



Audit of the Drug Enforcement Administration's Prescription Drug Take Back Activities



AUDIT DIVISION

20-114

SEPTEMBER 2020



Executive Summary

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Objective

The Drug Enforcement Administration (DEA) sponsors bi-annual drug Take Back Days to provide the public with a safe, convenient, and anonymous means for disposing of unused prescription drugs. The objective of this audit was to evaluate the DEA's policies, procedures, and practices for the collection, custody, and disposal of prescription drugs.

Results in Brief

The DEA reports that, since 2010, it has facilitated the collection and destruction of over 12 million pounds of unwanted and potentially dangerous pharmaceuticals through its Take Back Day activities. Additionally, law enforcement agency participation in Take Back Day events has increased approximately 64 percent over the same period. However, we found that the DEA could advance its Take Back Day events by conducting regular analysis of Take Back Day activities and results. Through such analysis, the DEA can better target its efforts to increase law enforcement agency participation and community awareness. The DEA should also enact other measures to improve law enforcement agency participation, particularly in areas with coverage gaps, to ensure that resources are devoted to areas with the most need.

Although we did not find evidence that collected drugs were lost, stolen, or misused during our testing, we found deficiencies in the DEA's practices in accounting for collected drugs that significantly increased the risk of such problems. For example, the DEA did not have adequate supporting documentation for nearly 70 percent of its reported collections or nearly 37 percent of its reported destructions for its April 2019 Take Back Day event. This occurred largely because the DEA did not have procedures sufficient to ensure accurate reporting.

Recommendations

Our report contains 10 recommendations to assist the DEA in improving its management and oversight of Take Back Day collection, custody, and disposal of prescription drugs.

Audit Results

Since the inception of Take Back Day in 2010, the DEA has facilitated 18 Take Back Day events at a cost of almost \$74 million. With the help of thousands of law enforcement agencies across the country, the DEA reports that it has collected over 12 million pounds of pharmaceuticals. In doing so, the DEA has provided a useful public service, but this audit revealed areas for improvement and ways to enhance the value of the program.

DEA Take Back Day Operations – When the DEA established the Take Back Day program, it was part of a multi-pronged federal approach to combat drug abuse in the United States. As part of that strategy, the DEA sought to supplement ongoing community prescription drug collection efforts by establishing biannual Take Back Day events and assisting law enforcement agency partners that host these events. We identified additional steps that the DEA can take to improve the reach of the program. For example, the DEA should analyze its historical Take Back Day results and incorporate Take Back Day events into other community outreach efforts. In addition, the DEA could use data that provides information on where prescription drug diversion and opioid use present the greatest challenge to identify locations that would most benefit from expanded efforts to encourage growth in those areas, which is an important step toward achieving the program's goals.

DEA Administration of Take Back Day Activities – Take Back Day events serve an important purpose. However, we found that the DEA's management and oversight of Take Back Day activities requires prompt corrective actions to ensure the safeguarding of and accounting for the collections and their disposal. In addition, the DEA should take actions to ensure that participating law enforcement agencies are following DEA guidance for Take Back Day events. Without such controls, the DEA cannot be certain that Take Back Day events are conducted as intended, and that collections are correctly reported and properly protected until destruction.

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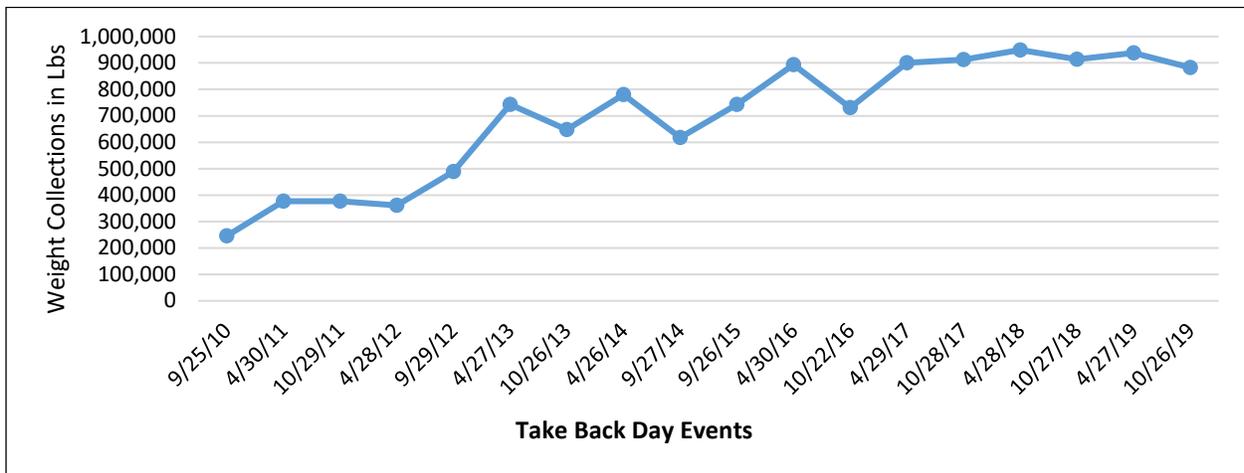
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INTRODUCTION

The DEA is responsible for organizing and facilitating prescription drug Take Back Day events nationwide. The DEA has reported that, since the inception of Take Back Day in 2010, over 12 million pounds of pharmaceuticals, including prescription drugs, non-prescription drugs, supplements, and other medications have been collected and disposed of through its sponsored Take Back Day events. In addition, the amount of collections has increased, from about 250,000 pounds during the first Take Back Day event in 2010 to an average of 916,000 pounds per event during 2017 through 2019, as shown in Figure 1 below. Through this program, the DEA is able to provide communities nationwide with an alternative to keeping expired and unused medications in their homes.

Figure 1
Take Back Day Collection Totals
September 2010 to October 2019



Source: OIG Analysis

Background

Several factors, including a growing concern over the effects that prescription drug and other toxic substance disposal is having on public health, led the DEA to establish and pursue national Take Back Days. Another contributing factor was the 2010 Office of National Drug Control Policy's National Drug Control Strategy (2010 Strategy), which discussed a multi-pronged approach to combatting drug abuse in the United States that involved communities, education, healthcare services, and law enforcement. One important element of the 2010 Strategy was encouraging community prescription drug take-back initiatives. Although many state and local law enforcement agencies were already conducting their own collections, the 2010 Strategy further motivated the DEA's efforts to establish Take Back Days nationwide.

Additionally, the passage of the Secure and Responsible Drug Disposal Act of 2010 (Act) enabled manufacturers, distributors, reverse distributors, retail pharmacies, hospitals and clinics with an on-site pharmacy, and narcotic treatment programs to become authorized collectors. The Act also permitted long-term care facilities to transfer unused and unwanted pharmaceutical controlled substances on behalf of residents and former residents of the facilities for disposal, and allowed prescription drug mail-back programs for consumers to return their unwanted prescription drugs to authorized entities.¹ Through the Act, the DEA was empowered to set guidance for these entities to develop a variety of methods of collection and disposal.

DEA and National Prescription Drugs Take Back Day

The DEA began facilitating Take Back Day events in September 2010 with the goal of providing a safe, convenient, and anonymous means for disposing of prescription drugs. Since that time, Take Back Day events have generally been held twice a year throughout the country.² The DEA has spent almost \$74 million on the program since 2010, excluding personnel costs for staff in the Diversion Control Division's (DCD) Liaison Section. This amount includes DEA field personnel costs, advertising expenses, Take Back Day supplies for law enforcement partners, collection destruction costs, and Take Back Day-related travel expenses for DEA personnel.

Within the DEA, Take Back Day activities are managed by the DCD's Liaison Section, which is responsible for establishing the date for Take Back Day, distribution of guidance, and compiling and reporting collection results. DEA's responsibilities regarding Take Back Day activities include coordinating and providing guidance to participating law enforcement agencies; receiving and recording Take Back Day collections; safeguarding, transporting, and destroying Take Back Day collections; and reporting the agency's Take Back Day results. The DEA also provides disposable Take Back Day collection receptacles and makes a variety of advertising materials available to local law enforcement for promoting their event, such as the graphic in Figure 2.³

¹ A "controlled substance" is a drug or other substance, or immediate precursor, which has been classified into one of five distinct categories or schedules based on the drug's acceptable medical use and the drug's abuse or dependency potential.

² Aside from 2010, in 2015, only one Take Back Day event was held, on September 26, 2015. The April 2020 event was postponed due to the coronavirus pandemic.

³ The Take Back Day receptacles are disposable cardboard boxes and are different from the drug receptacles maintained at permanent collection sites.

Figure 2
2019 DEA Take Back Day Advertising Graphic



Source: DEA

On Take Back Day, the public is invited to turn in any expired, unused, or otherwise unwanted prescription drugs for disposal at collection sites across the country. Specifically, upon arriving at the collection site, individuals deposit their medicines into the Take Back Day collection receptacles.⁴ DEA guidance states that neither the individual dropping off for disposal nor the items being disposed of are to be identified. After each Take Back Day event law enforcement agencies turn over the collections to a local DEA office, which usually occurs either directly following the event or on the following Monday. Upon receipt of the collections from law enforcement agencies, DEA personnel are required to document the exchange via a Form DEA-12, "Receipt for Cash or Other Items" (DEA-12). DEA personnel safeguard and then transport the collections to an authorized destruction site to be destroyed. Field Division Offices report their collection totals to DEA HQ, which in turn summarizes and releases Take Back Day results.

OIG Audit Approach

The objective of our audit was to evaluate the DEA's policies, procedures, and practices for the collection, custody, and disposal of prescription drugs. The scope of our audit generally included the DEA's Take Back Day activities in fiscal year 2019, unless otherwise stated, and a review of the DEA's management of Take Back Days including collection results, destruction records, law enforcement participation, public outreach, and policies and procedures.

To accomplish the audit objective, we interviewed DEA personnel, including officials from the DCD's Liaison Section and Diversion Planning and Resources, and DEA's Office of Congressional and Public Affairs at DEA headquarters in Arlington, Virginia, as well as DEA personnel in field offices in Oakland, Riverside, and San Francisco, California and Washington, D.C. We observed Take Back Day events and the destruction of Take Back Day collections in California; and conducted a review

⁴ According to the DEA, syringes, injectable medicines, medicinal inhalers, or intra-venous solutions are not accepted and included in Take Back Day collections. However, some law enforcement agencies provide separate disposal options for these items in conjunction with Take Back Day.

and analysis of DEA reported collections data, collection records, and destruction documentation. We also reviewed DEA's policies and procedures for planning and managing Take Back Day events and activities.

AUDIT RESULTS

The DEA provides a public service by facilitating the collection and destruction of potentially dangerous prescription drugs and other pharmaceuticals. Participation from law enforcement agencies in Take Back Day events has increased approximately 64 percent since the first Take Back Day in 2010 to the most recent event in October 2019. However, we found that the DEA has an opportunity to further advance its Take Back Day program. To do so, the DEA should conduct regular analysis of Take Back Day activities and results to identify coverage gaps and areas for improvement, ensure the accuracy of collection results, track and maintain documentation to support the destruction of collected items, and create and implement policies and procedures to ensure consistent implementation and sufficient accountability of collections and disposal. An analysis such as this could also provide insight into how Take Back Day efforts might benefit other DEA diversion program activities. We also found that the DEA can improve the program by identifying underserved areas and increasing efforts to expand law enforcement agency participation in Take Back Day.

During our audit, we additionally identified weaknesses with DEA's record retention, support for collection totals, and the security and destruction of collections. We further identified privacy risks for persons who participate in Take Back Day events. The DEA must establish adequate Take Back Day procedures for DEA personnel and participating law enforcement agencies to correct these issues.

DEA Take Back Day Operations

The DEA's Take Back Day operations rely on participation from both local law enforcement and the public. The DEA's ability to perform effective outreach for these events, assess law enforcement participation, and analyze external factors affecting both the public's and local law enforcements' participation are important to the DEA's goals for its drug Take Back Day program.

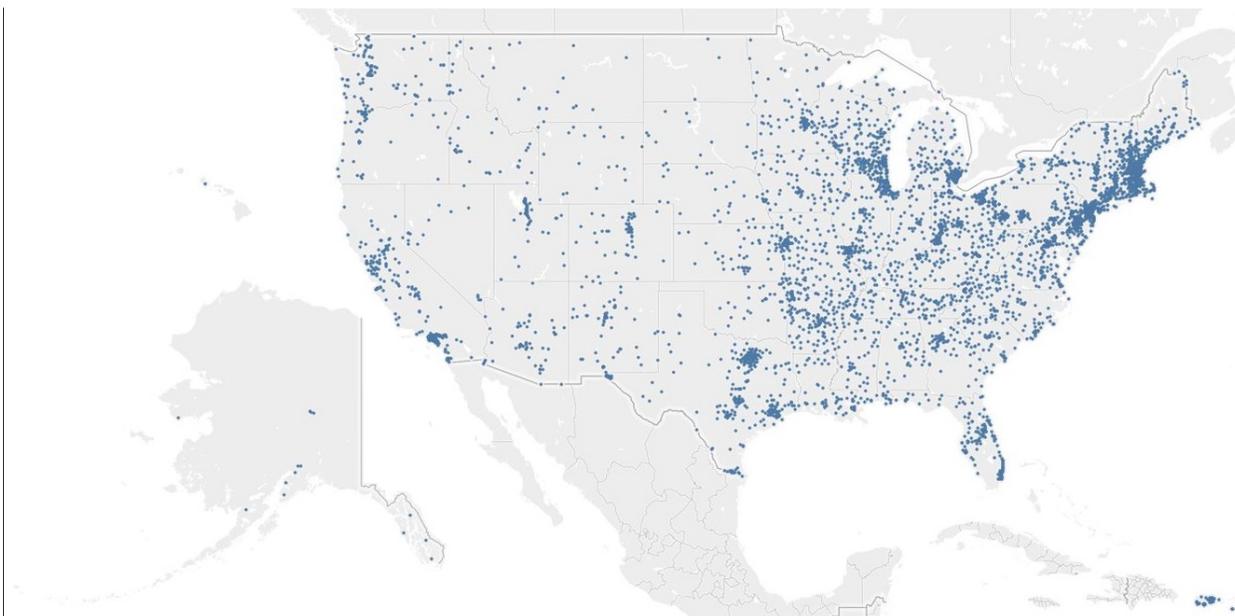
Expanding Participation and Eliminating Coverage Gaps

After each Take Back Day event, the DEA compiles Take Back Day results. Specifically, the DEA tallies and makes available, in total and by state, the collection weights, the number of participating law enforcement agencies, and the number of collection sites. However, the DEA has not used this data in conjunction with other data generally available to identify trends and opportunities or to perform other analysis in furtherance of future Take Back Day events or DEA's broader diversion control efforts. For example, data on law enforcement participation during the October 2019 Take Back Day indicated that 27 percent of all law enforcement agencies participated in the event. DEA officials offered several reasons to explain the participation level, including limited local law enforcement resources and challenges presented by a law enforcement agency's location, such as the remoteness of its community.

Figure 3 illustrates the registered participating law enforcement agencies as recorded by the DEA. As the map demonstrates, there are large gaps in coverage

in many parts of the country, notably the Midwest. While the number of participating law enforcement agencies positively correlated to a state's population, we found no correlation between the rate of participation in a state and the state's population. We did not see comparable analysis from the DEA of its Take Back Day operations. By performing similar and frequent analysis using all available data and information, the DEA will gain an understanding of coverage gaps to guide its efforts to expand participation in Take Back Day events.

Figure 3
Registered Law Enforcement Agency Participants
October 2019 Take Back Day

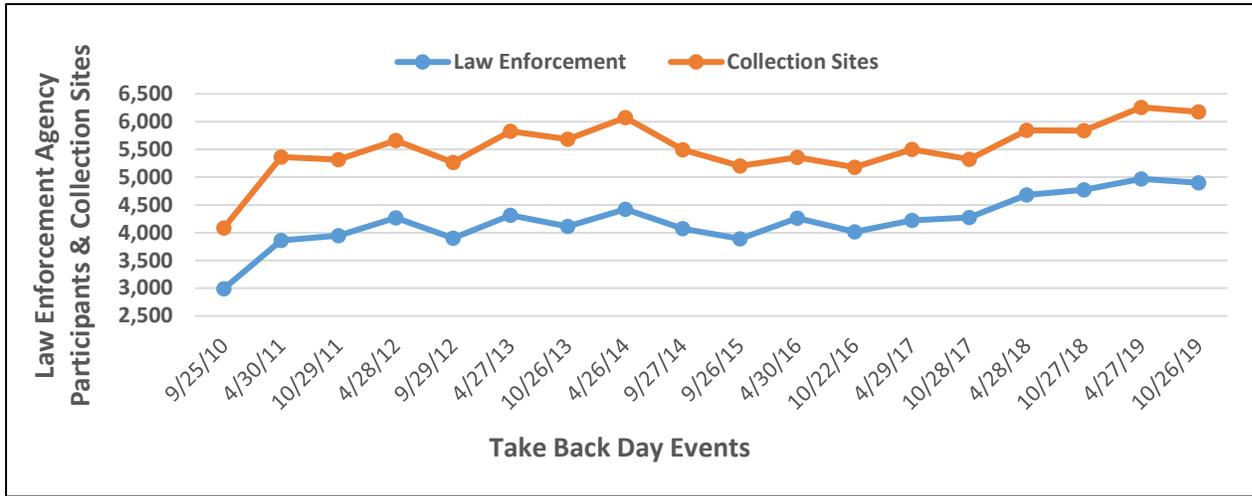


Source: OIG analysis of DEA Take Back Day data

Encouraging Law Enforcement Participation

State and local law enforcement participation is an essential component of Take Back Day events. Specifically, law enforcement agencies host local collection sites, advertise and market Take Back Day events, and encourage community participation. Without the efforts and resources of law enforcement, the reach of Take Back Day events would be greatly diminished. According to DEA data and as shown in Figure 4 below, law enforcement agency participation in Take Back Day events has increased approximately 64 percent since the first Take Back Day in 2010 (from 2,992 participating agencies in September 2010 to 4,896 participating agencies in October 2019). Additionally, the number of collection sites has had an overall increase of 51 percent during this time period.

Figure 4
Law Enforcement Agency Participation and Collection Sites
September 2010 to October 2019



Source: OIG Analysis

Although the number of participating agencies and collection sites have increased over time, as stated previously, total participation in October 2019 represented 27 percent of the nearly 18,000 law enforcement agencies in the country. We identified several aspects of the DEA's approach to Take Back Day outreach that we believe may limit the number of law enforcement agencies participating in Take Back Day events. For example, each DEA Field Division Office is required to assign a point of contact for each Take Back Day event, but this individual is not provided with procedures or guidance from DEA headquarters for conducting outreach to law enforcement agencies to increase participation in the events. DEA headquarters officials told us that rather than dictating outreach requirements to the Division Offices, the Division Offices make their own outreach determinations because individual offices are in the best position to determine the outreach needed to encourage law enforcement agency participation in their area of responsibility. However, as we noted above, the DEA does not provide Division Offices with data and other information to assist Division Offices outreach strategy and activities.⁵ We also found that Take Back Day points of contact only are required to reach out to law enforcement agencies who have already signaled intentions to participate in a Take Back Day event. We believe that this passive process risks conveying to Division Offices that outreach to law enforcement agencies is not a necessary and important part of Take Back Day event planning. Therefore, we recommend that the DEA improve Take Back Day outreach guidance and information provided to its Division Offices to encourage and increase law enforcement agency participation.

⁵ After our exit conference with the DEA, in August 2020, the DEA stated that it had supplied participation maps to Division Offices in 2018, and provided a participation map for one Division Offices.

Permanent Prescription Drugs Disposal Options

The DEA told us that some law enforcement agencies choose not to participate in Take Back Days because other resources for disposing prescription drugs, such as permanent prescription drug collection boxes, are available year-round. While permanent collection boxes provide another way for individuals to dispose of their unwanted prescriptions drugs, the DEA has limited information on these permanent collection boxes. A DEA official stated that it requires this information only of its registrants, such as hospitals and pharmacies, and does not have the authority to request this information from law enforcement agencies. However, not having this information potentially affects the DEA's ability to effectively allocate its limited resources for Take Back Day events.

The potential underlying effect of permanent collection boxes, as well as analysis of participation trends related to Take Back Day, provides an opportunity for the DEA to collect and analyze data for maximizing the impact of Take Back Day events. Having a comprehensive list of the permanent collection locations could potentially help the DEA improve its community outreach on Take Back Day events and other disposal options. Take Back Day data also has the potential to gauge the interest of communities in drug take back efforts. All of this information could be considered as part of the DEA's three-pronged approach to combat heroin and opioid use: law enforcement, diversion control, and community outreach.⁶ Given that DEA's 2018 Drug Threat Assessment stated that controlled prescription drug availability and abuse will continue to pose a significant threat to the United States, the DEA should consider how Take Back Day can play a more integrated role in its overall efforts.

We further believe that the DEA should explore taking actions to improve the public's access to complete collection site information. We determined that the potential for greater analysis and transparency of information is inhibited by the DEA not knowing where law enforcement agencies across the nation maintain permanent collection sites, and we observed that neither DEA's own search utility nor other public locator tools contain all permanent collection sites maintained by law enforcement agencies.⁷ Therefore, we recommend that the DEA perform regular analysis of Take Back Day activities in conjunction with available and applicable data from within the DEA or external sources, to identify strategies for

⁶ This three-pronged approach is the DEA's 360 Strategy, which was implemented by the DEA in November 2015. In September 2020, the DOJ OIG issued its report on the Audit of the Drug Enforcement Administration's Community-Based Efforts to Combat the Opioid Crisis, that include its review of DEA's 360 Strategy.

⁷ DEA's Controlled Substance Public Disposal Locations Search Utility is a directory including pharmacies, hospitals, and other medical offices that are authorized by the DEA to collect prescription drugs.

For example, the National Association of Boards of Pharmacy Drug Disposal Locator Tool contains some, but may not be a complete list of, permanent collection site locations maintained by law enforcement agencies. This is voluntary as a law enforcement agency needs to submit a request for inclusion into this locator database.

expanding Take Back Day participation, minimizing coverage gaps, and better informing the public of all prescription drug disposal options.

Public Outreach

To increase public awareness of Take Back Day events, the DEA has spent over \$37 million on advertising expenses, which represents over half of all Take Back Day expenses through October 2019. DEA's Take Back Day advertising campaigns have included a broad range of promotional activities on national and regional levels, including advertising on television, radio, newspaper, social media, and other communication platforms. Beginning in October 2017, the DEA substantially increased its spending on advertising for Take Back Day events, including production costs of a public service announcement, as well as expanded and targeted advertising efforts through various mediums. The DEA's Chief of Staff, Office of Congressional and Public Affairs, told us that this was done in response to heightened interest by the White House in seeing the DEA expand its efforts to combat opioid abuse. Prior to October 2017, the DEA spent an average of \$1.5 million for each event. Since October 2017, the DEA spent over \$3.2 million for each Take Back Day event, with a high of \$4.1 million in April 2018. While the DEA's data does not show an increase in the amount of Take Back Day collections following the spending increase in advertising (compare Figure 1, on page 1, with Table 1, below), we recognize that not all benefits can be measured through recorded collection totals. For example, we found that the increased advertising had consistently increased traffic to DEA's Take Back Day website, which indicates that more people obtained information on prescription drug disposal options.

Table 1

Take Back Day Advertising Expense Totals

Event	Expenses
Average of Prior Events	\$1.5 million
October 2017	\$3.2 million
April 2018	\$4.1 million
October 2018	\$3.5 million
April 2019	\$3.5 million
October 2019	\$4.0 million

Source: OIG Analysis

DEA Administration of Take Back Day Activities

The DEA's Take Back Day responsibilities include managing all aspects of planning and organizing the events in partnership with other law enforcement agencies, facilitating the receipt of collections from law enforcement agencies, ultimately destroying Take Back Day collections, and reporting Take Back Day results. The DEA also provides guidance to DEA personnel regarding Take Back Day activities and to participating law enforcement agencies on conducting Take Back Day events. We identified weaknesses in multiple areas related to the DEA's administration and management of Take Back Day activities that necessitate the DEA taking corrective action to improve certain policy, procedures, and practices.

Support for April 2019 Take Back Day Collections and Destruction

DEA policy governing Take Back Day activities requires that DEA personnel document the receipt of Take Back Day collections from law enforcement agencies on a Form DEA-12, "Receipt for Cash or Other Items" (DEA-12) and to maintain these DEA-12s. While the policy further requires that DEA personnel witness the destruction of the collections, it has no similar requirement to document the destruction. The DEA was able to provide some supporting documentation for both the collections and the destructions; however, our audit uncovered that the DEA requires significant improvement in this area. As we will discuss below and as shown in Table 2, the DEA cannot support that it has accurately reported its collections.

Table 2

OIG Reconciliation of DEA Reported April 2019 Take Back Day Collections to DEA Supporting Records on Collection and Destruction

	Division Office	Collections Reported by the DEA	Collection		Destruction	
			Supported	Unsupported	Supported	Unsupported
1	Atlanta	31,907	76	31,831	17,728	14,179
2	Caribbean ^a	3,003	0	3,003	0	3,003
3	Chicago ^b	109,484	27,029*	82,456*	0	109,484
4	Dallas	46,729	3,416	43,313	46,560	169
5	Denver	40,027	6,073	33,954	14,020	26,007
6	Detroit	74,514	12,340	62,174	76,930	(2,416)
7	El Paso ^a	11,888	7,160	4,728	0	11,888
8	Houston	46,758	552	46,206	38,972	7,786
9	Los Angeles	37,892	18,822	19,070	7,287	30,605
10	Louisville	40,844	30,199	10,645	40,400	444
11	Miami	35,775	8,936	26,839	33,440	2,335
12	New England	89,367	37,664	51,703	62,260	27,107
13	New Jersey	16,127	16,297	(170)	35,560	(19,433)
14	New Orleans ^a	45,672	15,410	30,262	0	45,672
15	New York	42,565	5,540	37,025	44,720	(2,155)
16	Omaha	32,713	9,098	23,615	39,120	(6,407)
17	Philadelphia	44,133	7,512	36,621	21,440	22,693
18	Phoenix	10,915	10,612	303	10,820	95
19	San Diego ^a	18,074	0	18,074	0	18,074
20	San Francisco	25,276	17,389	7,887	28,920	(3,644)
21	Seattle	37,826	747	37,079	18,740	19,086
22	St. Louis	58,711	29,188	29,523	37,380	21,331
23	Washington, D.C.	37,243	21,873	15,370	16,600	20,643
	Total (in pounds)	937,443	285,933*	651,511*	590,897	346,546

^a These DOs could not provide destruction documentation with sufficient details.

^b This DO could not provide any form of destruction support.

* Differences in the cross-footing of columns are due to rounding.

Source: OIG Analysis

Take Back Day Collections

After each Take Back Day, participating law enforcement agencies are required to turn over their collections to the DEA for destruction. Responsible DEA personnel are to document the receipt of these collections on a DEA-12, which acts as a chain of custody record for the collected drugs transferred from law enforcement agencies into DEA custody. The DEA also uses the DEA-12s as its primary source for compiling Take Back Day collection data.

The DEA Division Offices receiving the collections from law enforcement agencies are required to retain copies of all completed DEA-12s in a designated file for each event. To determine if the overall and individual Division Office collection totals for the April 2019 Take Back Day event were accurate and supported, we requested copies of all the DEA-12s issued to law enforcement agencies during the April 2019 Take Back Day event, for which the DEA reports that 4,969 law enforcement agencies participated. In response to our request, the DEA provided 2,598 DEA-12s, representing collections from just over half of the participating law enforcement agencies. DEA officials stated that DEA-12s were not always issued or retained by the Division Offices.

By failing to issue the DEA-12 initially or not retain the DEA-12s, Division Offices did not follow DEA Take Back Day policy. Take Back Day policy requires an event-specific memorandum (“waiver”), issued by the DCD’s Assistant Administrator, that waives requirements to follow the DEA’s evidence collection protocol, for Take Back Day. This waiver is the primary directive for the Take Back Day events. The waiver specifies that the number and weight of the boxes should be recorded before DEA personnel take custody of the collections. However, we found that many DEA-12s did not contain the number of boxes collected or the weight of collections, or both. We discuss our concerns with the waiver later in the report.

As represented in Table 2 above, for the April 2019 Take Back Day we determined that the DEA could not support nearly 70 percent of its total reported weight from Take Back Day collections and nearly 37 percent of its reported destructions. Without documentation, the DEA cannot definitively support the amount of prescription drugs it reportedly received and destroyed. Further, this inhibits DEA’s ability to account for the stated “weight” of collections as a measure of program accomplishment.

Although we did not find evidence that collections were lost, stolen, or misused during our testing, for the DEA-12s that were completed and retained, we found significant deficiencies with the manner in which DEA representatives completed the DEA-12s. Missing elements on the DEA-12s and inconsistencies in completion of the forms among the Division Offices contributed greatly to the discrepancies we identified. Specifically, we found that 924 of the 2,598 DEA-12s that the DEA provided us were issued outside of the Take Back Day activity period, could not be attributed to an external law enforcement agency or DEA-hosted collection site, or did not contain required details, such as the weight of collections

and the name of the receiving DEA office.⁸ Without sufficiently completed DEA-12s, the DEA cannot support the collection totals it reportedly received, thereby leaving thousands of dangerous pharmaceuticals unaccounted.

Because the Take Back Day policy waives standard DEA drug evidence collection requirements, it is imperative that the Take Back Day-specific requirements for completing the form are followed. Additionally, the usefulness of the DEA-12 as a control against loss and theft is greatly diminished if required information is not recorded. As a result of the DEA not following its policy for recording and tracking its Take Back Day collections, the DEA is unable to support the totals it has reported on the number of pounds of prescription drugs it has collected. Therefore, we recommend that the DEA ensure that the DEA-12s for the Take Back Day events are completed; include all required data elements, such as the date, weight of collections, number of boxes the DEA received, and recipient and witness signatures; and maintained in accordance with Take Back Day policy and DEA procedures.

Take Back Day Destructions

Ensuring that the potentially dangerous drugs and substances that are collected during Take Back Day events are ultimately destroyed is important in eliminating any risks of diversion through loss, theft, or illegitimate use of the drugs and substances. According to 21 C.F.R. §1317.65 and §1317.90, the prescription drugs collected during Take Back Day events must be rendered non-retrievable as a result of the destruction process. Although a DEA official stated that all Take Back Day collections are destroyed, the DEA lacks support to confirm it has done so.

The importance of retaining destruction records to illustrate that collections have been destroyed cannot be overstated. Without such proof, the DEA cannot demonstrate that it has effectively eliminated the risk of diversion and complied with federal regulations. Currently, Take Back Day policy does not specify what type of documentation should be maintained in order to verify the destruction of Take Back Day collections. In fact, the DEA does not require that Division Offices retain any record verifying the destruction of Take Back Day collections. Therefore, in response to our request for April 2019 Take Back Day destruction records, we were provided a variety of documents, including receipts from destruction sites, emails, memorandums, DEA-12s, Form DEA-19 "Requisition for Equipment, Supplies, or Services," and internal spreadsheets. Based on our review of the

⁸ For purposes of our reconciliation testing, we assessed whether: (1) the DEA-12 form was dated within the Take Back Day activity period, (2) the collection was attributable to an external agency site or a DEA-hosted site, (3) the collection weight was included, and (4) the receiving DEA office was identified. Although we noted that many forms were missing other information, we considered these four information points as the minimum required to tie a DEA-12 to a Take Back Day event and results. Specifically, 224 DEA-12s were issued outside of the Take Back Day activity period, 113 of the DEA-12s we reviewed were issued internally and could not be attributed to an external law enforcement agency or DEA-managed collection site, 291 DEA-12s did not include or we could not determine the weight of the collections, and 354 DEA-12s did not identify the receiving DEA office. Due to multiple instances in which more than one of the four elements was missing, the sum of these numbers does not equal 924.

documentation provided and as shown above in Table 2, we found that the DEA could not provide sufficient evidence to support the destruction of reported collections for any of its 23 Division Offices. Specifically, 4 Division Offices provided inadequate forms of documentation to support destruction; 18 Division Offices were unable to provide documentation that fully supported the destruction of their reported collections; and 1 Division Office could not provide any form of destruction support at all.⁹ In addition, we found discrepancies between reported collection totals and destruction totals for all Division Offices, including a few instances in which Division Offices reportedly destroyed more collections than they reported receiving.

Moreover, DEA's Take Back Day procedures require that DEA personnel transport the Take Back Day collections received from law enforcement agencies to a destruction site to be destroyed. While reviewing destruction documentation, however, we found evidence that at least two Division Offices allowed some law enforcement agency participants to transport Take Back Day collections directly to authorized commercial destruction sites, without DEA personnel being present. We recognize that it may be impractical for some remotely located law enforcement agencies to transfer collections to the DEA for destruction and that alternative solutions may be required. Therefore, we believe it is prudent for the DEA to consider adding language to Take Back Day policy that outlines actions to be taken in the event of deviations from the established policy, including controls sufficient to demonstrate its compliance to the federal regulations requiring it to ensure the collected drugs are rendered non-retrievable.

Without documentation supporting the entire process, the DEA cannot demonstrate its control over the destruction of prescription drugs and other substances collected during its Take Back Day events. During our audit, the DEA revised Take Back Day policy to more clearly state that destruction records must be retained. However, the Take Back Day policy still does not specify what the DEA considers to be an appropriate destruction record. Therefore, we recommend that the DEA strengthen existing record retention policy for Take Back Day events to specifically state what forms of documentation should be retained and what information must be included on the documentation to support the destruction of Take Back Day collections.

Timeliness of April 2019 Take Back Day Collections Destruction

According to the waiver, Take Back Day collections are required to be destroyed within the waiver period after each Take Back Day event. The primary source of guidance for DEA personnel related to a Take Back Day event is provided in a memorandum that is issued for each event. This memorandum (the waiver) waives compliance with specific DEA requirements and procedures pertaining to processing, tracking, reporting on drug evidence, and maintaining custody of evidence for prosecution purposes; and it establishes a waiver period for each event. Therefore, the time lapse between a Take Back Day event and the

⁹ We generally accepted destruction site receipts if they included both the date and weight destroyed.

destruction of the Take Back Day collections is potentially significant as it determines what procedures must be followed.

For example, the waiver for the April 2019 Take Back Day was valid from April 24, 2019, to May 17, 2019. A DEA official explained that all Take Back Day activities, including destruction, must be completed by the end of the waiver period. Of the 18 Division Offices that provided documentation for the April 2019 Take Back Day event, we found that 6 Division Offices reported that they completed destruction after May 17, 2019. Table 3 shows how many days these six Division Offices were tardy.

Table 3
April 2019 Take Back Day Collections Held Past Waiver Timeframe

	Division Office	Number of Days Held Past Waiver
1	Denver	4
2	Louisville	5
3	New York	35
4	Houston	40
5	Phoenix	41
6	Seattle	41

Source: OIG Analysis

While we were not informed of and did not find indication of any losses of Take Back Day collections, retaining collections beyond the timeframes established by the waiver increases the opportunity for collections to be mishandled or misplaced. Our concern with this risk is increased when compounded with the DEA’s unreliable support for Take Back Day collections and destructions. Further, establishing and documenting destruction expectations minimizes operational inconsistencies among the Division Offices, such as the Division Office instructing its law enforcement partners to manage destruction, as discussed above, and ensures that DEA personnel comply with established policies and protocols. Therefore, we recommend that the DEA implement controls to monitor its field offices’ compliance with established Take Back Day deadlines for the destruction of collections.

Take Back Day Performance Metrics Analysis

The DEA reports Take Back Day event results nationally and by state in three areas: (1) “total weight collected,” (2) number of participating law enforcement agencies, and (3) number of collection sites. The DEA releases Take Back Day results through various platforms for internal and external use. Specifically, DEA Headquarters and Division Offices issue press releases with collection details and post this information to the DEA’s public website and to the Take Back Day website.

However, as discussed previously, these reported totals are not supported. Further, the DEA reports its results as “total weight collected.” We found that the “total weight collected” results do not accurately reflect the amount of prescription drugs removed from circulation because, due to the anonymous nature of the

event, the collections inevitably may include an unknown quantity of non-prescription drugs, supplements, and packaging materials. A DEA official confirmed that the DEA does not adjust Take Back Day collection totals, or qualify public statements and reported totals, to account for these other items. While collecting unwanted or expired non-prescription medicines is unquestionably beneficial to the public and a prudent safety measure, we believe that the DEA should be more transparent and precise about what is included in the collection weight when reporting Take Back Day event results. Therefore, we recommend that the DEA ensure that reported collection results clearly state that materials other than prescription drugs may be included in the totals.

Further, the DEA compiles and publicly reports on the number of participating law enforcement agencies from Take Back Day event registration information, not from information on actual participation and collection site locations. Therefore, the actual number of participating agencies and collections sites may differ from the information that the DEA reports. To improve the accuracy of these reported metrics, the DEA should compile and release law enforcement participation and collection site location data based on the DEA-12s issued to the law enforcement agencies, as this would provide actual rather than anticipated participation.

In addition to improving the accuracy of reported performance metrics, the DEA can learn a great deal about Take Back Day activities by analyzing law enforcement participation and other information. DEA officials told us that the DEA had not conducted any analysis of Take Back Day data to identify trends, correlations, or outliers to assess its Take Back Day efforts. Further, DEA officials confirmed that they had not analyzed Take Back Day results or data in relation to drug usage or abuse information. Analyzing Take Back Day data in conjunction with other drug-related information could potentially allow the DEA to identify locations where increased Take Back Day participation could help reduce the amount of prescription drugs and other substances available for illegitimate use and abuse. We recommend that the DEA assess Take Back Day performance data in conjunction with other available data to provide multi-dimensional performance results to its law enforcement partners and the public, and for its own purposes in administering the program.

Review and DEA HQ Oversight

One likely factor contributing to the inaccurately-reported and unsupported Take Back Day collections data is the lack of any requirement for DEA Division representatives or DEA headquarters to verify reported Division Office Take Back Day collection results and subsequent destruction. Rather, DEA Division Offices record collection weights through a variety of methods and then report the total weight collected to DEA headquarters, without any verification. In addition, the Division Offices do not, and are not required to, report or confirm that Take Back Day collections have been destroyed. We believe that even a simple comparison of DEA-12s to reported collection totals, such as the comparison we conducted for the April 2019 event, would help reveal possible discrepancies and enable the DEA to make any needed adjustments to ensure that the reported collection and destruction results are accurate and supported. This also would help to minimize

the risk of Take Back Day collections being diverted for illicit use. Therefore, we recommend that the DEA establish reasonable procedures to verify the accuracy of reported Take Back Day collection totals and the subsequent destruction of the collections.

DEA Policy and Procedures for Take Back Day Activities

Rather than incorporating specific Take Back Day activities into its formal policy manuals, the DEA relies on the Take Back Day memorandum (“the waiver”) to plan for and manage the Take Back Day activities.¹⁰ However, throughout our audit and particularly during our detailed review of DEA-12s and destruction records for the April 2019 Take Back Day event, we noted several issues related to ambiguous language, missing or incomplete guidance, inconsistent application of the waiver among the Division Offices, and the security of Take Back Day collections. We believe that these issues may have been mitigated if the DEA had clearly documented and established Take Back Day policies and procedures.

Take Back Day Waiver

As of December 2019, the DEA had issued 17 event-specific waivers since it began facilitating Take Back Day events in 2010.¹¹ We reviewed each of the waivers and found that all 17 shared the following commonalities: (1) promoted a “no questions asked” approach to Take Back Day events; (2) established a specified waiver period; (3) waived requirements from the Special Agents Manual, Section 6662, addressing the acquisition of controlled substances; (4) specified procedures for documenting the receipt of Take Back Day collections from law enforcement agencies, including what information should be recorded on a DEA-12; and (5) required that DEA-12s be retained and kept on file for each Take Back Day.

The DEA made the following substantial revisions to the standard waiver in March 2016: (1) eliminated a waiver to Section 5171 of the DEA Diversion Investigator’s Manual regarding destruction procedures of received controlled substances because the section was no longer valid DEA-wide, (2) extended the length of the waiver period, (3) specified that a minimum of two DEA personnel were to take custody of Take Back Day collections, and (4) added requirements for Take Back Day collections that are stored in drug vaults.

In September 2019, while our audit was ongoing, the DEA again made significant revisions to the waiver. The revisions included language changes regarding information to be included on the DEA-12s, strengthening record retention requirements, removing the requirement that two DEA staff members witness the disposal of Take Back Day collections, and prohibiting Division Offices from storing Take Back Day collections in their drug vaults. The September 2019

¹⁰ The DEA has issued a period-specific waiver for each event, except for the first Take Back Day event held in 2010.

¹¹ The DEA did not issue a waiver for the first Take Back Day event in September 2010.

waiver revisions also established a requirement for Division Offices to scan all DEA-12s into DEA's IMPACT case management system.

When we provided the DEA with some of our audit findings related to the waiver, DEA officials stated that they believed the September 2019 revisions to the waiver addressed many of the waiver-related issues we found. Therefore, we reviewed the new waiver language and a judgmental sample of 115 DEA-12s issued during the October 2019 Take Back Day event to determine if DEA Division Offices improved their completion of the DEA-12s. We analyzed each form for the following seven pieces of information: (1) date, (2) external agency or DEA-hosted site, (3) collection weight, (4) receiving DEA office, (5) number of boxes recorded, (6) receiver printed name and signature, and (7) witness signature. Overall, we found that 44 of the 115 DEA-12's reviewed were not sufficiently completed and lacked at least 1 of the elements we tested. In 11 instances, the DEA-12s we reviewed lacked more than one element.

Policy Omissions

While we are encouraged by the DEA's willingness to address our concerns with the waiver, the September 2019 language changes do not fully address our concerns. Further, as we discuss above, the results of our limited testing of the October 2019 DEA-12s indicate that DEA personnel are still not preparing the forms in an adequate manner. The DEA can benefit from further waiver revisions or additional policy development. We identified the following areas that require further attention:

- The DEA removed the requirement for two DEA staff to witness the disposal of Take Back Day collection from the waiver. Requiring multiple DEA parties to witness the destruction helps ensure that the Take Back Day collections are ultimately destroyed and not diverted to further use. We believe that requiring Take Back Day collection disposal to be witnessed by at least two DEA staff is a critical security control that should be reestablished, especially in light of the deficiencies concerning Take Back Day collection disposal that are documented in this report.
- Although the updated waiver now indicates that "all records, including DEA-12s, be maintained throughout the Take Back Day process, from DEA's receipt to the destruction," the language is still not definitive enough. Without identifying what type of documentation is required for each step in the process, the DEA cannot support its reported collections and its claim that all collections have been destroyed. The guidance must also state what forms of documentation must be retained for each step in the process.
- The waiver states that "the number and weight of all containers collected from each and every collection site must be documented on Form DEA-12." However, while this change may improve DEA's Take Back Day collection reporting and better support its results, it does not ensure that DEA personnel will complete the DEA-12 in its entirety as reflected in our testing of October 2019 DEA-12s. The DEA's guidance must also stress the importance of the DEA-12 as a support document for Take Back Day events

and of fully and accurately completing it in accordance with the waiver and other DEA policy. Also, as described above, we believe that establishing oversight responsibility locally or at the HQ level would assist in improving the accuracy and completeness of the documentation.

- While the waiver stated that any deviations from the waiver must be approved prior to Take Back Day, it does not address deviations that may be required after the event has occurred, such as delays in destruction. Since the waiver is valid only for a specific timeframe, the DEA must clearly state that approval for deviations from the waiver after the event has occurred, including any delays in destruction, should be requested, obtained, documented, and retained.
- The waiver should provide for instances where it is not possible for the DEA to take possession of Take Back Day collections from law enforcement agencies. The waiver should specify what those circumstances are and what alternate procedures should be used to ensure the destruction is appropriately witnessed and documented by law enforcement personnel.

During our exit conference with the DEA, in August 2020, DEA officials stated that they have further revised the waiver, and that it has not yet been approved or disseminated. Therefore, in addition to the specific recommendations to Take Back Day operations and policies stated above, we recommend that the DEA enhance Take Back Day procedures to include all processes, and consider the utility of documenting Take Back Day collection activity procedures into its procedures manuals, as well as continued dissemination of the Take Back Day procedures through the waiver and electronic communications.

Guidance to Law Enforcement Agency Partners

Given the scale of Take Back Day, it is unrealistic for DEA personnel to be present at all Take Back Day events. For example, there were 6,174 collection sites for the October 2019 event. Therefore, in the absence of direct supervision by DEA personnel to ensure that the privacy of members of the public participating in Take Back Day is protected, and to safeguard collections against theft, the DEA developed procedures to guide participating law enforcement agencies.

In 2010 the DEA created the Take Back Day Collection Site Protocol (CSP) for law enforcement agencies to follow during Take Back Day events. According to DEA officials, the CSP documents procedures that must be followed by participating law enforcement agencies during the events. For example, the CSP states that law enforcement should protect the anonymity of individuals disposing of medications, remain with drug disposal boxes at all times, and make no effort to inventory or log medications. Additionally, the CSP states that all participants must retain possession of their own medication during the surrender process, and that law enforcement representatives should not handle the medications at any time.

During our observations of Take Back Day events, we noted four examples of local law enforcement representatives not adhering to the CSP at two of the five collection sites we visited. Specifically, at two locations, we saw local law

enforcement officers receive collections directly from the public instead of directing individuals to deposit their collections into the collection box. At one of the two locations, we also observed local law enforcement representatives asking individuals where they lived when receiving collections, and sorting through collections before placing them into the collection boxes. Each of these practices is contrary to the CSP. While law enforcement representatives may have been merely assisting by placing the drugs into the receptacles or compiling geographical data for future event planning, these practices potentially raise privacy concerns and may deter the public's participation in the event. When we brought these instances to the DEA's attention, DEA officials voiced concern and stated that these practices should not be occurring because anonymity of the participant and collected substance, are central elements of Take Back Day. DEA officials also stated that the only way that it would be aware of any mishandling of collections would be if it were reported. Therefore, we recommend that the DEA enhance the CSP and emphasize the requirement that all participating law enforcement agencies adhere to the CSP in order to preserve the privacy of the public who are disposing of medications during Take Back Day events.

CONCLUSION AND RECOMMENDATIONS

The DEA has stated that over 12 million pounds of pharmaceuticals, including prescription drugs, non-prescription drugs, supplements, and other medications, have been collected since the inception of the Take Back Day program in 2010. These events have provided an important public service to individuals who may otherwise have retained dangerous and addictive medicines in their homes or disposed of toxic substances in ways that create risks to public safety. The events also potentially assist the DEA in its efforts to prevent the diversion of prescription drugs and other substances for illicit sale and use.

Through our audit, we identified improvements for the DEA to consider in enhancing the management of its Take Back Day program and its publicly-released results. Specifically, we found that the DEA has an opportunity to advance its Take Back Day program and have greater impact if it were to conduct analysis of Take Back Day activities and results to identify Take Back Day coverage gaps, encourage continued and increased law enforcement participation, improve the public's access to information about prescription drug disposal options, and ensure the accuracy of Take Back Day collection results. We also found that the DEA needs to improve its policies and procedures for Take Back Day events, including its efforts to track and maintain documentation of collection and destruction activities, as the safeguarding and proper destruction of collected drugs and substances are integral to the success of the Take Back Day program and the safety of the communities in which the events occur.

Therefore, we make 10 recommendations to assist the DEA in improving its management and oversight of its Take Back Day events.

We recommend that the DEA:

1. Improve Take Back Day outreach guidance and information provided to its Division Offices to encourage and increase law enforcement agency participation.
2. Perform regular analysis of Take Back Day activities in conjunction with available and applicable data from within the DEA or external sources, to identify strategies for expanding Take Back Day participation, minimizing coverage gaps, and better informing the public of all prescription drug disposal options.
3. Ensure that the DEA-12s for the Take Back Day events are completed; include all required data elements, such as the date, weight of collections, number of boxes the DEA received, and recipient and witness signatures; and maintained in accordance with Take Back Day policy and DEA procedures.
4. Strengthen existing record retention policy for Take Back Day events to specifically state what forms of documentation should be retained and what

information must be included on the documentation to support the destruction of Take Back Day collections.

5. Implement controls to monitor its field offices' compliance with established Take Back Day deadlines for the destruction of collections.
6. Ensure that reported collection results clearly state that materials other than prescription drugs may be included in the totals.
7. Assess Take Back Day performance data in conjunction with other available data to provide multi-dimensional performance results to its law enforcement partners and the public, and for its own purposes in administering the program.
8. Establish reasonable procedures to verify the accuracy of reported Take Back Day collection totals and the subsequent destruction of the collections.
9. Enhance Take Back Day procedures to include all processes, and consider the utility of documenting Take Back Day collection activity procedures into its procedures manuals, as well as continued dissemination of the Take Back Day procedures through the waiver and electronic communications.
10. Enhance the CSP and emphasize the requirement that all participating law enforcement agencies adhere to the CSP in order to preserve the privacy of the public who are disposing of medications during Take Back Day events.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our audit was to evaluate the DEA's policies, procedures, and practices for the collection, custody, and disposal of prescription drugs.

Scope and Methodology

The audit scope generally focused on DEA's Take Back Day activities from FY 2019, unless otherwise stated. We reviewed DEA's management of Take Back Days including collection results, destruction records, law enforcement participation, public outreach, and policies and procedures.

To accomplish the audit objective, we interviewed DEA personnel, including officials from the DCD's Liaison Section and Diversion Planning and Resources, and DEA's Office of Congressional and Public Affairs at DEA headquarters in Arlington, Virginia, as well as DEA personnel in field offices in Oakland, Riverside, and San Francisco, California and Washington, DC. We observed Take Back Day events and the destruction of Take Back Day collections in California; conducted a review and analysis of DEA reported collections data, collection records, and destruction documentation. We also evaluated DEA's procedures related to Take Back Day activities.

To assess DEA's collection, custody, and disposal of drugs, we requested copies of all DEA-12s issued to law enforcement agencies for the April 2019 Take Back Day event. We also requested documentation supporting the destruction of the April 2019 Take Back Day collections. We then analyzed the DEA-12s to determine if the reported collections were supported. We also compared collection results to destruction documentation to confirm that all Take Back Day collections were destroyed. Further, we reviewed a judgmental sample of DEA-12s from the October 2019 Take Back Day event.

We conducted this performance audit 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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Internal Controls

In this audit, we performed testing of internal controls significant within the context of our audit objectives. We did not evaluate the internal controls of the DEA to provide assurance on its internal control structure as a whole. DEA's management is responsible for the establishment and maintenance of internal controls in accordance with 21 C.F.R. §1300 and DEA's Agents Manual. Because we

do not express an opinion on the DEA's internal control structure as a whole, we offer this statement solely for the information and use of the DEA.¹²

As noted in the Audit Results section of this report, we identified deficiencies in the DEA's internal controls that are significant within the context of the audit objective and based upon the audit work performed that we believe adversely affect the DEA's ability to accurately report and support Take Back Day collection results and activities. The DEA did not retain required documentation supporting Take Back Day collections and destruction of the Take Back Day collections. Without this documentation the DEA cannot definitively state that the DEA received, adequately handled, and destroyed collections as required.

Compliance with Laws and Regulations

In this audit we also tested, as appropriate given our audit objective and scope, select transactions, records, procedures, and practices, to obtain reasonable assurance that DEA's management complied with federal laws and regulations for which noncompliance, in our judgment, could have a material effect on the results of our audit. Our audit included examining, on a test basis, DEA's compliance with the following laws and regulations that could have a material effect on DEA's operations:

- Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513 (1970).
- Secure and Responsible Drug Disposal Act of 2010, Pub. L. No. 111-273 (2010).
- 21 C.F.R. § 1300 to End (2018).

This testing included interviewing auditee personnel, observing processes, and assessing internal control procedures. However, nothing came to our attention that caused us to believe that the DEA was not in compliance with the aforementioned laws and regulations.

Sample-based Testing

To accomplish our audit objective, we performed sample-based testing related to the issuances of DEA-12s for the October 2019 Take Back Day event. In this effort, we employed a judgmental sampling design to obtain broad exposure to numerous facets of the areas we reviewed. This non-statistical sample design did not allow projection of the test results to the universe from which the samples were selected.

Computer-Processed Data

During our audit, we obtained information from DEA's Take Back Day registration website. We did not test the reliability of those systems as a whole; therefore, any findings identified involving information from those systems were verified with documentation from other sources.

¹² This restriction is not intended to limit the distribution of this report, which is a matter of public record.

THE DRUG ENFORCEMENT ADMINISTRATION'S RESPONSE
TO THE DRAFT AUDIT REPORT



U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

MEMORANDUM

TO: David J. Gaschke
Regional Audit Manager
San Francisco Regional Audit Office
Office of the Inspector General

FROM: Mary B. Schaefer
Chief Compliance Officer
Office of Compliance

MARY
SCHAEFER

Digitally signed by
MARY SCHAEFER
Date: 2020.09.17
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SUBJECT: DEA's Response to the OIG Draft Report, "*Audit of the Drug Enforcement Administration's Prescription Drug Take Back Activities.*"

The Drug Enforcement Administration (DEA) has reviewed the Department of Justice (DOJ) Office of the Inspector General's (OIG) Draft Report titled, "*Audit of the Drug Enforcement Administration's Prescription Drug Take Back Activities.*" The DEA thanks the OIG for its review of DEA's Take Back Activities and for the OIG's recommendations for improving the program. DEA provides the following responses to the draft report's ten recommendations.

Recommendation 1. Improve Take Back Day outreach guidance and information provided to its Division Offices to encourage and increase law enforcement agency participation.

DEA Response

DEA concurs with this recommendation. DEA leadership has communicated directly with the field to encourage outreach to local law enforcement agencies in order to increase participation in National Take Back events. The Diversion Control Division will also work with the Office of Compliance to develop a Standard Operation Procedure (SOP) document to disseminate to all field offices outlining guidance on how to encourage maximum local law enforcement participation. The Diversion Control Division will also coordinate with the Office of Congressional and Public Affairs's Intergovernmental Liaison Section on how to maximize outreach and communication with state and local law enforcement agencies.

Recommendation 2: Perform regular analysis of Take Back Day activities in conjunction with available and applicable data from within the DEA or external sources, to identify strategies for expanding Take Back Day participation, minimizing coverage gaps, and better informing the public of all prescription drug disposal options.

DEA Response

DEA concurs with this recommendation. DEA will utilize various external data sources (i.e. CDC overdose death data and NFLIS data) as well as internal data sources (i.e. ARCOS and Drug Theft and Loss reporting data) to identify prescription drug trends across the U.S. In addition, DEA will provide mapping of Take Back sites in each state to the Field Offices, to help determine where Take Back Day collection sites should be expanded and to minimize coverage gaps. In addition, DEA websites are being updated to better inform the public of all prescription drug disposal options.

Recommendation 3: Ensure that the DEA-12s for the Take Back Day events are completed; include all required data elements, such as the date, weight of collections, number of boxes the DEA received, and recipient and witness signatures; and maintained in accordance with Take Back Day policy and DEA procedures.

DEA Response

DEA concurs with this recommendation. DEA has added additional instructions and emphasis to the “Waiver of Evidence Collection and Surrendered Drug Disposal Requirements of the Special Agents Manual and General Guidance for the National Takeback Initiative” (Guidance Memorandum) for the upcoming National Take Back event in October 2020 to ensure that all required data elements, such as the date, weight of collections, number of boxes that DEA received, and recipient and witness signatures are included on all DEA-12s and that all forms are maintained in accordance with existing policies and procedures.

DEA will request closure of this recommendation under separate cover.

Recommendation 4: Strengthen existing record retention policy for Take Back Day events to specifically state what forms of documentation should be retained and what information must be included on the documentation to support the destruction of Take Back Day collections.

DEA Response

DEA concurs with this recommendation. DEA has added additional instructions and emphasis to the Guidance Memorandum for the upcoming National Take Back event in October 2020 to ensure that all required data elements, such as the date, weight of collections, number of boxes that DEA received, and recipient and witness signatures are included on all DEA-12s and that all forms are maintained in accordance with existing policies and procedures. The Guidance Memorandum states that all records should be scanned into IMPACT for permanent record retention as well as outlines what information needs to be included on DEA-12.

DEA will request closure of this recommendation under separate cover.

Recommendation 5: Implement controls to monitor its field offices' compliance with established Take Back Day deadlines for the destruction of collections.

DEA Response

DEA concurs with this recommendation. DEA will require that DEA Field Offices inform the Diversion Control Division's Liaison Section (DPL) when destruction has occurred, and DPL will communicate directly with offices who have requested extensions for additional time for destruction (as detailed in Waiver of Evidence memo) to ensure the offices destroy within the timeframe they requested.

Recommendation 6: Ensure that reported collection results clearly state that materials other than prescription drugs may be included in the totals.

DEA Response

DEA concurs with this recommendation. For the upcoming October 2020 National Take Back event and all events moving forward, DEA will clearly state that the total amounts may include some non-controlled substances in addition to controlled substances. All talking points surrounding these events will continue to include that statement as well.

Recommendation 7: Assess Take Back Day performance data in conjunction with other available data to provide multi-dimensional performance results to its law enforcement partners and the public, and for its own purposes in administering the program.

DEA Response

DEA concurs with this recommendation. DEA will review National Take Back event results (law enforcement participation, total collection sites, and amount collected) with other internal and external data sets to provide multi-dimensional performance results to its law enforcement partners and the public.

Recommendation 8: Establish reasonable procedures to verify the accuracy of reported Take Back Day collection totals and the subsequent destruction of the collections.

DEA Response

DEA concurs with this recommendation. DEA is in the process of developing reasonable procedures to verify the accuracy of reported National Take Back Initiatives (NTBI) collection totals and subsequent destruction of the collections. All procedures will be incorporated into the planned NTBI SOP.

Recommendation 9: Enhance Take Back Day procedures to include all processes, and consider the utility of documenting Take Back Day collection activity procedures into its procedures

manuals, as well as continued dissemination of the Take Back Day procedures through the waiver and electronic communications.

DEA Response

DEA concurs with this recommendation. As reference above, DEA is in the process of developing an SOP that will outline all NTBI collection activity procedures and processes. DEA will also continue to disseminate NTBI procedures through the waiver, electronic communications, and conference calls.

Recommendation 10: Enhance the CSP and emphasize the requirement that all participating law enforcement agencies adhere to the CSP in order to preserve the privacy of the public who are disposing of medications during Take Back Day events.

DEA Response

DEA concurs with this recommendation. The DEA's October 2020 NTBI Waiver of Evidence memo emphasizes the requirement that all participating law enforcement agencies adhere to the CSP. DEA will also update the CSP to reflect the requirement that all participating law enforcement agencies adhere to CSP and reflect this requirement in the SOP that the Diversion Control Division is creating with the Office of Compliance.

Thank you for the opportunity to respond to the recommendations made in the OIG report. If you have any questions regarding this response, please contact the Audit Liaison Team, on 202-307-8200.

OFFICE OF THE INSPECTOR GENERAL ANALYSIS AND SUMMARY OF ACTIONS NECESSARY TO CLOSE THE REPORT

The Office of the Inspector General (OIG) provided a draft of this audit report to the Drug Enforcement Administration (DEA). The DEA's response is incorporated in Appendix 2 of this final report. In response to our audit report, the DEA concurred with our recommendations and discussed the actions it will implement in response to our findings. As a result, the status of the audit report is resolved. The following provides the OIG analysis of the response and summary of actions necessary to close the report.

Recommendations for the DEA:

- 1. Improve Take Back Day outreach guidance and information provided to its Division Offices to encourage and increase law enforcement agency participation.**

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that DEA leadership has communicated directly with the field to encourage outreach to local law enforcement agencies to increase participation in National Take Back Day events, and that the Diversion Control Division will work with the Office of Compliance to develop a Standard Operation Procedure (SOP) document to disseminate to all field offices outlining guidance on how to encourage maximum local law enforcement participation. Further, the DEA indicated that the Diversion Control Division also will coordinate with the Office of Congressional and Public Affairs's Intergovernmental Liaison Section on how to maximize outreach and communication with state and local law enforcement agencies. As a result, this recommendation is resolved.

This recommendation can be closed when we receive evidence of the documentation, implementation, and dissemination of the SOP adequately outlining guidance on how to encourage maximum local law enforcement participation.

- 2. Perform regular analysis of Take Back Day activities in conjunction with available and applicable data from within the DEA or external sources, to identify strategies for expanding Take Back Day participation, minimizing coverage gaps, and better informing the public of all prescription drug disposal options.**

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that it will utilize various external and internal data sources, including the Centers for Disease Control and Prevention overdose death data, National Forensic Laboratory Information System data, Automation of Reports and Consolidated Orders System, and Drug Theft and Loss reporting data, to identify prescription drug trends across the U.S. The DEA also

stated that it will provide to its field offices mapping of Take Back sites in each state to help determine where Take Back Day collection sites should be expanded and to minimize coverage gaps. The DEA further stated it would update its websites to better inform the public of all prescription drug disposal options. As a result, this recommendation is resolved.

This recommendation can be closed when we receive documentary evidence that the DEA has conducted analysis of DEA Take Back Day efforts in relation to other prescription drug data, and published the results of its analysis on its public website; that Take Back Day mapping or other data has been provided to field offices to assist with efforts to expand collection sites and minimize coverage gaps; and that the DEA has updated its websites to better inform of all prescription drug disposal options.

- 3. Ensure that the DEA-12s for the Take Back Day events are completed; include all required data elements, such as the date, weight of collections, number of boxes the DEA received, and recipient and witness signatures; and maintained in accordance with Take Back Day policy and DEA procedures.**

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that it added additional instructions and emphasis to the “Waiver of Evidence Collection and Surrendered Drug Disposal Requirements of the Special Agents Manual and General Guidance for the National Takeback Initiative” (Guidance Memorandum) for the upcoming National Take Back Day event in October 2020 to ensure that all required data elements, such as the date, weight of collections, number of boxes that DEA received, and recipient and witness signatures are included on all DEA-12s and that all forms are maintained in accordance with existing policies and procedures.

Additionally, under separate cover, the DEA provided the Guidance Memorandum for the October 2020 Take Back Day event and requested closure of this recommendation. Based on our review of the Guidance Memorandum, we believe the DEA has documented what data elements must be included on the DEA-12s and what Take Back Day activities information must be maintained to fulfill record retention requirements and procedures. However, the DEA did not provide evidence of procedures for ensuring adherence to the Guidance Memorandum in relation to the DEA-12s completion and record retention for Take Back Day activities.

The status of this recommendation is resolved. It can be closed when we receive documentary evidence that the DEA has established, implemented, and disseminated sufficient procedures to ensure that the DEA-12s are fully completed and the Take Back Day record retention requirements are followed.

4. Strengthen existing record retention policy for Take Back Day events to specifically state what forms of documentation should be retained and what information must be included on the documentation to support the destruction of Take Back Day collections.

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that it has added additional instructions and emphasis to the October 2020 Take Back Day Guidance Memorandum to ensure that all required data elements, such as the date, weight of collections, number of boxes that DEA received, and recipient and witness signatures are included on all DEA-12s and that all forms are maintained in accordance with existing policies and procedures. Further, the DEA stated that the updated Guidance Memorandum requires that all records should be scanned into IMPACT for permanent record retention, and it includes what information needs to be included on the DEA-12.

We determined that the Guidance Memorandum identified the data elements that must be included on the DEA-12, acceptable destruction documentation, and documentation retention requirements. We believe the revised Guidance Memorandum for the October 2020 event has addressed our concerns and that the DEA should include this important information in future guidance memoranda as applicable. However, we also believe these requirements should be documented outside of the Guidance Memorandum. As a result of DEA actions, this recommendation is resolved.

This recommendation can be closed when we receive evidence that the DEA has incorporated these enhancements into its existing record retention policy for Take Back Day events to specifically state what forms of documentation should be retained, what information must be included on the documentation to support the destruction of Take Back Day collections, and included this guidance in its newly developed SOP or other policy documentation.

5. Implement controls to monitor its field offices' compliance with established Take Back Day deadlines for the destruction of collections.

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that it will require that its field offices inform the Diversion Control Division's Liaison Section (DPL) when destruction has occurred. In addition, the DPL will communicate directly with offices who have requested extensions for additional time for destruction (as detailed in the Guidance Memorandum) to ensure the offices destroy Take Back Day collections within the timeframe requested. As a result, this recommendation is resolved.

This recommendation can be closed when we receive documentary evidence that requirements for DEA field offices to inform the DPL when destruction has occurred and DPL's further communication to ensure the offices destroy the collections within the extended timeframe requested have been

documented, implemented, and disseminated to appropriate individuals in the DEA.

6. Ensure that reported collection results clearly state that materials other than prescription drugs may be included in the totals.

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that for the upcoming October 2020 Take Back Day event, and all events moving forward, it will clearly state that the total amounts may include some non-controlled substances in addition to controlled substances. The DEA further stated that all talking points surrounding these events will continue to include that statement as well. As a result, this recommendation is resolved.

This recommendation can be closed when we receive documentary evidence that the DEA has clearly stated in its publication of Take Back Day results and its other presentations regarding its Take Back Day efforts that materials other than prescription drugs may be included in the totals.

7. Assess Take Back Day performance data in conjunction with other available data to provide multi-dimensional performance results to its law enforcement partners and the public, and for its own purposes in administering the program.

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that it will review National Take Back event results (law enforcement participation, total collection sites, and amount collected) with other internal and external data sets to provide multi-dimensional performance results to its law enforcement partners and the public. As a result, this recommendation is resolved.

This recommendation can be closed when we receive documentary evidence that the DEA has undertaken efforts to assess Take Back Day event results in relation to other internal and external data, and has disseminated the results of its review to applicable internal or external partners.

8. Establish reasonable procedures to verify the accuracy of reported Take Back Day collection totals and the subsequent destruction of the collections.

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that it is developing reasonable procedures to verify the accuracy of reported Take Back Day collection totals and subsequent destruction of the collections, and that all procedures will be incorporated into the planned Take Back Day events SOP. As a result, this recommendation is resolved.

This recommendation can be closed when we receive documentary evidence that the DEA has developed adequate procedures for verifying collections

totals and collections destruction, incorporated the procedures into the planned SOP, and implemented and disseminated the SOP to applicable staff.

9. **Enhance Take Back Day procedures to include all processes, and consider the utility of documenting Take Back Day collection activity procedures into its procedures manuals, as well as continued dissemination of the Take Back Day procedures through the waiver and electronic communications.**

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that it is developing an SOP that will outline all Take Back Day collection activity procedures and processes, and that it will continue to disseminate these procedures through its waiver document, electronic communications, and conference calls. As a result, this recommendation is resolved.

This recommendation can be closed when we receive a copy of the SOP and evidence of its implementation and dissemination, as well as evidence of the DEA's continued dissemination of Take Back Day procedures through its waiver document, electronic communications, and conference calls.

10. **Enhance the CSP and emphasize the requirement that all participating law enforcement agencies adhere to the CSP in order to preserve the privacy of the public who are disposing of medications during Take Back Day events.**

Resolved. The DEA concurred with our recommendation. The DEA stated in its response that the October 2020 Guidance Memorandum emphasizes the requirement that all participating law enforcement agencies adhere to the Take Back Day Collection Site Protocol (CSP). The DEA also indicated that it will update the CSP to reflect the requirement that all participating law enforcement agencies adhere to the CSP and include this requirement in the SOP that the Diversion Control Division is creating with the Office of Compliance. While the October 2020 Guidance Memorandum does not specifically mention the CSP, the memorandum emphasizes the adherence to practices within the CSP pertaining to issues we observed during the audit. As a result, this recommendation is resolved.

This recommendation can be closed when we receive documentary evidence that the DEA has sufficiently emphasized adherence to the CSP by law enforcement partners, that the requirement has been incorporated into the SOP when developed, and that the SOP has been implemented and disseminated to appropriate DEA staff.