



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Controlled Substances Management Issues

VA San Diego Healthcare System San Diego, California



DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, Desert Pacific Healthcare Network (10N22)

SUBJECT: **Final Report** - Healthcare Inspection – Controlled Substances Management Issues, VA San Diego Healthcare System, San Diego, California- Report Number: 01-00637-203

Purpose

The Department of Veteran Affairs (VA) Office of Inspector General's (OIG) Office of Healthcare Inspections (OHI) identified several issues in controlled substances (CS) management at the VA San Diego Healthcare System (the system), San Diego, California.

Background

OHI collaboration in a criminal drug diversion investigation exposed serious problems in CS management at the system's main medical facility. Numerous irregular practices related to CS use over a period of at least 1 year failed to raise suspicions with the charge nurse or supervisor.

The system's Director ordered an Administrative Investigation (AI), which resulted in a recommendation to terminate the responsible registered nurse (RN) for her actions. However, the processes that allowed this RN to successfully divert narcotics needed to be addressed and improved.

Scope and Methodology

We visited the facility and interviewed staff RNs, physicians, pharmacists, the CS Inspections Officer, and supervisory personnel. We reviewed the available medical records, CS control sheets, and relevant policies and procedures. We also reviewed the AI Board report.

We conducted the inspection in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Inspection Results

Issue 1: Oversight of Controlled Substances Usage

We found that nursing oversight should have been more thorough. During the 6-month period reviewed (June – November 2000), a RN committed 92 CS infractions involving 9 different narcotic pain medications in more than 400 doses. The infractions included:

- Signing out CS without physicians' orders for them.
- Signing out larger amounts of CS than the physicians ordered.
- Signing out CS with greater frequency than the physicians ordered.
- Signing out CS from other units than her assigned unit.
- Signing out CS for patients she was not assigned to.
- Making several irregular entries on the CS control sheets and medication administration record (MAR).
- Wasting CS doses without a witness' countersignature.
- Signing out extremely large amounts of CS to critically ill patients. If these patients had received all the doses, they would have experienced serious breathing and circulatory problems as a result of the drugs' actions.

All Veterans Health Administration facilities are required to have internal CS inspection processes.¹ We found that the system's inspectors performed their roles adequately according to local policy. CS inspectors check a small sample of doses on the CS control sheets to see that physicians' orders exist. The monthly inspection random selection included one of the patients assigned to the RN during the period we reviewed. However, the specific date analyzed by the inspector was 9 days after numerous discrepancies occurred. A proper physician's order was in place, and other RNs had made appropriate entries for the date the CS inspector reviewed. The inspector did not note any discrepancies.

The RN accounted for all the drugs on the CS control sheets, and no discrepancies were noted at the change-of-shift CS count, the routine pharmacist review, or the monthly CS inspections. The system policy 119-01 required that nursing supervisors perform and document random checks of entries on the CS control sheets for clarity and completeness and compare them with patients' medication administration histories. We found no evidence that these checks were performed. The Associate Chief of Staff for Nursing (ACOS/N) agreed that nursing oversight was lacking and told us that she had removed the Nursing Supervisor from her supervisory role and reassigned her.

The AI board members recommended that pharmacy, nursing, and patient care services should establish a process for checking completed CS sheets for accuracy and completeness. We agreed with this step, and we recommended adding regular reviews of

¹ Department of Veterans Affairs Handbook 1108.2, Inspection of Controlled Substances, July 23, 1997.

the physicians' orders and MAR. The ACOS/N agreed and stated that she and the Chief, Pharmacy had collaborated to improve the review process, which resulted in increasing the number of trained reviewers and assigning the Clinical Services Directors (CSDs) to perform routine reviews on all nursing units.

Issue 2: Policy Issues

In each situation described below, we found that local policies existed but were not enforced. The ACOS/N stated that she reinforced the policies with all staff nurses in a mandatory meeting on February 12, 2003.

Shift Change CS Count - The policy required that an RN from the off-going and oncoming shifts count CS together at each change-of-shift. Night shift staff RNs told us that a member of the night shift generally performed the CS count alone before the end of the shift. Some time after the day shift began, a member of the day shift verified the count. This practice violated local policy.² The ACOS/N agreed and stated that the shift change count was eliminated in 2003 with the purchase and deployment of Pyxis medication dispensing machines on all nursing units. She stated that the new procedure requires CSDs to perform a weekly review of Pyxis use reports and reconcile any discrepancies.

Key Control - During the review period, the keys fit the drawer locks in all three medication carts in the ICU area. This was corrected in 2001 by changing the locks and issuing single keys unique to one cart only. However, staff RNs told us that they freely shared the keys among RNs on duty, thus violating the policy limiting access to the drawer. Use of Pyxis machines, which do not use keys, in all areas where controlled substances are used, eliminated the key issue.

Borrowing and Wasting Doses - The policy allowed for borrowing only one dose of a narcotic drug if the cart had none of the drug in stock. However, the RN borrowed several doses and even a box full of morphine ampoules from another cart. We found 12 notations by the RN on CS control sheets from carts on other areas of the unit than her assigned area. Furthermore, in 7 of the 12 cases, adequate CS doses were available in the cart on the unit she was assigned to at the time she took doses from other carts.

While the policy defined the process for witnessing and countersigning the wasting of a partial or whole CS dose, the RN did not follow the defined process. CS sheets show two occasions where she made entries about wasting a dose, but no second RN witnessed or countersigned the entries. The ACOS/N told us that dose borrowing and wasting are two of the items the CSDs watch for in their weekly Pyxis reviews.

Ordering CS - The policy required that the charge nurse determine the amount of CS needed and place the order. At no time was the RN designated as the charge nurse on the

² VA SDHS Memorandum 119-01, Controlled Substances Records and Procedures, August 14, 2002.

nurse unit; however, the RN had ordered CS. The ACOS/N stated that she expected improved coordination with pharmacy to prevent inappropriate CS ordering.

Issue 3: Practice Issues

We found that the following situations were poor practices that needed improvement. We did not find local policies that addressed these situations.

Break Coverage – Night shift staff RNs reported that they frequently observed the RN entering the rooms of patients while the assigned RN was on break. Some of the RNs told us that they had specifically instructed the RN not to give any CS medication to their patient(s) while they were on break, only to return to find that the RN had signed out CS doses to those patients. Review of the CS sheets validated that the RN signed out CS for 15 patients she was not assigned to during the review period. She was not confronted or counseled for these actions. The ACOS/N stated that she addressed the issue with all staff nurses on February 12, 2003.

Infusion Bags - The practices involved in using CS drugs that are prepared for intravenous infusion needed improvement. Several staff RNs told us that accountability for the CS infusion bags was weak, and our review of medical records validated the vulnerability. Staff RNs often have to waste partial infusion bags because the patient does not need the entire amount, and policy required that bags be destroyed after 24 hours. The ACOS/N stated that accountability has improved because infusion bags are now bar coded. She told us that a task force consisting of representatives from infection control, nursing, and pharmacy reviewed applicable guidelines and concluded that the policy regarding destroying infusion bags after 24 hours should continue.

Issue 4: RN Responsibilities

It was apparent that many observations made by the night shift staff RNs over a period of several months were not brought to the attention of anyone in a position of authority. As a result, suspicious practices were allowed to continue. Staff RNs told us that they were suspicious of the RN and “would not let her relieve me for break.” The shift RNs who were designated as charge nurses told us that they had made the observations mentioned above, but they did not take any action. Fortunately, it does not appear that any patients suffered by the RN’s actions.

The supervisor told us that the night shift RNs rarely brought issues to her attention and had always preferred to solve their own problems. Neither the supervisor nor the clinical specialist spent significant time on the night shift. The ACOS/N agreed and stated that, on February 12, 2003, she reinforced with all staff nurses their responsibility to report improper or suspicious actions. In addition, she initiated a requirement that the ICU clinical specialist and CSD routinely overlap with the night shift on a regular basis. The

ACOS/N has completed one round of meetings on the night shift on all units and plans to do so on a rotating basis.

Conclusions

We concluded that nursing supervision in the ICU during the review period should have been more thorough, existing policies needed to be enforced, and the break coverage and infusion bag practices needed improvement. The ACOS/N agreed with the findings and has taken steps to address all of the issues. We recommend periodic reinforcement and continuous monitoring of CS management practices to ensure ongoing control.

Recommendations

The VISN Director needs to ensure that the system Director:

- a. Assures that nursing and pharmacy managers continuously collaborate to provide oversight of CS accountability and documentation.
- b. Monitors the effectiveness of the reviews of: Pyxis reports, physicians' orders, and MAR entries.
- c. Periodically reemphasizes the need for nursing employees to follow all policies related to CS and to report improper or suspicious actions.

VISN Director and System Management Comments

The VISN Director referenced the action plan from the system's ACOS/N (see Appendices A and B for full text). The action plan includes improved oversight of the CS inspection program, the Pyxis reports, and nursing review of CS orders. The changes in wording requested by the ACOS/N were made.



Inspector General's Comments

We find the actions designated in Appendix B, in addition to those already taken and mentioned in the report above, to be acceptable. These actions, which require ongoing vigilance, have the potential to substantially decrease employees' ability to illegally divert CS.

(original signed by:)
JOHN D. DAIGH JR., M.D.
Assistant Inspector General for
Healthcare Inspections

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 13, 2004

From: Network Director, VA Desert Pacific Healthcare Network
(10N/22)

Subject: **Response to Draft Report – Healthcare Inspection –
Controlled Substances Management Issues, VA San Diego
Healthcare System, San Diego, California – Project
Number: 2001-00637-HI-0260**

To: Director, Management Review Service (10B5)

1. The attached provides current status regarding project number 2001-00637-HI-0260, Healthcare Inspection - “Controlled Substances Management Issues” of the VA San Diego Healthcare System.
2. If you have any questions regarding the information, please contact my office at (562) 826-5963.

(original signature by:)
Kenneth J. Clark, FACHE

ACOS/N Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 6, 2004

From: ACOS/Nursing and Patient Care Services (118)

Subject: **Response to Draft Report/Controlled Substance Management Issues, OIG Project #2001-00637-HI-0260**

To: Network Director, VA Desert Pacific Healthcare Network (10N/22)

Thru: Director, VA San Diego Healthcare System

1. In response to your request, I have reviewed the Draft Report prepared by Office of the Inspector General addressing Project #2001-00637-HI-0260.

2. I discussed this report with Special Agent Julie Watrous, Project Manager, on August 5, 2004, and requested the following corrections to the document:

- a. Page 3, Borrowing and Wasting Doses: Change “carts on units other than her assigned unit” to read, “other areas of the unit which she had not been assigned to.”
- b. Page 4, RN Responsibilities: Change “ICU clinical specialist rotate to the night shift on a regular basis” to read, “ICU Clinical Specialist and Clinical Services Director routinely overlap with night tour staff.”
- c. Page 5, Conclusions: The statement “two poor practices need to be replaced with well-designed procedures” does not accurately reflect the issues identified within this report and should state the specific concerns they are referring to which are “break coverage” and “infusions.”

3. The Chief, Pharmacy Service and I are in full concurrence with the recommendations of this report. The action plan for the recommendations made is as follows:

- a. The Pharmacy and Nursing Services have designed an oversight group to review ongoing controlled substance audits, reports, and reviews. This group will consist of, at a minimum, the ACOS, Nursing and Patient Care Services, the Associate Chief, Inpatient Services, Chief, Pharmacy Service, and the Director, Medication Safety/Drug Use Evaluation and Pharmacy Quality Assurance.
- b. The Pharmacy and Nursing oversight group will review Pyxis controlled substance reports, nursing controlled substance order reviews, and other controlled substance data, as necessary, to identify trends and concerns and develop follow-up education and action plans for correction, as appropriate.
- c. The Pharmacy and Nursing oversight group will routinely review the need for staff education with regard to controlled substances and coordinate the provision of such education, as necessary.

4. I believe that the action items enumerated above will meet or exceed the recommendations requested by the Office of the Inspector General.

5. If I can be of further assistance, please contact me at 858-552-8585 extension 2530.

(original signed by Cathy Verbatim, RN, for:)

Janet M. Jones, Ed.D (c), R.N.

OIG Contact and Staff Acknowledgments

OIG Contact	Julie Watrous, Director, Los Angeles Office of Healthcare Inspections (310) 268-3005
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