

# Drug Diversion: Reporting and Liability Issues for Physicians



November 10, 2016  
Teresa D. Locke

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# Overview

- What is drug diversion and why should it matter to healthcare providers?
- Who is liable for drug diversion and what is a provider's role in preventing drug diversion?
- Strategies for prevention, detection, and response
- Reporting requirements
- HIPAA and Privacy Issues
- ACA's impact on drug diversion



# Helpful Written Materials

- **.ppt slides**
- **Drug Diversion Toolkit, “What is a Prescriber’s Role in Preventing the Diversion of Prescription Drugs?”**
- **Mayo Clinic, Controlled Substance Diversion, Detection and Prevention Program “Elements of Best Practice.”**

# What is Drug Diversion?



# What is Drug Diversion?

**“Drug diversion’ is best defined as the diversion of licit drugs for illicit purposes. It involves the diversion of drugs from legal and medically necessary uses towards uses that are illegal and typically not medically authorized or necessary.”**

**Source: “Drug Diversion in the Medicaid Program: State Strategies for Reducing Prescription Drug Diversion in Medicaid,” Centers for Medicare & Medicaid Services (Baltimore, MD: January 2012), p. 1**

**<https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/downloads/drugdiversion.pdf>**

# Who Diverts Drugs?

Deflection of prescription drugs from medical sources into the illegal market may occur at any point in the distribution process:

- Manufacturers
- Wholesale distributors
- Doctors
- Nurses
- Ancillary staff
- Patients
- Pharmacists
- Other healthcare professionals
- Burglars

# Drug Diversion in Healthcare

- By definition, diversion is a covert activity so statistics may not be accurate – it is likely underreported and under-detected.
- American Nurses Association estimates that 10% of nurses are dependent on some type of drug.
- U.S. Substance Abuse and Mental Health Services Administration estimated in 2007 that an average of 103,000 doctors, nurses, medical technicians and health care aides a year were abusing or dependent on illicit drugs.
- Various studies suggest the number could be far higher; an estimated one in 10 practitioners will fall into drug or alcohol abuse at some point in their lives, mirroring the general population.
- No doubt that drug diversion by healthcare providers is universal among healthcare institutions in the US and is a pervasive problem.



# Most Common Types of Drug Diversion

- Selling prescription drugs
- Doctor shopping
- Illegal internet pharmacies
- Drug theft
- Drug theft by healthcare professionals/workers
  - taking waste for personal use
  - stealing controlled substances (“CS”) from the patients
  - removing CS from automated dispensing machine (PRN)
  - tampering with patients’ CS medications
- Prescription pad theft and forgery
- Illicit prescribing

# What Drugs Are Commonly Diverted?

According to the Drug Enforcement Administration and the National Survey of Drug Use and Health Data, there are five drug classes with a high potential for diversion and abuse:

- **Anabolic steroids**
  - e.g., testosterone
- **Central nervous system depressants**
  - e.g., barbiturates, benzodiazepines
- **Hallucinogens**
  - e.g., ketamine
- **Opioids**
- **Stimulants**
  - e.g., amphetamine, dextroamphetamine, methamphetamine

Source: Medicare Learning Network, “Medicaid Program Integrity: What Is a Prescriber’s Role in Preventing the Diversion of Prescription Drugs,” <https://www.cms.gov/Outreach-and-Education/.../Drug-Diversion-ICN901010.pdf>.

# What Drugs Are Commonly Diverted?

The most commonly diverted controlled prescription drugs are opioid pain relievers, including:

- codeine
- fentanyl
- hydromorphone
- meperidine
- morphine
- oxycodone
- pentazocine
- dextropropoxyphene
- hydrocodone combinations (Vicodin, Lortab and Lorcet)
- methadone

Source: <http://www.oas.samhsa.gov/nhsda.htm>

# What Drugs Are Commonly Diverted?

In addition to opioids, significant diversion is occurring with high cost antipsychotic and mental health drugs:

- Abilify
- Risperdal
- Zyprexa
- Klonopin
- Geodon
- Seroquel
- Xanax
- Ativan

According to the Center for Behavioral Health Statistics and Quality, in 2014, the estimate of 6.5 million Americans aged 12 or older who were current nonmedical users of psychotherapeutic drugs represents 2.5 percent of the population aged 12 or older.

# Why Does it Matter?

## PRESCRIPTION DRUG ABUSE

In Florida every day:

**6.3 million**  
prescriptions for  
**Oxycodone**

**3.9%** of prescriptions  
for Oxycodone  
are for  
pain management



The Florida Medical Examiner's Office  
Reported, in 2011, that in

**322**

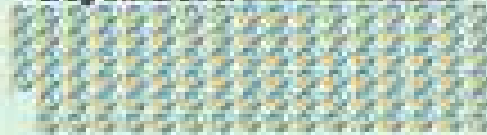
**Oxycodone**  
was either present or the cause of  
**Death**  
for Florida and Puerto Rico



St. Petersburg, Fl  
has the **highest**  
rate of deaths with Oxycodone.

**692 - 243**  
Motor vehicle  
Deaths  
Drug  
Deaths

More than **2,000**  
newborns  
were diagnosed with  
drug withdrawal



**2,500**  
leaves in possession  
of prescription drugs  
for the first time in the state

**181**  
Prescription Drug related  
accidental deaths in Florida County



Turnaround

# Consequences of Drug Diversion Generally

- **Health consequences**
  - to diverter (and to patients if the diverter is a healthcare provider)
- **Social consequences**
  - According to the Centers for Disease Control and Prevention, since 2009 more people in the United States have died each year from drugs than from motor vehicle crashes.
  - According to the National Drug Intelligence Center National Drug Threat Survey, violent and property crime associated with CPD diversion and abuse has increased in all regions of the US over the last five years.
- **Legal consequences**
  - criminal liability (diverter and supplier)
  - possible civil liability (healthcare provider)
- **Financial consequences**

# Financial Consequences of Drug Diversion

“The estimated cost of CPD diversion and abuse to public and private medical insurers is \$72.5 billion a year, much of which is passed to consumers through higher health insurance premiums. Additionally, the abuse of prescription opioids is burdening the budgets of substance abuse treatment providers, particularly as prescription opioid abuse might be fueling heroin abuse rates in some areas of the United States.”

Source: National Drug Intelligence Center, Drug Enforcement Administration, “National Prescription Drug Threat Assessment,” (Washington DC, April 2009), p. V (<http://www.justice.gov/archive/ndic/pubs33/33775/33775p.pdf>).

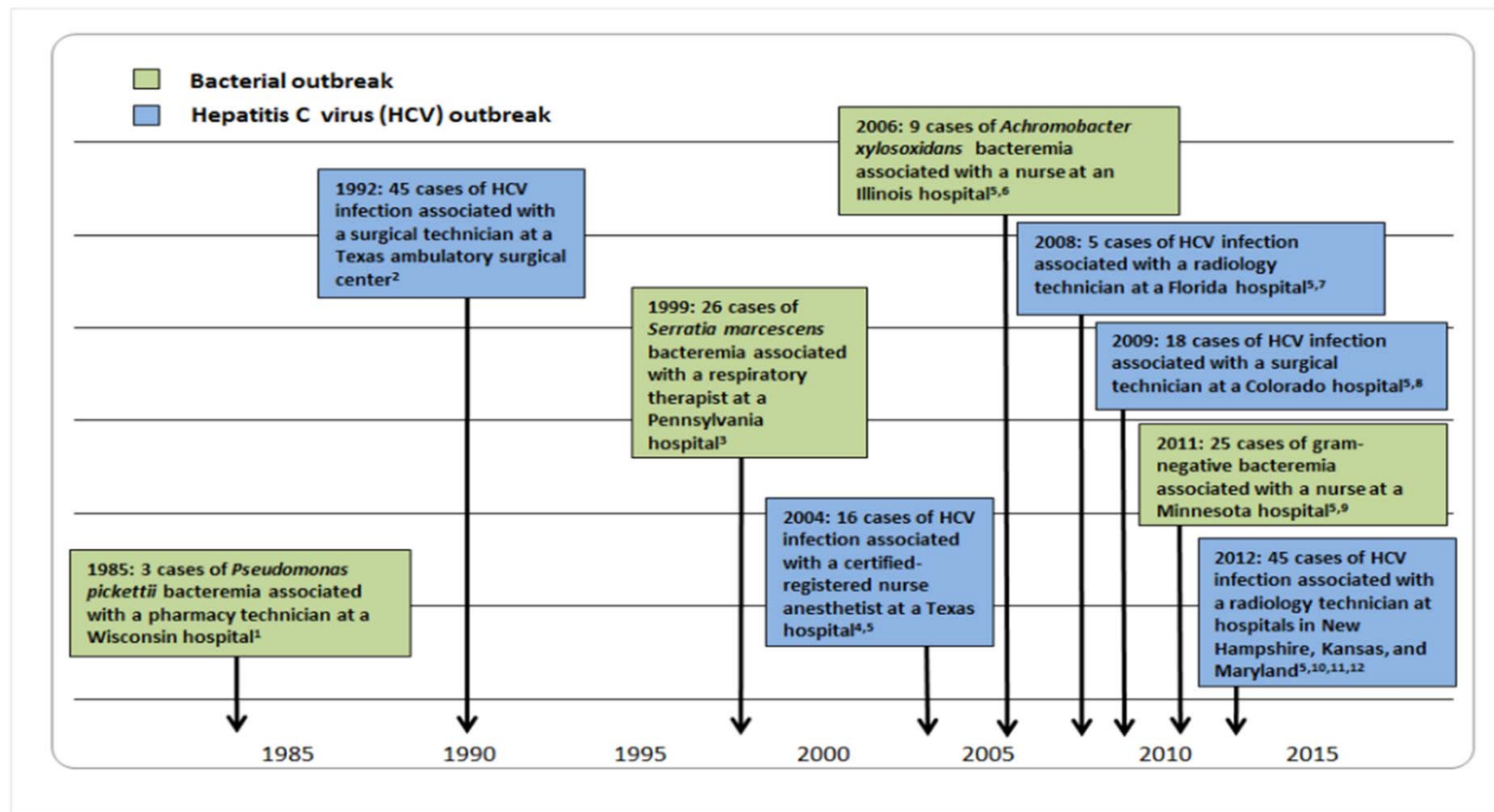
# The Impact of Drug Diversion by a Healthcare Provider

- **The diverter**
  - risk of morbidity and mortality to himself or herself
  - professional risks (felony criminal prosecution, civil malpractice)
- **Patients**
  - substandard care
  - undue pain and/or anxiety
  - risk of adulterated or contaminated drug in place of the diverted drug



# The Impact of Drug Diversion by a Healthcare Provider

U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013



# The Impact of Drug Diversion by a Healthcare Provider

- **Co-workers**
  - risk of mechanical injury
  - medicolegal liability
  - risk of disciplinary actions for breaches of policies and procedures
  
- **Healthcare institution**
  - loss of revenue from diverted drugs, poor work quality, absenteeism
  - risk of civil liability
  - cost of investigation, remediation
  - negative publicity

# Legal Consequences for Drug Diversion

- Prescribers
  - Recent trend toward civil liability exposure of physicians for drug diversion.
  - *Tug Valley Pharm. v. All Plaintiffs in Mingo County*, 2015 BL 148172, W.Va. No. 14-0144 (W.Va. 2015)
  - Court allowed ruling allowed substance abusers (patients) to sue the prescribers and pharmacists who supplied the medications, even though the patients acknowledged engaging in an array of illegal activities including criminally acquiring narcotics by misleading physicians and pharmacists, doctor shopping, and ingesting the medications in amounts greater than prescribed.
  - So if the physicians were negligent in prescribing—if they should have known that the patients were lying and might divert the drugs—they can be liable for damages.

# Legal Consequences for Drug Diversion

- Prescribers

- also risk of criminal liability (e.g., Michael Jackson's physician)
- Dr. Conrad Murray was charged with the involuntary manslaughter because he administered Propofol to the singer at Jackson's home, rather than at a hospital or out-patient care center where proper safeguards and monitoring of the patient's condition could be undertaken.
- Criminal prosecution of a healthcare provider for the death of a patient is a rare thing – requires intentional conduct or reckless disregard.
- It is generally believed that one third of all physicians in the low risk specialties will face at least one medical malpractice claim before they reach age 45.
- 2009 law review article found only 30 cases of criminal prosecution against physicians between 1981 and 2005 nationwide. D. Hoffmann, *Physicians Who Break the Law*, 53 St. Louis U.L.J. 1049, 1082 (2009).

# Legal Consequences for Drug Diversion

Boulder DailyCamera.com Colorado, News, Business, Sports, Homes, Jobs, Cars and Information

Story

## Former Boulder Community Hospital nurse sentenced to 4 1/2 years for stealing meds

*By Vanessa Miller, Camera staff writer*

NEWS

### Hospital tech who spread hep C via drug thefts gets 30 years

### Ex-hospital worker gets 39 years for causing hepatitis C outbreak

By Luisa Navarro, CNN

🕒 Updated 8:13 AM ET, Tue December 3, 2013



# Legal Consequences for Drug Diversion

Resources - Cases Against Doctors

https://www.deadiversion.usdoj.gov/crim\_admin\_actions/

Apps Integrated Colorado Co Free Hotmail Integrated Colorado Co Lexis-Nexis MSN.com Suggested Sites Tarantella Westlaw Imported From IE



## U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION

 Search

HOME

REGISTRATION

REPORTING

RESOURCES

ABOUT US



RESOURCES > Cases Against Doctors

### Cases Against Doctors

#### Criminal Cases Against Doctors (PDF)

This is a listing of investigations of physician registrants in which DEA was involved that resulted in the arrest and prosecution of the registrant. DEA is in the process of adding to this site cases against DEA physician registrants since 2003 which have resulted in arrests and prosecutions.

#### Administrative Actions Against Registrants

[2016](#), [2015](#), [2014](#), [2013](#), [2012](#), [2011](#), [2010](#), [2009](#), [2008](#), [2007](#), [2006](#), [2005](#), [2004](#), [2003](#), [2002](#), [2001](#), [2000](#)

- Cases Against Doctors
- Chemical Control Program
- CMEA (Combat Meth Epidemic Act)
- Controlled Substance Schedules
- DATA Waived Physicians
- Drug Disposal Information
- Drug and Chemical Information
- E-commerce Initiatives
- Federal Agencies & Related Links
- Federal Register Notices
- National Take-Back Initiative

# Legal Consequences for Drug Diversion

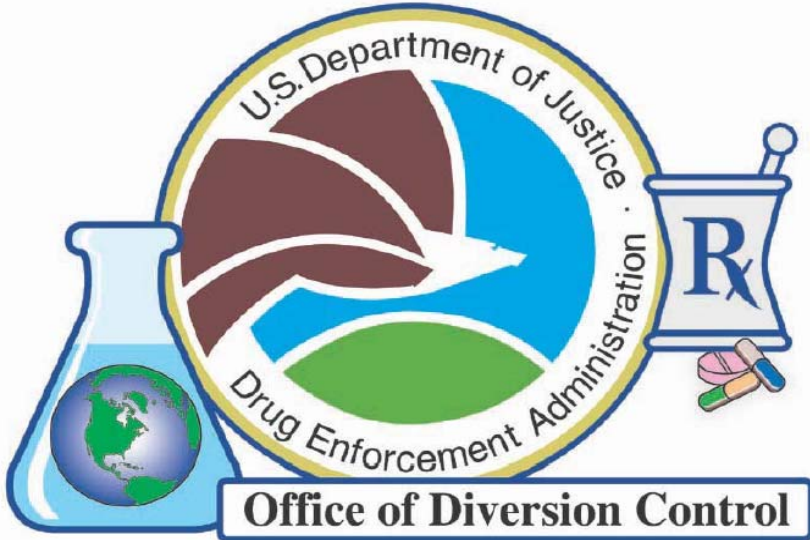
doctors\_criminal\_cases.pdf - Adobe Acrobat Pro

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1 / 1 [Navigation Icons] 111% [Tools] Fill & Sign Comment

## Cases Against Doctors



This is a listing of investigations of physician registrants in which DEA was involved that resulted in the arrest and prosecution of the registrant.

Last Updated: March 31, 2016

# Legal Consequences for Drug Diversion

- **Healthcare facility – possible criminal liability**
  - some states make it a crime to fail to report theft or significant loss of a controlled substance
  - DEA focus on organization’s responsibility for preventing diversion
  - OIG investigations of drug diversion are on the rise
- **Healthcare facility – possible civil liability**
  - Negligent hiring by hospital
  - Negligent retention, training and supervision
  - Respondeat superior – responsible for the actions taken by employees within scope of employment
  - Reckless and intentional infliction of emotional distress
  - Violations of Consumer Protection Act



# Legal Consequences for Drug Diversion

NEWS

## First individual lawsuit filed over hep-C-infected needles at Rose Medical Center



By JESSICA FENDER

PUBLISHED: May 2, 2010 at 2:31 pm | UPDATED: September 17, 2016 at 10:59 am

The first individual lawsuit filed by a hepatitis C-infected patient of Rose Medical Center debuted Sunday in Denver District Court naming the hospital and anesthesiologist Shawn Roth.



# Legal Consequences for Drug Diversion

**DISTRICT COURT, DENVER COUNTY, COLORADO**

1427 Bannock Street, Room 256  
Denver, Colorado 80202

PATRICK AND LESLIE EVANS, GARY ANDERSON,  
JOHN AND MARTHA ANDERSON, DAWN AVERY,  
FRANK BISHOP, SANDRA AND JAMES BLOWERS,  
ROBIN BROWN, JOHN AND LYNDA CHESNEY, MARIE  
COLES, GARY AND MICHELLE FIELDS, DENISE  
FAUSTINO, SAMANTHA GAGLIANO, KIM HARTMAN,  
PAUL HATTERY, NIKKI MILES, MICHAEL MOREAU,  
VALERIE PELC, DESIREE PHILLIPS, JANE P., MONICA  
ROBINSON, MICHELE SAVAGE, WILLIAM SMITH,  
TRACI STANCIL, RANDY SWEARINGEN, JOHN  
VALDEZ, LURLENE WAYMAN, MARK AND MARY  
WIESE, ANTHONY WEAVER, MARGARET WEGRZYN,  
LIYING YI, AND JACK YORK,

**Plaintiffs,**

v.

HCA-HEALTHONE LLC, d/b/a Swedish Medical Center,  
HEALTHONE OF DENVER, INC., and HOSPITAL  
CORPORATION OF AMERICA,

DATE FILED: March 18, 2016 4:30 AM  
FILING ID: 51679B03BC4DE  
CASE NUMBER: 2016CV30961

▲ COURT USE ONLY ▲

# Legal Consequences for Drug Diversion

- **Healthcare facility – regulatory issues**
  - Hospitals are required to be in compliance with Federal requirements set forth in the Medicare Conditions of Participation in order to receive Medicare/Medicaid payment.
  - § 428.25(a)(3) – current and accurate records must be kept of the receipt and disposition of scheduled drugs
  - § 428.25(b)(2)(i)-(ii) – all drugs and biologicals must be kept in a secure area, and locked when appropriate
  - § 428.25(b)(7) – abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate
  - Hospitals must comply with Joint Commission Medication Management Standards.

# A Provider's Role in Preventing Drug Diversion



# AMA's Four Categories of Physician Mis-Prescribers

- **Deficient/Dated Practitioner**
  - Too busy to keep up with CME
  - Unaware of controlled drug categories
  - Only aware of a few treatments or medications for pain
  - Prescribes for friends or family without a patient record
  - Unaware of symptoms of addiction
  - Remains isolated from peers
  - Only education is from drug representatives

# AMA's Four Categories of Physician Mis-Prescribers

- **Duped Practitioner**

- Always assumes the best about his patients and is gullible
- Leaves script pads lying around
- Falls for hydrophilic medicine excuse – fell into the toilet or sink
- Patients only want specific medications (i.e., OxyContin or Percocet)
- Co-dependent – cannot tell patients “No” when they ask for narcotics

# AMA's Four Categories of Physician Mis-Prescribers

- **Deliberate (Dealing)**
  - Practitioner becomes a mercenary
  - Sells drugs for money, sex, street drugs, etc.
  - Office becomes a pill factory – full of drug seekers
  - Prescribes for known addicts who will likely sell drugs to others

# AMA's Four Categories of Physician Mis-Prescribers

- **Drug Dependent (Addict)**
  - Starts by taking controlled drug samples
  - Asks staff to pick up medications in their names
  - Uses another prescribers' DEA number
  - Calls in scripts in names of family members or fictitious patients and picks them up himself

<http://www.acpm.org/?UseAbuseRxClinRef>



# Understanding and Addressing Diversion Tactics

- **Doctor shopping – searching for a cooperative professional who will willingly prescribe and/or visiting multiple physicians to simply procure drugs for personal use or sale:**
  - **Communicate with other providers and pharmacies when shopping is suspected**
  - **Provide better record keeping for controlled substance prescribing**
  - **Employ electronic medical records integrated between pharmacies, hospitals and managed care organizations**
  - **Periodically request a report from your state prescription drug monitoring program on the prescribing of opioids to your patients by other providers**

# Understanding and Addressing Diversion Tactics

- **Deception – patient purposely fake pain or exaggerate pain severity:**
  - Employ more careful scrutiny during patient encounters
  - Do a thorough history and first rate physical examination to determine the case of pain
  - Inquire about prescription, OTC, and illicit drug use
- **Drug theft – includes patients who steal drugs as well as physicians who steal drugs from their patients:**
  - Keep samples in a locked cabinet
  - Report known abuses
  - Seek help if you are the offender

# Understanding and Addressing Diversion Tactics

- **Forged or altered prescriptions**
  - Use triplicate copies of prescriptions
  - Use electronic prescriptions
  - Secure prescription pads
- **Family sharing of medications – nearly 60% of prescription medications used non-medically are obtained from family or friends:**
  - Educate patients on the dangers of sharing their drugs with family and friends
  - Teach patients how to cope with pain without the use of medications
  - Stress that “doing prescription drugs” is the same as “using street drugs”

# Prescriber Precautions to Minimize Diversion

## CMS recommendations:

- Exercise caution with patients who use or request combination or layered drugs for enhanced effect.
- Document thoroughly when prescribing narcotics or choosing not to prescribe.
- Protect access to prescription pads.
- Keep DEA or license number confidential.
- Ensure that prescriptions are written clearly to minimize potential for forgery.
- Move to electronic prescribing so paper prescriptions not required.

# Prescriber Precautions to Minimize Diversion

- Adhere to strict refill policies and educate staff.
- Use state Prescription Drug Monitoring Programs.
- Refer patients with extensive pain management or controlled medication needs to specialized practices.
- Communicate with pharmacists or other providers.
- Collaborate with pharmacy benefit managers and managed care plans as they seek to determine medical necessity of prescriptions.
- Educate patients on proper disposal of controlled **substances** ([fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm](https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm)).

# Prescribing Principles to Curb Diversion

## CMS recommendations:

- Complete a full evaluation and assessment to verify the need for pain medication.
- Request a report of patient's medication history from the state PDMP before prescribing opioids to patients.
  - Most states require pharmacies to report controlled substance prescription data at least biweekly to their PDMP
- Screen for substance abuse and ask about the medications a patient is taking and why.
- Prescribe opioids only if alternative therapies do not deliver adequate pain relief.

# Prescribing Principles to Curb Diversion

- Use pain assessment tools to monitor the effectiveness of controlled substances.
- Document concerns – put it in the record for next time.
- Educate yourself and get involved.
- Network with other healthcare providers, law enforcement and industry.
- Seek a consult from a pain or other specialist for doses of more than 120 milligram equivalents of morphine or other opioid derivative Schedule II drugs per day without substantial improvement in pain and function.

# Strategies for Diversion Prevention, Detection and Response





# Strategies for Diversion Prevention with Patients

- Use screening tools:
  - To identify potential abusers can employ risk stratification. Patients at low risk need minimal structure, whereas those at greatest risk need more frequent visits, fewer pills per prescription, specialist-level care, and urine drug tests
    - saliva drug testing
    - hair drug testing for measuring long-term use
  - Screen patients for substance abuse and other forms of psychological dependence prior to prescribing controlled substances
  - Opiate risk assessment and screening tools can be found at: [www.prescriberresponsibly.com/sites/default/files/pdf/risk/Opioid%20Risk%20Tool.pdf](http://www.prescriberresponsibly.com/sites/default/files/pdf/risk/Opioid%20Risk%20Tool.pdf).

# Strategies for Diversion Prevention with Patients

## CRAFFT Questionnaire: A Brief Screening Test for Adolescent Substance Abuse

<b>C</b>	Have you ever ridden in a <b>C</b> ar driven by someone (including yourself) who was "high" or who had been using alcohol or drugs?
<b>R</b>	Do you ever use alcohol or drugs to <b>R</b> elax, feel better about yourself, or fit in?
<b>A</b>	Do you ever use alcohol or drugs while you are <b>A</b> lone?
<b>F</b>	Do you <b>F</b> orget things you did while using alcohol or drugs?
<b>F</b>	Do your family or <b>F</b> riends ever tell you that you should cut down on your drinking or drug use?
<b>T</b>	Have you gotten in <b>T</b> rouble while you were using alcohol or drugs?

Note: Two or more "yes" answers suggests a significant problem.

Center for Adolescent Substance Abuse Research. CeSAR, Children's Hospital, Boston [21]

# Strategies for Diversion Prevention with Patients

- **Document every patient encounter**
  - Chart everything you see, think, feel and hear about your patient
  - Provide details so every chart entry stands alone if separated from the chart
  - Have a progress note for every prescription written or telephoned to a pharmacy – explain why a controlled drug is necessary, what alternatives have been considered and document follow-up plans
- **Obtain informed consent – have patient sign so there is no doubt about treatment plan**
- **Do not provide automatic refills**
  - Do not write open-ended prescriptions with refills
  - See patients when new prescriptions are written
  - Do not allow staff to give out the prescriptions

# Strategies for Diversion Prevention with Patients

- **Consider universal precautions**
  - Recognize that all patients have the potential to get addicted to their medications
  - Assess all patients for past or present abuse
  - Determine a diagnosis that considers the pathology of pain
  - Routinely use treatment agreements
  - Employ regular supervision and monitoring
  - Provide extra support for patients at risk (e.g., telephone consults, care coaching, additional education, appointment reminders)
- **Educate staff**
- **Educate patients**

# Strategies for Diversion Prevention with Patients

- Develop regular use of medication agreements – have patient sign a document that states that they:
  - will receive medications only from this practice
  - will not obtain drugs via emergency rooms or other doctors
  - will only use one pharmacy
  - will not abuse alcohol or other substances
  - will adhere to clinic protocols, such as urine/toxicology screens and random pill counts
  - will keep scheduled appointments
  - will not sell or share medication
  - understand that lost, stolen or misplaced medication will not be replaced and that consideration of replacement would only occur at a clinic visit

# Strategies for Diversion Prevention with Patients

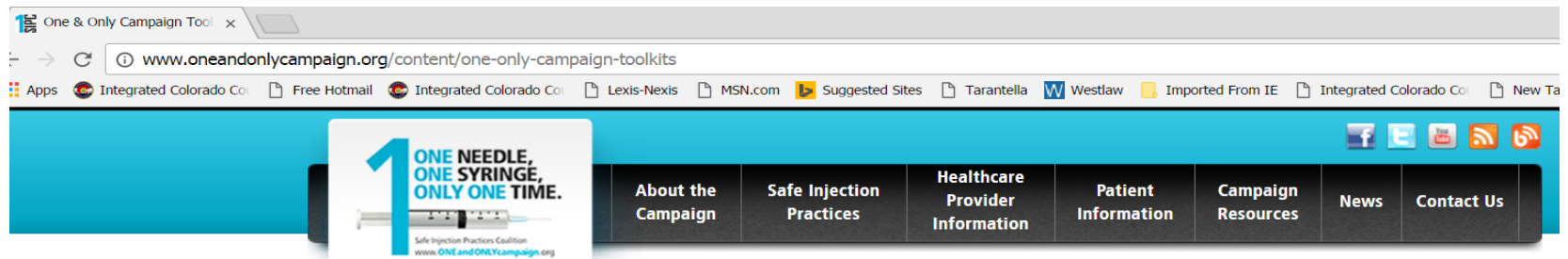
- understand that requests for medication renewals will occur only during regular business hours and not by phone request
  - understand that background checks for criminal drug and alcohol convictions will be performed
- 
- If patient breaches agreement, do not further prescribe.

# Strategies for Diversion Prevention with Providers/Staff

- Conduct background checks (criminal, regulatory, licensure)
- Develop comprehensive employee screening program
  - Have you ever been disciplined, terminated, allowed to resign or denied employment because of mishandling of a controlled substances or a drug diversion issue?
- Develop policies related to drug diversion
  - pharmacy staff should work with medical staff to develop protocols for the handling of medications
- Develop reporting flowchart
- Consider surveillance technology
- Educate and train employees (orientation and periodically thereafter)
  - [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)
  - place educational materials on intranet, bulletin boards, staff libraries, in-service trainings

# Strategies for Diversion Prevention with Providers/Staff

<http://www.oneandonlycampaign.org/content/one-only-campaign-toolkits>



## One & Only Campaign Toolkits

The *One & Only Campaign* offers evidence-based toolkits that focus on important aspects of injection safety. These toolkits can be accessed for free on the following links:

### Healthcare Provider Toolkit

This toolkit will assist individuals and organizations with educating healthcare providers and patients about safe injection practices. The materials in this toolkit have broad application among healthcare providers of most specialty types and across all healthcare settings.

#### Print Materials:

- *One & Only Campaign* Posters
- *One & Only Campaign* Provider & Patient Brochures
- Injection Safety Guidelines Pocket Card
- Injection Safety Frequently Asked Questions
- Injection Safety Myths & Truths
- Injection Safety Check List
- Injection Safety Communication Documents

#### Multimedia Materials:

### State/Local Health Department Toolkit

This toolkit is designed to provide health departments with background and information to implement the *One & Only Campaign*. The contents of this toolkit provide guidance for other health departments about lessons learned from their efforts.

#### Contents:

- Impacts Related to Unsafe Injection Practices
- Building a Working Group
- Developing Partnerships
- Media/Press Relations
- What Works? And What Might Not?
- Key Contacts/Resources





# Strategies for Diversion Prevention with Providers/Staff

- **Conduct random compliance checks**
  - when practitioners begin diverting drugs and practicing while impaired, one of the first visible signs of impairment is sloppy record keeping and lapses in charting
- **Discipline and accountability for violations**
  - make employees aware that random compliance checks are taking place
  - repercussions for violations of policies
  - discipline should be consistent with seriousness and frequency
  - should be continuous accountability and record keeping for drug usage
- **Verify withdrawals from drug storage against physicians' orders**
- **Review record keeping**
  - failing to document or make any controlled substance record may be criminal
- **Random drug testing**
  - recommended, but at a minimum for cause when drugs are missing
  - failing to cooperate should be grounds for dismissal

# Strategies for Diversion Prevention with Providers/Staff

- Division of duties – two-person activities
- Drug counts/audit balance -- things to look for :
  - removing controlled substances with no doctor's order
  - removing controlled substances for patients not assigned to the nurse
  - removing controlled substances for recently discharged patients
  - removing controlled substances and not documenting the administration of the drug on the medication administration record
  - patient chart reveals excessive pulls for PRN medication compared to other nurses assigned to that patient or removing PRN medications too frequently
  - discrepancies from the Omnicell machines on a regular basis
  - pulling out larger dosages of injectable controlled substances to obtain more waste
  - patient continuing to complain about pain even though the nurse has documented the administration of pain medications
  - falsified records
  - not documenting waste

# Strategies for Diversion Detection

- Utilize Prescription Drug Monitoring Program
- Involve the entire team
- Recognize suspicious behavior
- Be alert to warning signs:
  - Know the patient's history and family history of drug abuse
  - Note whether patient exhibits aberrant behavior such as requesting early refills or appearing sedated, intoxicated, or experiencing withdrawal during clinic visit
  - Be familiar with anxiety, depression, and pain syndromes
  - Identify manipulative behavior
  - Be suspicious of patients exhibiting the following behaviors:
    - Arriving after regular hours or wanting an appointment toward the end of office hours

# Strategies for Diversion Detection

- Stating that he/she is traveling through, visiting friends or relatives
- Providing convincing, textbook-like description of symptoms but giving a vague medical history
- Providing old clinical report and/or x-ray in support of their request
- Declining physical examination or permission to obtain past records or undergo diagnostic tests
- Unwillingness or inability to provide the name of regular doctor or stating the doctor is unavailable
- Claiming to have lost a prescription, or forgotten to pack their medication, or saying their medication was stolen or damaged
- Showing an unusual knowledge about opioid medications
- Stating that specific nonopioid medications do not work or that he/she is allergic to them
- Pressuring the doctor by eliciting sympathy or guilt or by direct threats

# Strategies for Diversion Detection

- **Be alert to warning signs in healthcare professionals:**
  - Volunteering to administer medications
  - Forgetting to have waste witnessed
  - Over-exaggerating patient symptoms
  - Spending excess time by the drug supply (cart or medicine room)
  - Requesting prescriptions from co-workers
  - Keeping blank prescription pads close
  - Prescribing for family members
  - Signs and symptoms of drug abuse
  - Signs and symptoms of withdrawal
  - Chronic absenteeism, often without notification, and use of excessive sick days

# Strategies for Diversion Detection

- Long unexplained breaks, including taking frequent trips to the bathroom or medicine room where drugs are kept
- Volunteering for overtime or appearing at work when not scheduled
- Unreliability in keeping appointments and meeting deadlines
- Work performance varies widely
- Poor judgment
- Appears confused at times, exhibits difficulty concentrating or recalling details or instructions
- Interpersonal relations with colleagues, staff and patients suffering
- Insists on personally administering injections of narcotics to patients

# Strategies for Diversion Detection

- Appears progressively disheveled and lacking in personal hygiene
- Changes are evident in handwriting and chart
- Wears long sleeves inappropriately
- Personality changes become evident
- Others, including patients and staff make complaints about co-worker's attitude or behavior
- Becoming increasingly isolated from others

# Prescription Drug Monitoring Programs

- **Electronic database – collects designated information on substances dispensed**
- **Almost all states have Prescription Drug Monitoring Program requirements**
  - [www.namsdl.org/pmpmap.html](http://www.namsdl.org/pmpmap.html)
- **PDMPs may be categorized as reactive, proactive or a combination of the two**
  - **reactive – generate reports in response to a specific request**
  - **proactive – generate reports based on patterns of behavior that raise red flags and provide this unsolicited data to an authorized individual or agency for further investigation or action.**



# Prescription Drug Monitoring Programs

<http://www.pdmpassist.org/content/state-profiles>

The screenshot shows a web browser window with the URL [www.pdmpassist.org/content/state-profiles](http://www.pdmpassist.org/content/state-profiles). The page features the PDMP TTAC logo (Prescription Drug Monitoring Program Training and Technical Assistance Center) and the affiliation with Brandeis University The Heller School for Social Policy and Management. A navigation menu includes Home, About the TTAC, Newsroom, Events, Calendar, Resources, Data Driven Pilots, and Contact, along with a search bar. The main content area is divided into two columns. The left column contains 'State Contact Information' (with links to State PDMP Contacts, State PDMP Web Sites, and PDMP Program Status), a 'Resources Menu' (with links to Introduction, Funding, Guidelines, PMIX Architecture, Partners, State Profiles, State Profiles Reports, FAQs, PDMP Acronyms and Terms, PDMP Maps and Tables, Case Studies, and PBSS), and a 'Find a PDMP Contact' section with an input field for name, state, or affiliation. The right column is titled 'State Profiles' and contains a paragraph explaining that the TTAC constructs informational profiles for each state, displayed alphabetically, and that users can click on a PDF icon for a printable Summary Profile. Below this text is a grid of 32 links, each with a PDF icon and a state name: Alabama, Idaho, Missouri, Pennsylvania, Alaska, Illinois, Montana, Rhode Island, Arizona, Indiana, Nebraska, South Carolina, Arkansas, Iowa, Nevada, South Dakota, California, Kansas, New Hampshire, Tennessee, Colorado, Kentucky, New Jersey, Texas, Connecticut, Louisiana, New Mexico, Utah, Delaware, Maine, New York, Vermont, District of Columbia, Maryland, North Carolina, Virginia, Florida, Massachusetts, North Dakota, and Washington.

# Prescription Drug Monitoring Programs

- **Benefits – inform, intervene, investigate (per AMA)**
  - access a patient’s prescription history for opioids and other controlled substances quickly during the patient encounter
  - determine whether patients have received opioids and other controlled substances from other providers/dispensers
  - evaluate and manage patients with persistent pain more effectively
  - create alerts when a patient reaches certain thresholds
  - identify the need to counsel the patient
  - be prompted when co-prescribing naloxone may be clinically indicated
  - identify other prescribers to help coordinate care and follow-up activities

# Prescription Drug Monitoring Programs

- **CMS recommends considering the following actions to maximize the efficiency and effectiveness of PDMPs:**
  - become familiar with your State’s specific compliance and reporting requirements and follow them
  - offer data submission and retrieval training to qualified personnel
  - incorporate PDMP database screening into workflow schematics
  - integrate PDMP monitoring into voluntary, comprehensive compliance programs to maximize PDMP use and improve patient care by reducing prescription drug diversion, misuse and abuse

# Provider Strategies for Diversion Response

- **Stay abreast of change**
  - specific physician training in pain management and addictionology
  - AMA and Office of National Drug Control Policy encourage better physician education
  - Only 19% of physicians receive training in prescription drug diversion in medical school
  - Attend educational seminars
  - Read current literature on strategies to minimize drug abuse
- **Report non-medical drug use**
  - Medicaid/Medicare fraud control, local law enforcement, DEA
- **Address substance abuse issues with patients**
  - be respectful
  - be firm
- **Enforce medication agreement**

# Facility Strategies for Diversion Response

- **Educate employees**
  - Employers are required to make employees aware of federal regulation 21 CFR 1301.90 where employees with knowledge of illegal drug activity are expected to be mandatory reporters.
  - Let employees know that hospital's overall operations and liabilities are more important than one individual and hospital cannot afford to be placed at risk by people violating drug laws.
  - Employees violating these laws/policies should know that there are repercussions for violations.

# Facility Strategies for Diversion Response

- Immediately remove person from patient contact
- Notify keeper of drugs regarding status of employee
- Conduct diversion investigation – document everything
  - suspension pending conclusion of investigation?
  - interview staff who made report of suspicious activity
  - audit of drugs
  - review of records
  - interview suspected diverter
  - test the explanation
  - drug testing
  - involve risk management
  - expand review of transactions if necessary
  - keep track of expenses of investigation

# Facility Strategies for Diversion Response

- Report non-medical drug use to relevant entities
  - law enforcement
  - DEA
    - (report theft/significant loss of controlled substances within one day – [http://www.deadiversion.usdoj.gov/21cfr\\_reports/theft/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html))
  - licensing agencies (most states require mandatory reporting)
  - HHS-OIG (HHSTips@oig.hhs.gov)
- Determine employment disposition
- Consider billing implications caused by diversion – may need to rebill
- Notify patients if necessary
- Ensure hospital representation on medical staff/peer review entities

# Facility Strategies for Diversion Response

- Ensure consistent treatment
- Include language in hospital contracts requiring notification of impairment or disciplinary issues
- Review employees on probation or being monitored by licensing board
- If diversion involves medications that are administered with syringes, monitor infection issues
- Consider pursuing action against diverter to recover losses



# Best Practices – Mayo Clinic’s 77 points

eAppendix

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

1

No	Best Practice Element	PRIORITY TIER
	Legend: CS-Controlled Substances; DEA-Drug Enforcement Administration; ADM-Automated Distribution Machine	
<i>Tier 1 - Essential element and should be in place</i>		
<i>Tier 2 - Recommended element. Progress toward implementation should be made over time</i>		

**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

## Best Practices

**Mayo Clinic suggests ten ways to halt drug diversion by healthcare workers:**

- 1. Have a zero tolerance policy for theft of any drugs from anywhere.**
- 2. Make friends with law enforcement agencies such as U.S. Drug Enforcement officials.**
- 3. Employ a 24-hour diversion hotline for workers to report suspicious behavior.**
- 4. Assemble a team like the Mayo's D-DiRT.**
- 5. Employ a waste retrieval system everywhere injectable opioids are used in patient care.**

## Best Practices

6. Throw out assumptions about healthcare workers who divert drugs.
7. Know and keep track of areas throughout your organization that are the most vulnerable.
8. Report it.
9. Make sure hospital leaders understand that as healthcare systems get better at creating barriers to theft, the theft will happen closer and closer to patient care.
10. Offer treatment once an employee is caught and terminated.

Source: <http://www.healthleadersmedia.com/quality/10-ways-halt-drug-diversion-healthcare-workers>.

# Reporting Requirements



# Reporting Requirements

- **Internal reporting by employee/staff**
  - patient safety concerns require suspected impairment or diversion be reported
  - employees should understand that concerns will be taken seriously and confidentially
- **Why many don't report:**
  - uncertainty or disbelief
  - turning a blind eye
  - hoping the problem will go away – isolated event
  - concern about what getting involved will mean for them
- **Failure to report enables the diverter**

# Reporting Requirements

- Prescribing physicians should be familiar with federal and state prescribing laws - most stringent law takes precedence
- Must report theft of controlled substances to DEA immediately
- Other reporting:
  - State licensure board
  - Local law enforcement -- some states mandate reporting of crime
  - State Pharmacy Board
  - Possibly FDA/OCI
  - OIG
  - State Medicaid fraud control unit

# HIPAA and Privacy Issues



But she did and the pharmacy had to pay \$1.4 Million

# Reporting a Crime and Privileged Information

- **Information communicated to a physician in an effort to procure unlawfully a prescription drug is not privileged communication.**
  - The physician no longer is bound by the physician-patient relationship.
  - However, the physician is not obligated to report the criminal behavior.



# HIPAA and Privacy

- Under 45 C.F.R. §164.512, a covered entity may disclose PHI without receiving permission of the individual for national priority purposes including:
  - Disclosure required by law
  - Public health activities
  - Health oversight activities
  - Law enforcement
- Under §164.506, disclosures are also allowed for treatment, payment, and health care operations.
  - Health care operations include (i) quality assessment and improvement activities, including case management and care coordination, and (ii) fraud and abuse detection and compliance activities.

## HIPAA and Privacy

- In disclosing dispensed prescription drug data pursuant to 45 C.F.R. §164.512(b), (d), (f), or health care operations under 45 C.F.R. §164.506, a covered entity must limit the PHI to that minimally necessary to accomplish the intended purpose of the use, disclosure or request. 45 C.F.R. §164.502(b)(1).
- Not authorized to turn over the patient's entire chart.

## **HIPAA and Privacy When State Laws Mandate Reporting**

- **HIPAA generally preempts contrary state law.**
- **HIPAA identifies several exceptions – a contrary state law will not be preempted if the Secretary of HHS determines that the provision:**
  - **is necessary (i) to prevent fraud and abuse related to the provision of or payment for health care, or . . . (iv) for the purposes of serving a compelling need related to public health (45 CFR 160.203(a)(1)) or**
  - **has as its principal purpose the regulations of the manufacture, registration, distribution, dispensing or other control of any controlled substance (45 CFR 160.203(a)(2)) or**
  - **provides for reporting of disease or injury . . . or for the conduct of public health surveillance, investigation or intervention (45 CFR 160.203(c)).**

# The Impact of the Affordable Care Act



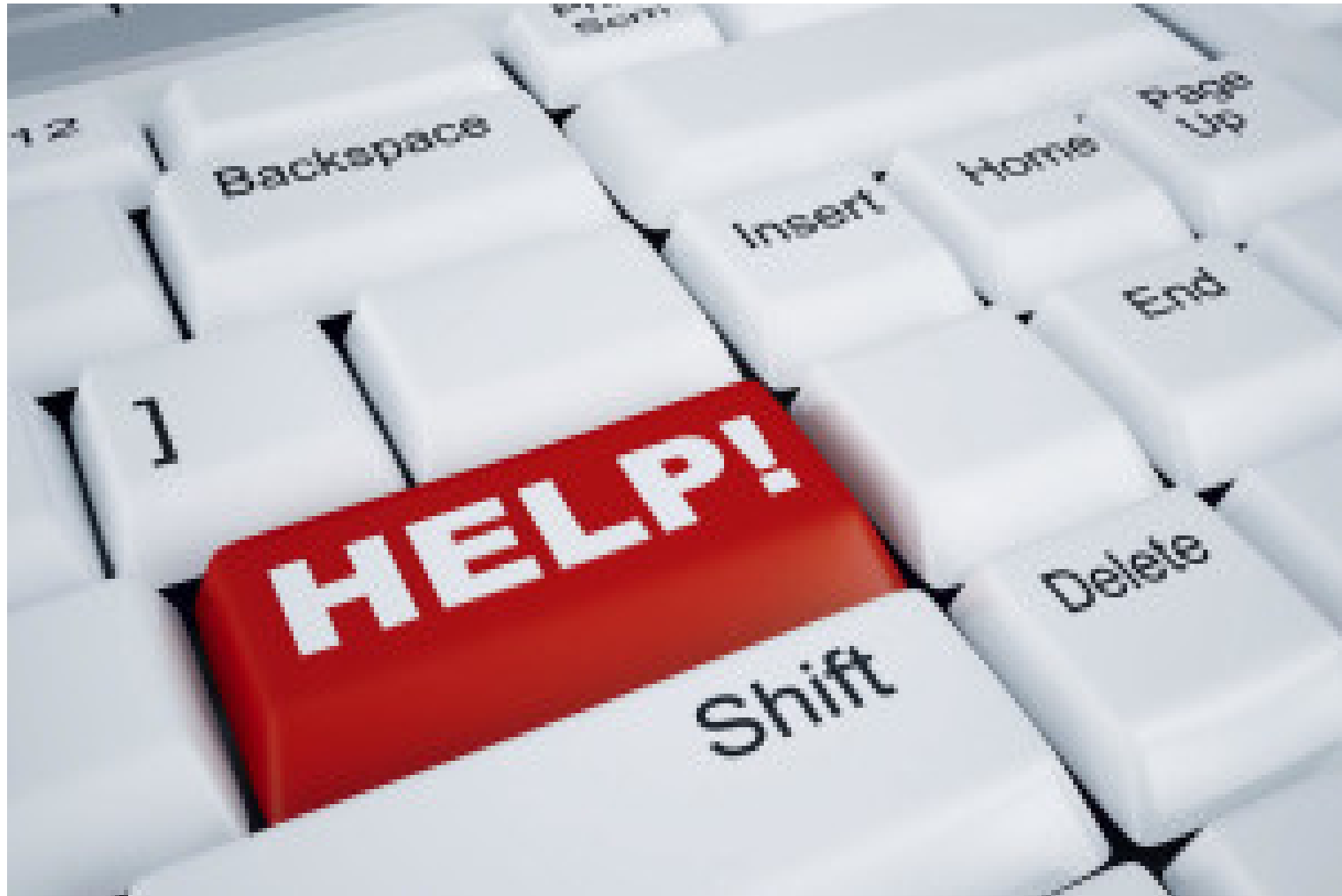
# The Impact of the Affordable Care Act

- The ACA grants States significant new authority to fight fraud and abuse in the area of drug diversion including the ability to:
  - establish enhanced oversight for new providers
  - establish periods of enrollment moratoria or other limits on providers identified as being high risk for fraud and abuse
  - establish enhanced provider screening
  - require States to suspend payment when there is a credible allegation of fraud which may include evidence of overprescribing by doctors, overutilization by recipients or questionable medical necessity.

# The Impact of the Affordable Care Act

- **ACA provides more stringent penalties for submitting false statements and false claims**
  - includes knowingly submitting false information related to ordering or prescribing prescription drugs
- **Requires State Medicaid agencies to suspend payments automatically for physicians and other providers who have credible allegations of fraud against them.**
- **Requires that if providers are terminated for cause by Medicare or any Medicaid agency, they must be terminated by Medicaid and the Children's Health Insurance Program in all states.**

# Additional Resources



# Additional Resources

- American College of Preventive Medicine, “Use, Abuse, Misuse & Disposal of Prescription Pain Medication Clinical Reference,”  
<http://www.acpm.org/?UseAbuseRxClinRef>.
- Missouri Bureau of Narcotics & Dangerous Drugs, “Drug Diversion in Hospitals: A Guide to Preventing and Investigating Diversion Issues,”  
<https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF-8#q=drug%20diversion%20in%20hospitals>.
- DEA Diversion Control Division, “Theft or Loss of Controlled Substances,”  
[https://www.deadiversion.usdoj.gov/21cfr\\_reports/theft/index.html](https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html).
- Department of Health and Human Services, Centers for Medicare & Medicaid Services, “Prescription Drug Monitoring Programs: A Resource to Help Address Prescription Drug Abuse and Diversion,”  
<https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se1250.pdf>.



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## Healthcare

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Holland & Hart provides a comprehensive health law practice to assist clients in navigating the dynamic healthcare industry. In recent years, healthcare has experienced dramatic change, extraordinary competition, and increasingly complex regulation. Our experienced attorneys and staff skillfully respond to these challenges. By remaining on the forefront of healthcare law, we are able to provide coordinated services to meet the business, transactional, litigation, and regulatory needs of our clients.

Our healthcare clients include hospitals, individual medical providers, medical groups, managed care organizations (MCOs), third-party administrators (TPAs), health information exchanges (HIEs), practice managers and administrators, independent practice associations (IPAs), owners of healthcare assets, imaging centers, ambulatory surgery centers, medical device and life science companies, rehabilitation centers, and extended and eldercare facilities. We have also assisted clients with the significant changes enacted by the Affordable Care Act, including advice regarding employer and health plan compliance, health insurance exchanges, accountable care organizations, and nonprofit cooperative health plans.

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### - Publications

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*Holland & Hart News Update*  
Author(s): **Patricia Dean**

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HIPAA Resources

# Additional Resources

- *Health Law Basics* monthly webinar series
  - Past webinars available at [www.hhhealthlawblog.com](http://www.hhhealthlawblog.com)
- *Healthcare Update* and *Health Law Blog*
  - Under “Publications” at [www.hollandhart.com](http://www.hollandhart.com).
  - E-mail me at [tlocke@hollandhart.com](mailto:tlocke@hollandhart.com)

# Questions?

**Teresa D. Locke**

**Holland & Hart LLP**

**[tlocke@hollandhart.com](mailto:tlocke@hollandhart.com)**

**(303) 295-8480**

