America's Health Emergency
The Opioid Crisis

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Relevant Disclosure and Resolution

Under Accreditation Council for Continuing Medical Education guidelines disclosure must be made regarding relevant financial relationships with commercial interests within the last 12 months.

Dale W. Bratzler

I have no relevant financial relationships or affiliations with commercial interests to disclose.

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Professional Practice Gap

Gap 1: Overdose due to opioids has become a leading cause of death in the United States.

Gap 2: The "gateway" to opioid dependence often starts with legitimate prescriptions from licensed health providers.

Gap 3: There is increasing evidence that policies directed at reducing opioid prescription provide patients with adequate pain relief and reduce risk of dependence.

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Learning Objectives

Upon completion of this session, participants will improve their competence and performance by being able to:

1. Discuss the scope of the opioid crisis and the "waves" of opioid deaths in the United States and Oklahoma.
2. Describe interventions in healthcare that have been shown to reduce the use of opioid medications.
3. Recognize the requirements of Oklahoma law for opioid prescribing.

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America's Opioid Crisis

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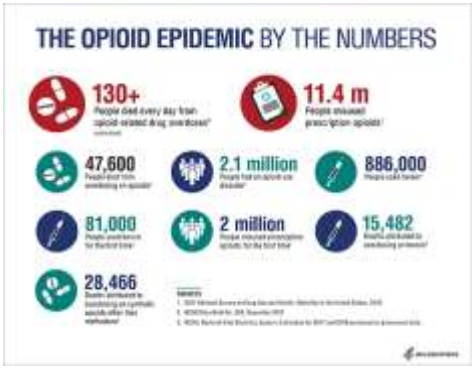
https://www.npr.org/2017/10/26/560083795/president-trump-may-declare-opioid-epidemic-national-emergency



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The Opioid Crisis – The Facts

- More than six out of 10 drug overdose deaths involve an opioid.
- About 21 to 29 percent of patients prescribed opioids for chronic pain misuse them.
- About 80 percent of people who use heroin first misused prescription opioids.
- Opioid overdoses increased 30 percent from July 2016 through September 2017 in 52 areas in 45 states.

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https://www.cdc.gov/drugoverdose/data/statedeaths.html

In 2016, Oklahoma ranked 30th in the nation for opioid-related overdose deaths/100,000

https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state

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Opioid Prescribing

State	Opioid Related Overdose Deaths Per 100,000	Opioid Prescriptions Per 100 Persons
Alabama	7.5	120.3
Tennessee	18.1	118.3
Arkansas	5.9	111.2
West Virginia	43.4	110.0
Indiana	12.6	109.1
South Carolina	13.1	109.0
Mississippi	6.2	107.5
Louisiana	7.7	103.2
Oklahoma	11.6	101.7*
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Hawaii	5.2	45.3

*9th in the nation

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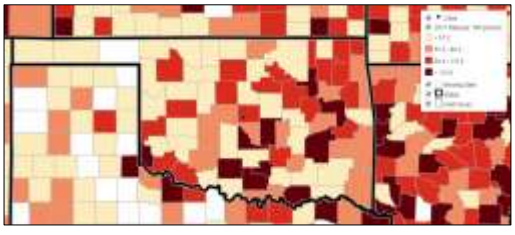
https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state

Opioid Prescribing – Oklahoma

Substantial Variation By County



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https://www.cdc.gov/drugoverdose/maps/rxcounty2017.html

Opioid Prescriptions – Oklahoma

By County

County	Prescribing Rate Per 100 Persons
HARMON	178.0
CARTER	148.4
PITTSBURG	130.4
MURRAY	128.7
BRYAN	128.2
MCCLAIN	126.2
STEPHENS	121.9
POTTAWATOMIE	118.2
MUSKOGEE	114.4
TULSA	113.2
PONTOTOC	106.9
WASHINGTON	103.3
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Oklahoma	96.5

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https://www.cdc.gov/drugoverdose/maps/rxcounty2017.html

State	Opioid Deaths (2017)
PA	5,388
OH	5,111
FL	5,088
CA	4,868
NY	3,921
TX	2,989
IL	2,778
MI	2,694
NJ	2,685
NC	2,414
MD	2,247
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OK (28th)	775

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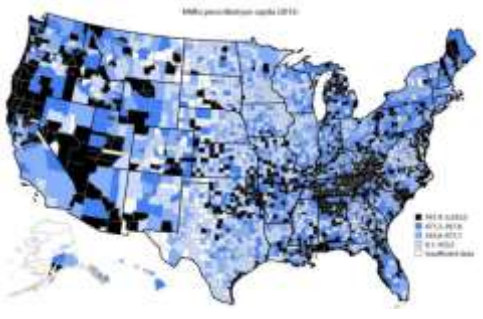
https://www.cdc.gov/drugoverdose/data/statedeaths.html



Dosing variations by County

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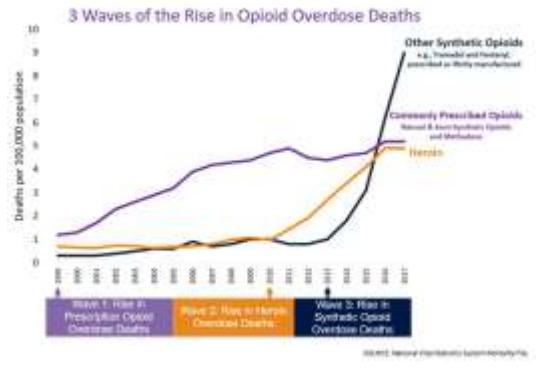
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5726238/

The Opioid Crisis

The Centers for Disease Control and Prevention estimates that the total "economic burden" of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

Medicine

Florence CS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Med Care*. 2016;54(10):901-906.



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According to the People article, Curtis's drug addiction began when she was prescribed opioids for minor plastic surgery in 1989 to correct "hereditary puffy eyes."

"I was ahead of the curve of the opiate epidemic," Curtis told the magazine. "I had a 10-year run, stealing, conniving. No one knew. No one."

https://www.everydayhealth.com/drug-addiction/living-with/jamie-lee-curtis-speaks-out-about-decade-long-struggle-with-opioid-addiction/

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How did we get here???

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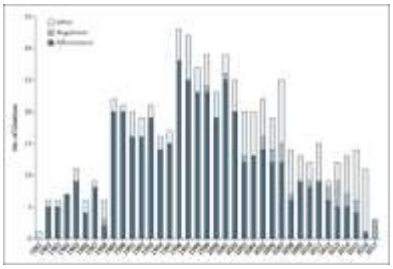
The impact of a research letter??

Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction.

Medicine

Porter J, Jick H. Addiction rare in patients treated with narcotics. *N Engl J Med*. 1980; 302:123.

Citations of "the letter"



Of the articles that included a reference to the 1980 letter, the authors of **439 (72.2%) cited it as evidence that addiction was rare in patients treated with opioids**.

"Of the 608 articles, the authors of 491 articles (80.8%) did not note that the patients who were described in the letter were hospitalized at the time they received the prescription,……"

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Leung P, et al. *N Engl J Med* 2017; 376:2194-2195

The impact of a research letter…

In conclusion, we found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.

Medicine

Leung P, et al. *N Engl J Med* 2017; 376:2194-2195

It is not that simple

- Purdue Pharma inaccurately claimed that Oxycontin was a less addictive opioid—and that its effects lasted longer than they really did.
- The research shows that some people who developed new addictions were *not* pain patients. Instead, they were mainly friends, relatives, and others to whom those pills were diverted—typically young people.

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The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy

In 2001 alone, the company spent $200 million in an array of approaches to market and promote OxyContin.

From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker-training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue's national speaker bureau.

Medicine

Zee AV. *Am J Public Health*. 2009; 99:221-227.

Risk Factors for Misuse of Opioids

Often ignored or not recognized

- **Known risk factors of opioid misuse and addiction include**:
  - Poverty
  - Unemployment
  - Family history of substance abuse
  - Personal history of substance abuse
  - Young age
  - History of criminal activity or legal problems including DUIs
  - Regular contact with high-risk people or high-risk environments
  - Problems with past employers, family members and friends (mental disorder)
  - Risk-taking or thrill-seeking behavior
  - Heavy tobacco use
  - History of severe depression or anxiety
  - Stressful circumstances
  - Prior drug or alcohol rehabilitation

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American Journal of Preventive Medicine

RESEARCH LETTER

Opioid Prescribing by Specialty and Volume in the U.S.

Gary P. Guy Jr., PhD, MPH, Kun Zhang, PhD

Most common specialty groups among opioid prescribers were internal medicine (16.4%); dentists (15.8%); nurse practitioners (12.3%); and family medicine (10.3%)

The specialty groups accounting for the greatest proportion of dispensed opioid prescriptions were family medicine (20.5%); internal medicine (15.7%); nurse practitioners (9.9%); physician assistants (9.3%); pain medicine (8.9%); and dentists (8.6%)

The average number of opioid prescriptions per prescriber was 215.8, with the highest among pain medicine (1,314.9) and physical medicine and rehabilitation (1,023.1) specialty groups, followed by orthopedics (438.7) and family medicine (428.4).

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Am J Prev Med. 2018;55: e153–e155.


The Journal of the American Dental Association

Dental opioid prescribing and multiple opioid prescriptions among dental patients: Administrative data from the South Carolina prescription drug monitoring program

….during 2012 and 2013, dentists accounted for only 8.9% of all opioid prescribers but prescribed 44.9% of the initial opioids dispensed to patients.*

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*on average 20 tablets.


Drug and Alcohol Dependence

Unused opioid analgesics and drug disposal following outpatient dental surgery: A randomized controlled trial

Fifty-four percent of opioids prescribed in this pilot study were not used*. ……Dentists and oral surgeons could potentially reduce opioid diversion by moderately reducing the quantity of opioid analgesics prescribed after surgery.*

Healthcare providers routinely overestimate the pain medication needs of patients with acute events.

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Interventions to Reduce the Use of Opioids

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GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Initiating Opioids:

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient

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https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Dose, duration, and followup:

- Use immediate-release opioids when starting
- Start low and go slow
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- Follow-up and re-evaluate risk of harm; reduce dose or taper and discontinue if needed.

Medicine

https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Addressing Risk:

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

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https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf

Opioids and Benzodiazepines

- More than 30 percent of overdoses involving opioids also involve benzodiazepines.
- A cohort study in North Carolina found that the overdose death rate among patients receiving both types of medications was **10 times higher** than among those only receiving opioids.

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Dasgupta N, et al. Cohort Study of the Impact of High-Dose Opioid Analgesics on Overdose Mortality. *Pain Med Malden Mass*. 2016;17(1):85-98.

Provider perception versus reality..

- Most patients complain of less pain than providers predict
- Most studies reveal that patients do not use all of the opioids they are prescribed

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Opioid Sparing Pathways - Surgery

Multi-modal Approach

- Pre-operative medications (e.g., NSAID, gabapentin)
- Intraoperative management (nerve blocks, spinal anesthesia, ketamine)
- Postoperative management with non-narcotic options
- Discharge management – protocols for prescribing

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Few guidelines exist to guide opioid prescribing practices for surgery

- Patients (n = 332) undergoing breast surgical oncology procedure were surveyed one week postoperatively for opioid use. The surgeons were surveyed about pain management preferences by surgery type.
  - Wide variation in opioid use by breast surgical oncology procedure type was noted with substantial unused MME regardless of prescribing preference.

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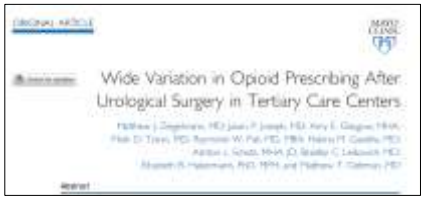
Park KU, et al. Surgeon perception versus reality: Opioid use after breast cancer surgery. *J Surg Oncol*. 2019 Feb 8. doi: 10.1002/jso.25395. [Epub ahead of print]


Wide Variation in Opioid Prescribing After Urological Surgery in Tertiary Care Centers

We identified 11,829 patients who underwent 21 urological surgical procedures at 3 associated facilities from January 1, 2015, through December 31, 2016. After converting opioids to oral morphine equivalents (OMEs), prescribing patterns were compared within and across procedures.

"Striking variation in prescribing patterns was observed within and across surgical procedures."

Medicine

Mayo Clin Proc. 2019;94(2):262-274.

Reduction of opioid prescribing through the sharing of individual physician opioid prescribing practices☆

- We compared opioid prescriptions written on patient discharge before and after an intervention consisting of sharing individual and comparison prescribing data. **Clinicians at or over one standard deviation above the mean were notified via standard template electronic communication.**
- ……..in the post-intervention period there was a **28% reduction in the overall rate of opioid prescriptions written per patient discharged**.

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Audit and Feedback!

JAMA Network | Open

Ultrarestrictive Opioid Prescription Protocol for Pain Management After Gynecologic and Abdominal Surgery

Implementation of an ultrarestrictive protocol was associated with a significant decrease in the overall amount of opioids prescribed to patients after gynecologic and abdominal surgery at the time of discharge for all patients, and for the entire perioperative time for opioid naïve patients without changes in pain scores, complications, or medication refill requests.

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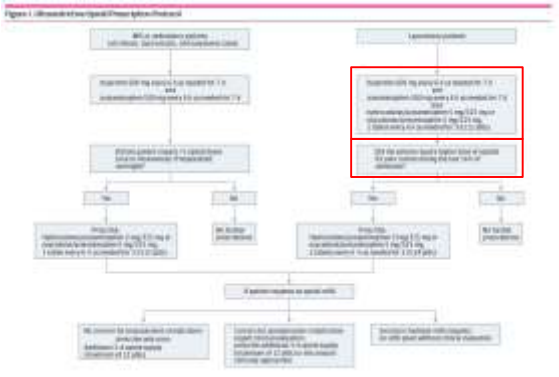
JAMA Network Open. 2018; 1(8):e185452.

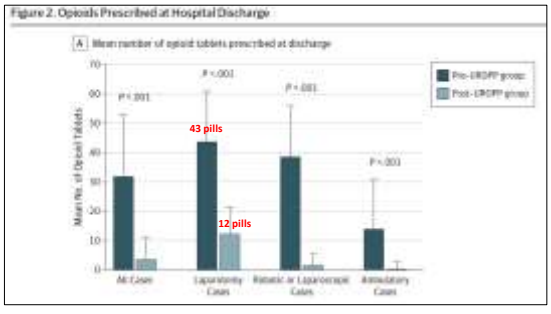


Medicine

JAMA Network Open. 2018; 1(8):e185452.

Protocol-based Prescribing

Dramatic reductions in opioid prescriptions



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JAMA Network Open. 2018; 1(8):e185452.

SB 1446 (2018) and SB 848 (2019) – Opioid Prescribing in Oklahoma

http://webserver1.lsb.state.ok.us/cf_pdf/2017-18%20ENR/SB/SB1446%20ENR.PDF
http://webserver1.lsb.state.ok.us/cf_pdf/2019-20%20ENR/SB/SB848%20ENR.PDF

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SB 1446 and SB 848

- Amends and adds new regulations for the Uniform Controlled Dangerous Substances Act* and has penalties, including fines or incarceration for physicians who violate the provisions.

*63 O.S. §2-309I (OSCN 2019)

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SB 1446 and SB 848

Regulation of Opioid Drugs

- Requires that all licensees receive at least one hour of education in pain management OR one hour of education on use of opioids or addiction annually to renew license.*
- Defines terms such as
  - Acute pain
  - Chronic pain
  - "Initial Prescription"

*A physician who does not have a valid DEA number and therefore does not prescribe opioids is exempt.

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Acute Pain

- Pain, whether resulting from disease, accidental or intentional trauma, or other cause that the practitioner reasonably expects to last only a short period of time.
  - Does not include chronic pain, pain being treated as part of cancer care, hospice or other end-of-life care, or pain being treated as part of palliative care.

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Chronic Pain

- Pain that persists beyond the usual course of an acute disease or healing of an injury. May or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

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New Authorization

- The Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) can provide unsolicited notification to the licensure board if -
  - A patient receives prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards*
  - If the practitioner has exhibited prescriptive behavior indicating "potentially problematic prescribing patterns."

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*For example, more than 100 morphine milligram equivalents (MMEs) per day of an opioid.

Initial Prescription

- A prescription issued to a patient who:
  - has never previously been issued a prescription for the drug or its pharmaceutical equivalent in the past year, or
  - requires a prescription for the drug or its pharmaceutical equivalent due to a surgical procedure or new acute event and has previously had a prescription for the drug or its pharmaceutical equivalent within the past year.

Note: In order to determine if the patient was previously issued a prescription for a drug or its equivalent, the provider will consult with the patient and review the medical record and prescription monitoring (PMP) information of the patient.

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Initial Prescription

- SB 1446: Sections 5 and 6 – new law
- In a patient (adult or minor) with acute pain, the provider's initial prescription for an opioid must be limited to a seven-day supply (lowest effective dose and immediate-release opioid drug).

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Requirements for Issuing Initial Prescription

Prior to initial prescription for acute or chronic pain, must document:

1. Take and document the results of medical history including substance abuse history and experience of the patient with non-opioid treatment.
2. Conduct and document physical exam.
3. Develop treatment plan with attention focused on determining the cause of pain.
4. Access PMP and document access date in EMR.
5. If patient is under 18 years of age, a patient-provider agreement must be completed by a parent or guardian.
6. If patient is pregnant, a patient-provider agreement must be completed by the patient.

A ruling from the Oklahoma Office of the Attorney General allows either the provider or mid-level provider to do the patient assessments.

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Prior to the Initial Prescription and before a Third Prescription

- Discuss and document risks of addiction and overdose, dangers of taking opioid drugs with alcohol, benzodiazepines, and other CNS depressants. Discuss reasons why prescription is necessary and any alternative treatments available.

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Requirements for Issuing Second (Subsequent) Prescription

- A second prescription may not be prescribed until seven days after issuing the initial prescription.*
  - A second prescription must not exceed a seven day supply.
- Provider† will document the rationale for a subsequent prescription and document that the subsequent prescription does not present an undue risk of abuse, addiction, or diversion.

*Next two slides detail changes to this requirement under emergency rules signed by the Governor in 2018.

†Either the provider or mid-level provider to do the patient assessments.

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Emergency Rule

- A practitioner can provide a second or "subsequent prescription" on the same day as the "initial prescription" to patients who have had a **major surgical procedure**, or to patients who are "**confined to home**" as defined by Federal rules for Medicare. but must:
  - Provide written instruction on the subsequent prescription indicating the earliest date on which the prescription may be filled (i.e. "do not fill until" date); and
  - The subsequent prescription is dispensed no more than five (5) days after the "do not fill until" date indicated on the prescription.

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Emergency Rule

Homebound as defined in 42 U.S.C. 1395 n(a)

A patient is considered "homebound" if:

- The patient has trouble leaving their home without help (like using a cane, wheelchair, walker, or crutches; special transportation; or help from another person) because of an illness or injury, or
- Leaving home isn't recommended because of the patient's condition, and they are normally unable to leave their home because it's a major effort.

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See the hyperlink to "homebound" at: https://www.medicare.gov/coverage/home-health-services

Requirements for Issuing Third Prescription

- If a third prescription is required provider* must discuss the risks including:
  - Risks of addiction and overdose, and interactions between opioids and benzodiazepines, alcohol, or other CNS depressants.
  - The reason why the prescription is necessary
  - Alternative treatments that may be available
  - Risks associated with the drugs being prescribed
- Must be documented in chart.
- Must have a pain-management agreement with the patient

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SB 1446

Regulation of Opioid Drugs

- Lays out the details that must be documented in a "Patient-provider agreement" (a contract for chronic pain treatment)

"The provider shall be held harmless from civil litigation for failure to treat pain if the event occurs because of nonadherence by the patient with any of the provisions of the patient-provider agreement."

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Patient-Provider Agreement must Include:

- Explain possible risk of dependence and addiction
- Document understanding of provider and patient regarding the pain-management plan
- Establish rights of the patient in association with treatments and obligation of the patient to responsible use, discontinuation, and storage
- Identify specific medications and other modes of treatment
- Specify the measure the provider may employ to monitor compliance
- Explain process for terminating the agreement

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Patient-Provider Agreement

- Required for:
  - At the time a third prescription for an opioid is written
  - Any patient on more than 3 months of opioid treatment
  - If the patient is prescribed opioids and benzodiazepines together
  - If the patient requires more than 100 MME of opioids
  - If the patient is pregnant
  - With the parent or guardian if the patient is a minor

Medicine

Requirements for Chronic Pain

- For any opioid continuously prescribed for three months or more:
  - Review and document every three months in the chart the course of treatment, new info about the pain etiology, and progress towards treatment objectives
  - Must assess the patient before every renewal to see if they are having any problems and must document the assessment
  - Periodically make reasonable efforts and document measures taken to stop drugs unless contraindicated
  - Review the PMP and document date and findings in EMR at least every 180 days.
  - Monitor compliance with the Patient-provider agreement

Excludes patients with cancer, hospice care, palliative care, or LTCF patients, or drugs used to treat addiction.
After one year of compliance with a patient-provider agreement, the provider may review the treatment plan and assess the patient at 6-month intervals.

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Qualifying Opioid Therapy Patient

- A patient requiring opioid treatment for more than three (3) months;
- A patient who is prescribed benzodiazepines and opioids together; or
- A patient who is prescribed a dose of opioids that exceeds one hundred (100) morphine equivalent doses.

Any provider authorized to prescribe opioids shall adopt and maintain a written policy or policies that include execution of a written agreement to engage in an informed consent process between the prescribing provider and qualifying opioid therapy patient.

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Two Other Things to Consider

- Use of medical marijuana – may increase risk of overdose when used simultaneously with opioids
- Consider synchronous prescription for naloxone (Narcan)*
  - Does the patient's history or the state's PMP show that the patient is on a high opioid dose?
  - Is the patient on a concomitant benzodiazepine prescription?
  - Does the patient have a history of substance use disorder?
  - Does the patient have an underlying mental health condition?
  - Does the patient have a medical condition, such as a respiratory disease, sleep apnea or other comorbidities, that might make him or her susceptible to opioid toxicity, respiratory distress or overdose?
  - Are there children in the home?

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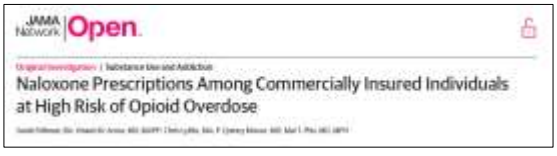
*See AMA Opioid Task Force recommendations.


JAMA Network Open.

Naloxone Prescriptions Among Commercially Insured Individuals at High Risk of Opioid Overdose

***CONCLUSIONS AND RELEVANCE** Patients at high risk of opioid overdose rarely received prescriptions for naloxone despite numerous interactions with the health care system. Prescribing in emergency, inpatient, and outpatient settings represents an opportunity to improve access.*

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JAMA Network Open. 2019;2(5):e193209. doi:10.1001/jamanetworkopen.2019.3209

First Rise in U.S. Death Rate in Years Surprises Experts

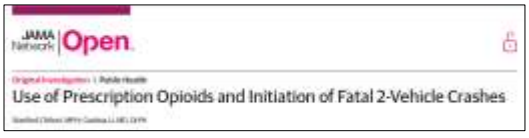
By Sabrina Tavernise

WASHINGTON — The death rate in the United States rose last year

Medicine

https://www.nytimes.com/2016/06/01/health/american-death-rate-rises-for-first-time-in-a-decade.html

Is there another liability you need to think about?



JAMA Network Open

Use of Prescription Opioids and Initiation of Fatal 2-Vehicle Crashes

Before the opioid epidemic began in the mid-1990s, prescription opioids were rarely implicated in fatal motor vehicle crashes, detected only in approximately 1% of fatally injured drivers. In the past 2 decades, **the prevalence of prescription opioids detected in fatally injured drivers has steadily increased to more than 7%.***

Chihuri S, Li G. *JAMA Network Open*. 2019;2(2):e188081.

*Chihuri S, Li G. Trends in prescription opioids detected in fatally injured drivers in 6 US States: 1995-2015. *Am J Public Health*. 2017;107(9):1487-1492.

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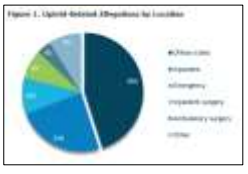
LITIGATION BLOG



Opioids Top List of Malpractice Claims Linked to Medications

Providers should be aware of the legal risks associated with prescribing opioids and incorporate practice strategies to minimize those risks. Legal risks include criminal prosecution, civil liability in malpractice litigation, and disciplinary action by governing licensing boards.

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COMMENTARY

Managing Increasing Liability Risks Related to Opioid Prescribing

Opioid prescribers can be **criminally charged** under the federal Controlled Substances Act and state equivalents. Under the Controlled Substances Act, the Drug Enforcement Administration is increasingly prosecuting physicians who knowingly and intentionally prescribe drugs outside of the usual course of medical practice or for non-legitimate medical purposes.

Physicians can also face homicide charges under state laws when opioids they prescribe result in overdose death.

Medicine

Yang YT, et al. *Am J Med*. 2017; 130: 249-50.

THE NEW ENGLAND JOURNAL of MEDICINE

Perspective

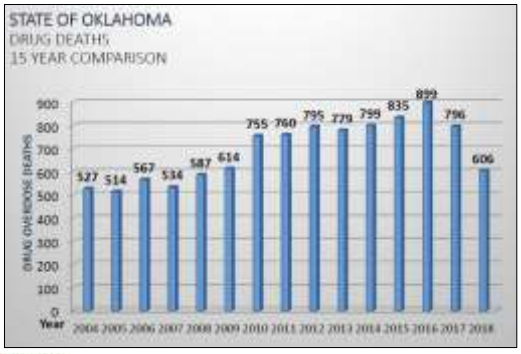
No Shortcuts to Safer Opioid Prescribing

"Unfortunately, some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations. A consensus panel has highlighted these inconsistencies which include inflexible application of recommended dosage and duration thresholds and policies that encourage hard limits and abrupt tapering of drug dosages, resulting in sudden opioid discontinuation or dismissal of patients from a physician's practice."

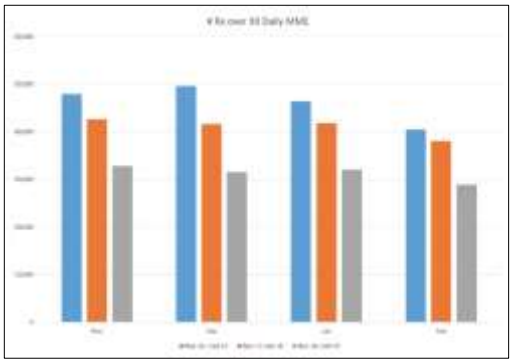
Medicine

N Engl J Med. 2019: DOI: 10.1056/NEJMp1904190

There is some good news…



Medicine



Medicine

Oklahoma Data

Conclusion

- Deaths from opioids is America's health emergency
- Like it or not, our prescribing practices for common procedures and diagnoses has contributed to the epidemic
- Opioid prescribing is often based on past experience and habit rather than evidence-based guidance – we often overestimate the need for opioids in our patients

Medicine

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Medicine