UNIVERSITY OF CALIFORNIA, SAN FRANCISCO AUDIT & ADVISORY SERVICES

Clinic Operations – Pharmacy Inventory Project #23-019

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Audit & Advisory Services

UCSF Box 0818 1855 Folsom Street San Francisco, CA 94143

tel: 415.476.3851 fax: 415.476.3326 www.ucsf.edu April 19, 2023

ALEKSANDRINA EPPEL Director, Faculty Practice

JASON SELINGER

Director, Faculty Practice

SUBJECT: Clinic Operations – Pharmacy Inventory

As a planned internal audit for Fiscal Year 2023, Audit & Advisory Services ("A&AS") conducted a review of pharmacy inventory management at select Faculty Practice Organization Clinics. The purpose of this review was to assess the processes and internal controls in place for the management of pharmaceuticals at ambulatory clinic locations.

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 March 2023. Management provided their final comments and responses to our observations in April 2023. 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 Executive Committee, 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 & Advisory Services



EXECUTIVE SUMMARY

Ι. BACKGROUND

As a planned audit for Fiscal Year (FY) 2023, Audit & Advisory Services conducted a processes and controls review to ensure appropriate pharmaceutical inventory control and management in the clinics.

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 400 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 Inventory Management Technicians 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.

Per the Pharmaceutical Services Purchasing Policy (220.200 – Purchasing), drugs that are not available from 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. Inventory Management Technicians 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 Inventory Management Technicians 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.

For Ambulatory clinics with a Pyxis Automated Dispensing Cabinet (Pyxis), Pharmacy manages the drug inventory and delivers medications. Pyxis captures the removal and return of medications, as well as allows for capturing wastage. Ambulatory clinics without Pyxis order medications through ABC's online portal, which is then sent to Pharmacy staff to review and approve the order before it is sent for fulfillment. Drug shipments are received by the Pharmacy and repackaged for clinic staff to pick up their orders. Clinic personnel (RN, LVN, MA, and other ancillary personnel) pick-up the order and transport it back to the clinics. They then are responsible for reconciling orders with shipments and monitoring inventory usage and re-ordering supplies as necessary.

II. AUDIT PURPOSE AND SCOPE

The purpose of this review was to ensure that pharmaceuticals transferred to and from select clinics and Pharmacy are appropriately accounted for and managed in the clinic inventory. Processes reviewed included receiving and transport, usage and documentation, wastage and returns of pharmaceuticals.

The scope of the review covered transactions and activities for FY22 at the following locations:

Clinic	FY 22 Pharmaceutical spend as of xx/xx/2022	Average monthly pharmaceutical spend	Pyxis or Non-Pyxis
General Pediatrics at Mount Zion	\$1,242,610.89	\$112,964.63	Non-Pyxis
Pediatrics Endocrinology at Mission Bay	\$2,829,951.06	\$257,268.28	Pyxis
The Migraine Center at Mount Zion	\$1,237,463.06	\$112,496.64	Non-Pyxis
Weill Neuro-Surg MVMT Disorder at Mission Bay	\$1,157,399.64	\$105,218.15	Pyxis

Procedures performed as part of the review included reviewing current process flows related to obtaining pharmaceuticals from the Pharmacy and how inventory is received and managed by the clinic and returned to Pharmacy when necessary. For more detailed steps, please refer to Appendix A.

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 December 2022.

III. SUMMARY

Based on work performed, controls are in place and operating effectively for monitoring purchasing and receiving activity. Regular reconciliation is occurring, and discrepancies are being investigated. Inspections of clinic pharmaceutical areas are being performed regularly by Pharmacy, and items identified are followed-up and resolved. Physical security of medications is controlled, with limited access and logging of access (in Pyxis clinics only).

Opportunities for improvement exist in the areas of separation of duties, medication administration/wastage documentation and charging, transport of medications, and streamlining operational processes.

The specific observations from this review are listed below.

- 1. Separation of duties is not always maintained at non-Pyxis clinics.
- 2. Medication documentation was not always consistent between the encounter notes, the Medication Administration Record (MAR), and the charges.
- 3. Transportation of medications at non-Pyxis clinics introduces risk of medication loss and safety concerns.
- 4. Manual efforts required at non-Pyxis clinics create operational burden and reduce staff availability for patient care.

Additionally, during the course of this review, a potential opportunity for improvement was noted for improving temperature controls for non-refrigerated medications.

IV. OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS (MCAs)

No.	Observation	Risk/Effect	Recommendation	MCA
1	Separation of duties is not always maintained at non-Pyxis clinics. At clinics without Pyxis, separation of duties is not being maintained between ordering, receiving, and dispensing of medications. At the Migraine Center, Medical assistants are responsible for ordering medications, picking up medications from pharmacy, and performing manual counts of medications twice a day in the clinic logbook. They are also able to pull meds from the refrigerator and give them to providers. At the General Pediatrics clinic, there is one individual primarily responsible for ordering, receiving, and managing inventory, with two others functioning as backups; however, the functions may also be performed by the Clinic Manager, depending on the level of staffing and availability of staff.	Insufficient separation of duties may result in diversion going undetected.	Pyxis implementation is evaluated on a cost and risk basis; clinics should consult with Pharmacy to determine if the medications in use at their locations would qualify. If not, clinics should evaluate leveraging administrative staff or implementing compensating controls in consultation with Pharmacy.	The non-Pyxis clinics will consult with Pharmacy as to whether they meet the criteria for implementing Pyxis; if not, what leading practices can be put in place to mitigate risks. Responsible Party: Clinic Director Target Completion Date: 7/1/2023
2	Medication documentation was not always consistent between the encounter notes, the Medication Administration Record (MAR), and the charges.While substantial monitoring is performed for the purchasing of drugs, and dashboards, reports, and other tools have been implemented to assist clinics in this monitoring, the final portion of inventory management relating to administering and charging for drugs does not have the same visibility associated with it. Review of 10 medications from each of the four clinics identified the following discrepancies between drug administration/wastage documentation and charges:Migraine Center	Revenue opportunities may be missed, and patient safety compromised if not all medications administered are documented centrally. Insufficient administration or wastage documentation may lead to diversion	Clinics should emphasize the need for consistent medication documentation and perform regular checks to ensure medication is being documented accurately.	General Pediatrics has previously identified issues relating to ordering that can affect MAR documentation and will investigate reporting options to compare orders to MAR to determine if additional issues

<u>No.</u>	Observation	Risk/Effect	Recommendation	MCA
<u>No.</u>	Observation • 5 cases where medications documented in the encounter notes (but without lot number or expiration date) were not on the MAR and did not have charges (5 lidocaine, 3 bupivicaine, 1 marcaine) Weill Neuro-Surg MVMT Disorder • 1 case where waste in the encounter notes does not match MAR and charges (onabotulinum toxin A) Pediatrics Endocrinology • 2 cases where lidocaine injection was in the notes, but lidocaine cream was documented in the MAR and charged • 1 case where lidocaine cream was on MAR and charges, but was not in the notes General Pediatrics • 4 cases where the quantity in notes and MAR do not match the quantity charged (2 albuterol, 2 dexAMETHasone) • 1 case where the strength in notes is 80mcg for albuterol; however, the MAR and charges have 90 mcg strength • 7 cases where medication is not documented in the notes (2 ibuprofen, 1 medroxyPROGESTERone, 1 albuterol, 1cefTRIAXone, 1 lidocaine, 1 acetaminophen, 1 influenza vaccine)	Risk/Effect going undetected, as the ability to reconcile usage with purchasing is inhibited.	Recommendation	MCA need to be addressed. Responsible Party: Clinic Director Target Completion Date: 7/1/2023 Clinics will reiterate the requirements for consistent medication documentation and periodically review to ensure medication is documented appropriately, providing feedback when issues are identified. Responsible Party: Clinic Director Target
3	Transportation of medications for at non-Pyxis clinics introduces risk of medication loss and safety concerns.	Insufficient chain of custody reduces accountability if	The General Pediatrics clinic is assessing use of existing	Completion Date: 7/1/2023 Clinics will assess options for implementing dual custody or escorts

<u>No.</u>	<u>Observation</u>	Risk/Effect	Recommendation	MCA
	At non-Pyxis clinics, clinic staff are responsible for picking up medications from	drugs are missing or	transportable	for medication
	Pharmacy. Limited staffing does not allow for the pickups to occur in dual	damaged.	coolers to maintain	transportation.
	custody, and there is no chain of custody maintained between the Pharmacy		temperature of the	
	and clinics, resulting in a lack of accountability for missing or damaged drugs.	Absence of	vaccines during	Responsible
	Additionally, some of the drugs transported by clinic staff have significant street	adequate measures	transport.	Party: Clinic
	value, and the lack of dual custody/escort may compromise the physical security of the clinic staff while transporting these drugs.	to ensure physical safety may increase	For transport,	Director Target
	security of the child stall while transporting these drugs.	the risk that	clinics should	Completion Date:
	Several of the drugs being picked up by clinic staff from Pharmacy require	employees carrying	evaluate dual	12/01/23
	refrigeration; however, they are in non-refrigerated bags for transport, which	drugs may be	custody or security	12/01/20
	may compromise the drugs stability if any delays or extreme weather conditions	physically harmed	escort when	
	occur during transport.	by individuals	warranted.	
		seeking to obtain		
		those drugs.		
		Insufficient		
		temperature controls		
		may result in		
		damaged or ineffective drugs.		
4	Manual efforts required at non-Pyxis clinics create operational burden and	Manual, labor	Clinics should	The non-Pyxis
-	reduce staff availability for patient care.	intensive activities	consult with	clinics will consult
	reduce stan availability for patient care.	reduce time	Pharmacy to	with Pharmacy as
	Non-Pyxis clinics do not have official par usage processes for all medications,	available for staff to	identify leading	to whether they
	so additional efforts are required. The General Pediatrics clinic has par levels	conduct patient care.	practices that can	meet the criteria
	set for vaccines but uses an informal visual inventory assessment twice a week		be implemented at	for implementing
	for other drugs. The Migraine Center does not have formal par levels set, but		their locations and	Pyxis; if not, what
	manually tracks inventory levels twice daily, and uses the patient schedules to		determine if	leading practices
	determine ordering needs on a weekly basis.		implementing Pyxis	can be put in place
			would be feasible.	to more efficiently
	Expirations are also checked manually at the non-Pyxis clinics. The General			mitigate risks.
	Pediatrics clinic has a paper printout of medications and expiration dates that is			Deeneneleis
	updated and reviewed monthly, while the Migraine Center does a check every			Responsible
	two weeks on the Code Carts/E-kits (other medications are used with sufficient frequency that expiration dates have not been a problem)			Party: Clinic Director
	frequency that expiration dates have not been a problem).	l		Director

<u>No.</u>	Observation	Risk/Effect	Recommendation	MCA
	Inventory reconciliations are also being performed manually; however, there are			Target Completion Date:
	challenges with out of stock or alternative drugs, and investigation is often required to validate completeness and accuracy of items ordered and received.			7/1/2023

V. <u>OPPORTUNITIES FOR IMPROVEMENTS</u>

<u>No.</u>	Observation	Risk/Effect	Recommendation
6	Improving temperature control can reduce the risk of damage to medications and burden on staff.	Medications staying at a temperature outside their	Clinics should assess their ability to regulate temperature for
	At the Migraine Center, the air conditioning was turned off during the weekends due to noise concerns. In a period of excessive heat, the non-refrigerated medications ended being stored at a temperature outside the appropriate range. This required the Clinic Manager to return to the Migraine Center during the weekend, pack up the relevant medications, transport them to the Pharmacy, and retrieve them at the beginning of the work week when the air conditioning was back on and the storage room had returned to an appropriate temperature.	tolerance could cause damage to the medications and lessen their usability. Additionally, this may result in	medications and consider instituting additional safeguards when unusual weather events are predicted to occur.
	While the temperature monitoring control functioned as designed to alert the Clinic Manager to the issue, the time needed to travel to the Migraine Center and pack and transport the medications created the risk of the medications being at an inappropriate temperature beyond their tolerance, as well as being an additional operational burden on staff and potentially creating a delay in the schedule when the medications were returned.	additional cost if the medications are unusable and would need to be replaced.	
	This risk of temperature excursions applies to the Pediatric Primary and Acute Care Clinics as well, as the air conditioning is regularly turned off on weekends and the designated medication rooms do not have independent temperature control.		

<u>APPENDIX A</u>

To conduct our review the following procedures were performed for the areas in scope:

- Obtained and reviewed relevant policies and procedures related to obtaining pharmaceuticals from the Pharmacy and how inventory is received and managed by the clinic and returned to Pharmacy if and when necessary
- Interviewed key clinic personnel and performed walkthroughs to gain and understanding of the tracking of pharmaceuticals and assess the accurate accounting of drugs
- Reviewed criteria used to determine if inventory management is consistent and ensure documentation in patient accounts is appropriate
- Validated that dispensed drugs were documented appropriately in patient accounts.