



October 2017

PREVENTING DRUG ABUSE

Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs

GAO Highlights

Highlights of [GAO-18-25](#), a report to congressional requesters

Why GAO Did This Study

In 2015, 3.8 million Americans reported misusing prescription drugs within the last month, and deaths from prescription opioids have more than quadrupled since 1999. About half of the people who reported misusing prescription drugs in 2015 received them from a friend or relative.

One way to help prevent this kind of diversion and potential misuse is by providing secure and convenient ways to dispose of unused, unneeded, or expired prescription medications. The Secure and Responsible Drug Disposal Act of 2010 authorizes pharmacies and other entities already authorized by DEA to handle controlled substances to also collect unused prescription drugs for disposal. In 2014, DEA finalized regulations for the implementation of the Act, establishing a voluntary process for eligible entities to become authorized collectors of unused prescription drugs using disposal bins.

GAO was asked to review participation among authorized collectors that maintain disposal bins. In this report GAO describes (1) participation rates among entities eligible to collect unused prescription drugs and (2) factors that affect participation. GAO analyzed the most currently available DEA data from April 2017 on entities eligible to participate and those participating as authorized collectors. GAO also conducted interviews with DEA officials and a nongeneralizable sample of 11 stakeholder organizations selected to illustrate different types of authorized collectors and long-term care facilities. GAO is not making any recommendations. DEA provided technical comments, which GAO incorporated as appropriate.

View [GAO-18-25](#). For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

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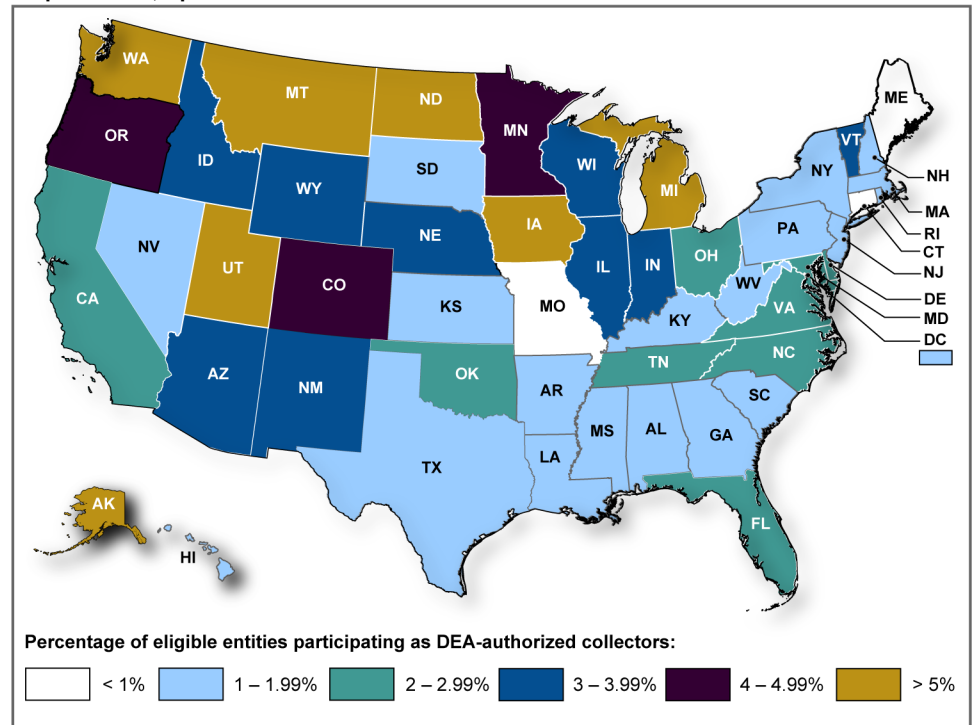
PREVENTING DRUG ABUSE

Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs

What GAO Found

GAO found that about 3 percent of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. The Drug Enforcement Administration (DEA) authorizes these entities to dispose of unused drugs to help reduce their potential misuse. Analysis of DEA data shows that as of April 2017, 2,233 of the 89,550 (2.49 percent) eligible entities—that is, certain entities already authorized by DEA to handle controlled substances—had registered with DEA to use disposal bins to collect unused prescription drugs. Most—about 81 percent—of the authorized collectors were pharmacies, followed by hospitals or clinics. GAO also found that participation rates varied by state, though in 44 states less than 5 percent of the state’s pharmacies and other eligible entities had registered to become authorized collectors.

Percentage of Eligible Entities Authorized by DEA to Collect Unused Prescription Drugs Using Disposal Bins, April 2017



Sources: GAO analysis of Drug Enforcement Administration data; Map Resources (map). | GAO-18-25

Stakeholders cited several factors that may explain why relatively few pharmacies and other eligible entities have registered with DEA as authorized collectors of unused drugs. Most notably, stakeholders representing authorized collectors told GAO that because participation is voluntary, the cost associated with maintaining a disposal bin—which includes purchasing and installing the bin according to DEA requirements and paying for the destruction of its contents—is an important factor to weigh against potential benefits. DEA noted that availability of disposal by law enforcement agencies also contributes to low participation.

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Abbreviations

DEA	Drug Enforcement Administration
Disposal Act	Secure and Responsible Drug Disposal Act of 2010

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October 12, 2017

The Honorable Charles E. Grassley
Chairman
Judiciary Committee
United States Senate

The Honorable Joni K. Ernst
United States Senate

The misuse of prescription drugs is widespread and contributes to overdoses and deaths. Federal data show that in 2015, 3.8 million Americans reported misusing prescription drugs within a 1-month period and that prescription drug misuse was the second most common type of illicit drug use, after marijuana use.¹ The misuse of prescription drugs has also contributed to the nation's opioid epidemic and the overdoses associated with it, as 91 people in the United States die each day, on average, from an opioid overdose, including overdoses involving prescription opioids and heroin. Furthermore, the number of deaths resulting from prescription opioids has more than quadrupled since 1999.²

About half of the people who reported misusing prescription drugs in 2015 received them from a friend or relative.³ One way to help prevent this type of diversion of prescription drugs from their intended users and the resulting potential for abuse is by providing secure and convenient disposal mechanisms for unused, unneeded, or expired prescription medications. Under the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act"), the Drug Enforcement Administration (DEA) may

¹See Center for Behavioral Health Statistics and Quality, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2015 National Survey on Drug Use and Health*, HHS Publication No. SMA 16-4984, NSDUH Series H-51, (September 2016).

²Centers for Disease Control and Prevention, *Understanding the Epidemic*, <https://www.cdc.gov/drugoverdose/epidemic/index.html>, accessed July 5, 2017.

³According to the National Survey on Drug Use and Health data from 2015, of the people who misused pain relievers, about 41 percent reported that a friend or relative provided the drug for free, about 9 percent reported that they bought the drug from a friend or relative, and about 4 percent reported that they took the drug from a friend or relative without asking. See Center for Behavioral Health Statistics and Quality, *Results from the 2015 National Survey on Drug Use and Health: Detailed Tables*, (September 2016).

authorize eligible retail pharmacies and other entities—which are certain entities already authorized by the DEA to handle controlled substances—to also collect unused prescription drugs from the public.⁴ In September 2014, DEA finalized regulations for the implementation of the Disposal Act, providing pharmacies and other eligible entities the option to register with DEA to become authorized collectors of unused controlled prescription drugs using collection receptacles, which are bins used to collect drugs meant for disposal.⁵ The regulation establishes requirements participating entities must meet, such as installing the disposal bin securely to a permanent structure and making the bin inaccessible to the public when an employee is not present.

You requested that we review DEA’s requirements for authorized collectors of prescription drugs and participation rates. In this report, we describe

1. participation rates of eligible pharmacies and other entities as DEA-authorized collectors of unused prescription drugs, and
2. factors that affect voluntary participation as authorized collectors of unused prescription drugs.

To describe the rates of eligible pharmacies and other entities that participate as DEA-authorized collectors of unused prescription drugs using disposal bins, we analyzed DEA data as of April 20, 2017, the most current data available at the time of our analysis. We determined the number and percentage of eligible entities participating as authorized collectors nationwide, by state, and by type of entity.⁶ We also determined

⁴Pub. L. No. 111-273, 124 Stat. 2858 (Oct. 12, 2010). According to the Controlled Substances Act, the term “controlled substance” means “a drug or other substance, or immediate precursor, included [by DEA in one of five classification schedules.]” 21 U.S.C. § 802(6). A controlled substance is placed in a respective schedule based on whether it has a currently accepted medical use in treatment in the United States and based on its relative abuse potential and likelihood of causing dependence. The order of the schedules reflects substances that are progressively less dangerous and addictive. The term “controlled substance” as used in this report includes controlled prescription drugs such as opioid pain relievers. For simplicity, in this report, we use the term “prescription drugs” to refer to controlled prescription drugs.

⁵We use the term “disposal bin” to refer to collection receptacles.

⁶For the purposes of this report, we include Washington, D.C., when we refer to data for states. We did not analyze data on authorized collectors in U.S. territories or international military locations. As of April 2017, of the 1,493 DEA eligible entities located in territories or international military locations only 4 were participating as authorized collectors—3 in Puerto Rico and 1 in the Northern Mariana Islands.

the number of eligible and participating authorized collectors in rural and urban areas, using DEA's data and Rural-Urban Commuting Area codes.⁷ Finally, we analyzed DEA's data and data from the U.S. Census Bureau's American Community Survey 5-year population estimates for 2011 through 2015 to estimate the number of individuals and the percentage of the U.S. population living within varying distances of a DEA authorized collector's disposal bin.⁸ For all data used in these analyses, we interviewed knowledgeable officials and reviewed related documentation and, based on these steps, determined that the data were sufficiently reliable for our purposes. Our review is limited to DEA-authorized collectors that use disposal bins to collect unused prescription drugs from the public. Other methods of drug disposal by eligible entities and all methods of disposal by law enforcement agencies, which do not require DEA authorization to dispose of controlled substances, are outside the scope of our work.⁹

⁷Rural-Urban Commuting Area codes characterize all Census tracts regarding their rural and urban status using Bureau of Census Urbanized Area and Urban cluster definitions in combination with work-commuting data. We used the most recent zip code version of the Rural-Urban Commuting Area codes, version 3.1, which are based on 2010 Census data. Zip codes defined as urban and suburban by code were grouped as "urban" and the remainder were grouped as "rural." We obtained additional information on Rural-Urban Commuting Area codes from the University of North Dakota's Center for Rural Health.

⁸The 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. These data were the most current data available at the time of our analysis. To conduct this analysis, we calculated the distance between the central point of each zip code and the nearest DEA authorized collector's disposal bin. 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.

⁹79 Fed. Reg. 53,520 (Sept. 9, 2014) (codified at 21 C.F.R. pt. 1317). DEA regulations provide for three methods for disposing of prescription drugs: (1) disposal bins; (2) a mail-back program, where packages are made available for the public to ship prescription drugs to collectors for destruction; and (3) take-back events, where federal, state, and local law enforcement collect prescription drugs for destruction. DEA may authorize eligible entities to use disposal bins or the mail back program, while law enforcement agencies may use all three methods without the need for authorization by DEA. For the purposes of this report, we use the term "authorized collector" to refer to those pharmacies and other DEA-authorized entities that offer a disposal bin.

To describe the factors that affect voluntary participation as authorized collectors of prescription drugs, we interviewed DEA officials. In addition, we conducted interviews with 11 stakeholder organizations—8 selected because they represent different types of authorized collectors, such as pharmacies and reverse distributors, and 3 selected because they represent long-term care facilities.¹⁰ Our findings cannot be generalized beyond the stakeholder organizations we interviewed.

We conducted this performance audit from November 2016 to October 2017 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

The DEA, within the Department of Justice, is responsible for ensuring the availability of controlled substances for legitimate uses while preventing their diversion through its administration and enforcement of the Controlled Substances Act and its implementing regulations.¹¹ Under 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. For example, DEA regulates pharmaceutical companies that manufacture controlled substances, health care providers who prescribe them to patients, and pharmacies that dispense them.

¹⁰We selected stakeholders from among those that had publicly available comments on the processes for disposing of controlled substances and asked stakeholders we interviewed for additional recommendations. Among the 8 authorized collector stakeholder organizations we interviewed, 5 represented pharmacies, 1 represented hospitals with pharmacies, and 2 represented reverse distributors. Reverse distributors are typically waste management companies that acquire controlled substances from other entities authorized to handle controlled substances for the purpose of return or destruction. Long-term care facilities are not authorized collectors, but pharmacies and hospitals participating as authorized collectors are able to also maintain disposal bins in long-term care facilities.

¹¹The Controlled Substances Act was enacted in 1970 to regulate and facilitate the use of controlled substances, including certain prescription drugs such as opioid pain relievers, for legitimate medical, scientific, research, and industrial purposes while preventing them from being diverted for illegal uses. Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (codified as amended at 21 U.S.C. § 801 et seq.).

In October 2010, the Disposal Act amended the Controlled Substances Act to allow the public to deliver unused controlled substances to an entity authorized by DEA to dispose of the substances.¹² DEA was given responsibility for promulgating the implementing regulations, and the Disposal Act stipulated that the regulations should prevent diversion of controlled substances while also taking into consideration public health and safety, ease and cost of implementation, and participation by various communities. In addition to disposal bins, DEA's regulations describe two other options for the public to transfer controlled substances for the purpose of disposal: mail-back programs and take-back events. Law enforcement agencies may use all three methods of drug disposal without the need for authorization by DEA.¹³ The Disposal Act stipulates that the regulations cannot require an entity to participate in or establish any of the disposal options.

Requirements for Authorized Collectors of Unused Prescription Drugs

To participate as authorized collectors of unused prescription drugs, eligible entities—retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment programs, reverse distributors, distributors, and drug manufacturers that are already authorized by DEA to handle controlled substances—must modify their DEA registration.¹⁴ According to DEA officials, such modification is free and simple to do. Eligible retail pharmacies or hospitals/clinics that become authorized collectors are able to install and maintain disposal bins in long-term care facilities in addition to their own location. DEA's website contains a public search feature to identify authorized collectors located near a specific zip code or address.¹⁵

¹²Specifically, the law allows disposal by ultimate users, which it defines as people who have lawfully obtained and who possess a controlled substance for their own use or for the use of a member of their household.

¹³The National Association of Drug Diversion Investigators maintains a website with a search feature for the law enforcement locations that accept unused prescription drugs (see <http://www.rxdrugdropbox.org>). An official from the National Association of Drug Diversion Investigators said that the website includes those locations for which agencies have chosen to provide information.

¹⁴Authorization to be a collector is subject to renewal, and if an authorized collector ceases its disposal activities it must modify its DEA registration to reflect the change.

¹⁵See <https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main>.

Authorized collectors must install, manage, and maintain the disposal bins following DEA regulations. For example, under DEA's regulations for maintaining the disposal bins,

- the disposal bin must be securely fastened to a permanent structure, securely locked, substantially constructed with a permanent outer container and removable inner liner, and have a small opening that allows contents to be added but not removed;
- the bin must also prominently display a sign indicating which types of substances are acceptable;¹⁶
- users must dispose the unused prescriptions into the collection receptacle themselves without handing them to staff at the pharmacy;¹⁷
- the disposal bin must typically be located in an area where an employee is present and near where controlled substances are stored, and the bin must be made inaccessible to the public when an employee is not present;¹⁸
- the inner liner of the disposal bin must meet certain requirements, including being waterproof, tamper-evident, tear-resistant, opaque, and having the size and identification number clearly labeled; and
- the installation and removal of inner liners must be performed under the supervision of at least two employees of the authorized collector.

DEA regulations also require that all controlled substances collected in the disposal bin's inner liners must be destroyed in compliance with applicable federal, state, and local laws and rendered non-retrievable. According to DEA regulations, non-retrievable 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. Authorized collectors are permitted to

¹⁶Only schedule II-V controlled substances and non-controlled substances are acceptable. Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate users, and other illicit or dangerous substances are not permitted.

¹⁷A long-term care facility may dispose of controlled substances on behalf of a user who resides in or previously resided at the facility.

¹⁸Disposal bins in a hospital must be located in an area monitored by employees regularly and cannot be located near an area where emergency or urgent care is provided. Additionally, bins in narcotic treatment programs must be located in a room with controlled access and without any other controlled substances.

destroy the inner liner on their premises if they have the capacity to do so. If not, the inner liners can be transported to a separate location to be destroyed. Typically, in this case, an authorized collector contracts with a reverse distributor to periodically remove, transport, and destroy the inner liners. DEA regulations require that two reverse distributor employees transport the inner liners directly to the disposal location without any unnecessary stops or stops of an extended duration. Authorized collectors must document certain information, including inner liner identification numbers and the dates that each liner is installed, removed, and transferred for destruction. The authorized collectors must maintain these records for 2 years. Figure 1 summarizes the steps involved in the collection of unused prescription drugs.

Figure 1: Steps Involved In the Collection of Unused Prescription Drugs Using Disposal Bins



Source: Drug Enforcement Administration. | GAO-18-25

About 3 Percent of Eligible Pharmacies and Other Entities Voluntarily Participate as DEA-Authorized Collectors of Unused Prescription Drugs

About 3 percent of pharmacies and other eligible entities have voluntarily chosen to become DEA-authorized collectors of unused prescription drugs, according to DEA data. As of April 2017, 2,233 of the 89,550 (2.49 percent) of eligible entities—which are already authorized by DEA to handle controlled substances—had registered to use disposal bins to collect unused prescription drugs. Most of the authorized collectors—about 81 percent—were pharmacies, followed by hospitals or clinics. (See table 1). Narcotic treatment programs, reverse distributors, and distributors made up approximately 1 percent of the authorized collectors.

Table 1: Entities Eligible to Register with the Drug Enforcement Administration (DEA) to Become Authorized Collectors of Unused Prescription Drugs, and Participating Collectors, by Type, as of April 2017

	Number of entities eligible to become authorized collectors	Number of authorized collectors	Percentage of eligible entities participating as authorized collectors
Pharmacy	69,192	1,803	2.6
Hospital/Clinic	17,442	405	2.3
Narcotic Treatment Program	1,523	16	1.1
Reverse Distributor ^a	62	8	12.9
Distributor	777	1	0.1
Manufacturer	554	0	0
Total	89,550	2,233	2.49

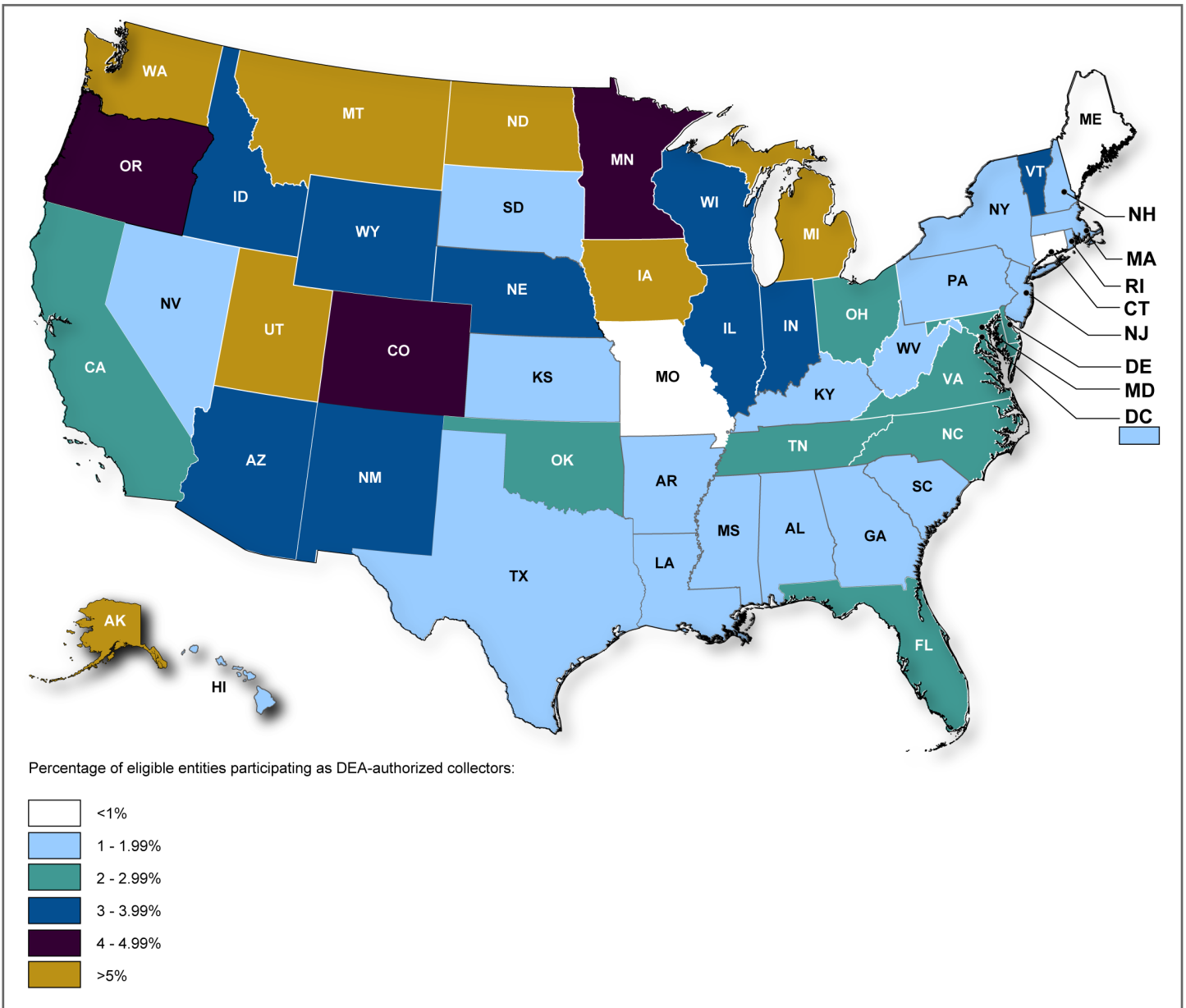
Source: GAO analysis of DEA data. | GAO-18-25

^aReverse distributors are typically waste management companies that acquire controlled substances from other entities authorized to handle controlled substances for the purpose of return or destruction.

We also found that participation rates varied by state, though in most states relatively few of the eligible entities had registered with DEA to become authorized collectors of unused prescription drugs. In 44 states, less than 5 percent of the eligible entities had registered. (See figure 2 and appendix I for more information on the participation rates of authorized collectors in each state). As of April 2017, Connecticut, Missouri, and Maine had the lowest participation rates, with 0.11, 0.22, and 0.70 percent, respectively.¹⁹ In contrast, North Dakota had the highest participation rate, with 32.0 percent of its pharmacies and other eligible entities registered to be authorized collectors. The state with next highest participation rate was Alaska, with 8.96 percent. In North Dakota, the state’s Board of Pharmacy provides funding for authorized collectors to purchase and maintain the disposal bins. According to a board official, the board decided to fund these activities to increase participation rates and plans to continue its funding indefinitely using revenue generated from prescription drug licensing fees it collects.

¹⁹According to DEA officials, two states—Missouri and Hawaii—have state-level laws or regulations that prohibit retail pharmacies from installing bins to collect prescription drugs from the public. As of April 2017, Missouri had four authorized collectors and Hawaii had six authorized collectors—all hospitals or clinics located on military bases or at Veterans Health Administration facilities. According to DEA officials, registrants located on military bases or at Veterans Health Administration facilities are federal entities and not subject to state pharmacy laws.

Figure 2: Percentage of Pharmacies and Other Eligible Entities Authorized by the Drug Enforcement Administration (DEA) to Collect Unused Prescription Drugs, April 2017



Sources: GAO analysis of Drug Enforcement Administration data; Map Resources (map). | GAO-18-25

In addition, our analysis shows that about 82 percent of all authorized collectors were located in urban areas as of April 2017. However, when comparing the entities registered to be authorized collectors with the total number of eligible entities, we found that a larger percentage of the eligible entities in rural areas became authorized collectors compared with those in urban areas (see table 2).

Table 2: Participation Rates of Authorized Collectors of Unused Prescription Drugs among Pharmacies and Other Eligible Entities, by Urban and Rural Location, as of April 2017

	Total number of pharmacies and other entities eligible to become authorized collectors	Number of authorized collectors	Percentage of pharmacies and other eligible entities registered to participate as authorized collectors
Urban	78,071	1,836	2.35
Rural	11,436	395	3.45

Source: GAO analysis of DEA data. | GAO-18-25

Note: The Rural-Urban Commuting Area codes used to determine urban and rural locations did not include the zip codes of 43 pharmacies and other entities eligible to become authorized collectors, 2 of which were participating as authorized collectors. These 43 entities are not included in the table.

The data we obtained on the number of eligible and participating authorized collectors and their locations are the only available DEA data on the use of disposal bins to collect unused prescription drugs. According to DEA officials, the agency does not collect any other information on the use of disposal bins, such as the extent to which the bins are used, or the amount and types of prescription drugs deposited into the bins. For example, to minimize the risk of diversion, DEA regulations do not allow authorized collectors to open and inspect the inner liners of the disposal bins, so information on their contents cannot be collected.²⁰ According to DEA officials, the agency is not responsible for collecting information on the amount and types of prescription drugs destroyed through the disposal bins. DEA officials told us that the agency

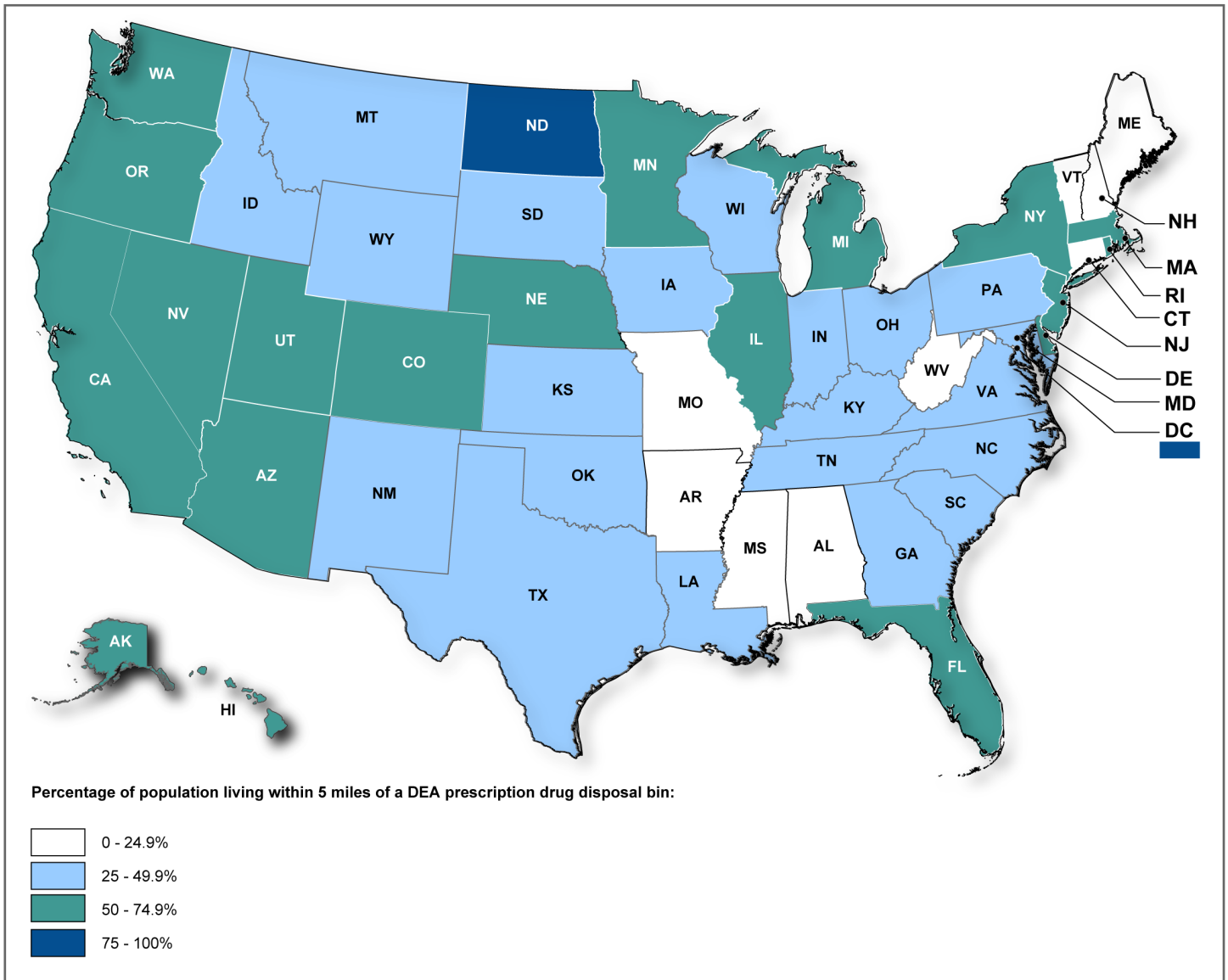
²⁰In contrast, DEA collects and publishes information on the weight of the prescription drugs collected and destroyed through DEA’s national take-back days, during which DEA partners with local law enforcement twice a year to collect and destroy prescription drugs brought in by the community. DEA reported that during its April 29, 2017 national take-back day, about 450 tons of drugs were collected at more than 5,000 collection sites.

views its responsibility solely as giving pharmacies and other eligible entities the opportunity to become authorized collectors.²¹

Though we do not have information on the extent to which individuals use DEA's prescription drug disposal bins, we were able to estimate that as of April 2017, about half of the country's population lived less than 5 miles away from a pharmacy or other DEA-authorized entity offering a prescription disposal bin. In 21 states, at least 50 percent of the state's population lived within 5 miles of a prescription disposal bin. (See figure 3).

²¹DEA officials noted that the agency requires authorized collectors to keep records related to the disposal bins, such as records of when a disposal bin's inner liner is installed, removed, and then destroyed. DEA officials told us that any entity authorized to handle controlled substances, including authorized collectors, may be subject to periodic DEA inspections. For example, DEA officials told us that each of the agency's 21 regional offices conducts inspections of at least 10 pharmacies per year, without regard to whether the pharmacies are authorized collectors. According to officials, DEA may review the records kept by authorized collectors as part of these inspections.

Figure 3: Estimated Percentage of Population Who Lived within 5 Miles of a Drug Enforcement Administration (DEA) Prescription Drug Disposal Bin, by State, April 2017



Sources: GAO analysis of Drug Enforcement Administration and U.S. Census Bureau data; Map Resources (map). | GAO-18-25

While close to half of the nation’s population lived less than 5 miles from a disposal bin as of April 2017, the availability of nearby disposal bins varied significantly for people depending on whether they lived in an urban or a rural area. Specifically, about 52 percent of the population in urban areas lived less than 5 miles away from a disposal bin, compared

to about 13 percent of the population in rural areas. Furthermore, about 44 percent of the population in rural areas lived even further away—more than 30 miles away from a disposal bin. An exception to this is North Dakota, where about 86 percent of its urban population and about 64 percent of its rural population lived within 5 miles of a disposal bin.

Stakeholders Cited Cost and Other Factors as Affecting Decision to Become DEA-Authorized Collectors of Unused Prescription Drugs

According to officials from the 11 stakeholder organizations we interviewed—which represent authorized collectors and long-term care facilities—several factors may explain why relatively few pharmacies and other eligible entities have chosen to become authorized collectors of unused prescription drugs. These factors include the associated costs of participating, uncertainty over proper implementation, and participation in other, similar efforts for disposing of unused prescription drugs.

Costs: Stakeholders said that the costs associated with purchasing, installing, and managing the disposal bins is a factor that explains the relatively low rate of participation. One stakeholder told us that many eligible entities may decide that the benefit of participating does not outweigh the costs associated with doing so. Specifically, stakeholders told us that the major costs associated with participating include

- the one-time cost of purchasing and installing a disposal bin;
- the ongoing costs to train personnel to manage the bins; and
- the cost of contracting with a reverse distributor to periodically dispose of the bin's inner liner and contents.

Stakeholders gave varying examples of the specific costs associated with these investments. For example, one stakeholder estimated the yearly costs of maintaining a disposal bin ranged from \$500 to \$600 per location; another stakeholder said that the cost is thousands of dollars per location per year, but did not provide a specific estimate. These stakeholders added that costs can increase if the disposal bins fill more quickly and need to be emptied more often than expected.

For their part, officials from the reverse distributor stakeholders we interviewed cited incinerating hazardous waste, the availability of incinerators, and the cost of personnel as factors that increase the cost of their services for authorized collectors. One reverse distributor stakeholder told us that there are not many incinerators available, requiring them to travel long distances to incinerate collected waste. The other reverse distributor stakeholder added that DEA's requirement that a

second employee be present during the transportation and disposal increases the cost of their services.

While some stakeholders speculated that costs are a reason for low participation, a few stakeholders told us that the benefits are worth the costs. In fact, two stakeholders we spoke with told us that the benefit to the communities was so important that they decided to provide funding to retail pharmacies, alleviating an individual pharmacy's concern about the cost of installing and maintaining the disposal bins. We found that as of April 2017, over a quarter of the 2,233 authorized collectors using disposal bins received external funding to pay for the costs associated with installing and maintaining the disposal bins. In addition, stakeholders told us that some localities have enacted laws known as extended producer responsibility ordinances, which require that pharmaceutical manufacturers pay for certain costs associated with drug disposal. When asked about the costs associated with operating disposal bins, DEA officials told us that addressing cost issues with eligible participants falls outside of their responsibilities.

Uncertainty: Stakeholders also told us that uncertainty regarding how to comply with aspects of DEA's regulations for prescription drug disposal bins affected their decisions to participate. One stakeholder added that many eligible entities decide not to participate because uncertainties over participation requirements could result in inadvertent non-compliance with DEA's regulations.

As an example of their uncertainty over some of the requirements governing the disposal bins, officials from both of the reverse distributor stakeholders we interviewed cited DEA's non-retrievable standard for destruction of the inner liners of the bins. DEA requires that the method of destruction be sufficient to render all controlled substances non-retrievable, meaning that the physical and chemical conditions of the controlled substances must be permanently altered and unusable in order to prevent diversion for illicit purposes. Both reverse distributor stakeholders told us that they are uncertain about whether certain disposal methods meet this standard, and they said that the agency has not provided further guidance on how reverse distributors can meet this requirement. DEA officials told us that the agency responds to questions about whether a specific method of destruction meets the non-retrievable standard by telling the registrant to test the remnants after destruction, to see if any components of the controlled substance are still present. In its summary of the regulations implementing the Disposal Act, DEA stated that in order to allow for the development of various methods of

destruction, the agency did not require a specific method of destruction as long as the desired result is achieved.²² However, DEA officials stated that to their knowledge, incineration is the only method known to meet the non-retrievable standard to date, but the officials hoped other methods will be developed in the future.

When asked about the guidance they provide to authorized collectors of unused prescription drugs or those eligible to become authorized collectors, DEA officials told us that they post frequently-asked questions on their website, routinely answer questions from participants and others, and give training presentations at conferences that include information on the disposal bins. In our prior work, we found problems with DEA's communication and guidance to stakeholders. In 2015, we recommended that DEA identify and implement cost-effective means for communicating regularly with pharmacies and other entities authorized to handle controlled substances.²³ DEA agreed with the recommendation, and officials told us that, starting in August 2017, these entities can subscribe to DEA's website to receive notifications when it is updated with new guidance.

Stakeholders also noted that some DEA requirements related to disposal bins may conflict with other state and federal requirements governing the transportation and disposal of hazardous waste, which includes some controlled substances. For example, the two reverse distributor stakeholders told us that some incinerator permits issued by states require that hazardous waste be examined before incineration; however, DEA requirements do not allow the contents of the liners to be examined, even at the time of incineration. To address the incinerator permit requirements, one reverse distributor told us that they use the Environmental Protection Agency's hazardous waste household exemption, which treats the liners as household waste and thereby allows incinerator facilities to destroy the liners without examining the contents or violating their state permit.²⁴ In addition, some stakeholders raised

²²See 79 Fed. Reg. 53,520, 53,522 (Sept. 9, 2014).

²³See GAO, *Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access*, [GAO-15-471](#) (Washington, D.C.: June 2015).

²⁴Environmental Protection Agency regulations exclude household waste collected from a personal residence from the definition of hazardous waste. 40 C.F.R. § 261.4(b)(1). The agency has stated that this exclusion applies even when personal residence waste is collected at another location.

concerns that DEA's regulations may conflict with other federal regulations. For instance, one stakeholder noted that they recently learned that transporting the disposal bin's inner liners could violate Department of Transportation regulations. DEA officials told us that they were aware of this, explaining that the conflict was between DEA's requirement that controlled substances be transported in liners and the Department of Transportation's requirement that this type of waste be transported in sturdy containers. According to DEA officials, this conflict has been resolved by the Department of Transportation allowing reverse distributors to place the liners inside sturdy containers kept on trucks.

Participation in or Availability of Similar Efforts: Stakeholders said that some pharmacies and other eligible entities were already participating in other, similar efforts that allow for the safe disposal of controlled substances, and therefore they did not want to invest additional resources into participating as authorized collectors using disposal bins. For example, the Centers for Medicare & Medicaid Services has an established process that long-term care facilities use to dispose of their unused controlled substances.²⁵ As a result, all of the long-term care stakeholders told us that long-term care facilities may choose not to partner with pharmacies interested in placing disposal bins within their facilities because it adds significant cost and effort without any additional benefit. Furthermore, pharmacy stakeholders noted that because of the availability of other prescription drug collection efforts in their communities, they did not think that maintaining a disposal bin at their locations was needed. For example, two of the stakeholders explained that local law enforcement precincts already had a similar type of disposal bin in place to collect unused prescription drugs.²⁶ DEA officials told us that they were aware of other options for the public and entities such as long-term care facilities that are not registered as authorized collectors to dispose of controlled substances. The officials also indicated that the availability of disposal options at law enforcement agencies contributes to

²⁵The Centers for Medicare & Medicaid Services requires that nursing homes keep records of the usage, disposition, and destruction of all controlled substances and conduct periodic reconciliation of records at least monthly, among other requirements. See Centers for Medicare & Medicaid Services, "State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care Facilities."

²⁶Federal, state, tribal, or local law enforcement may collect controlled substances from ultimate users using disposal bins, among other methods. According to DEA officials, law enforcement entities do not have to register to handle controlled substances. These disposal bins are not included in DEA data and are outside the scope of our analysis.

the low participation rates among pharmacies as authorized collectors of unused prescription drugs.

Agency Comments

We provided a draft of this report to the Department of Justice for comment. DEA, part of the Department of Justice, provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Attorney General of the United States and the Administrator of DEA. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or draperd@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 II.



Debra A. Draper
Director, Health Care

Appendix I: Entities Eligible to Register with DEA to Become Authorized Collectors and Participating Collectors, by State, April 2017

	Number of authorized collectors	Number of entities eligible to become authorized collectors	Percentage of eligible entities participating as authorized collectors
AK	19	212	8.96
AL	20	1,687	1.19
AR	12	998	1.20
AZ	56	1,463	3.83
CA	184	8,117	2.27
CO	56	1,205	4.65
CT	1	909	0.11
DC	4	220	1.82
DE	7	323	2.17
FL	131	6,529	2.01
GA	34	2,819	1.21
HI	6	376	1.60
IA	63	954	6.60
ID	13	407	3.19
IL	90	2,795	3.22
IN	63	1,721	3.66
KS	19	1,012	1.88
KY	29	1,486	1.95
LA	30	1,701	1.76
MA	29	1,676	1.73
MD	38	1,835	2.07
ME	3	428	0.70
MI	147	2,896	5.08
MN	57	1,313	4.34
MO	4	1,845	0.22
MS	12	1,089	1.10
MT	29	398	7.29
NC	89	3,541	2.51
ND	88	275	32.00
NE	23	647	3.55
NH	6	376	1.60
NJ	30	2,409	1.25
NM	25	701	3.57
NV	11	668	1.65
NY	85	5,780	1.47

**Appendix I: Entities Eligible to Register with
DEA to Become Authorized Collectors and
Participating Collectors, by State, April 2017**

	Number of authorized collectors	Number of entities eligible to become authorized collectors	Percentage of eligible entities participating as authorized collectors
OH	75	3,570	2.10
OK	27	1,260	2.14
OR	38	924	4.11
PA	73	3,895	1.87
RI	4	251	1.59
SC	19	1,705	1.11
SD	4	313	1.28
TN	46	2,011	2.29
TX	133	7,413	1.79
UT	46	782	5.88
VA	50	2,182	2.29
VT	7	201	3.48
WA	118	1,824	6.47
WI	58	1,474	3.93
WV	14	728	1.92
WY	8	206	3.88
Total	2,233	89,550	2.49

Source: GAO analysis of Drug Enforcement Administration (DEA) data. | GAO-18-25

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Debra A. Draper (202) 512-7114 or draperd@gao.gov

Staff Acknowledgments

In addition to the contact name above, Elizabeth H. Curda (Director), Will Simerl (Assistant Director), Kathryn Richter (Analyst-In-Charge), Nick Bartine, Giselle Hicks, Jessica Lin, and Emily Wilson made key contributions to this report. Also contributing were Muriel Brown and Krister Friday.

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