

HOW CONTROLLED ARE YOUR CONTROLLED SUBSTANCES?

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OBJECTIVES

- ✓ Define controlled substances
- ✓ Discuss common locations for controlled substances in higher education
- ✓ Understand the complexities of controlled substance program compliance
- ✓ Discuss methods for evaluating the effectiveness of a controlled substances program

CONTROLLED SUBSTANCES DEFINED

Pharmaceuticals or chemical precursors
with a high degree of danger to humans
and a significant probability of abuse.

-U.S. Controlled Substances Act

DRUG SCHEDULES

Schedule I

Schedule II/IIIN

Schedule III/IIIN

Schedule IV

Schedule V

DEA SCHEDULE I



- A high potential for abuse.
- Have no currently accepted medical use in treatment in the U.S.
- Lack of accepted safety for use of the drug or other substance under medical supervision.

Some examples of substances listed in schedule I are:

- Heroin,
- Lysergic acid diethylamide (LSD)
- Marijuana (cannabis)
- Peyote, methaqualone
- 3,4-methylenedioxymethamphetamine (“ecstasy”)

DEA SCHEDULE II

- A high potential for abuse.
- Has a currently accepted medical use in treatment in the US or a currently accepted medical use with severe restrictions.
- Abuse may lead to severe psychological or physical dependence.



Some examples of substances listed in Schedule II:

- Cocaine
- Amphetamines
- Pentobarbital
- Etorphine
- Fentanyl
- Codeine
- and many other opioids

DEA SCHEDULE III

- Potential for abuse less than the drugs or other substances in schedules I and II.
- Has a currently accepted medical use in treatment in the United States.
- Abuse may lead to moderate or low physical dependence or high psychological dependence.



Some examples of substances listed in Schedule III:

- Barbiturates
- Hydrocodone
- Ketamine

DEA SCHEDULE IV



- Low potential for abuse relative to the drugs or other substances in schedule III.
- Has a currently accepted medical use in treatment in the US.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Examples of Schedule IV drugs:

- Diazepam
- Phenobarbital
- Butorphanol
- Phenobarbital

DEA SCHEDULE V

- Low potential for abuse relative to the drugs or other substances in schedule IV.
- Has a currently accepted medical use in treatment in the US.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

Examples of Schedule V drugs:

- Buprenorphine
- Diphenoxylate
- Cough syrup with codeine



NON-DRUG CONTROLLED SUBSTANCES

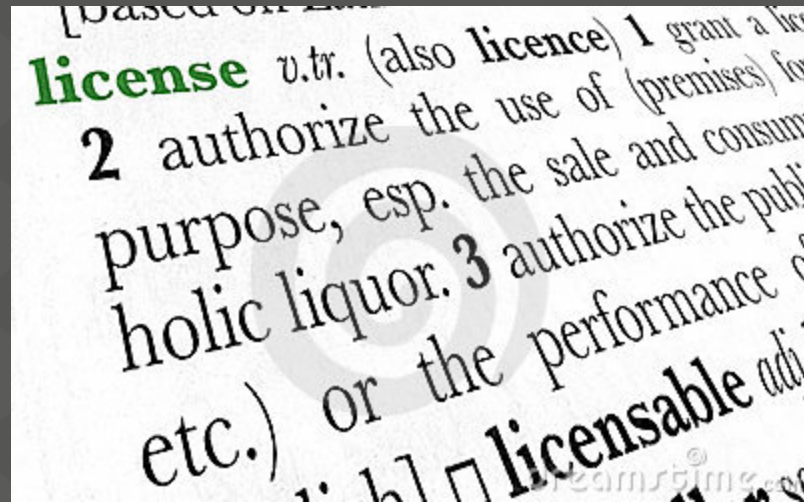
- **List I Chemicals** – used in manufacture of controlled substances and important to their manufacture
 - Ephedrine
 - Benzyl Cyanide
 - Iodine
- **List II Chemical** – used in manufacture of controlled substances
 - Acetone
 - Hydrochloric gas
- **Lab Apparatus**
 - Certain flasks and thermometers
 - Heating mantel
 - Adaptor tube
- **Registration with DEA not typically required unless selling chemicals**
 - Must maintain records
 - Notify DEA of excessive losses

CONTROLLED SUBSTANCES REGULATIONS

- U.S. Controlled Substances Act
 - Enforced by the Drug Enforcement Agency
- Part 21, CFR, Chapter II, DEA, Part 1300-End
- Texas Controlled Substances Act
 - Enforced by the Texas Department of Public Safety
- Texas Department of Public Safety Drug Rules
- Memorandum of Understanding between the Texas Department of Public Safety and the Texas Higher Education Coordinating Board

LICENSING REQUIREMENTS

- **All** practitioner's handling controlled substances must be registered with the DEA unless specifically exempted by law.



CONTROLLED SUBSTANCES ON CAMPUS

- Pharmacies
- Student / Employee Health Clinics
- Medical Clinics
- Research Labs
- Veterinary Care
- Athletic Facilities
- Any place where items or chemicals reside that could be used or combined to create a controlled substance

POLICIES

- DEA requires that there be written policies detailing how you will manage your program.
- The policy needs to detail what is considered a discrepancy.
- How will you dispose of expired drugs.
- Who will purchase.
- How will drugs be stored.
- Disposal procedures.

PURCHASING

- The vendor must have a copy of the DEA license on file to order Controlled Substances.
- The Drug can only be shipped to the address on your license.
- Purchasing of schedule 3-5 drugs only requires a license.
- Purchasing schedule 1 or 2 drugs requires a 222 form.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0326632	06-30-2008	FEE PAID

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5,	DISTRIBUTOR	06-26-2007

DC DYNA INC
45085 OLD OX ROAD
DULLES, VA 20166-0000


Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (4/07)

PURCHASE DOCUMENTATION

- Keep copies invoices or other purchase documentation.
- Need to have 222 forms on file for schedule 2 purchases.
- Documentation must be 'readily' available for a period of two years

TRANSFERRING

- Transferring of controlled substances within the institution requires documentation.
- Can only be transferred between individuals with a license.
- Schedule 2 drugs require a 222 form.

DISPOSALS

- **Must utilize a reverse distributor unless an exemption is provided by DEA (case-by-case)**
 - Requires invoices and 222 forms
- **If exemption provided must have dual witnesses and must be documented**
- **Disposal of minute amounts from syringe acceptable with two witnesses**
- **Disposal is not allowed in the sink, sharps container, etc**

STORAGE

- Secure location
limited access
- Schedule 2 locked
- Dual custody when
needed



INVENTORY

- The DEA does not require a perpetual inventory, but that you know what your inventory is.
- You need to know within a reasonable time frame if something was missing.
- Information needs to be accurate and readily available.

BIENNIAL INVENTORY

- The DEA requires Biennial inventory counts.
- Inventory of Schedule 3-5 do not have to be exact counts only estimates are required unless bottle is over 1,000 pills
- Schedule 2 inventory counts are required to be exact.

INVENTORY DISCREPANCIES

- DEA requires significant inventory discrepancies (or suspected theft) to be reported
- Does not detail what a significant loss is
- Up to your organization to detail this in policy based on operations

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

- Three campuses across West Texas region.
- Broad range of patient clinics
- Research (including human & animal)
- Operates two teaching retail pharmacies
- Student health clinic and pharmacy

AUDIT PLANNING

- Identification of areas utilizing controlled substances
- Review of institutional policies and procedures
- **FINDINGS**
 - No centralized tracking of usage
 - No TTUHSC or SOM policies and procedures

AUDIT OBJECTIVE

- Identify areas, departments clinics storing using or dispensing controlled substances.
- Determine whether identified areas are TTUHSC are compliant with federal and state regulations and have sufficient internal controls to secure controlled substances.

HOW WE APPROACHED THE AUDIT

- **Looked at three main areas**
 - Clinics
 - Live Animal Research Center and Research Labs
 - Pharmacy

HOW WE APPROACHED THE AUDIT CONTINUED

- Documentation of inventories
- Documentation of ordering and transfers
- Secure storage with limited access
- Documentation of inventory counts
- Documentation of usage log
- Performed inventory counts
- Interviewed personnel to determine processes

CLINICS

- Clinics have small number of controlled substances and quantities.
- Found that most of the clinics tried to do the right thing, but lacked the knowledge to receive, store, and dispose of the substances properly.

RESEARCH LABS

- Had documentation processes in place, and overall sought to do right thing
- Did a good job of securely storing controlled items
- Identified substances during inventory counts in which no records existed (Schedule II)
- Many researchers did not have appropriate licenses

LARC

- Had documentation in place, but contained multiple errors and discrepancies
- Used pre-signed 222 forms at satellite location
- Did not maintain records of expired or disposed drugs
- Sent controlled items to Safety Services and reverse distributor without appropriate documents

LUBBOCK PHARMACY

- Great controls and documentation.
- Maintained monthly inventories of CII
- All records tied out
- Prior to current PIC, lost bottle of 100 hydrocodone.

AMARILLO PHARMACY

- Poor controls and documentation.
- Could not reconcile multiple CII substances
- Annual inventory adjustments (plug)
- Left CII drugs out while OAS onsite
- Did not keep pharmacy locked
- Poor attitude about the need to comply

AUDIT FINDINGS AND RECOMMENDATIONS

- Institutional Policy
- Identification of controlled substances
- Unreported missing substances
- Unauthorized disposal of controlled substances
- Incomplete and inaccurate records
- Non-drug controlled substance reporting

QUESTIONS?

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