



# How to Prepare for a DEA Audit

# Disclosure

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies



# DEA's Mission Statement

The mission of the DEA is to enforce the controlled substance laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international market.

# DEA Diversion Control Division's Mission Statement

The mission of DEA's Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an uninterrupted supply for legitimate medical, commercial, and scientific needs.



# DEA's Role

- DEA's statutory responsibility under the Controlled Substance Act (CSA) is twofold:
  - 1) prevent diversion and abuse of drugs
  - 2) ensure an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs.
- In carrying out this mission, DEA works in close cooperation with state and local authorities and other federal agencies.

# Records

- ▶ Records are required to be kept for two years and be readily available.
- ▶ Schedule II records must be kept separate from schedule III through V records.





# Required Records -1304; 21 USC 827



- ▶ Biennial Inventory – 1304.11(a) and (c).
- ▶ Dispensing and Receiving Records – 1301.01(b) and 1304.04(f)(2);(h)(2).
- ▶ Receiving Records will include: Invoices and DEA 222 Order Forms.
- ▶ Dispensing Records will include: What ever is considered to be your dispensing record, DEA Forms 106 and 41.



# Inventories



- ▶ Initial Inventory = the biennial totals taken from your inventory.
- ▶ Closing Inventory = is the drugs on hand the day we arrive.





# Regulations of Concern

- ▶ Complete and accurate records: CFR 1304.21 (a); 21 USC 827
- ▶ Dispensing records: CFR 1304.22(c)
- ▶ Effective controls against theft and diversion: CFR 1301.71; 21 USC 823(a)(1)
- ▶ Employee background checks: CFR 1301.93 and 1301.76(a)
- ▶ Biennial Inventory: 21 USC 827(a)(1); CFR 1304.11(a) and (c)
- ▶ Responsibility to report diversion: CFR 1301.91
- ▶ Security: CFR 1301.71



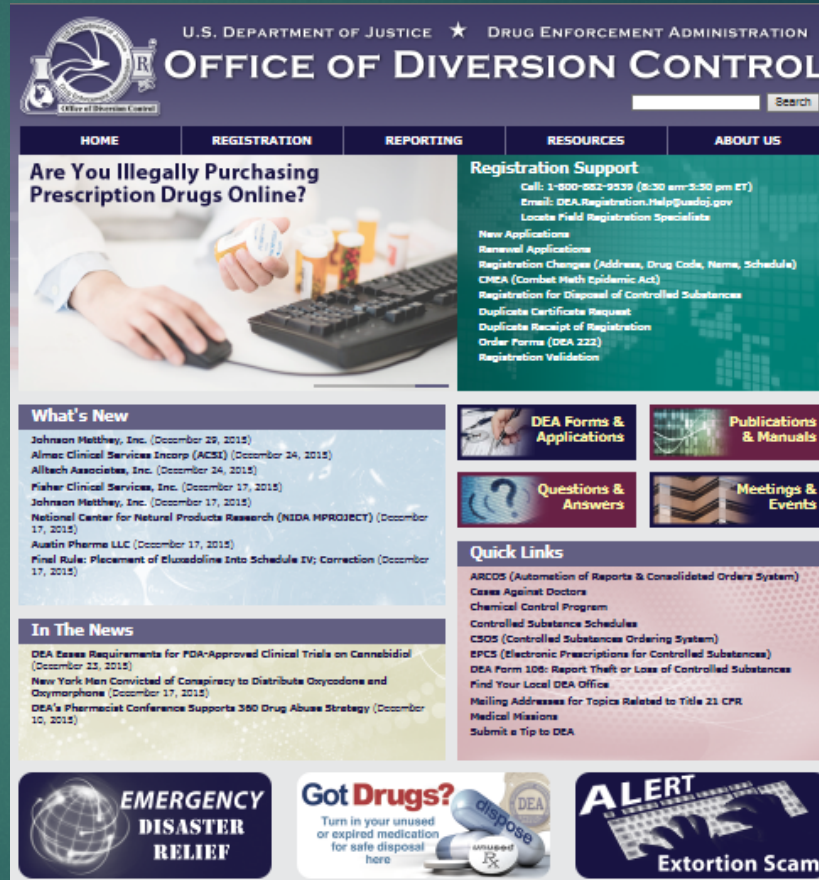
# Forms You Should be Familiar

- ▶ DEA Form 106 = Theft and Loss Report.
- ▶ DEA Form 41 = Registrants Inventory of Drugs Surrendered.
- ▶ DEA Form 82 = Inspection of Controlled Premises.



# DEA Diversion Website

- Registration Support
- Publications & Manuals
- Federal Regulations
- Drug Take Back Locations





# Questions

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