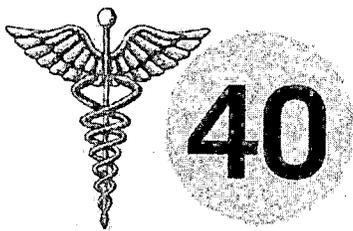


CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Promoting Patient Care and Safety

THE US OPIOID OVERDOSE EPIDEMIC

The United States is in the midst of an epidemic of prescription opioid overdoses. The amount of opioids prescribed and sold in the US quadrupled since 1999, but the overall amount of pain reported by Americans hasn't changed. This epidemic is devastating American lives, families, and communities.



More than 40 people die every day from overdoses involving prescription opioids.¹



Since 1999, there have been over 165,000 deaths from overdose related to prescription opioids.¹



4.3 million Americans engaged in non-medical use of prescription opioids in the last month.²

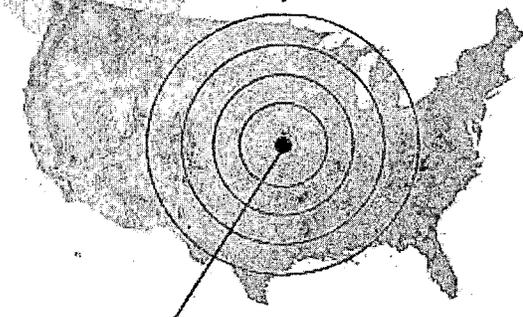
PRESCRIPTION OPIOIDS HAVE BENEFITS AND RISKS

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.

R_x

249M

prescriptions for opioid pain medication were written by healthcare providers in 2013



enough prescriptions were written for every American adult to have a bottle of pills

¹ Includes overdose deaths related to methadone but does not include overdose deaths related to other synthetic prescription opioids such as fentanyl.

² National Survey on Drug Use and Health (NSDUH), 2014



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

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

NEW CDC GUIDELINE WILL HELP IMPROVE CARE, REDUCE RISKS

The Centers for Disease Control and Prevention (CDC) developed the *CDC Guideline for Prescribing Opioids for Chronic Pain* (Guideline) for primary care clinicians treating adult patients for chronic pain in outpatient settings. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care. The Guideline was developed to:

- Improve communication between clinicians and patients about the benefits and risks of using prescription opioids for chronic pain
- Provide safer, more effective care for patients with chronic pain
- Help reduce opioid use disorder and overdose

The Guideline provides recommendations to primary care clinicians about the appropriate prescribing of opioids to improve pain management and patient safety. It will:

- Help clinicians determine if and when to start prescription opioids for chronic pain
- Give guidance about medication selection, dose, and duration, and when and how to reassess progress, and discontinue medication if needed
- Help clinicians and patients—~~together~~—assess the benefits and risks of prescription opioid use

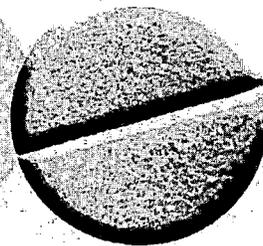
Among the 12 recommendations in the Guideline, there are three principles that are especially important to improving patient care and safety:

- ✓ Nonopioid therapy is preferred for chronic pain outside of active cancer, palliative, and end-of-life care.
- ✓ When opioids are used, the lowest possible effective dosage should be prescribed to reduce risks of opioid use disorder and overdose.
- ✓ Clinicians should always exercise caution when prescribing opioids and monitor all patients closely.

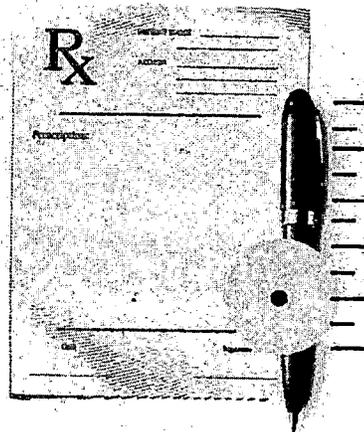
To develop the Guideline, CDC followed a transparent and rigorous scientific process using the best available scientific evidence, consulting with experts, and listening to comments from the public and partners.

As many as

1 in 4



patients receiving long-term opioid therapy in primary care settings



struggle with opioid use disorder.

PATIENT CARE AND SAFETY IS CENTRAL TO THE GUIDELINE

Before starting opioids to treat chronic pain, patients should:

- Make the most informed decision with their doctors
- Learn about prescription opioids and know the risks
- Consider ways to manage pain that do not include opioids, such as:
 - Physical therapy
 - Exercise
 - Nonopioid medications, such as acetaminophen or ibuprofen
 - Cognitive behavioral therapy (CBT)

CDC RECOMMENDATIONS

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

1 OPIOIDS ARE NOT FIRST-LINE THERAPY

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.

Nonpharmacologic therapies and nonopioid medications include:

- Nonopioid medications such as acetaminophen, ibuprofen, or certain medications that are also used for depression or seizures
- Physical treatments (eg, exercise therapy, weight loss)
- Behavioral treatment (eg, CBT)
- Interventional treatments (eg, injections)

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. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

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.

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

4 USE IMMEDIATE-RELEASE OPIOIDS WHEN STARTING

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

Immediate-release opioids: faster acting medication with a shorter duration of pain-relieving action

5 USE THE LOWEST EFFECTIVE DOSE

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.

Extended release opioids: slower acting medication with a longer duration of pain-relieving action

6 PRESCRIBE SHORT DURATIONS FOR ACUTE PAIN

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.

Morphine milligram equivalents (MME)/day: the amount of morphine an opioid dose is equal to when prescribed; often used as a gauge of the abuse and overdose potential of the amount of opioid that is being given at a particular time

7 EVALUATE BENEFITS AND HARMS FREQUENTLY
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

8 USE STRATEGIES TO MITIGATE RISK
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 REVIEW PDMP DATA
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.

Naloxone: a drug that can reverse the effects of opioid overdose

Benzodiazepine: sometimes called "benzo," is a sedative often used to treat anxiety, insomnia, and other conditions

PDMP: a prescription drug monitoring program is a statewide electronic database that tracks all controlled substance prescriptions

10 USE URINE DRUG TESTING
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 AVOID CONCURRENT OPIOID AND BENZODIAZEPINE PRESCRIBING
Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

12 OFFER TREATMENT FOR OPIOID USE DISORDER
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.



**NEARLY
2M**
Americans, aged 12 or older, either abused or were dependent on prescription opioids in 2014

Medication-assisted treatment: treatment for opioid use disorder including medications such as buprenorphine or methadone

Opioid Misuse:

Options for Prevention, Identification, and Treatment

(including certain policies already implemented in Utah)

Revised 4/21/16

This is an evolving document. Suggestions for change are welcome.
The inclusion of options in this document is not any indication of their merit.

1. PHARMACEUTICAL MANUFACTURERS

- a. Improve prescriber education
- b. Increase production of abuse-deterrent opioids (extended-release and long-acting)

2. PRESCRIBERS

- a. Engage in continuing professional education about opioid prescribing
- b. Comply with opioid prescribing guidelines
 - i. Utah Department of Health 2009 Guidelines
 - ii. U.S. Centers for Disease Control and Prevention 2015 Guidelines
 1. Limit to acute pain for 3 – 7 days
 2. Use alternatives for chronic pain
 3. Use of lowest possible dose
 4. Use of immediate-release formulations
 5. Exceptions for active cancer, end-of-life care, and surgery
 - iii. Condition-specific pain management protocols
- c. Screen patients for substance misuse and refer them to treatment programs
- d. Improve patient education
- e. Co-prescribe naloxone with opioids
- f. Use patient assessment tools and pain management contracts
- g. E-prescribe controlled substances (or a subset thereof) to reduce fraud and monitor treatment compliance
- h. Use secure prescription pads
- i. Engage in peer review of prescribing practices
- j. Abide by prescribing limits
 - i. Limit the amount of first-time prescription (or other prescriptions) to a specified number of days
 - ii. Limit daily supply to a morphine equivalent
 - iii. Limit patient's daily morphine equivalent for all prescriptions combined
 - iv. Limit emergency department prescribing/dispensing
 - v. Prohibit doctor dispensing of opioids

- vi. Limit the prescribing of pain medications by prescribers who are not pain specialists to a specified number of morphine equivalents per day (e.g., 50 under CDC's proposed prescribing guidelines and 120 in Washington; see 2010 Washington legislation)
- vii. Refer patient to a pain specialist
- k. Use the controlled substance database (prescription drug monitoring program) more effectively
 - i. Increase usage (check for first-time prescriptions; check periodically for each patient; check always; etc.)
 - ii. Develop workflow-friendly interface with electronic health records and other processes
 - iii. Evaluate prescribing practices in light of:
 - 1. notices from DOPL about the prescriber's patients who have died from drug related causes;
 - 2. notices from DOPL about the prescriber's patients who have been treated for overdose or poisoning or who have been convicted of drug related DUI
 - iv. Request controlled substance database notification for patients meeting specified dispensing criteria
- l. Involuntarily commit a person who is an immediate danger to self or others to a drug treatment facility for up to 72 hours (proposed in Massachusetts)
- m. Use pain medication treatment plans
- n. Use pain medication agreements and informed consent
- o. Perform a physical examination and substance use disorder assessment prior to prescribing a controlled substance
- p. Obtain continuing professional education on alternatives to opioids
- q. Use baseline drug testing for new patients and periodic drug testing for other patients to monitor compliance with treatment plan and detect use of other drugs

3. DISPENSERS

- a. Increase use of controlled substance database
 - i. Check all nonresidents
 - ii. Check all cash transactions
 - iii. Check all out-of-state prescriptions
- b. Integrate use of controlled substance database into pharmacy workflow (Kroger pharmacists check nearly 100% of controlled substance prescriptions)
- c. Improve pharmacist response to red flags
- d. Install pharmacy drop-boxes for the disposal of unused drugs
- e. Require identification of those picking up prescriptions
- f. Dispense at-home deactivation kits with drugs (Delaware completed a pilot program)
- g. Obtain standing order for dispensing naloxone
- h. Allow partial fills so that only the amount requested by a patient is dispensed, up to the amount prescribed

4. INSURERS

- a. Structure coverage, prior authorization, and cost sharing parameters to incentivize compliance with CDC guidelines and other prescribing guidelines
- b. Educate insureds
- c. Cover abuse-deterrent opioids (extended-release and long-acting) (however, see results of 2015 PEHP study)
- d. Cover naloxone
- e. Cover the broad spectrum of treatment services, including medication-assisted treatment
- f. Cover controlled substance database access by prescribers and dispensers
- g. Use a patient review and restriction program to limit an at-risk patient to a single prescriber and a single pharmacy or pharmacy chain (e.g., BlueCross BlueShield of Massachusetts)
- h. Require prior authorization for an initial prescription (e.g., BlueCross BlueShield of Massachusetts)
- i. Limit initial quantities prescribed (e.g., BlueCross BlueShield of Massachusetts)
- j. Work on development of more user-friendly controlled substance database interface
- k. Use claims analysis to analyze dispensing patterns and notify, educate, and intervene as appropriate

5. PATIENTS

- a. Securely store medications
- b. Properly dispose of unused medications
- c. Obtain and act on education by prescribers, dispensers, public service campaigns, etc.
- d. Obtain naloxone for family and friends
- e. Reduce drug sharing behaviors
- f. Reduce drug seeking behaviors
- g. Develop realistic expectations about pain management
- h. Complete periodic education and counseling during treatment of chronic pain (proposed by Georgia 2015 H.B. 407)
- i. Use a voluntary revocable non-opioid directive, where appropriate, to alert practitioners to not prescribe or administer opioids

6. TREATMENT COMMUNITY

- a. Co-locate substance use and mental health treatment providers with physical healthcare providers
- b. Build infrastructure for full spectrum of treatment options

7. STATE – PRESCRIPTION DRUG MONITORING PROGRAM, INCLUDING USE OF THE CONTROLLED SUBSTANCE DATABASE

- a. DOPL notify prescribers of patient overdose, poisoning, drug related DUI
- b. DOPL notify prescribers of patients meeting criteria established by prescriber
- c. DOPL notify patient-designated third parties when a controlled substance is dispensed to a patient
- d. DOPL notify prescribers with suspect prescribing patterns
- e. Map controlled substance database data geographically
- f. Promote third-party analysis of de-identified data
- g. Batch process to screen an entire day's calendar of patients
- h. Develop workflow-friendly interface (e.g., single sign-on) with electronic health record systems and other processes, and dispensers' point of sale system (see 2016 H.B. 239, Access to Opioid Prescription Information via Practitioner Data Management Systems (McKell); see also "Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis," Statement by Michael P. Botticelli, Director of National Drug Control Policy, before the United States House of Representatives Subcommittee on Health of the Committee on Energy and Commerce, Thursday, October 8, 2015)
- i. Expand access to database information, as appropriate (e.g., to drug courts, treatment professionals, prisons and jails, law enforcement, prosecutors, state medical examiner, physician assistants, physician residents, licensing boards, etc.)
- j. Maintain data quality
- k. Monitor database use to ensure data security
- l. Mandate use for patients meeting certain criteria (KY, TN, and NY mandate use of a PDMP; "As of June 2014... 22 states had law, mandating that prescribers and in some cases dispensers use the PDMP in certain circumstances")
- m. Mandate use for first prescription and at least once every year thereafter
- n. Notify third-party payers (see Kentucky)
- o. Provide unsolicited reports to law enforcement and professional regulatory boards
- p. Develop automated expert systems to expedite analyses and reports (e.g., NARxCHECK)
- q. Share analytics for identifying problem patients and prescribers with prescribers, dispensers, insurers, and third-party researchers
- r. Create a Controlled Substance Database Advisory Board to make recommendations to the Legislature and the Division of Occupational and Professional Licensing
- s. Provide immunity to prescribers and dispensers for use of database
- t. From "Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices," by The Prescription Drug Monitoring Program Center of Excellence, Brandeis University
 - i. Collect positive ID on persons picking up prescriptions
 - ii. Collect data on method of payment, including cash transactions
 - iii. Integrate electronic prescribing with PDMP data collection
 - iv. Improve data quality
 - v. Link records to permit reliable identification of individuals
 - vi. Determine valid criteria for possible questionable activity

- vii. Conduct periodic analyses of questionable activity
- viii. Develop expert systems to guide analyses and reports
- ix. Record data on disciplinary status, patient lock--ins
- x. Optimize reporting to fit user needs
- xi. Integrate PDMP data with health information exchanges, electronic health records
- xii. Publicize use and impact of PDMP
- xiii. Proactively identify and conduct outreach to potential high--impact users
- xiv. Conduct recruitment campaigns
- xv. Streamline certification and enrollment processing
- xvi. Mandate enrollment
- xvii. Mandate utilization
- xviii. Institute financial incentives
- xix. Delegate access
- xx. Evaluation of PDMPs
- xxi. Funding of PDMPs
- xxii. Adopt a uniform and latest ASAP reporting standard
- xxiii. Collect data on nonscheduled drugs implicated in abuse
- xxiv. Reduce data collection interval; move toward real--time data collection
- xxv. Enable access to data by appropriate users; encourage innovative applications
- xxvi. Enact and implement interstate data sharing among PDMPs
- xxvii. Collaborate with other agencies and organizations
- xxviii. Collect data on all schedules of controlled substances
- xxix. Institute serialized prescription forms
- xxx. Conduct epidemiological analyses
- xxxi. Provide continuous online access to automated reports
- xxxii. Send unsolicited reports and alerts
- xxxiii. Conduct promotional campaigns
- xxxiv. Improve data timeliness and access
- xxxv. Conduct user education

8. STATE – OTHER

- a. Update Department of Health 2009 opioid prescribing guidelines
- b. Improve availability of behavioral health treatment services for incarcerated population
- c. Expedite Medicaid coverage following incarceration
- d. Promote the availability of “on-demand” treatment (see Baltimore)
- e. Leverage medical examiner’s role
- f. Use patient review and restriction programs for Medicaid, Workers’ Compensation, and state employees health program
- g. Regulate pain clinics
- h. Leverage Workers’ Compensation to identify and treat misuse

- i. Use Medicaid and PEHP to incentivize prescriber compliance with prescribing guidelines
- j. Increase funding for treatment
- k. Promote stakeholder collaboration
- l. Implement syringe exchange programs (See 2016 H.B. 308, Disease Prevention and Substance Abuse Reduction (Eliason))
- m. Create safe-injection sites (connection to substance use treatment and medical care for overdose victims)
- n. Create adequate and sustainable funding stream for deterrence, intervention, and treatment
- o. Leverage drug courts
- p. Incentivize diversion to treatment by all stakeholders at all points of contact with substance users
- q. Develop Medicaid as a model for identification, intervention, and treatment, including the use of claims analysis
- r. Use public health model to address misuse epidemic
- s. Join with other states to reduce illegal online prescribing of opioids. "According to the National Association of Boards of Pharmacy, 96 percent of entities selling drugs online are illegitimate and operating in violation of U.S. law. These illegal online drug sellers provide easy access to opioid pain relievers."
- t. Promote take-back programs conducted by law enforcement in conjunction with the DEA
- u. Screen elementary and secondary students for substance use disorders
- v. Require Schedule II prescriptions to be filled within a specified number of days (e.g., 3, 7, 30, 60, etc.)
- w. Create a pain management resource center to offer technical assistance to prescribers
- x. Urge the Centers for Medicare and Medicaid Services to revise Hospital Consumer Assessment of Healthcare Providers and Systems survey measures relating to pain management

9. OTHERS

- a. Report number of drug exposed infant births (hospitals)