ASIS PHARMACEUTICAL SECURITY COUNCIL

Controlled Substance Compliance Program

ASIS INTERNATIONAL®
Pharmaceutical Security Council

Controlled Substance Compliance Program

Contents

Executive Summary

This paper discusses the history, governing authorities, and regulations that support U.S. Drug Enforcement Administration (DEA) registered corporations and entities involved in manufacturing, distributing, and dispensing controlled substances. The paper focuses on the challenges facing the pharmaceutical industry to develop, implement, and maintain an effective controlled substance compliance program that satisfies the regulations enforced by the DEA.

The misuse and abuse of prescription drugs has been referred to as an epidemic in the United States and is more prevalent than the abuse of illicit drugs. The DEA is responsible for the enforcement of the Controlled Substances Act (CSA) and its corresponding regulations. These regulations mandate that the pharmaceutical industry maintain a closed system of distribution, thereby preventing the illicit diversion of controlled substances. This paper presents best practices necessary to maintain an effective regulatory compliance program that will enhance operations and prevent the illicit diversion of controlled substances.

BNDD as a Precursor to the DEA

Prior to the creation of the U.S. Drug Enforcement Administration (DEA) in 1973, multiple U.S. law enforcement and intelligence organizations carried out federal drug enforcement policies.

The Bureau of Narcotics and Dangerous Drugs (BNDD) was formed in 1968 with the introduction into the U.S. Congress of Reorganization Plan No. 1 by President Lyndon B. Johnson, who proposed combining two agencies into a third new drug enforcement agency.

President Johnson's proposal merged the Federal Bureau of Narcotics (FBN), then under the Treasury Department, with the Bureau of Drug Abuse Control (BDAC), then part of the Department of Health, Education, and Welfare. The BDAC was responsible for the control of dangerous drugs, including stimulants and hallucinogens such as LSD. The FBN was responsible for the control of marijuana and narcotics such as heroin. The new agency, the Bureau of Narcotics and Dangerous Drugs (BNDD), was placed under the Department of Justice, which is the government agency primarily concerned with federal law enforcement.

The Controlled Substances Act (CSA) was enacted by Congress as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA is the federal drug policy under which the manufacture, importation, possession, uses, and distribution of certain substances are regulated.

The legislation created five schedules (classifications) into which substances fall based on their various properties. Two federal agencies, the DEA and the Food and Drug Administration (FDA), determine which substances are added to or removed from the various schedules, through the statute passed by Congress creating the initial listing.

The CSA also:

- Established a closed system of distribution for those authorized to handle controlled substances. The cornerstone of this system is the registration of all those authorized by the DEA to handle controlled substances. All individuals and firms that are registered are required to maintain complete and accurate inventories and records of all transactions involving controlled substances, as well as security for the storage of controlled substances.
- Created the Compliance Program (1971), later renamed the Diversion Control Program, to monitor the legitimate manufacture and distribution of controlled substances.
- Clearly differentiated controlled substances from other legend drugs handled under the FDCA. (Legend drugs are approved by the FDA and are required by federal or state law to be dispensed to the public only on prescription of a licensed physician or other licensed provider.)
- Authorized the DEA to register dispensers, practitioners, manufacturers, and distributors.
- Addressed through the CSA and regulations the creation, signature, and retention of prescriptions and records.

The DEA's Role

The role of the DEA is to enforce the U.S. controlled substances laws and regulations and to bring before the criminal and civil justice system those organizations and their principal members that are involved in the illicit growing, manufacture, or distribution of controlled substances in the United States, as well as to recommend and support nonenforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.

The DEA's Office of Diversion Control is responsible for two distinct problems: the diversion of controlled pharmaceuticals and the diversion of controlled chemicals. Many pharmaceutical products manufactured for legitimate medical use are subject to abuse and therefore have been brought under control. The controls have been established to ensure that the controlled substances are available for medical use and to prevent their distribution for illicit sale and abuse. Similar controls have been placed on obtaining the chemicals necessary to manufacture drugs of abuse.

Basic Registration Principles

DEA regulations (21 CFR.1301.11) require that every person who manufactures, distributes, dispenses, imports, or exports any controlled substance, or who proposes to engage in the manufacture, distribution, dispensing, importation, or exportation of any controlled substance, shall obtain a registration unless exempted by law or pursuant to 1301.22-1301.26 (i.e., exemptions for agents, law enforcement and certain military officials, and others).

DEA registrations are issued for specific business activities. Only persons actually engaged in such activities are required to obtain a registration. The persons that require a DEA registration include:

- Manufacturers (bulk and all others)
- Distributors (wholesale and reverse)
- Practitioners, including mid-level
- Researchers (Schedule I and Schedules II-V), analytical labs, and teaching institutions
- Narcotic treatment programs
- Importers and exporters
- Retail pharmacies
- Hospitals and clinics
- Chemical manufacturers, distributors, importers, and exporters

The DEA investigates and prosecutes violations of the Controlled Substances Act, including the dispensing of controlled substances without a legal prescription from an authorized and registered practitioner.

A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

The ABCs of DEA Compliance

All applicants and registrants are required to provide effective security controls and procedures to guard against theft and diversion of controlled substances. The DEA has established standards for effective security controls and operating procedures necessary to prevent diversion. The DEA general security requirements are found in 21 CFR 1301.71. Compliance with the standards in CFR 1301.72-1301.76 may be deemed sufficient after evaluation of the overall security system and the needs of the applicant or registrant. The DEA administrator may consider any of the following factors as relevant to the need for strict compliance with security requirements:

- The type of activity conducted.
- The type and form of controlled substances handled.
- The quantity of controlled substances handled.
- The physical location of the premises.
- The types of building construction comprising the facility and general characteristics of the building or buildings.
- The types of vaults, safes, secure enclosures, or other storage systems in use.
- The types of closures on the vaults, safes, and secure enclosures.
- The adequacy of key-control, combination, and lock-control systems.
- The adequacy of electronic detection and alarm systems, including the use of supervised transmittal lines and standby power sources.
- The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing.
- The adequacy of supervision of employees who have access to manufacturing and storage areas.
- The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel.
- The availability of local police protection or of the registrant's or applicant's security personnel.
- The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.
- The applicability of the security requirements contained in all federal, state, and local laws and regulations governing the management of waste.

Getting Started

Partnerships with Internal Business Units

Successful controlled-substance order monitoring, reporting suspicious orders, and know your customer (KYC) due diligence programs must be a collaborative effort across a wide range of internal business units. The effort is a delicate balance between regulatory compliance and customer service. This balance can be achieved through constant communication, flexibility, and consistency.

Policies and Procedures

A program for reporting suspicious orders and preventing diversion of controlled substances contains the following elements:

I. KYC Due Diligence

Knowing the customer extends beyond cursory verification of licenses and registrations. Site visits allow firsthand observations of the business and its clientele. Account managers who are encouraged to act as eyes and ears in the field can also provide information.

II. Monitoring for Suspicious Orders

Suspicious orders are defined as being of unusual size or frequency, deviating substantially from a normal pattern, and are generally considered high-risk or prone to diversion.

III. Suspend or Stop an Order of Interest Shipment

An order of interest is one that is electronically flagged based on threshold parameters established by the registrant. Because orders of interest often address a legitimate need, they should be investigated promptly.

IV. Investigation of Orders of Interest

Direct communication with the customer is the most effective method for determining the validity of an order of interest. The justification provided by the customer, in combination with historical ordering data, can assist the investigator to make an accurate determination within a relatively short time frame. An order of interest that is determined to be suspicious should not be shipped.

V. File Suspicious Order Reports with the DEA

The registrant must design and operate a system to disclose suspicious orders. Investigated orders deemed genuinely suspicious must be reported in a timely fashion to the DEA office in the registrant's jurisdiction.

VI. Employees, Training, and Standard Operating Procedures

New employees, compliance-critical employees, and employees who have regular customer contact should be well versed on diversion control and the policies and procedures that govern the diversion control program.

Regulatory Inspections

The mission of the DEA Office of Diversion Control (OD) is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels while ensuring an adequate and uninterrupted supply to meet legitimate medical, commercial, and scientific needs.

DEA OD diversion investigators are authorized to enter controlled premises and conduct inspections. When entering any DEA-registered place of business, diversion investigators state the purpose of their visit and present the owner, operator, or person in charge of the premises with their credentials and a DEA Form 82, Notice of Inspection (NOI). The NOI shall contain:

- The name and title of the owner, operator, or person in charge of the controlled premises
- The name of the controlled premises
- The address of the controlled premises to be inspected
- The date and time of the inspection
- The name of the diversion investigator conducting the inspection
- A place for the diversion investigator to sign his or her name

An inspection may include but not be limited to the following:

- Reviewing Schedule II order forms
- Reviewing Schedule III-V receipt records
- Reviewing Schedule II-V controlled substance prescriptions
- Reviewing theft or loss and drug destruction records
- Reviewing security procedures for controlled substances

Scheduled Regulatory Investigations

Diversion investigators conduct scheduled regulatory investigations as part of their statutory requirements under the CSA. Registrants such as distributors, reverse distributors, manufacturers, narcotic treatment programs, researchers, importers, and exporters who fall into the Type B category should be periodically investigated by diversion investigators.

Administrative Inspection Warrant

In cases where administrative action against a registrant is contemplated, a diversion investigator may obtain an Administrative Inspection Warrant (AIW). Failure by the registrant to allow entry after being presented with an AIW can lead to arrest and a $25,000 civil fine. The execution of an AIW may involve the following:

- Inspecting, copying, and verifying the correctness of records, reports, and other documents required to be kept under the CSA.
- Inspecting, within reasonable limits and to a reasonable manner, all pertinent equipment, finished and unfinished controlled substances, listed chemicals, and other substances or materials, containers, and labeling, at the premises relating to the CSA.
- Making a physical inventory of all controlled substances and listed chemicals on hand at the premises.
- Checking records and information on the distribution of controlled substances or listed chemicals by the registrant to discover, for example, whether the distribution of controlled substances or listed chemicals has increased markedly within the past year, and if so, why.
- Except as provided in Title 21, CFR 1316.04, all other things therein, including records, files, papers, processes, controls, and facilities, appropriate for verification of the above or otherwise bearing on the provisions of the CSA and the regulations thereunder.

Security's Role

The general security requirements set forth in the Code of Federal Regulations (CFR) require that all registrants and applicants for registration provide effective physical security controls and operating procedures to guard against the theft and diversion of controlled substances. Substantial compliance with these requirements and standards set forth in Title 21 CFR Sections 1301.72-1301.76 may be deemed sufficient by the DEA after evaluation of the overall security system and needs of the individual applicant or registrant considering the following factors, with examples of each:

1. **The type of activity conducted**
   - processing of bulk chemicals
   - preparing dosage forms
   - packaging
   - labeling
   - cooperative buying

2. **The type and form of controlled substances**
   - bulk liquids or dosage units
   - usable or nonusable powders

3. **The quantity of controlled substances**

4. **The location of the premises as it affects security needs**
   - high- versus low-crime areas
   - waterfront boundaries
   - adjacent or attached buildings
   - urban versus suburban versus rural areas

5. **Type of building construction and general characteristics**
   - metal curtain
   - wood frame
   - masonry
   - number and type of doors, windows, and other openings

6. **Types and properties of safes, vaults, and secure enclosures**
   - automatic storage and retrieval
   - construction of vaults and cages
   - modular vaults
   - container weight and type
   - UL listing
   - GSA rating

7. **Types of closures**
   - built-in combination locks
   - keyed locks
   - padlocks
   - self-closing and locking day gates
   - vault doors and frames

8. **Types of key and lock control**
   - adequacy
   - accountability
   - routine changing, issuance, and control procedures
   - logging
   - central repository
   - combination security

9. **Alarm systems**
   - adequacy of supervision
   - method of signal transmission
   - proprietary versus central station versus police connection
   - adequacy of standby power sources
   - maintenance and testing
   - signal and response time

10. **Public access and perimeter fencing**
    - adequacy of gates and fencing
    - control at entry and exit points
    - parking locations and proximity to facility
    - the extent of unsupervised public access to the facility

11. **Supervision of employees**
    - access to manufacturing and storage areas
    - identification media and systems
    - control and accountability for identification
    - responsibilities of employees

12. **Guest or visitor procedures**
    - access control
    - logging procedures
    - identification media
    - internal movement control

13. **Local police or security force**
    - availability
    - legal obligation to respond
    - frequency of patrol
    - adequacy of training
    - alarm response time
    - size of force

14. **Adequacy of internal systems for monitoring controlled substances**
    - storage security
    - common or contract carrier security

Due Diligence

The DEA is responsible for ensuring that those licensed to handle controlled substances are in compliance with the CFR and are not illegally diverting them. Due to the growing problem of illegal diversion and the dramatic increase in the misuse and abuse of controlled pharmaceuticals, the DEA has focused its efforts on bringing awareness to the pharmaceutical industry of its responsibility to prevent diversion before it occurs. In turn, the Healthcare Distribution Management Association (HDMA) has established industry compliance guidelines that include close scrutiny and KYC due diligence. The DEA does not certify or assist registrants in conducting their due diligence responsibilities, such as identifying customers to whom they should or should not sell. It is incumbent upon registrants to have comprehensive, established, internal policies and guidelines to better know their customers and more accurately identify suspicious orders of controlled substances.

In recent years, there has been a dramatic increase in civil fines and administrative penalties levied against those registrants who were not in compliance with the CSA's requirements. This has led many DEA registrants to change the way they conduct business.

Negligence

DEA registrants must operate within the strict guidelines of the CSA and its supporting regulations in the CFR. In some instances a company that conducts business with controlled substances may operate under flawed or subjective standard operating policies (SOPs), therefore creating an environment within the company that results in negligent compliance practices. Actions that can be considered negligent can vastly differ depending on the segment of the supply chain in which the registrant is engaged. For instance, a practitioner who overprescribes pain medication to patients in a manner that may be considered negligent is different from a registered distributor that determines it is illicitly distributing pharmaceuticals and then continues to do so. Negligence on behalf of a DEA registrant resulting in significant diversion or a threat to the public welfare can lead to revocation of the DEA registration number, as well as civil and criminal action.

Internal and External Investigations

All registrants are required to maintain complete and accurate inventories and records of all transactions involving controlled substances, as well as security of the controlled substances. Additionally, Section 823(b) and (d) of the CSA calls for the maintenance of effective controls against the diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

All registrants who handle controlled substances share a mission and a responsibility to continuously monitor, protect, and enhance the safety of the pharmaceutical supply chain and to combat increasingly sophisticated criminals who attempt to breach it.

Documentation and Confidentiality

Individuals and firms authorized to handle controlled substances should develop and implement an effective compliance program. The compliance program should incorporate an ongoing evaluation process that is thoroughly documented. For a compliance program to work, employees must be able to ask questions and report problems. Management is critical in responding to employee concerns and it is appropriate that they serve as a first line of communications. Pharmaceutical firms should consider adopting open-door policies to foster dialogue between management and employees. The compliance program should encourage communications, confidentiality, and nonretaliation policies that should be developed and distributed to all employees. These policies and protocols will institutionalize the commitment to compliance and address specific areas of potential fraud and abuse.

Cooperation versus Self-Incrimination

DEA investigators will work closely with pharmaceutical firms, or their compliance departments, to identify and target employees or others who are suspected of illicitly diverting and or distributing controlled substances. Often, the DEA initiates an investigation after being contacted by a registrant who suspects that diversion has occurred or is occurring. The DEA will cooperate with the individual or firm to develop and corroborate evidence, and if appropriate, arrest and prosecute those responsible for diverting controlled substances.

About the ASIS International Pharmaceutical Security Council

The ASIS International Pharmaceutical Security Council is comprised of professionals from all links of the pharmaceutical supply chain, including DEA-registered manufacturers, distributors, and retail pharmacies. Several members of the council are responsible for their organizations' controlled substance compliance programs. The Pharmaceutical Security Council presents this whitepaper as a guide for the pharmaceutical industry to prevent the illicit diversion of controlled substances.

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