

Opioid Crisis: Big Pharma Got Us Here, Can Compliance Get Us Out?

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Agenda

- Pharma
- Federal Response
- SUPPORT Rule
- What Compliance Officers Can Do

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Opioid Use



Are you or
someone you know
struggling with
addiction?

- CDC – Overdoses involving opioids resulted in >47,000 deaths in 2017 alone
- NPR/Ipsos poll – 1/3 of Americans have been touched directly by the opioid epidemic
- NPR/Ipsos poll – 57% of Americans believe pharmaceutical companies should be held responsible for making the crisis worse

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Pharma Story

A Fentanyl-based medication, Subsys was prescribed to patients who did not need it.

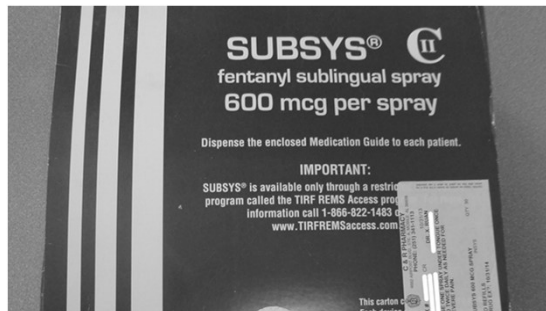


Photo from NPR online June 5, 2019

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Pharma Story

Teva Pharmaceuticals

***\$85 MM
settlement***

- Agreed to an \$85 MM settlement with the state of Oklahoma
- Teva is the world's largest generic drug maker
- Money from the settlement will go towards combating the crisis – Mike Hunter, OK Attorney General
 - State attorneys estimate the cost to be \$12.7 billion to \$17.5 billion over 20-30 year period to abate the crisis

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Pharma Story

Purdue Pharmaceuticals

***\$270 MM
settlement***

- Founded in 1892 by 2 MDs, Purdue Pharma is one of the oldest and largest drug manufacturers in the USA
- March 2019 – Purdue, maker of Oxycontin, reached a settlement ending the opioid lawsuit brought by the State of Oklahoma
- Motivated by corporate desire to avoid a public trial and anticipated negative press
- Purdue Pharma and its owners are facing over 1600 lawsuits involving their corporate & personal roles in creating and propagating the opioid epidemic driving the drug crisis in America
- Purdue sought bankruptcy protection to immediately halt all lawsuits
 - Purdue negotiates settlements with each plaintiff supervised by a bankruptcy judge

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Pharma Story

"Purdue is very pleased to have reached an agreement with Oklahoma that will help those who are battling addiction now and in the future."

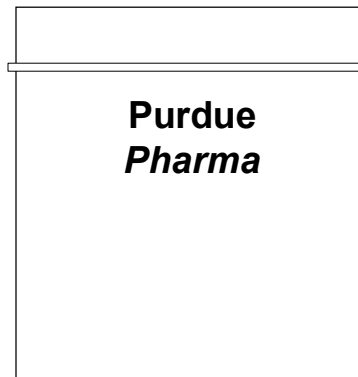


All Purdue information for this presentation was found online, mostly from the website for Ashwood Recovery at Northpoint.

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Pharma Story



- Brothers Dr. Mortimer Sackler & Dr. Raymond Sackler bought Purdue in 1952
- Purdue focused on pain management drugs since 1991
- Calls itself "a pioneer in developing medications for reducing pain, a principle cause of human suffering"
- Aggressively marketed the drug as extremely safe & effective
- Reality – they are extremely habit-forming with a high potential for dependence, misuse, and addiction

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Pharma Story

**What did Purdue
know?**

***When did
Purdue know?***

- In 1996 – Purdue's General Counsel, Howard Udell & Purdue's President, Richard Sackler, received a medical journal article describing how addicts could extract morphine from MS Contin & inject the drug.
 - This was 5 months after Oxycotin received FDA approval
- Purdue scientist researched the article & sent results to Mortimer & Raymond Sackler: "I found MS Contin mentioned a couple of times on the internet underground drug culture scene. Most of it was mentioned in the context of MS Contin as a morphine source."

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Pharma Story

**What did Purdue
know?**

***When did
Purdue know?***

- 1997-1999 – there were 117 internal sales memos & emails showed representatives using the words "snort," "street value," or "crush"
- In 1998 – Udell sent a memo to 7 Sackler family members titled "MS Contin Abuse" and included newspaper articles reporting abuse and the current black market prices

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Pharma Story

**What did Purdue
know?**

***When did
Purdue know?***

- In 1999, Howard R. Udell, General Counsel for Purdue stated in an internal email "We have in fact picked up references to abuse of our opioid products on the Internet."
 - Udell testified before Congress that Purdue did not learn about the abuse of Oxycontin until 2000
- In 2001, Connecticut AG Blumenthal admonished Purdue to take stronger action regarding the abuse of Oxycotin

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Pharma Story



**Project
*Tango***

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The Federal Response to the Opioid Epidemic

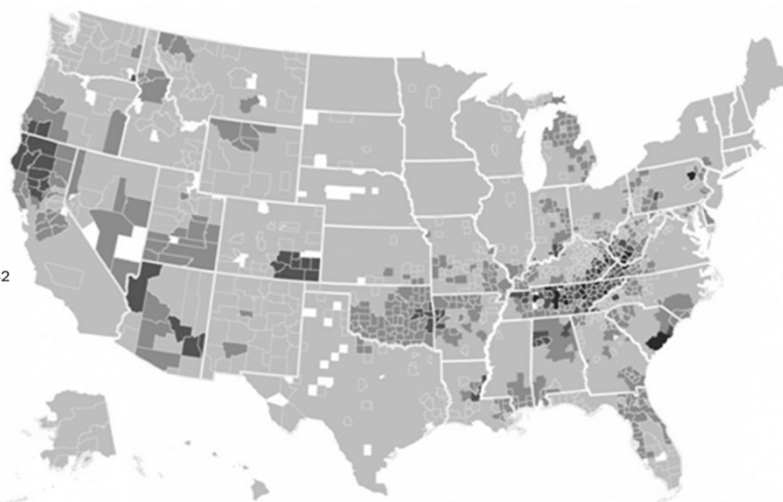
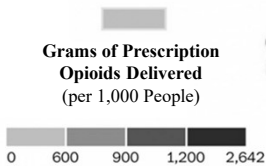


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Opioid overdoses nationwide

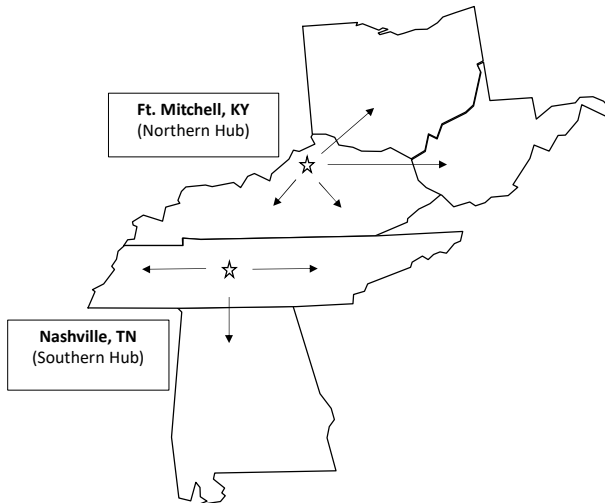


Highest Quarter of Overdose Rates
(by County)



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Appalachian Regional Prescription Opioid Strike Force



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Legal considerations



- The Controlled Substances Act allows certain licensed practitioners to prescribe drugs that would otherwise be illegal to dispense, such as opioids.
- The Supreme Court held in *U.S. v. Moore (1975)* that prescribers can be subject to federal criminal prosecution “when their activities fall outside the usual course of professional practice.”
- Prescriptions must be “issued for a legitimate medical purpose...”
- Moore
 - Gave inadequate physical exams or none at all
 - He ignored the results of the tests he did make
 - In practical effect, he acted as a large-scale “pusher” – not as a physician

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Dr. Darrel Rinehart



After 5 deadly overdoses, Tennessee doctor now practicing in Indiana

DR. DARREL RINEHART'S PRESCRIPTIONS WERE SO DANGEROUS HE WAS FORCED OUT OF TENNESSEE. BUT THAT HASN'T STOPPED HIM FROM STARTING OVER IN INDIANAPOLIS.

Brett Kelman, Nashville Tennessean

Published 7:00 a.m. CT Jan. 24, 2019 | Updated 4:22 p.m. CT Jan. 24, 2019



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Victims



Bonnie Blackburn holds a photo of her son, **Mathew Blackburn**, one of five patients of Dr. Darrel Rinehart who died within an 11-month span. "It's wrong," Blackburn said. "He needs to go to jail, and he should never be able to practice again."



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Compliance intervention



- March 4, 2016
 - Anonymous complaint alleges Rinehart is responsible for 7 patient overdose deaths
- March 15, 2016
 - CEO meets with Rinehart and gives him Tennessee pain management guidelines and hospital policies
- April 2016
 - Rinehart is given a letter saying he is violating the terms of his contract
- April/May 2016
 - Weekly meetings with compliance highlighting deficiencies discovered in chart reviews



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Chart reviews



- Problems in Rinehart's charts included:
 - One drug screen or none at all
 - Drug screens showing patients were not taking prescribed drugs (but he continued to prescribe)
 - Drug screens also showed patients taking drugs not prescribed by Rinehart, such as benzodiazepines
- Rinehart was violating hospital policies including:
 - Prescribing Methadone
 - Prescribing Methadone in combination with opioids
 - Prescribing opioids to women of child bearing age



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Medical board investigation



The Tennessee medical license of Darrel R. Rinehart M.D., license number 15431, is hereby **SUSPENDED** until May 31, 2019 at which time his license will expire. Dr. Rinehart will be prohibited from renewing this license, reinstating this license, or applying for a new license.



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Possible overdoses



indicate inconsistencies in this patient's medication but Respondent did not document counseling this patient on these aberrant results. On or about November 12, 2015, this patient died, three days after filling his last prescription from Respondent. Respondent signed the death certificate for this patient and recorded the cause of death as, "Acute myocardial infarction." An autopsy was not performed on this patient.



MORPHINE SULFATE ER	90.000
MORPHINE SULFATE	180.000

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Possible overdoses



Respondent prescribed patient T.S. Adderall and alprazolam. Respondent failed to consult the CSMD before beginning a course of treatment with benzodiazepines. A urine drug screen taken from this patient by Respondent on or about November 16, 2015 indicates that this patient was taking non-prescribed hydrocodone in addition to her alprazolam, but Respondent did not document counseling the patient about this aberrant result. The patient died on or about January 21, 2016. Respondent signed the death certificate for this patient and recorded the cause of death as, "Acute myocardial infarction." An autopsy was not performed on this patient.



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Combined drug toxicity



<p>IMMEDIATE CAUSE (Final disease or condition resulting in death)</p> <p>Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that invovates the events resulting in death) LAST</p>	<p>→ a. Acute combined drug (morphine, alprazolam, and amitriptyline) intoxication</p> <p style="text-align: right; font-size: small;">Due to (or as a consequence of)</p> <hr/> <p>b. _____</p> <p style="text-align: right; font-size: small;">Due to (or as a consequence of)</p> <hr/> <p>c. _____</p> <p style="text-align: right; font-size: small;">Due to (or as a consequence of)</p> <hr/> <p>d. _____</p>
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Patient VP died on January 29, 2016. She was 56 years old and had received a prescription for #120 Alprazolam (Xanax) from Dr. Rinehart the day before.



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Combined drug toxicity



IMMEDIATE CAUSE

(Final disease or condition resulting in death)

Sequentially list conditions, if any, leading to the cause listed on line a. Enter the UNDERLYING CAUSE (disease or injury that initiated the events resulting in death) LAST

a. Acute combined drug toxicity (alprazolam, morphine)

Due to (or as a consequence of)

b. _____

Due to (or as a consequence of):

c. _____

Due to (or as a consequence of):

d. _____



Patient RG died on December 20, 2015. She was 48 years old. She received prescriptions from Dr. Rinehart on December 6, 2015 for #75 Alprazolam and #60 Morphine Sulfate.

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DOJ expert opinion



Death occurs due to apnea (cessation of breathing). DR went to sleep and died, was described to have been snoring, had hydrocodone present postmortem, and there was pulmonary edema. Therefore, the cause of DR's death was opioid intoxication from hydrocodone.

CONCLUSION: DR would not have died but for the hydrocodone prescribed by Dr. Rinehart on 1/21/2016.



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Criminal charges and plea



FILED
U.S. DISTRICT COURT
MIDDLE DISTRICT OF TENN.

MAR 27 2019

BY *[Signature]*
DEPUTY CLERK

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
COLUMBIA DIVISION

UNITED STATES OF AMERICA)

No.)

1-19-00008

v.)

21 U.S.C. § 841(a)(1)

DARREL R. RINEHART)

INDICTMENT

THE GRAND JURY CHARGES:



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ARPO Strike Force Takedown



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FOR IMMEDIATE RELEASE

Wednesday, April 17, 2019

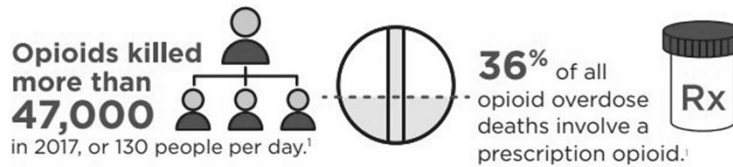
Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals

Charges Involve Over 350 Thousand Prescriptions for Controlled Substances and Over 32 Million Pills; ARPO Strike Force Grows to 10 Districts, Expanding to Include the Western District of Virginia



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CMS Roadmap



- Key areas of CMS Focus
- As one of the largest payers of healthcare services, CMS has a vital role in addressing the opioid epidemic and is focused on three key areas



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The SUPPORT for Patients and Communities Act



- Enacted on October 24, 2018
- Medicaid Provisions to Address the Opioid Crisis
 - State Medicaid programs are required to have safety edits in place for opioid refills, monitor concurrent prescribing of opioids and certain other drugs and monitor antipsychotic prescribing for children
 - Improve care for infants with neonatal abstinence syndrome and their mothers
 - Medicaid health homes for substance-use-disorder Medicaid enrollees
 - Medicaid substance use disorder treatment via telehealth
 - Enhancing patient access to non-opioid treatment options

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The SUPPORT for Patients and Communities Act



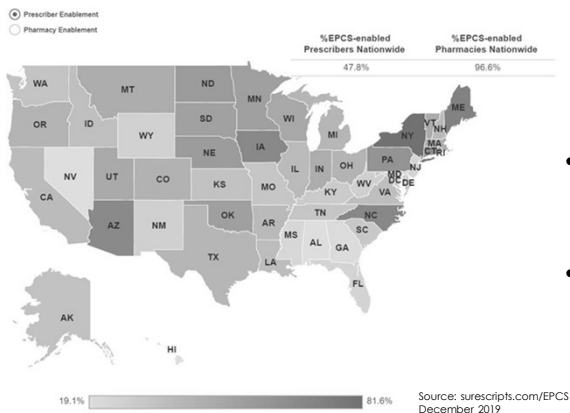
- Medicare Provisions to Address the Opioid Crisis
 - Expanding the use of telehealth services for the treatment of opioid disorder and other substance use disorders.
 - Screening for seniors
 - E-prescribing of a Schedule II, III, IV, or V controlled substance
 - By 2022, requiring prescription drug plan sponsors under Medicare to establish drug management programs for at-risk beneficiaries
 - For Medicare to include Opioid Treatment Programs in participants coverage

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E-prescribing of a Schedule II, III, IV, or V controlled substance

EPCS Readiness: Which States Lead the Charge?



- Electronic prescribing for controlled substances (EPCS) is required for all controlled substances under Medicare Part D by January 1, 2021
- Individual State EPCS Mandates – many have their own mandates
- *Pharma and other organizations have implemented private mandates*

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Examples of EPCS Reports

Right: Our Controlled Substance Prescription Report

Below: A daily EPCS Audit Report on anyone that failed to log on to our EMR

Controlled Substance Prescription Report Results			
Provider:	Date Range:	Run Date:	* = Refilled
Patients	Account	Drug Name	Date Issued
		Norco 5-325 MG Tablets	01/02/20
		Oxycodone HCL 5 MG Tablets	01/02/20*
		Norco 5-325 MG Tablets	01/03/20
		Norco 5-325 MG Tablets	01/06/20
		Norco 5-325 MG Tablets	01/06/20
		Norco 5-325 MG Tablets	01/07/20*
		Norco 5-325 MG Tablets	01/07/20
		Norco 5-325 MG Tablets	01/07/20
		Norco 5-325 MG Tablets	01/10/20*
		Norco 5-325 MG Tablets	01/14/20
		Norco 5-325 MG Tablets	01/14/20
		Percofet 5-325 MG Tablets	01/22/20*
		ULTRAM 50 MG Tablets	01/25/20*
		Norco 5-325 MG Tablets	01/28/20
		TRAMADOL HCL 50 MG Tablets	01/31/20

EPCS Audit Report

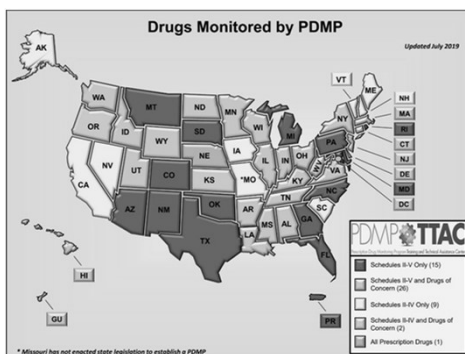
This is a report of the previous day's security events related to EPCS. This report is mandatory per the DEA. You must review this and determine whether any event represents a security incident. Any such incidents must be taken action on within one business day. After reviewing this report, if no such incidents must have action taken on them, you can just close this triage.

User: N/A Not Found	2020-02-13T12:26:30-05:00 Thursday
Login Failed	Unidentified Logon Name In Privacy Screen: *
User: N/A Not Found	2020-02-13T09:24:36-05:00 Thursday
Login Failed	Unidentified Logon Name: "KAT"

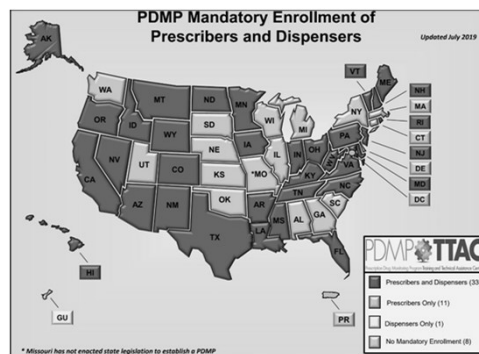
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PDMP Prescription Drug Monitoring Program



Source: https://www.pdmpassist.org/pdf/PDMP_Substances_Tracked_20190731.pdf



Source: https://www.pdmpassist.org/pdf/Mandatory_Enrollment_20190731.pdf

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The SUPPORT for Patients and Communities Act



- Public Health Provisions
 - Report on effects on public health of synthetic drug use among adolescents and young adults to further educate parents and the medical community
 - First responder training to allow first responders to administer a drug or device to treat an opioid overdose.
 - Establishment of substance use disorder information dashboard
 - Study on prescribing limits – may limit the length, quantity or dosage of opioid prescriptions
 - Inclusion of opioid addition history in patient's records.
 - Protecting moms and infants

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CMS



Campaign for Meds Management
INSPIRED BY YOU – IMPACTING PEOPLE EVERYWHERE



- Working with patients and caregivers to identify and share promising medication management strategies and resources
- Collecting and sharing patient, caregiver and provider stories and emerging practices
- Hosting a Learning Community via MLN (Medical Safety Learning and Action Network)

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What Compliance Officers Can Do



Look for continued rules and guidance published by:

- OIG
- CMS
- OCR

- Policies and Procedures
 - With PDMP and ECPS, the addition of policies and procedures
 - Creating policies and procedures for physicians using guidance from the CDC on patients with chronic pain
- Compliance Officer/Compliance Committees
 - Work with internal groups or committees have a focus on opioid fraud and abuse
- Training/Education
 - Educate and train on focused training efforts as new laws and rules are available
 - Look to MLN for assistance
- Monitoring/Auditing
 - Look at what your EMR/EHR software already provides
 - Expand on those to include all of the elements

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Thank You

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