DRUG DIVERSION: ENFORCEMENT TRENDS, INVESTIGATION, & PREVENTION

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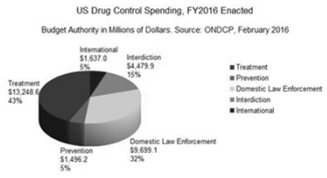
AGENDA

- Definitions, causes, and sources
- Regulations and enforcement trends
- Role of the Compliance Officer
- Investigating and preventing drug diversion
- Case study



The estimated cost of controlled prescription drug diversion and abuse to Federal, State, and private medical insurers is approximately $72.65 billion a year.

National Drug Control Budget: FY 2017 Funding Highlights (Washington, DC: Executive Office of the President, Office of National Drug Control Policy), Februrary 2017, Table 1, p.16, and Table 3, p. 19

IN *"CRAIN'S HEALTHCARE PULSE"* *(SEPTEMBER 2016)*

DEFINITION, CAUSES, AND SOURCES

DEFINITION

Drug diversion is the illegal distribution or abuse of prescription drugs or their use for unintended or illicit purposes

- Often due to addiction or for financial gain
- Proliferation of pain clinics has led to an increase in the illegal distribution of expired or counterfeit medications
- High-value and Schedule II – V Controlled Substances frequently diverted:
  - Opioids
  - Performance enhancing drugs (e.g. erythropoietin, anabolic steroids)
  - Psychotropic drugs
  - Antiretroviral drugs

THE CONTROLLED SUBSTANCES ACT OF 1970

- **Schedule I** - drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.
  - Example: heroin, lysergic acid diethylamide (LSD), ***marijuana (cannabis),*** 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote
- **Schedule II** - drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.
  - Examples: Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin
- **Schedule III** - drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.
  - Example: Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone
- **Schedule IV** - drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.
  - Example: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol
- **Schedule V** - drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.
  - Example: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin

See 21 U.S.C. §802(32)(A) for the definition of a controlled substance analogue and 21 U.S.C. §813 for the schedule

CAUSES AND SOURCES

- Theft of sample medications
- Substituting or changing medications provided to patients
- Re-directing expired medications for use or distribution elsewhere
- Altering or falsifying medical record documentation
- 'Wasting' of medications
- Forged or counterfeit prescriptions
- Diverting large drug quantitates when they are purchased or during delivery and receipt
- From automated storage and dispensing systems* (ASDU or ADU)

DRUG DIVERSION @ HEALTHCARE FACILITIES

- New and complex drug diversion schemes are fueling this epidemic of prescription drug abuse
- Until recently, it was believed that most diverted controlled substances came from doctor shoppers, prescription forgery rings, pharmacy thefts, pill mills, and rogue Internet pharmacies
- Drug diversion has been associated with virtually every category of healthcare worker – from professional clinical staff to EMTs, nurses, to facility staff
  - Theft of drugs by employees with access to bulk pharmacy supplies or computerized medication delivery cabinets
  - Addicted employees stealing controlled substances intended for patients for personal use by substituting non-controlled substances for the ordered medication
- Even if the quantity of drugs that are diverted is relatively small, the hospital's liability is significant

OIG Spotlight on Drug Diversion – https://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp;
DEA Diversion Control Website - https://www.deadiversion.usdoj.gov

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REGULATORY ENFORCEMENT TRENDS

ENFORCEMENT TRENDS

- Drug diversion contributed to a 4-fold increase in substance abuse treatment admission from 1998 to 2008 for individuals ages 12 and over
  - Since 2009 more people in the US have died annually from drug poisoning than from car crashes
- Healthcare providers are one of the leading sources of diverted drugs
  - Variety, types, and quantities of controlled substances purchased
  - Number of personnel involved in purchase, distribution, administration

CMS Medicare Learning Network – "Medicaid Program Integrity – What is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?", ICN 909010 arch 2014
https://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp

ENFORCEMENT TRENDS

- Involvement of criminal networks
  - include patient recruiters
  - money launderers, and
  - street dealers and gangs
- Some of these culprits have violent criminal histories, increasing the challenges and risks to law enforcement agents investigating these cases
- Top law enforcement priority
  - 9% increase in the 2016 DEA budget dedicated to diversion control

REGULATIONS & IMPACT

Legal Framework

- **Controlled Substances Act**

This law regulates the manufacture and distribution of many drugs, including controlled substances

- ***Conditions of Participation***

To qualify for Medicare certification and reimbursement, providers, and suppliers of health services must comply with minimum health and safety standards called "Conditions of Participation" ("CoPs"), including proper securing and distribution of drugs.

- **JCAHO Requirements (or those related to Certifications of ACS, procedural suits, etc.)**

JCAHO standards are the basis of an objective evaluation process that can help health care organizations measure, assess, and improve performance.

- **Pharmacist licensure requirements**

Each state board of pharmacy has a set of requirements that a pharmacist must meet.

Impact

- Civil, criminal, and regulatory liability (FCA, certification status, CoPs)
- Impact on corporate liability rating and insurability (MedMal, D&O, etc.)
- Reputational harm (PR & Media attention)
- Impact on non-for-profit/ charitable status

FCA

- Providing medically unnecessary service
- Billing for
  - Services not rendered
  - Medically worthless
- Violating statutory, regulatory or contractual provision with a nexus to payment

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SHARE

FOR IMMEDIATE RELEASE Monday, September 28, 2015

MGH to Pay $2.3 Million to Resolve Drug Diversion Allegations

BOSTON – In the largest settlement of its kind involving allegations of drug diversion at a hospital, Massachusetts General Hospital (MGH) has agreed to pay the United States $2.3 million to resolve allegations that lax controls enabled MGH employees to divert controlled substances for personal use. In conjunction with this record monetary settlement, MGH has agreed to implement a comprehensive corrective action plan to prevent, identify, and address future diversions.

"Under the law, hospitals like MGH have a special responsibility to ensure that controlled substances are used for patient care and are not diverted for non-medical uses," said U.S. Attorney Carmen M. Ortiz. "Diversion of these drugs feeds addiction, contributes to potential illegal drug sales, and fuels the opioid epidemic that has had a devastating effect on the Commonwealth. We commend MGH for disclosing and addressing its diversion problems and for taking steps to ameliorate future diversion by hospital personnel."

"The DEA is committed to investigating hospitals that are not in compliance with the Controlled Substances Act (CSA)," said Special Agent in Charge Michael J. Ferguson. "Failure to do so increases the potential for diversion and jeopardizes the public health and safety. The diversion of prescription pain killers, in this case oxycodone, contributes to the widespread abuse of opiates, is the gateway to heroin addiction, and is devastating our communities. DEA pledges to work with our law enforcement and

Human Cost

IS IT A BIG DEAL?

About 100 people die from drug overdoses daily, with opioids accounting for 75%

- Reliable statistics on the prevalence of drug diversion by nurses are not available
- By its nature, diversion is a clandestine activity, and methods in place in many institutions leave cases undiscovered or unreported
- Drug diversion by healthcare providers is universal among institutions in the US

If your institution is not finding and reporting drug diversion, review your program with the goal of identifying its weak points

WHY DON'T WE HEAR ABOUT IT MORE?

- Under-reporting
  - to appropriate oversight agencies
  - To licensing authorities
- Fear of negative publicity
- Concern of State and Federal agency involvement
- Uncertainty about reporting requirements
- Justification that terminating the offender is enough

WHAT IS THE CCO'S ROLE?

- Drug diversion prevention, training, and controls must be incorporated in the elements of Compliance Program
- Efforts expanded, findings, and reports should be incorporated into overall Compliance Program dashboards
  - Management level compliance committee
  - Board level compliance committee
- Licensed professionals (PharmD, MD, DO, et al) expected to take an active part in prevention and reporting of diversions, and 'red flags'

INVESTIGATIONS

- Notifying GC if diversion is suspected (privileging investigation, as appropriate)
- Put together an investigation Work Plan / steps
- Conducting staff interviews
- Review of medical records
- Reconciling discrepancies
- Identifying and quantifying the issue (scope)
- Analyzing potential repayment and self-disclosure (FCA) obligations
- Reviewing DEA reporting requirements
- ***Developing and retaining documentation trail***

CORRECTIVE ACTIONS

- Implementing written policies, procedures, and standards
- Reviewing communication flow to ensure transparency
- Initiating internal monitoring and auditing
- Training and education
  - Re-train staff in affected areas

For significant findings:

- Develop and implement organizational communication plan
- Report the event through appropriate Board level committee

- Consider HR policy on mandatory drug testing

INVESTIGATION

- A FEW THOUGHTS

DECISION POINTS

- Who leads investigation –
  - Generally – CCO, with support of GC, HR, Clinical leads
- In-house or outsource; fully or partially
  - Organizational sensitivities
  - Scope of the discovered issue and potential for risk exposure
  - Availability of impartial and confidential in-house clinical review by 'like' licensure
- Expert witness use
  - Retained through attorney-client privilege
  - Available to testify, if needed
  - Have experience testifying as an expert
  - Carefully selected in same specialty, same experience
  - Facilitating expert witness review, and report

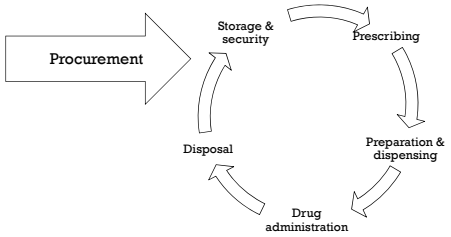
MONITORING - RECONCILIATION

- What should be reconciled:
  - Drug inventory at the start of the day/ shift
  - Drug disbursements
  - Supply on hand at the end of the day/ shift
- Proper and ongoing monitoring detect issues in real time
- Publicizing the processes deters potential offenders

AD HOC AND PERIODIC AUDITING

- Identify vulnerabilities/ prescription spikes/ by provider
- Review sample of medical records/ administration records/ orders
- Review ASDU activity logs
- Reconcile variances
- Discuss findings with appropriate clinical/ administrative staff

PREVENTION ALONG THE CHAIN



INTEGRATING PREVENTION PRACTICES

- Establishing oversight authority with clear reporting lines and ongoing monitoring activities
- Immediate communication of 'red flags' through the proper chain of command
  - Individual MD request for controlled substance (or family members)
- Implementation of e-prescribing (i-Stop in New York)
- Review of personnel involved in procurement, job rotations, and mandatory vacations for purchasing staff & management
- Segregation of duties
- Monitoring for COI / potential collusion

Centers for Medicare & Medicaid Services: "Partners in Integrity: What is the Prescriber's Role in Preventing the Diversion of Prescrtiption Drugs?" January 2014. Available at http://go.cms.gov/1Ljb4uY

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ESTABLISHING RELEVANT CONTROLS

- Daily reconciliation
- Properly securing and reconciling DEA-222 forms (if applicable)
- Orders vs receipts vs stocking
- Reviewing and securing delivery process
  - PharmD sign-off of receipt
  - Controlled and secure delivery to floors (if applicable)
- Access to pharmacy vault
  - Limited (periodic review of access)
  - Secure
  - Monitored
- Ad hoc inventory review

SYSTEM CONTROLS

- Access controls to ASDU
  - Limiting number of staff with access
  - Limiting number of "Super Users"/ "Administrators"
- Ongoing review of ASDU reports
  - By frequency of discrepancies (individual & area)
  - Higher wasting
  - Higher utilization

POLICIES AND PROCEDURES

- Risk assessment and process revisions documented through policies and procedures for
  - Ordering
  - Receiving
  - Stocking
  - Wasting
  - Destruction
  - Reporting
- Staff education
  - On processes
  - Reporting obligations and timelines
  - Proper use of ASDU system
    - Physical access
    - Software

ENGAGING CLINICIANS

- In March of 2016 the Centers for Disease Control and Prevention (CDC), developed the first-ever guidelines for dispensing addictive painkillers
  - The guidelines urge doctors to avoid prescribing opioids for patients with chronic pain, noting that the risks of such drugs outweigh the benefits for some people.
- In light of the new guidelines, some physicians are now
  - Requiring patients to sign "pain management contracts"
  - Agreement to random drug tests before receiving an opioid prescription
  - Some are implementing opioid prescribing guidelines.
- Access to tools ≠ utilization of tools:
  - Screening
  - Pain scale
  - Alternative protocols
- State-specific best practice guidelines

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. 2016;315(15):1624-1645

DEVELOPING ALTERNATIVE TREATMENT PROTOCOLS

- Creating and promulgating awareness of the issue
  - Mayo Clinic study indicates that up to 1 in 5 Pt with opioid Rx are at risk
- Alternative:
  - Nerve blocks,
  - Periarticular injections
  - Neuraxial anesthesia
  - Anti-inflammatory drugs
  - Multi-modal therapies with post-op pain pumps
- Avoiding Rx for minor ailments (toothache, sprained ankle, etc.)
- Ongoing education
  - Clinicians
  - Patients

INTEGRATING PREVENTION PROTOCOLS INTO PRACTICE & ENGAGING NPP

- **Preventing Prescription Drug Misuse:** *Screening, Evaluation, and Prevention*
- **Treating Patients At-Risk for Substance Use Disorders:** *Engage Patients in Safe, Informed, and Patient-Centered Treatment Planning*
- **Managing Substance Use Disorders as a Chronic Disease:** *Eliminate Stigma and Build Awareness of Social Determinants*

August 22, 2016, Massachusetts Executive Office of Health & Human Services, Initiative to expand on Core Competencies to Combat Opioid Epidemic (http://www.mass.gov/eohhs/gov/newsroom/press-releases/eohhs/core-competencies-to-combat-opioid-epidemic-expanded-.html)

- Increase in DEA budget signals increase in enforcement
- Heightened public concerns diversion and impact on communities
- Organizational and individual liability
- Imperative of proactive rather then reactive approach to mitigation

WHY NOW?

Critical Time

FROM THE TRENCHES – CASE STUDY

THE ISSUE

- Housekeeper opens a locker in the ER staff room
- A vial with a syringe and needle stuck in the top falls on her head
- Chaos ensues…

THE PLAYERS

- Nursing (including nursing administration)
- Doctors (ER Dept. Chair, Staff and PAs)
- Executive Administration
- Human Resources
- Pharmacy
- Compliance
- Security (physical, not IT)
- Consultants
- Outside Counsel
- Nurses Union

KEY STEPS

- Consultants were hired to conduct forensic interviews, review ER documentation and analyze use of the automated distribution cabinets (Omnipro) used to dispense drugs.
- Definition of the "relevant period" for the investigation was agreed upon by all players.
- The entire process from the ordering of drugs, to posting of orders in the electronic health record, to removing drugs from Omnipro, to administering the medication, documenting the administration and procedures for waste of excess narcotics were discussed with each interviewee to determine consistency and understanding of hospital policy and best practice.

CHAOS ENSUES

- Everyone is on the defensive as facts are gathered

What do we know?

- Verbal orders are issued, not followed up by written orders, against hospital policy.
- Nurses are not obtaining medications correctly from the Omnipro cabinets. Wrong patients are getting charged.
- Nurses are not consistently documenting the administration of medication.
- The ER Chair wants to blame Nursing.
- Nursing wants to blame the ER docs and Pas.

WHAT ELSE DO WE KNOW?

- Standard change of shift processes regarding counting of narcotics are not being followed.
- Pharmacy does not appropriately reconcile narcotics that are dispensed through the Omnipro cabinets.
- Nursing administration is conducting interviews in a biased manner, shutting out the consultants.
  - For instance, the Director of Nursing hugs(!) an interviewee who is a prime suspect for drug diversion after her interview is over.

THE SIDE SHOW

- The Union took the position that nurses were being singled out as being at fault for the alleged diversion.
- Union representative mandated their presence at all member's interviews.
- The ER nursing staff threatened a walkout and/or work slowdown as well as notified Administration that they were going to leaflet on the perimeter of the hospital.
- In a show of solidarity, all of the ER day staff marched into Administration to protest the investigations.
- Administration, understandably, wanted quick resolution and end to the disruption.

THE FEDS AND THE STATE

- DEA notification is required for all material theft of narcotics in the hospital setting. The reports are made by the head of Pharmacy.
- As well, in New York City, the Bureau of Narcotics Enforcement is also notified and can re-interview people at will.
- It was decided in this case to make the report to the DEA under privilege and guidance by outside legal counsel.

RESOLUTION

About nine months later -

- One nurse terminated.
- Final written warnings issued to other nurses and PAs.
- One nurse put on probation and reassigned to a floor.
  - She wound up failing probation and being terminated from employment.
- Overhaul of processes in the ER and Pharmacy.

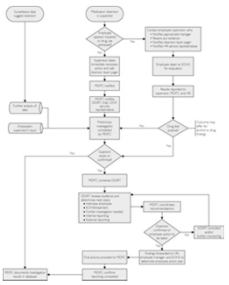
AND THEY ALL LIVED HAPPILY EVER AFTER

The End

(of that story)

IN IDEAL WORLD

FIGURE



Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention
Mayo Clinic Proceedings 2012 87, 674-682DOI: (10.1016/j.mayocp.2012.03.013)012 Mayo Foundation for Medical Education and Research

INVESTIGATION OF SUSPICIONS

- Diversion team put on alert
- Verification of data and analysis of situation
- Nurse(s) immediately removed from patient contact or intercepted; drug cabinet access discontinued
- Urine drug screen (12 panel)
- Suspension pending conclusion of investigation
- Initial interview of nurse including review of underlying medical record and drug cabinet records (if available/ identified)
- If interviews involve multiple staff:
  - Consistency of interview questions (standard for union staff)
  - Documentation consistency retention
- Periodic communications with diversion/ investigative team

"To privilege or not to privilege?"

IF DIVERSION IS CONFIRMED

- Determine employment disposition(s) and implications
  - Part time, Locum
  - Union implications
- Review clinical documentation
  - Consider billing implications and rebill if necessary (self-disclosure potential)
  - Coordinate medical record amendment, if necessary, with HIM
- Was patient safety affected
  - Notify patients if applicable

RESOLVING THE ISSUES

- If repayment obligation is identified
  - Define scope
  - Self-disclosure requirement
- Re-billing for patients with missing medication/ services
- Address patient safety/ care issues

REPORTING

- Drug Enforcement Agency
  - Prompt reporting is expected (Form 106) (www.deadiversion.usdoj.gov)
- Pharmacy Board/ American Society of Health-System Pharmacists (www.ashp.org)
- State Licensure Board(s)
- Department of Health (patient harm issues)
- DEA position that obtaining certain information
- FDA/ OCI (tampering cases)
- Law Enforcement (crimes, issues of abuse/ neglect/ reckless endangerment, fraud
- OIG
- Accreditation agencies (Joint Commission, AAAASF, etc.) (www.jointcommission.org)
- Professional Liability Carrier(s)

GOING FORWARD

A few thoughts

PROFILING THE DIVERTER

- Can be exemplary employees
- Someone you least expect
- Often first to volunteer to pick up extra shifts

Things to watch for:

- Increasing absenteeism
- Frequent/prolonged disappearances from work area/site (bathroom breaks, etc…)
- Personality changes
- Progressive deterioration in personal appearance/hygiene
- Increasing absenteeism
- Frequent/prolonged disappearances from work area/site (bathroom breaks, etc…)

MONITORING: USUAL SUSPECTS

- Correlation of Dx, Rx, and documentation
- Appropriateness of wasting – consistency of utilization vs. waste; timeliness
- Utilization of all Rx prescribed to Pt
- Documenting pain scores inconsistent with colleagues
- Giving implausible excuses for not administering narcotics (“may be discharged today”)
- Documenting administration of narcotics at the time of and after the discharge
- Administering narcotics to patients for whom it is not appropriate

BEST PRACTICES

eAppendix

Controlled Substance Diversion, Detection and Prevention Program
Elements of Best Practice
(excluding Outpatient Pharmacies)

No	Best Practice Element	PRIORITY TIER
	Legend: CS-Controlled Substances; DEA-Drug Enforcement Administration; ADM-Automated Distribution Machine	
	Tier 1 - Essential element and should be in place	
	Tier 2 - Recommended element. Progress toward implementation should be made over time	
	CORE PRINCIPLES	
1	The chain of custody and individual accountability of Controlled Substances (CS) are maintained at all times.	1
2	Organizational policies exist that address all aspects of CS medication use processes. Policies are regularly reviewed and are compliant with federal and state regulations.	1
3	Organizational policies are adhered to by all staff.	1
	STORAGE & SECURITY	
4	CS are securely stored in a locked location (i.e. ADM, safe, locked cabinet/drawer) at all times unless in the direct physical control of an authorized individual.	1
5	CS that are under the control of an authorized individual are not placed where their view may be obscured or where a distraction may prevent direct observation at all times.	1
6	Access to CS storage areas is minimized and limited to authorized staff.	1
7	CS brought in by a patient that cannot be returned home are inventoried by two authorized healthcare staff, and stored in a locked, limited-access area.	1
	PROCUREMENT	
8	All CS are obtained from pharmacy.	1
9	Only authorized pharmacy staff can purchase CS.	1
10	The number of individuals authorized to order CS is minimized.	1
11	Separation of duties exist between the ordering and receipt of CS.	1
12	Two individuals count and check-in CS received and confirm that order, invoice, and product-received documentation match.	1
13	CS inventory levels are based upon usage in order to minimize excess stock.	1
14	Automated CS safe technology is utilized.	1
15	Electronic CS Ordering System (CSOS) is utilized (eliminates paper DEA 222 forms).	1
16	A process is in place to identify unusual "peaks" in quantity or frequency of CS ordered.	2
17	All CS procurement paperwork is reviewed for completion and filed according to applicable laws and regulations.	1

http://www.mayoclinicproceedings.org

eAppendix

Controlled Substance Diversion, Detection and Prevention Program 2
Elements of Best Practice
(excluding Outpatient Pharmacies)

No	Best Practice Element	PRIORITY TIER
	ORDERING / PRESCRIBING	
18	CS are ordered only by licensed authorized prescribers with DEA authorization.	1
19	CS orders are generated by electronic systems with controlled access except in emergency situations or when not practical.	1
20	CS are not prescribed by an authorized prescriber for him/herself or an immediate family member.	1
21	Range orders for CS are eliminated.	2
	PREPARATION & DISPENSING	
22	CS are dispensed in unit dose packaging whenever possible.	1
23	CS waste from Compounded Sterile Product (CSP) preparation area in the pharmacy is collected and randomly assayed.	2
24	ADM technology is utilized in high volume CS pharmacy areas.	2
25	Secure, lockable, non-transparent medication delivery carts / containers are used to deliver CS.	1
26	ADM technology is utilized in patient care areas for the distribution and accountability of CS.	1
27	ADM managed CS are stored in a location with single pocket access.	1
28	Bar code scanning is utilized when replenishing ADM Medstations.	2
29	A "blind count" process is used for all ADM managed CS. (A, see below)	1
30	The number of CS on ADM override status is minimized. (B, see below)	1
31	Bio-ID ADM technology (biometric thumbprint entry) is used instead of passwords.	1
32	CS delivery to non-ADM areas requires co-signature for delivery and return.	1
33	Non-ADM CS cabinets are secured with an electronic lock that requires a user specific code or badge swipe.	2
34	ADM down time procedures are defined to maintain the control, documentation and accountability of CS.	1
	ADMINISTRATION	
35	A valid order from an authorized prescriber exists for all CS administered.	1
36	CS are only administered by licensed independent practitioners or other licensed or registered health care providers within their scope of practice.	1
37	CS are retrieved from storage areas as close to the time of administration as possible.	1
38	The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered.	1
39	CS for one patient at a time are obtained from the ADM / locked storage area.	1
40	The individual retrieving the CS from ADM / locked storage area is also the person that administers the medication.	1
41	All CS drawn up into syringes, if not immediately administered, are labeled per institutional policy and the initials of the individual that drew up the drug are written on the label.	1

eAppendix

Controlled Substance Diversion, Detection and Prevention Program 3
Elements of Best Practice
(excluding Outpatient Pharmacies)

No	Best Practice Element	PRIORITY TIER
42	Initials on prepared syringes are verified immediately prior to administration to ensure that the syringe has not been switched.	1
43	CS waste from high risk areas (e.g surgical, anesthesia, procedural, high volumes) and/or specific high-risk CS medications (e.g. fentanyl) are returned to and reconciled by the pharmacy. Universal precautions are used when handling waste.	1
44	Approved methods for wasting a CS are defined in policy (e.g. squirted into sink, flushed down toilet).	1
45	The wasting of all CS requires an independent witness and documentation, except in situations where waste is being returned to Pharmacy for assay and wasting.	1
46	An individual witnessing CS wasting verifies that the volume / amount being wasted matches the documentation and physically watches the medication being wasted per policy (e.g. squirted into sink, flushed down toilet).	1
47	Patient-specific CS infusions are contained in a locked box utilizing no-port tubing unless under constant surveillance.	2
48	Unused ADM managed CS are returned to a return bin and not to the original ADM pocket.	1
49	All CS returns to the pharmacy require co-signature in the patient care area and in the pharmacy.	1
50	Limited access lock boxes are available in all procedural areas where CS may be left unattended.	1
51	Empty containers of CS (e.g. vials) are discarded in limited-access waste containers (e.g. sharps boxes).	1
52	All CS administered are documented in the medical record.	1
	INVENTORY & RECORD KEEPING	
53	A perpetual inventory of all CS is maintained.	1
54	ADM managed CS counts are verified each time a CS drawer is is accessed.	1
55	ADM managed CS are manually inventoried by two authorized health care providers if a blind count has not been performed within one week.	1
56	ADM CII Safe managed CS are manually inventoried by two licensed or authorized pharmacy providers on a regular basis.	1
57	Non-ADM managed CS are manually inventoried by two authorized health care providers every shift.	1
58	A biennial physical inventory of all CS is completed and documented per DEA requirements.	1
	SURVEILLANCE	
59	CS waste is randomly tested for content.	1
60	ADM CS discrepancies created by a blind count are resolved by two authorized health care providers within the shift / business day in which these are discovered. A processis in place for investigating discrepancies that are not satisfactorily resolved.	1
61	ADM CS surveillance reports are regularly created and assessed.	1
62	All paper CS "Disposition and Inventory" sheets are reviewed and audited.	1
63	Ordering vs Dispensing vs Administration documention is audited (electronic preferred).	1

eAppendix **Controlled Substance Diversion, Detection and Prevention Program** 4
Elements of Best Practice
(excluding Outpatient Pharmacies)

No	Best Practice Element	PRIORITY TIER
64	Patient assessment and medication administration documentation is audited on a regular basis.	2
65	Camera surveillance is present in primary CS pharmacy storage area (e.g CS vault).	2
66	Camera surveillance is present in high use CS pharmacy preparation areas.	2
67	Camera surveillance is present in high risk areas (e.g. external return and waste bins) as appropriate and when "for cause" surveillance is required.	2
	INVESTIGATION and RESPONSE	
68	A 24 hour x 7 days-per-week medication diversion pager or phone number is available to report (anonymously if desired) suspected medication diversion.	1
69	A multidisciplinary "Drug Diversion Response Team," or equivalent, is in place to provide consultation, direction, and oversight for suspected diversion incidents.	1
70	A standardized process exists for interviewing suspected CS diverters.	1
71	Guidelines are in place for the handling of suspected impaired employees and drug testing.	1
72	A defined process is in place for the internal and external reporting of medication diversion incidents.	1
	EDUCATION	
73	Education on medication diversion and CS policies and procedures is required prior to authorized staff having access to CS.	1
74	An ongoing medication diversion education program is in place to promote the safe handling of CS and awareness of medication diversion.	2
	QUALITY IMPROVEMENT	
75	A "Medication Diversion Prevention Committee," or equivalent, exists to provide leadership and direction for all medication diversion activities.	2
76	CS diversion incidents are collated, reviewed, and analysed to identify further opportunities for improvement in existing systems.	2
77	A defined process is in place for the ongoing, timely management of employee access to CS when employee is terminated or transferred.	1

REFERENCES

- CMS **"Prescription Drug Trafficking—Recognizing Suspicious Prescriptions," 2.12.2016**

https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/drugdiversion-drugtrafficking-booklet.pdf

- "Following Pharmaceutical Products Through the Supply Chain,", Lisa Daigle, August 2012 American Society of Health System Pharmacists Policy Analysis

https://www.ashp.org/DocLibrary/Advocacy/AnalysisPaper/Following-Pharmaceutical-Products.aspx

WERTHER, NORMAN, MD
WILLOW GROVE, PA

- Date of Arrest: 8/10/2011 Date of Conviction: 9/24/2013 Judicial Status: Jury Conviction
- Conviction: Conspiracy to Distribute a Controlled Substance; Distribution of a Controlled Substance Resulting in Death; Distribution of a Controlled Substance; Maintaining a Drug-Involved Premises; and Money Laundering
- DEA Registration: Surrendered 8/22/2011

In Sum:

Norman Werther, MD, of Willow Grove, PA, was found guilty in U.S. District Court, Eastern District of Pennsylvania, of one count of Distribution of a Controlled Substance Resulting in Death, five counts of Conspiracy to Distribute a Controlled Substance; one count of Maintaining a Drug-Involved Premises; 117 counts of Money Laundering, and over 180 counts of Distribution of a Controlled Substance. According to court documents, from on or about February 2009, to on or about August 2011, Werther, while running a family practice/physical therapy and rehabilitation practice, conspired to distribute Oxycodone, a Schedule II Controlled Substance, to pseudo (fake) patients recruited by one of the at least six different drug trafficking organizations (DTO). Werther was part of multi-million dollar drug conspiracy involving thousands of illegal prescriptions, phony patients, and multiple DTOs. Werther was paid for each prescription he wrote to these pseudo patients, who in turn, provided the pills to the heads of each DTO to be resold in bulk to street level drug traffickers for a profit. During the course of the conspiracy, Werther was responsible for the illegal distribution of over 1,000,000 Oxycodone pills.

Werther was also convicted of causing the death of a patient not related to any of the six DTOs by illegally prescribing this patient, an admitted recovering drug addict who Werther had been treating with Suboxone, large amounts of Oxycodone pills; this patient died within 24 hours of ingesting the Oxycodone pills he obtained via a prescription from Werther.

Werther was sentenced to 25 years incarceration, followed by three years supervised release. Werther was also ordered to pay a $25,000 fine; a $30,900 special assessment fee; and forfeit $10,000,000.00. Werther has appealed his conviction.