The CDC Prescribing Guidelines

IS IT TIME FOR A CHANGE?

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MS Physician Health Program

Where it began…2016

- In response to the opioid epidemic, the CDC developed prescribing guidelines to hopefully curtail the rampant overprescribing/misuse of controlled substances.

The Problem

- Opioid abuse and overdoses
- Roughly half of opiate prescriptions from primary care
- Risks not clearly understood by prescribers or patients
- Mis-education by pharmaceutical industry

The Quandary – What is inappropriate?

- Treatment of pain is an ethical obligation
- Inadequate treatment of pain was focus of policy in 1990s
- "Mis-prescribing" should refer to behaviors which depart from standard of care.
- Cannot anticipate bad outcomes or diversion

4D Model

- Dated – not up to date on current standards of care
- Duped – deceived by drug-seeking patients
- Disabled – cognitive decline, other impairment
- Dishonest – overprescribe for personal gain

Endorsed by AMA many years ago

The problem with Duped

- Are expectations of prescribers unreasonable?
  - No crystal ball
  - Should we expect that our patient is lying?
  - Where is the “truth” skill taught?

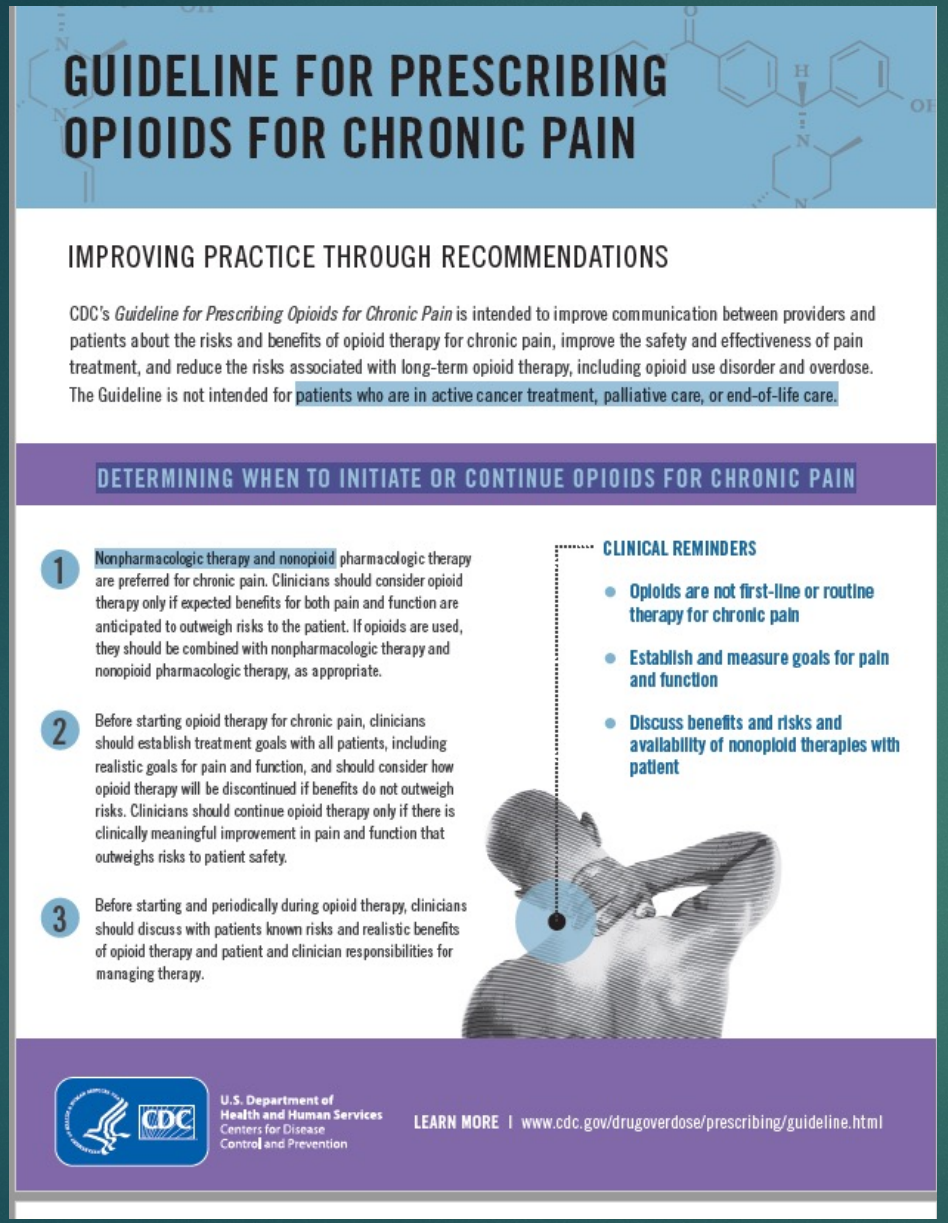
- Law enforcement and regulatory agencies often buy in

A newer model – 3C

- Careless
- Corrupt
- Compromised

CDC Guideline for Prescribing Opioids for Chronic Pain (2016)

- First guideline issued to address overuse/misuse of opiates
- CDC communicated intent to reassess evidence and recommendations as new evidence presented itself
- Agency for Healthcare Research and Quality (AHRQ) funded by CDC

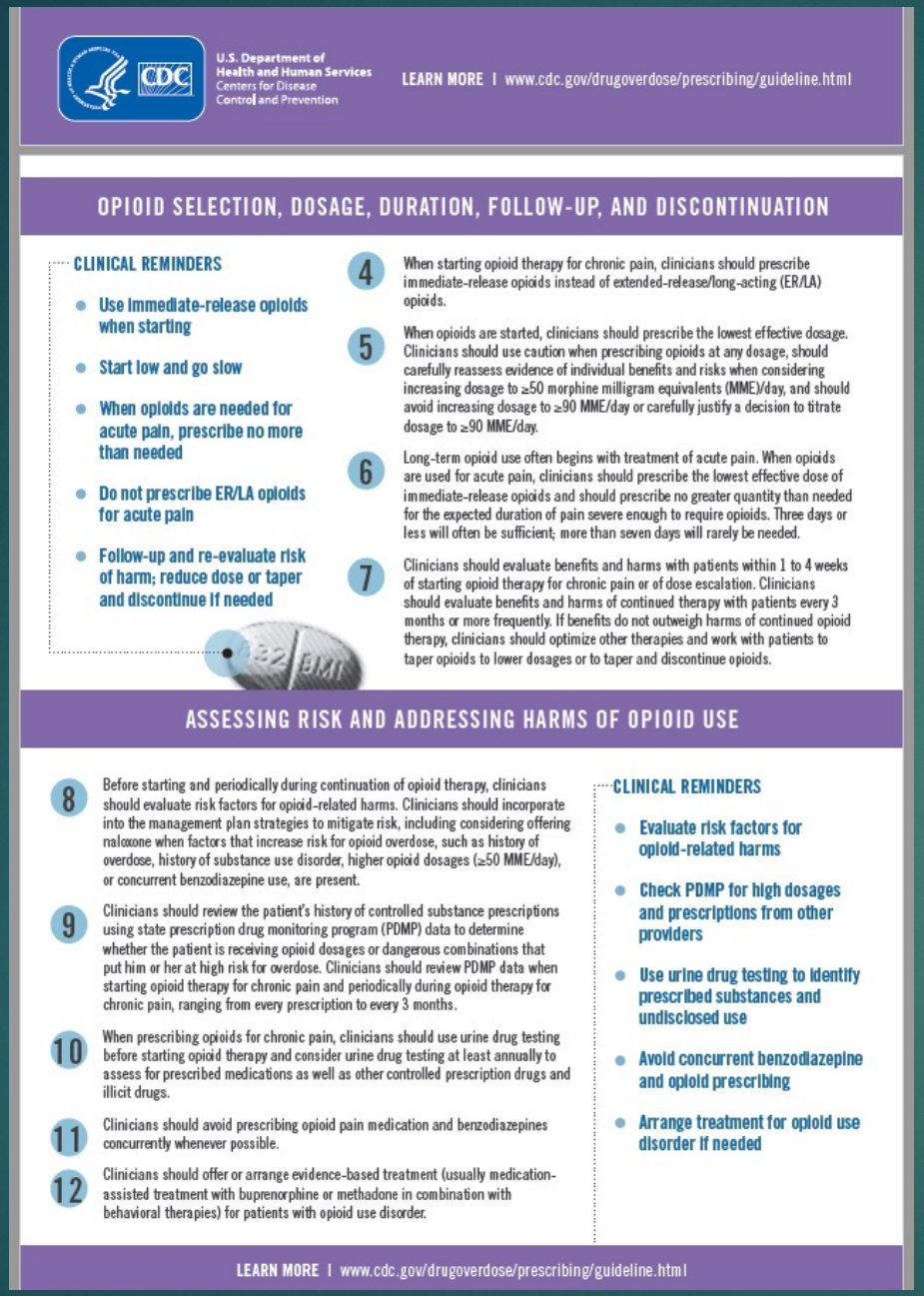


REMEMBER THE TARGET AUDIDENCE

REMEMBER THE TARGET PATIENTS

"This guideline provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care."

1. Non-pharm/Non-opioid
2. Establish goals for pain/function
3. Explain risk/benefits



4.Immediate-release
5.Lowest effective dose
6.No more than needed
7.F/up and re-evaluate risk/benefit
8.Mitigate Risk
9.Prescription Monitoring Program
10.Urine Drug Screen
11.Avoid opioid + benzodiazepines
12.Opioid Use Disorder Suspected?

https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html

MS regulations - 2018

- Documented visit with good faith exam
- UDS at initiation, then 3x/year
- PMP with every new CS rx
  - *few exceptions, read regs carefully
- No more than 3-month supply
- MME thresholds

Rationale for re-visiting

- Tapering harms
- Rigid use of guidelines applied to all
- 3rd party denials
- Little room for individualization

FDA Tapering Harm 4-9-19

FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering

FDA Drug Safety Communication

Share | Tweet | Linkedin | Email | Print

Drug Safety and Availability

Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan

Safety Announcement

[4-9-2019] The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious

Content current as of:
04/09/2019

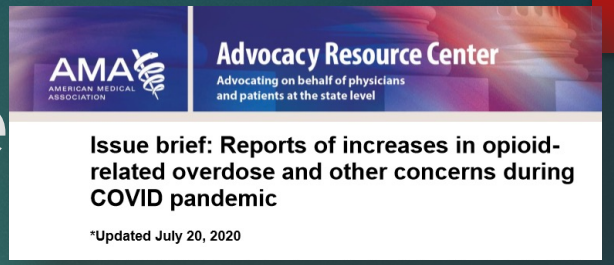
Regulated Product(s)
Drugs
Safety - Issues, Errors, and

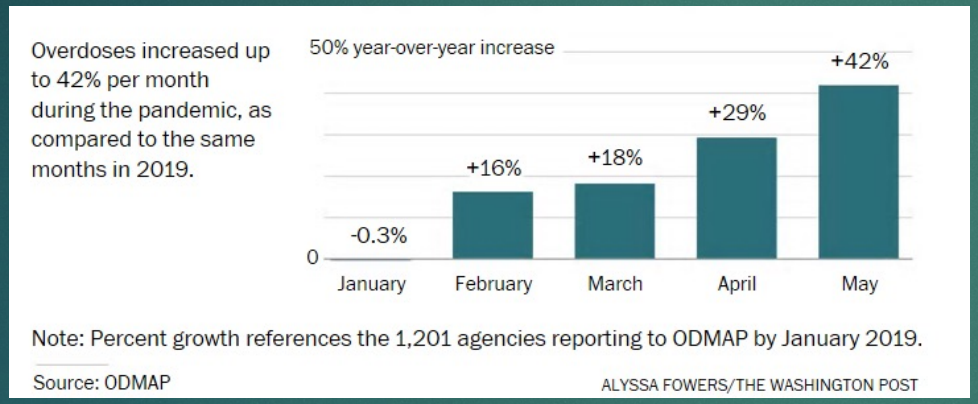
https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes

Backsliding?…

- The revised guidelines follow the news from last November that annual drug overdoses exceeded 100,000 for the first time in the U.S. for a 12-month period that ended in April 2021[4]
  - COVID-related loss of access
  - Increased fentanyl, heroin and other illicit narcotics
  - ? Prescriber rigidity

Opioid-related overdose *and COVID-19*





"**Synthetic opioids** (primarily illicitly manufactured fentanyl) appear to be the primary driver of the increases"

https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html

https://www.washingtonpost.com/health/2020/07/01/coronavirus-drug-overdose

Preliminary Data
National Vital Statistics System Release 4-21
https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

"More than 87,000 Americans died of drug overdoses over the 12-month period that ended in September, according to preliminary federal data, eclipsing the toll from any year since the opioid epidemic began in the 1990s. "

"Deaths from overdoses started rising again in the months leading up to the coronavirus pandemic — after dropping slightly in 2018 for the first time in decades…."

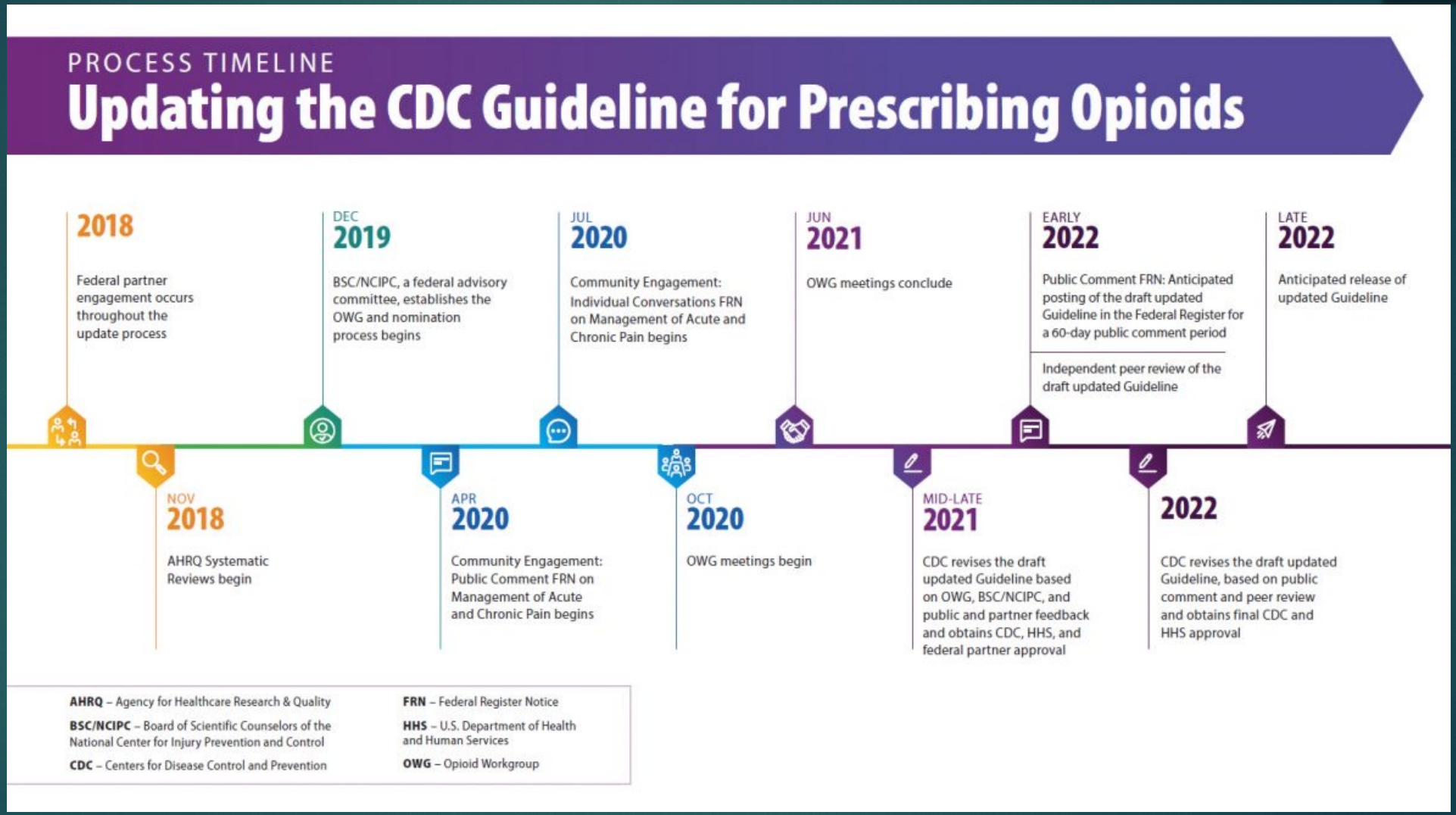
https://www.nytimes.com/interactive/2019/07/17/upshot/drug-overdose-deaths-fall.html

From the CDC

- "A key aim of pain management is the provision of individualized, patient-centered care that focuses on optimizing function and supporting activities of daily living."

From the AMA

- “ The AMA is urging the CDC to remove arbitrary thresholds, restore balance and support comprehensive, compassionate care as it revises the guideline.”


PROCESS TIMELINE
Updating the CDC Guideline for Prescribing Opioids
2018
Federal partner engagement occurs throughout the update process
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BSC/NCIPC, a federal advisory committee, establishes the OWG and nomination process begins
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CDC – Centers for Disease Control and Prevention
FRN – Federal Register Notice
HHS – U.S. Department of Health and Human Services
OWG – Opioid Workgroup

Focus areas[4]

- Determining Whether or Not to Initiate Opioids for Pain
- Opioid Selection and Dosage
- Opioid Duration and Follow-Up
- Assessing Risk and Addressing Harms of Opioid Use

AHRQ Reviews

- Noninvasive nonpharmacologic treatments for chronic pain
- Nonopioid pharmacologic treatments for chronic pain
- Treatments for acute pain
- Acute treatments for episodic migraines

Notes on the guideline

- Based on GRADE framework (SOR)
- Voluntary, no mandated compliance
- Aims to improve communication between clinician and patient regarding risks and benefits
- Aims to improve safety and efficacy while restoring or maintaining function
- Hope to reduce risks of OUD, overdose, death

Changes at a glance

- Categories included for acute pain (< 1 month duration) and subacute pain (1-3 months duration)
- Sickle cell disease added to list of conditions to which guideline recommendations do NOT apply
- Remain targeted at primary care/outpatient

Key Timeline Dates

- Dec. 4-5, 2019: CDC provides background presentation; BSC/NCIPC establishes OWG
- July 20, 2020: OWG roster presented
- Feb. 16, 2021: OWG provides status update
- July 16, 2021: OWG presents its report

Observations of the Opioid Workgroup of the Board of Scientific Counselors of the National Center for Injury Prevention and Control on the Updated CDC Guideline for Prescribing Opioids

All patients with pain should receive treatment that provides the greatest benefits relative to risks. See Recommendation 1 for determining whether to initiate opioids for acute pain (i.e., with a duration of less than one month) and Recommendation 2 for determining whether or not to initiate opioids for subacute (i.e., with a duration of at least one month and less than three months) or chronic pain (i.e., with a duration of three months or more).

1. **Nonopioid therapies are effective for many common types of acute pain. Clinicians should only consider opioid therapy for acute pain if benefits are anticipated to outweigh risks to the patient (recommendation category: B, evidence type: 3).**

Implementation considerations:

- *There is an important role for opioid therapy for acute pain related to severe traumatic injuries (including crush injuries and burns), invasive surgeries typically associated with moderate to severe postoperative pain, and other severe acute pain when NSAIDs and other therapies are contraindicated or likely to be ineffective.*
- *Opioids are not first-line therapy for many common acute pain conditions, including low back pain, neck pain, pain related to other musculoskeletal injuries (such as sprains, strains, tendonitis, bursitis), pain related to minor surgeries typically associated with minimal tissue injury and only mild postoperative pain (e.g., dental extraction), dental pain, kidney stone pain, and headaches including episodic migraine.*
- *When diagnosis and severity of acute pain are reasonably assumed to warrant the use of opioids, clinicians should prescribe immediate-release opioids (see Recommendation 3) at the lowest dose to achieve expected effects (see Recommendation 4) and for no longer than the expected duration of pain severe enough to require opioids (see Recommendation 6).*
- *Clinicians should maximize use of nonopioid pharmacologic (e.g., NSAIDs and/or acetaminophen) and nonpharmacologic (e.g., ice, heat, elevation, rest, immobilization and/or exercise) therapies as appropriate for the specific condition and continue these therapies as needed once opioids are discontinued.*
- *Clinicians should prescribe and advise opioid use only as needed (e.g., hydrocodone 5 mg/acetaminophen 325mg, one tablet not more frequently than every 4 hours as needed for pain) rather than on a scheduled basis (e.g., one tablet every 4 hours) and encourage and include an opioid taper if opioids will be taken around the clock for more than a few days (see Recommendation 6).*
- *If patients already receiving opioids in a long-term fashion require additional medication for acute pain, nonopioid medications should be used when possible, and if additional opioids are*

Want to read the whole thing?

- Regulations.gov
- Docket 2022-0024-0002

Opioid Workgroup

- Observations on the Updated CDC Guideline for Prescribing Opioids for Chronic Pain

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

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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.

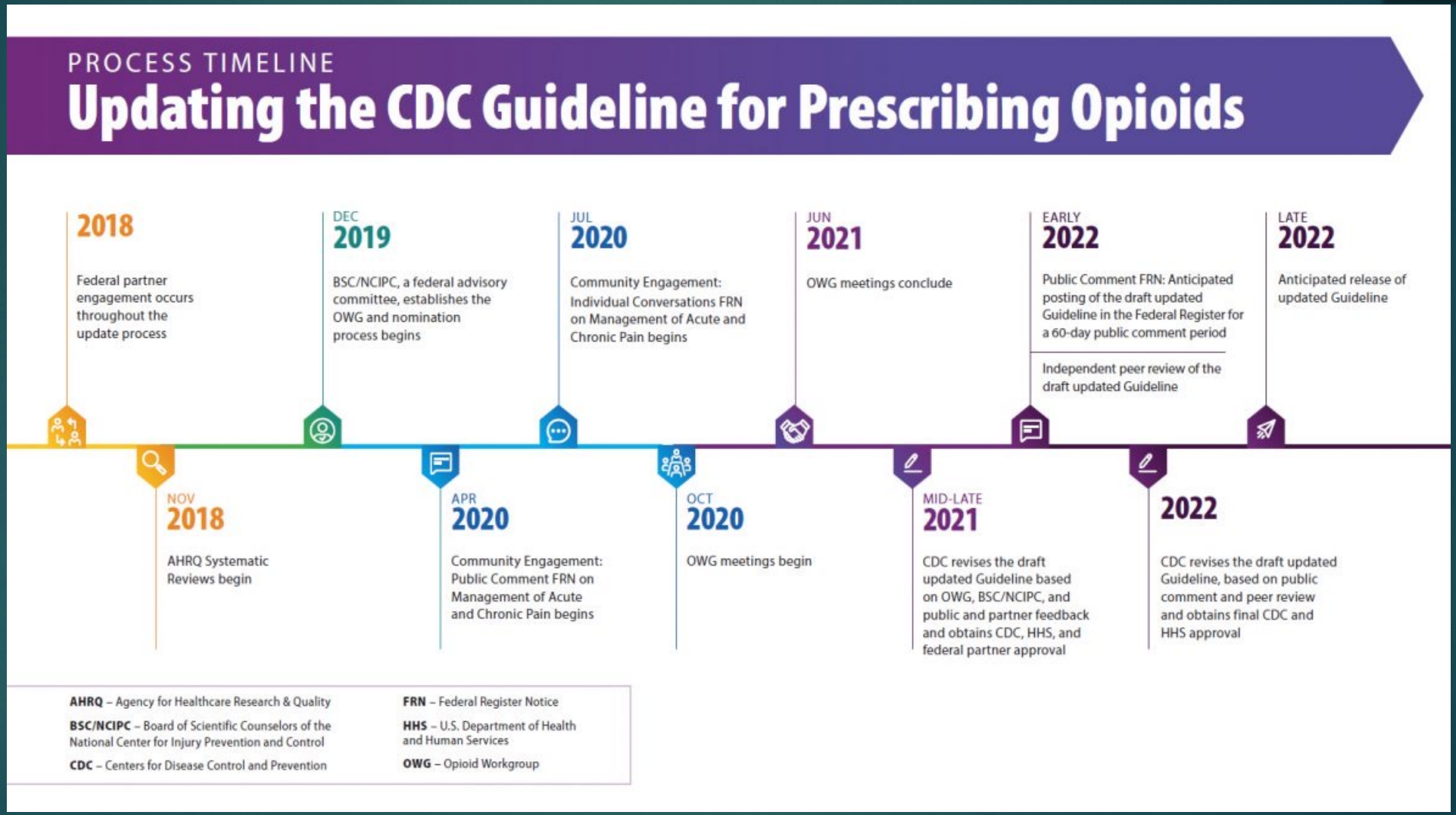
11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

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

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html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Updated…now what?

- State regulations would have to be re-written
- Period of public comments
- Approval by appropriate subcommittee
- Publishing/ ? Grace period

BOTTOM LINE: 1-2 year process

MS regulations - 2018

- Documented visit with good faith exam
  - To include risk/benefit analysis, goals
- UDS at initiation, then 3x/year
- PMP with every new CS rx
  - *few exceptions, read regs carefully
- No more than 3-month supply

MPMP Requirements

Review the PMP prior to each outpatient opioid and benzodiazepine RX

Document PMP review in the chart.

Document PMP review for all other controlled substance prescriptions upon initiation and at least every 3 months thereafter (exceptions: Lomotil®, Lyrica®, Testosterone, Pseudoephedrine, Amphetamines for patients <16).

Report must review at least the length of time from previous review

Documentation, such as a copy of the report itself and/or reflection in the chart dictation and/or notes must be kept within the patient's record and made available for inspection upon request.

MPMP Requirements Continued…..

Running MPMP is NOT required for inpatient or ER treatment but it is required prior to writing controlled substance discharge prescriptions.

"Inpatient": a patient in a hospital, nursing home, longterm care facility, inpatient (not home-bound) hospice, or any other facility wherein medications are dispensed to a patient by a third party duly licensed and/or certified to dispense medications in a healthcare or related facility.

May have properly registered designees run the report. There is no limit on the number of designees.

Register for the MPMP: *https://mississippi.pmpaware.net/login*

~~A global PMP report for the practice must be run at least yearly~~ (*withdrawn*).

Point of Service Drug Testing Requirements

Do point of service drug testing 3 times per year if prescribing Schedule II opioids for chronic noncancerous/nonterminal pain or benzodiazepines for chronic psychiatric or medication conditions.

Must test, at a minimum: opioids, benzodiazepines, amphetamines, cocaine, and cannabis.

Inpatient and hospice are exempt from UDS requirement.

"Inpatient" is defined a patient in a hospital, nursing home, long term care facility, inpatient (not home-bound) hospice, or any other facility wherein medications are dispensed to a patient by a third party who is duly licensed and/or certified to dispense medications in a healthcare or related facility.

Point of Service Drug Testing

Remember exactly what is required:

- Schedule II for *chronic* non-cancer/non-terminal pain
- Benzodiazepines for *chronic* medical and/or psychiatric conditions which are non-cancer/non-terminal
- At least 3 times per year

Screening is all that is required in the regulations; however….

Screening may tell you what you need to know clinically; it may not.

Unexpected Positive on a screen?

- May be taking something that you did not prescribe
- May be a cross-reaction to another product

Unexpected Negative on a screen?

- May be truly not taking
- May a concentration issue
- May not be sensitive enough to test for what you are looking for

Mississippi State Board of Medical Licensure Prescribing Rules Summary

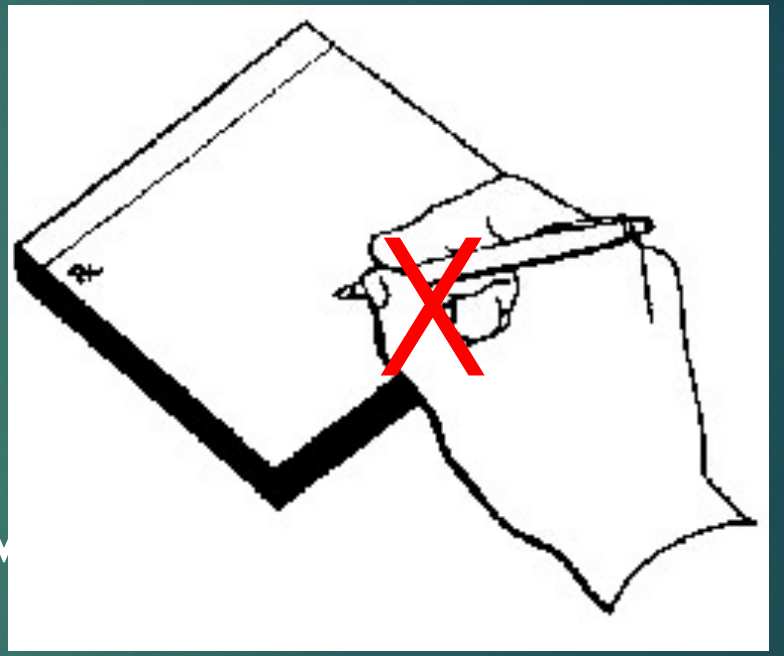
MSBML Prescribing Rules Summary:	
Acute Pain	◦ Recommended < 3 days ◦ Max 10 days, may give 1 additional (max 10 day) prescription
Chronic Pain	◦ Use lowest effective dose ◦ Recommend ≤ 50 MME daily ◦ Should not exceed 90 MME daily ◦ If > 100 MME must be in pain clinic ◦ Methadone for chronic pain only through pain clinics (by physician)

Benzodiazepines	◦ Max 90 days per prescription
	◦ Should not co-administer with opioids
	  ◦ Short term acceptable
	  ◦ Patients on chronic benzodiazepines and opioids should be gradually weaned off one or both
	  ◦ Chronic co-administration in rare, extreme circumstances

Mississippi Prescription Monitoring Program (MPMP)	◦ All licensees must register with MPMP ◦ Must check on all opioid prescriptions for acute and/or chronic non-cancerous/non-terminal pain upon issuance ◦ Must utilize the MPMP upon initial contact with new patients and at least every 3 months thereafter for all controlled medications other than opioids ◦ Must document MPMP review (must include time from last check) ◦ PMP check not required for inpatients but must be checked if discharged on opioids
Drug Screening	◦ Point of Service Drug Testing must be done at least 3 times per calendar year when Schedule II medications is written for the treatment of chronic non-cancerous/non-terminal pain ◦ Applies also for Benzodiazepines for chronic medical and/or psychiatric conditions which are non-cancerous/non-terminal ◦ Inpatient treatment/hospice patients exempt
Exemptions	◦ Terminal/Cancer treatment ◦ Hospice patients ◦ Inpatients (nursing home, rehab, hospitals, etc.) ◦ Prescriptions for Pseudoephedrine, Lomotil, Lyrica, Testosterone, and/or Amphetamines prescribed for patients under the age of 16 for the treatment of Attention Deficit Hyperactivity Disorder
Pain Management	◦ If ≥ 50% of patients receive controlled substances for chronic pain, must register as pain clinic ◦ If advertises as pain clinic, must register ◦ Must check MPMP every time controlled substance prescribed ◦ Must see a pain management physician prior to initiating controlled substance

***MME – Morphine Milligram Equivalent**

Finding the Balance




So, we wait…

References

- 1. Centers for Disease Control, cdc.gov
- 2. Food and Drug Administration, fda.gov
- 3. American Medical Association, ama-assn.org
- 4. Dineen and Dubois, ***BETWEEN A ROCK AND A HARD PLACE: CAN PHYSICIANS PRESCRIBE OPIOIDS TO TREAT PAIN ADEQUATELY WHILE AVOIDING LEGAL SANCTION? Am J Law Med, July 2017***
- 5. Craig, *CDC Revises Opioid Prescription Guidelines.* CIPROMS Medical Billing. February, 2022.
- 6. Federal Register, *Proposed 2022 CDC Clinical Practical Guideline for Prescribing Opioids.* February, 2022
- 7. AAFP News, *CDC Issues Call for Comments on Updated Opioids Guideline.* March 30, 2022

Questions?

THANK-YOU