

**UNIVERSITY OF CALIFORNIA, DAVIS
AUDIT AND MANAGEMENT ADVISORY SERVICES**

**UC Davis Health System
Department of Pharmacy
Wasting of Controlled Substances
Project #16-38**

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MANAGEMENT SUMMARY

Background

UC Davis Medical Center units and hospital-based clinics withdrew controlled substances for administration to patients approximately 1.2 million times in fiscal year (FY) 2015. These medications are stored, tracked and dispensed using an automated medication dispensing system, Pyxis. The medication is packaged in standard sized containers and in an estimated 25% of dispenses, some medication remains once the amount ordered has been given to the patient and is considered “waste”. Almost all controlled substances waste is liquid. This waste must be tracked and appropriately disposed of to reduce the risk of diversion and comply with all applicable policies, laws and regulations from multiple federal, state and local agencies.

Current UC Davis Health System (UCDHS) policy calls for controlled substances to be disposed of down the sink in the presence of a witness. UCDHS has a waiver from the local sewer district to allow controlled substances to be discarded into the sewer.

Purpose and Scope

As part of planned audits for FY 2016, Audit & Management Advisory Services (AMAS) conducted a review of the wasting of controlled substances at UCDHS. The purpose of the audit was to assess compliance with policy and internal controls over the disposal of wasted controlled substances. To focus the audit on areas of UCDHS where the most controlled substances are utilized and resultantly wasted, the scope of the audit was narrowed to the Medical Center and hospital based clinics. In conducting our audit we surveyed a sample of nurses; reviewed management and operational reports; assessed applicable policies, laws and regulations; and interviewed key personnel from the Department of Pharmacy, high-use Medical Center units and hospital-based clinics, and Environmental Health & Safety (EH&S).

Conclusions

The original focus of the audit was to assess compliance with current policy governing controlled substances wasting. In conducting our research of relevant policies, laws and regulations, however, we determined that the current policy may not comply with all applicable laws and regulations, including the Medical Waste Management Act of California (MWMA) and a new proposal from the Environmental Protection Agency (EPA). The MMWA requires destruction via incineration or treatment using an approved technology; while the EPA proposal bans disposal of any hazardous waste in the sewer system and instead requires destruction through incineration.

Our survey disclosed that while UCDHS nursing staff work diligently to safely dispose of controlled substances waste, fewer than 50% of the survey respondents comply with the current policy of wasting to the sink. Survey respondents are mindful of the necessity of disposing of the waste as soon as possible and in the presence of a witness. Nevertheless, many reported wasting to the pharmaceutical waste containers and sharps containers, due in large part to structural impediments to quickly accessing a sink with a witness in order to be able to waste in accordance with policy.

UCDHS will need to reevaluate its policy for wasting of controlled substances in order to ensure compliance with applicable laws and regulations, and minimize barriers to compliance by UCDHS personnel.

Additional information is contained in the body of this report.

I. OBSERVATIONS, RECOMMENDATIONS, AND MANAGEMENT CORRECTIVE ACTIONS

A. Compliance with State and Federal Regulations

Current UCDHS policy on disposal of controlled substances waste may not comply with all state and federal regulations.

UCDHS policies regarding controlled substances, including wasting of controlled substances, are designed to ensure compliance with all applicable laws and regulations. While federal Drug Enforcement Agency (DEA) regulations primarily govern controlled substances, guidance issued by DEA in January 2014 clarify that DEA regulations do not cover controlled substances waste, as it is no longer considered part of controlled substances inventory. Other state and local regulations still apply. Thus, UCDHS designed its policy for wasting of controlled substances to require wasting occur down the sink or in the toilet (in the presence of a witness), consistent with a waiver from the local sewer district permitting such a practice.

Since the current policy was developed and implemented, UCDHS EH&S has determined that the MWMA, which addresses the disposal of pharmaceutical waste, is applicable to the disposal of controlled substances waste. MWMA defines pharmaceutical waste as “A prescription or over-the-counter human or veterinary drug”. MWMA regulations provide an exemption for pharmaceuticals regulated by the DEA. However, as previously noted, the DEA has stated it does not regulate controlled substances waste. Under MWMA, pharmaceutical waste must be incinerated or treated with an approved alternative technology. Additionally, the proposed EPA regulation specifically bans putting any sort of hazardous waste into the sewer system, requiring incineration of such waste. A small number of controlled substances are considered hazardous waste.

To comply with all applicable laws and regulations, it will be necessary to discard controlled substances waste into a pharmaceutical waste or hazardous waste container and incinerate it. UCDHS currently has its pharmaceutical waste (other than controlled substances) picked up and incinerated by Stericycle. This change in disposal methods will require new practices that may conflict with Stericycle's processes for two reasons. First, the local Stericycle office states that under their Waste Acceptance Policy they will not knowingly collect controlled substances. Second, Department of Transportation (DOT) rules apply to pharmaceutical waste containers being transported to an incinerator. DOT requires no free liquids be transported. Stericycle indicates they cannot include absorbent pads in pharmaceutical waste containers, because the pads interfere with the washing process of the new recyclable containers.

Among the five UC Medical Centers, only UC Davis and UC San Diego dispose of controlled substances waste down the sink. UC San Francisco, UC Los Angeles and UC Irvine have policies requiring disposal of controlled substances waste into the pharmaceutical waste or hazardous waste containers. Stericycle is the pharmaceutical waste collection vendor for all the UC Medical Centers. The Stericycle contract is managed by the UC Office of the President (UCOP), so its terms should be consistent across the state.

Non-compliance with laws and regulations related to disposal of controlled substances waste could lead to fines and penalties, as well as the possibility of negative publicity for UCDHS and UC Davis as a whole.

Recommendations

Ensure that UCDHS policy and practices for controlled substances waste disposal complies with all applicable federal and state regulations.

Management Corrective Action

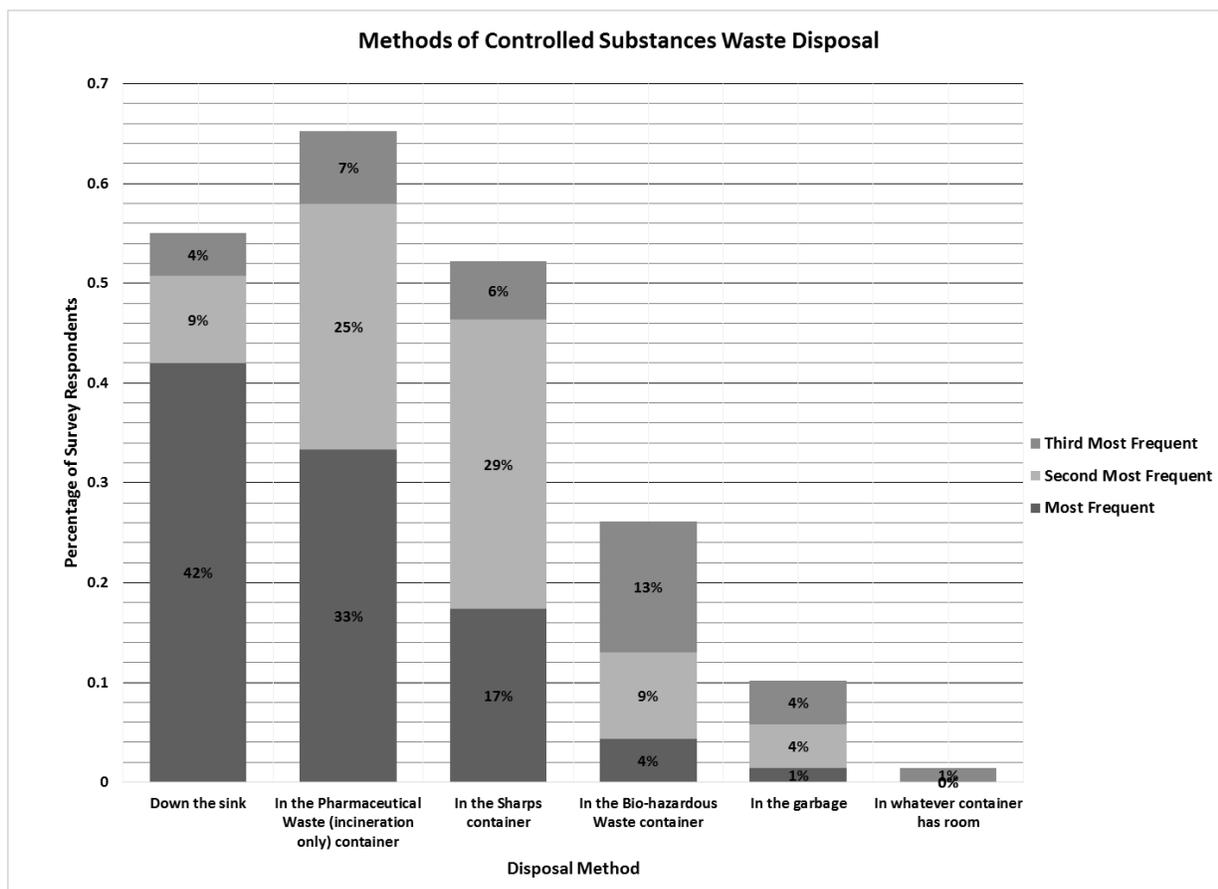
- a. The Departments of Pharmacy and EH&S will work with the University of California Office of the General Counsel to craft a draft UCDHS policy on disposal of controlled substances that complies with applicable laws and regulations by 12/15/2016.
- b. The Departments of Pharmacy and EH&S will consult as necessary within UCDHS and UCOP to clarify the terms of the Stericycle contract and ensure that it complies with applicable laws and regulations by 07/15/2016.

B. Staff Compliance with Policy

Staff compliance with policy on disposing of controlled substances waste could be improved.

UCDHS Policy 1630, “Pharmaceutical Waste Management”, currently calls for controlled substances waste to be disposed of down the sink in non-Pharmacy areas. To assess compliance with the policy, AMAS conducted an anonymous survey of nursing staff across units in the Medical Center and the hospital-based clinics. The survey found less than 50% compliance with the policy.

The survey asked respondents to rank methods for the disposal of controlled substances waste by how often they use that method. The survey results show that 42% of the respondents most frequently discard controlled substances waste down the sink. Placing the waste in the pharmaceutical waste container was the most frequent method used by 33% of respondents, and another 17% reported most frequently disposing of controlled substances waste in the sharps container. The chart below combines the top three choices for controlled substances wasting of survey respondents (not weighted for frequency of wasting). More detailed survey results are contained in the attached Appendix.



Some causes for non-compliance with the current policy are common to all units, mostly centering on the physical layout of treatment areas and the demands of patient care. Pyxis machines are usually in or near the nurses' station, with the pharmaceutical waste containers in close proximity. The common reasons given for discarding controlled substances waste in these containers rather than down the sink are:

- Sinks are distant from the Pyxis machines.
- No witness is available at the sink location, while witnesses are generally available in the nurses' station.
- The need to stay near a patient precludes going to the sink.

Certain units also have unique circumstances that hamper efforts to discard down the sink:

- There are no sinks in the operating rooms (ORs);
- Sinks in the Emergency Department (ED) and the Post Anesthesia Care Unit (PACU) can be especially distant from the Pyxis machines, creating even greater challenges in wasting to a sink.
- Patients in the Burn Unit are in isolation and staff must be gowned. Wasting to a sink would require the nurse to leave isolation, dispose of the waste and then re-gown to enter the patient's room.

Finally, some staff reported concerns about the potential effect on the water system of wasting down the sink, and in certain instances, that impacted their level of compliance with the current policy.

The survey results show controlled substances waste is being discarded in a variety of ways. Although disposing of the waste down the sink is the least expensive method, compliance with that policy is inconsistent. Because current required practices do not work well throughout the UCDHS patient care environment, internal controls over controlled substances are weakened. This can lead to an increase in medication diversion and penalties associated with improper disposal over these medications.

Recommendations

Ensure that the UCDHS policy and practices for wasting of controlled substances address structural barriers that are currently inhibiting compliance.

Management Corrective Action

- a. By 12/15/2016, dependent on the outcome of the conversation with University of California Office of the President, the Department of Pharmacy will make a plan to implement the revised policy with attention to minimizing the impact on staff.

C. Wasting of Controlled Substances in Pyxis

Processes for recording and monitoring wasting of controlled substances in Pyxis are not effective in controlling the risk of undocumented waste and diversion.

1. Recording Waste in Pyxis

When a medication is withdrawn from the Pyxis machine, Pyxis compares the physician's order transmitted from the Electronic Medical Record (EMR) with the amount withdrawn and calculates the expected waste. The nurse chooses between recording the waste immediately or waiting and recording it later.

If the nurse decides to waste immediately, he or she must leave the Pyxis drawer open while the drug is administered, a witness located, and the remainder wasted, witnessed and documented. Pyxis drawers typically contain multiple units of controlled substances, so during the time the drawer remains open the risk of diversion is increased if the nurse must leave the area.

Choosing to waste later allows the nurse to close the Pyxis machine and depart the area to attend to the patient, but also leaves the nurse with controlled substances in their possession and increases the risk that the waste will not be recorded. Undocumented Waste Alerts were added in a recent Pyxis upgrade, which alert the nurse to the need to document the waste at the end of their shift. However, due to the perceived occurrence of inaccurate Undocumented Waste Alerts within Pyxis (Pyxis may overestimate the amount of waste in the case of titrated doses¹), patient care staff realize that not all alerts represent unaccounted for waste and may disregard or discount the alerts, substantially reducing their effectiveness. Additionally, in some locations, particularly the ED, the patient may have already been discharged, necessitating reestablishing the patient profile in Pyxis in order to record the waste later in the nurse's shift.

Recommendations

The Department of Pharmacy should work with Pyxis to address Pyxis related issues that inhibit the timely and accurate recording of controlled substances waste in the Pyxis machines.

Management Corrective Action

- a. On 1/28/2016, the Department of Pharmacy submitted a request to Pyxis for an enhancement which would allow staff to close the drawer during medication administration and disposal when choosing to waste immediately.
- b. By 12/15/2016, the Department of Pharmacy will implement a Pyxis upgrade which includes an easier process to review and resolve undocumented wastes resulting from titrated dosing.

¹ Titrated dosing refers to administering a small amount of medication every few minutes as needed by the patient.

2. Reporting from Pyxis

Transaction information from Pyxis is reported using RxAuditor. These reports could be helpful in identifying potential issues with controlled substances wasting where they are more widely used. RxAuditor reports are distributed to Medical Center units and hospital-based clinics in the form of very large monthly .pdf files. To use them effectively, patient care staff need more training on the abbreviations and notations used in the reports and what information is available. Our survey results indicated that of the staff receiving the reports, forty percent had no training on how to read the data, instead learning “on the job”. Staff also commented that the reports are difficult to interpret and not useful. AMAS’s review of the reports also indicated some of the data seems incorrect (e.g., listing more medication wasted than dispensed).

Reports that are seen as difficult to read or unreliable are much less likely to be reviewed. When transaction information is not thoroughly reviewed, UCDHS misses an opportunity to detect diversion, incorrect billing or other types of errors in medication administration and wasting.

Recommendations

The Department of Pharmacy should develop monitoring reports highlighting exceptions and problems in an easily used format, to be distributed to the Nurse Managers monthly for their review.

Management Corrective Action

- a. By 10/15/2016, the Department of Pharmacy will identify the modifications needed and submit a request to Pyxis, EPIC and RxAuditor for improved reports to monitor controlled substances use and waste.
- b. The Department of Pharmacy will discuss the identified modifications and the proposed reports with the Medication Diversion Oversight Committee 10/15/2016.
- c. The Department of Pharmacy will incorporate the Committee’s feedback and present the proposed reports to the Patient Care Services Council for additional feedback by 12/15/2016.

APPENDIX A Significant Results From Nursing Staff Survey

A total of 247 surveys were sent out and 71 responses received, a response rate of 29%. The tables below show the results for the most significant survey questions. The question is shown below the table number, and then a grid showing the number and percentage of respondents that selected each choice. Comments from respondents who selected "Other" are shown as footnotes to the corresponding table.

TABLE 1

| Q: Please rank your methods for disposing of liquid controlled substances waste by frequency. | | | | | | | | | | | | | | | | |
|--|--------------|-----|---------------|-----|--------------|-----|---------------|----|--------------|----|--------------|----|----------------|----|--------------|-----|
| Method | First | | Second | | Third | | Fourth | | Fifth | | Sixth | | Seventh | | Total | |
| Down the sink | 29 | 42% | 6 | 9% | 3 | 4% | 5 | 7% | 4 | 6% | 1 | 1% | 1 | 1% | 49 | 71% |
| In the Pharmaceutical Waste container | 23 | 33% | 17 | 25% | 5 | 7% | 1 | 1% | 0 | 0% | 1 | 1% | 0 | 0% | 47 | 68% |
| In the Sharps container | 12 | 17% | 20 | 29% | 4 | 6% | 2 | 3% | 0 | 0% | 0 | 0% | 0 | 0% | 38 | 55% |
| In the Bio-hazardous Waste container | 3 | 4% | 6 | 9% | 9 | 13% | 3 | 4% | 2 | 3% | 0 | 0% | 0 | 0% | 23 | 33% |
| In whatever container has room | 0 | 0% | 0 | 0% | 1 | 1% | 4 | 6% | 5 | 7% | 4 | 6% | 0 | 0% | 14 | 20% |
| In the garbage | 1 | 1% | 3 | 4% | 3 | 4% | 2 | 3% | 5 | 7% | 5 | 7% | 0 | 0% | 19 | 28% |
| Other ² | 0 | 0% | 0 | 0% | 0 | 0% | 0 | 0% | 0 | 0% | 0 | 0% | 4 | 6% | 4 | 6% |

TABLE 2

| Q: How did you learn this method for disposal of controlled substances waste? | Count | Percent |
|--|--------------|----------------|
| Trained by supervisor | 11 | 18% |
| Trained by Pharmacy staff | 4 | 7% |
| Trained by another department | 1 | 2% |
| Learned on the job | 30 | 49% |
| Don't remember | 12 | 20% |
| Other ³ | 3 | 5% |

² *While I know I am supposed to waste controlled substances down the sink due to the liability of a controlled medication, I feel conflicted due to environmental reasons. Also, we do not have readily available pharmaceutical waste containers in ICU rooms.

*I do not personally dispose of controlled substances in the garbage, but I have seen others do it.

*Pharmaceutical waste container is not located conveniently for wasting meds.

³ *Other facilities where I have worked.

*Memos.

APPENDIX A (continued)

TABLE 3

| Q: When do you most commonly dispose of controlled substances waste? | Count | Percent |
|---|--------------|----------------|
| As soon as I have time | 5 | 8% |
| Immediately after administering the dose | 26 | 43% |
| When the patient no longer needs the medication | 8 | 13% |
| As soon as I can find a witness | 18 | 30% |
| At the end of my shift | 0 | 0% |
| Other ⁴ | 4 | 7% |

TABLE 4

| Q: Do you have another staff member watch while you dispose of controlled substances waste? | Count | Percent |
|--|--------------|----------------|
| When someone is available | 3 | 5% |
| Always | 44 | 72% |
| Sometimes | 5 | 8% |
| Another staff members signs the record as witness, but may not watch the actual disposal | 7 | 12% |
| Other ⁵ | 2 | 3% |

*Preceptor taught me.

⁴ *Depends on the situation with my patient.

*When I am wasting the med.

*At the end of the procedure.

*As soon as I pull from Pyxis with a witness.

⁵ *Sometimes person who signs leaves before witnessing. Seems to be happening less often.

*Family in the home is instructed on how to dispose of substances.

*Most of the time.

APPENDIX A (continued)

TABLE 5

| Q: When do you most commonly report the amount of controlled substances that is wasted? | Count | Percent |
|--|--------------|----------------|
| Report waste at the time of withdrawal | 40 | 67% |
| Report waste later, when I have time | 10 | 17% |
| Report waste when I receive an Undocumented Waste alert | 0 | 0% |
| Report waste when reminded by supervisor or other staff member | 0 | 0% |
| Other ⁶ | 10 | 17% |

TABLE 6

| Q: What problems do you have when disposing of controlled substances waste? (Choose all that apply) | Count | Percent |
|--|--------------|----------------|
| Lack of time to go through disposal process | 12 | 22% |
| No other staff available to witness disposal of controlled substances waste | 42 | 78% |
| Pyxis machine/inventory log too far away from sink or disposal container | 10 | 19% |
| No sink or disposal container | 8 | 15% |
| Disposal container full | 13 | 24% |
| Other ⁷ | 8 | 15% |

⁶ Waste w/ co-worker at the end of case.

*Later, once I have determined how much I have left to waste.

*After administration- report unused.

*Report waste when I am wasting the med.

*At time of withdrawal if it is a one-time only dose, at the end of the procedure if it is procedural medication

*Only reported if patient in facility.

*Report waste when I waste the med at Pyxis.

*When med no longer needed.

*After completing wound care- we often take out the maximum range of controlled substances at the beginning of wound care and if there is some left at the end of the procedure, I will waste with another nurse at that time.

*Report waste later after the patient no longer needs the medication.

⁷ *None.

*Having to leave Pyxis drawer open while witness wastes which leaves controlled substances exposed and causes obstacle for getting to keyboard.

*Entering amount wasted instead of given.

*Is it safe to dispose via sink though? Does not contaminate the water system?

*We need readily available pharmaceutical waste bins in the ICU.

*Have to go in search of someone so I can waste at time I draw out of Pyxis.

APPENDIX A (continued)

TABLE 7

| Q: Have you been trained on how to read and use Pyxis reports? | Count | Percent |
|---|--------------|----------------|
| We have a Pyxis machine, but I do not get reports | 29 | 54% |
| I get Pyxis reports but I have not been trained on their use | 0 | 0% |
| I was trained on reading Pyxis reports by my supervisor | 7 | 13% |
| I was trained on reading Pyxis reports by another staff member | 6 | 11% |
| I was trained on reading Pyxis reports by Pharmacy staff | 2 | 4% |
| I was trained on reading Pyxis reports by another department | 0 | 0% |
| I learned how to read the Pyxis reports on the job | 10 | 19% |
| Other | 0 | 0% |

TABLE 8

| Q: How do you use Pyxis reports on controlled substances usage? (Choose all that apply) | Count | Percent |
|--|--------------|----------------|
| Review the reports to see if usage is reasonable | 6 | 23% |
| Review the reports to look for problems | 14 | 54% |
| I do not get usage reports | 7 | 27% |
| I get usage reports, but I do not have time to review them | 0 | 0% |
| I get usage reports, but I do not know how to read and use them | 0 | 0% |
| I get usage reports, but I do not find them useful | 1 | 4% |
| Other ⁸ | 4 | 15% |

⁸ *To verify we have wasted all of our drugs administered for the day.

*Review my personal report to make sure my waste matches up with what I gave the patient.

*Reports are difficult to interpret.

*To resolve discrepancies.

APPENDIX A (continued)

TABLE 9

| Q: How do you use Pyxis reports on controlled substances inventory discrepancies? (Choose all that apply) | Count | Percent |
|--|--------------|----------------|
| Review the reports to see if discrepancy rate is reasonable | 6 | 24% |
| Review the reports to look for problems | 9 | 36% |
| Investigate all discrepancies | 14 | 56% |
| I do not get discrepancy reports | 5 | 20% |
| I get discrepancy reports, but I do not have time to review them | 0 | 0% |
| I get discrepancy reports, but I do not know how to read and use them | 0 | 0% |
| I get discrepancy reports, but I do not find them useful | 2 | 8% |
| Other ⁹ | 4 | 16% |

⁹ *To verify last user of the involved medication.

*But charge RN will fix the problem.

*We handle own discrepancies before leaving at end of shift.

*To resolve discrepancies when noted.

*I find discrepancies from more than a few days and those employees are not even here. I then give it to an AN2 (Administrative Nurse II).