



UCSB Audit and Advisory Services  
Internal Audit Report

**Controlled Substances**

May 18, 2017

**Performed by:**  
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**Approved by:**  
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Report No. 08-17-0020

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AUDIT AND ADVISORY SERVICES  
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May 18, 2017

To: John Sterritt, Director, Environmental Health & Safety  
Mary Ferris, Executive Director, Student Health Services  
Dustin Olson, Chief of Police

Re: **Controlled Substances**  
**Audit Report No. 08-17-0020**

As part of the 2016-17 annual audit services plan, Audit and Advisory Services has completed an audit of Controlled Substances. Enclosed is the report detailing the results of our work.

The purpose of this project was to determine whether Controlled Substances administration and select business processes are consistent with state and federal regulations, and University of California (UC) and University of California Santa Barbara (UCSB) policies and procedures. The scope of our audit focused on the oversight, controls, and processes for purchasing, storage, use and disposition of controlled substances relevant to Environmental Health and Safety Services (EH&S), Student Health Services, UC Santa Barbara Police Department, and selected research laboratories during fiscal year 2015-16.

Based on the results of the work performed, we found the three audited areas have adequate internal controls related to controls over the security, storage, usage log, biennial inventory, and destruction of controlled substances consistent with state and federal requirements and University policies. However, our review did identify opportunities for improvement to formalize written policy and procedures, enhance procurement receipt and chain of custody documentation, and improve reporting procedures.

Detailed observations and management corrective actions are included in the following sections of the report. The management corrective actions provided indicate that each audit observation was given thoughtful consideration, and positive measures have been taken or planned in order to implement the management corrective actions.

We greatly appreciated the assistance on this project provided by Environmental Health and Safety, Student Health Services, UC Santa Barbara Police Department and laboratory personnel. If you have any questions, please contact me.

Respectfully submitted,

A handwritten signature in blue ink that reads "Jessie Masek".

Jessie Masek  
Acting Director  
Audit and Advisory Services

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Enclosure

cc: Chancellor Henry Yang

Vice Chancellor Administrative Services Marc Fisher

Vice Chancellor Student Affairs Margaret Klawunn

Assistant Vice Chancellor Student Affairs Debbie Fleming

Associate Vice Chancellor Renee Bahl, Design Facilities and Safety Services

UCSB Audit Committee

Senior Vice President and Chief Compliance and Audit Officer John Lohse

## PURPOSE

The purpose of this project was to determine whether controlled substances administration and select business practices are consistent with state and federal regulations, University of California (UC), and University of California, Santa Barbara (UCSB) policies related to controlled substances. This audit is part of the University of California, Santa Barbara's fiscal year 2016-17 audit services plan.

## SCOPE, OBJECTIVES AND METHODOLOGY

The scope of this audit focused on the oversight, controls, and processes for storage, purchasing, receipt, use and disposition of controlled substances relevant to Environmental Health and Safety (EH&S), Student Health Services, UC Santa Barbara Police Department, and selected research laboratories.

The objectives of this audit was to determine whether:

- There is a formal written UCSB Controlled Substance Program.
- There are physical security compliance controls in place, with storage of controlled substances and access being restricted to only authorized personnel.
- There is adequate recordkeeping for purchasing, delivery, receipt, inventory, destruction records and adjustments to inventory for lost or stolen controlled substances.

To accomplish our objectives, we:

- Researched and reviewed relevant UCSB audits and reports from other institutions of higher education related to management over controlled substances.
- Researched and reviewed UC and UCSB policies, best practices, and other guidance relevant to the scope of the audit. See Table 1 for summary of policies. Key guidance includes:
  - UC Business and Finance Bulletin BUS-50, *Controlled Substances* (UC Policy BUS-50), dated May 2009.
  - UCSB Policy and Procedures: *Controlled Substances*, dated December 2016.
- Gained an understanding of EH&S, Student Health Services, UC Santa Barbara Police Department and laboratory operations through interviews with key personnel and review of the department's business processes and internal controls.
- Examined EH&S, Student Health Services, and the UC Santa Barbara Police Department's written policy and procedures.
- Performed a risk analysis that considered procedures and compliance with controlled substance regulations, UC and UCSB policies, and laboratory processes.

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- Tested a sample of transactions to determine whether controlled substance management practices and processes were in compliance with federal requirements, and University policies and procedures in the areas of authorization, Drug Enforcement Administration registration, routine and unannounced audits.
- On a sample basis, conducted specific audit testing or utilized direct observation and inspections of processes required for the security and storage of controlled substances.
- Evaluated recordkeeping procedures, biennial inventory requirements and disposition manifests to determine compliance with UC Policy BUS-50. Recordkeeping procedures included the acquisition, receipt, perpetual inventory, and transfer processes. In addition, we obtained disposal documentation to ensure compliance with regulations, as appropriate.
- Reviewed department inventory and chain of custody tracking procedures.

This audit was conducted in conformance with the *International Standards for the Professional Practice of Internal Auditing*.

## **BACKGROUND<sup>1</sup>**

The Drug Enforcement Administration (DEA) was established in 1973 to serve as the primary federal agency responsible for the enforcement of the Controlled Substances Act (CSA). The CSA sets forth the federal law regarding both illicit and licit (pharmaceutical) controlled substances. With respect to pharmaceutical controlled substances, DEA's statutory responsibility is twofold: to prevent diversion and abuse of these drugs while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. In carrying out this mission, DEA works in close cooperation with state and local authorities and other federal agencies.

A controlled substance is generally a drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated a controlled drug. Drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. An updated and complete list of the schedules is published annually in Title 21 Code of Federal Regulations (C.F.R.) §§ 1308.11 through 1308.15. Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused.

### *Environmental Health & Safety Services*

University of California Office of the President has directed the UC campuses to develop a Controlled Substance Program (CSP) that follows the revised UC Policy BUS-50 and best practices. The development and implementation of CSP has been assigned to the EH&S Department. UC Policy BUS-50 applies only to research activities using controlled substances, not the university's clinical activities such as those performed by a university medical center, veterinary teaching hospital, pharmacy, or clinic.

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<sup>1</sup> Source: Environmental Health & Safety, Student Health Services, and UC Santa Barbara Police Department websites.

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*Student Health Services*

Student Health Service (SHS) is a primary health care facility that is available to all UCSB students. Over the years, college health centers have become sophisticated, freestanding medical clinics and public health promotion centers that include everything from complete medical care, to massage and specialty services.

UCSB Student Health Services employs over 140 people, including primary care physicians, psychiatrists, consulting medical specialists, nurse practitioners, registered nurses, physician assistants, pharmacists, social workers, dentists, physical therapists, registered dietitians, optometrists, and other health professionals.

A Practitioner’s Manual has been prepared by the Drug Enforcement Administration, Office of Diversion Control, to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner’s profession.

*UC Santa Barbara Police Department*

UC Santa Barbara Police Officers have statewide jurisdiction; are duly sworn under section 830.2 of the California Penal Code, and are trained under state guidelines and mandates. The UC Santa Barbara Police Department is a full service police organization that is open 24-hours a day, 7 days a week, 365 days a year.

The Property Unit safeguards the custody and disposal of police evidence, contraband, and processes campus lost & found property in accordance with state laws.

Table 1	Relevant Policies
Policy	Summary
UC BFB-BUS-50, <i>Controlled Substances</i> (UC Policy BUS-50)	Establishes requirements for management and control of controlled substances.
United States Department of Justice, <i>Practitioner’s Manual</i> , Drug Enforcement Administration, Office of Diversion Control	Addresses general requirements to assist registrants authorized to prescribe, dispense, and administer controlled substances in their understanding of the CSA and its implementing regulations as they pertain to the practitioner’s profession.
DEA Regulations, <i>Title 21</i> , Code of Federal Regulations, Parts 1300-1316	Governs CSA for control and enforcement.
University of California Santa Barbara, Student Health Service, <i>Pharmacy: Controlled Substances Policy and Procedures</i>	Provides guidelines for controlled substances prescriptions written, filled, and dispensed in accordance with all state and federal requirements to prevent unauthorized access and reduce the risk of diversion and or theft.
University of California Santa Barbara, Police Department, <i>Evidence Procedures</i> , Policy 323	Establishes the University’s Police Department’s guidelines related to the packaging and booking of controlled substance evidence.

Source: Federal, UC, and UCSB Policies

**SUMMARY OPINION**

In our audit of 11 compliance categories related to controlled substances, we found that six of the 11 categories had overall compliance with UC and UCSB policies. However, in the remaining five compliance categories reviewed, we found opportunities for improvement in written policy and procedures, pre-screening and online training of personnel for controlled substance access, routine and unannounced audits, procurement acquisition and receiving, controlled substance transfers to other laboratories, and chain of custody documentation.

Audit observations and management corrective actions are detailed in the remainder of the audit report.

**DETAILED OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS**

**A. Environmental Health and Safety**

*Controlled Substance Program*

Our review found that during our audit period June 30, 2015 to July 1, 2016, EH&S department did not have a documented Controlled Substance Program as required in UC Policy BUS-50. Within the scope of our audit, we identified that the Program Administrator was conducting required annual audits, however the results of the audit were not documented. It was also noted that unannounced laboratory audits were not performed.

*Pre-screening and Online Training*

In our pre-screening and online training compliance testing categories, we examined records associated with 15 employees in three laboratories. This testing identified that three of the 15 employees (33%) had not completed the pre-screening form which is required before purchasing, receiving, and working with controlled substances should be allowed. Additionally, our testing resulted in determining that 10 of the 15 employees (66%) had not yet completed the online training which is also required before access to controlled substances should be granted.

At the time of issuance of this audit report, the EH&S Program Administrator had already initiated action to address these findings resulting in 11 of the 15 employees (73%) completing the pre-screening form and eight of the 15 (53%) completing the online training. Total compliance is expected after completion of the management corrective action.

*Controlled Substance Policy*

Our work determined that there is a need to strengthen the UCSB Controlled Substance Policy to comply with UC Policy BUS-50 requirements and to develop and implement a UCSB Controlled Substance Program.

We recommend Environmental Health and Safety Program Administrator:

- Enhance UCSB Controlled Substance Policy to be in compliance with UC Policy BUS-50 requirements to include:
  - Required unannounced audits be performed and documented.
  - Prescreening forms be updated every three years.
  - All acquired controlled substances be approved by the Program Administrator, including orders directly from a vendor by the Drug Enforcement Administration registrant.
  - Only authorized personnel sign for and receive controlled substances.
  - Copies of the dually signed Controlled Substance Delivery Record be sent to the Program Administrator.

In addition, we recommend Environmental Health and Safety Program Administrator:

- Develop and implement a local UCSB Controlled Substance Program to comply with UC Policy BUS-50 requirements and to specifically address the findings in our review to:
  - Ensure pre-screening and online training is completed by laboratory personnel prior to purchasing, receiving or working with controlled substances.
  - Validate and certify that laboratory personnel are retrained at regular intervals.
  - Document routine and unannounced audit inspections of investigator-maintained substances and records for compliance with state and federal laws governing the use of controlled substances in University activities.

### Management Corrective Actions

Environmental Health and Safety Program Administrator will:

- Enhance and strengthen the UCSB Controlled Substance Policy to comply with UC Policy BUS-50 requirements to include:
  - Required unannounced audits be performed and documented.
  - Prescreening forms be updated every three years.
  - All acquired controlled substances be approved by the Program Administrator, including orders directly from a vendor by the Drug Enforcement Administration registrant.
  - Only authorized personnel sign for and receive controlled substances.
  - Copies of Controlled Substance Delivery Record be sent to the Program Administrator.

In addition, the Environmental Health and Safety Program Administrator will:

- Develop and implement a local UCSB Controlled Substance Program to ensure compliance with UC Policy BUS-50 and UCSB Controlled Substance Policy and:
  - Ensure pre-screening and online training is completed by laboratory personnel prior to purchasing, receiving or working with controlled substances.
  - Validate and certify that laboratory personnel are retrained at regular intervals.
  - Document routine and unannounced audit inspections of investigator-maintained substances and records for compliance with state and federal laws governing the use of controlled substances in University activities.

*Audit and Advisory Services will follow up on the status of this management action plan by July 1, 2017.*

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*Recordkeeping and Inventory Requirements*

Our work in this area identified that recordkeeping was not consistently enforced and that delivery and transfer notifications were not received by the Program Administrator. Although the current processes appear to be in compliance with UC Policy BUS-50, the current way of administering the purchasing, receipt, and transfer of controlled substances could be viewed as a way of circumventing approval and documentation (receipt) requirements. Table 2 summarizes our audit findings.

Table 2	UC and UCSB Controlled Substances Policy Compliance		
Criteria	Environmental Health & Safety/Laboratories	Student Health	Police Department
Written Policy and Procedures	X	P	P
DEA Registration Requirements	✓	✓	N/A
Online Training and Personnel Screening Form Authorization	P	N/A	N/A
Routine and Unannounced Audits	P	✓	N/A
Security and Storage Requirements	✓	✓	✓
Acquisition Requirements	P	✓	N/A
Receipt Requirements	P	✓	N/A
Biennial Inventory Requirements	✓	✓	N/A
Usage Logs	✓	✓	N/A
Transfers/Chain of Custody	✓	N/A	✓
Disposal Requirements	✓	✓	✓

Source: Auditor analysis.  
 ✓ = Criteria met.  
 ✗ = Criteria not met.  
 P = Criteria partially satisfied.  
 N/A = Criteria not applicable.

Our detailed findings are as follows:

- The Program Administrator did not approve all purchases of controlled substances through the UCSB procurement system, Gateway, or purchases by the Drug Enforcement Administration registrant who acquired controlled substances directly through the National Institute of Drug Abuse. We noted that five of seven (71%) purchases tested did not have Program Administrator approval.
- Laboratory personnel did not complete the required Controlled Substance Delivery Record receipt and notify the Program Administrator when controlled substances had been received.
- The required transfer record between laboratories was not provided to the Program Administrator.
- The Program Administrator did not receive final disposition documentation as required by UC Policy BUS-50.

We recommend that Environmental Health and Safety Program Administrator develop a written Controlled Substance Program to comply with UC Policy BUS-50 and UCSB Controlled Substance Policy and to:

- Approve all purchases of controlled substances through the Gateway procurement system and monitor for inappropriately procured substances that may have been procured under a departmental purchase.
- Ensure notification by the Drug Enforcement Administration registrant when they acquire controlled substances free of charge through the National Institute of Drug Abuse for a specific grant.
- Receive the required dually signed Controlled Substance Delivery Record from authorized personnel including any reported discrepancies.
- Receive notification of controlled substance transfers between laboratories evidenced by a transfer record with appropriate documentation by the transferee and the recipient.
- Enhance methods of notification of destruction of controlled substances by laboratories forwarding a copy of the reverse distributor manifest to the Program Administrator in Environmental Health and Safety.

### **Management Corrective Actions**

Environmental Health and Safety Program Administrator will:

- Approve all purchases of controlled substances through the Gateway procurement system and monitor for inappropriately procured substances that may have been procured under a departmental purchase.
- Ensure notification by the Drug Enforcement Administration registrant when they acquire controlled substances free of charge through the National Institute of Drug Abuse for a specific grant.
- Receive the required dually signed Controlled Substance Delivery Records from authorized personnel including any reported discrepancies.
- Receive notification of controlled substance transfers between laboratories evidenced by a transfer record with appropriate documentation by the transferee and the recipient.
- Enhance methods of notification of destruction of controlled substances by forwarding a copy of the reverse distributor manifest to the Program Administrator.

*Audit and Advisory Services will follow up on the status of this management action plan by July 1, 2017.*

## **B. Student Health Services**

In our review of Student Health Services policy and procedures, we found that Student Health Services' existing controls were overall compliant surrounding the ordering, delivery, receipt, inventory, disposal, and physical security of controlled substances. However, while monthly controlled substance inventory audits are performed, detailed procedures are not documented.

We recommend Student Health Services enhance the department written policy and procedures to include more details to the monthly inventory audit process.

### **Management Corrective Actions**

Student Health Services will enhance the department written policy and procedures to include more details to the monthly inventory audit process.

*Audit and Advisory Services will follow up on the status of this management action plan by June 30, 2017.*

## **C. UC Santa Barbara Police Department**

Based on the review of evidence procedures, we found UC Santa Barbara Police Department controls were in compliance with the chain of custody of evidence of controlled substances requirements. However, there are opportunities for improvement by updating the evidence procedures to include the new tracking system and to formalize the destruction process to be in compliance with UC Policy BUS-50 requirements related to controlled substances.

We recommend the UC Santa Barbara Police Department:

- Update their evidence procedure to include the new tracking system for recording the chain of custody of controlled substance evidence.
- Formally document their process for destruction of controlled substances.

### **Management Corrective Actions**

The UC Santa Barbara Police Department will:

- Update the evidence procedure to include the new evidence tracking procedures.
- Document the destruction process of controlled substances.

*Audit and Advisory Services will follow up on the status of this management action plan by June 23, 2017.*