

# **Regulatory Section**

**DEA Headquarters**  
**ODG**

# Regulatory Section (ODG)

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# Responsibilities of Regulatory Section (ODGR)

- ▶ Employment Waivers
- ▶ Distributor Briefings
- ▶ Section 303 Investigations
- ▶ Registrant Security
- ▶ Maintaining Data Bases (Civil Fines and OTSC)
- ▶ Scheduled Investigations
- ▶ Drug Theft or Loss
- ▶ Suspicious Order Reporting
- ▶ Controlled Substance Ordering System
- ▶ DATA Waived Physicians
- ▶ Comprehensive Regulatory Training

# Responsibilities of the Import/Export Section (ODGI)

- ▶ Import/Export Permits/Declarations of controlled substances
- ▶ Imports/Exports of Listed Chemicals
- ▶ Mail Order Distribution Reports
- ▶ Medical Missions
- ▶ Transshipments
- ▶ Monitor UN reportable drugs
- ▶ Tableting & Encapsulating Machines
- ▶ DEA Data Bases (CHEMS/CTRANS & IMEX)

# Employment Waivers

- ▶ Applies only to Practitioners, Hospital Clinics and Retail Pharmacies
- ▶ A waiver is required for the employer of a prospective employee who will have access to controlled substances and has been convicted of a drug related felony, has had an application for a DEA Registration denied or has had a DEA Registration revoked or surrendered for cause
- ▶ The employer must request a waiver in writing from DEA
- ▶ The employee cannot work in the controlled substance setting until the DEA Registrant is granted a waiver

# Distributor Briefings

- ▶ DEA HQs personnel will meet with each and every registered Distributor and Manufacturer to discuss their due diligence responsibilities found in Title 21, Code of Federal Regulations, Section 1301.74(b)
- ▶ As of 5/21/10: Distributors: 806; Manufacturers: 441
- ▶ Briefing book provided to DEA Registrant

# Distributor Briefing

- ▶ Closed system of distribution
- ▶ Knowing one's customers
- ▶ Suspicious orders
- ▶ Review of firm's ARCOS data
- ▶ Current national trends
- ▶ Discussion of case law

# ARCOS (Automation of Reports and Consolidated Orders System)

- ▶ State and local Agencies with established MOU's receive annual statistical ARCOS Reports and data graphics.
- ▶ Controlled Substance transactions for specific DEA Registrants can be requested via your local DEA Office. Data must be validated by ODPT (Targeting and Analysis Unit) prior to its release.
- ▶ ODPT provides Drug Trends and Geographic "Hot Spots" in support of pending investigations. Requests made through local DEA Office.

# Section 303 Investigations

- ▶ Schedule I and II Bulk Manufacturers and Importers
- ▶ Bulk Manufacturers 21 CFR 1301.33
- ▶ Importers 21 CFR 1301.34
- ▶ Establishes the regulations which govern the approval and renewal processes for Schedule 1 and II bulk manufacturer and importer applications

# Section 303 Investigations

- ▶ All applications must be published in the Federal Register
- ▶ Comment period by the public
- ▶ All Section 303 investigations require yearly on-site inspections by DEA
- ▶ DEA HQ approves or denies the application

# Registrant Security

- ▶ Security has two aspects:
- ▶ Physical Security 21 CFR 1301.71
- ▶ HQ to provide guidance to both the DEA field offices and industry relative to DEA security requirements
- ▶ Industry works through their respective field offices
- ▶ Prevention of diversion, theft, and pilferage is the ultimate goal

# Registrant Security

- ▶ Personnel Security 21 CFR 1301.90-93
- ▶ Employee screenings
- ▶ Employee training and reporting
- ▶ Illicit activities by employees

# Scheduled Investigations

- ▶ Manufacturers, Distributors, Importers, Exporters and NTPs
- ▶ Conduct file check on registrant
- ▶ ARCOS check: Identify customers and primary controlled substances sold
- ▶ Firm's background information
- ▶ Controlled substances audit
- ▶ Security review and alarm test
- ▶ Customer verification

# Drug Theft or Loss

- ▶ Regulatory Authority: 21 CFR 1301.74(c)
- ▶ Registrants are required to notify the local DEA Office in writing or online ([DEAdiversion.usdoj.gov](http://DEAdiversion.usdoj.gov)) of any theft or significant loss of controlled substances
- ▶ Requires the completion of a DEA Form 106
- ▶ Prior to 2005, only handwritten forms were available. On July 28, 2005 the electronic version was implemented. Today over 90 percent of DEA Forms 106 are submitted online

# Suspicious Orders

- ▶ DEA will no longer accept Excessive Purchase Reports. Previously excessive purchase reports were received after drugs had already been shipped by registrants
- ▶ Registrants must know their customers
- ▶ Registrants can only ship a suspicious order once they have investigated the order, found it to be legitimate, and documented their findings
- ▶ DEA cannot tell registrants whether or not to ship

# Suspicious Orders

- ▶ The registrant shall design and operate a system to detect suspicious orders of controlled drugs (21 CFR 1301.74(b))
- ▶ Upon discovery the registrant shall notify the local field office of the suspicious order
- ▶ Once determined an order is suspicious it cannot be shipped
- ▶ Examples: Unusual size, frequency, deviating substantially from a normal pattern, percentage of controlled versus non-controlled substances purchases, methods of payment, location and operation of customer, and range of products being purchased.

# Suspicious Order Reporting System

- ▶ Some Registrants by Agreement (MOA) report suspicious orders directly to DEA HQs (currently ten firms)
- ▶ ODT (Technology Section) receives and processes the data
- ▶ ODP (Pharmaceutical Investigations Section) oversees the program and disseminates the information to the appropriate field office

# Controlled Substance Ordering System (CSOS)

- ▶ Voluntary option for the ordering of Schedule II drugs
- ▶ Replaces DEA Forms 222, Official Order Forms, creates an electronic ordering system
- ▶ DEA approves registrant's application to enroll in CSOS and issues a digital certificate to registrant

# Controlled Substance Ordering System (CSOS)

- ▶ Seller and Purchaser must maintain all CSOS orders for two years
- ▶ All records must be linked to the original archived CSOS order
- ▶ All CSOS records must be readily retrievable
- ▶ All CSOS records must be rendered to a format that is easily readable

# Drug Addiction Treatment Act of 2000 (DATA)

- ▶ The Drug Addiction Treatment Act of 2000 (DATA) was passed by Congress on October 17, 2002 and amended the CSA, 21 USC 823 (g)
- ▶ The Act waived the requirement to obtain a separate DEA registration as a Narcotic Treatment Program for qualified physicians
- ▶ The Act permits qualified physicians to treat narcotic dependence with FDA approved Schedule III-V narcotic controlled substances. The only controlled substances approved for such use are Subutex ® and Suboxone ®

# Drug Addiction Treatment Act of 2000 (DATA)

- ▶ Hospitals and mid-level practitioners do not qualify under DATA
- ▶ Data Waived physicians are subject to on-site inspections by DEA to ensure compliance with DATA and implementing regulations
- ▶ DATA Waived physicians may treat up to 30 to 100 patients at a time per SAMHSA authorization

# DATA Waived Physician's DEA Registration

- ▶ Approved physicians are issued a Unique Identification Number (UIN)
- ▶ Similar to the physician's DEA Registration number in which the first character is replaced by an "X"
- ▶ A new DEA Registration Certificate is issued containing the physician's registration number and his or her UIN

# Data Waived Physicians

Data Waived Physician Population

18,020 (per CSA as of 5/19/10)

DEA began inspecting the registered locations of DATA Waived physicians on a Scheduled basis on October 1, 2003.

# Scope of On-Site Investigation

- ▶ Verify appropriate DEA and State licenses
- ▶ Administer, dispense or prescribe?
- ▶ Number of patients authorized to treat
- ▶ Number of patients actually being treated
- ▶ Recordkeeping

# Scope of On-Site Investigation

- ▶ Administers/Dispenses?

Conduct an audit for a minimum of three months

- ▶ Prescribes Only?

Conduct a review of a minimum of three months worth of prescribing

# Recordkeeping Requirements

- ▶ Inventories (21 CFR 1304.11)
- ▶ Receipt Records (21 CFR 1304.21)
- ▶ Dispensing Records (21 CFR 1304.03(d) and 1304.24)

# Scope of On-Site Investigation

- ▶ Prescribing Physicians
- ▶ Prescribing Records (21 CFR 1304.03(c ))
- ▶ Review records of controlled substances prescribed in the course of maintenance or detoxification treatment of an individual

# Scope of On-Site Investigation

- ▶ Review security controls
- ▶ ID individuals with access to the controlled drugs
- ▶ Discuss any thefts or losses of controlled drugs

# Scope of On-Site Investigation

- ▶ Discussion with Physician
- ▶ Inform physician of any violations and document his/her response
- ▶ How does he/she advertise his/her services
- ▶ General practice medicine?
- ▶ Pain Specialty office?

# Scope of On-Site Investigation

- ▶ Percentage of patients being treated for illicit versus licit drugs
- ▶ Type of drugs for which patients are being treated
- ▶ Verify the physician has not exceeded the 30 or 100 patient limit

# Scope of On-Site Investigation

- ▶ Inquire as to which controlled substance the physician prescribes, administers or dispenses for narcotic addiction treatment (Subutex ®, generic Subutex or Suboxone®)
- ▶ Inquire if the physician prescribes, administers or dispenses these drugs to patients for the treatment of any condition other than narcotic addiction

# Other Issues

- ▶ Should an investigation warrant civil or criminal action involving the possible seizure of patient records, the Investigator should consult with an AUSA in order to obtain a Court Order through a Federal Magistrate
- ▶ Data Waived Physicians who want to surrender their UIN “X” from their DEA Registration must submit written notification of the request

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**Questions or Comments**