# 2019 Casualty Loss Reserve Seminar

# Opioid Issues Affecting Risk Decisions

Alix C. Michel, Esq. David J. Ward, Esq.

## Today's Presenters





Alix Michel, JD
Michel & Ward, PC.
Instructor on "The Legal
Issues Surrounding the
Rx Drug Epidemic"

David Ward, JD
Michel & Ward, PC.
Instructor on "The Legal
Issues Surrounding the
Rx Drug Epidemic"

## **Educational Objectives for Attendees**

- I. Describe information learned from the National Opioid Litigation and its potential impact on risk decisions.
- II. Describe information learned from healthcare provider opioid diversion investigations/lawsuits and its potential impact on risk decisions.

I. Information learned from National Opioid Litigation and its potential impact on risk decisions.

File Name: 19a0133p.06

### UNITED STATES COURT OF APPEALS

### FOR THE SIXTH CIRCUIT

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION.

HD MEDIA COMPANY, LLC (18-3839); THE W.P. COMPANY, LLC, dba The Washington Post (18-3860), Intervenors-Appellants,

Nos. 18-3839/3860

ν.

UNITED STATES DEPARTMENT OF JUSTICE; DRUG ENFORCEMENT ADMINISTRATION,

Interested Parties-Appellees,

DISTRIBUTOR DEFENDANTS; MANUFACTURING DEFENDANTS; CHAIN PHARMACY DEFENDANTS,

Defendants-Appellees.

June 21, 2019

Appeal from the United States District Court for the Northern District of Ohio at Cleveland

The crux of the appeal was the question of who should receive access to the data in the DEA's ARCOS database, and the related question of how disclosure of the ARCOS data would further the public's interest in understanding the causes, scope, and context of the opioid epidemic. The trial Judge had entered a blanket protective order that resulted in the Plaintiffs receiving the ARCOS data, but also ordered (in blanket fashion) that the information could not be made public.

The 6th Circuit Judges note that the Intervenors [The Washington Post] convincingly argue that "[t]he dosage of the pill is of immense public interest, as people want to know whether their neighborhood was supplied with 5 mg oxycodone pills, such as Percocet, which are generally prescribed for minor dental procedures and routine injuries, or 30 mg oxycodone tablets, which have been shown to be the most abused and diverted pills[.]"

The 6<sup>th</sup> Circuit Judges also noted that "specific transactional data has proved extremely effective and consequential in calling attention to the horrors of the opioid crisis'" and that "[T]he ARCOS data does not contain sensitive information like trade secrets, and the age of the data makes the risk of anticompetitive harm slight and speculative."

Ultimately, the 6<sup>th</sup> Circuit vacated the trial Judge's Protective Order and ordered him [the trial Judge] to fashion a new Protective Order which is not a blanket one.

# Drilling into the DEA's pain pill database

By The Washington Post Updated July 21, 2019

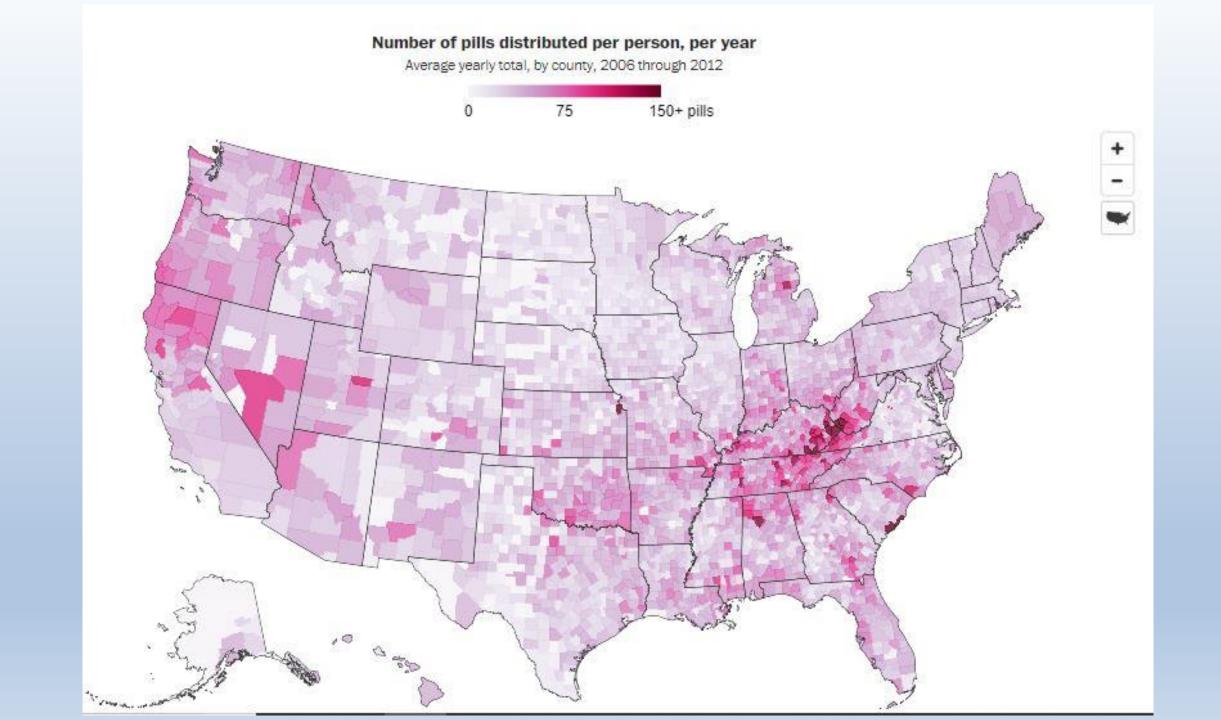
For the first time, a database maintained by the Drug Enforcement

Administration that tracks the path of every single pain pill sold in the United

States — by manufacturers and distributors to pharmacies in every town and city

— has been made public.

The Washington Post sifted through nearly 380 million transactions from 2006 through 2012 that are detailed in the DEA's database and analyzed shipments of oxycodone and hydrocodone pills, which account for three-quarters of the total opioid pill shipments to pharmacies. The Post is making this data available at the county and state levels in order to help the public understand the impact of years of prescription pill shipments on their communities.



Texas ▼ Travis County ▼

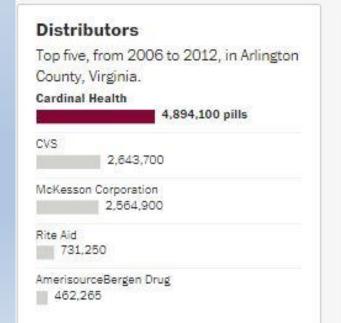
- From 2006 to 2012 there were 176,320,805 prescription pain pills, enough for
   25 pills per person per year, supplied to Travis County, Tex.
- 60,456,780 of the pills were distributed by Walgreen Co and 77,475,038 were manufactured by Actavis Pharma, Inc.
- WALGREEN CO., AUSTIN pharmacy received the highest number of pills. See a
  map of pharmacies in Travis County, Tex.







- From 2006 to 2012 there were 12,494,089 prescription pain pills, enough for 9
  pills per person per year, supplied to Arlington County, Va.
- 4,894,100 of the pills were distributed by Cardinal Health and 7,510,700 were manufactured by SpecGx LLC.
- VIRGINIA CVS PHARMACY, L.L.C., ARLINGTON pharmacy received the highest number of pills. See a map of pharmacies in Arlington County, Va.





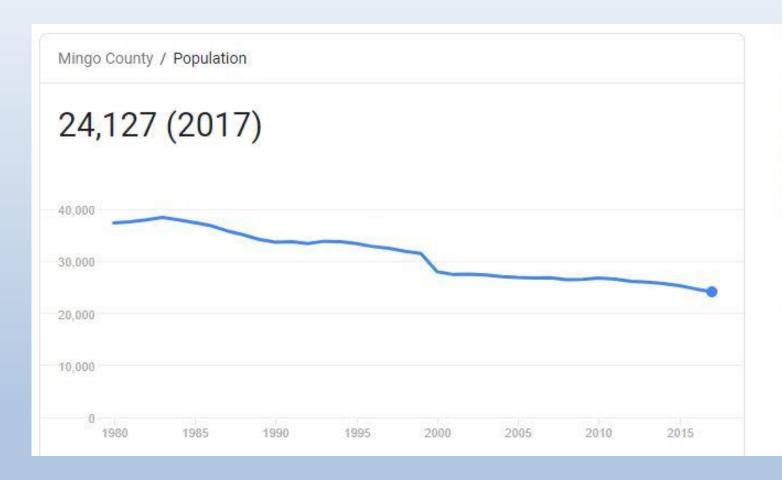


West Virginia ▼ Mingo County ▼

- From 2006 to 2012 there were 38,269,630 prescription pain pills, enough for
   203 pills per person per year, supplied to Mingo County, W.Va.
- 11,390,120 of the pills were distributed by Miami-Luken and 29,548,720 were manufactured by Actavis Pharma, Inc.
- STROSNIDER, KERMIT pharmacy received the highest number of pills. See a map of pharmacies in Mingo County, W.Va.





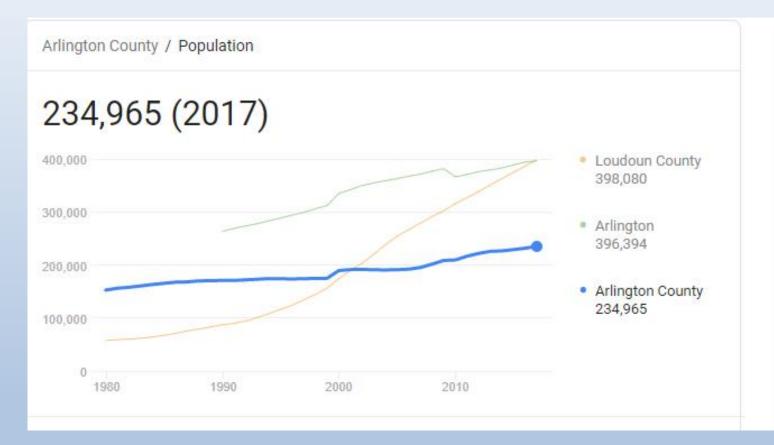




### Mingo County

County in West Virginia

Mingo County is a county in the U.S. state of West Virginia. As of the 2010 census, the population was 26,839. Its county seat is Williamson. Created in 1895, Mingo is West Virginia's newest county, named for the historic Iroquoian Mingo people. Wikipedia





### **Arlington County**

County in Virginia

Arlington County is a county in the Commonwealth of Virginia, often referred to simply as Arlington or Arlington, Virginia. The county is situated in Northern Virginia on the southwestern bank of the Potomac River directly across from the District of Columbia, of

## Opioid Distributors Propose \$10 Billion to End State Claims

By Jef Feeley | August 7, 2019

McKesson Corp., Cardinal Health Inc. and AmerisourceBergen Corp. have proposed paying \$10 billion to settle claims they helped to fuel the U.S. opioid epidemic — the first sign of progress in resolving state lawsuits against the drug distributors, according to people familiar with negotiations.

### **COVERAGE?**

Cincinnati Ins. Co. v. H.D. Smith, LLC., No. 15-2825 (7th Cir. 2016)

West Virginia sued pharmaceutical distributors, seeking to hold them liable for contributing to the state's epidemic of prescription drug abuse. The complaint alleged that certain pharmacies, "pill mills," knowingly provided citizens with hydrocodone, oxycodone, codeine, and other prescription drugs, not for legitimate uses, but to fuel and profit from their addictions. The state contends that those pharmacies ordered drugs in quantities so large that the distributors should have known they would be used for illicit purposes.

H.D. Smith, a distributor, had a general commercial liability insurance policy issued by Cincinnati Insurance. The policy covered damages that H.D. Smith became legally obligated to pay "because of bodily injury," defined as "bodily injury, sickness or disease sustained by a person, including death." "[D]amages because of bodily injury" include "damages claimed by any person or organization for care, loss of services or death resulting at any time from the bodily injury."

Cincinnati refused to defend the suit and obtained a declaratory judgment. The Seventh Circuit reversed summary judgment. The plain language of the policy requires Cincinnati to defend a suit brought by a plaintiff to recover money paid to care for someone who was injured by H.D. Smith. West Virginia's suit fits that description.

### **Takeaways**

How can you or your clients use that data?

II. Information learned from healthcare provider opioid diversion investigations/lawsuits and its potential impact on risk decisions.



Traveling medical technician who was charged with causing an outbreak of Hep C in New Hampshire.

- 2003 Kwiatkowski became a Radiology Technician in his home state of Michigan.
- 2007 Kwiatkowski Began Working as a Travelling Technician
- January 2007 September 2007 Kwiatkowski Worked at Oakwood Annapolis Hospital in Wayne, Michigan as a medical technician.
- **November 2007 February 2008** Kwiatkowski Worked at Saint Francis Hospital in **Poughkeepsie, New York.**
- March 17, 2008 May 7, 2008 (47 Days) Kwiatkowski worked at UMPC Presbyterian in Pittsburgh, Pennsylvania as a medical technician.
- May 7, 2008 A UPMC hospital employee observed Kwiatkowski enter an operating room, lift his shirt, put a syringe in his pants, and exit the room. Officials report that empty syringes were found in his pockets and locker. His blood was tested and Fentanyl and other drugs were found in his system. Kwiatkowski was fired that day.

May 2008 - November 2008 Kwiatkowski moved on to Maryland and worked at Baltimore Veterans Affairs Medical Center.

**December 2008 - February 2009** Kwiatkowski Worked for **Southern Maryland Hospital**.

March 9, 2009 - June 27, 2009 Kwiatkowski Worked for Maryvale Hospital in Arizona. It is reported that he worked in the cath lab.

July 10, 2009 - January 9, 2010 Kwiatkowski Worked for Johns Hopkins in Baltimore, Maryland.

January 2010 - March 2010 Kwiatkowski Worked for Maryland General Hospital.

March 22, 2010 - April 2, 2010 Kwiatkowski Worked for Arizona Heart Hospital. An incident took place where Kwiatkowski was found passed out in bathroom stall with Fentanyl syringe floating in toilet. He was fired and the staffing agency that employed Kwiatkowski at the time, SpringBoard, reported the incident to the American Registry of Radiologic Technologists, according to a spokeswoman for the agency. The ARRT said that they did not punish Kwiatkowski because they did not have firsthand evidence of the 2010 incident. The director of the Arizona Radiation Regulatory Agency said officials stopped their investigation when Kwiatkowski moved out of state.

**April 7, 2010 - April 30, 2010** Kwiatkowski Worked for Temple University Hospital in **Philadelphia**, **Pennsylvania**.

May 2010 - September 2010 Kwiatkowski Worked for Hays Medical Center, Hays, Kansas.

October 2010 - March 2011 Kwiatkowski Worked for Houston Medical Center in Warner Robins, Georgia.

**April 2011 - May 2012** Kwiatkowski worked for Exeter Hospital in **New Hampshire.** 

May 2012 - 3 Doctors at Exeter reported that their patients who were recently treated in the Cath Lab tested positive for the Hepatitis C Virus. The State began an investigation...

▲ HIDE CAPTION

Exeter Hospital has settled 32 of the 33 lawsuits brought against the hospital and other agencies by patients infected in the hepatitis C outbreak of 2012. - Rich Beauchesne photo, file

## Sample Patient Letter B – Disease Transmission Identified, Issued by Health Department

Dear Sir or Madam,

| ln           | (DATE) the HEALTH DEPARTMENT          | NAME began investigating reports of recent   |
|--------------|---------------------------------------|--|
| (hepatitis C | , hepatitis B, and HIV) among severa  | I people who had undergone procedures at the |
| MEDICAL C    | ENTER NAME, located at                | Through the investigation, we identified an  |
| unsafe pract | tice, which may have exposed patients | to the blood of other clinic patients.       |

This letter serves as notification that you have been identified in clinic records as a former patient of the clinic who was placed at risk for possible exposure to bloodborne pathogens. As a precaution, and in order to take appropriate steps to protect your health, we recommend that you get blood tests for hepatitis C, hepatitis B, and HIV. We are committed to providing you with support through every step of this process.

It is not possible to determine specifically which people were exposed, but all patients who received injected medicine at the center were placed at increased risk for exposure. As a result, we are notifying all people who received injected medications between DATE and DATE. Our investigation has identified that the infections were associated with the unsafe injection practices and not with the procedures themselves.

People infected with viruses such as hepatitis B, hepatitis C, or human immunodeficiency virus (HIV) may not have symptoms for many years, so you may have been infected and not know it. Even though you may not feel ill or remember getting sick, you should get a blood test in order to make sure you are not infected. Although testing cannot determine where you were infected (at the clinic or at another location), knowing whether you are infected is important, so you can be treated if your test results are positive.

We recommend that you are tested at your own healthcare provider's office, as he or she will be able to best advise you on what to do if your blood test reveals that you have been infected with hepatitis B, hepatitis C, or HIV. If you do not have a regular healthcare provider, a list of resources is available on the HEALTH DEPARTMENT NAME website at <a href="http://www.website.com">http://www.website.com</a>. Wherever you choose to be tested, be sure to bring this letter with you and give it to your healthcare provider. Information for your provider is included at the end of this letter.

We understand that this may be an upsetting situation for you, and that you and your family may have additional questions or concerns about the information you have received. To help answer them, we have established a hotline at (555) 555-5555. The hotline will be available starting DATE. You may also obtain additional information on the HEALTH DEPARTMENT NAME website at <a href="http://www.website.com">http://www.website.com</a>.

NOTA: Para obtener esta información en español llame al (555) 555-5555 o visite el sitio web <a href="http://www.website.com">http://www.website.com</a>.

Sincerely,

NAME

Chief Health Officer



### **Potential Legal Claims**

- 1)Battery
- 2) Lack of Informed Consent
- 3) Medical negligence (breach of the standard of care)
- 4) Negligent Infliction of Emotional Distress

#### [J-74A-2017, J-74B-2017, J-74C-2017, J-74D-2017, J-74E-2017, J-74F-2017, J-74G-2017 and J-74H-2017] IN THE SUPREME COURT OF PENNSYLVANIA WESTERN DISTRICT

SAYLOR, C.J., BAER, TODD, DONOHUE, DOUGHERTY, WECHT, MUNDY, JJ.

THOMAS D. WALTERS AND CLARA M. WALTERS, HIS WIFE

: No. 15 WAP 2017

V.

Appeal from the Order of the Superior Court entered July 21, 2016 at No. 309 WDA 2015, affirming in part and reversing in part the Order of the Court of Common Pleas of Allegheny County entered February 6, 2015 at No. GD-12-018339 and remanding.

UPMC PRESBYTERIAN SHADYSIDE; MAXIM HEALTHCARE SERVICES, INC., AND MEDICAL SOLUTIONS L.L.C. D/B/A MEDICAL SOLUTIONS

ARGUED: October 18, 2017

APPEAL OF: MAXIM HEALTHCARE SERVICES, INC.

LINDA FICKEN AND WILLIAM FICKEN, HER HUSBAND

No. 16 WAP 2017

V.

Appeal from the Order of the Superior Court entered July 21, 2016 at No. 310 WDA 2015, affirming in part and reversing in part the Order of the Court of Common Pleas of Allegheny County entered February 6, 2015 at No. GD-12-016165 and remanding.

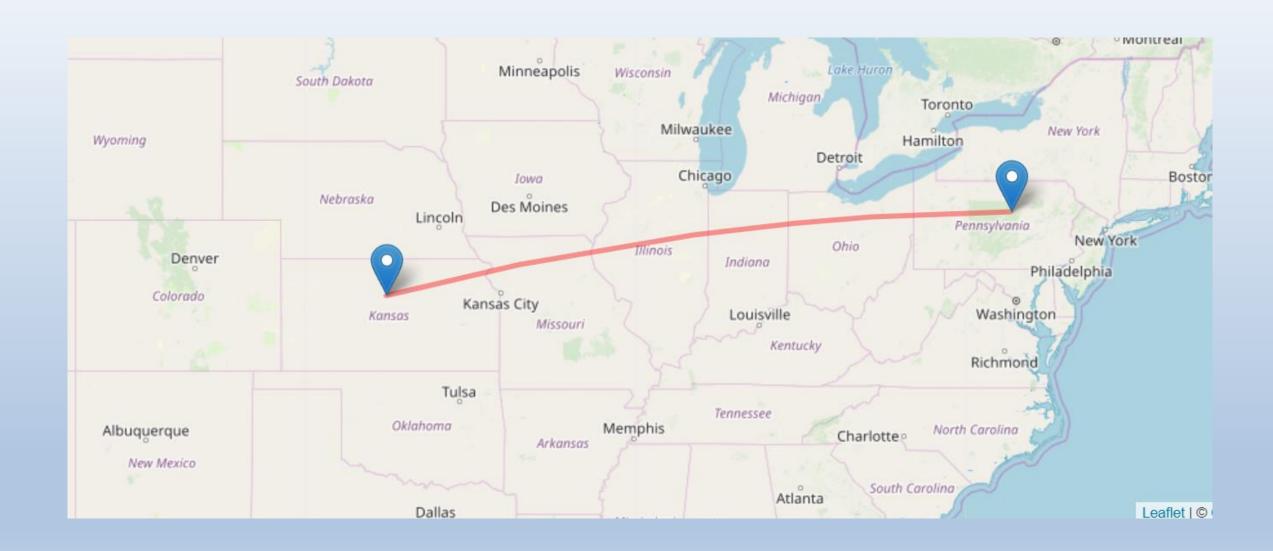
UPMC PRESBYTERIAN SHADYSIDE; MAXIM HEALTHCARE SERVICES, INC., AND MEDICAL SOLUTIONS L.L.C. D/B/A MEDICAL SOLUTIONS

ARGUED: October 18, 2017

APPEAL OF: MAXIM HEALTHCARE SERVICES, INC.

WANDA J. BRAUN AND EDWIN J. BRAUN, HER HUSBAND No. 17 WAP 2017

Appeal from the Order of the Superior Court entered July 21, 2016 at No. 311 WDA 2015, affirming in part and reversing in part the Order of the Court



### OPINION

DECIDED: JUNE 19, 2018

#### JUSTICE WECHT

In these consolidated cases, we granted allowance of appeal to determine whether and to what extent a hospital and a health care staffing agency have a legal duty to prevent a terminated employee from causing harm to patients at another health care facility.

Plaintiffs claim that David Kwiatkowski, a radiology technician formerly employed at UPMC Presbyterian Hospital ("UPMC"), who was placed there by staffing agency Maxim Healthcare Services, Inc. ("Maxim"), engaged in the diversion and substitution of intravenous fentanyl. Specifically, Kwiatkowski injected himself with fentanyl from a preloaded syringe, refilled the syringe with saline or another substance, and then replaced the now-contaminated syringe where it could be used by others to inject patients. In doing so years later at a Kansas hospital, Kwiatkowski allegedly communicated hepatitis C to Plaintiffs, who were patients at that hospital.

Pursuant to federal regulation, UPMC (but not Maxim) indisputably had a legal obligation to report the diversion of controlled substances to the United States Department of Justice's Drug Enforcement Administration ("DEA"). UPMC failed to do so. The Superior Court determined that Plaintiffs established that both UPMC and Maxim (collectively, "Defendants") had a duty to report Kwiatkowski's misconduct to the

DEA and to "law enforcement," and that Defendants' failure to do so could provide a basis for negligence claims. See Walters v. UPMC Presbyterian Shadyside, 144 A.3d 104 (Pa. Super. 2016). We affirm the Superior Court's ruling with respect to UPMC (albeit with a modest caveat), and we reverse the Superior Court's ruling to the extent it imposed the same duty upon Maxim.

## University of Michigan Health System to pay record drug diversion settlement Posted Aug 30, 2018

ANN ARBOR, MI - The University of Michigan Health System has agreed to pay the United States \$4.3 million as part of a settlement resolving allegations that it violated certain provisions of the Controlled Substances Act...

It is the nation's largest settlement of its kind involving allegations of drug diversion at a hospital...

The DEA began its investigation after two tragic incidents occurred in December 2013 involving two UMHS employees - a nurse and an anesthesiology resident...

On a single day that December, <u>a nurse</u> and <u>doctor</u> both overdosed on stolen pain <u>medication</u> in different areas of the sprawling University of Michigan Health System. Both were found in hospital bathrooms with drugs meant for patients injected into their own bodies.

## Grand Rapids nursing facility staffer diverted 1,900 opioid pills, report says

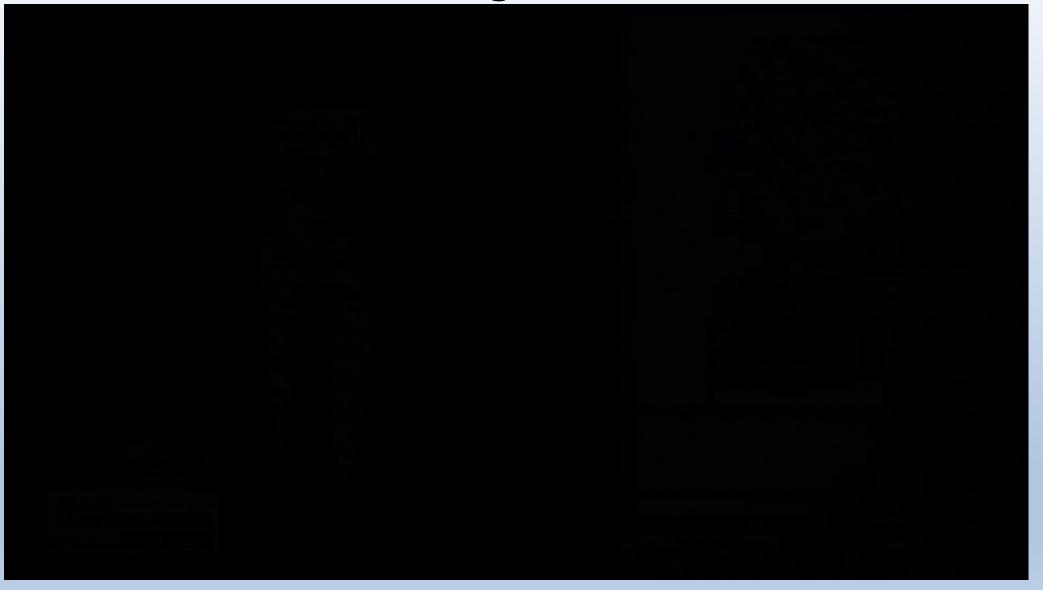
By **John Lundy** on Dec 26, 2018 at 5:34 p.m.

An employee at a Grand Rapids nursing facility kept more than 1,900 opioid tablets intended for clients for herself over two years, according to a state agency's investigation.

The facility's clients sometimes went without pain medications as a result, according to the report.

The investigation by the Minnesota Department of Health's Office of Health Facility Complaints also found that other staff members were aware of the theft but didn't report it because of fear of retaliation by the employee and by management at the facility, Majestic Pines Senior Living.

## **A Growing Problem**



#### 2019 DRUG DIVERSION DIGEST

47.2 million doses lost due to healthcare employee misuse and theft in 2018

Protenus, Inc.

## One-third of reported incidents took place in a hospital or medical center setting

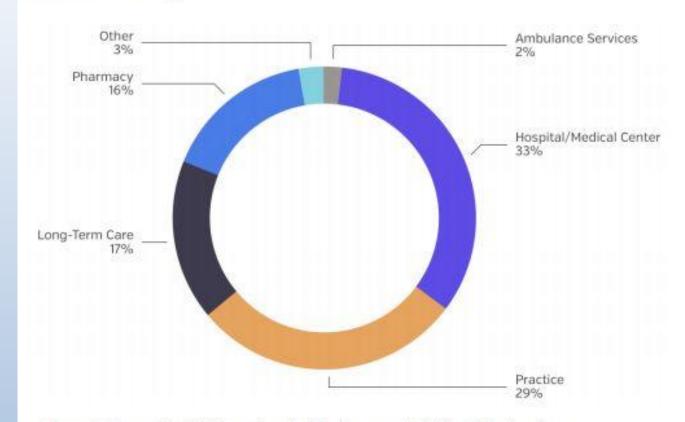


Figure 4: Types of institutions where incidents occurred, 2018 public diversion incidents

Of the 324 incidents publicly reported in 2018, there were available data on institution type for 303 incidents. The single largest category of institution affected by diversion was hospital and medical center category, which accounted for 34% of the publicly reported incidents.

# 2019 The Joint Commission, Division of Healthcare Improvement

Issue: In every organization, drug diversion is a potential threat to patient safety. Risks to patients include inadequate pain relief and exposure to infectious diseases from contaminated needles and drugs, compounded by potentially unsafe care due to the health care worker's impaired performance. Furthermore, diversion may cause undue suffering to patients who don't receive analgesic relief, can be costly to an organization by damaging its reputation, and may lead to major civil and criminal monetary penalties.

Statistics from both the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the American Nurses Association (ANA) suggest that about 10 percent of health care workers are abusing drugs. Due to the availability of and access to medications in health care organizations, diversion of controlled substances can be difficult to detect and prevent without a comprehensive controlled substances diversion prevention program

#### Nurses struggling with addiction turn to hospital drugs

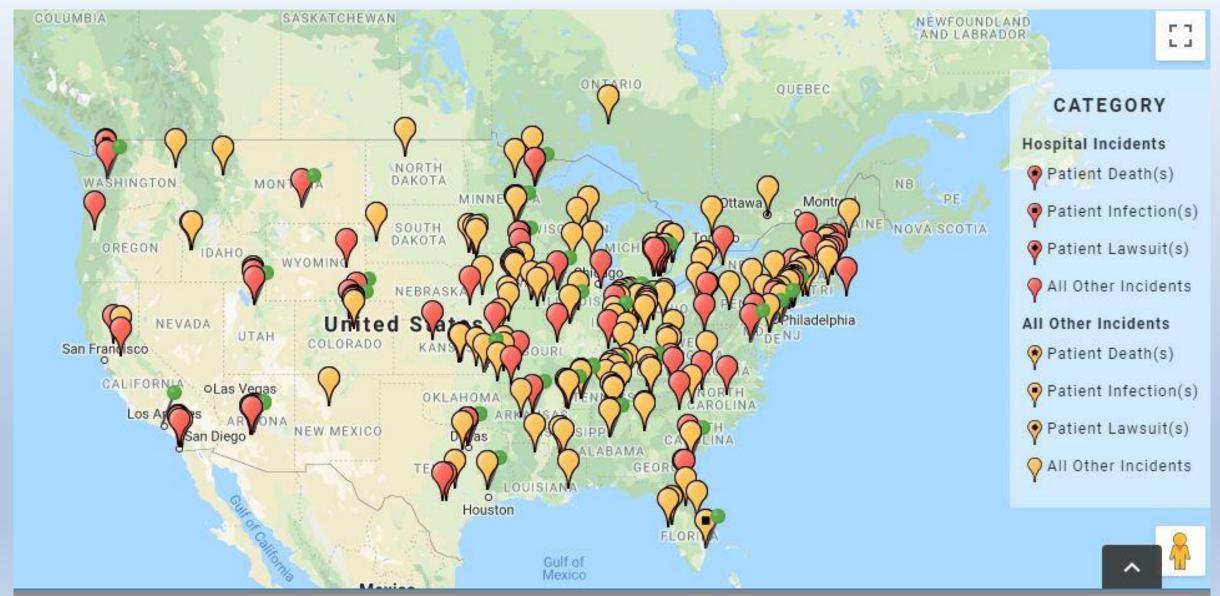
Boston Herald.com July 27, 2019

According to Ann Scales, spokeswoman at the Massachusetts Department of Public Health, 393 nurses have enrolled in Massachusetts's Substance Abuse Recovery Program (SARP) since 2009.

So far this year, 10 nurses have enrolled in SARP and another 24 have applied, meaning the program is on track to more than double last year's enrollment of 16 nurses.

Cases of drug diversion at Boston-area hospitals have resulted in giant settlements for some institutions, most notably at Massachusetts General Hospital, which agreed to pay \$2.3 million to resolve drug diversion allegations in **2015 after two of its nurses stole nearly 16,000 pills from automated dispensing machines**, according to the United States Department of Justice.

#### Healthcare Diversion. Org



Pennsylvania, West Virginia, Michigan were all included in a DOJ-led initiative started in 2017 that assigned Assistant US Attorneys to twelve states for a three-year term. Their job is to focus solely on investigating and prosecuting healthcare fraud including "pill mill schemes and pharmacies that unlawfully divert or dispense prescription opioids of illegitimate purposes."

#### Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit

Attorney General Jeff Sessions today announced the formation of the Opioid Fraud and Abuse Detection Unit, a new Department of Justice pilot program to utilize data to help combat the devastating opioid crisis that is ravaging families and communities across America.

Speaking at the Columbus Police Academy today, Attorney General Sessions said that the new Opioid Fraud and Abuse Detection Unit will focus specifically on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to this prescription opioid epidemic.

Additionally, as part of the program, the Department will fund twelve experienced Assistant United States Attorneys for a three year term to focus solely on investigating and prosecuting health care fraud related to prescription opioids, including pill mill schemes and pharmacies that unlawfully divert or dispense prescription opioids for illegitimate purposes.

The following districts have been selected to participate in the program:

- 1. Middle District of Florida.
- 2. Eastern District of Michigan,
- 3. Northern District of Alabama,
- 4. Eastern District of Tennessee,
- 5. District of Nevada,
- 6. Eastern District of Kentucky,
- 7. District of Maryland,
- 8. Western District of Pennsylvania,
- 9. Southern District of Ohio,
- 10. Eastern District of California,
- 11. Middle District of North Carolina, and
- 12. Southern District of West Virginia.

#### **Emerging trend:**

# Baltimore County physician assistant admits to overprescribing opioids, having sexual contact with patients BALTIMORE SUN | JUL 17, 2019 | 1

A Baltimore County physician assistant pleaded guilty to conspiracy to distribute several prescription drugs as he admitted he helped prescribe several opioids, including fentanyl, not for legitimate medical purposes, and engaged in sexual contact with some of his female clients.

William Soyke, 66, of Hanover, Pa., pleaded guilty to conspiracy to distribute and dispense oxycodone, fentanyl, methadone and alprazolam while he was a physician assistant at the Rosen-Hoffberg Rehabilitation and Pain Management clinic in Towson.

#### **Disclaimer**

This presentation is provided with understanding that the presenters are not rendering legal advice or services. Laws are constantly changing, and each federal law, state law, and regulation should be checked by legal counsel for the most current version. We make no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the information contained in this presentation. Do not act upon this information without seeking the advice of an attorney.

This outline is intended to be informational. It does not provide legal advice. Neither your attendance nor the presenters answering a specific audience member question creates an attorney-client relationship.