

It's Time to Explore Emerging Liabilities in the Opioid Epidemic

Date of Webinar: October 30, 2017

Time(s) of Webinar:

2–3 p.m. Eastern
1–2 p.m. Central
Noon–1 p.m. Mountain
11 a.m.–noon Pacific

Learning Objectives

This presentation will enable participants to:

- Examine new risk areas emerging due to the ongoing opioid crisis
- Analyze case studies which illustrate unanticipated opioid risks
- Explore resources which mitigate risk from opioid prescribing liability

Presenters

Ann Lambrecht, RN, BSN, JD, FASHRM

Ann Lambrecht is a Senior Risk Specialist in the Risk Management department at Coverys. Ann provides consultative and educational clinical risk management services to hospitals, clinics, and physician offices.

Ann is licensed as a registered nurse and attorney in North Carolina and Michigan. She spent her nursing career in the coronary and intensive care units and her legal career defending healthcare providers. Ann also holds the designation of Improvement Advisor from the Institute for Healthcare Improvement. She is a past President of the North Carolina Society for Healthcare Risk Management and a member of the Georgia Society for Healthcare Risk Management. Ann is a Fellow of the American Society for Healthcare Risk Management and serves on the Chapter Leadership Committee of that organization. Prior to joining Coverys, Ann served as Vice President of Risk Management and Patient Safety at MAG Mutual Insurance Company and Vice President of Risk Services at McNeary, Inc. in North Carolina.

Alix Michel, JD, Michel & Ward, PC

Alix C. Michel, JD, is a principal in the firm of Michel & Ward. In response to the growing problem of prescription drug diversion, Alix has been presenting on the "Legal Issues Surrounding Rx Drug Diversion" to and for all types of healthcare providers. For example, in 2012, he presented for the University of Tennessee College of Pharmacy to over 3,500 pharmacists from Tennessee, Alabama, and Kentucky on "Strategies to Combat Prescription Drug Diversion." He has presented on prescription drug abuse issues at the National Rx Drug Abuse & Heroin Summits I, II, and III; to insurance companies at the 2012 and 2013 Medical Liability Insurance ExecuSummits; and at the 2014 Crittenden Conference. He has also provided training for the staff and employees of Chartis Insurance and Coverys. Alix makes television and radio appearances and has authored/coauthored several articles to help raise public awareness on the various advances being made (as well as setbacks) in the fight to stem prescription drug abuse in America.

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In order to receive your participation certificate (which includes continuing education credit information), participants must complete an online evaluation. The link is included here:

<https://www.surveymonkey.com/r/Opioid103017>. After you complete the evaluation, there will be a pop-up which will allow you to access and print your certificate.

Disclosure

All faculty and planning committee members have indicated that they have no actual or potential conflict of interest in relation to this educational activity.

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Presented by:

Ann Lambrecht, RN, JD, FASHRM

and

Alix C. Michel, JD

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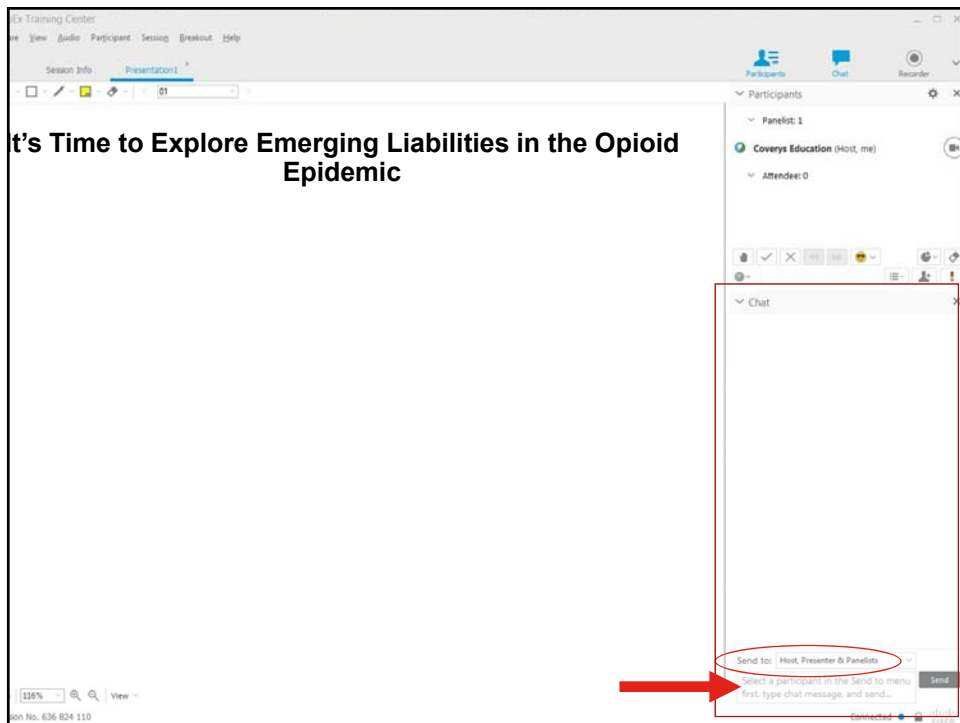
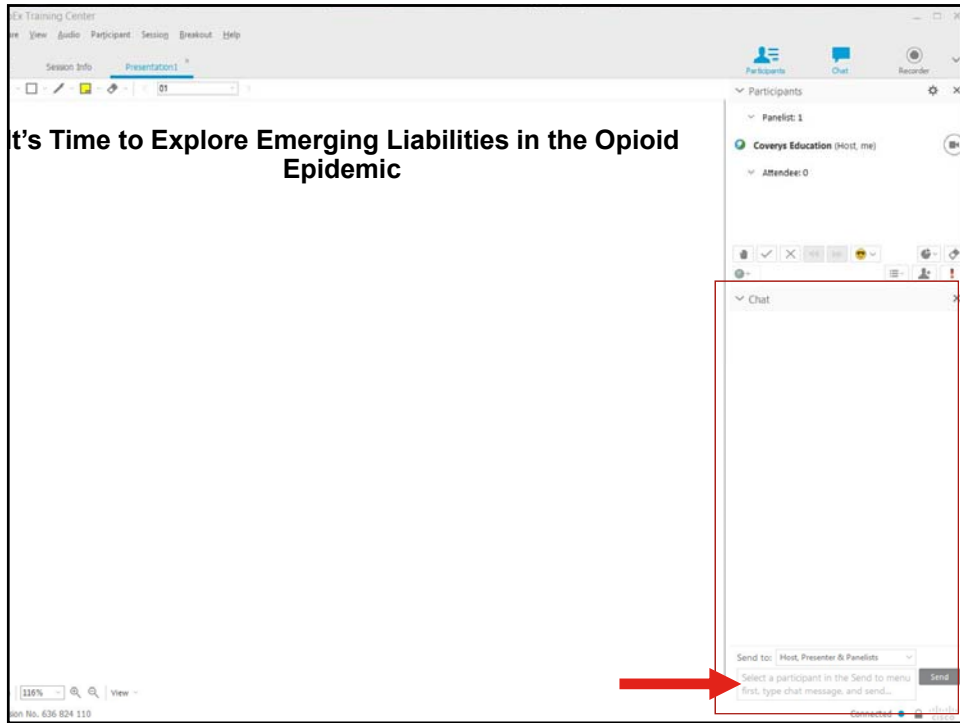
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Today's Presenters



**Ann Lambrecht,
RN, BSN, JD, FASHRM
Senior Clinical Risk
Consultant, Coverys**



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

Objectives

After participating in this program, the attendee will be able to:

- Examine new risks emerging due to the ongoing opioid crisis
- Analyze case studies which illustrate unanticipated opioid risks
- Explore resources which mitigate risk from opioid prescribing liability

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National Opioid Statistics

- Between 26 – 36 million people abuse opioids worldwide
- US comprises 5% of world population and consumes 80% of opioids
- In 2014 more than 47,000 people died from a drug overdose in the US
 - Of these 61% of drug overdose deaths involved an opioid
- In 2015 more than 52,000 people died from a drug overdose in US
 - Of these, 63.1% involved a prescription or illicit opioids

CDC Morbidity and Mortality Weekly Report, December 2016

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National Opioid Statistics, Continued

- Two distinct but related trends:
 - A 15-year increase in prescription opioid-related overdose deaths
 - A more recent increase in illicit overdose deaths largely due to heroin and illicitly produced fentanyl (synthetic opioid)
- Past misuse of prescription opioids is strongest risk factor for starting heroin
- Since 2000, more than 500,000 Americans have lost their lives to an opioid overdose
- We will address state data in the risk management recommendation

CDC Mortality and Morbidity Weekly Report, January 2016

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Other Opioid – Related Impacts

- 75% injured workers receive opioid prescriptions ¹
- Hospitalization for opioid overdoses among Medicare recipients quintupled from 1993 through 2012.^{4 2}
- Every 25 minutes an infant is born with NAS ³
- 829 total pharmacy robberies in 2014, a 16% increase since 2013 ⁴
- 70% of employers feeling the impact of prescription drug misuse in their workplace ⁵

¹ Worker's Comp Research Institute, Oct.2014 ² [https:// www.hcup-usahrq.gov/ reports/statbriefs/sb177](https://www.hcup-usahrq.gov/reports/statbriefs/sb177) ³ CDC Mortality and Morbidity Weekly Report, March 2017 ⁴ Pharmacy Times, May 2015, ⁵ National Safety Council, March 2017

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State & Municipal Lawsuits Against Distributors

- The Prescription Drug Supply Chain
 - Drug Manufacturers
 - Wholesalers: Organizations that purchase, warehouse and distribute approved medications.
 - Doctors / Medical Providers
 - Pharmacies/Pharmacists
 - Consumer / Patient

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Distributors & Wholesalers

- State of West Virginia v. AmerisourceBergen Drug Corp., 2:12-CV-03760 June 26, 2012
 - To support its claims., the state pointed
 - to the town of Kermit, population 300.
 - The town's drugstore received 3.19 million doses of hydrocodone in 2006, which was the 22nd highest level of purchases among all pharmacies in the country. The licensed pharmacist who owned the store testified his business was filling one prescription per minute.

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Distributors & Wholesalers

- West Virginia "pill-mill" Lawsuit → Full Steam Ahead
Motions to dismiss were denied
 - West Virginia judge rejects drug firms' request to dismiss W.Va. 'pill-mill' lawsuit. Eleven out of state drug companies lost their bid to have the suit dismissed as the trial judge held that a jury could conclude that the pill distributors' "acts and omissions were a substantial factor" that damaged "the state and its citizens."

<http://www.wvgazette.com/article/20150910/GZ01/150919917/1419#sthash.QkVJqBeu.dpuf>

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Distributors & Wholesalers Argue Confidentiality

- JUDGE TO RULE ON REQUEST TO UNSEAL ALLEGATIONS AGAINST DRUG-SHIPPING FIRMS
- Charleston Gazette-Mall asked Circuit Judge to unseal records regarding numbers of Rx opioids shipped to WV
- Drug wholesalers are trying to block the news paper's request
- Madison attorney states, "We think delaying getting this information out is harmful to the public—the sooner this information is out the better." (Tim Conaway)

Tues 4/21/16 Eric Eyre, Staff Writer

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Judge Orders Disclosure of Drug Company Shipments - May 7, 2016

- Boone County judge issued order to unseal the Rx shipment records
- Records disclosed allegations on numbers of Rx painkillers shipped to WV, specific to regions and towns
- The judge ruled they could keep their pill shipment records secret IF they agreed to settle the state's lawsuit against them within two weeks
- A Miami-based drug wholesaler Miami-Luken reached a \$2.5 million settlement with the state in order to keep allegations against them sealed

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Distributors & Wholesalers Pay Two Large Settlements



Drug Wholesalers to pay \$36 Million over West Virginia Pill Mill Claims

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Municipalities Follow West Virginia's Lead

- One of the nation's largest drug distributors says WV's poorest and most drug-ravaged county has no authority to sue the company for problems caused by prescription painkillers
- Cardinal Health asked a federal judge to dismiss the suit, arguing the county should be **pointing the finger at "pill mill" doctors and pharmacies**

Charleston
Gazette-Mail



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City of Huntington Files Lawsuits Against 3 Opioid Distributors

HUNTINGTON — The City of Huntington has filed a lawsuit in Cabell Circuit Court against a local doctor and three distributors of opioid drugs.

The lawsuit was filed Thursday against Dr. Gregory Donald Chaney, AmerisourceBergen Drug Co., Cardinal Health Inc., and McKesson Corp.

“The devastation caused by these Defendants goes beyond the economic damage. The City of Huntington’s families have lost children, parents and grandparents,” the filing states.

The Herald Dispatch January 17, 2017
Updated January 22, 2017

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West Virginia Files Suits Against Pharmacies

- West Virginia sues 3rd pharmacy in a month over painkillers...
 - Attorney General Patrick Morrisey says Crab Orchard Pharmacy Inc. dispensed 4.6 million doses of hydrocodone and oxycodone over seven years in Raleigh County, despite the presence of 32 competing pharmacies and eight medical facilities. The Raleigh County town has less than 3,000 residents.
 - “Every participant in the supply chain must guard against diversion and abuse,” Attorney General Morrisey said. “Every red flag and warning sign must be examined, and this lawsuit demonstrates my commitment to taking appropriate action when stakeholders fail to meet that standard.”

By WHSV Newsroom ; Associated Press | Updated: Thu 4:23 PM, Jan 05, 2017

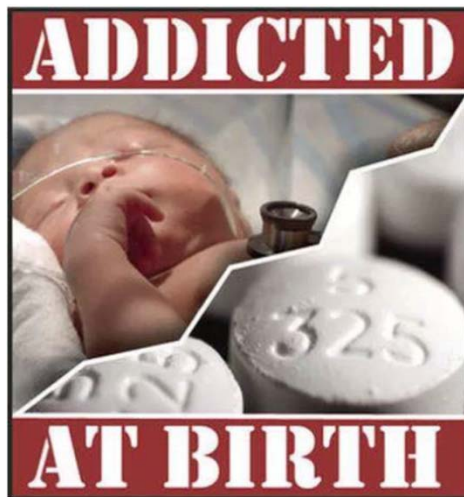
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Trend

Expect States/Municipalities to pursue claims against Healthcare providers to recover costs, expenses, harm to the community caused by Rx Drug Epidemic.

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Neonatal Abstinence Suits (NAS) – Emerging Threats



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Baby Doe NAS Lawsuit

- “We’re going to swing for the fences” – Northeast Tennessee brings unprecedented lawsuit against opioid manufacturers
- Three Northeast Tennessee counties have filed a lawsuit against the pharmaceutical companies responsible for the production of narcotic pain killers because of the ongoing opioid epidemic in the region.
- It is also named three medical doctors (Elizabeth Ann Bowers Campbell, Pamela Moore and Abdelrahman Hassabu Mohamed) and a medical clinic (Center Point Medical Clinic) as defendants.
- [NICK SHEPHERD](#) • UPDATED JUN 13, 2017

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Baby Doe NAS Lawsuit Alleges

- Purdue Pharma embarked on a fraudulent campaign to convince physicians that OxyContin created minimal risk of addiction;
- As opioid prescriptions rapidly increased, Mallinckrodt, Endo Pharmaceuticals and other opioid manufacturers joined Purdue in its fraudulent scheme;
- The campaign by the defendants led to an opioid epidemic, created an environment for thousands of individuals in Tennessee to become addicted to opioids, and fueled a dramatic increase in Sullivan County, Tennessee, in the number of individuals exposed to, and addicted to, OxyContin, Roxycodone®, Opana ER and other opioids, and;
- The police departments, schools, district attorneys’ offices, hospitals, doctors, insurance companies, and taxpayers of the state of Tennessee and Sullivan County will bear the financial burden of Purdue’s fraudulent campaign for decades to come.

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Baby Doe Defendant Opioid Companies Seek Removal to Federal Court

[NICK SHEPHERD](#) • AUG 7, 2017

Endo, one of the pharmaceutical companies named in a lawsuit against opioid manufacturers is attempting to get the lawsuit moved to federal court and is also seeking to remove the three physicians and medical clinic from the suit...

In the removal order, Endo claims the providers were fraudulently added to the lawsuit in order to keep the lawsuit from being moved out of Sullivan County.

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Trend

Expect plaintiffs to continue to prevent removal of drug cases to federal court by naming local physicians and pharmacists as parties to an action.

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Damage Caps Being Challenged

Lawsuit against opioid drug makers also targets Tennessee tort reform

[Jamie Satterfield](#), USA TODAY NETWORK -

In a strange twist, a lawsuit targeting opiate drugmakers filed Tuesday will pit one group of elected officials - three upper East Tennessee prosecutors - against another group of politicians - state legislators. Prosecutors Barry Staubus, Dan Armstrong and Tony Clark, who collectively represent nine counties in upper East Tennessee, filed a lawsuit Tuesday in Sullivan County Circuit Court against three drugmakers ...

Tucked at the end of the 87-page lawsuit is a challenge of the constitutionality of tort reform state lawmakers passed in 2011 that caps the amount of "non-economic" damages such as pain and suffering and punitive damages to a total of \$1.25 million in civil lawsuits against businesses, manufacturers, doctors, medical providers and the like.

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Are You in a Opioid Malpractice Claim Danger Zone?



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Pharmacy Defamation Lawsuits

Refusing a prescription and defaming the prescriber

December 01, 2015
On the Docket



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Defamation Suits - Refusal to Fill Prescription - Background

- Virginia case
 - Made critical statements about the physician to the patient
- Indiana case
 - Told patient the doctor, "Operates a pill mill"
- Pennsylvania case
 - Told patient doctor was "irresponsible" and "being investigated by the DEA" and "that nobody in this area fills his prescriptions"

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Defamation Suits - Rational

- In all cases above, defendant pharmacies sought dismissal based upon pharmacist – patient qualified privilege that must:
 - Be made in good faith
 - Intended to uphold legitimate interest
 - Is limited in scope and purpose
 - Made on proper occasion
 - Made in proper location to appropriate parties
- Negates malice required for defamation suit
- Courts in all cases held insufficient facts to prove privilege and grant dismissal



Defamation Suits

Discussion

- Refusal by a pharmacist to fill a prescription is a significant statement
- It is potentially defamatory for pharmacists to make critical statement about prescribers when asked why an opioid Rx has been refused
- Resist the temptation to criticize!
- Best option for response: “We can’t honor this prescription based on company policy”

Based on : *Mimms v CVS Pharmacy, Inc.*, 2015, *Goulmaine v CVS Pharmacy, Inc.*, 2015, *Yarus v Walgreen Co.*, 2015 --All US Dist LEXIS



Defamation Defense - Act in Good Faith (Florida Case)

- A prescribing physician plaintiff filed *slander per se* claims alleging that various Walgreens employees defamed him by making false statements pertaining to his medical reputation and ethics.
- The Federal District Court found a qualified privilege existed because:
 1. The statements at issue were made by a Walgreens' pharmacist to pharmacy customers at the time the customers attempted to fill prescriptions, and the apparent purpose of the statements was to inform the customers about the physician who wrote the prescription.
 2. The Walgreens' pharmacists acted in good faith and were upholding a legitimate interest since the statements were made while the pharmacists were filling prescriptions and giving general advice as they a duty to do...

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Example of Acting in Good Faith

- Lefrock v Walgreens Co. Court granted dismissal and held:
- In essence, the pharmacists made the statements in the proper location and manner since they rendered the advice to the customers while the customers were seeking advice regarding treatments and seeking to fill prescriptions.
- The statements were made in the proper manner since the statements were limited in scope to the specific prescriptions being filled and were not mere generalizations.

Lefrock v Walgreens Co., 2015 WL 226034 (M.D. Fla. Jan 16, 2015)

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St. Louis Blockbuster Verdict in Opioid Prescribing Suit

- \$17.6 Million verdict rendered against PCP and his employer
- \$15 Million punitive damages
- Evidence showed:
 - 2008 daily dose = 49 morphine equivalent mg
 - 2012 daily dose = 1,555 morphine equivalent mg
- Basic trial theme “Problem started with the doctor”

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Risk Management Recommendations

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Access State Opioid Statistics

- Obtain state statistics - look at 2 sets of statistics:
- Number of painkiller prescriptions/100 people ¹
- Deaths from drug overdoses and the percent attributable to opiate overdoses ²
 - Example
 - Ohio 100 = Number of painkiller prescriptions/100 people
 - Ohio – deaths from drug overdoses
 - 2015, 3,310 – 82% related to opioids
 - 2014, 2,744
 - 2013, 2,347

¹ CDC Vital Signs, July 2014 ² CDC Mortality and Morbidity Weekly Report, January 2016

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Prescribers

- Educate yourself on opioid risks and best practices ^{1,2}
- Implement standard patient assessment and screening protocols
 - Use standardized screening tools when considering opioid therapy
 - Use standardized tools to assess patients currently on opioid therapy
- Develop prescribing protocols
- Use controlled substance agreements
- Monitor and document patient progress
- Use available technology to assist
 - Alerts

¹ CDC Vital Signs, July 2014 ² CDC Mortality and Morbidity Weekly Report, January 2016

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Access Prescription Drug Monitoring Programs (PDMP) Before Prescribing

Case #1

- 25 y/o F, history appendectomy, cholecystectomy, C-section mostly presents to ED with chronic abdominal pain or abscesses. No admitted IV drug use.
- 23 ER visits in past 12 months
- 39 Rx from 12 Providers past 12 months

Case #2

- Husband of Case #1.
- 35 y/o Male, history of depression, polysubstance abuse
- 11 visits past 12 months, no clear trend to complaints
- 1 admission this year for overdose + psychosis
- 59 Rx from 15 providers

<http://www.namsdl.org/library/1810E284-A0D7-D440-C3A9A0560A1115D7/>

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Outline Actions for Suspected Misuse, Abuse, or Addiction

- Confirm contact information and address
- Verify prescriptions with dispensing pharmacy
- Re-check PDMP
- Conduct drug screen
- Address concerns and findings with patient
- Prescribe limited quantity until concerns are resolved
- Increase frequency of visits and random drug screens
- Obtain pain management consultation
- Document carefully and thoroughly

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Facilities

- Implement Centers for Medicare & Medicaid Services recommendations for prescribing and monitoring ¹
 - Implement The Joint Commission Pain Assessment and Management Standards released August 20, 2017 ²
- Ensure prescriber access to pharmacist
- Empower nursing and pharmacy staff to hold opioid dose or dispensing until clarification obtained
- Implement chain of command for patient care differences
- Use available technology to assist in prescribing

¹ CMS Survey & Certification Letter: 14 – 15 Hospital ² R3 Report, Requirement, Rationale, Reference, Issue11, August 29, 2017

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Employers

- Implement Employee Screening and Education
 - Conduct thorough background checks
 - Require employees to report offenses related to impairment - DUI
 - Educate employees on drug diversion tactics
 - Advise employees when random drug testing may be conducted
 - Use the more extensive screens that detect opioids
 - Implement an anonymous reporting system

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Pharmacies

- Require government – issued photo ID when dispensing opioids
- Access PDMP before dispensing opioids
- Communicate with other pharmacies when denying a prescription or when receiving a denied prescription
- Be wary of:
 - Pattern prescribing – same drugs, quantities, diagnosis codes
 - Local prescribing for out-of-state patients
 - Cash paying patients
- Use caution when communicating prescription denials with patients

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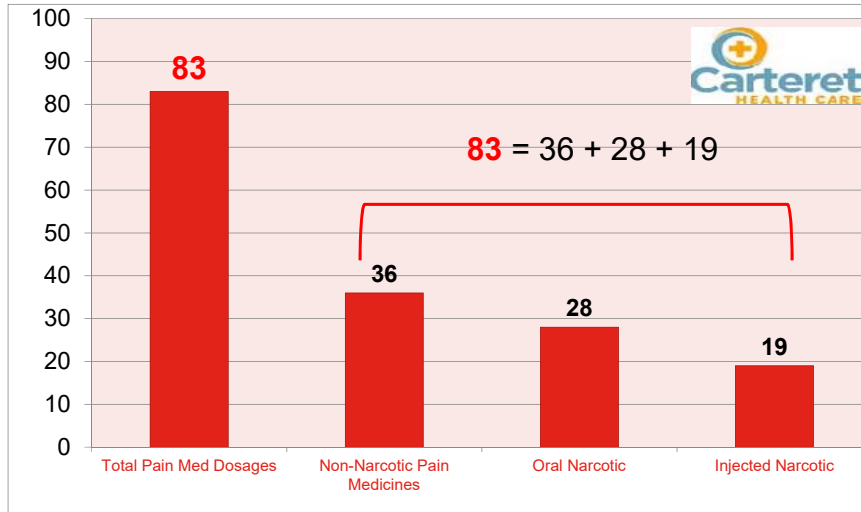
Success Stories – Carteret Health

- Carteret Health
 - Carteret County - Highest rate of Controlled Substance Prescribing among the NC Eastern Seaboard Counties
 - 3rd Highest per capita Death Rate secondary to Narcotic overdose
 - Youth report higher usage of prescribed painkillers (for non-medical purposes) than their peers throughout NC
- Goals:
 - Improve the quality of care for ED patients presenting with pain
 - Reduce ED drug seeking behaviors
 - Reduce inappropriate opiate prescribing



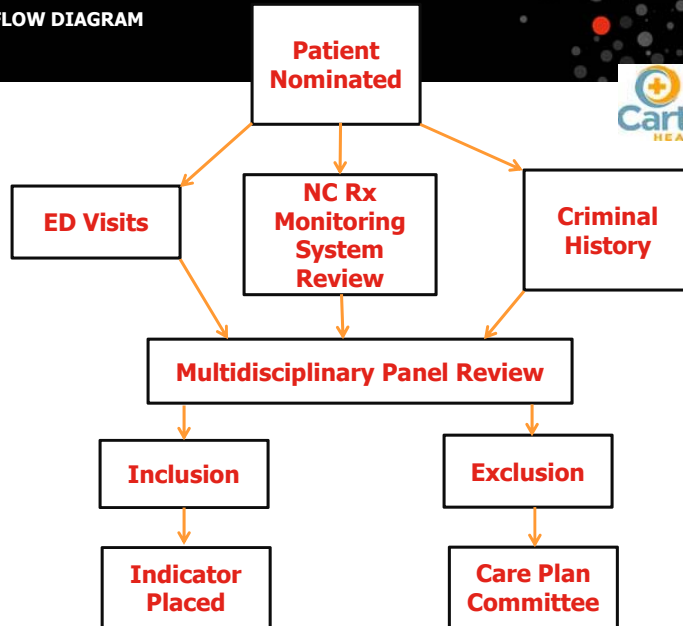
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CHC Pain Medication Doses Administered Per 100 Visits



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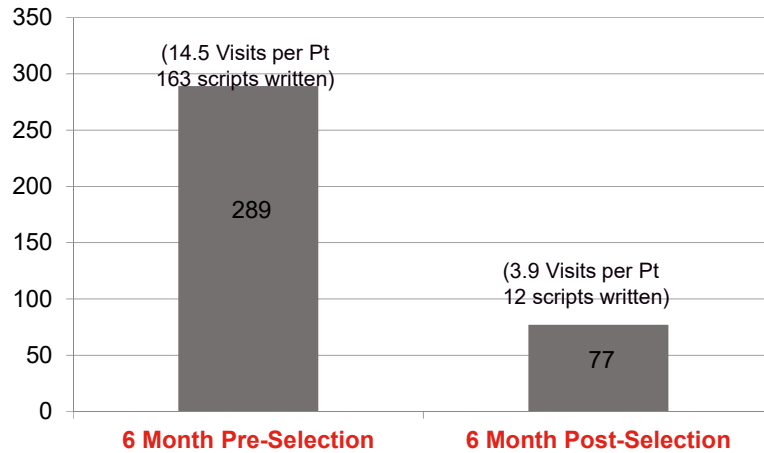
PROCESS FLOW DIAGRAM



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Results: ED Visits Pre- and Post-Intervention
n=20 Patients

19 of 20 Pts: With Decreasing Visit Frequency (73%)
12 of 77 Visits Resulted in Reduced CS Rx (93%)



Success Stories - Catholic Health Initiatives

- #1 reason for ED visits = request narcotics for pain
- 60% of clinic - prescribed narcotics diverted by patients for illegal sales
- Launched community based care coordination project
 - Multidisciplinary team
 - Leadership oversight team
 - Community – wide prescription drug task force
- Goal = serve patients needs beyond traditional care model
- Drug seeking diagnosis fell off top 20 list
- 20% decrease in narcotics prescriptions
- Over \$400 K reduction in pharmacy claims

Health & Hospital Networks – August 2017

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- After you complete and submit the survey, you will have an opportunity to immediately download and print your certificate.

