UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT & ADVISORY SERVICES

Pharmacy
Prescription Drug Receiving Review

Project #21-052

July 2021

July 15, 2021

Desi Kotis
Chief Pharmacy Executive
UCSF Health

SUBJECT: Pharmacy Prescription Drug Receiving, Project #21-052

Audit and Advisory Services ("A&AS") conducted a review of Pharmacy prescription drug receiving processes. The purpose of this review was to validate that the processes for receiving inventory, including compliance with the Drug Supply Chain Security Act (DSCSA), and related controls are in place at the UCSF Pharmacy.

Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the "IIA Standards").

Our review was completed and the preliminary draft report was provided to department management in May 2021. Management provided their final comments and responses to our observations in July 2021. The observations and corrective actions have been discussed and agreed upon with department management and it is management's responsibility to implement the corrective actions stated in the report. A&AS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Board, and is not intended to be and should not be used by any other person or entity.

Sincerely,

Irene McGlynn
Chief Audit Officer
UCSF Audit and Advisory Services

EXECUTIVE SUMMARY

I.   BACKGROUND

As a planned audit for Fiscal Year 2021, Audit & Advisory Services (A&AS) conducted a process and controls review surrounding the receiving of inventory at the UCSF Pharmacy to validate that appropriate controls are in place.

UCSF Pharmaceutical Services was established in 1965 with its first clinical pharmacy at Moffit Hospital. Since then, it has continued to lead the profession through integration of advanced technology, comprehensive pharmaceutical care and clinical services at a national level. Today, the department employs over 200 staff who work at multiple campus locations in San Francisco, both at the main pharmacies and at several satellite pharmacy locations.

UCSF Pharmaceutical Services is responsible for procuring and receiving inventory, with four buyers and nine storekeepers dedicated to these functions at the main pharmacy locations. Generally, drug orders are ordered either through Amerisource Bergen (ABC), a wholesaler vendor, or various direct vendors. The Kanban inventory system indicates for storekeepers the drugs for restock and subsequent ordering.

Per the Pharmaceutical Services Purchasing Policy (220.200 – *Purchasing*), drugs that are not available from the ABC are ordered by the Pharmacy Purchasing Manager (PM) or delegate directly from the vendor (direct orders). Once prescription drug orders are delivered to the pharmacy, storekeepers perform receiving functions to ensure prescription drugs are received and delivered to the appropriate location. There are different processes for receiving ABC and direct ordered drugs, but all require storekeepers scanning the package label and reconciling it with the contents. Invoices are sent with ABC orders; whereas direct orders include a packing slip with order information, which are forwarded to Pharmacy Accounts Payable for payment processing.

On November 27, 2013, The Drug Quality and Security Act (DQSA) was enacted by Congress. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The law empowers the Food & Drug Administration (FDA) to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. Additionally, the DSCSA aims to improve detection and removal of potentially dangerous drugs from the drug supply chain to protect consumers of prescription drugs. The requirements, development of standards and the system for product tracing continues to be implemented in phases, and this will occur until 2023. For a more detailed description of the requirements, please see Appendix A.

To comply with the DSCSA, the UCSF Pharmacy utilizes TraceLink, a third-party software system that maintains transaction history, transaction information, and transaction statements (T3 data) for the pharmacy. Electronic T3 data is transferred to UCSF from each trading partner. If the trading partner does not provide electronic T3 data, the Pharmacy buyer will manually scan and upload the T3 data from paper packing slips. As of the end of this review, it was noted that direct vendor uploads are experiencing a backlog beyond August 24, 2020.

II.   <u>**AUDIT PURPOSE AND SCOPE**</u>

The purpose of this review was to review processes surrounding the receiving of prescription drugs, including compliance with the Drug Supply Chain Security Act (DSCSA) and to validate that appropriate controls are in place.

The scope of the review covered transactions and activities for September 2020 – April 30, 2021 at the Mission Bay and Parnassus Main Pharmacies and satellite pharmacies.

Procedures performed as part of the review included obtaining and reviewing applicable policies and procedures for purchasing and receiving prescription drugs, performing walkthroughs with department personnel at the pharmacies in scope to understand current processes, and reviewing a sample of prescription drug transactions within the pharmacy to validate that they are received appropriately and traceable to required authorized trading partners as required by the DSCSA. For more detailed steps, please refer to Appendix B.

Work performed was limited to the specific activities and procedures described above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in April 2021.

III.   <u>**SUMMARY**</u>

Based on work performed, controls are functioning well in the proactive efforts for certain process improvements, separation of duties, and various inventory reconciliation processes.

Opportunities for improvement exist in the areas of workflow efficiencies in receiving processes for prescription drugs and invoice processing, as these require a high level of manual effort.

The specific observations from this review are listed below.

Direct Vendor Orders and Traceability

1. TraceLink does not always match the information on the packing slip, which could lead to potential issues with drug traceability.
2. Ordering process controls regarding communication of the order delivery location and status are lacking, causing confusion and avoidable additional effort.

Invoice Process Documentation

3. Current practices and expectations for early payments to obtain cash discounts are informal and not documented.
4. Overreliance on paper for the invoicing process creates additional manual effort and challenges in tracing invoices.

Additionally, during the course of this review, potential opportunities for improvement were noted for enhanced process efficiency regarding processes surrounding disruptions to the pharmacy workflow.

IV.   OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS

A. Direct Vendor Orders and Traceability

No.	Observation	Risk/Effect	Recommendation	MCA
1	*TraceLink data does not always match the information on the packing slip, which could lead to potential issues with drug traceability.* A sample of 25 pharmacy transactions (17 wholesaler and eight direct) were tested for traceability (in TraceLink) as required by the DSCSA and completed invoicing. There were no issues noted in tracing wholesaler invoices. Of the eight direct vendor transactions in the sample: • Three could not be matched in TraceLink • One had a dosage discrepancy • Three were exempt from tracing as 503B compounded drugs[1] • One had no exception noted Because TraceLink is the system of record for supply chain traceability, it should reflect what is stated on the packing slip for direct invoices.	Mismatches in data between TraceLink and the actual order leads to challenges in accurate tracing of product, potentially creating a compliance issue with the DSCSA.	The noted instance of mismatched data should be investigated and corrected. A process for correcting incorrect TraceLink data should be created. For DSCSA-exempt pharmaceuticals, a process should be in place to ensure proper receiving of the drug including verifying proper chain of custody, licensed vendor, and proper labeling.	**Management Response/ Action** The mismatched data was investigated and it was determined that the dosages are the same concentration stated differently, and the NDCs match. No further action is required. It was noted at the time of review that there is a backlog for uploading the items that were unable to be located into TraceLink. Discussions to address the backlog will occur to ensure the

---

[1] The Drug Quality and Security Act, signed into law on November 27, 2013, created a new section 503B in the Federal Food, Drug and Cosmetic Act to designate 503B pharmacies as compounding pharmacies. Per Title II of the DSCSA, Section 581(13), drugs compounded in compliance with section 503A or 503B are exempt from the DSCSA.

No.	Observation	Risk/Effect	Recommendation	MCA
				transactions are up to date. **Responsible Party:** Assistant Chief Pharmacy Officer, Business Services **Target Completion Date:** July 31, 2021
2	***Ordering process controls regarding communication of the order delivery location and status are lacking, causing confusion and avoidable additional effort.*** All pharmacies have access to the online prime vendor wholesaler system[2], to eliminate paper ordering. Only drugs that have been pre-approved on the ordering template can be ordered by pharmacy units. For drugs needing to be ordered that are not on the Kanban inventory list and pre-approved, storekeepers or purchasers receive notification of an order for them to request via email. The storekeeper or purchaser enters the request to order on a "want list," which is kept on a SharePoint site, where the buyers view items for order and place the order with direct vendors. During a walkthrough with a storekeeper, it was noted that certain direct orders, such as those that are patient-specific or high cost, are challenging to deliver to the appropriate location because patient information is missing in the delivery itself or in the order communication with the direct vendor. This causes the	The lack of a unique identifier for patient-specific medications and not updating order status in the order tracking system creates disruptions in receiving workflow, as well as increased time and effort to identify the intended patient, location and order status.	A smartsheet containing order information, including requested orders and status of the order should be utilized by those placing orders as well as the storekeepers. Access to the smartsheet should be limited with access to those with ordering responsibility. Additionally, notes should be included	**Management Response/Action** When placing orders on the SharePoint order tracking site, the data fields for the intended patient and/or specific site location will be required to be completed. Re-training on which fields to be completed in SharePoint order tracking system will occur, and it will be the system

_____

[2] Wholesaler Vendors include Amerisource Bergen (ABC), Cardinal and McKesson.

No.	Observation	Risk/Effect	Recommendation	MCA
	storekeeper to sort through various email communications to try and track the order; and, in the event they cannot locate the order information in email, the storekeeper then has to contact the buyer. The storekeeper also indicated that there is a lack of communication regarding the turnaround time for certain medications on the want list. After requests to purchase a particular drug order on the want list, storekeepers are often waiting without appropriate follow-up from the purchasing team regarding arrival time. Ordering from the want list is a regular occurrence, and the additional investigation into where these drugs are in the ordering workflow may cause repeated additional effort. Additionally, because the satellite locations do not always inform the storekeepers of certain prescription drug orders that they have requested to be placed by purchasers, considerable effort may need to be taken to trace an order and deliver it to the correct location. The lack of patient information in direct orders creates disruptions to the receiving workflow, and ultimately a delay in delivering the prescription drug to the intended recipient.		with the order to indicate the drug's intended location.	of record for orders on the Want List. **Responsible Party:** Assistant Chief Pharmacy Officer, Business Services **Target Completion Date:** July 31, 2021

B. Invoice Process Documentation

No.	Observation	Risk/Effect	Recommendation	MCA
3	***Current practices and expectations for early payments to obtain cash discounts are informal and not documented.*** Wholesaler invoice payments are due within ten days after the invoice date, and invoices are paid every Friday. Direct invoice payments are due within 30 days of the invoice date. The general practice is to prioritize invoices that offer discounts and/or late charge fees for processing, though there are currently	A lack of written protocols to clearly identify and monitor lost discounts could lead to unrealized cost	Enhanced controls surrounding the timing of payments to avoid forfeitures of cash discounts for early payment, such as creating a written policy to address	**Management Response/Action** Written protocols to address discounts offered for early payment of invoices will be drafted. The protocols will

No.	Observation	Risk/Effect	Recommendation	MCA
	no written protocols stating so. However, one direct invoice in the sample tested had discount forfeiture language, indicating that the vendor offered a discount for early payment on the invoice. The Accounts Payable analyst has set up a process to pay vendors and their related invoices offering an early pay discount on a Net1 basis, or within the next check run. Currently, there is no written protocol surrounding collection of early cash payment and corresponding timelines for varying payment terms to prevent forfeitures of potential discounts. Further, the system around tracking vendors who offer this discount is informal.	savings for the pharmacy.	discounts, should be considered. Additionally, a system to flag vendors that offer discounts may help to consistently identify which invoices to prioritize.	include a process to identify and monitor these types of cost savings. These protocols will be communicated to Accounts Payable. **Responsible Party:** Assistant Chief Pharmacy Officer, Business Services **Target Completion Date:** July 31, 2021
4	***Overreliance on paper for the invoicing process creates additional manual effort and challenges in tracing invoices.*** **A. Missing Packing Slips** Out of the eight direct vendor transactions tested, two did not have the associated packing slips. Packing slips serve as proof of delivery for Accounts Payable to begin the payment process. When packing slips are not included or forwarded to Accounts Payable, additional effort is undertaken to locate documentation of receipt. For example, the Pyxis system, a system for controlled medication management, tracks the receipt of controlled substances and helps with automating inventory. When packing slips for controlled substances are not received, Accounts Payable	The manual effort required to trace supporting documentation for scheduled drugs creates workflow inefficiencies in processing payment. Further, in the event that a	Scanning paper invoices and packing slips as they arrive, prior to sending the documentation to Accounts Payable for processing should be considered, to eliminate batch uploaded of invoices and packing slips.	**Management Response/Action** An electronic management system or database will be reviewed for feasibility, with the goal of integrating the receiving and payment processes.

No.	Observation	Risk/Effect	Recommendation	MCA
	refers to the Pyxis-exported CII Safe report to locate the drug in inventory to match the invoice. Other methods of locating invoice-related information is to verify via a UPS or FedEx tracking number sent after a drug delivery, but tracking numbers expire after 120 days. Though Accounts Payable reconciles each individual invoice with a packing slip or delivery service tracking information, the variation in the invoicing process of different drugs creates extra work, leading to inefficiencies in the workflow. **B. Tracing Paper Documentation for Invoicing** Currently, there are separate systems for the invoicing of wholesale orders and for direct orders. *Wholesale Orders* Invoices for orders that are placed via the ABC platform are included in the delivery. The invoice indicates the items, quantity and price of the prescriptions in the order, acting as a packing slip as well. Once the storekeeper receives the order and reconciles the contents with the invoice, it is date stamped and initialed and sent to Accounts Payable for processing. Once a week, invoices are batch uploaded onto a SharePoint site accessible by the Accounts Payable personnel. *Direct Orders* Direct orders only contain a packing slip when the order is received, which indicates the item and quantity of the prescriptions in the order. The invoice is separately and directly emailed or mailed to Accounts Payable for processing and payment. Accounts Payable reconciles each individual invoice sent directly by the vendor with a packing slip or UPS/FedEx tracking information.	particular invoice needs to be located due to a drug recall or other recall for illegitimacy, considerable time and effort must be taken to sort through files.	An electronic file management process should also be considered to help reduce the paperwork burden and ease the process when searching for individual invoices.	**Responsible Party:** Assistant Chief Pharmacy Officer, Business Services in coordination with the Director of Supply Chain Management **Target Completion Date:** June 30, 2022

No.	Observation	Risk/Effect	Recommendation	MCA
	Because the documentation source is paper-heavy, it takes considerable manual effort to gather the invoices or packing slips. Further, because these documents are batch uploaded into either SharePoint or a shared network drive, it is burdensome to locate a particular invoice. Some files include more than 100 pages of invoices to sort through.			

V.   OPPORTUNITY FOR IMPROVEMENT

No.	Observation	Risk/Effect	Recommendation
1	***COVID-related restrictions are impacting the pharmacy workflow, creating additional effort spent on retrieving deliveries.*** During the COVID-19 pandemic, delivery personnel from UPS or FedEx stopped making deliveries to the pharmacies themselves. Only pharmacy directors are authorized to sign for prescription drug deliveries, which is challenging because the pharmacy is not located near the delivery area. Further, deliveries are not always made at the same time every day. This process takes considerable time and requires both the pharmacy director and storekeeper to be away from the pharmacy, causing potential disruption and delays to the general pharmacy workflow.	Considerable disruptions to pharmacy workflow are created by having to physically retrieve deliveries at the receiving dock as opposed to at the pharmacy.	As COVID-related restrictions are lifted, a provision to allow delivery personnel to deliver packages directly to the main pharmacies could be considered.

APPENDIX A – DSCSA Implementation Timeline[3]

Section of DSCSA	Deliverable Type	Deliverable Description	Estimated Target Date
202	FR Notice	Issue notice of public docket to collect stakeholder comments on standards for interoperable exchange of transaction information/history/statement in paper or electronic format	2/20/2014
202	Guidance	Publish draft guidance establishing standards for interoperable exchange of transaction information/history/statement in paper or electronic format	11/27/2014
202	Guidance	Publish guidance on processes for waivers, exceptions, exemptions	11/27/2015
202	Guidance	Publish final guidance on grandfathering product	11/27/2015
203	Assessment	Conduct and complete a technology and software assessment on feasibility of small dispensers to conduct drug tracing at the package level	TBD
203	Guidance	Publish guidance on identification of suspect product and termination of notifications of illegitimate product for finished human prescription drugs	12/09/2016
203	Public Meeting	Conduct at least 5 public meetings	TBD
203	Pilot Project	Establish 1 or more pilot projects in coordination with stakeholders to explore and evaluate methods to enhance the safety and security of supply chain	TBD
203	Guidance	Publish final guidance on system attributes necessary to enable secure tracing at the package level	11/27/2022
203	Guidance	Publish final guidance on standards for interoperable data exchange to enhance secure tracing of product at the package level	11/27/2022
203	Regulation	Develop regulations establishing enhanced drug distribution security system for interoperable electronic tracing of product at the package level	11/27/2021
204	Database	Establish a system for wholesale drug distributor reporting to FDA and public database with licensing information	1/1/2015
204	Regulation	Develop regulations establishing standards for licensing of wholesale drug distributors	11/27/2015
205	Database	Establish a system for third-party logistic provider reporting to FDA	11/27/2014
205	Regulation	Develop regulations establishing standards for licensing of third-party logistic providers	11/27/2015

---

[3] Current as of January 27, 2021

APPENDIX B – Detailed Procedures Performed

To conduct our review the following procedures were performed for the areas in scope:
- Reviewed relevant regulations, including the Drug Supply Chain Security Act (DSCSA)
- Reviewed UCSF Medical Center Pharmaceutical Services policies, including:
  o Policy 110.600 *Medication Management: Procurement (rev. 9/15)*
  o Policy 220.00 *Purchasing (rev. 12/18)*
  o Policy 220.700 *Ordering Controlled Substances (rev. 1/18)*
  o Policy 221.200 *Recall of Medications (rev. 1/18)*
  o Policy 221.300 *Returns & Destructions of Medications (rev. 1/18)*
  o Policy 1220.160 *Online Wholesaler Ordering by Clinic Department (rev. 1/19)*
  o Draft Policy *Drug Supply Chain Security Act (DSCSA): Drug Product Tracing Requirements (rev. 3/21)*
- Interviewed and performed walkthroughs with key department personnel for pharmacies in scope to determine drugs are received appropriately, including:
  o Directors of Operations
  o Storekeepers
  o Pharmacy Receiving Manager
  o Procurement Analyst
  o Accounts Payable Analyst
- Reviewed a sample of pharmacy transactions (both direct and wholesale) for prescription drugs and validated that they are traceable to required authorized trading partners in TraceLink, as required by the DSCSA
- Validated that there are established systems regarding quarantine and investigation of suspect product to determine legitimacy
- Validated monitoring processes are performed regularly and that any identified discrepancies are addressed in a timely manner