



DEA Registrant Responsibilities and Administrative Penalties



The following visual presentation is not legal advice and is intended to be used with the live presentation given by the authors.

Agenda



- Overview
 - The Controlled Substances Act
 - DEA Certificate of Registration
- Registrant Responsibilities
- “Effective Controls” & Security Controls
- Results of CSA Violations
- Problems
- Recommendations

What is the CSA?



The Controlled Substances Act (CSA)

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A system created to ensure a closed distribution of controlled substances



U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control

DEA Certificate of Registration



- 21 U.S.C. 822(a)(1)
 - Manufacturers and distributors shall obtain a registration issued by the AG in accordance with the rules and regulations promulgated by him.



Registration Responsibilities



- 21 U.S.C. Sections 824(a):
 - Suspension or Revocation:
 - ✦ Material falsification
 - ✦ Felony conviction relating to CS
 - ✦ No state license
 - ✦ Has committed such acts as would render registration “inconsistent with the public interest”—Section 823

Registration Responsibilities



- **Section 823(a) and (d)**
 - (a): I and II
 - (d): III-V
- Maintenance of effective controls against diversion
- Compliance with State and local law
- Prior conviction record under Federal and State laws relating to manufacture, distribution, and dispensing of controlled substances ((a)(4) and (d)(4))
- Past experience in distributing CS ((a)(5) and (d)(5))
- "Such other factors" – catch-all ((a)(6) and (d)(6))

Effective Controls



- 21 C.F.R. § 1301.71 – Security requirements **generally**
 - The “take away” here – “all applicants and registrants”
 - ✦ **Must provide effective controls and procedures to guard against the theft and diversion of CS**



Security Controls – Generally



- Substantial compliance
 - §§ 1301.72-1301.74
 - May be deemed sufficient
- In addition, § 1301.71(b) factors – “evaluation of the overall security system” and “needs of the applicant/registrant”:
 - Notable regulatory examples:
 - Type of activity (processing of bulk chemicals, packaging, labeling, etc.)
 - Location of the premises and relationship between location and security
 - Type of vault and storage systems used
 - Type of closures on vaults, safes, and secure enclosures
 - Adequacy of key control systems
 - Extent of unsupervised public access
 - Adequacy of supervision of employees with access to CS
 - Adequacy of supervision over employees having access to manufacturing and storage areas

Security Controls – Generally



- For manufacturers: §§ 1301.72, 1301.73, 1301.74
 - Key provisions:
 - Storage of raw material in Schedules I and II (§ 1301.72(a)(3))
 - (i) through (v)
 - If frequent access, equipped with a self-closing and self-locking gate
 - Alarm system
 - Section 1301.73 – applicable to “all manufacturing activities”
 - (a): In-process substances shall be securely locked
 - (b): Manufacturing activities conducted in limited access areas
 - (c): During production, areas accessible only to required employees; all others require observation by designated employee
 - Report suspicious orders and make theft and loss reports (§ 1301.74)
 - Employee Screening
 - §§ 1301.90 through 1301.93

CSA Violations—Administrative



- Orders to Show Cause
- Immediate Suspension Orders
- Letters of Admonition
- Enforcement Hearings
- Memoranda of Agreement



CSA Violations—Administrative



- Suspension – Section 824(d)
 - + (an added factor)
 - ✦ “Imminent threat to the public health and safety”
 - Generally:
 - ✦ “About to occur”
 - ✦ “Near at hand”
 - Case law:
 - ✦ *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012)
 - ✦ *Holiday CVS, LLC v. Holder*, 839 F. Supp. 2d 145 (D.D.C. 2012).

CSA—Recordkeeping Requirements



- Each registrant manufacturing, distributing, or dispensing a controlled substance must maintain, on a current basis, a complete and accurate record of each such substance received, sold, delivered, or otherwise disposed of by it. 21 U.S.C. § 827(a)(3); 21 CFR 1304.03, 1304.04, 1304.21.
- Records must be kept and be available for inspection and copying for at least two years. 21 U.S.C. § 827(b)(3), 21 CFR 1304.04.
- It is unlawful to fail to make, keep, or furnish a required record or report. 21 U.S.C. § 842(a)(5), (10).
- A registrant must be able to account for all controlled substances it receives.

CSA—Recordkeeping Violations



- Required records
 - Inventories. 21 U.S.C. § 827(a); 21 CFR 1304.
 - DEA Form 222s. 21 U.S.C. § 828; 21 CFR 1305
- Required reports
 - Theft or significant loss. 21 CFR 1304.74(c), 1310.05(a)(3)
- Audit Results (accurate records): Confirmed shortages or overages of controlled substances constitute record-keeping violations. 21 U.S.C. § 827(a)(3); *U.S. v. Little*, 59 F.Supp.2d 177, 185-186 (D.Mass. 1999).
- Must show negligence (failure to use reasonable care)

“Problems”—May Result in DEA Action



- “We don’t maintain a biennial inventory.”
- “The customer does not have a valid DEA registration.”
- “We have not installed cameras on-site to ensure controlled substances are not diverted.”
- “I’m not responsible for what my customer does with the drugs.”

Recommendations



- ✓ Know your responsibilities under the Act and regulations
- ✓ Make timely ARCOS reports
 - ✓ Timely report errors
- ✓ Develop an internal recordkeeping system that complies with the CSA
- ✓ Make employees knowledgeable about policies and procedures
 - ✓ Train employees
 - ✓ Provide access to controlled substances to only those employees who need access

Recommendations



- ✓ Document—Make complete and accurate reports
- ✓ Be prepared during DEA cyclical investigations
- ✓ Account for all controlled substances throughout manufacturing processes
- ✓ Ensure controlled substances are properly safeguarded
- ✓ Comply with State and local laws
- ✓ Report thefts and losses



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