Prescribing Update - 2021

Sponsored by the Oklahoma State Medical Association

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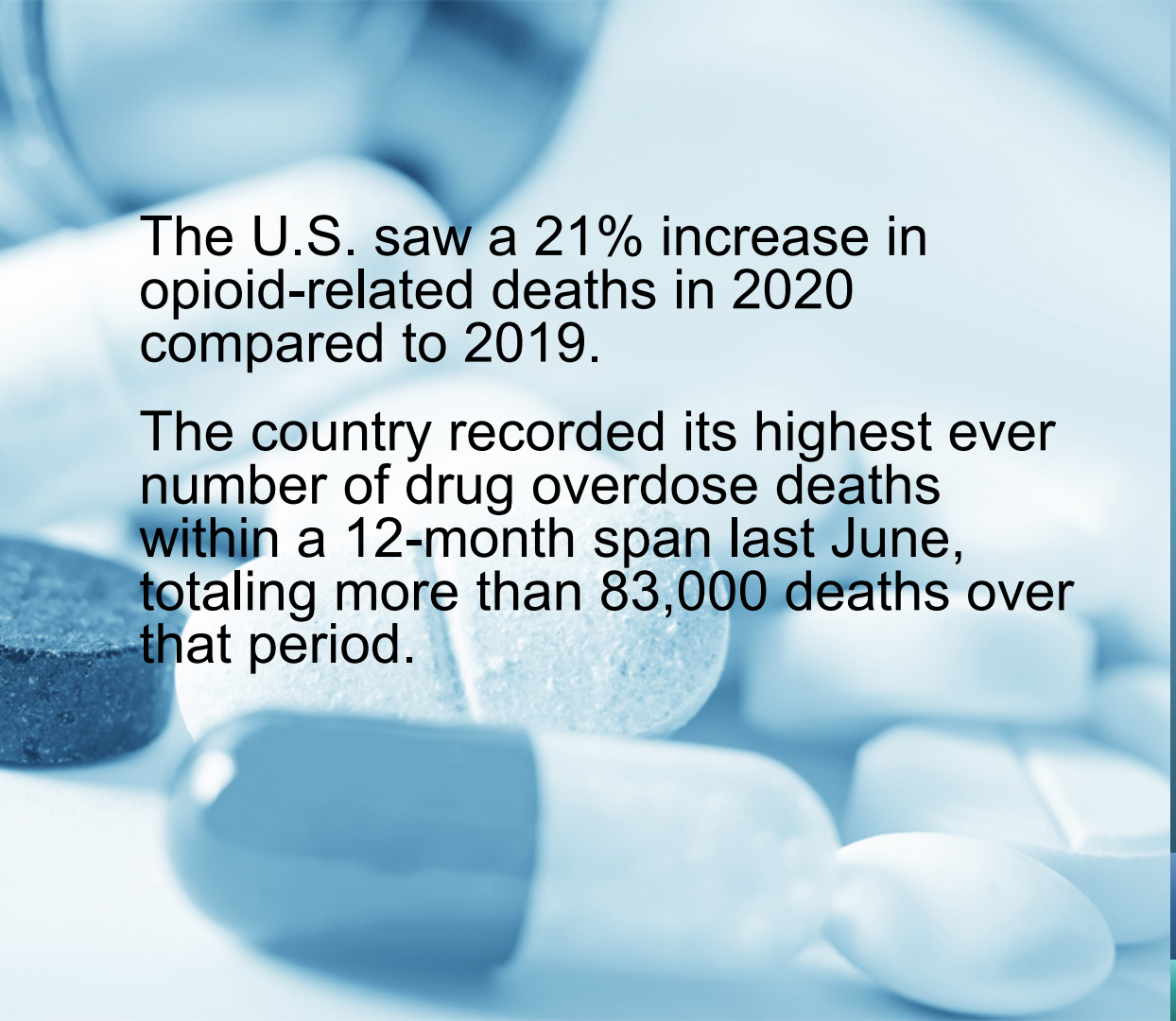
AGENDA

- 2020 Recap
- Regulatory Developments
- Payment Issues
- Legislative Update
- Enforcement
- CDC Prescribing Best Practices



The U.S. saw a 21% increase in opioid-related deaths in 2020 compared to 2019.

The country recorded its highest ever number of drug overdose deaths within a 12-month span last June, totaling more than 83,000 deaths over that period.

2020 was a rough year. . .

According to the CDC

Press Release, Thursday, December 17, 2020

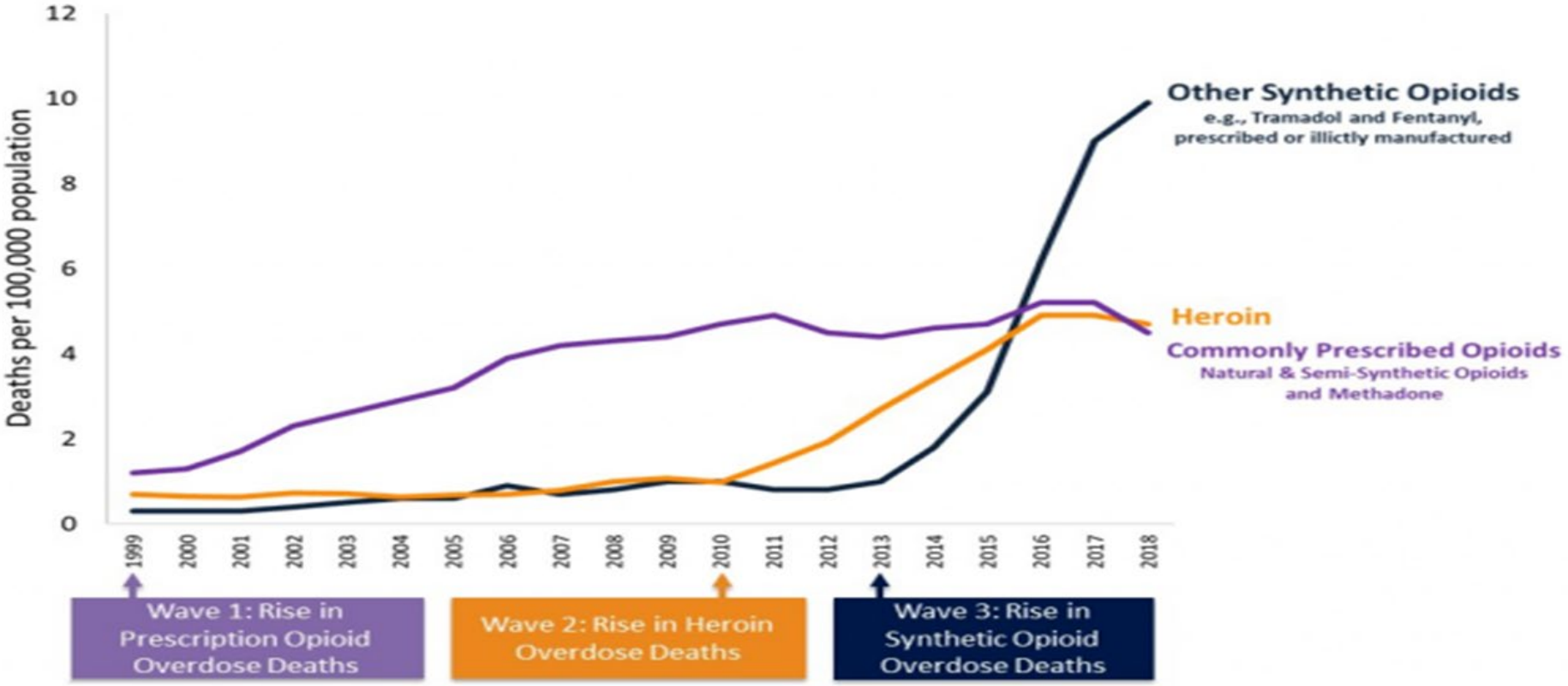
“The disruption to daily life due to the COVID-19 pandemic has hit those with substance use disorder hard,” said CDC Director Robert Redfield, M.D. “As we continue the fight to end this pandemic, it’s important to not lose sight of different groups being affected in other ways. We need to take care of people suffering from unintended consequences.”

According to the CDC

Press Release, Thursday, December 17, 2020

- Synthetic opioids appear to be the primary driver of the increases in overdose death.
- From June 2019 – May 2020:
  - 37 of the 38 U.S. jurisdictions with available synthetic opioid data reported increases in synthetic opioid-involved overdose deaths.
  - 18 of these jurisdictions reported increases greater than 50 percent.
  - 10 western states reported over a 98 percent increase in synthetic opioid-involved deaths.

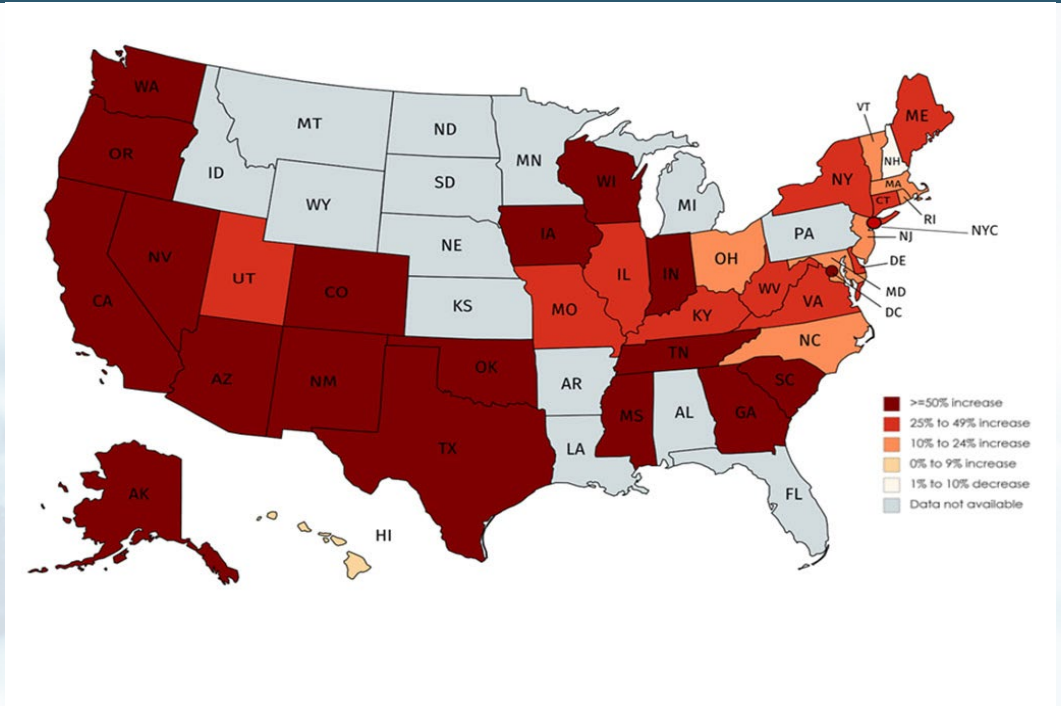
3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

CDC Health Advisory

Issued on December 17, 2020



Oklahoma – more than 50% increase in fatal overdoses involving synthetic opioids.

Regulatory/ Advocacy Updates

CDC Health Advisory Recommendations

- Expand distribution and use of naloxone and overdose prevention education.
- Expand awareness about and access to and availability of treatment for substance use disorders.
- Intervene early with individuals at highest risk for overdose.
- Improve detection of overdose outbreaks to facilitate more effective response.

Expand Uses of Naloxone

- *Healthcare providers:*
  - Talk to patients about the changing illicit drug supply and risks for overdose and exposure to highly potent opioids such as illicitly manufactured fentanyl.
  - Prescribe naloxonepdf iconexternal icon to individuals at risk for opioid overdose, such as those with a prior history of overdose, those with opioid use disorder, and individuals using illicit opioids and other drugs that might be mixed with illicitly manufactured fentanyl.
  - Co-prescribe naloxone to patients with high morphine milligram equivalents and those receiving opioids and benzodiazepines.[15]

Expand Uses of Naloxone

- *Healthcare providers:*
  - Expand locations in which overdose prevention education and take-home naloxone are provided. These locations can include inpatient and outpatient treatment programs, primary care settings, retail pharmacies, counseling and support groups, and other community-based settings. Expanding locations may be especially important in rural areas.
  - Counsel patients that multiple doses of naloxone may be needed for a single overdose event because of the potency of illicitly manufactured fentanyl and fentanyl analogs,19 and that multiple doses of naloxone may be needed over time due to prolonged effects of opioids in some cases.

Expand Access to Treatment for SUDs

- *Healthcare providers:*
  - **Provide Medications for Opioid Use Disorder (MOUD)**
    - Treatment with the FDA-approved medications methadone, buprenorphine, or naltrexone are lifesaving and the most effective forms of treatment for opioid use.
    - During the COVID-19 public health emergency, the Federal Government has made it easier to obtain MOUD through telehealth.
      - Find treatment options call **1-800-662-HELP (4357).**
      - SAMHSA's Buprenorphine Practitioner Locatorexternal icon can help identify a qualified practitioner who can prescribe buprenorphine.

Intervene Early

- Healthcare providers:
  - Initiate or continue medications for opioid use disorder among people leaving correctional and detention facilities.
  - Provide active referral-to-treatment options and recovery support services.
  - Implement post-overdose response protocols, including in emergency departments, that incorporate links between public health, treatment providers, community-based service organizations, and healthcare providers. These protocols promote overdose education, treatment, linkage to care and MOUD, and naloxone distribution.

AMA Issue Brief

Updated February 2, 2021

Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic

AMA Call To Action

The AMA urges governors and state legislatures to take action:

Adopt SAMHSA and DEA rules and guidance in-full for the duration of the national emergency–this includes flexibility for evaluation and prescribing requirements using telemedicine;

Support the removal of prior authorization, step therapy and other administrative barriers for medications used to treat opioid use disorder; meaningful enforcement of mental health and substance use disorder parity laws is long overdue

Remove existing barriers for patients with pain to obtain necessary medications. This includes removing arbitrary dose, quantity and refill restrictions on controlled substances; and

Implement and support harm reduction strategies, including removing barriers to sterile needle and syringe services programs.

SAMHSA

March 16, 2020

- Opioid Treatment Program (OTP) Guidance
  - Permitted states to request blanket exceptions for all stable patients in an OTP to receive 28 days of Take-Home doses of the patient's medication for opioid use disorder.
  - Also permitted states to request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication.

DEA

- *https://www.deadiversion.usdoj.gov/faq/coronavirus_faq.htm#ADMINISTERING_FAQ.*
- COVID-19 Information Page

HHS – Buprenorphine Confusion

anuary 14, 2021 06:47 PM UPDATED 16 HOURS AGO

HHS removes some requirements for opioid treatment prescribing

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Buprenorphine is used as an alternative to methadone to help addicts recovering from heroin use.

- Of the more than 1 million physicians currently practicing medicine in the U.S., only around 66,000 are certified to prescribe buprenorphine, which coupled with behavioral health counseling is considered by many experts to be the gold standard therapy for substance use disorder.

HHS - Buprenophrine Confusion

- New practice guidelines released by HHS on January 14, 2021 will allow any physician licensed by the DEA to prescribe buprenorphine to up to 30 patients without having to go through the standard process to become authorized, which requires clinicians to undergo eight hours of training.
- Only physicians can qualify for the exemption, and the 30 patient cap will not apply to hospital-based physicians, such as those who work in emergency departments.
- Does not include the prescribing of methadone.

State Attorney General

MIKE HUNTER
ATTORNEY GENERAL OF OKLAHOMA

FOR IMMEDIATE RELEASE

January 15, 2021

Attorney General Hunter, OSU's Dr. Beaman Comment on Removal of Federal Barriers to Treat Opioid Addiction

OKLAHOMA CITY – Attorney General Mike Hunter and OSU Center for Health Sciences Dr. Jason Beaman today praised the U.S. Department of Health and Human Services (HHS) for removing federal barriers that hindered health care professionals treating opioid addiction.

The new guidelines expand access to medication-assisted treatment by exempting physicians from certain certification requirements needed to prescribe buprenorphine for opioid addiction treatment.

In 2019, Attorney General Hunter led a bipartisan, 39 state coalition in sending a letter to Congressional leadership urging the move.

"This is a significant step in the right direction in our battle with the nation's opioid crisis that has been amplified by the Covid-19 pandemic," Attorney General Hunter said. "By eliminating barriers and giving doctors the authority to do what they believe is in the best interest of their patients struggling with opioid addiction will save lives. I commend the leadership at HHS, and everyone involved in this decision, for their meaningful action that will benefit those who are struggling with this deadly brain disease.

"I also appreciate the widespread support from state leaders like Dr. Beaman and the members on the Commission on Opioid Abuse, as well as other state entities, that have been behind this effort. While there is more work to do in our fight against the opioid epidemic, this gives doctors an important tool that is proven to help."

During the 12-month period ending in June 2020, the United States experienced a 21% increase in overdose deaths, representing the highest number ever recorded in a 12-month timeframe according to provisional data from the Center for Disease Control and Prevention.

During that same timeframe, the data show Oklahoma experienced a 14.9% spike in overdose deaths.

"What's more tragic about the current spike in overdose deaths is that it's likely an undercount due to incomplete data," said Dr. Beaman, who serves as Chair of the Department of Psychiatry and Behavioral Sciences at Oklahoma State University Center for Health Sciences. "That is why removing these barriers, expanding access to medication-assisted treatment and giving physicians more latitude to treat those struggling with addiction is critical. Medication-assisted treatment is a proven, individually personalized program that comprehensively addresses the needs of those struggling with addiction.

HHS - Buprenophrine Confusion

HHS Cancels Last-Minute Trump Plan To Let More Physicians Prescribe Opioid-Treatment Drug

The Washington Post (1/27, Diamond) reports that the Biden Administration "said Wednesday that it is canceling a last-minute plan by the Trump administration to let more physicians prescribe an opioid-treatment drug, despite exhortations from lawmakers and physician groups to keep it." The White House's drug policy office "said in a message obtained by The Washington Post: 'On January 14, 2021, HHS announced forthcoming Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder. Unfortunately, the announcement was made prematurely. Therefore, the Guidelines previously announced cannot be issued at this time.'"

E-Prescribing Changes

- SUPPORT Act (2018)
  - Required all US-based health facilities to adopt electronic prescribing of controlled substances for all regulated substances covered in Medicare Part D or Medicare Advantage by January 2021.

E-Prescribing Changes

- The CMS Final Rule pertaining to physician payment, released in December 2020 set a **new** compliance date of January 1, 2022.
  - Delays enforcement.
  - No penalties until 2022.

E-Prescribing Changes

- Oklahoma e-prescribing requirement went into effect January 1, 2020.
  - But waivers were liberally granted.
- The OBMLS issued a document with the heading: “E-Prescription Waiver Upon Application No Longer Offered by Medical Licensure Board Effective January 1, 2021.”

DEA

- Section 306 of the CSA requires that the Attorney General establish aggregate production quotas for each class of controlled substance listed in schedules I and II, and for the list I chemicals–the authority of which has been delegated to the Administrator of the DEA.

DEA

- The SUPPORT Act mandates that the DEA, with the assistance of DHHS, determine reliable rates of overdose deaths and public health when estimating diversion for the five types of covered controlled substances: (1) fentanyl, (2) hydrocodone, (3) hydromorphone, (4) oxycodone, and (5) oxymorphone.
- In other words, it requires annual production quotas for opioids to be adjusted to account for factors such as diversion rate, death and abuse of opioids, and public health.

DEA Quotas – SUPPORT

- In April 2020, as a response to the unprecedented coronavirus, the DEA increased the aggregate production quotas for opioid production.
- The coronavirus has resulted in an increase in ventilated patients and, therefore, has necessitated an increase in the demand for and the production of painkillers.
- While this quota increase earlier in 2020 has helped pharmaceutical companies, hospitals, and other healthcare entities deliver painkillers to ill patients, it has also resulted in an increase in opioid-related deaths and illicit uses.

DEA Quotas

- The DEA's April 2020 quota increase elicited some negative responses from Capitol Hill.

- On July 30, 2020, two U.S. senators—Dick Durbin (D-IL) and John Kennedy (R-LA)—wrote a letter to the DEA urging it to reduce its opioid production quotas for 2021 and prevent pharmaceutical companies from producing high levels of opioids.

- Their letter was written in response to both a "recent surge in opioid overdose deaths linked to the COVID-19 pandemic" and after the CDC reported an increase to "the highest ever level" of fatal drug overdoses in 2019.

DEA Quotas

- The DEA apparently heeded the senators' urgent appeal in its 2021 proposed aggregate production quotas.
- Production quotas for 4 out of 5 controlled substances have been reduced:
  - Fentanyl, Hydrocodone
  - Hydromorphone
  - Oxymorphone
  - Oxycodone

Oklahoma Proposed Legislation

Bill Number Status as of 2.12	Summary
SB 57 (Rader/Echols) Passed Senate; to House Committee	• Grants Opioid Overdoes Fatality Review Board access to PMP. • Requires physicians to provide patient's who request it a copy of their history. • Clarifies pill limit exception for hospice care.
SB 58 (Rader) Passed Senate; to House Committee	Permits a practitioner to electronically order a controlled dangerous substance when administered through a hospice program.

Oklahoma Proposed Legislation

Bill Number Status as of 2.12	Summary
HB 1013 (Talley/Rader) House public health committee	• Provides protections from penalties under the Anti-Drug Diversion Act to practitioners serving stable long-term opioid therapy patients. • Prohibits average prescribed doses from being used as sole basis for certain actions.
SB 605 (Standridge/Echols) Senate Health & Human Services	Provides liability protections to licensed practitioners with prescribing authority who meet certain requirements when making opioid prescriptions.

Oklahoma Proposed Legislation

Bill Number Status as of 2.12	Summary
HB 610 (McCortney/Hilbert) Senate A&B	• Creates the Opioid Settlement and Judgment Revolving Fund to be managed and invested by the State Treasurer. • A portion of the fund to be available each year for appropriation by the Legislature into opioid abatement programs.
SB 888 (Standridge/Echols) Senate Health & Human Services	Provides protections against disciplinary action to licensed practitioners with prescribing authority who meet certain requirements when making opioid prescriptions.

Reimbursement Issues

Medicare Part D

A Prescriber's Guide to the New Medicare Part D Opioid

Medicare Part D

- Real-time safety alerts at the time of dispensing
  - 7 day supply limit for opioid naïve patients.
    - Hard safety edit requiring override
  - Opioid care coordination alert
    - Regardless of whether individual prescription(s) are written below 90 MME threshold, the alert will be triggered by the fill of the prescription that reaches the cumulative threshold of 90 MME or greater.

Medicare - OTP

- January 1, 2020, Medicare began paying Medicare-enrolled OTPs to deliver OUD treatment services to Medicare beneficiaries.

- Beginning January 1, 2021, Medicare Part B covers hospital outpatient Opioid Treatment Program services.
  - Health care organizations may now apply on the Medicare Enrollment Application for Institutional Providers (CMS-855A) or through PECOS when they enroll in the Medicare Program.
  - These providers submit claims electronically using the 837 Institutional or the paper claim form CMS-1450.

- https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf.

OHCA - SoonerCare

- Pain Management Program
  - 263 page toolkit
  - Contains forms/checklists
  - https://oklahoma.gov/content/dam/ok/en/okhca/documents/a0304/23193.pdf.

OHCA Medication Assisted Treatment

- In an effort to combat prescription drug abuse, OHCA is working to reduce barriers related to substance use treatment:
  - Prior authorization requirement on certain products were removed on July 31, 2019.
  - Prescribers must have an active DEAX number on file with OHCA to prescribe MAT products.
- Continued PA requirements can be checked at: http://okhca.org/MAT.

OHCA - SoonerCare

- No Prior Authorization Required
  - Suboxone (brand preferred)
  - Buprenorphine/naloxone (generic only)
  - Vivtirol (naltrexone injection)

OHCA MME Requirements

- In January 2019, OHCA began incorporating MME into the claims processing system.
- Overlapping opioid claims are totaled to include a member's aggregate MME per day.
- The cutoff is 90 MME per day (effective October 2019).

OHCA Lock-In Program

- SoonerCare pharmacy-administered program.
- Locks a member into one pharmacy AND one prescriber.
  - Pharmacy claims will deny if not from designated providers.
  - Multiple medications monitored.

OHCA Lock-In Program Referral

- Members are referred anonymously via the pharmacy lock-in form (PHARM-16). FAX 866-802-4384 or call the Pharmacy Lock-in Program at 800-522-0114, Option 4.
- Any health care provider, emergency department, pharmacy, case worker or ancillary staff that may be concerned about a member with substance abuse issues.
- Upon inclusion into the Patient Review and Restriction Program, members are locked in for a period of two years, with monthly review and yearly reevaluation.

OHCA - SoonerCare

Enforcement

Enforcement

DOJ Enforcement

- Controlled Substances Act (CSA)
  - 21 USC 801-904.
- Section 841 is used by prosecutors to criminally charge overprescribing physicians.
- Prosecutors are required to show the targeted physician distributed prescription drugs:
  - knowingly and intentionally;
  - without a legitimate medical purpose; and
  - outside the course of professional practice

DOJ – Recent Examples

- January 15, 2021
  - Federal Court Restrains Toledo Pharmacy and Two Pharmacists From Dispensing Opioids or Other Controlled Substances
- December 22, 2020
  - Department of Justice Files Nationwide Lawsuit Against Walmart Inc. for Controlled Substances Act Violations
- December 17, 2020
  - Former Medical Director of Suboxone Manufacturer Indivior Sentenced in Connection with Drug Safety Claims
- December 16, 2020
  - Federal Court Orders North Carolina Pharmacy, Pharmacy Owner, and Pharmacist-in-Charge to Pay More Than $1 Million and Stop Dispensing Opioids
- October 21, 2020
  - Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family
- June 22, 2020
  - Doctor Charged with Illegally Distributing Controlled Substances Which Resulted in the Death of Three Patients
- June 19, 2020
  - Former Norfolk Doctor Sentenced For Role In Internet Pharmacy Organization

DEA Enforcement

- September 24, 2020
- Ft. Worth Doctors Leave Patients Wasted and Dazed in a Pill Mill Operation; 49 Arrested
- **FORT WORTH, TX** - Forty-nine defendants, including two doctors and five pharmacists, have been charged with participating in an $18 million pill mill scheme, announced by the DEA Dallas Field Division.

DEA Enforcement

August 12, 2020Tulsa “Pill Mill” Doctor Pleas Guilty to Opioid Drug Conspiracy

- **TULSA, Okla.** – DEA Special Agent in Charge Eduardo A. Chavez of the Dallas Field Division, announced that Tulsa physician Dr. Christopher V. Moses pleaded guilty today in U.S. District Court for the Northern District of Oklahoma to conspiring to distribute controlled substances, as well as maintaining a drug involved premises at his medical clinic where he and others acting on his behalf unlawfully issued prescriptions for controlled substances.

July 27, 2020Former Long Island Doctor Pleads Guilty to conspiring to illegally distribute oxycodone

- BROOKLYN, N.Y. - Earlier today, in federal court in Central Islip, Tameshwar Ammar, a former medical doctor in Roslyn, New York, pleaded guilty via teleconference to conspiring to illegally distribute oxycodone. Ammar was indicted in November 2019. On June 22, 2020, he relinquished his license to practice medicine. Today’s plea was entered before United States District Judge Denis R. Hurley.

- April 6, 2020Wisconsin physician agrees to pay penalties to resolve allegations of prescribing opioids illegally and violating False Claims Act
- Dr. Heydarpour routinely prescribed multiple opioid medications at extremely high doeses to patients, often for years and without any documented evaluation of the patietns or improvement in the patients' pain or condition.

Opioid Use Causes Increase in Medical Malpractice Litigation

- White paper by the Expert Institute:
  - Over the past 4 years, medication-related claims have been cited as the 4th most common medical malpractice cause of action.
  - Opioid prescriptions make up almost 25% of such claims, making pain medication the most frequent root cause of medical malpractice actions involving prescriptions.

Opioid Use Causes Increase in Medical Malpractice Litigation

- According to Robert Hanscom, M.D., V.P. of Coverys and co-author of a study: "Physicians continued to renew prescriptions without monitoring patients to see if they were getting better or not, if there were any changes in their clinical status. . . If patients are still in pain, that's red flag. It's not helpful to keep prescribing the same opioid if they're not improving."

Review of Oklahoma Pill Limit Statute

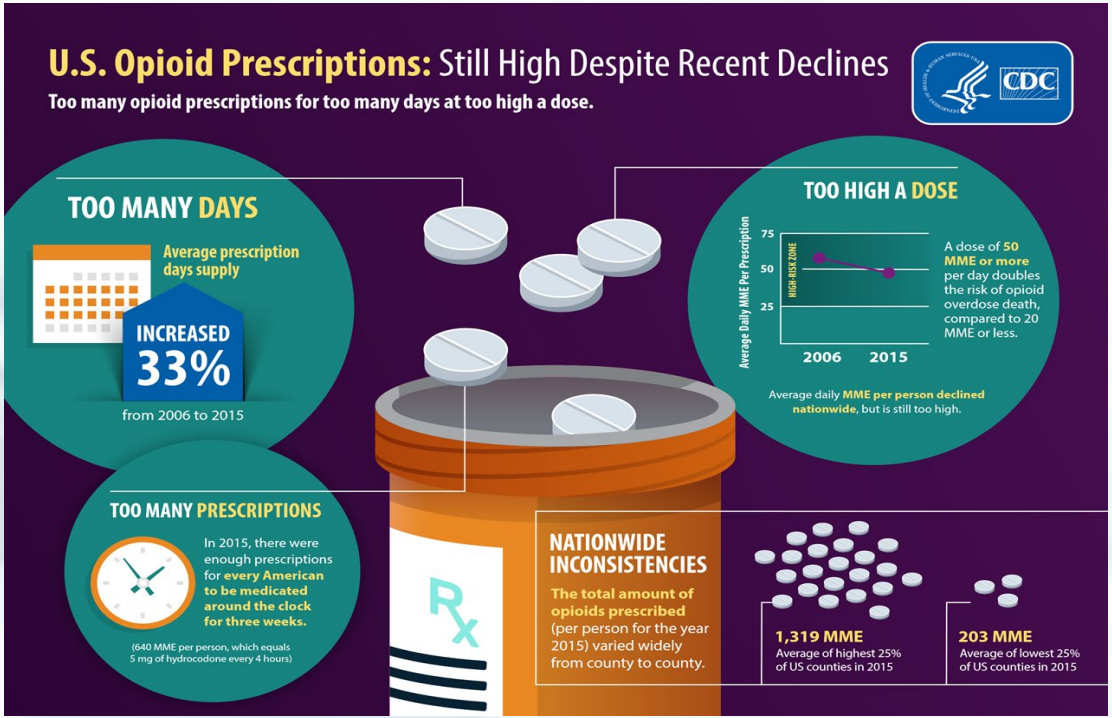
Pill Limit Bill

- Initial prescription for “opioids” used to treat **acute** pain are limited to 7-day supply unless exception applies.
- Should be limited to lowest effective dose of an immediate-release drug.

State Regulation

- Supporters of opioid limits such as the Centers for Disease Control and Prevention argue that "prescriptions with fewer days” supply will minimize the number of pills available for unintentional or intentional diversion."

The Goal of Pill Limit Statutes



Exception

- Upon issuing an initial prescription for acute pain, the practitioner may issue 1 subsequent prescription for an opioid in a quantity not to exceed 7 days if:
  - The subsequent prescription is due to a major surgical procedure or “confined to home”;
  - The practitioner provides the subsequent prescription on the same day as the initial prescription
  - The practitioner provides written instructions on the subsequent prescription indicating the earliest date on which the prescription may be filled, otherwise known as a “do not fill until” date; and
  - The subsequent prescription is dispensed no more than 5 days after the “do not file” date.

Prior to Initial Prescription

- Take and document history.
- Conduct and document a physical examination.
- Develop a treatment plan.
- Access PMP.
- Enter into provider agreement with parents/guardians of minor or pregnant woman.

Patient-Provider Agreement

- A patient requiring opioid treatment for more than 3 months.
- A patient who is prescribed benzodiazepines and opioids together for more than 1 24-hour period; or
- A patient who is prescribed a dose that exceeds 100 MMEs.

Prescriptions

- Must indicate on prescriptions whether they are for “acute” or “chronic” pain.

Subsequent Prescriptions

- After consulting with the patient (in person or by telephone), a subsequent prescription may be issued in a quantity not to exceed 7-day supply.
- Must be necessary and appropriate and low risk of abuse or diversion.

Licensure Board Guidance

- Consult “Compliance and Best Practice for An Act Regulating the Use of Opioid Drugs” available on the OBMLS and Board of Osteopathic Examiner websites.

CDC Best Practices

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.
2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

CLINICAL REMINDERS

- 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

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

CLINICAL REMINDERS

- 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

4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.

7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

CLINICAL REMINDERS

- 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

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

Misapplication of Guidelines

- **Misapplication of recommendations to populations outside of the Guideline's scope.** The Guideline is intended for primary care clinicians treating chronic pain for patients 18 and older. Examples of misapplication include applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain.

Misapplication of Guidelines

- **Misapplication of the Guideline's dosage recommendation that results in hard limits or "cutting off" opioids.** The Guideline states, "*When opioids are started*, clinicians should prescribe the lowest effective dosage. Clinicians should… avoid *increasing* dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day." The recommendation statement does not suggest discontinuation of opioids already prescribed at higher dosages.

Misapplication of Guidelines

- **The Guideline does not support abrupt tapering or sudden discontinuation of opioids**. These practices can result in severe opioid withdrawal symptoms including pain and psychological distress, and some patients might seek other sources of opioids. In addition, policies that mandate hard limits conflict with the Guideline's emphasis on individualized assessment of the benefits and risks of opioids given the specific circumstances and unique needs of each patient.

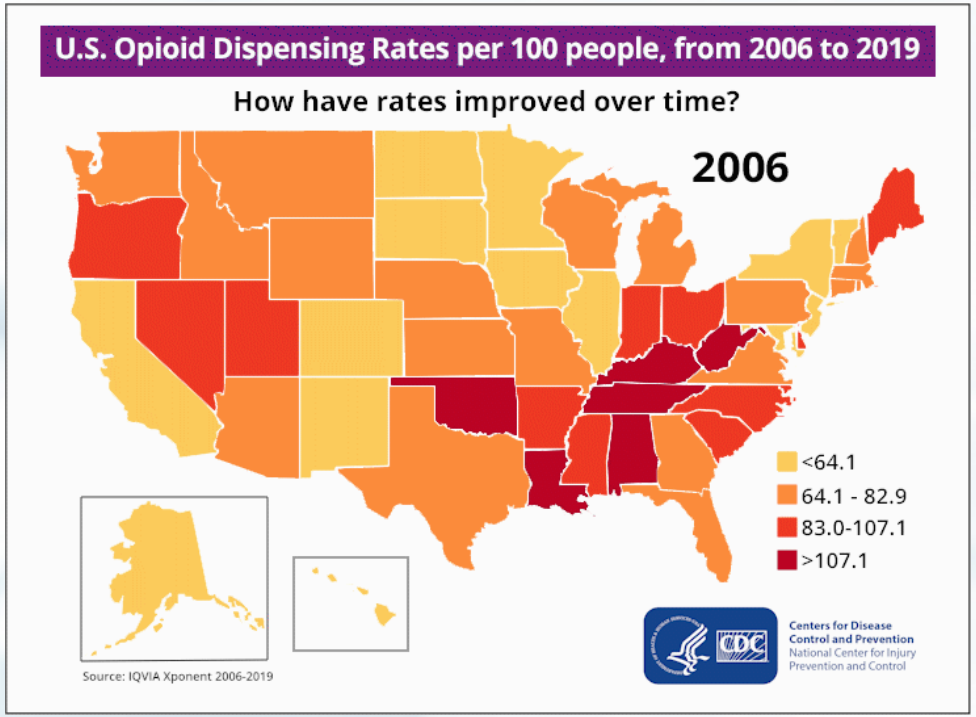
Misapplication of Guidelines

- **Misapplication of the Guideline's dosage recommendation to patients receiving or starting medication-assisted treatment for opioid use disorder.** The Guideline's recommendation about dosage applies to use of opioids in the management of chronic pain, not to the use of medication-assisted treatment for opioid use disorder. The Guideline strongly recommends offering medication-assisted treatment for patients with opioid use disorder.

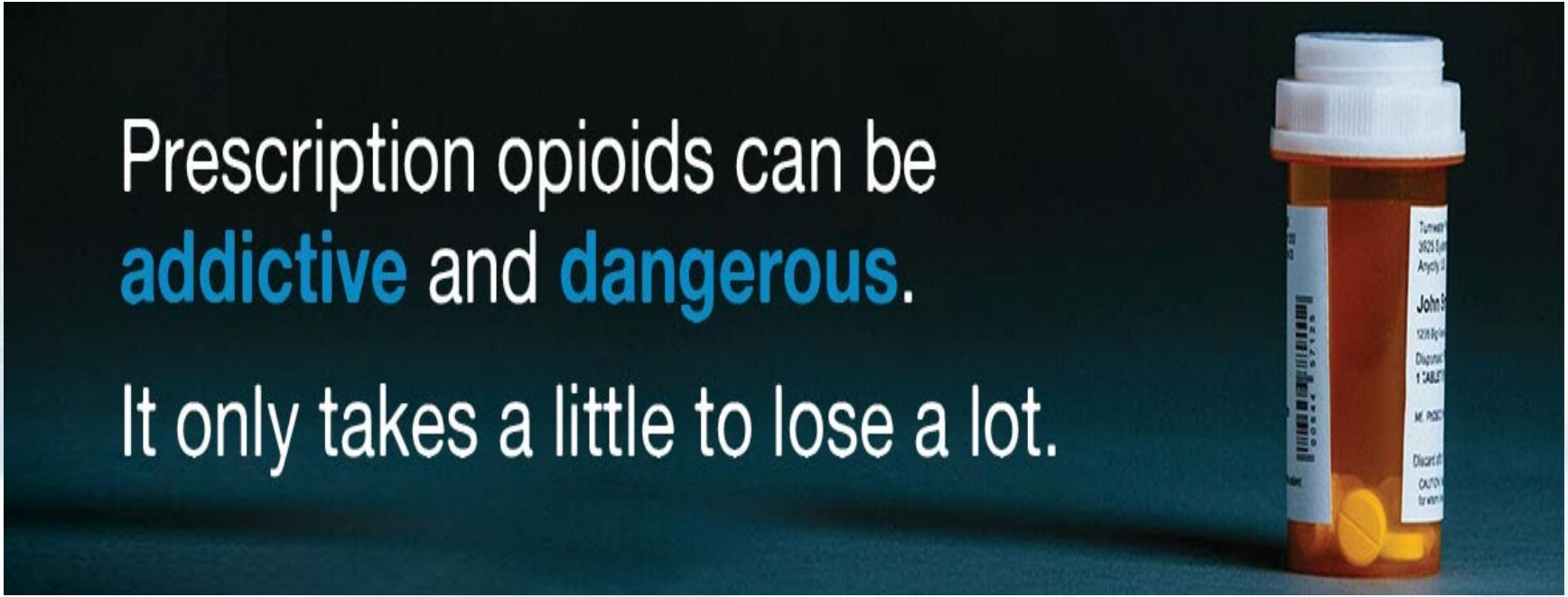
What is the CDC saying?

"Many Americans suffer from chronic pain. These patients deserve safe and effective pain management. Prescription opioids can help manage some types of pain in the short term. However, we don't have enough information about the benefits of opioids long term, and we know that there are serious risks of opioid use disorder and overdose – particularly with high dosages and long-term use."

CDC Dispensing Rates



CDC RX Awareness Campaign



CDC Chronic Pain

Interactive Training Series for Healthcare Providers

https://www.cdc.gov/drugoverdose/training/online-training.html.

Applying CDC's Guideline for Prescribing Opioids: An Online Training Series for Providers

This interactive online training series aims to help healthcare providers apply CDC’s recommendations in clinical settings through patient scenarios, videos, knowledge checks, tips, and resources. Providers can gain a better understanding of the recommendations, the risks and benefits of prescription opioids, nonopioid treatment options, patient communication, and risk mitigation. Each stand-alone module is self-paced and offers free continuing education.

13 CDC Modules

1	Addressing the Opioid Epidemic: Recommendations from CDC
2	Treating Chronic Pain Without Opioids
3	Communicating with Patients
4	Reducing the Risks of Opioids
5	Assessing and Addressing Opioid Use Disorder
6	Dosing and Titration of Opioids: How Much, How Long, and How and When to Stop
7	Determining Whether to Initiate Opioids for Chronic Pain

13 CDC Modules

8	Implementing CDC's Opioid Prescribing Guideline into Clinical Practice
9	Opioid Use and Pregnancy
10	Motivational Interviewing
11	Collaborative Patient-Provider Relationship in Opioid Clinical Decision Making
12	A Nurse's Call to Action for Safer Opioid Prescribing Practices
13	Using the Prescription Drug Monitoring Program to Promote Patient Safety in Opioid Prescribing and Dispensing

CDC Fact Sheets

1	New Opioid Prescribing Guideline
2	Assessing Benefits and Harms of Opioid Therapy
3	Prescription Drug Monitoring Programs
4	**Calculating Total Daily Dose of Opioids for Safer Prescribing**
5	Pregnancy and Opioid Pain Medications
	Checklist for Prescribing Opioids for Chronic Pain

Newest CDC Training Module

Addressing the Opioid Overdose Epidemic in the Emergency Department

Learn strategies for reducing opioid administration and prescribing in the emergency department, recognizing the signs of opioid use disorder (OUD), and initiating treatment for OUD.

Course #WB4431

Module #14

Other Available Trainings

CDC Clinical Tools

1	Quick Reference for Healthcare Providers
2	Urine Drug Testing
3	Mobile App (includes MME calculator)
4	Calculating Dosage
5	Pocket Guide: Tapering
6	Fact Sheet
7	Checklist
8	Nonopioid Treatments

CDC App


Overview
4x
Overdose Deaths
Overdose deaths involving opioids, including prescription opioids, have quadrupled since 1999.
SAFER PRESCRIBING AT YOUR FINGERTIPS.
DOWNLOAD THE OPIOID GUIDE APP TODAY
www.cdc.gov

CDC - 12 Guidelines (1)

- **Opioids are not first-line therapy**
  - Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
    - Nonopioids medications
    - Physical treatments
    - Behavioral treatment
    - Interventional treatments (injections)

CDC - 12 Guidelines (2)

- **Establish Goals for Pain and Function**
  - Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks.

CDC - 12 Guidelines (3)

- **Discuss Risks and Benefits**
  - Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

CDC - 12 Guidelines (4)

- **Use Immediate-Release Opioids When Starting**
  - Clinicians should prescribe immediate-release opioids instead of extended release/long-acting (ER/LA) opioids.

CDC - 12 Guidelines (5)

- **Use the Lowest Effective Dose**
  - Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to more than 50 MME/day and should avoid increase dosage to more than 90 MME/day or carefully justify a decision to titrate dosage to more than 90 MME/day.

CDC - 12 Guidelines (6)

- **Prescribe Short Durations for Acute Pain**
  - Long-term opioid use often begins with treatment of acute pain.
  - Prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.
  - Three (3) days or less will often be sufficient; more than seven (7) days will rarely be needed.

CDC - 12 Guidelines (7)

- **Evaluate Benefits and Harms Frequently**
  - Evaluate with patients within 1-4 weeks of starting opioid therapy for chronic pain or of dose escalation.
  - Evaluate benefits and harms of continued therapy with patients ever 3 months or more frequently.

CDC - 12 Guidelines (8)

- **Use Strategies to Mitigate Risk**
  - Clinicians should incorporate into the management plan strategies to mitigate risk including considering offering naloxone when factors that increase risk for opioid overdose are present.
    - History of overdose or substance use disorder
    - Mental health conditions such as anxiety or depression
    - Sleep apnea
    - Older age (65 or older)
    - Pregnancy
    - Higher opioid dosages
    - Concurrent use of Benzodiazepines, Muscle relaxants, Hypnotics or other opioids

CDC Assessing Benefits and Harms

- A 30% improvement in pain and function is considered clinically meaningful.

Assess Harms of Opioid Therapy

- Assess (1)
  - Evaluate for factors that could increase your patient's risk for harm from opioid therapy such as:
    - Personal or family history of SUD
    - Renal or hepatic insufficiency
    - COPD

Assess Harms of Opioid Therapy

- Check (2)
  - Consider urine drug testing for other prescription or illicit drugs and check the state PDMP for:
    - Possible drug interactions
    - High opioid dosage
    - Obtaining opioids from multiple providers.

Assess Harms of Opioid Therapy

- Check (2)
  - Consider urine drug testing for other prescription or illicit drugs and check the state PDMP for:
    - Possible drug interactions
    - High opioid dosage
    - Obtaining opioids from multiple providers.

Assess Harms of Opioid Therapy

- Discuss (3)
  - Ask your patient about concerns and determine any harms they may be experiencing such as:
    - Nausea or constipation
    - Feeling sedated or confused
    - Breathing interruptions during sleep
    - Taking or craving more opioids than prescribed or difficulty controlling use.

Assess Harms of Opioid Therapy

- Observe (4)
  - Look for early earning signs for overdoes risk such as:
    - Confusion
    - Sedation
    - Slurred speech
    - Abnormal gait

CDC - 12 Guidelines (9)

- **Review PDMP Data**
  - Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

CDC Prescription Drug Monitoring Programs

- “State requirements vary, but CDC recommends checking at least once every 3 months and consider checking prior to every opioid prescription.”

What should I do if I find information about a patient in the PDMP that concerns me?

- “Patients should not be dismissed from care based on PDMP information. Use the opportunity to provide potentially life-saving information and interventions.”

What should I do if I find information about a patient in the PDMP that concerns me?

1. Confirm that the information in the PDMP is correct.
2. Assess for possible misuse or abuse.
   a. Offer or arrange for treatment.
3. Discuss any areas of concern with your patient and emphasize your interest in their safety.

CDC - 12 Guidelines (10)

- **Use Urine Drug Testing**
  - Clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

CDC Urine Drug Testing

- “All patients on long-term opioid therapy should have periodic urine drug tests. Medical experts agree that an annual UDT for all patients should be standard practice. Subsequent UDTs should be determined on an individual patient basis, at the discretion of the clinician.

What to discuss with patients **BEFORE** ordering and conducting a UDT

- **Establish provider/patient trust**
  - Requiring a UDT does not imply a lack of trust on the part of the provider; it is part of a standardized set of safety measures offered to all patients taking opioids.

What to discuss with patients **BEFORE** ordering and conducting a UDT

- **Discuss the purpose of UDTs**
  - What drugs the test will cover, and the expected results (e.g., presence of prescribed medication and absence of other drugs, including illicit drugs, not reported by the patient).

What to discuss with patients **BEFORE** ordering and conducting a UDT

- **Go over the potential cost**
  - If the UDT is not covered by insurance.
- **Review dosage**
  - Review the time and dose of the opioids most recently consumed by the patient.

What to discuss with patients **BEFORE** ordering and conducting a UDT

- **Discuss any prescribed or unprescribed drugs**
  - Discuss any other prescribed or unprescribed drugs thte patient has taken; unprescribed drugs may include marijuana or other illicit drugs.

- **Ask the patient what UDT results he/she expects**
  - To aid in eliciting information on other drugs taken as well as to assess his/her understanding of test result interpretation.

What to discuss with patients **BEFORE** ordering and conducting a UDT

- **Establish the expectation of random repeat testing.**
  - Establish the expectation of random repeat testing depending on treatment agreement and monitoring approach.
- **Review**
  - Review actions that may be taken based on the results of the test.

Talking with Patients about UDT Results

- “If unexpected results occur when ordering a UDT, remember that the focus is to improve patient safety. Have a plan in place for communicating results and practice the difficult conversations you may have to have with your patients.”

Talking with Patients about UDT Results

- CDC Tips
  - Always keep the focus on the patient's well-being and safety.
  - Do not jump to conclusions about unexpected results; have a candid conversation with the patient about possible explanations.

Talking with Patients about UDT Results

- CDC Tips
  - **Do not dismiss patients from care based on UDT results.**
  - Consider using the CDC mobile app to practice the types of conversations you may encounter with patients.

Actions to take post-UDT

- Discuss unexpected results with the local laboratory or toxicologist if assistance is needed with interpretation.

- Inform the patient of the test results.

Actions to take post-UDT

- Take time to discuss unexpected results with the patient and refer to pre-UDT information the patient may have shared with you.
- Review the treatment agreement and focus conversations around patient safety.

Actions to take post-UDT

- Determine if frequency and intensity of monitoring should be increased and keep the patient informed.

CDC - 12 Guidelines (11) and (12)

- **Avoid Concurrent Opioid and Benzodiazepine Prescribing**

- **Offer Treatment for Opioid Use Disorder**
  - Usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies.

Drug Cocktail – “Holy Trinity”

- Opiate + Benzodiazepine + Muscle Relaxer
  - Combo of Oycodone/Hydrocodone, Alprazolam, & Carisoprodol
  - Oxy, Soma and Xanas

CDC Tapering Pocket Guide

- Consider tapering when your patient:
  - Requests dosage reduction
  - Does not have clinically meaningful improvement in pain and function (e.g., at least 30% improvement on the 3-item PEG scale)

CDC Tapering Pocket Guide

- Consider tapering when your patient:
  - Is on dosages greater than 50 MME/day without benefit or opioids are combined with benzodiazepines
  - Shows signs of substance use disorder (e.g., work or family problems related to opioids use, difficulty controlling use)

CDC Tapering Pocket Guide

- Consider tapering when your patient:
  - Experiences overdose or other serious adverse event
  - Shows early warning signs of overdose risk such as confusion, sedation or slurred speech

CDC Tapering Pocket Guide

- “A decrease of 10% per month is a reasonable starting point if patients have taken opioids for more than a year. A decrease of 10% per week may work for patients who have taken opioids for a shorter time (weeks to months).”

CDC Tapering Pocket Guide

- “Discuss the increased risk for overdose if patients quickly return to a previously prescribed higher dose.”

Medical Record Documentation

- Physicians who treat patients with chronic pain **MUST** maintain accurate and complete medical records:
  - Copies of the signed informed consent and treatment agreement.
  - Patient's medical history.

Medical Record Documentation

- Results of the physician examination and all laboratory tests (if you billed for it, it better be there).
- Results of the risk assessment.
- A description of the treatments provided.
- Instructions to the patient, including discussions of risks and benefits.

Medical Record Documentation

- Results of ongoing monitoring of patient progress.
- Notes of evaluations by and consultations with specialists.
- Results of queries to the State PMP.
- Any other information used to support the initiation, **continuation**, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors.

DHHS Recommendation

December 19, 2018

- Prescribe or co-prescribe naloxone to individuals at risk for opioid overdose including individuals who:
  - Are on relatively high doses of opioids
  - Take other medications which enhance opioid complications
  - Have underlying health conditions

Thank you for attending and listening!

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