UNIVERSITY OF CALIFORNIA, RIVERSIDE

AUDIT & ADVISORY SERVICES

AUDIT REPORT R2025-07

STUDENT HEALTH SERVICES PHARMACY

July 10, 2025

Performed By:

Ricardo Pardo Jr., Associate Auditor

Approved By:

Gregory Moore, Director





UNIVERSITY OF CALIFORNIA, RIVERSIDE

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July 10, 2025

To: Jackie Rodriguez, Executive Director, Holistic Health Operations

VC Health & Wellness Department

Samuel Tran, Pharmacy Manager Student Health Services Pharmacy

Re: Internal Audit of the Student Health Services Pharmacy

Audit No. R2025-07

We have completed the internal audit of the Student Health Services Pharmacy in accordance with the University of California, Riverside Audit Plan. The audit was conducted in accordance with the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing* (in effect during 2024). Our report is attached for your review.

We will perform audit follow-up procedures in the future to review the status of management corrective action plans. This follow-up may take the form of a discussion or perhaps a limited review. Audit R2025-07 will remain open until we have evaluated the actions taken.

UC wide policy requires that all draft reports be destroyed after the final report is issued. We also request that draft reports not be photocopied or otherwise redistributed.

We appreciate the cooperation and assistance provided by you and your staff. Should you have any questions concerning the report, please do not hesitate to contact me.

Respectfully,

Gregory Moore Director Audit & Advisory Services

cc: Chief Financial & Administrative Officer, Veronica Ruiz Ethics & Compliance Risk and Audit Controls Committee

Executive Summary

Purpose and Scope

University of California Riverside (UCR) Audit & Advisory Services (A&AS) completed an audit of the Student Health Services Pharmacy (SHS Pharmacy) in accordance with the fiscal year 2024-25 UCR internal audit plan. The purpose of this audit was to evaluate the adequacy and operating effectiveness of internal controls over pharmacy operations including purchasing, handling, and storage of pharmaceutical inventory, and to evaluate compliance with various regulations and applicable University policies and procedures.

The scope of this audit included a review of control processes in effect at the time of audit fieldwork during October 2024 through January 2025 and transactional data from July 2024 through January 2025. Based on the assessed risks, the scope of this audit focused on the following areas:

- Drug purchasing
- Drug receipt and storage
- Drug inventory management
- Drug diversion
- Drug traceability and accountability
- Prescription filling and dispensing
- Waste management and expired drugs
- Physical security

We evaluated the adequacy and effectiveness of internal controls for the areas described above through discussions with key employees, by reviewing documentation to corroborate and understand processes that support key control activities, and by selecting transactions and reviewing documentation to assess compliance. A summary of the audit testing is provided in the Appendix.

Our audit standards require that we gather information and evidence that is relevant, reliable, and sufficient to achieve the engagement objectives and perform analysis and evaluations that provide a reasonable basis for our engagement findings and conclusions.

Results

Based on the work performed, we concluded that internal controls are adequately designed and operating effectively. We identified areas of improvement needed to strengthen internal controls and/or compliance with University of California (UC) policies and procedures. The issues are noted below and further discussed in the Observations section:

- Observation #1 Power of Attorney for DEA Forms 222 and Electronic Orders
- Observation #2 Documented Review and Approval of Inventory Adjustments
- Observation #3 Documented Review and Approval of the Annual Inventory Count of Noncontrolled Substances
- Observation #4 Documented Review and Approval of Pharmacy Orders
- Observation #5 Pharmacy Room Temperature Monitoring

The observations, recommendations, and management corrective action plans are discussed in more detail in the report below.

Background

The mission of the UCR SHS Pharmacy is to provide professional pharmacy services to help improve the health and well-being of UCR students and make access to prescription and non-prescription medications convenient and affordable so that students can better focus their attention on academic endeavors. The SHS Pharmacy is a service provided by the Student Health Services department to currently enrolled undergraduate and graduate students. Additional services provided by the department include primary care, women's health, x-ray, and lab services.

The SHS Pharmacy provides a range of pharmacy services including prescription filling, dispensing, oral consultations, and medication refills. These services are provided and supervised by a pharmacist licensed by the State of California. Students can obtain prescription medications by making an appointment with UCR Student Health. If they are issued a prescription, it will be transmitted electronically to the SHS Pharmacy. If a prescription is issued by an off-campus provider, students can bring it to the pharmacy and they will process it for them. Students can also have prescriptions processed at an off-campus pharmacy.

The SHS Pharmacy also carries many over-the-counter medications that can be purchased without a prescription to treat common illnesses such as: cough/cold/allergies, sore throat, pain, plan B, vitamins, and other general health supplies. Students can pick up prescriptions and over-the-counter medications in-person at the SHS Pharmacy located on the first floor of the Student Health and Counseling Center.

The SHS Pharmacy bills OptumRx for students currently enrolled in the University of California Student Health Insurance Plan (UCSHIP). They do not bill any other insurance plan. If a student does not have UCSHIP, they have the option to purchase the medication at cash price and submit the receipt to their insurance provider for reimbursement.

The SHS Pharmacy is currently staffed with six employees composed of one pharmacist in-charge, one senior staff pharmacist, two per diem pharmacists, and two pharmacy technicians with active licenses from the California State Board of Pharmacy. The SHS Pharmacy utilizes a pharmacy management system by ProPharm to manage prescriptions, medication dispensing, inventory management, and reporting.

Pharmacies who dispense controlled substances are required to comply with federal and state regulations. Controlled substances are divided into five schedules. A controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. The SHS Pharmacy currently dispenses schedule II-V controlled substances.

The Drug Supply Chain Security Act (DSCSA) is a federal regulation that outlines steps to achieve an interoperable and electronic way to identify and trace certain prescription drugs at the package level as they move through the supply chain. This helps prevent harmful drugs from entering the U.S. drug supply chain, detect harmful drugs if they do enter the supply chain, and enable rapid response to remove harmful drugs from the supply chain to protect patients. On October 9, 2024, the FDA granted an exemption from DSCSA requirements to small dispensers (25 or fewer FTEs) until November 27, 2026, to provide additional time to stabilize operations and fully implement the enhanced drug distribution security requirements of the Drug Supply Chain Security Act. As a result, we did not test these requirements as part of the scope of this audit.

The Administrative Services and Strategic Executive Team (ASSET) supports the SHS Pharmacy by providing many administrative services including financial, procurement, and other business support services.

Observations and Management Corrective Actions

Observation #1 - Power of Attorney for DEA Forms 222 and Electronic Orders

Condition: Any registrant may authorize one or more individuals to obtain and execute DEA Forms 222 and to sign orders for schedule II-controlled substances by granting a power of attorney to each such individual. During our audit procedures, we reviewed the power of attorney and verified it was signed by an officer of the registrant (the Chancellor) and the person to whom the power of attorney is being granted to (the Pharmacy Manager). However, we noted it was not signed by two witnesses as required by 21 CFR 1305.05(d).

Criteria: In accordance with the DEA Pharmacist's Manual and 21 CFR 1305.05 (d), the power of attorney must be signed by:

- 1. The registrant, if an individual; a partner of the registrant, if a partnership; or an officer of the registrant, if a corporation, corporate division, association, trust or other entity;
- 2. The person to whom the power of attorney is being granted; and
- 3. Two witnesses.

Cause: The power of attorney was inadvertently drafted without knowledge of the required witness signatures.

Effect: The pharmacy would not be in compliance with federal regulations which can result in fines and penalties, license suspension or revocation, loss of DEA registration, reputational damage, or other regulatory action.

Recommendation: We recommend the SHS Pharmacy update the power of attorney to include the two witness signatures as required by the DEA Pharmacist's Manual and federal regulations.

Management Action Plan: We have revised form 224 for the Power of Attorney that includes spaces for the witness signatures. We will forward an executed form to you once we have all the necessary signatures.

Expected Implementation Date: August 15, 2025. Internal audit will validate the implementation through its standard corrective action follow-up process.

Observation #2 – Documented Review and Approval of Inventory Adjustments

Condition: Inventory adjustments are corrections made in the inventory management system to align recorded inventory levels with actual physical inventory on hand. During our audit procedures, we reviewed a sample of 10 inventory adjustments and noted eight adjustments were performed by the Senior Staff Pharmacist and two were performed by the Pharmacy Manager.

Although inventory adjustments were verbally discussed with the Pharmacy Manager, we noted there is no formal documented review and approval process of inventory adjustments by the Pharmacy Manager, supervisor, or secondary user to ensure the adjustment is both appropriate and accurate. As a result, we were not able to verify the inventory adjustments were properly reviewed and approved because supporting documentation did not exist.

Criteria: Per review of the Pharmacy's Inventory Management procedure, we noted no documented processes or procedures to review and approve inventory adjustments. Although documented procedures around who may perform inventory adjustments including the various reasons to perform an adjustment exist, we noted no such procedures for reviewing and approving inventory adjustments. A supervisor or secondary user should review and approve inventory adjustments to ensure the adjustment is both appropriate and accurate.

Internal control best practices require that management design and implement control activities to achieve business objectives and respond to risks. A supervisory or secondary review and approval process will help prevent and detect inappropriate actions and reduce the risk of fraud and error. This process helps ensure that one employee's actions are verified and approved by another. One employee prepares the inventory adjustment, while another reviews and approves the inventory adjustment by verifying inventory counts, the reason for the adjustment, and reviewing documentation that supports the discrepancy. This would decrease the risk of unauthorized adjustments being entered into the inventory system. Documentation should be kept on file to help support that this review took place.

Cause: Inventory adjustments were not required to be formally reviewed and approved by a supervisor or second user.

Effect: Without a formal review and approval process, inappropriate inventory adjustments can result in theft, errors, misleading inventory reports, and operational inefficiencies. Pharmaceuticals can be misappropriated and the act concealed by adjusting inventory records.

Recommendation: We recommend the SHS Pharmacy update their policies and procedures and implement a formal documented process for requesting, reviewing, approving, and monitoring inventory adjustments. Inventory adjustments should be reviewed and approved by a supervisor or secondary user and should be properly documented. The reason for the adjustment should be supported and verified with documentation.

Management Action Plan: We have updated the P&P with the following language: "The Annual Inventory of all Rx and OTC products and the Quarterly Inventory of controlled substances are reviewed and signed by both the Pharmacy Manager and the Executive Director, Holistic Health Operations. Manual inventory adjustments are reviewed weekly by a pharmacist who did not perform the original adjustment."

Expected Implementation Date: This corrective action has been implemented.

Observation #3 – Documented Review and Approval of the Annual Inventory Count of Noncontrolled Substances

Condition: During our audit procedures, we reviewed the annual inventory count of noncontrolled substances (OTC and Rx) conducted during the scope of our audit. Based on our review of the annual inventory count of noncontrolled substances conducted between December 2024 and January 2025, we noted there is no formal documented review and approval process of the annual inventory count by a supervisor or secondary user to ensure the count is both accurate and complete.

Criteria: In accordance with the Pharmacy's Inventory Management procedure, "all Rx and OTC products are physically counted and compared against the pharmacy software's electronic inventory records on an annual basis." Although documented procedures exist around the annual inventory count of noncontrolled substances, we noted no such procedures for reviewing and verifying the inventory counts.

Additionally, UCR Campus Policy 750-52: Physical Inventories states, "Currently all departments with cumulative supplies in excess of \$50,000 are to conduct at least an annual physical inventory count. Physical counts should be conducted by individuals who have no inventory responsibilities such as custody and recordkeeping. On a sampling basis, someone independent of the supply inventory operation should verify physical counts, prices, extensions, and totals."

A supervisory or secondary review and approval process can help ensure checks and balances by verifying inventory counts and helping reconcile inventory discrepancies. This can strengthen the

internal control structure and ensure that any issues are caught and corrected promptly, leading to more accurate and reliable inventory records. A supervisory or secondary verification can also help encourage diligence and adherence to established procedures by staff and reduce the risk of inappropriate actions. A formal documented process will help support that this review took place.

Cause: The annual inventory count of noncontrolled substances was not required to be formally reviewed and approved by a supervisor or second user.

Effect: Without a formal review and approval process, theft, miscounts, losses, or other errors can occur resulting in inaccurate inventory records which can include stockouts, overstock, or obsolescence.

Recommendation: We recommend the Pharmacy Manager, supervisor, or secondary user formally document their review and approval of the annual inventory count of noncontrolled substances including verifying physical inventory counts and investigating any discrepancies.

Management Action Plan: We have updated the P&P with the following language: "The Annual Inventory of all Rx and OTC products and the Quarterly Inventory of controlled substances are reviewed and signed by both the Pharmacy Manager and the Executive Director, Holistic Health Operations. Manual inventory adjustments are reviewed weekly by a pharmacist who did not perform the original adjustment."

Expected Implementation Date: This corrective action has been implemented.

Observation #4 – Documented Review and Approval of Pharmacy Orders

Condition: During our audit procedures, we reviewed a sample of pharmaceutical purchases consisting of 15 controlled substances (schedules II-IV) and 15 noncontrolled substances (Rx and OTC). Pharmacy orders for purchase of pharmaceuticals are sent to the ASSET department who then generate a purchase order, punch-out the purchase via Oracle Financials, and submit the order to the wholesaler. Orders of schedule II-controlled substances are sent back to the pharmacy and reviewed and approved by the Pharmacy Manager who electronically signs a Controlled Substance Ordering System (CSOS) certificate to complete the order.

Based on review of the processes and documentation provided for orders of schedule III-V controlled substances and noncontrolled substances, we were not able to verify the pharmacy orders were properly reviewed and approved by the pharmacist-on-duty, supervisor, or a secondary user prior to ASSET finalizing and submitting the orders to the wholesaler because supporting documentation did not exist.

Criteria: In accordance with the Pharmacy's Purchasing procedure, "all pharmacy orders, except those for Schedule II (CII) medications, are reviewed by the pharmacist on duty, then finalized

("punch-out"), and submitted to the wholesaler by the ASSET staff. For orders of CII medications, after the ASSET staff has submitted the order, the pharmacy manager must review it and electronically sign a CSOS certificate. This electronic signature is required to complete the order for CII medications. The order cannot be processed without this critical step."

One employee should prepare the order of pharmaceuticals, while another (i.e. management) reviews and approves the pharmacy order prior to sending it to ASSET to ensure the purchase is both appropriate and accurate. Documentation should be kept on file to help support that this review took place.

Cause: Orders of schedule III-V controlled substances and noncontrolled substances were not reviewed and approved by a supervisor or second user prior to sending them to ASSET.

Effect: Purchasing is a major expenditure of any department and critical to a department's success. Without a formal review and approval process, unauthorized purchases can occur resulting in fraud, losses, or errors such as incorrect items, drug strength, size, or quantities being ordered. A strong purchasing function will help ensure continual supply of needed pharmaceuticals.

Recommendation: We recommend a supervisor or secondary user (i.e. pharmacy management) formally document their review and approval of schedule III-V controlled substances and noncontrolled substances orders, prior to sending them to ASSET for finalization and submission to the wholesaler.

Management Action Plan: In recognition of additional safeguard for unauthorized pharmacy orders, we have modified our ordering procedure to include the final approval of either the pharmacy manager, the executive director, or a designated pharmacist to grant the approval and final submission of all pharmacy orders. The procedure for CII's remains unchanged in that only the pharmacy manager will approve with a CSOS e-signature. The wording in the new policy and procedure will include the following language:

"All pharmacy orders - excluding Schedule II (CII) medications—must be initially reviewed by the pharmacist on duty. After this review, the orders are submitted to the ASSET team for further review and approval. Once approved, the requisition is routed to the pharmacy manager, executive director, or a designated pharmacist for final submission to the wholesaler. Approval history is documented and accessible via the Oracle platform."

Expected Implementation Date: This corrective action has been implemented.

Observation #5 – Pharmacy Room Temperature Monitoring

Condition: During our audit procedures, we reviewed the SHS Pharmacy's temperature monitoring log for the month of October 2024. The temperature monitoring log records both the

refrigerator and the ambient room temperature and is documented by staff twice daily, once in the morning and once in the afternoon. Based on our review of the temperature monitoring log, we identified the following instances where the temperature monitoring was not documented:

- One instance where both the afternoon refrigerator and ambient room temperature was not documented.
- One instance where the afternoon ambient room temperature was not documented.

However, the SHS Pharmacy utilizes an electronic temperature monitoring system from Sonicu that continuously monitors the refrigerator temperature and provides real-time alerts to designated personnel via email and text in the event the refrigerator temperature falls outside of the acceptable range. Although a continuous temperature monitoring system is in place that monitors for any refrigerator temperature excursions, we noted this system does not monitor the ambient room temperature of the pharmacy where room temperature pharmaceuticals are stored.

Criteria: In accordance with the Pharmacy's Temperature Monitoring procedure, "the refrigerator's temperature is monitored twice daily, once in the morning and once in the afternoon. The paper log records both the interior refrigerator temperature and the ambient room temperature." Monitoring of the pharmacy's room temperature will help identify and/or prevent any temperature excursions which is essential for maintaining the quality and reliability of pharmaceuticals.

Cause: Pharmacy staff inadvertently did not document their monitoring of the pharmacy's ambient room temperature.

Effect: Temperature sensitive medication can degrade or lose effectiveness if not maintained at optimal temperatures resulting in financial loss to the pharmacy, regulatory non-compliance, risks to patient safety, or reputational damage.

Recommendation: We recommend the SHS Pharmacy provide a refresher training on temperature monitoring and manual logging procedures. A documented secondary review of the temperature monitoring log can help identify any discrepancies and ensure procedures are being followed.

Management Action Plan: SHS Pharmacy acknowledges your observation and agrees that accurate and consistent documentation of temperature logs is important. We recognize the importance of not missing any refrigerator temperature entries, even when using redundant systems.

While the paper log is reviewed and completed by staff twice daily per our internal procedure, it is intended as a redundant backup to our primary temperature monitoring system, Sonicu. Sonicu provides real-time, continuous temperature monitoring of the pharmacy's refrigerators and automatically generates alerts in the event of any temperature excursion. In addition, Sonicu temperature reports are reviewed weekly by the pharmacy manager.

The two isolated omissions noted in the October 2024 paper log were inadvertent and did not result in any temperature excursions. While the current system already provides strong safeguards, we will continue to remind staff of the importance of complete and timely documentation on the paper log as part of our commitment to operational redundancy.

Expected Implementation Date: This corrective action has been implemented.

Appendix - Objective, Scope, and Methodology

Audit Objective

The purpose of this audit was to evaluate the adequacy and operating effectiveness of internal controls over pharmacy operations including purchasing, handling, and storage of pharmaceutical inventory, and to evaluate compliance with various regulations and applicable University policies and procedures.

Audit Criteria

During the audit planning, we identified the following criteria which was significant to the audit:

- Drug Enforcement Administration Pharmacist's Manual-Revised 2022
- California State Board of Pharmacy 2024 Pharmacy Lawbook
- Relevant regulations, including the Controlled Substances Act and the Drug Supply Chain Security Act (DSCSA)
- Various documented SHS Pharmacy procedures, including:
 - o Pharmaceutical Purchasing, Receiving, and Inventory Management Procedure
 - o Temperature Monitoring Policy and Procedure
 - o Pharmacy Controlled Substances Inventory Procedure
 - o Employee Impairment and Drug Theft Policy and Procedure
 - o Drug Supply Chain Security Act (DSCSA) Policy and Procedure
 - Medication Recalls Procedure
 - o Temporary Absence of the Pharmacist Procedure
 - o Pharmacist Duty to Consult Procedure
 - o Disposal of Outdated Drugs Procedure
 - o Pharmacy Security and Access Procedure
 - o PHA 002 Pharmaceutical Inventory Process Policy
 - o UCR Campus Policy 750-52: Physical Inventories

Audit Testing Completed

The scope of this audit included a review of control processes in effect at the time of audit fieldwork during October 2024 through January 2025 and transactional data from July 2024 through January 2025. Based on the assessed risks, the scope of this audit focused on the following areas:

- Drug purchasing
- Drug receipt and storage
- Drug inventory management
- Drug diversion
- Drug traceability and accountability
- Prescription filling and dispensing
- Waste management and expired drugs
- Physical security

To fulfill the audit objectives, we completed the following testing:

- Obtained an understanding of relevant UCR policies, procedures, and federal and state regulations related to the activities under review within the scope of our audit.
- Discussed current processes and internal controls with key personnel from the SHS Pharmacy and ASSET.
- We performed walkthroughs and reviewed documentation describing key processes and internal controls related to drug purchasing, drug receipt and storage, drug inventory management, drug diversion, drug traceability and accountability, prescription filling and dispensing, waste management and expired drugs, and physical security.
- We reviewed the pharmacy's manual binder consisting of policies, standard operating
 procedures, and other documentation to ensure compliance with federal and state
 regulations such as: pharmacy state license information, power of attorney, personnel
 license information, past inspections, drug wholesalers, and reverse distributor
 information.
- We reviewed a sample of drug purchases to verify proper approval, payment, and agreement with supporting documentation.
- We reviewed a sample of controlled substances to verify compliance with federal regulations including use of the required DEA form for purchase of schedule II-controlled substances.
- We obtained the pharmacy's power of attorney to order schedule II-controlled substances and reviewed for compliance with federal regulations.
- We traced a sample of drug purchases to the pharmacy inventory management software and reviewed documentation to verify all drug deliveries were signed, received, and reconciled by authorized personnel.
- We reviewed documentation to determine whether temperature-controlled drugs are properly monitored and stored.
- We performed a site visit of the pharmacy to verify if controlled substances are stored, locked, and restricted to appropriate personnel.
- We obtained the most recent inventory count of controlled and noncontrolled substances to determine if any discrepancies were properly accounted for and inventory counts were reviewed by a supervisor or secondary user.
- We obtained a listing of manual inventory adjustments to determine whether the report is monitored and reviewed. Additionally, we reviewed a sample of inventory adjustments to determine appropriateness and review by a supervisor or secondary user.
- We reviewed for any segregation of duties conflicts and determined whether effective mitigating controls are in place. We reviewed processes to identify, monitor, and prevent drug diversion.
- We reviewed the FDA exemption granted to small dispensers (25 or fewer FTEs) through November 27, 2026, to provide additional time to stabilize operations and fully implement the enhanced drug distribution security requirements of the Drug Supply Chain Security Act. We did not test these requirements as part of the scope of this audit.
- We reviewed a sample of recently filled and dispensed controlled substances prescriptions
 to verify that there are signed written prescriptions by the issuing practitioners and to verify
 they were reviewed, filled, and dispensed by an authorized Pharmacist.

- We obtained the most recent list of wasted drugs that have been disposed of and determined whether a waste management program is in place as required by federal regulations. We reviewed the DEA Forms-222 for each disposed schedule II-controlled substance.
- We obtained a listing of all individuals with access to the pharmacy and controlled substances. We determined if their access is appropriate based on staff roles. We observed the security measures in place at the pharmacy to prevent unauthorized entry and theft.

Evaluation of Internal Controls

Internal control is a process effected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. These objectives and related risks can be broadly classified into one or more of the following three categories:

- Operations Effectiveness and efficiency of operations
- Reporting Reliability of reporting for internal and external use
- Compliance Compliance with applicable laws and regulations

We obtained an understanding of internal controls relevant to the audit. Based on our audit testing, with the exception of the areas of improvement discussed in the Observations section, we concluded that internal controls are adequately designed and operating effectively.