the medication had unused opioids.¹² Two studies reported that over one-half of patients did not use all of the opioids prescribed to them after surgery; these studies found that patients reported leaving 15 to 20 pills unused, representing 54 percent to 72 percent of the opioids they were prescribed.¹³ Another study on patient opioid use after a cesarean section and thoracic surgery found that most patients, 83 percent and 71 percent respectively, used less than half of the total opioids they were prescribed.¹⁴

Federal Authorities

There is no federal law or regulation imposing requirements for how patients are to dispose of unused opioids. However, DEA, FDA, and EPA all have authorities and initiatives related to patient disposal of opioids.

DEA

DEA regulations specify three take-back options that patients can opt to use to dispose of their unused controlled substances: take-back events, permanent collection sites, and mail-back programs. DEA hosts semi-annual events called National Prescription Drug Take-Back Days, where

¹¹Controlled substances are regulated under the Controlled Substances Act, which is enforced by DEA. See Pub. L. No. 91-513, tit. III, 84 Stat. 1236, 1242-84 (1970) (codified, as amended, at 21 U.S.C. § 801 et seq.).

¹²A. Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," *JAMA Internal Medicine*, vol. 176, no. 7 (2016): p. 1027-1029.

¹³M. V. Hill et al., "Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures," *Annals of Surgery*, vol. 265, no. 4 (2017): p. 709-714 and B. C. Maughan et al., "Unused Opioid Analgesics and Drug Disposal Following Outpatient Dental Surgery: A Randomized Control Trial," *Drug and Alcohol Dependence*, vol. 168 (2016): p. 328-334.

¹⁴K. Bartels et al., "Opioid Use and Storage Patterns by Patients after Hospital Discharge following Surgery," *PLoS ONE*, vol. 11, no. 1 (2016).

temporary collection sites are set up in locations such as police stations.¹⁵ Advertisements encourage community participation in the events and educate the community on safe disposal of unused medications, including opioids. DEA also registers collectors and provides information to the public about the location of permanent collection sites for take-back, such as at local retail pharmacies or hospital pharmacies, and sets requirements for the provision of postage-paid envelopes that patients can use to mail unused drugs to a collector for destruction.¹⁶

DEA regulations establish a standard for the destruction of controlled substances that applies to DEA registrants, which can destroy opioids on patients' behalf.¹⁷ DEA registrants include pharmaceutical companies that manufacture controlled substances, health care providers who prescribe them, and pharmacies that dispense them. The standard for destruction requires that controlled substances maintained or collected by DEA registrants be rendered non-retrievable. This means that the physical and chemical conditions of the controlled substance must be permanently altered, thereby rendering the controlled substance unavailable and unusable for all practical purposes. According to DEA, as of May 2019, the only method currently used to meet this standard is incineration, and DEA rulemaking states that DEA will not evaluate, review, or approve methods used to render a controlled substance non-retrievable.¹⁸

FDA

FDA has broad authority under the Federal Food, Drug, and Cosmetic Act to evaluate whether a drug is safe and effective and ensure the benefits of drugs outweigh the risks. FDA may require manufacturers to develop a

¹⁵Federal, state, tribal, and local law enforcement may also collect unused controlled substances through other take-back events, mail-back programs, or collection receptacles located inside the law enforcement's premises. See 21 C.F.R. §§ 1317.35 and 1317.65 (2018).

¹⁶Under the Controlled Substances Act, all persons or entities that manufacture, distribute, or dispense controlled substances are required to register with DEA, unless specifically exempted. DEA regulates these entities to limit diversion and prevent abuse. DEA registrants must receive authorization from DEA to collect controlled substances for disposal. Authorized collectors may (1) receive and destroy mail-back packages; (2) install, manage, and maintain collection receptacles located at their collection locations; and (3) dispose of sealed inner liners from collection receptacles, including their contents. 21 C.F.R. § 1317.40(c) (2018).

¹⁷A patient who receives a prescription for a controlled substance is not a DEA registrant and therefore is not subject to this standard.

¹⁸79 Fed. Reg. 53,520, 53,548 (Sept. 9, 2014). DEA regulations do not specify a test for evaluating whether a method meets the non-retrievable standard.

risk evaluation and mitigation strategy (REMS) for drugs with serious safety risks, including the risk of abuse, to ensure that the benefits outweigh the risks.¹⁹ Under one REMS, for example, manufacturers of opioids intended for outpatient use must make training available to health care providers involved in the treatment and monitoring of patients who receive opioids. The training must contain certain elements, including how providers should counsel patients and caregivers about the safe use and disposal of these opioids, among other things.

In October 2018, the SUPPORT Act authorized FDA to, at its discretion, require specific packaging or disposal systems as a part of certain drugs' REMS.²⁰ For drugs with a serious risk of overdose or abuse, FDA may require the drug to be made available for dispensing to certain patients with "safe disposal packaging" or a "safe disposal system" for purposes of rendering the drug non-retrievable in accordance with DEA regulations.²¹ Before imposing these requirements, FDA must consider the potential burden on patient access to the drug and the health care delivery system. As of May 2019, FDA had not imposed any REMS requirements using the new SUPPORT Act authority.

EPA

Under the Resource Conservation and Recovery Act (RCRA), EPA has authority to regulate the generation, transportation, treatment, storage, and disposal of hazardous waste, including certain discarded opioids.²² However, hazardous waste pharmaceuticals generated by households are not regulated as hazardous waste even if the waste would otherwise

¹⁹GAO has forthcoming work that examines risk evaluation and mitigation strategies.

²⁰Pub. L. No. 115-271, § 3032(a), 132 Stat. 3894 (2018) (codified at 21 U.S.C. § 355-1(e)(4)).

²¹The SUPPORT Act also authorized FDA to require that certain drugs be made available for dispensing in unit dose packaging, packaging that provides a set duration, or another packaging system that FDA determines may mitigate serious risk of overdose or abuse. On May 31, 2019, FDA issued a notice in the Federal Register soliciting comments about unit dose packaging for opioids. 84 Fed. Reg. 25,283 (May 31, 2019).

²²A waste is "hazardous" under RCRA if EPA has specifically listed it as such by regulation, or if it exhibits one of four hazardous characteristics (ignitability, corrosivity, reactivity, or toxicity). See 40 C.F.R. § 261.3(a)(2)(2018). EPA may authorize states to implement their own hazardous waste management programs in lieu of the federal program as long as, among other things, the state programs are at least equivalent to the federal program. Authorized states may implement regulations that are more stringent or broader in scope than the federal regulations. 42 U.S.C. § 6926(b).

be considered hazardous.²³ Opioids and other household waste pharmaceuticals collected through a take-back option are also exempt from most hazardous waste regulations, provided certain conditions are met.²⁴ Some states and localities have imposed additional requirements for pharmaceutical disposal, such as requirements for drug manufacturers to manage or fund the disposal of collected household pharmaceuticals.

²³While a small percentage of pharmaceuticals discarded by households meet the definition of hazardous waste under RCRA, EPA regulations specify that solid waste generated by households, including pharmaceuticals, are not regulated as hazardous waste. 40 C.F.R. § 261.4(b)(1) (2018) and 84 Fed. Reg. 5,816, 5,941 (Feb. 22, 2019) (to be codified at 40 C.F.R. § 266.501(g)(7)). Household hazardous waste pharmaceuticals are allowed to be disposed of as municipal solid waste when discarded by individuals at their residences.

²⁴To meet the conditional exemption, collected household hazardous waste pharmaceuticals must be: (1) managed in compliance with EPA's prohibition on discharging hazardous waste pharmaceuticals to a sewer system that passes through to a public-owned treatment works; (2) collected, transported, stored, and disposed of in compliance with all applicable DEA regulations for controlled substances; and (3) destroyed by a method DEA has publicly deemed in writing to meet the non-retrievable standard of destruction or combusted at one of five permitted types of hazardous waste combustors. 84 Fed. Reg. 5,816, 5,945 (Feb. 22, 2019) (to be codified at 40 C.F.R. § 266.506). If these conditions are not met, it is the entity collecting the pharmaceuticals, and not the consumer, that is subject to EPA's hazardous waste regulations.

Federal Agencies Recommend Take-Back Options as the Preferred Disposal Method

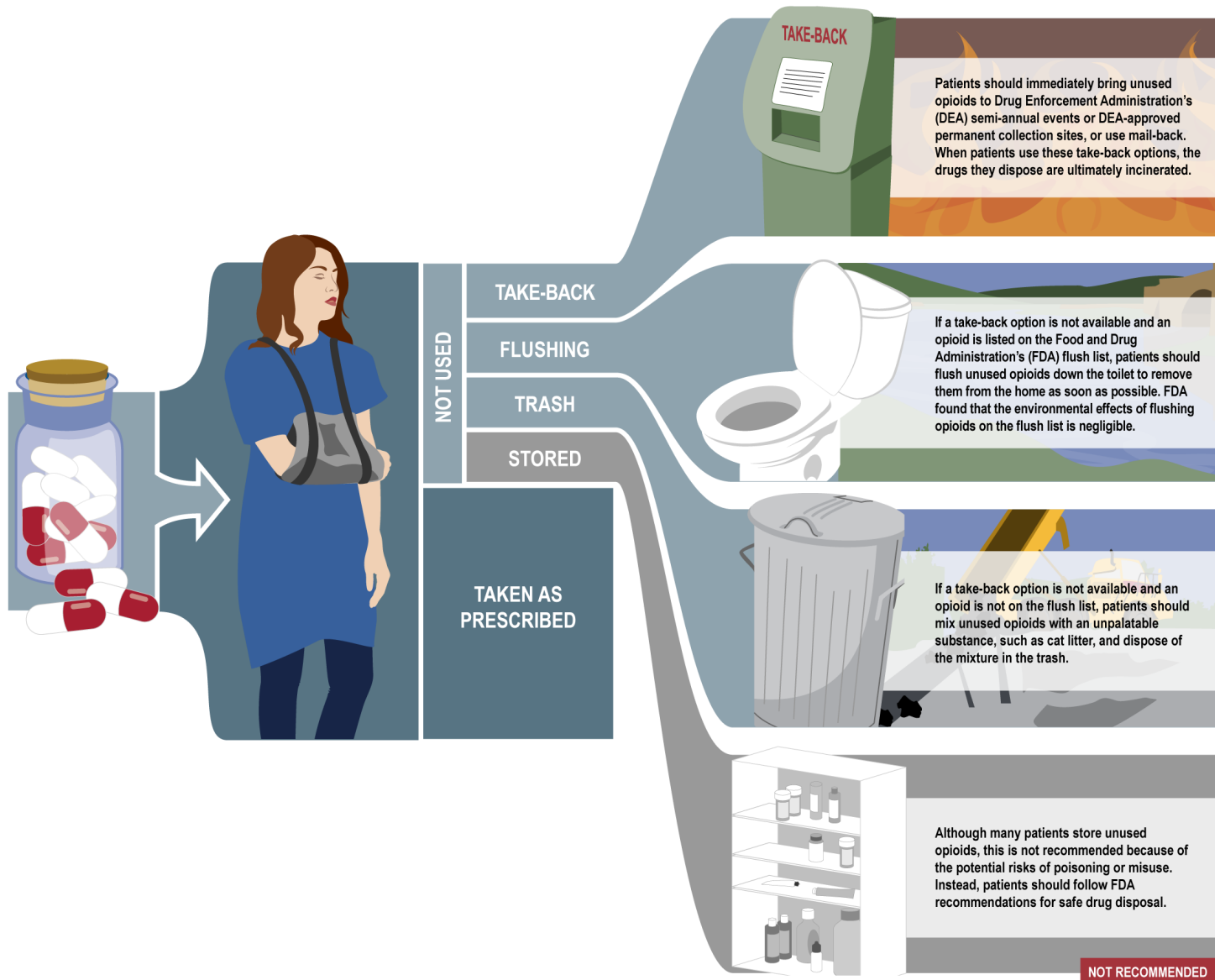
Federal Agencies Recommend Take-Back Options Whenever Feasible, Followed by Disposal Using the Toilet or Trash

According to DEA, FDA, and EPA, patients should use take-back options to dispose of unused opioids, whenever feasible. Only if take-back options are not feasible, FDA recommends flushing opioids on FDA's flush list down the toilet to remove them from the home as soon as possible.²⁵ For opioids not on the flush list, the agencies recommend placing the drugs in the household trash mixed with an unpalatable substance.²⁶ (See fig. 1). Officials from FDA said that the primary goal of these recommendations is to remove dangerous substances from the home as soon as possible to reduce accidental poisoning, which also may address issues related to intentional misuse. FDA officials explained that the agency has not measured the effects of its recommendations for disposing of opioids on opioid misuse, as of May 2019, because it is difficult to establish a causal link between the recommendations and any reductions in misuse.

²⁵See *Environmental Health: Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water*, [GAO-11-346](#) (Washington, D.C.: Aug. 8, 2011) for prior GAO work related to pharmaceuticals in drinking water.

²⁶FDA officials reported that these drug disposal recommendations were first developed by the Office of the National Drug Control Policy in 2007.

Figure 1: Patient Use and Food and Drug Administration’s Recommendations for Disposal of Prescription Opioids



Source: GAO analysis of FDA documents. | GAO-19-650

Take-Back Options

DEA, FDA, and EPA recommend using a take-back option as the preferred method for patients to dispose of unused prescription opioids. Under this method, patients can bring unused opioids to DEA’s semi-annual take-back events or to DEA-registered permanent collection sites,

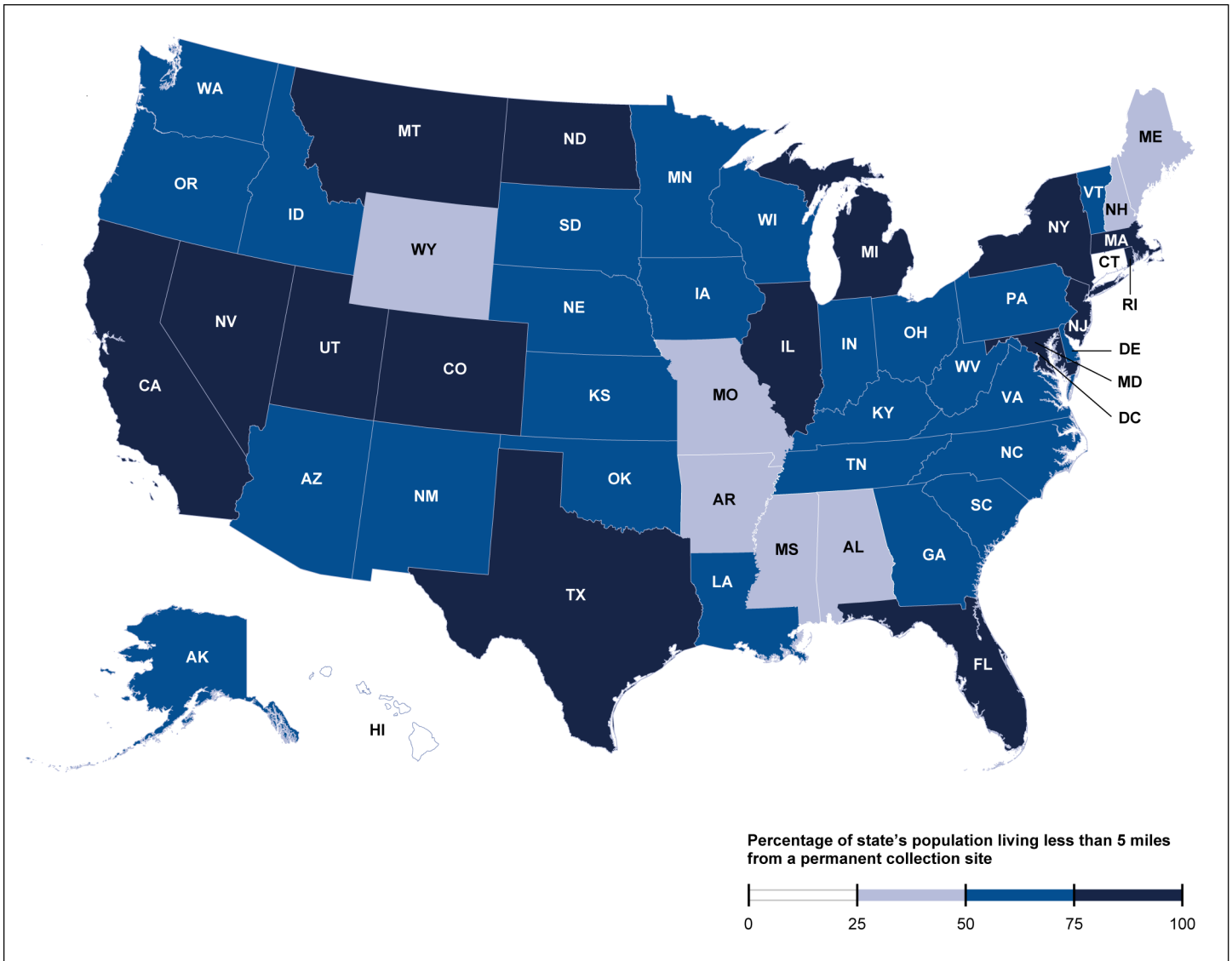
or use mail-back to deliver opioids to a DEA-registered collector for destruction. When patients use these take-back options, the drugs they dispose of are ultimately incinerated, which is the only method that DEA officials said is known to render the drugs non-retrievable, that is, permanently and irreversibly destroyed.

Our analysis of DEA and U.S. Census Bureau data shows that as of April 2019, 71 percent of the country's population lived less than 5 miles from a permanent collection site, and in 42 states, at least half of the population lived within 5 miles of a site. (See fig. 2). This number has increased since our April 2017 report, when we found that about half of the country's population lived less than 5 miles away from a site.²⁷ Our analysis also shows that 90 percent of the population lived within 15 miles of a site, though in rural areas only 57 percent lived within 15 miles. In addition, two studies found that patients were willing to bring unused opioids to a take-back location as long as it was located within 5 to 8 miles of their home address.²⁸

²⁷See GAO, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs*, [GAO-18-25](#) (Washington, D.C.: Oct. 12, 2017). Our analysis was limited to permanent DEA-registered collection sites that use receptacles to collect unused prescription drugs from the public and does not include disposal options provided by law enforcement agencies, which do not need to register with DEA to collect controlled substances.

²⁸K. I. Stoddard et al., "Investigating Research Gaps of Pharmaceutical Take-Back Events: An Analysis of Take-Back Program Participants' Socioeconomic, Demographic, and Geographic Characteristics and the Public Health Benefits of Take-Back Programs," *Environmental Management*, vol. 59 (2017): p. 871-884 and M. A. Kozak, "A Needs Assessment of Unused and Expired Medication Disposal Practices: A Study From The Medication Safety Research Network of Indiana," *Research in Social and Administrative Pharmacy*, vol. 12 (2016): p. 336-340.

Figure 2: Estimated Percentage of Population Living Less Than 5 Miles From a Drug Enforcement Administration (DEA)-Registered Drug Take-Back Permanent Collection Site, by State, April 2019



Source: GAO analysis of Drug Enforcement Administration and U.S. Census Bureau data; Map Resources (map). | GAO-19-650

Note: We analyzed April 2019 data from DEA about the locations of non-law enforcement entities that are authorized to install receptacles to collect controlled substances for disposal by the general public. We also used 2017 U.S. Census Bureau population estimates to estimate, by zip code, the portion of the population within certain distances of a permanent collection site.

Flushing

Food and Drug Administration's Flush List, as of May 2019

- Benzhydrocodone/Acetaminophen
- Buprenorphine
- Fentanyl
- Diazepam*
- Hydrocodone
- Hydromorphone
- Meperidine
- Methadone
- Methylphenidate*
- Morphine
- Oxycodone
- Oxymorphone
- Tapentadol
- Sodium Oxybate*

*These drugs are not opioids.

Source: Food and Drug Administration | GAO-19-650

If take-back options are not feasible, FDA recommends flushing the opioids on its flush list down the toilet, because a single dose can be fatal to a child or a pet. Flushing is a permanent way to remove opioids from the home.²⁹ FDA confirmed that as of June 2019, 11 of 14 drugs on the flush list are opioids, which represents about three-quarters of the approved opioid active ingredients intended for outpatient use (see sidebar). Some portion of drugs that are flushed down the toilet ultimately enter surface and wastewater streams. However, a 2017 FDA study on the environmental impact of drugs listed on the flush list concluded that flushing these opioids has negligible effects on the environment and human health, particularly relative to the amount of opioids that are excreted after taking them as prescribed, because not all of the drug is metabolized.³⁰ (See text box for a summary of the effects of disposal options on the environment.)

²⁹The flush list does not include antibiotics and hormones, which have known detrimental environmental effects. See <https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know> (accessed June 4, 2019). Opioids have been detected in wastewater samples in the US, Canada, Europe, South America, and Asia. See Campos-Manas et al, "Trends in Environmental Analytical Chemistry," (2018).

³⁰U. Khan et al., "Risks Associated With the Environmental Release of Pharmaceuticals on the U.S. Food and Drug Administration 'Flush List'," *Science of the Total Environment*, vol. 609 (2017). This study did not examine the human and environmental impacts of flushing drugs other than those on FDA's flush list.

Environmental Effects of Disposal Options

The environmental impact of opioid disposal depends on the method used—take-back options, flushing, or trash. According to Environmental Protection Agency (EPA) and Drug Enforcement Agency (DEA) officials, disposal of drugs through take-back options results in disposal by permitted incineration, which fully destroys the active form of the drugs. EPA officials told us that flushing or placing opioids in the trash can introduce active opioids into wastewater streams, groundwater, and surface waters.

Incineration of Drugs from Take-Back Options. Opioids disposed of using take-back options are destroyed by incineration, which, according to DEA officials, is the only method currently used to meet its non-retrievable standard for destruction. EPA officials told us that based on data from DEA, the amount of household pharmaceutical waste gathered and incinerated during DEA's semi-annual take-back events is small compared to the total amount of waste one incinerator burns on an average day. EPA officials recommended take-back options as the preferred method of opioid disposal.

Flushing. Opioids enter the water supply when excreted by patients who take opioids as prescribed and when patients intentionally flush unused opioids down the toilet. EPA officials told us that most wastewater treatment facilities are not designed to eliminate opioids from wastewater streams. Further, measurable concentrations of opioids have been reported in surface and ground water sources around the world.

Trash. Disposal of unused opioids in the trash often introduces opioids into landfills. Studies in scientific literature show that pharmaceutical ingredients have been observed in the water that passes through landfills, called leachate. Similar to opioids that are flushed, opioids in landfill leachate can end up in wastewater streams and other water sources, according to EPA officials.

Source: GAO analysis of information from EPA and DEA | GAO-19-650

Household Trash

If an opioid is not on the FDA flush list and a take-back option is not feasible, the agencies direct patients to take a series of steps to dispose of their opioids in household trash by:

- (1) mixing the drugs in an unpalatable substance such as dirt, cat litter, or used coffee grounds,
- (2) placing the mixture in a sealed container or plastic bag, and
- (3) throwing the container in the trash.

An EPA official said that mixing the drugs with an unpalatable substance is meant to deter misusers from searching through the trash to retrieve the drugs. Disposal of opioids in the trash—either with an unpalatable substance or in-home disposal product—removes them from the home, but this option may not be permanent and the drugs still may be available for misuse. Drugs that are disposed in the trash ultimately are introduced to landfills, where they can escape landfill containment and enter wastewater streams or ground water sources.

FDA Has Not Evaluated Commercial Disposal Methods

FDA's website notes the availability of commercial products for disposing of unused opioids and other drugs in the home.³¹ FDA officials stated that, as of May 2019, the agency had not evaluated the effectiveness of these products or made any recommendations related to their use, but they are aware that patients may opt to use these products.³² These products, known as in-home disposal products, are proprietary substances that patients can mix with their unused drugs, including opioids, before disposing of them in the trash. In-home disposal product vendors told us they sell or donate their products to pharmacies, local law enforcement, and community groups, which then distribute them to patients.³³ A representative from a group that distributes these products, the AmerisourceBergen Foundation, noted that in-home disposal products may be a convenient option for patients for whom take-back options are not feasible, and marketing materials from a product vendor instruct patients to use their product if a take-back option is not available. Vendors indicate that their products can prevent misuse of opioids by rendering drugs non-retrievable at home and by motivating patients to dispose of unused opioids. According to DEA officials, rendering opioids non-retrievable by using an in-home disposal product is challenging, because the drugs have a variety of chemical and physical properties and potencies. Furthermore, according to DEA officials, a lethal dose of fentanyl can be as low as 250 micrograms in adults—and lower in children—underscoring the importance of effective disposal.

Some vendors have presented evaluations of their commercial products. A recent comprehensive review of eight in-home disposal products raised concerns about the credibility of vendors' evaluations and concluded that additional independent laboratory analysis is needed to fully examine product performance and assess how well these products achieve stated

³¹See <https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know> (accessed June 4, 2019).

³²The SUPPORT Act allows FDA to require as part of a REMS that certain drugs be dispensed with safe disposal packaging or a safe disposal system for purposes of rendering the drug non-retrievable in accordance with DEA regulations. Pub. L. No. 115-271, § 3032(a), 132 Stat. 3894 (2018) (codified at 21 U.S.C. § 355-1(e)(4)).

³³All three product vendors we spoke with said that all or nearly all of their sales are to organizations that distribute products to patients rather than to patients themselves. For example, one vendor representative said that the in-home disposal product is available to patients for free at approximately 40 percent of all chain drugstores nationwide.

goals.³⁴ Our review of evaluations from three vendors found that the studies contained some inconsistencies and gaps in the evaluation methods used, raising questions about the studies' conclusions that the products are effective for disposing of opioids.

- In some cases, studies included detailed, but inconsistent, methods. For example, in four studies about one product, the researchers concluded that the product deactivated most of an opioid dissolved in water. However, one of the earlier studies reported that whole pills did not dissolve in water, which could impact the results, but later studies did not include similar data.
- In other cases, companies' evaluations were summaries of results that did not provide enough information to independently verify or assess whether the products deactivate opioids and prevent misuse. For example, one company's research documents presented images of a mixture as evidence that the drugs had degraded, rather than results of a test measuring if drugs were still detectable.
- In addition, the studies included little information about the products' effectiveness at treating mixtures of multiple drugs at the same time, a scenario that stakeholders have referred to as "real world" use testing.

³⁴Community Environmental Health Strategies LLC, *Medicine Disposal Products: An Overview of Products and Performance Questions*, (2019).

Few Patients Use Federally Recommended Opioid Disposal Methods; FDA and Others Have Taken Steps to Educate the Public

Few Patients Use Federally Recommended Methods to Dispose of Unused Opioids

Disposal methods—when patients use them promptly—remove unused opioids from the home and therefore can be effective at reducing opioid misuse. FDA officials said that the federally recommended methods for disposing unused opioids are intended to remove these substances from the home as soon as possible, and stated that as long as individuals dispose of opioids promptly rather than storing them, then FDA has achieved its goal.

However, the studies we reviewed suggest that most patients do not dispose of unused opioids using a federally recommended method. Specifically, three studies examined how patients disposed of unused opioids and found that between 12 percent and 41 percent of patients disposed of them using a federally recommended method.³⁵ For example, one of the studies found that of 570 survey respondents who had unused opioids, 12 percent of respondents reported using a take-back option, 14 percent reported that they flushed them down the toilet, and 6 percent reported that they threw them in the trash after mixing with an unpalatable substance.³⁶

³⁵M. V. Hill et al., “Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures,” 709-714 and A. Kennedy-Hendricks et al., “Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults,” 1027-1029 and M.J. Sabatino et. al., “Excess Opioid Medication and Variation in Prescribing Patterns Following Common Orthopaedic Procedures,” *Journal of Bone and Joint Surgery*, vol. 100-A, no. 3 (2018): p. 180-188.

³⁶Kennedy-Hendricks et al., “Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults,” 1027-1029.

Other studies we reviewed show that take-back options are often used to dispose of drugs other than opioids. Two studies found that less than 10 percent of the catalogued drugs brought to DEA take-back days were controlled substances, which included opioids, while another study weighed drugs brought to take-back events and permanent collection sites and reported less than 3 percent were controlled substances, including opioids.³⁷ The same study found that annually, controlled substances disposed of at take-back events and permanent collection sites accounted for about 0.3 percent of those dispensed in the area, and concluded that take-back events may have a minimal impact on reducing the availability of unused opioids for misuse.³⁸

Studies indicate that patients who receive an in-home disposal product may be more likely to dispose of unused opioids, but they may also be less likely to use federally recommended options like take-back or flushing. Two studies in our review found that patients who receive an in-home disposal product have reported that they are more likely to dispose of unused opioids than those who did not receive the product.³⁹ Use of in-home disposal products—which may not be effective at permanently destroying drugs—may deter patients from using federally recommended options, like take-back, that have been proven effective. For example, one of these studies found that only one of the 70 patients who received

³⁷DEA regulations prohibit authorized collectors from opening and cataloging the contents of permanent collection receptacles. 21 C.F.R. § 1317.75(c) (2018). Evaluations of the use and contents of collection receptacles are limited to receptacles maintained by law enforcement agencies, which are not subject to this prohibition. We identified three studies conducted in conjunction with law enforcement agencies that quantified the amount of opioids collected via collection receptacles: C. S. Ma et al., “Drug Take Back in Hawai’i: Partnership Between the University of Hawai’i Hilo College of Pharmacy and the Narcotics Enforcement Division,” *Journal of Medicine and Public Health*, vol. 73, no. 1 (2014): p. 26-30 and H. Stewart et al., “Inside Maine’s Medicine Cabinet: Findings From Drug Enforcement Administration’s Medication Take-back Events,” *American Journal of Public Health*, vol. 105, no. 1 (2015): p. e65-e71 and K. L. Egan et al., “From Dispensed to Disposed: Evaluating the Effectiveness of Disposal Programs Through a Comparison with Prescription Drug Monitoring Program Data,” *The American Journal of Drug and Alcohol Abuse*, vol. 43, no. 1 (2017): p. 69-77.

³⁸K. L. Egan et al., “From Dispensed to Disposed,” 69-77.

³⁹C. M. Brummett, R. Steiger, M. Engelsbe, et. al., “Effect of an Activated Charcoal Bag on Disposal of Unused Opioids After an Outpatient Surgical Procedure: A Randomized Clinical Trial,” *JAMA Surgery*, (2019) and A. E. Lawrence, A. J. Carsel, K. L. Leonhardt et al., “Effect of Drug Disposal Bag Provision on Proper Disposal of Unused Opioids by Families of Pediatric Surgical Patients: A Randomized Clinical Trial,” *JAMA Pediatrics*, (Published online June 24, 2019).

an in-home disposal product used a take-back option for disposal, despite the study taking place in a state where we estimated that 77 percent of the population lived less than 5 miles from a permanent collection site.

Studies indicate that patients are often unaware of federally recommended disposal options. Three of the 25 studies we reviewed suggest that many patients were not aware of federally recommended methods for disposing of opioids.⁴⁰ For example, a study of cancer patients who received opioid prescriptions reported that more than three-quarters of these patients were unaware of proper opioid disposal methods.⁴¹ Another 2016 study of 1,032 patients found that nearly half of the respondents did not recall receiving information on proper disposal from pharmacists, medication packaging, or media outlets.⁴²

Studies also indicate that patients choose not to dispose of unused opioids, and that they knowingly participate in the majority of opioid misuse. Five of the studies we reviewed found that between one-quarter and three-quarters of patients stored unused opioids for future use or had misplaced their unused opioids.⁴³ For example, one of these studies found that 49 percent of survey respondents kept or planned to keep unused opioids for future use, and 14 percent were likely to let a family member use their opioid medications in the future.⁴⁴ Federal data about

⁴⁰Kozak et al., "A Needs Assessment of Unused and Expired Medication Disposal Practices," 336-340 and Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," 1027-1029 and J. Silvestre et al., "Frequency of Unsafe Storage, Use, and Disposal Practices of Opioids Among Cancer Patients Presenting to the Emergency Department," *Palliative and Supportive Care*, vol. 15 (2017): p. 638-643.

⁴¹J. Silvestre et al., "Frequency of Unsafe Storage, Use, and Disposal Practices of Opioids Among Cancer Patients Presenting to the Emergency Department," 638-643.

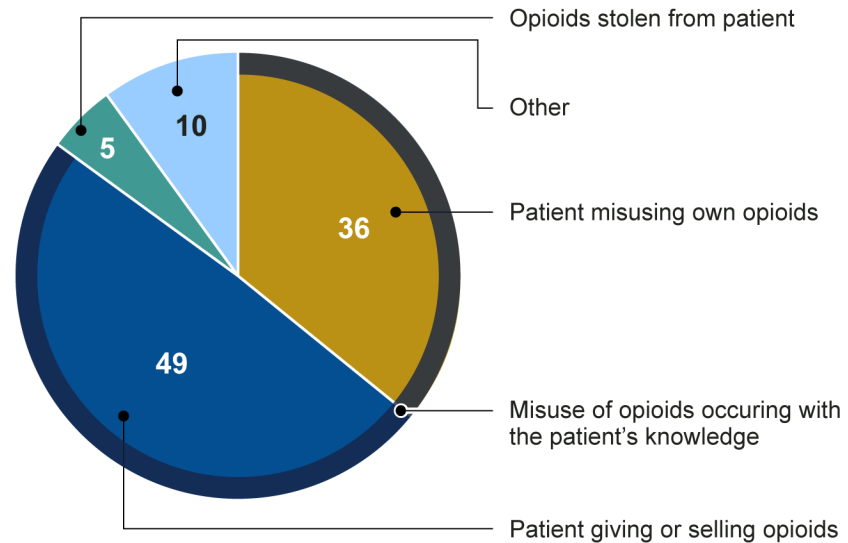
⁴²Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," 1027-1029

⁴³Hill et al., "Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures," 709-714; Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," 1027-1029; D. D. Maeng et. al., "Unused Medications and Disposal Patterns at Home: Findings From a Medicare Patient Survey and Claims Data," *Journal of the American Pharmacists Association*, vol. 56 (2016): p. 41-46; and M.J. Sabatino et. al., "Excess Opioid Medication and Variation in Prescribing Patterns Following Common Orthopaedic Procedures," 180-188.

⁴⁴Kennedy-Hendricks et al., "Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults," 1027-1029.

the sources of misused opioids indicate that patients are complicit with most misuse. SAMHSA estimates that 5 percent of people nationwide who misused opioids in 2017 took these drugs from someone else without asking. In contrast, SAMHSA estimates that 85 percent of opioid misuse occurs with the patient's knowledge or active participation, either through the patient misusing his or her own prescription by taking the drug for pain other than for which it was prescribed or by giving or selling the prescribed opioids to another person. (See fig. 3).⁴⁵

Figure 3: Ways People Obtained Opioids for Misuse in 2017 (percent)



Source: GAO analysis of Substance Abuse and Mental Health Services Administration data. | GAO-19-650

Note: "Other" sources for misused opioids include approximately 6 percent of misusers who bought the opioids from a drug dealer or other stranger and about 5 percent who obtained them some other way. These data are from the 2017 National Survey on Drug Use and Health, a nationally representative survey that asks people about their drug use within the past year, among other things, and includes a question about the source of the last opioids that a respondent misused. Misuse occurs when a person uses a drug in a way not intended by the prescriber, such as a patient taking a prescribed medicine to relieve pain other than the pain for which the drug was prescribed or taking a prescription intended for another person.

⁴⁵SAMHSA, *Key Substance Use and Mental Health Indicators*.

FDA and Others Have Taken Steps to Educate Patients and Providers about Appropriate Opioid Disposal

To motivate patients to use federally recommended methods to dispose of unused opioids, FDA and some physician organizations have created educational materials on safe disposal methods. For example, FDA launched a public awareness campaign called “Remove the Risk” on April 25, 2019—complete with educational materials such as public service announcements, social media posts, fact sheets, and other web-based content.⁴⁶ AMA representatives reported that the AMA has provided physicians with educational material on drug disposal and prescribing. Specifically, AMA representatives told us that the association has compiled a two-page document for physicians containing information about drug disposal, links to DEA information on nearby permanent collection sites and take-back events, and FDA guidance on safe disposal of medications. This document included recommendations for physicians to talk to patients about safe use of prescription opioids, remind patients to store their medications in a safe place out of reach from children, and have a conversation with patients about the most appropriate ways to dispose of expired, unwanted, or unused opioids.

The AmerisourceBergen Foundation has also partnered with communities to promote safe opioid disposal by providing education about take-back options and commercial in-home disposal products to patients. A representative from the Foundation explained that its Safe Disposal Support Program provides non-profit organizations or municipalities with commercial in-home disposal products, which then can be distributed free of charge to other organizations, individuals, or households. It also recommends that patients use take-back options when available. The representative said that organizations are to demonstrate to patients how these products work either through a brief in-person demonstration at an event or through a video. According to the representative, these products and demonstrations help people reflect on what is in their home and needs to be disposed of, either using a product or a take-back option.

Despite such efforts, little is known about the extent to which stakeholders’ efforts to educate the public are effective in increasing use of federally recommended disposal methods. FDA officials said that they are not aware of the extent to which providers are familiar with all disposal methods or the extent to which providers discuss the importance

⁴⁶See <https://www.fda.gov/drugs/ensuring-safe-use-medicine/safe-opioid-disposal-remove-risk-0-utreach-toolkit> (accessed June 11, 2019).

of proper disposal with patients. As part of FDA's REMS requirements for outpatient opioids, manufacturers must make training available to health care providers involved in the treatment and monitoring of patients who receive opioids, which includes information about the need to communicate with patients about disposal of unused drugs. FDA officials said that opioid manufacturers must assess the effectiveness of their REMS, including an assessment of prescribers', other health care providers including pharmacists', and patients' understanding of the key risk messages conveyed through the educational materials. FDA expects to receive the next REMS assessment with the results of these analyses in 2020. The AMA has not been able to measure the effects of its recommendations, but provided anecdotal feedback from its members that many physicians do not consistently speak to their patients about disposal.

FDA officials and AMA representatives indicated that in addition to educating patients on opioid disposal methods, focusing efforts on reducing the amount of unused opioids would be an effective approach for reducing misuse and abuse. For example, FDA officials said that adding packaging configurations that contain smaller quantities of certain opioids could help prescribers to more carefully consider the amount of opioid pain medication they prescribe.⁴⁷ This in turn may reduce the number of unused opioids available in the home that could be inappropriately accessed by family members or visitors, and could potentially reduce the risk for misuse and abuse. Representatives from the AMA explained that it and other organizations are working to provide opioid prescribing resources and guidance to help physicians effectively manage patients' pain, which representatives said will reduce the number of unused opioids available for misuse.⁴⁸ FDA officials and a researcher also noted that dispensing opioids in packaging that makes it easy to count the number of unused pills may help patients identify intentional misuse.

⁴⁷On May 31, 2019, FDA issued a notice in the Federal Register soliciting comments about unit-dose packaging for opioids. 84 Fed. Reg. 25,283 (May 31, 2019).

⁴⁸For example, CDC developed and published the *CDC Guideline for Prescribing Opioids for Chronic Pain* to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. AMA representatives cautioned, however, that opioid restriction policies have had unintended negative consequences on substance use and pain care. Representatives from the AMA explained that it and other organizations also provide resources and guidance to help physicians effectively screen and refer patients for substance use disorders.

Agency Comments

The FDA and EPA provided technical comments on a draft of this report, which we incorporated as appropriate; the DEA did not have comments.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, the Administrator of the DEA, the Administrator of the EPA, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix I.



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Appendix I: GAO Contact and Staff Acknowledgments

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In addition to the contact named above, individuals making key contributions to this report include Leslie V. Gordon (Assistant Director), A. Elizabeth Dobrenz (Analyst-in-Charge), Sam Amrhein, Jieun Chang, Diana Chung, Kaitlin Farquharson, and Dennis Mayo. Also contributing were Giselle Hicks, Cynthia Khan, and Ethiene Salgado-Rodriguez.

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