

UNIVERSITY of HOUSTON
MANUAL OF ADMINISTRATIVE POLICIES AND PROCEDURES

SECTION: Safety
AREA: Specific Area Guidelines

Number: 06.04.01

SUBJECT: Controlled Substances and Dangerous Drugs

I. POLICY AND SCOPE

- A. The University of Houston strives to provide every opportunity for its employees and students to attain excellence in their educational and employment experiences, and thereby further the mission of the institution. The university recognizes that to help employees and students realize these goals, it must provide safe environments conducive to employment and educational activities. The university shall seek ways to minimize the hazards of working with controlled substances and dangerous drugs in the university's clinical and non-clinical settings while meeting federal and state laws.
- B. Nothing in this policy is to be construed as authorizing any individual to engage in any act that such individual is not authorized or permitted to do under federal or state laws or rules. Compliance with this policy is not to be construed as compliance with all applicable federal or state laws or rules.
- C. Personal medication is exempt from the requirements of this guide if the drug was obtained in accordance with the Texas Health and Safety Code, chapters 481 and 483.
- D. University registrants who use controlled substances and dangerous drugs in the university's clinical and non-clinical settings must obtain and keep current federal Drug Enforcement Administration (DEA) and Texas Department of Public Safety (DPS) registrations, unless exempted by law. Registrants are responsible for procuring, maintaining security, keeping records, and disposing of controlled substances and dangerous drugs in accordance with federal and state regulations and rules.

II. DEFINITIONS

- A. Clinical setting: A setting where a controlled substance or dangerous drug is used in a medical application.
- B. Controlled substances: A Substance, including a drug, an adulterant, and a dilutant, listed in Schedules I-V or Penalty Groups 1, 1-A, 2 through 4 of the Texas Health and Safety Code, chapter 481. The term includes the aggregate weight of any mixture, solution, or other substance containing a controlled substance.

- C. Dangerous drug: Device or drug that is unsafe for self-medication and that is not included in schedules I-V or penalty groups 1-4 of the Texas Health and Safety Code, Chapter 481. The term includes a device or a drug that bears, or is required to bear, either of the following labels:
1. “Caution: Federal law prohibits dispensing without prescription” or “Rx only” or another label that complies with federal law; or
 2. “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”
- D. DEA: Federal Drug Enforcement Administration.
- E. DPS: Texas Department of Public Safety.
- F. Non-Clinical settings: A setting where a controlled substance or dangerous drug is used in research or education which is not a clinical usage of the controlled substance or dangerous drug.
- G. Registrant: Practitioner, physician, dentist, nurse, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Texas.

III. PROCEDURES

University faculty or staff members who work with controlled substances and dangerous drugs must obtain and keep current DEA and DPS registrations, unless exempted by law. Registrants are also responsible for procuring, securing, maintaining records, and disposing of controlled substances and dangerous drugs in accordance with federal and state guidelines.

- A. Registration Process
1. Schedule an inspection by the university’s Environmental Health and Risk Management Department (EHRM) for the location where controlled substances or dangerous drugs are to be stored/used. EHRM will provide the registrant written confirmation when adequate security controls are in place. Individuals inspecting for security measures will be trained in what constitutes adequate controls.
 2. A university faculty or staff member who qualifies as a registrant must obtain a DEA registration application by calling (713) 693-3660 or visit the website below for more information.
<http://www.deadiversion.usdoj.gov/drugreg/index.html>

3. Apply for a DEA registration number using DEA Form 225. The certifying signature on the form must be the registrant's supervisor. The proposed business address for non-clinical settings should be listed as:

Dr. _____ (Registrant)
Environmental Health and Risk Management
University of Houston
4211 Elgin, Room 183
Houston, Texas 77204-1005

4. After receipt of a DEA registration number, apply for a DPS Registration.

- a. Application forms for a DPS registration may be obtained from:

Department of Public Safety
Controlled Substances Registration Section
P.O. Box 4087
Austin, Texas 78773-0001
(512) 424-2188

- b. Registrants must furnish their DEA registration numbers on the DPS application.
- c. Apply for a DPS registration using DPS Form NAR-77. The certifying signature on the form must be the registrant's supervisor. The proposed business address for non-clinical settings should be listed as:

Dr. _____ (Registrant)
Environmental Health and Risk Management
University of Houston
4211 Elgin, Room 183
Houston, Texas 77204-1005

5. Provide copies of current registrations, and subsequent renewal registrations from DEA and DPS to the university's Environmental Health and Risk Management Department at EHRM 1005.

B. Procurement Process**1. For non-clinical settings**

- a. Registrant must use a DEA Form 222 to order controlled substances in schedules I & II. A DEA Form 222 is issued only to a registrant who has a DEA registration number, and can be obtained from the local DEA office.

Drug Enforcement Administration
1433 W. Loop South, Suite 600
Houston, TX 77027
(713) 693-3660

- b. A DEA Form 222 is not required to order controlled substances in schedules III – V.
- c. Complete university purchasing documents and DEA form 222 if required. The certifying signature on DEA Form 222 must be the registrant's supervisor. Fax or forward these documents and copies of current DEA and DPS registrations to EHRM 1005 for approval. EHRM will verify information, approve and then return these documents to the registrant or registrant's business office. Registrant must order through the Purchasing Department per UH MAPP 04.01.01.

- d. Verify the delivery address on the purchase order is

Dr. _____ (Registrant)
Environmental Health and Risk Management
University of Houston
4211 Elgin, Room 183
Houston, TX 77201-1005

- e. EHRM will receive all controlled substances and contact the registrant to schedule delivery. EHRM will ensure items are properly logged in and out.
- f. The package will be delivered to the registrant by EHRM. The registrant will be required to show one form of photo proof of identification. The registrant will then verify the contents and sign for their controlled substances order.

- g. A Dispensing Record Form in Addendum B must be used as the controlled substance is dispensed. A copy of this form must be sent to EHRM 1005 once the controlled substance is depleted or expired/disposed.
- h. Dangerous Drugs, prescription drugs that are non-controlled substances, can be ordered by registrants through routine purchasing procedures.

2. For clinical setting

- a. Registrant must use a DEA Form 222 to order controlled substances in schedules I & II. A DEA Form 222 is issued only to a registrant who has a DEA registration number, and can be obtained from the local DEA office.

Drug Enforcement Administration
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- b. A DEA Form 222 is not required to order controlled substances in schedules III – V.
- c. Registrants must order controlled substances in schedules I – V through the Purchasing Department per UH MAPP 04.01.01.
- d. Dangerous drugs, prescription drugs that are non-Controlled Substances, can be ordered by registrants through routine purchasing procedures.

C. Security Controls

Registrants are responsible for establishing and maintaining effective controls and procedures to safeguard against controlled substances and dangerous drugs being diverted from legitimate sources to the illicit market. Controlled substances and dangerous drugs may only be used for a legitimate purpose as authorized by appropriate university official(s). Registrants are directly responsible for:

- 1. Establishing adequate security to prevent unauthorized access to controlled substances and dangerous drugs.
- 2. Establishing adequate security to prevent the diversion of controlled substances and dangerous drugs.

3. Not allowing any unauthorized individual access to controlled substances and dangerous drugs storage areas.
4. Storing controlled substances listed in schedules I-V in a securely locked, substantially constructed cabinet, or security cabinet.
 - a. A “substantially constructed cabinet” is a structure of wood or metal so constructed as to resist easy entry by simple tools such as screwdrivers, crowbars, tire tools, or pry bars.
 - i. Hinges should not be mounted with bolts or screws on outside of doors, and the locking devices should be installed internally as deadbolt type, or the device should be of a type that has protected mounting screws or bolts to make removal difficult.
 - ii. The cabinet should be permanently constructed or attached to the building structure or fixtures so as to prevent the cabinet from being physically removed from the premises.
 - iii. If the cabinet is a metal file cabinet type, it should be permanently attached to prevent easy removal and have an external locking bar that secures the drawers.
 - b. A “substantially constructed security cabinet” is a security cabinet or safety cabinet equivalent in construction to a Class 6 Mosler Government Sales Security filing cabinet or a Class 5 Mosler Government Sales safe.
 - c. A cabinet less substantially constructed may meet security requirements provided the cabinet is located in a room or an area where the entrance has been so constructed that the hinge mounting inhibits removal and a limited number of employees have keys or combinations to the locking device. If combination locks are used, the combination must be changed upon termination of employees who have knowledge of the combination.

Note: EHRM generally requires a small non-removable safe in a secure area to comply with these regulations. An alternate security cabinet may be required for refrigeration consideration or other special situation
5. The registrant shall notify the local DEA office, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to local DEA office, DEA Form 106 regarding the loss or theft.

Note: The registrant must first send copies of all correspondence reports regarding the incident to the University of Houston Department of Public Safety (UH-DPS) and EHRM for review prior to notification of DEA.

6. Dangerous Drugs must be secured in a locked area.

D. Inventory

1. Controlled substances schedules I-V

a. The registrant shall take an initial inventory of all stocks of controlled substances on hand on the date he/she starts newly registered storage location. Each registrant must then complete an inventory of all Controlled Substances (schedules I-V) every six months after the initial inventory is taken, using the EHRM Inventory Form in Addendum A. EHRM will send out a notice with the form when the inventory is due. The university Health Center pharmacy will follow Texas State Board of Pharmacy regulations.

b. The regulations require that an inventory of controlled substances must be conducted on a biennial basis for each registered location. Biennial inventories of all controlled substances schedules I-V must be kept by each registrant, and must include the following information:

- i. The name of the substance;
- ii. Each formulation of the substance (e.g., liquid, tablet), and
- iii. The number of units or volume of each formulation in each commercial container.

Note: This requirement is fulfilled by the six months EHRM inventory.

c. Inventories of controlled substances schedules I and II require an exact count or measurement. Schedules III, IV, and V can be estimated, if the commercial container holds fewer than 1,000 tablets or capsules.

d. Inventory records must be kept for two years from the date of the inventory in accordance with the regulations outlined in the Texas Controlled Substances Act, Health and Safety Code, Chapter 481.

2. Dangerous Drugs

Each registrant must conduct and maintain an inventory of all dangerous drugs annually, using EHRM inventory Form in Addendum A. The university Health Center pharmacy will follow Texas State Board of Pharmacy regulations.

E. Records

1. Persons registered under the Federal and Texas Controlled Substances Acts to manufacture, distribute, analyze, or dispense controlled substances or dangerous drugs, or to conduct research with controlled substances or dangerous drugs must keep and maintain inventories and records required for two years from the date such inventories and records are made. A “record” is any notification, order form, statement, invoice, prescription, inventory information, or other document for the acquisition or disposal of controlled substances or dangerous drugs in conformance with record keeping and inventory requirements of federal law and the Texas Controlled Substances Act.
2. Inventories and records shall be available for inspection and copying by authorized employees of EHRM, UH-DPS, Internal Auditing, DPS, DEA, or appropriate state health regulatory agency.
3. Registrants must also maintain complete and accurate records of purchases (to include samples received from pharmaceutical manufacturer representatives), transfers, and disposals of controlled substances listed in schedules I-V and dangerous drugs.
4. Records of purchases, transfers, acquisitions, and disposals of controlled substances and dangerous drugs must include the following information:
 - a. Name, quantity, and strength of drug;
 - b. Invoice number or purchase order number;
 - c. Date of purchase or acquisition;
 - d. Date and quantity administered or disposed; and
 - e. Reason for administering or disposing of the controlled substance.

5. The records must be maintained in a bound record book, ledger, or other device equal in durability and capacity to record the required data. The record-keeping device shall have a numbered page for each drug, by drug strength.
6. Records of purchases, acquisitions, transfers, and disposals of dangerous drugs are to be maintained by the registrant for two years beyond acquisition or disposal.

F. Disposal Process

The registrant is responsible for the return or disposal of controlled substances and dangerous drugs within 30 days of the expiration date.

1. There are two disposal options:
 - a. Expired or unusable controlled substances and dangerous drugs may be returned to the supplier.
 - i. Contact the supplier for specific details on returning expired or unusable controlled substances and dangerous drugs.
 - ii. The supplier signs for the controlled substance and arranges expired or unusable doses to be destroyed by an enforcement agency. (The supplier may require an assay of the dose prior to issuing a receipt.)
 - iii. The receipt is maintained as proof of disposal and an entry is made in the controlled substance record on the appropriate page indicating the date, strength, and disposed amount of the expired or unused drug.
 - b. Expired or unused controlled substances and dangerous drugs may be placed in a container and submitted for appropriate disposal by EHRM. Currently, the university conducts onsite destruction of controlled substances and dangerous drugs as approved by DEA, which meet environmental waste disposal laws.
 - i. The UH-DPS oversees the disposal of controlled substances and dangerous drugs.
 - ii. EHRM documents the disposal of the controlled substances and dangerous drugs using DEA Form 41.

- iii. A copy of DEA Form 41 will be given to the registrant by EHRM after disposal. This form must be maintained with the registrant's records to provide accountability for the disposal of these controlled substances and dangerous drugs.
 2. Incidents in which controlled substances and dangerous drugs are destroyed accidentally and cannot be recovered must be documented in detail and co-signed by a witness to the destruction. The documentation must indicate the date, name, strength, amount of substances destroyed, and method of disposal. This documentation must be attached to the log record.
 3. Wasted controlled substances and dangerous drugs are to be handled in the same manner as accidentally destroyed controlled substances and dangerous drugs.
 4. Registrants who plan to leave the university's employment must first complete a checkout procedure conducted by EHRM. The department chair or equivalent is responsible for notifying EHRM when a registrant terminates their employment with the university so that the laboratory checkout procedure may begin. At this time, EHRM will coordinate, with UH-DPS, the disposal of all controlled substances and dangerous drugs, which have not been transferred by the registrant. Failure to comply with this section will result in the controlled substances and dangerous drugs being appropriately disposed by EHRM as approved by the DEA for disposal, with a written explanation of the incident and parties involved.
- G. Compliance Review
 1. The Environmental Health and Risk Management Department will conduct periodic reviews of each registrant to verify compliance with regulations and the provisions of this policy.
 2. The Internal Auditing Department will perform periodic reviews to ensure compliance with the provisions of this policy.

IV. REVIEW AND RESPONSIBILITY

Responsible Party: Associate Vice President for Plant Operations

Review: Every three years, on or before August 1

V. APPROVAL

John Rudley

Vice President for Administration and Finance

Jay Gogue

President

Effective Date August 31, 2006

VI. REFERENCES

Title 21 Code of Federal Regulations - Part 1300 Food and Drugs; Texas Health and Safety Code, chapters 481 and 483

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