Massachusetts General Hospital

DEA Investigation

Massachusetts General Hospital (MGH): Academic Medical Center

- 1000+ bed Acute Care Services
  - Admits 47,000 patients/yearly
  - Delivers 3,600 births/yearly
- Emergency Department
  - Records 100,000 emergency room visits/yearly
- Operating Room Services
  - Performs 38,000 operations/yearly

MGH In Perspective

- Massachusetts General Hospital is the oldest and largest hospital in the Harvard Medical School system.
- Chartered in 1811, the hospital has over 30,000 employees and more than 1,000 inpatient beds.
  - 2,400 Physicians
  - 3,800 Staff Nurses
  - 380 Pharmacy Personnel
  - 450 Anesthesia Providers
**MGH Inpatient Dispenses and Medication Transactions**

- 1.8 million CS dispenses annually (34,840 weekly)
- 240 Omnicell machines
- 8.9 million Omnicell transactions annually (171,000 weekly)
- 2.3 million Omnicell CS transactions annually (43,500 weekly)

**The Back Story**

- Over the course of a year, a nurse stole more than 14,000 oxycodone pills from an automated dispensing machine (ADM) at MGH. She discovered a loop hole in the ADM settings and was able to remove 10-30 pills at a time. Upon discovery, MGH reported the theft to DEA and DPH and terminated the nurse.
- A second, unrelated, nurse was shortly thereafter discovered to have stolen 1,429 oxycodone pills from a different ADM at MGH, again manipulating a loop hole in the ADM settings. Upon discovery, MGH reported the theft to DEA and DPH and terminated the nurse.
- Immediately corrected the loop hole in the ADM settings.
- DPH, DEA, and FDA meeting at MGH.
- DPH investigation and findings.

**The DEA Investigation**

- **DEA Administrative Inspection Warrant**: On October 29, 2013, Nancy Coffey, former DEA Diversion Program Manager of the New England Field Division, and 8 DEA agents served an administrative inspection warrant on MGH pharmacy ("the Warrant") and conducted a physical audit of MGH pharmacies and Omnicell machines. The Warrant sought documents and information going back two years.
- **Document productions**: In response to the warrant and subsequent document requests, MGH produced over 5000 pages of documents and data to the DEA including: Inventories; Omnicell and Pandora data and reports; DEA Form 222's; DEA Form 106's; state reporting forms; invoices; and copies of relevant MGH policies and procedures.
The DEA Investigation

- **Interviews**: The DEA conducted at least 20 interviews of MGH employees in pharmacy, anesthesia and nursing.
- **Omnicell Subpoenas**: DEA served two administrative subpoenas on Omnicell seeking documents and data relevant to this investigation. Specifically, the subpoenas to Omnicell sought summary data going back two years, login reports, and copies of audits Omnicell had performed for MGH.
- **Accountability Audit**: MGH hired an independent consultant to conduct an accountability audit involving 7 controlled substances.

The Settlement

- **Alleged Conduct** included (1) failure to timely report initial nurse thefts, and (2) recordkeeping violations involving initial and biennial inventories, 222 forms, and Omnicell discrepancies.
- **Detailed Statement of Relevant Conduct**
- **$2.3 million**
- **3 Year CAP**

MGH CAP

- **Establish a Drug Diversion Team**
- **Hire a full-time Drug Diversion Compliance Officer**
- **Pandora (Controlled Substance Surveillance Software)**
- **Mandatory annual training of all staff with access to CS**
  - Signs & symptoms of substance abuse/addiction
  - Drug diversion monitoring and prevention
  - Duty to report
  - Compliance documentation for all trainings
MGH CAP

- Enhanced, multi-disciplinary diversion monitoring
  - Daily Pharmacy review of Pandora reports—overrides; greater than 5 reports; destock verifications
  - Weekly Nursing review of the Anomalous User Report
  - Daily Nursing review of unit activity
  - Compliance checks by senior nursing leadership
  - Daily OR Reconciliation—Anesthesia
  - Daily discrepancy triage
  - Trend analysis
  - Trend and Pattern Reports reviewed quarterly by Drug Diversion Team

- Improved Diversion Investigation Process
  - An interdisciplinary response team is activated which includes Nursing, Pharmacy, and Police & Security.
  - Pharmacy and unit leadership conduct an in depth data and record analysis including Omnicell reports, Pandora reports, eMAR and the medical record.
  - Police & Security interview witnesses and suspects, analyze handwriting, facilitate urine and hair drug testing, and analyze med room and parking garage card reader access.
  - Employee’s access to medications is immediately inactivated and employee is placed on investigative leave.

- Recordkeeping
  - Annual Biennial Inventories for all Registrations.
  - MGH shall maintain two years of Omnicell data on its servers.
  - Annual Accountability Audits of all registrations to be performed by an independent auditor (5 drugs randomly chosen by auditors; unannounced visits)
  - Annual certified compliance self-evaluations
• **Physical Security**
  - ADM’s in all OR’s
    - 90 Day Password Reset for all Omnicell Users
    - Implementation of Biometric Fingerprinting
  - Restricted Access to Vault
  - Limited employee access to Omnicell Server