

Rules for Controlled Substances

In accordance with the Code of Federal Regulations 21 CFR Part 1300 and Chapter 657 of the Iowa Administrative Code, the following procedures must be followed when purchasing, dispensing or destroying controlled substances..

A. What are controlled substances

Controlled substances are drugs or chemicals whose manufacture, possession, and use are regulated by the government. A complete listing of controlled substances may be viewed at the Drug Enforcement Agency website at

https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

B. Who must register

Departments in which controlled substances are being used for teaching purposes and professors who use them for the intention of research must obtain and maintain a registration with the Iowa Board of Pharmacy Examiners (IBPE) and the Drug Enforcement Agency (DEA).

C. Controlled Substances Registration

Prior to purchase of controlled substances, the primary user must register with the Iowa Board of Pharmacy Examiners and the Drug Enforcement Agency. The pdf registration form for the Iowa Board of Pharmacy Examiners may be obtained from the IBPE website at <https://pharmacy.iowa.gov/application-forms> The registration process for the Drug Enforcement Agency can be completed online at the DEA website at

<https://www.deadiversion.usdoj.gov/drugreg/process.htm>

D. Storage Security

Upon acquisition of the controlled substance, it shall be stored in a locked cabinet with a solid door in an area that can be locked when it is not occupied. The number of keys to access that room should be kept at maximum of 3.

E. Controlled Substances Log

A controlled substances log shall be maintained at each location where controlled substances are stored. A separate page shall be maintained for each controlled substance.

The following information will be kept in the log:

- The date the substance was received at the storage location
- The substance name assigned by the manufacturer
- The manufacturer of the substance or vendor
- The quantity and strength of the substance added to the storage area
- Name of individual adding product to the inventory

F. Dispensing Controlled Substances

Whenever drugs are dispensed either for teaching purposes, research or surrendered for disposal the following information must be logged.

- Date used or disposed of
- Quantity dispensed
- Strength dispensed
- Name of person to whom it was dispensed
- Quantity remaining in inventory

G. Disposal

- Controlled substances shall be removed from inventory and disposed of by one of the following methods:
 - If possible, the user shall utilize the services of a DEA-registered and Iowa licensed reverse distributor.
 - The Iowa Pharmacy Board may authorize and instruct the user to dispose of the controlled substances by:
 - Delivery to an agent of the board or to the board office
 - Destruction of the drugs in the presence of a board officer, agent, inspector or other authorized individual
 - By such other means as the board may determine to ensure that drugs do not become available to unauthorized persons.

- If the services of a reverse distributor is not possible due the substance being expired, partially used or is not returnable, user will need to log the substance to be destroyed on DEA form 41. Contact the Risk Management/Environmental Safety Office (3-3445) to make arrangements with the Iowa Pharmacy Board for the item's destruction.

H. Inventory and Audits

In addition to previously listed requirements:

- Chemical inventories including those of controlled substances are collected annually by EH&S in order for the University to remain compliant with the Tier II provision of the Emergency Planning and Community Right-to-Know Act (EPCRA).
- All records of inventories and logs of controlled substances shall be kept a minimum of two years and be available for inspections and copying by a member of the Iowa Board of Pharmacy Examiners.