

Federal Regulations and the Disposal of Controlled Substances

*National Conference
Pharmaceutical and Chemical Diversion
Dallas, Texas
December 13, 2017*

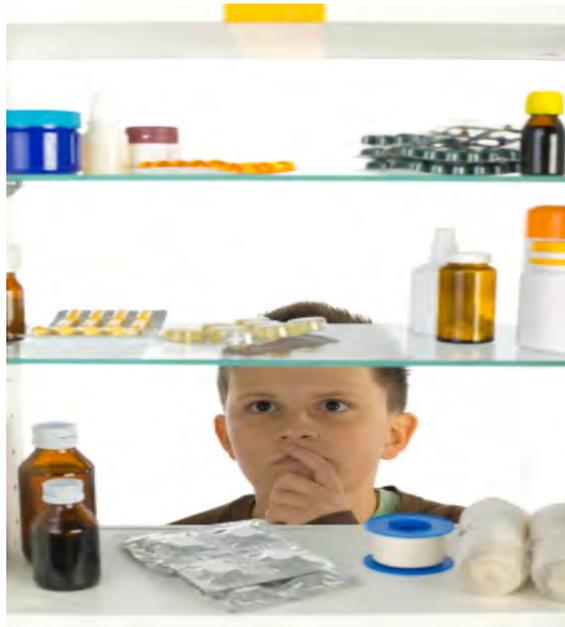
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Chief, Policy Unit
Drug Enforcement Administration



Legal Disclaimer

The following presentation was accompanied by an oral presentation on **December 13, 2017, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on DEA. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. **I have no financial relationships to disclose.****

The Medicine Cabinet and Pharmaceutical Controlled Substances



Study: Sharing of Medication

1. University of Pennsylvania Dental School Study:

More than half of the narcotics prescribed for wisdom teeth removal go unused...findings suggest that more than 100 million pills prescribed go unused...leaving the door open for possible misuse or abuse.

Study: Sharing of Medication

2. John Hopkins Study:

- **60% had leftover opioids they hung on for “future use”**
- **20% shared their medications**
- **8% likely will share with a friend**
- **14% likely will share with a relative**
- **10% securely lock their medication**

Secure and Responsible Drug Disposal Act of 2010

P.L. 111-273

October 12, 2010

Federal Register

September 9, 2014

Secure and Responsible Drug Disposal Act of 2010

Legislation that provides **Ultimate Users** and **LTCF** with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner.

Secure and Responsible Drug Disposal Act of 2010

- Authorized DEA to promulgate regulations that allow ultimate users to transfer pharmaceutical controlled substances to authorized entities for disposal in a safe and effective manner consistent with effective controls against diversion.

Secure and Responsible Drug Disposal Act of 2010

Regulations do not limit the ways that ultimate users may dispose of pharmaceutical controlled substances—they expand them.

Secure and Responsible Drug Disposal Act of 2010

Participation is voluntary

DEA may not require any person to establish or operate a disposal program.

Secure and Responsible Drug Disposal Act of 2010

Ultimate Users may continue to utilize the FDA and EPA guidelines for the disposal of medicines, available at:

[*www.fda.gov*](http://www.fda.gov)

[*www.epa.gov*](http://www.epa.gov)

Ultimate User

Ultimate User: “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”

21 USC § 802(27)

CLEAR CHANNEL

Got **Drugs?**



**Oct.
22ND**
10AM - 2PM

Turn in your unused or
expired medication.

For Drop off Locations **visit. DEA.gov**

14th National Take Back Day

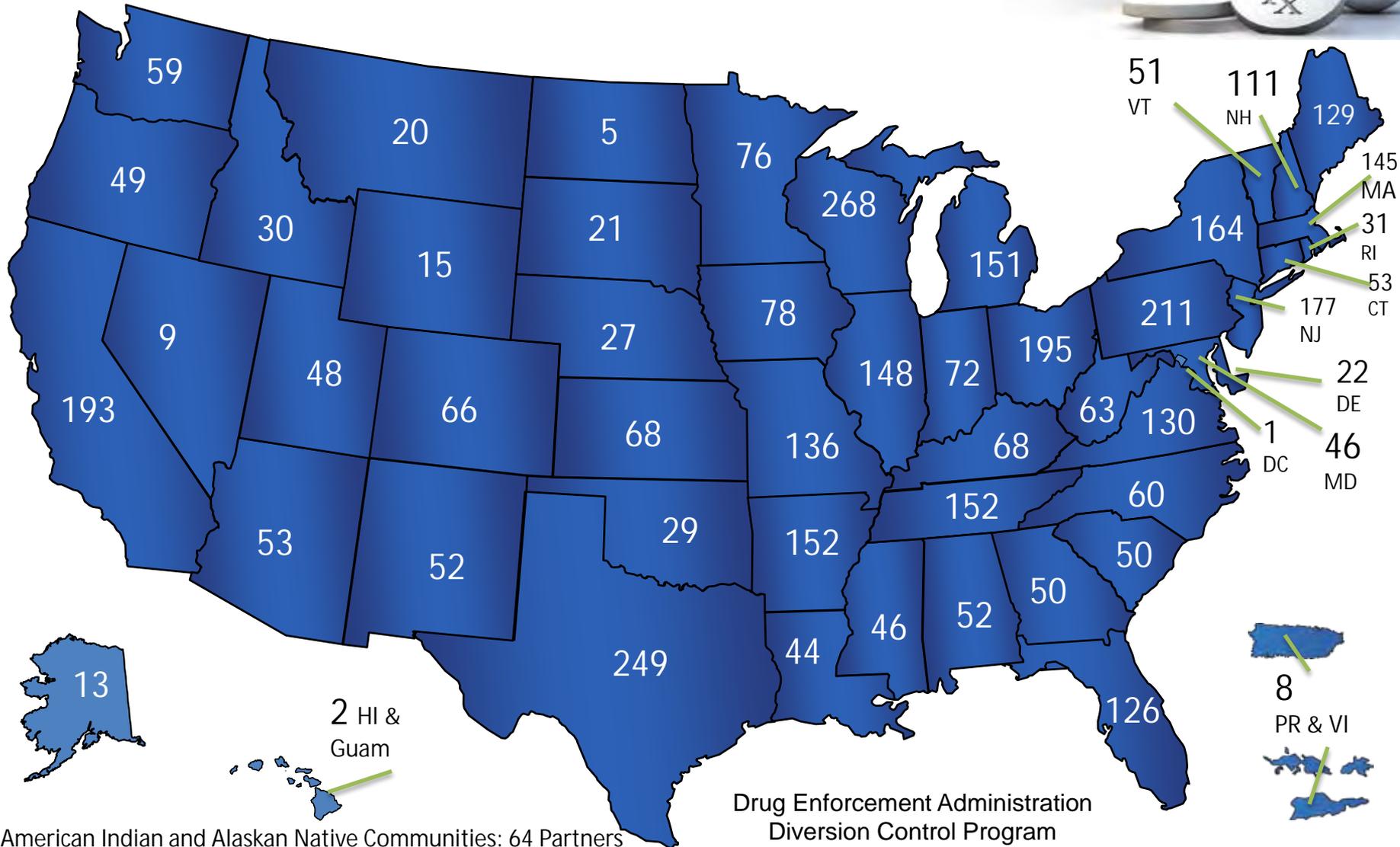
October 28, 2017

DRUG ENFORCEMENT
ADMINISTRATION
DIVERSION CONTROL PROGRAM



14th National Take Back Day: October 28, 2017

Total Law Enforcement Participation: 4,274

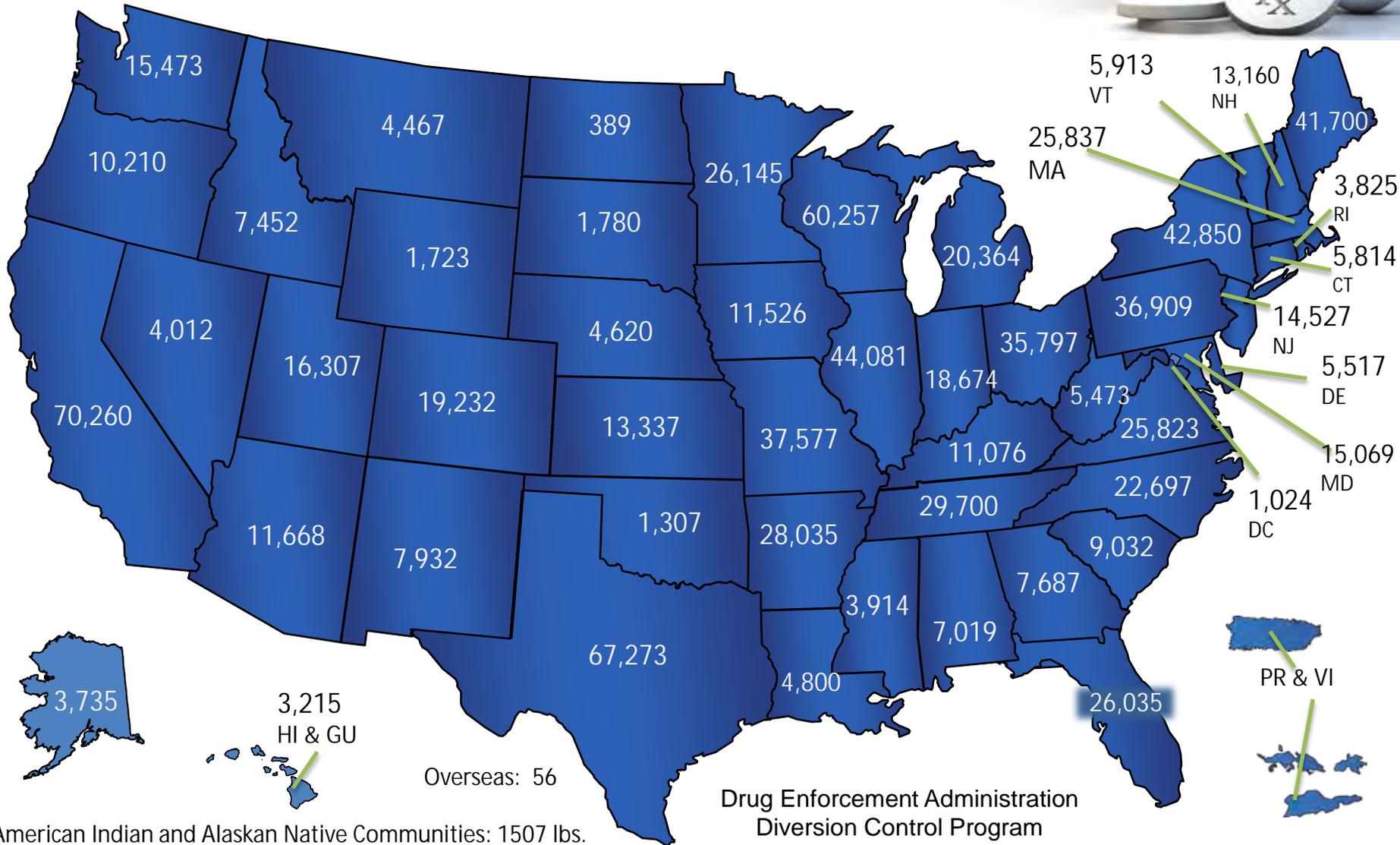


*American Indian and Alaskan Native Communities: 64 Partners

Drug Enforcement Administration
Diversion Control Program

14th National Take Back Day: October 28, 2017

Total Weight Collected (pounds): 912,305 lbs. (456 Tons)



*American Indian and Alaskan Native Communities: 1507 lbs.

Drug Enforcement Administration
Diversion Control Program

14th National Take Back Day

American Indian and
Alaskan Native Communities Participation

October 28, 2017

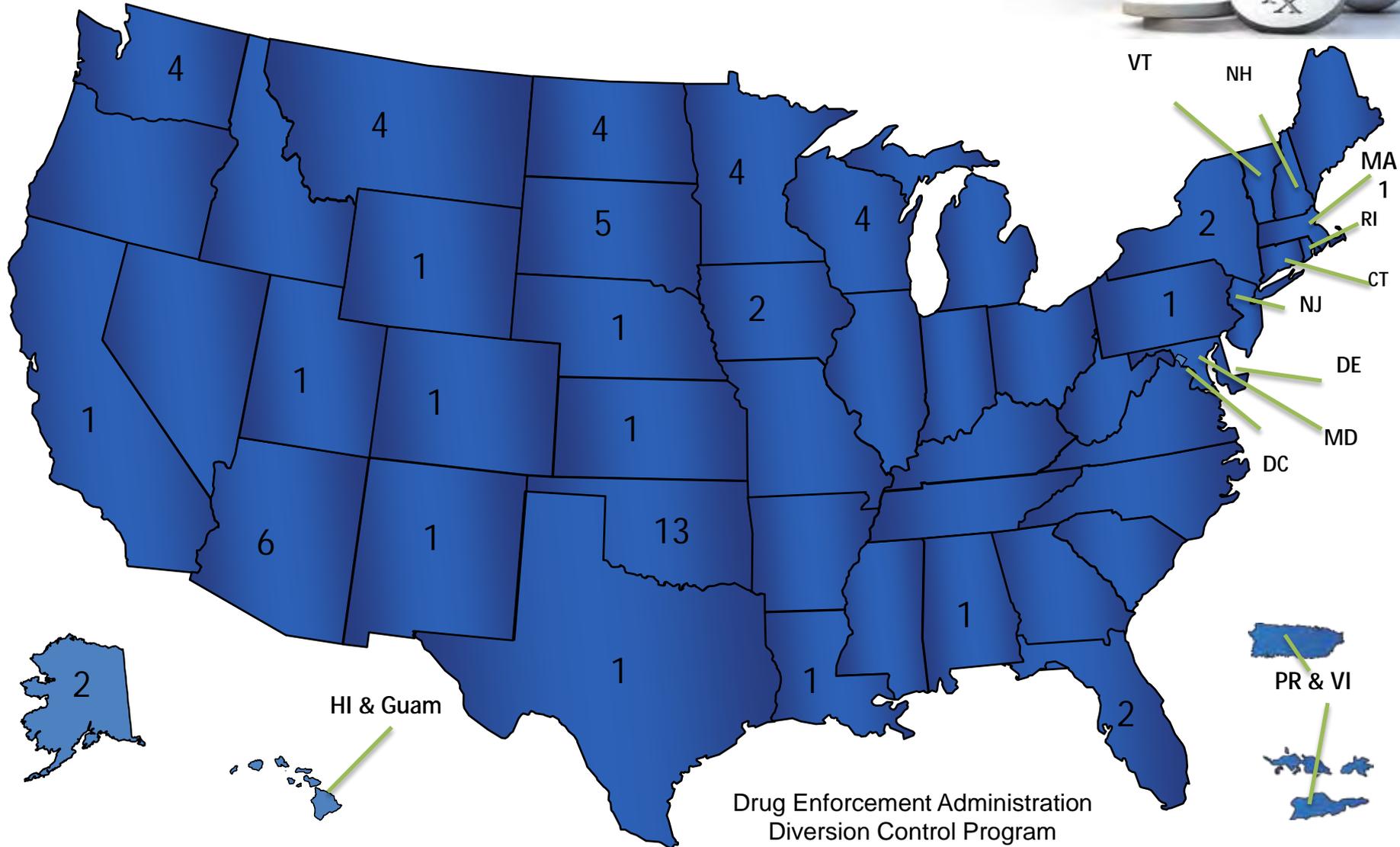
DRUG ENFORCEMENT
ADMINISTRATION
DIVERSION CONTROL PROGRAM



14th National Take Back Day: October 28, 2017

Total American Indian and Alaskan Native Communities

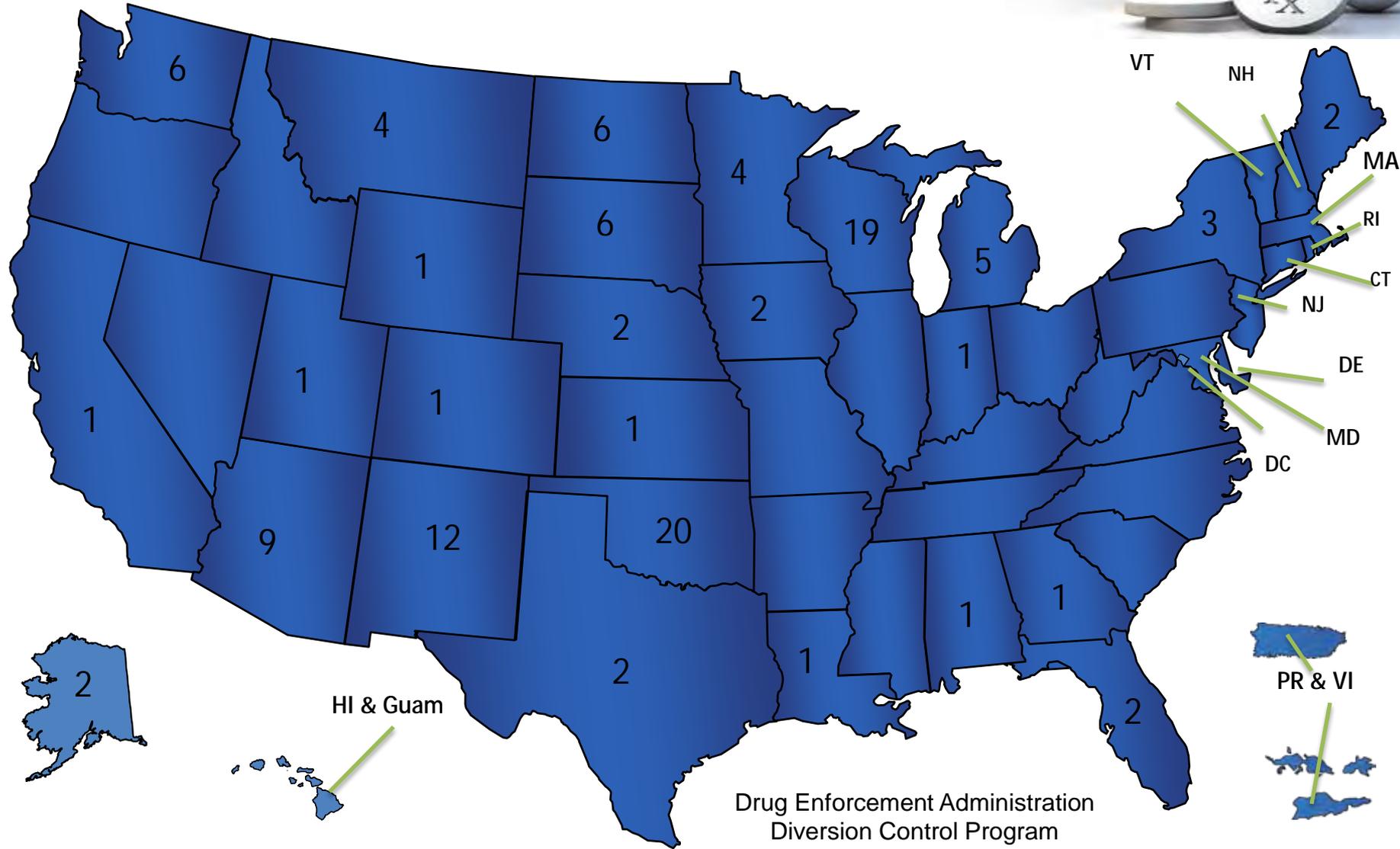
Law Enforcement Participation: 64



Drug Enforcement Administration
Diversion Control Program

14th National Take Back Day: October 28, 2017

Total American Indian and Alaskan Native Communities Collection Sites: 115

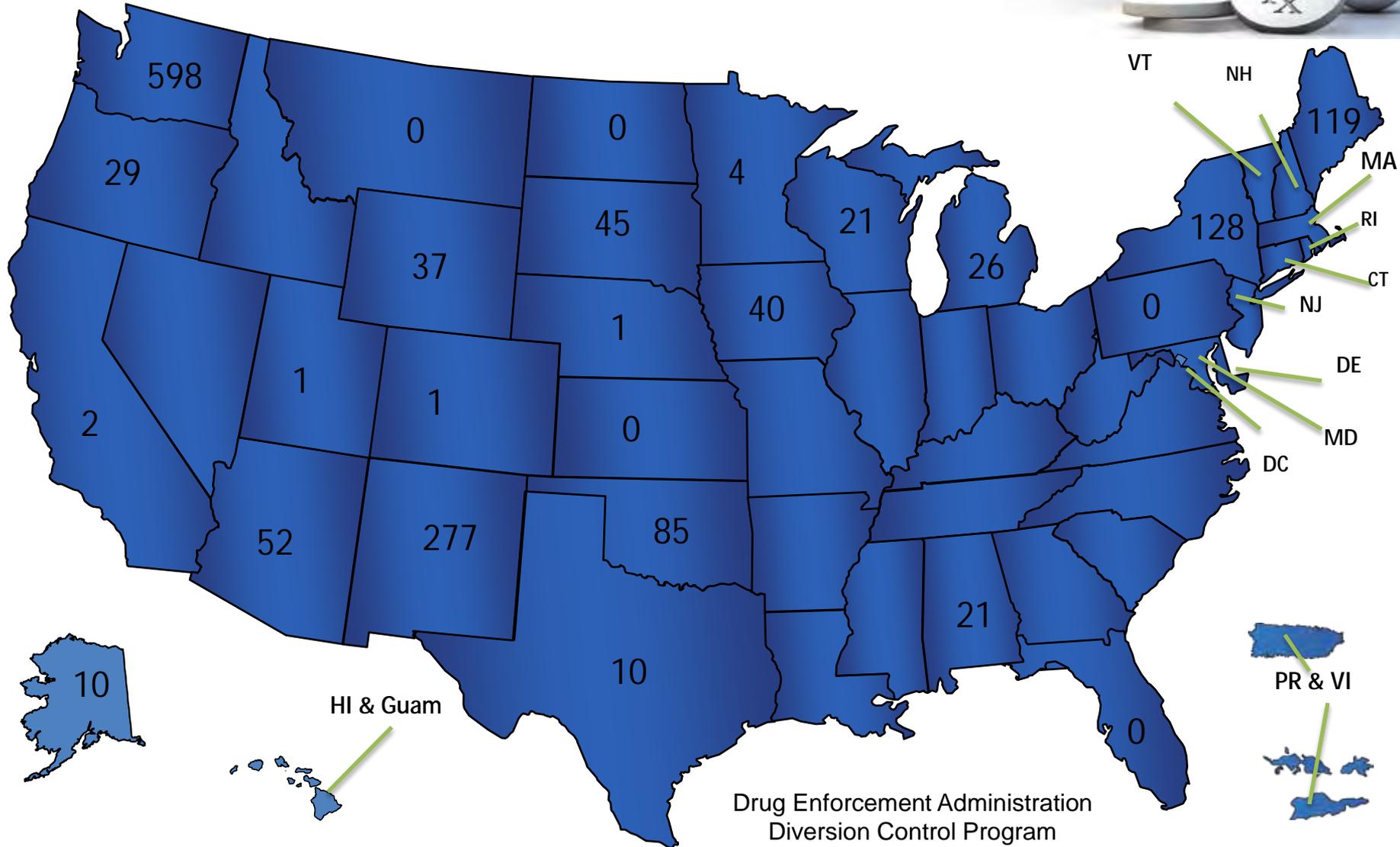


Drug Enforcement Administration
Diversion Control Program

14th National Take Back Day: October 28, 2017

Total American Indian and Alaskan Native Communities

Weight Collected (pounds): 1507 lbs. (.754 Tons)



Authorized to Collect

Following persons are authorized to collect from ultimate user and other non-registrants for destruction:

- Any **DEA registrant** authorized pursuant to § 1317.40
- Federal, State, tribal, or local law enforcement** when in the course of official duties and pursuant to § 1317.35

21 CFR § 1317.30

Authorized to Collect

DEA Registrants authorized to collect:

- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs
- Hospitals with an on-site pharmacy
- Retail Pharmacies

21 CFR § 1317.40

New Authorized Methods of Collection

Lawful collection/possession of controlled substances acquired from ultimate users or other non-registrant persons shall be disposed of in the following ways:

Mail-back Programs
Collection Receptacles



Collection Receptacles

Design of Collection Receptacle



Collection Receptacle Location

Must be securely placed and maintained:

- Inside collector's registered location
- Inside law enforcement's physical location, or
- Inside an authorized LTCF



Design of Collection Receptacle

- Securely fastened to a permanent structure.
- Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.

21 CFR § 1317.75(e)



Mail-Back Programs

Mail-Back Program – Who is Authorized to Operate?

Any authorized collector that has and utilizes at its registered location (on-site) a method of destruction consistent with § 1317.90

21 CFR § 1317.70

Mail-Back Program

Requirements of mail-back program

- Only lawfully-possessed Schedules II-V controlled substances may be collected
- Controlled and non-controlled substances may be collected and comingled

21 CFR § 1317.70 (b)

Mail-Back Packaging

Packages may be made available for sale or free of charge

Any person may partner with a collector or law enforcement to make packages available

21 CFR § 1317.70 (c)

Mail-Back Package Specifications

Packages may only be mailed from the customs territory of the United States:

- 50 States
- District of Columbia
- Puerto Rico

21 CFR § 1317.70



Personally identifiable information shall not be required when using mail-back package.

Disposal 21 CFR Part 1317



Inventory

vs

Waste

**Disposal
of
Inventory
By
Practitioners**

Disposal for Practitioners

21 CFR § 1317.05

(a) *Practitioner inventory.* Any registered practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

Disposal for Practitioners

(1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;

Disposal for Practitioners

(2) Promptly deliver that controlled substance to a **Reverse Distributor** (registered location) by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location

Disposal for Practitioners

(3) For the purpose of **return or recall**, promptly deliver that controlled substance ... to ... (T)he registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf

Disposal for Practitioners

(4) Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located.

Destruction of Controlled Substances

Non-retrievable ... a process that permanently alters the substance's physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable and unusable for all practical purposes.

21 CFR § 1300.05(b)



Destruction of Controlled Substances

All controlled substances destroyed by a registrant, or caused to be destroyed by a registrant, shall be destroyed **in compliance with applicable Federal, State, tribal, and local laws and regulations** and shall be rendered **non-retrievable**.

21 CFR § 1317.90

**Disposal
of
Waste
By
Practitioners**

Destruction of Controlled Substances

All controlled substances destroyed by a registrant, or caused to be destroyed by a registrant, shall be destroyed **in compliance with applicable Federal, State, tribal, and local laws.**

See “Dear Practitioner” Letter,
Destruction of Pharmaceutical Waste
October 17, 2014.

Records: Destruction of Inventory

21 CFR § 1304.21 (e)

- **DEA Form 41**
- **Complete and Accurate Record**
- **Name and Signature of the Two Employees who Witnessed the Destruction**

Records: Destruction of Waste

21 CFR § 1304.21 (e)

No DEA Form 41

21 CFR § 1304.22(a)(2)(ix)

Date, Quantity, and Manner of
Disposal

Drug Recall

or

Investigational Drug Return

Drug Recall: Ultimate User Return

If controlled substances are recalled, ultimate users may deliver the recalled substance to the manufacturer, or another registrant authorized to accept recalled substances on the manufacturer's behalf.

21 CFR § 1317.85(a) & (b)

Termination of Ability to Collect

Registrant shall notify the DEA in writing or online.

21 CFR § 1301.52(f)

21 CFR § 1317.70 (e)(3)



Patient Resources for Disposal (Anytime of the Year)

<https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1>

(Disposal location search tool, for disposal of medications)

www.rxdrugdropbox.org

(Police Department Locations, for disposal of medications)

www.disposemy meds.org

(Pharmacy Locations, for disposal of medications)

www.fda.gov (Search: Disposal)

<https://www.epa.gov/sites/production/files/2015-06/documents/how-to-dispose-medicines.pdf>

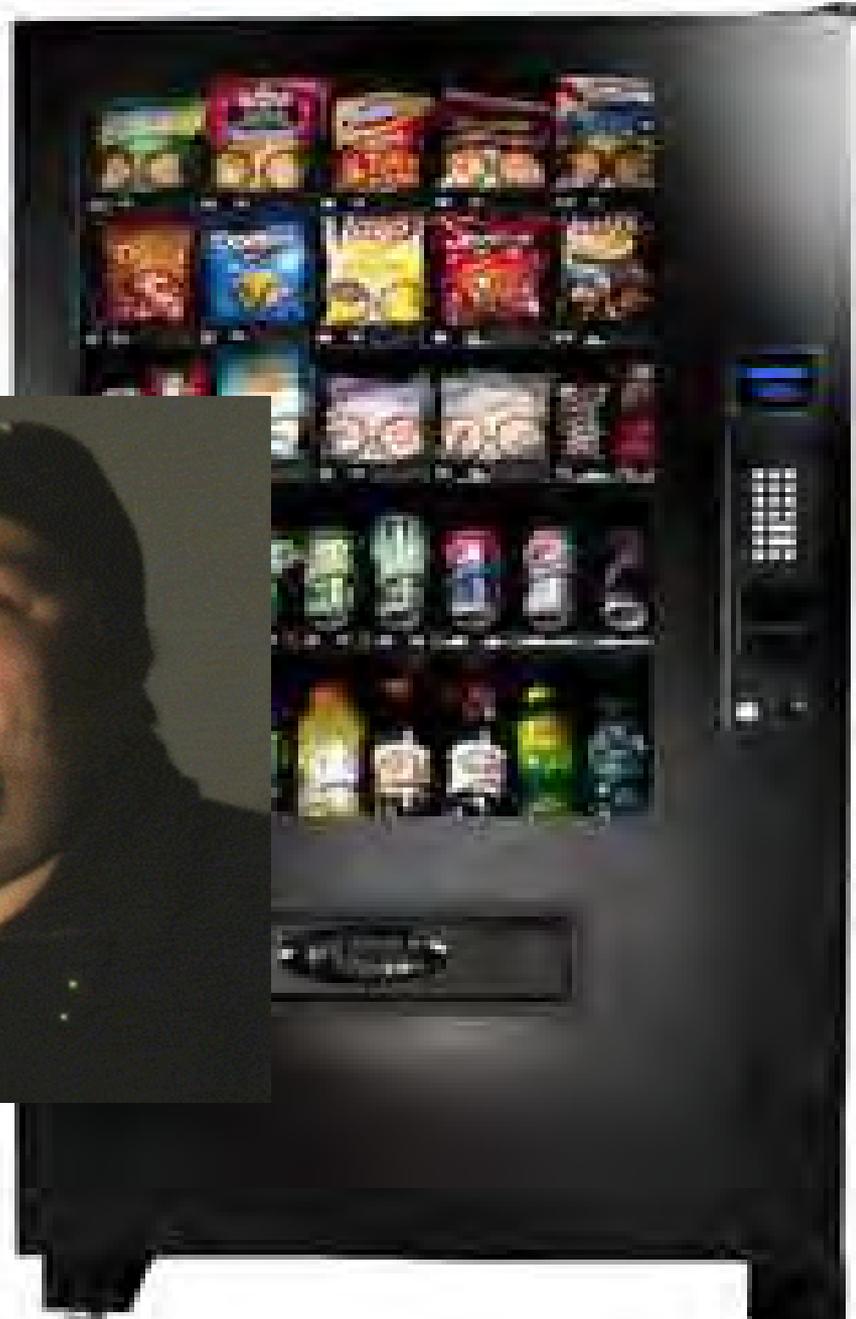


Contact Information

DEA Diversion Control
Division
Attn: Liaison and Policy
Section
8701 Morrisette Drive
Springfield, VA 22152

Phone: 202-307-7297
E-mail: ODLP@usdoj.gov





DIVERSION OF THE DISPOSED

- PRACTITIONERS

- ü Using unapproved destruction devices
- ü Take drugs from patients



- REVERSE DISTRIBUTORS

- ü Failure to have two employees handle the drugs including transportation and destruction



DIVERSION OF THE DISPOSED

- PHARMACY

- ü Take drugs from patients



- ü Do not complete records accurately with reverse distributors

- Others

- ü Stealing from Sharps Containers



- ü LTC Facilities stealing decreases patient's drugs

- ü LTC Facilities – own pharmacy (use left over meds)

EQUAL OPPORTUNITY DESTROYER

Officer Accused Of Stealing
Painkillers From Evidence
Room, Drug Drop Box
Aberdeen, Maryland

Meeker County deputy is
accused of stealing drugs
from a drop box and toys
from a holiday toy drive
Litchfield, Minnesota

Vineland officer charged with
taking meds from
prescription drop box
Bridgeton, New Jersey

Questions / Thank You

