

Controlled Substances Regulations

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Controlled Substances Act

- Harrison Narcotic Act of 1914
- Single Convention on Narcotic Drugs of 1961
- Convention on Psychotropic Substances of 1971
- Chemical Diversion Trafficking Act of 1988
- Methamphetamine Control Act of 1996
- Combat Methamphetamine Epidemic Act of 2005

Purposes of Controlled Substance Act

- To place abusable and/or addictive drugs in certain Schedules (under “control”)
- To create a “closed system” of distribution of controlled substances
- To regulate the distribution of chemicals used in the illicit manufacture of illegal drugs
- Codified in the Code of Federal Regulations (21 CFR 1300 to end)

Controlled Substances

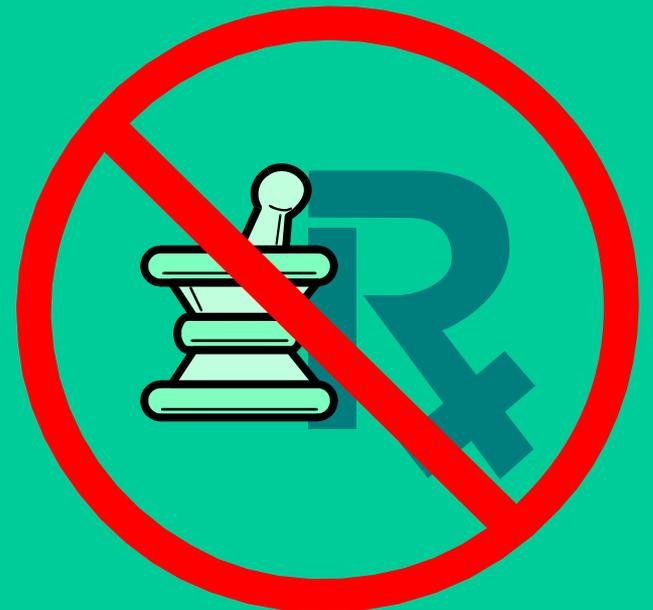
- Drug or other substance or immediate precursor included in Schedule I, II, III, IV, or V
- Not all prescription drugs are controlled substances, but almost all controlled substances are prescription drugs

Factors Considered for Scheduling Drugs

- Actual or relative potential for abuse
- Scientific evidence of pharmacological effect
- State of current scientific knowledge
- History and current pattern of abuse
- Risk to public health
- Psychic or physiological dependence liability
- Whether substance is immediate precursor of a substance already controlled

Schedule I

- No current medical use in the United States
- Very high potential for abuse
- Examples
 - Heroin
 - MDMA (Ecstasy)
 - LSD
 - Marijuana



Schedule II

- Legitimate medical use
- High potential for abuse
- Narcotics (II) and Non-narcotics (IIN)
- Examples

IIN

Methamphetamine

Cocaine

Ritalin

Adderall

II

Dilaudid

Morphine

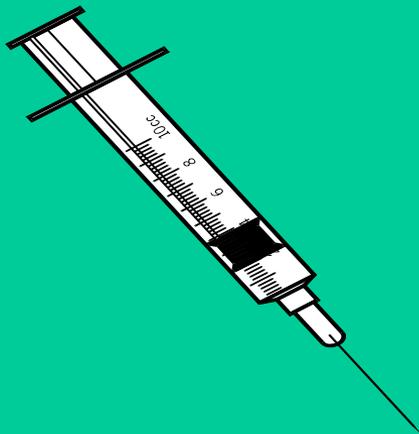
Percocet, Percodan

Oxycontin



Schedule III

- Legitimate medical use
- Lesser potential for abuse
- Narcotic (III) and Non-narcotic (IIIN)
- Examples



Vicodin, Lortab (Hydrocodone) (III)

Tylenol with Codeine (III)

Buprenorphine (Suboxone) (III)

Butorphanol (Stadol) (III)

Anabolic Steroids, Ketamine (IIIN)

Schedule IV

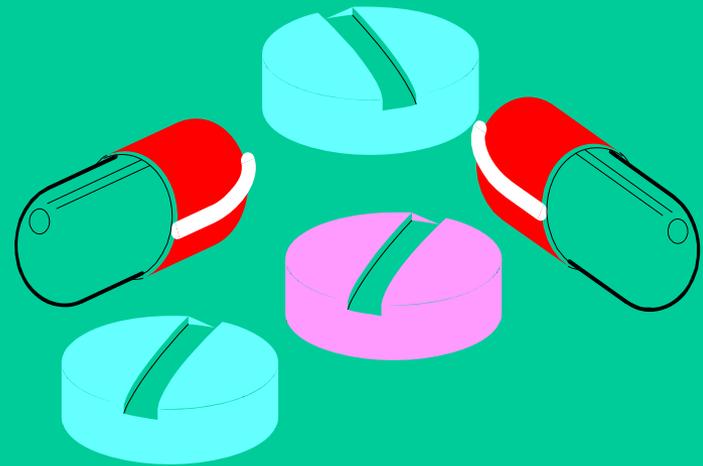
- Low potential for abuse
- Examples

Valium

Xanax

Darvocet

Diet Drugs



Schedule V

- Lowest potential for abuse
- Examples

Cough syrups

Lyrica

Lomotil



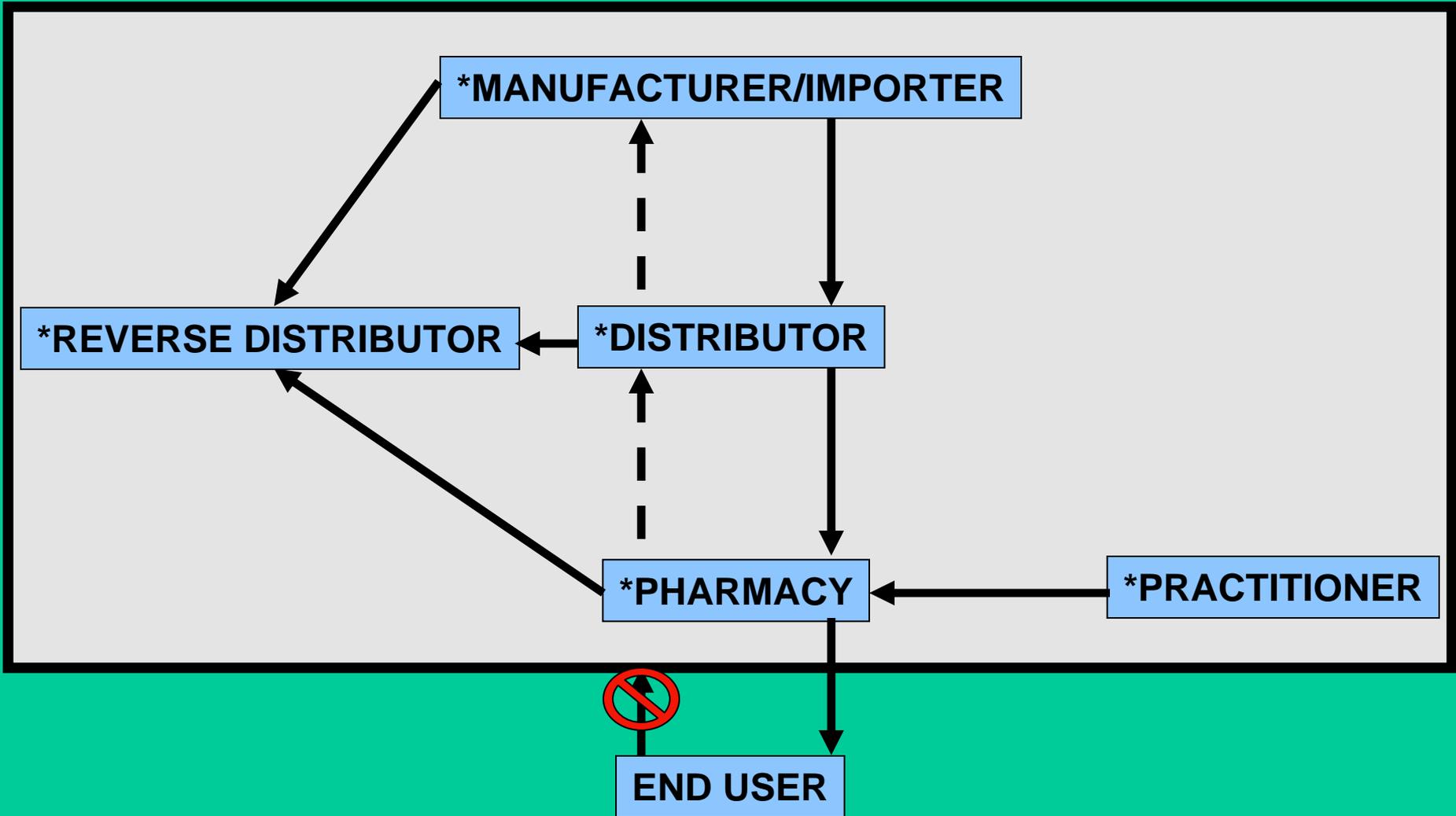
Closed System of Distribution

- All handlers (“registrants”) of controlled substances (except the end user) must maintain a DEA registration
- Each registrant involved in a transaction must verify the other registrant’s DEA registration (until dispensed to end user)
- Any transfer by the end user to any other person is illegal distribution

DEA Registrants (Handlers of Controlled Substances)

- Importers, Manufacturers
- Distributors (Wholesalers), Exporters
- Pharmacies
- Narcotic Treatment Programs (NTPs)
- Practitioners (MD, DO, DDS, DVM)
- Mid-Level Practitioners (PA, ARNP)
- Researchers, Analytical Labs
- “Reverse Distributors”

CLOSED SYSTEM



*DEA Registrant

Disposition of Unwanted Controlled Substances

- For Registrants:
 - Return to supplier
 - Send to “Reverse Distributor”
 - Receive permission from DEA to destroy on-site
 - Requires written approval from DEA
 - Requires two persons to witness
 - Must be recorded on DEA Form 41
 - Must be destroyed “beyond reclamation”

Disposition of Unwanted Controlled Substances

- For End-User
 - Can NOT return to DEA registrant (back into closed system)
 - If destroying on own, should destroy “beyond reclamation”
 - Can participate in community collection program IF community program has law enforcement involvement

Community Collection Programs

- Pharmacies, “Reverse Distributors,” and other registrants can NOT accept controlled substances (CS) at community collection programs
- To accept CS, community programs MUST have law enforcement participation
 - Law enforcement is exempt from registration requirements (can accept CS without being in the “closed system”)
 - The law enforcement agency must destroy the collected CS in accordance with agency evidence destruction guidelines

What DEA is Doing to Address the Issue of Unwanted CS

- DEA Detroit has been advising that flushing or pouring down the drain are not acceptable methods of destruction
- DEA HQ is currently drafting regulations to permit end users to surrender unwanted CS for destruction
 - Drafting regulations is a long process and takes time
 - DEA drafts proposal
 - Published in Federal Register with request for comments
 - Published as Final Rule

DEA Diversion Web Site

- www.deadiversion.usdoj.gov

The screenshot shows a web browser window titled "America Online 9.0 Optimized SE provided by Dell". The address bar displays "http://www.deadiversion.usdoj.gov". The website content includes the following elements:

- Header:** U.S. DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION OFFICE OF DIVERSION CONTROL
- Navigation Menu:** HOME, PRIVACY POLICY, CONTACT US, WHAT'S NEW, HOT ITEMS, SITEMAP, SEARCH
- Left Sidebar:**
 - DIVERSION PROGRAMS**
 - APPLICATIONS & ON-LINE FORMS
 - ARCOS
 - CHEMICALS
 - CONTROLLED SUBSTANCE SCHEDULES
 - IMPORT AND EXPORT
 - IFELIS
 - QUOTAS
 - REGISTRATION SUPPORT
 - REPORTS REQUIRED BY 21 CFR
 - RESOURCES**
 - CAREER OPPORTUNITIES
 - DRUGS/CHEMICALS OF CONCERN
 - e-COMMERCE INITIATIVES
 - FEDERAL REGISTER NOTICES
 - MEETINGS & EVENTS
 - OFFICES & DIRECTORIES
 - PROGRAM DESCRIPTION
 - PUBLICATIONS
 - QUESTIONS & ANSWERS
 - REGULATIONS & CODIFIED CSA
 - LINKS**
 - FEDERAL AGENCIES & RELATED
 - INDUSTRY RELATED
- Main Content Area:**
 - WELCOME TO THE DIVERSION CONTROL PROGRAM**
 - Registration Number
Toll Free: 1-800-882-9539
 - REGISTRATION SUPPORT**
 - Save time by applying for and/or renewing your DEA Registration on-line. Data will be entered through a **secure connection** to the ODWIF on-line web application system. Minimum requirements: Credit Card and a web browser that supports **128-bit encryption**.
 - SAVE TIME** (with an image of a stopwatch)
 - Links:**
 - To Apply for Renewal Applications for Registration On-Line
 - To Apply for New Applications for Registration On-Line
 - To Apply for Registration by Mail
 - For Registration Changes
- Right Sidebar:**
 - RENEWAL**
Apply On-Line
REGISTRATION APPLICATIONS
Renewal Applications
 - NEW APPLICATIONS FOR REGISTRATION**
New Registration Applications
 - DEA FORM 106 ONLINE**
REPORT THEFT OR LOSS OF CONTROLLED SUBSTANCES

DEA Diversion

313-234-4377

313-234-4388

www.dea.gov

www.deadiversion.usdoj.gov