

Compliance Considerations Diversion HCCA Conference October 20 2017

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What is Diversion?

- ▶ Definition: a medical and legal concept involving the transfer of any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.

Most commonly abused are Controlled Substances

- ▶ Benzodiazepines – including diazepam, temazepam, clonazepam, and alprazolam – prescription anxiolytics and sedatives
- ▶ Opioids – including morphine, hydrocodone, oxycodone and codeine – prescription pain medications
- ▶ Stimulants – amphetamine, methylphenidate, and modafinil – prescribed to treat ADHD and narcolepsy
- ▶ Z-drugs – including zolpidem (Ambien), Eszopiclone (Lunesta) – prescription sleep medications

Why?

Declared an Epidemic in 2013

One of 4 of biggest epidemics

More than car accidents

Over half are related to opiates

One Day in the United States

1. 650,000
Opioid
Prescriptions
are
dispensed

2. 3,900
people
initiate non
medical
use

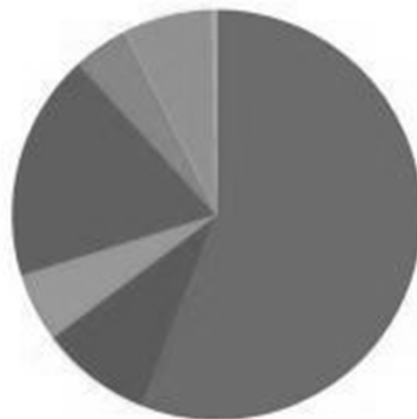
3. 580
people
initiate
heroin use



Public Health Epidemic

- ▶ 2000-2014
- ▶ Unintentional drug overdose deaths in US increased 137% which was 200% increase in overdose death involving opioids.
- ▶ 500,000 deaths due to prescription overdose
- ▶ 2016:
 - ▶ Over 60,000 drug related overdose deaths
 - ▶ 135 deaths every 24 hours
 - ▶ 46 deaths by end of today's presentation
 - ▶ 1 death every 11.16 minutes
 - ▶ 26,647 deaths involved opioids including heroin
 - ▶ 19,000 deaths involved prescription opioid

Sources of prescription drugs used illegally



- 55.9% Friend or relative (free)
- 8.9% Friend or relative (bought)
- 5.4% Friend or relative (stolen)
- 18.0% Prescription from one doctor
- 4.3% Drug dealer or stranger
- 7.1% Unreported
- 0.4% Internet

At least half of all opioid overdose deaths involve prescription opioids

CDC NATIONAL VITAL STATISTICS

Heroin use is part of a larger substance abuse problem.

Nearly all people who
used heroin also used
at least 1 other drug.

Most used at least
3 other drugs.

Heroin is a
highly addictive
opioid drug with a high
risk of overdose and
death for users.

People who are addicted to...



ALCOHOL

are

2x



MARIJUANA

are

3x



COCAINE

are

15x



Rx OPIOID PAINKILLERS

are

40x

...more likely to be addicted to heroin.

SOURCE: National Survey on Drug Use and Health (NSDUH), 2011-2013.

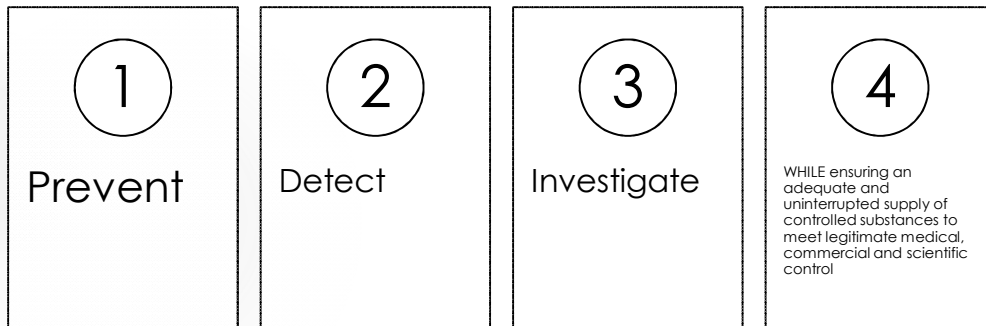
Health Care Professionals - Are they also at risk of Diversion?

- ▶ 1 in 10 health care professionals struggling with opioid use disorder. This is the same rate for the general population. -CDC

Controlled Substance Act

- ▶ The Controlled Substances Act (CSA) is the statute prescribing federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. It was passed by the 91st United States Congress as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and signed into law by President Richard Nixon.

MISSION of the DEA



Closed
System of
Distribution

► Foreign
Manufacturer >
Importer >
Manufacturer >
Distributor >
Practitioner/Phar
macy Hospital
Clinic > Patient

Effective Controls

All Applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

In order to determine whether a registrant has provided effective controls, the Administrator shall use the security requirements set forth by DEA as standard for physical security, and operating procedures necessary to prevent diversion.

21 CFR 1301.72(a)

Corresponding Responsibility by the Pharmacist

- ▶ The responsibility for proper prescribing and dispensing of controlled substances is upon the prescribing practitioner but a corresponding responsibility rests with the pharmacist who fills the prescription.
- ▶ A Pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate
- ▶ When a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription.

▶ 21 CFR 1306.04(a)



What should be considered to ensure effective controls are used?

SOMETHING TO THINK ABOUT!!

Setting the Tone

- ▶ 1. All Registrations in place
- ▶ 2. Hospital and Pharmacies must demonstrate what is the most important thing
- ▶ 3. Setting the Expectations of all Hospital Employees: Employers must also make employees aware of federal regulations around reporting diversion
- ▶ 4. 21 CFR 1301.91 EMPLOYEE RESPONSIBILITY to report Diversion
- ▶ 5. 21 CFR 1301.92 Illicit Activity by employees – Subject to federal prosecution

SECURITY/ACCOUNTABILITY OF CONTROLLED SUBSTANCES

Prevention

- Criminal background checks
- Education of employees
- Training for employees
- Policies
- Information available to staff
- Random compliance checks
- Discipline for violations

Supervision

- Review record keeping
- Drug counts/audits balance
- Verify orders against withdrawals
- Division of duties-2 person activities
- Random compliance checks

Investigation

- Variances reported to pharmacy
- Pharmacy leads investigation team
- Initial reports filed with
- Interviews/audits/records reviews
- Findings reported to administration
- Final loss reports to DEA

Administrative Issues to Consider

- Employee removed from schedule
- No access to drugs/patients
- Do you want this person back?
- Risks from diverting employees
- Infection control
- Media coverage/reputation
- Amending false billing
- Employee reimburses hospital for cost of hospital investigation

Prevention

- ▶ Background checks for non-practitioners
- ▶ Also state policy might state, hospital has to have a policy – but it may not be clear to employee if policy states, “follow all laws.”
- ▶ Important that policies use words, like shall and must
- ▶ RANDOM Compliance Checks must be un-announced
- ▶ Record keeping must be thorough – When a practitioner begins diverting drugs, record keeping becomes sloppy
- ▶ Discipline and accountability – There are usually at least 3 violations cited by the bureau: 1. False record, 2. Diversion for personal use, 3. employee did not pay the hospital bill

Supervision

- ▶ Review Record Keeping Regularly
 - ▶ One of the first signs of impairment is bad charting
 - ▶ Incomplete records means drugs cannot be audited to verify accountability
 - ▶ Reviews reveal counts and balances that have discrepancies
 - ▶ Reviews reveal drugs withdrawn that no physician authorized
 - ▶ Pharmacy employees have purchased extra shipments unknown to supervisors
 - ▶ Time frames for orders should be in policy

Continued...

- ▶ Define 2 person activities, like waste, and disposal
- ▶ Random compliance checks
- ▶ Medication is never to be returned to the pharmacy or the hospital.

Collection Receptacle Locations must be Registered

Long Term Facility

Located in secure area regularly monitored by LCTF employees

Hospital / Clinic

Located in an area regularly monitored by employees – not in proximity of where emergency or urgent care is provided

NTP

Located in a room that does not contain any other controlled substances and is securely locked with controlled access.

Collection Receptacles

- ▶ 1. Ultimate users shall put the substances directly into the collection receptacle
 - ▶ 2. Controlled and non-controlled may be co-mingled
 - ▶ 3. Collected Substances shall not be counted, sorted, inventoried or otherwise handled
 - ▶ 4. Registrants SHALL NOT DISPOSE OF STOCK OR INVENTORY in collection receptacles.
- ▶ 21 CFR 1317.75(b) and ©



Disposal Events

