

# Medication Take Back Programs and the DEA Regulations

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# My Background

- ▶ 2001 graduate of Tx Tech School of Pharmacy
- ▶ Completed drug information residency in 2002
- ▶ Began position as director of poison center in 2003
- ▶ Started med take back program in 2009
- ▶ To date, have conducted 49 med take back events across the Texas panhandle
  - ▶ Non-controlled substances = 32,245 pounds
  - ▶ Controlled substances = 2,231 pounds
  - ▶ Sharps = 1,792 pounds

# Objectives

- ▶ Review the DEA rules regarding medication take-back programs
- ▶ Determine requirements for law enforcement presence at take-back events
- ▶ Discuss surveys and outcome measures as they pertain to take-back programs
- ▶ Develop a strategy for gaining law enforcement assistance


# Medication Take Back Rules & Regulations to Consider

- ▶ State Board of Pharmacy
- ▶ Law Enforcement
- ▶ Environmental Regulations
- ▶ Department of Transportation
- ▶ Federal vs. State
  - ▶ Whichever is more strict is typically the one to apply
  - ▶ In many cases, there are no rules/regs specific to take back programs



# Drug Enforcement Administration

Code of Federal Regulations -  
Part 1300



I am not a representative  
of the DEA. The views  
presented here are my  
views and interpretations  
only, and do not necessarily  
represent those of the DEA.

# DEA Rules

- ▶ Rules related to medication “take back” and disposal are based on the Controlled Substances Act (Title 21 United States Code)
- ▶ Code of Federal Regulations: Part 1317 - Disposal (<https://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>)

## Title 21 Code of Federal Regulations

### PART 1317 — DISPOSAL

#### Subpart A — Disposal of Controlled Substances by Registrants

- 1317.01 Scope.
- 1317.05 Registrant disposal.
- 1317.10 Registrant return or recall.
- 1317.15 Reverse distributor registration requirements and authorized activities.

#### Subpart B — Disposal of Controlled Substances Collected From Ultimate Users and Other Non-Registrants

- 1317.30 Authorization to collect from non-registrants.
- 1317.35 Collection by law enforcement.
- 1317.40 Registrants authorized to collect and authorized collection activities.
- 1317.55 Reverse distributor and distributor acquisition of controlled substances from collectors or law enforcement.
- 1317.60 Inner liner requirements.
- 1317.65 Take-back events.
- 1317.70 Mail-back programs.
- 1317.75 Collection receptacles.
- 1317.80 Collection receptacles at long-term care facilities.
- 1317.85 Ultimate user delivery for the purpose of recall or investigational use of drugs.

#### Subpart C — Destruction of Controlled Substances

- 1317.90 Methods of destruction.
- 1317.95 Destruction procedures.

Authority: 21 U.S.C. 821, 822, 823, 827, 828, 871(b), and 958.

Source: 79 FR 33565, Sept. 9, 2014, unless otherwise noted.

Cases Against Doctor  
Chemical Control Pro  
CMEA (Combat Meth  
Controlled Substance  
DATA Waived Physi  
Drug Disposal Inform  
Drug and Chemical In  
E-commerce Initiativ  
Federal Agencies & R  
Federal Register Not  
National Take-Back I  
NFLIS  
Publications & Manua  
Questions & Answer  
Significant Guidance  
Synthetic Drugs  
Title 21 Code of Fede  
Regulations  
Title 21 USC Codified



# Part 1317 - Disposal

- ▶ Subpart A is for “registrants” (pharmacies, reverse distributors, etc. that are registered with DEA)
- ▶ Subpart B is for disposal from ultimate users and other “non-registrants” (this is relevant to most take-back programs)
  - ▶ Who is eligible to collect controlled substances from non-registrants?
    - ▶ 1317.30 (2) Federal, State, tribal, or local law enforcement when in the course of official duties and pursuant to §1317.35.
  - ▶ How do we fit into this?
    - ▶ We operate in conjunction with local law enforcement (not security guards or security teams, but certified peace officers)

# Part 1317 - Disposal

- ▶ 1317.35 Collection by law enforcement
  - ▶ Federal, State, tribal, or local law enforcement may collect controlled substances from ultimate users ...using the following methods:
    - ▶ Take back events in accordance with 1317.65
- ▶ Law enforcement that conducts a take back event...should maintain any records of removal, storage, or destruction...consistent with that agency's recordkeeping requirements for illicit controlled substances evidence

# 1317.65 Take Back Events

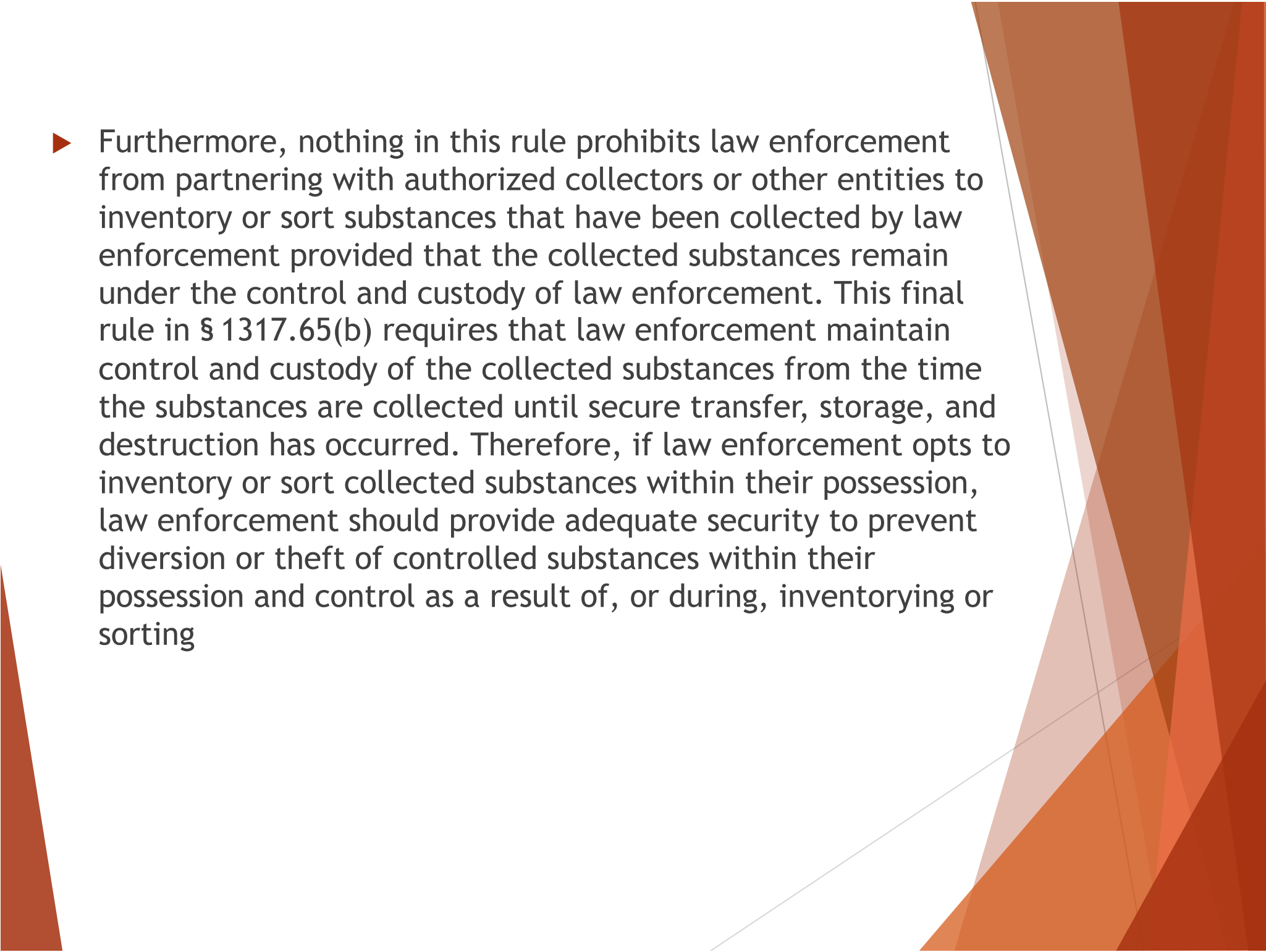
- ▶ ...Any person may partner with law enforcement to hold a collection take-back event in accordance with this section
- ▶ Law enforcement will appoint a law enforcement officer employed by the agency to oversee the collections...(and)...shall maintain control and custody of the collected substances from the time the substances are collected from the ultimate user ...until secure transfer, storage, or destruction...
- ▶ Only those controlled substances listed in Schedule II, III, IV, or V... may be collected
- ▶ Only ...persons entitled to dispose of an ultimate user decedent's property ... may transfer such substances to law enforcement during the take-back event.

# Where to find more details

- ▶ Title 21 of the CFR is brief
- ▶ The full document can be found at:  
<https://www.federalregister.gov/documents/2014/09/09/2014-20926/disposal-of-controlled-substances>
  - ▶ This document is primarily in Q & A format
  - ▶ Answers many questions related to specifics of take back events

# Can we inventory items accepted at take-back events?

- ▶ **J. Prohibition on Handling, Sorting, and Inventorying Inner Liner Contents and Mail-Back Package Contents (8 Issues)**
- ▶ Pursuant to § 1317.65, law enforcement may continue to conduct take-back events when a law enforcement officer maintains control and custody of collected substances at take-back events and only the ultimate user transfers controlled substances to law enforcement control and custody. However, non-law enforcement personnel may assist the law enforcement officer, and the final rule does not prohibit healthcare professionals from voluntarily polling ultimate users about the substances they are discarding or from assisting ultimate users to separate pharmaceutical controlled substances from non-controlled substances during the disposal process, and inventorying the non-controlled substances.

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- The slide features abstract orange geometric shapes. On the right side, there is a large, complex shape composed of several overlapping triangles and polygons in various shades of orange and red. On the left side, there is a smaller, solid orange triangle pointing towards the center. A thin, light gray diagonal line runs from the bottom left towards the top right, passing behind the text.
- ▶ Furthermore, nothing in this rule prohibits law enforcement from partnering with authorized collectors or other entities to inventory or sort substances that have been collected by law enforcement provided that the collected substances remain under the control and custody of law enforcement. This final rule in § 1317.65(b) requires that law enforcement maintain control and custody of the collected substances from the time the substances are collected until secure transfer, storage, and destruction has occurred. Therefore, if law enforcement opts to inventory or sort collected substances within their possession, law enforcement should provide adequate security to prevent diversion or theft of controlled substances within their possession and control as a result of, or during, inventorying or sorting

# Approach to Law Enforcement

- ▶ Have a clear plan before you make contact
- ▶ Be prepared to ask for what you need
- ▶ 1 certified peace officer to provide oversight and “maintain control & custody” of controlled substances; additional officers?
  - ▶ Are you willing to pay for officers?
- ▶ Will they need to remove collections at conclusion of event?
  - ▶ Everything vs. just controlled substances
  - ▶ Hold until DEA can pick up

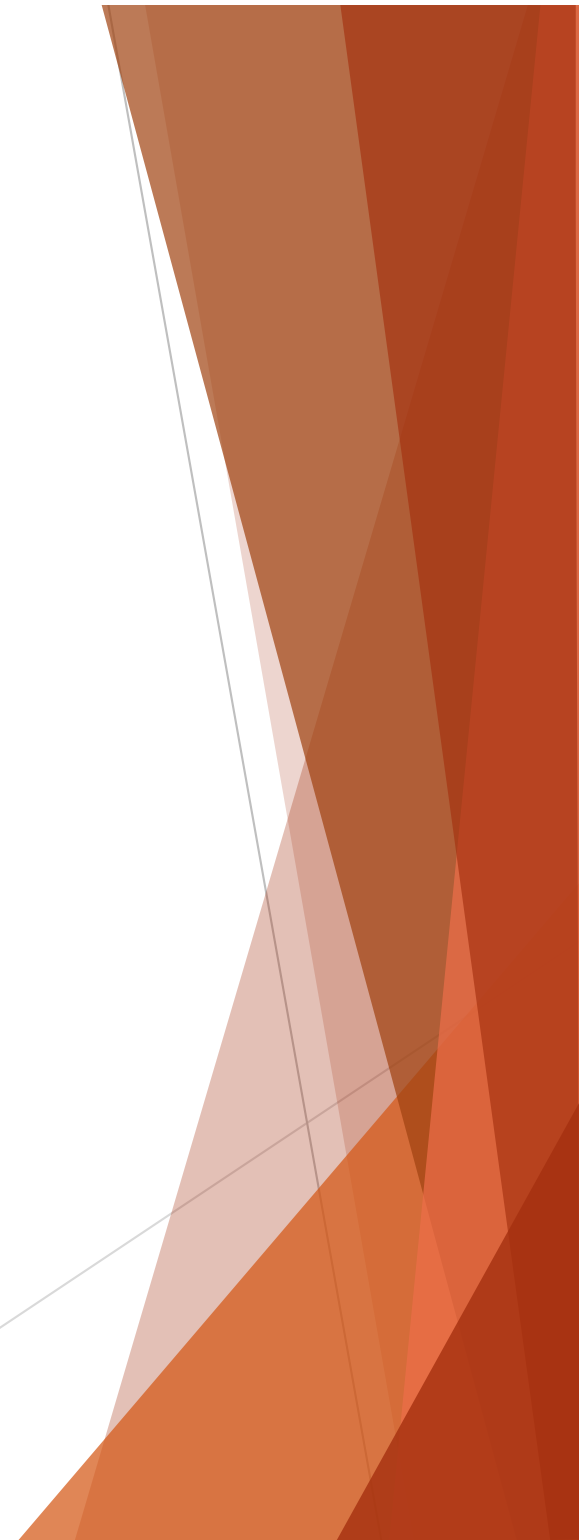
# Can we conduct curbside surveys?

- ▶ ...the final rule does not prohibit healthcare professionals from voluntarily polling ultimate users about the substances they are discarding ....
- ▶ Guidance from individual DEA representatives varies and some state that information should not be collected, however, according to the rule, this is not prohibited



# Why survey? Why collect data?

- ▶ Many programs need outcome measures to report to funding agencies
  - ▶ Weight collected
  - ▶ Survey data
  - ▶ Inventory
- ▶ Collected data can help facilitate change on a broad scale



Please consider helping us by taking our survey.

Thank you for coming today. May I ask a few questions to help with our research program?

1. We DO accept sharps, needles, lancets, injections. Did you bring any of these items today?

☐ Yes ☐ No ☐ I don't know

2. What is your home zip code (postal code – where you receive your mail)? \_\_\_\_\_

3. Have you participated in a Medication Cleanout event before?

☐ Yes; How many? \_\_\_\_\_ ☐ No

4. Do you receive any medications through a mail-order service?

☐ Yes ☐ No ☐ I don't know

5. You probably have several different reasons, but what would you say is **THE ONE MAIN** reason for disposing of these medications today?

CHOOSE  
ONLY  
ONE  
ANSWER

☐ Not sure what they're for ☐ No longer using/don't need  
☐ Patient died ☐ Medication expired  
☐ Other (please specify: \_\_\_\_\_)

6. Below are several good reasons for properly disposing of medications. Which **ONE** of the following do you feel is **THE MOST** important?

CHOOSE  
ONLY  
ONE  
ANSWER

☐ prevent abuse ☐ protect the environment ☐ prevent poisonings

7. What would you have done with the products if this event had not taken place?

☐ thrown them in the trash ☐ kept them  
☐ flushed them down toilet ☐ other: \_\_\_\_\_

8. Do you have the number to the Poison Center:

Somewhere in your home?

☐ Yes ☐ No

Saved in your cell phone?

☐ Yes ☐ No



Collection Number: \_\_\_\_\_

# Questions?

- ▶ Contact Information
  - ▶ Jeanie Jaramillo-Stametz
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