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June 21, 2013

Honorable Toni Preckwinkle
and the Board of Commissioners of Cook County
118 North Clark Street
Chicago, Illinois 60602

Dr. Ramanathan Raju
and the Board of Directors for the
Cook County Health and Hospitals System
1900 West Polk Street
Chicago, Illinois 60612

Re: IIG12-0065 (DEA Audit - Pharmacies)

Dear President Preckwinkle, Dr. Raju and Members of the Boards:

This letter is written in accordance with Section 2-289(c)(2) of the Independent Inspector General Ordinance, Cook County, Ill., Ordinances, No. 07-0-52 (2007) (OIIG Ordinance), in connection with a U.S. Drug Enforcement Administration (DEA) accountability audit of John H. Stroger Hospital's six pharmacies (the "Pharmacies"). The accountability audit results revealed that the Pharmacies failed to maintain proper inventory records. Additionally, the Pharmacies failed to file accurate, complete, and timely reports related to controlled substances to the DEA pursuant to federal laws and regulations. The following is a summary of the investigation.

Summary

During discussions with John H. Stroger Hospital ("Hospital") personnel, we discovered that the Hospital's receiving dock area lacked adequate security related to hospital supplies and pharmaceuticals, including controlled substances. We subsequently conducted site inspections of the Hospital's receiving dock area and confirmed that security practices and procedures were lax to nonexistent. We subsequently consulted with the DEA regarding our security concerns, and the DEA agreed to conduct an unannounced comprehensive accountability audit of the Pharmacies through its Office of Diversion Control.

As a result of the DEA audit, it was determined that the pharmacy's inventory records were lacking and possibly inaccurate. Consequently, the DEA Audit Team concluded that the Hospital was not in compliance with the DEA's reporting requirements for controlled

substances. In April 2013, the DEA found that the Hospital was not in compliance with federal regulations for certain practices, such as inadequate recordkeeping, failure to conduct regular inventories, and failure to satisfy reporting requirements related to controlled substances.

OIG Review

The receiving dock is the primary point of accepting deliveries of the Hospital's supplies and pharmaceuticals from vendors. In October 2012, we visited the loading dock area on four separate occasions over a period of one month. During our inspections of the receiving dock area, the Hospital's personnel assigned to the docking area allowed us to enter and observe the facility without being questioned regarding our identity or purpose.

During our site inspections, we discovered certain situations that caused us to question the level of security at the docking area. For example, we found vehicles parked for extended periods of time in the loading dock area without vendor identification markings. Even though vendor delivery vehicles were not making deliveries, we noted that the garage door on Polk Street remained opened for the entire time we were present. We observed individuals driving personally owned vehicles into the loading dock area, without challenge, to either pick up or drop off people. We also saw the loading dock supervisor's personally owned vehicle parked in the loading dock area. In addition, the security surveillance camera was not being monitored by the security staff on duty at the time.

After we completed our site inspections, we requested copies of police reports from the Hospital's Police Department related to missing, lost or stolen pharmaceuticals from December 2006 to May 2012. Due to no automation of records, police personnel had to manually review their files to retrieve the requested reports. The reports indicated 85 incidents of missing, lost or stolen pharmaceuticals within this timeframe.

Since the Police Department does not have a method to conduct an automated analysis within its record system, we had to review each report individually. We determined that the vast majority of incidents were not resolved. The police reports further revealed that the quantity of reported missing and/or stolen pharmaceuticals ranged from one unit to several units (*e.g.*, tablets, vials, syringes, etc.). Additionally, the dollar value was seldom reported; therefore, it was impossible to determine dollar loss in the aggregate. The reports also revealed that in certain instances some of the pharmaceuticals reported as missing or stolen were from nursing stations, secured storage cabinets, or refrigerators. As such, the reports revealed no evidence of tampering to suggest forced entry. There were several incidents contained in the police reports that documented prescriptions being lost while in transport from the Pharmacies to the nursing stations. However, there were several documented incidents that concerned the Pyxis dispensing system of pharmaceuticals that were classified as discrepancies. Due to the lack of information

available from the police reports and the nature of the problem, we were unable to make a determination as to whether these Pyxis “discrepancies” were the result of the pharmaceuticals being lost or stolen.

During our analysis, we discovered that there were less than five incidents reported to the police during 2006. In 2009, however, we found the most reported incidents (approximately 28) of missing, lost or stolen pharmaceuticals. We identified two blocks of time (4 months and 5 months) in which no incidents of reported missing, lost or stolen pharmaceuticals were documented. It is unclear why no reports were filed during these two periods of time. Based upon the content of the police reports and our observations, it appears that not all missing, lost or stolen pharmaceuticals are being accurately reported.

We notified the DEA of our findings because the Pharmacies have a legal duty to report certain situations related to controlled substances.¹ Upon review, it was determined that there was a difference between the reports the DEA had on file and the reports on file with the Pharmacies.

The CCHHS Director of Pharmacy confirmed there was no system wide reporting system that collects data as it pertains to controlled substances that are reported missing, lost or stolen. She agreed that a uniform reporting system needs to be implemented so the police department, her office and senior hospital managers have a management tool to take corrective action. It was also revealed that there is a lack of internal controls regarding “wasted narcotics” (expired, contaminated, spoiled or partially destroyed narcotics) which requires attention.

During November 2012, the DEA conducted the audits of the Pharmacies. The DEA audit team encountered difficulty in conducting its audit because the inventory records did not provide an adequate audit trail. Therefore, the audit team was unable to determine whether the Hospital’s Pharmacies were experiencing diversion because there was no clear audit trail from which to make a determination.

Findings and Conclusions

As a result of the OIIG’s site inspection and the DEA’s accountability audit, several deficiencies were identified in the management and control of Pharmaceuticals and controlled substances. Those deficiencies are identified as follows:

¹ See 21 C.F.R. § 1301.76(b) (requiring registrants to notify the DEA Field Division Office of the theft or significant loss of any controlled substances in writing within one business day of discovery of such loss or theft and complete a DEA Form 106 regarding such loss or theft).

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- Inadequate security practices and procedures at the receiving loading dock area.
- Lack of detailed police reports as to the dollar loss value of the reported missing, lost or stolen pharmaceuticals.
- Lack of an automated, system wide reporting program for lost or stolen pharmaceuticals.
- Failure to resolve incidents involving missing, lost or stolen pharmaceuticals.
- Lack of internal controls over pharmaceuticals reported missing from the nursing stations.
- Lack of training for Pharmacy and nursing personnel regarding the DEA reporting requirements.
- Failure to comply with DEA reporting requirements.
- Use of an outdated inventory system (MSDOS).
- Lack of internal controls regarding the disposal of “wasted drugs.”

To the Hospital’s credit, we have learned that certain Hospital personnel have already begun to address problems discovered by the DEA.

OIG Recommendations

The following recommendations are encouraged to address the foregoing deficiencies in the management and control of the Hospital’s Pharmacies. Failure to act on these issues could place the Hospital’s drug registration at risk.

- The Hospital has to comply with the DEA reporting requirements and address the remaining violations cited from the accountability audit.
- The Hospital should implement a training program with annual retraining regarding DEA reporting requirements to all personnel who have access to controlled substances. The training should be documented and maintained in each employee’s personnel file.
- The Hospital should implement a system wide internal reporting protocol regarding missing, lost, and stolen pharmaceuticals. This data should be collected and reported to senior management and police on a quarterly basis for use in conducting investigations, analyzing trends, and taking corrective action.
- The Hospital should implement a system wide internal protocol regarding the proper disposal of “wasted drugs.”

Hon. Toni Preckwinkle and Board of Commissioners

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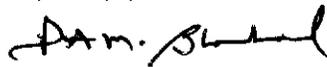
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- CCHHS should improve the security procedures and practices for the receiving and loading dock area and nursing stations. For example, CCHHS should prohibit personnel from parking their personal vehicles in the loading dock area.
- CCHHS police officers should try to determine the dollar loss value of any property and include those figures in their investigative reports. The police should also compile and analyze data relating to missing and stolen pharmaceuticals in order to determine patterns and trends with respect to employees and service areas.
- In order to compile and analyze data, the CCHHS Police Department needs to acquire an automated records system.
- The Pyxis dispensing stations need to be improved in order to reduce the amount of discrepancies reported.
- The Hospital should consider improving its inventory operating system to facilitate accurate and efficient inventory management.
- CCHHS should conduct regular inventory audits and ensure the timely submission of reports to DEA pursuant to federal rules and regulations.

Finally, in accordance with Section 2-285(e) of the OIIG Ordinance, this office respectfully requests notification within 30 days of any action taken in response to the these recommendations. Please do not hesitate to contact me if you have questions or would like to discuss this or any other matter further. Thank you for your consideration of this issue.

Very truly yours,



Patrick M. Blanchard
Independent Inspector General

cc: Mr. G.A. Finch, Chief of Staff, Office of the President
Ms. Laura Lechowicz Felicione, Special Legal Counsel to the President
Ms. Elizabeth Reidy, General Counsel, CCHHS
Ms. Cathy Bodnar, Chief Compliance Officer