

UC Davis Policy and Procedure Manual

Chapter 290, Health and Safety Services

Section 70, Controlled Substances

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Responsible Department: Environmental Health and Safety

Source Document: Business and Finance Bulletin BUS-50, Materiel Management: Acquisition and Use of Narcotics and Dangerous Drugs

Exhibit A, Controlled Substance Transfer

I. Purpose

This section describes the special requirements and procedures applicable to the procurement, storage, use, transfer, disposal, and inspections of controlled substances at all locations that are the responsibility of the UC Davis administration. Licensed UCD pharmacies are exempt from this policy, unless specifically stated otherwise.

II. Definitions

- A. Controlled substances—narcotics, dangerous drugs, and anabolic steroids regulated under terms of Public Law 91-513, the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Federal Controlled Substances Act), the Anabolic Steroids Act of 1990, and any subsequent amendments.
- B. Authorized custodian—The Principal Investigator and approved designees within the requesting department who are authorized by the Office of Environmental Health and Safety (EH&S) to receive and store substances and are responsible for the maintenance of the daily usage logs and biennial inventory. The authorized custodian may also be identified as the end user.
- C. Temporary receiver—No more than three individuals physically located within the requesting department's designated delivery stop (see Section 350-35) who have been designated as temporary receivers of controlled substance shipments prior to final delivery to the authorized custodian. These individuals are identified to Central Receiving in advance.
- D. End user—person identified on the Purchase Requisition (PR) approved by the department head or one designee to use the substance. The end user is responsible for checking out the controlled substance by annotating the daily usage log, and returning any unused portions to the authorized custodian.

III. Policy

- A. UCD shall comply with all applicable Federal and State laws and regulations governing controlled substances.
- B. All procurement and use of controlled substances must be under a registration granted to UCD by the Drug Enforcement Administration (DEA).
 - 1. The UCD registrations cover controlled substances in Schedules II through V. Additional UCD registrations must be obtained for Schedule I substances or for substances that will be used at a remote site (i.e., a location away from the main campus or UCD Medical Center, such as a field station). The use of personal DEA numbers is prohibited for University Business.

2. Authority to sign Purchase Orders for controlled substances is restricted to authorized persons in the Purchasing Department.
 3. Authority to requisition controlled substances from the Purchasing Department is limited to the department head and one designee.
 4. Use of controlled substances is limited to the end user identified on the Purchase Requisition. (See V.B, below.)
- C. UCD pharmacies (the UCDHS pharmacy and its satellites, the pharmacy at Cowell Student Health Center, and the pharmacy at the Veterinary Medicine Teaching Hospital) operating under the supervision of a licensed pharmacist and dispensing controlled substances for clinical use shall maintain internal policies and procedures governing procurement, use, storage, dispensing, and disposal of controlled substances consistent with licensing requirements and applicable laws and regulations. Pharmacies shall not dispense controlled substances for use in research, except when such use is approved by the Institutional Review Board (IRB). (See Section 240-50.)
- D. Researchers, teachers, or anyone else obtaining or using controlled substances (other than from a UCD pharmacy for clinical use) must comply with policies and procedures contained herein. Individuals obtaining controlled substances from a pharmacy for clinical use must comply with the pharmacy's policies and procedures.
- E. Violation of these policies or DEA regulations may result in revocation of a department's privilege to obtain and use controlled substances, rescission of campus registrations, and imposition of fines and/or imprisonment of individuals responsible for the violations.

IV. Responsibilities

- A. The Chancellor or designee applies for all DEA registrations granted to UCD.
- B. The Purchasing Department administers the terms of the DEA registrations relating to procurement of controlled substances.
- C. The department head is responsible for determining the need for and authorizing DaFIS Purchase Requisitions for controlled substances by department members and for assuring that the storage, use, inventories, transfers, and disposal of controlled substances by department members comply with applicable laws, regulations, and campus policies.
- D. The Office of Environmental Health and Safety (EH&S) reviews departmental handling procedures for controlled substances, assures compliance with DEA regulations, authorizes storage facilities for controlled substances, conducts site inspections, requests and reviews the biennial inventories and drug logs, and disposes of unused, expired, or waste controlled substances.
- E. The University Police Department investigates all suspected thefts or misuse of controlled substances.

V. Procedures

- A. Signature authorization

1. The head of any department in which controlled substances are to be used must complete a DaFIS Approval Authorization or Cancellation form (available at <http://accounting.ucdavis.edu>) authorizing one designee (if such delegation is desired), to approve Purchase Requisitions for controlled substances. This form is maintained in the department.
2. The department head may designate temporary receivers authorized to receive shipments of controlled substances by completing the Controlled Substance Receipt Authorization form available from the Purchasing Department (530-747-3850). The completed form shall be submitted to the Purchasing Department where the name of the temporary receiver is added to the Controlled Substance Receipt Authorization (CSRA) list.
 - a. Deliveries to individuals other than departmental receiving personnel will be handled by Materiel Management on a recharge basis.
 - b. The end user whose name appears on the Purchase Requisition (see V.B, below), may or may not be listed on the CSRA; regardless, he or she is automatically authorized to receive his/her shipments of controlled substances subject to EH&S approval of the storage site. The purpose of the additional authorization, acquired by submitting the form noted above, is only to allow a person other than the end user to be a temporary receiver for the purpose of receiving shipments until the drug can be received by the authorized custodian or end user.

B. Procurement from outside sources

Procurement of controlled substances must comply with the following procedures. Procurements that do not comply may result in revocation of a department's privilege to obtain and use controlled substances, rescission of campus registrations, and imposition of fines and/or imprisonment of individuals responsible for the violations.

1. Determine if a drug is a controlled substance through one of the following references:
 - a. Refer to the Drug Enforcement Administration website for a searchable list of controlled substances.
 - b. Use the Physicians' Desk Reference, Red Book, or Veterinary Pharmaceuticals and Biologicals.
 - c. Contact a member of the Purchasing Department.
2. Ordering controlled substances
 - a. All orders for controlled substances must be placed by the Purchasing Department, regardless of whether the controlled substance is purchased or obtained free of charge from the supplier. Departments must complete a Purchase Requisition (PR) and cite an appropriate controlled substance commodity code. No order for controlled substances may be placed by any other means.
 - b. Schedule I and II controlled substances may be included on one PR, but must not be included on a PR with substances from any other schedules or any other products. Controlled substances on Schedules III, IV and V may be combined on a

separate PR with no other products.

- c. Include the following information on the PR:
- 1) A statement that the substance requested is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.
 - 2) A full description of the item requested, including quantity, size of package, name of drug, and the number of the Federal Schedule of Controlled Substances to which it is assigned.
 - 3) A detailed statement of the purpose and/or manner of use that is planned and if it is to be used for teaching, research or clinical applications.
 - 4) The name of the authorized custodian.
 - 5) The name of the end user, even if the same as the authorized custodian.
 - 6) The final delivery and storage location.

Information on the PR must be very specific. Example language is provided at <http://purchasing.ucdavis.edu/geninfo/controlledsubs.cfm>.

- d. The PR must be ad hoc routed to the approving department head or one authorized designee for approval. If the department head/designee is not a DaFIS user, a hard copy signature must be sent to Purchasing as an attachment to the PR (see Section 350-25). PRs citing controlled substance commodity codes will special conditions route to the Office of Environmental Health and Safety (EH&S) for approval.
- e. Purchasing will monitor for inappropriately procured substances that may have been procured under a departmental purchase delegation (Section 350-21) or through use of an incorrect commodity code. EH&S will also monitor for inappropriately acquired substances during site visits.

3. Receiving

- a. Controlled substances may only be received at the UC Davis addresses currently registered with the DEA.
- 1) With the exception of pharmacies and a very few remote locations, all controlled substances are delivered to Central Receiving who takes possession of the drug and initiates a Controlled Substance Delivery Record, which will follow the shipment to the authorized storage site.
 - 2) All controlled substances received require that a record of chain of custody be kept on a Controlled Substance Delivery Record. Each shipment received shall be opened and the contents verified, under dual custody, every time it changes hands. Authorized recipients (Central Receiving personnel, temporary receivers, authorized custodians and end users) shall sign and note any discrepancy or damage on the Controlled Substance Delivery Record each time the drug changes hands.

- b. The ordering department will receive a photocopy of the purchase order from Purchasing and shall complete the area stamped in red. The end user designated on the Purchase Requisition must, as the ultimate receiver of the substance, sign the photocopy and be the last to sign the Controlled Substance Delivery Record.
- c. Both of the signed documents must be returned to Purchasing within 15 days of receipt of the controlled substance. If the required documentation is not returned to Purchasing within 15 days, a notice of negligence will be sent to the end user with a copy to the department head and EH&S. If the information is not returned within 15 additional days, the Purchasing department will no longer place orders for the end user in question and will send another letter to the end user, department head, the appropriate Deans' office, and EH&S. The Purchasing Controlled Substance Database will be annotated, and all controlled substance buyers and managers will be notified.
- d. Purchasing will provide information to EH&S about the details of the delivery, including whether a partial delivery or complete delivery was made.
- e. If the supplier delivers a controlled substance directly to a department (other than approved remote locations), the department must immediately contact Central Receiving (530-752-0663) to notify them that the delivery bypassed them and add a note to the photocopy of the purchase order stating that the delivery bypassed Central Receiving and was made directly to the department.
- f. Under no circumstances must a controlled substance be left unattended, unless in a location approved by EH&S.

4. Delivery Troubleshooting

All controlled substance deliveries are opened and verified for accuracy at the Central Receiving department. If there is a discrepancy or damage, Central Receiving will contact Purchasing to arrange for return of product. Purchasing will work with the department and the vendor to ensure that the most appropriate action is taken.

C. Procurement from other UCD end users (transfers)

1. Departments and authorized custodians may transfer a controlled substance to another UCD authorized custodian following the conditions and procedures below for each controlled substance transfer.
 - a. The transferor must ensure that the recipient of the controlled substance is a UCD authorized custodian with an approved storage site. Contact EH&S (530-752-1493) to verify that the recipient is approved.
 - b. Complete the transfer form (see Exhibit A or contact EH&S for a 3-part NCR form). Both authorized custodians involved in the transfer must maintain a copy of the transfer. The third copy of the transfer record must be faxed to EH&S (530-752-4527) within 24 hours of the transfer.
 - c. Each authorized custodian (transferor and recipient) must document the transfer in his or her Controlled Substance Usage Log.

- d. Records for each transfer must be maintained for three years.
 - e. Drugs must be used only for the same purposes for which they were acquired (i.e., teaching, research, or clinical use).
2. Transfers of controlled substances that do not comply with the above procedure may result in revocation of a department's privilege to obtain and use controlled substances, rescission of campus registrations, and imposition of fines and/or imprisonment of individuals responsible for the violations.

D. Procurement of Schedule I substances

Each research project using a Schedule I substance will need a separate DEA registration, approval by the State Research Advisory Panel of California (RAPC), and approval of the Office of Research (OR), IRB. The Purchasing Department applies for controlled substance registrations with the DEA. A copy of the RAPC approval must be submitted to the Purchasing Department before initiating a new DEA registration application. Obtaining a new DEA registration is a lengthy process; departments should anticipate that this could take several months.

E. Procurement of Schedule II substances for human research

Proposals requiring use of Schedule II substances (except stimulants) that will be used in human research must be reviewed and approved by the RAPC prior to procurement. OR will assist the Principal Investigator to obtain RAPC approval. The Purchasing Department applies for controlled substance registrations with the DEA. A copy of the RAPC approval must be submitted to the Purchasing Department before initiating a new DEA registration application. Obtaining a new DEA registration is a lengthy process; departments should anticipate that this could take several months.

F. Procurement of substances for use at remote sites

A separate DEA registration is required for each remote site using controlled substances. The researcher must submit a description of the research requiring the use of the substance to EH&S at least 3 to 6 months in advance of the time the controlled substance will be ordered. EH&S will evaluate the storage site, the proposal for security and safety procedures, and transmit the approval to Purchasing. The Purchasing Department will submit the application for registration to the DEA.

G. Training

EH&S will provide the Controlled Substance Training and Reference Guide to all principal investigators or designees applying for approval as an authorized custodian. Upon approval of the proposed storage site and written acknowledgment that the guide has been read, EH&S will approve the authorized custodian.

H. Storage and Use

- 1. Controlled substances may be stored only in locations approved by EH&S. Minimum requirements for storage facilities include the following:
 - a. An acceptable storage cabinet must have inaccessible hinges when the door is

closed, and a lockable hasp that allows no access to the mounting hardware when the door is closed and locked.

- b. The cabinet must have either a built-in tumbler-type lock or a padlock.
 - c. If a keyed lock is used, a maximum of 2 keys must be available, and each key must be kept in the physical custody of a person assigned responsibility for storage of controlled substances at that location at all times.
 - d. There cannot be any sign or other indication that the cabinet is used for storage of controlled substances.
2. Etorphine hydrochloride and diprenorphine must be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.
 3. All records of withdrawals of controlled substances from storage must be signed by the person making the withdrawal.
 4. All authorized custodians are responsible for maintaining usage logs (available at <http://safetyservices.ucdavis.edu/environmental-health-safety/health-safety/controlled-substances>) for each container of controlled substance. Controlled substance usage must be tracked on a per dose (use) basis and must be recorded to the nearest metric unit weight or the total number of units finished form. The authorized custodian must maintain all controlled substance usage logs for three years.
 - a. "Received" includes drugs imported, manufactured, purchased or delivered.
 - b. "Use" includes exported, disposed, sold, transferred or otherwise utilized.
 5. Some teaching and research units may require controlled substances for the health maintenance of their animals. These substances may be kept in the approved storage site, but must be separated from the teaching and research substances. Documents must be available upon request to demonstrate the substances were purchased or prescribed for health maintenance.
- I. Inventory
1. Each authorized custodian must conduct an inventory of all existing stocks of controlled substances in their possession, biennially, for UCD to maintain registration with the DEA.
 2. An individual other than the authorized custodian must perform the physical inventory of all controlled substances in the authorized custodian's possession.
 3. EH&S will inform all authorized custodians at least one month in advance of the inventory due date.
 4. Instructions for completing the biennial inventory are as follows:
 - a. Complete the Controlled Substance Inventory form (available at <http://safetyservices.ucdavis.edu/environmental-health-safety/health-safety/controlled-substances>) for all controlled substance(s) in your possession.

- b. Obtain the three required signatures (authorized custodian, person performing the inventory, and the department chairperson).
 - c. Return the completed forms along with a copy of your usage log sheets for the past 2 years to EH&S.
5. The inventory must include the following information for each controlled substance in finished form:
- a. The name of the substance.
 - b. The purpose the substance is being maintained by the researcher.
 - c. The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form. The number of units of each finished form of a controlled substance in a commercial container that has been opened will be determined as follows:
 - 1) For Schedule II, an exact count or measure of the contents.
 - 2) For Schedule III, IV, or V, an estimated count or measure of the contents unless the container holds more than 1,000 tablets or capsules, in which case an exact measure of the contents must be made.

J. Disposal

The person having custody of the controlled substance must request disposal from EH&S (752-1493). EH&S is responsible for securing permission for disposal from the DEA. At UCDHS and the VMTH pharmacies, the Chief Pharmacist is responsible for disposal of controlled substances used in clinical applications.

K. Loss or Theft

Any loss, theft, or mysterious disappearance of controlled substances must be reported to the University Police Department and EH&S immediately upon discovery. Upon notification that a loss or theft has taken place:

- 1. EH&S will complete DEA Form 106 and forward it to the Purchasing Department, which transmits it to the DEA.
- 2. The University Police will investigate and prepare a police report of the circumstances surrounding the loss or theft and submit to the Provost & Executive Vice Chancellor a separate memorandum explaining the circumstances.

VI. References and Related Policies

- A. 21 CFR, Chapter II, DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfrv9_01.html
- B. Office of the President: Delegation of Authority--Registration and Acquisition of Narcotics and Dangerous Drugs (DAO378), 8/14/72.

- C. Business & Finance Bulletin BUS-50, Materiel Management: Acquisition and Use of Narcotics and Dangerous Drugs, 4/15/88.
- D. UCD Policy and Procedure Manual:
 - 1. Section 240-50, Principles and Policies.
 - 2. Section 350-21, Departmental Purchase Delegations.
 - 3. Section 350-25, Procurement through the Purchasing Department.
 - 4. Section 350-35, Receipt and Delivery of Goods.