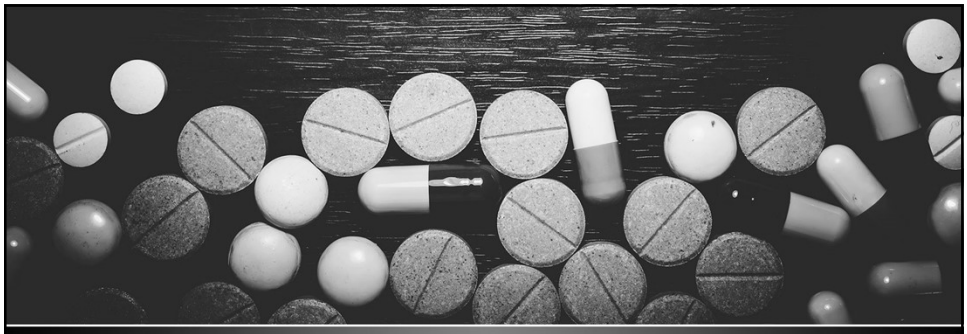

Compliance Concerns Related to the Opioid Crisis

Kansas City Regional HCCA Conference
September 20, 2019

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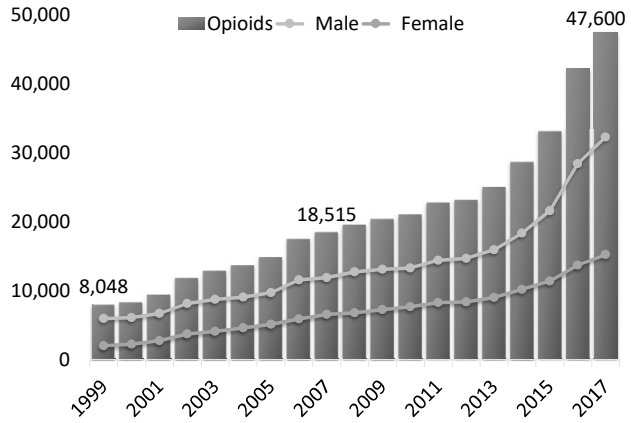
Overdose and Opioids

- Opioid overdose has now surpassed motor vehicle crashes as the leading cause of preventable death
- Drug overdose deaths involving any opioid rose from 8,048 in 1999 to 47,600 in 2017
- Growing concerns about abuse of both prescription fentanyl and illicitly manufactured fentanyl

*Eric D. Hargan, Acting Secretary, U.S. Department of Health and Human Services, HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis, October 26, 2017
**National Institute of Drug Abuse, Overdose Death rates, National Drug Overdose Deaths Involving Any Opioid, number among all ages, by gender, 1999-2017
***HHS OIG Data Brief, Opioid Use in Medicare Part Remains Concerning (June 2018)

2

National Drug Overdose Deaths Involving Any Opioid,
All Ages, by Gender, 1999-2017



Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018

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Opioid Crisis – Enforcement

- October of 2017:declared a public health emergency in
- DOJ has made opioid crisis a high enforcement priority
- Issuance of warning letters
  - US Attorney in Massachusetts e sent letters to opioid prescribers where data identified them as having prescribed opioids to a patient within 60 days of that patient's death
  - Strike Forces
    - April 2019 – Appalachian Regional Prescription Opioid Strike Force charged 60 individuals, including 53 medical professionals, across 11 federal districts, for their alleged participation in illegally prescribing and distributing opioids

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Discussion Agenda

- Overview of regulation of controlled substances
- Recent developments in opioid prescribing and dispensing
- Practical tips for compliance reviews and risk mitigation

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Baseline Legal Standards – Controlled Substances Act

- Numerous technical requirements
  - Prescriber must have DEA registration number
  - No refills permitted for Schedule 2
  - Must use tamper-resistant prescription pads
  - Patient ID verification requirements
  - Verbal orders (*e.g.*, limited to emergency for Schedule 2)
  - Mandatory reporting to DEA of theft, loss or other events
  - Various DEA record-keeping regulatory requirements (*e.g.*, DEA Form 222s)

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Baseline Legal Standards – Controlled Substances Act

- "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."
- "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

21 C.F.R. § 1306.04

7

Baseline Legal Standards – Controlled Substances Act

- "An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription … and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. 21 C.F.R. § 1306.04

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Baseline Legal Standards – Controlled Substances Act

What is the "usual course of professional practice" or "legitimate medical purpose"?

- "[I]n the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States."

  United States v. Moore, 432 U.S. 122 (1975)

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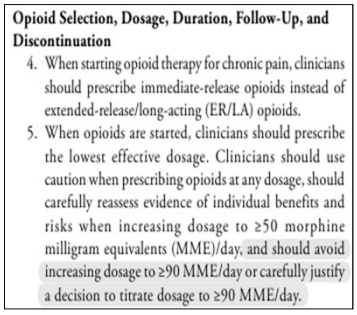
Recent Developments – Flashback to 2016

CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016

- Recommendations to primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care
- Treatment recommendations organized into three areas: (1) determining when to initiate or continue opioids for chronic pain, (2) opioid selection, dosage, duration, follow-up, and discontinuation, and (3) assessing risk and addressing harms of opioid use



Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

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 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.

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Recent Developments – Push Back to CDC Guidelines

The Washington Post

Health-care providers say CDC's opioid guidelines are harming pain patients

By **Lenny Bernstein**

March 6, 2019

More than 300 health-care experts told the Centers for Disease Control and Prevention Wednesday that the agency's landmark guidelines for the use of opioids against chronic pain are harming patients who suffer from long-term pain and benefit from the prescription narcotics.

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Recent Developments – 90 MME "Limit" Discredited

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Drug Safety Communications

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

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 withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.

Health care professionals should not abruptly discontinue opioids in a patient who is physically dependent. When you and your patient have agreed to taper the dose of opioid analgesic, consider a variety of factors, including the dose of the drug, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. No standard opioid tapering schedule exists that is suitable for all patients.

Patients taking opioid pain medicines long-term should not suddenly stop taking your medicine without first discussing with your health care professional a plan for how to slowly decrease the dose of the opioid and continue to manage your pain. Even when the opioid dose is decreased gradually, you may experience symptoms of withdrawal (See Additional Information for Patients). Contact your health care professional if you experience increased pain, withdrawal symptoms, changes in your mood, or thoughts of suicide.

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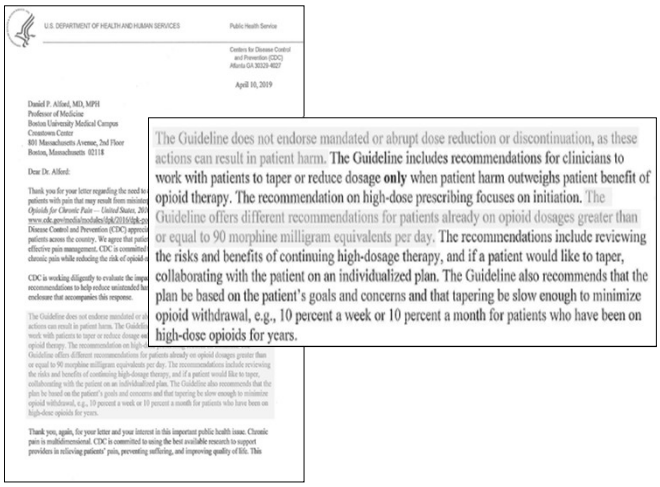
Recent Developments – 90 MME "Limit" Discredited



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30329-4027

April 10, 2019

Daniel P. Alford, MD, MPH
Professor of Medicine
Boston University Medical Campus
Countway Center
801 Massachusetts Avenue, 2nd Floor
Boston, Massachusetts 02118

Dear Dr. Alford:

Thank you for your letter regarding the need to
patients with pain that may result from mistaker
Opioids for Chronic Pain — United States, 201
www.cdc.gov/media/mediakit/dpk/2016/dpk-pr
Disease Control and Prevention (CDC) appreci
patients across the country. We agree that patie
effective pain management. CDC is committed
chronic pain while reducing the risk of opioid-

CDC is working diligently to evaluate the impa
recommendations to help reduce unintended ha
enclosure that accompanies this response.

The Guideline does not endorse mandated or ab
actions can result in patient harm. The Guidelin
work with patients to taper or reduce dosage **o**
opioid therapy. The recommendation on high-d
Guideline offers different recommendations for patients already on opioid dosages greater than
or equal to 90 morphine milligram equivalents per day. The recommendations include reviewing
the risks and benefits of continuing high-dosage therapy, and if a patient would like to taper,
collaborating with the patient on an individualized plan. The Guideline also recommends that the
plan be based on the patient's goals and concerns and that tapering be slow enough to minimize
opioid withdrawal, e.g., 10 percent a week or 10 percent a month for patients who have been on
high-dose opioids for years.

Thank you, again, for your letter and your interest in this important public health issue. Chronic
pain is multidimensional. CDC is committed to using the best available research to support
providers in relieving patients' pain, preventing suffering, and improving quality of life. This

The Guideline does not endorse mandated or abrupt dose reduction or discontinuation, as these actions can result in patient harm. The Guideline includes recommendations for clinicians to work with patients to taper or reduce dosage **only** when patient harm outweighs patient benefit of opioid therapy. The recommendation on high-dose prescribing focuses on initiation. The Guideline offers different recommendations for patients already on opioid dosages greater than or equal to 90 morphine milligram equivalents per day. The recommendations include reviewing the risks and benefits of continuing high-dosage therapy, and if a patient would like to taper, collaborating with the patient on an individualized plan. The Guideline also recommends that the plan be based on the patient's goals and concerns and that tapering be slow enough to minimize opioid withdrawal, e.g., 10 percent a week or 10 percent a month for patients who have been on high-dose opioids for years.

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Recent Developments – CDC Backtracks

The NEW ENGLAND JOURNAL of MEDICINE

June 13, 2019
N Engl J Med 2019; 380:2285-2287
DOI: 10.1056/NEJMp1904190

No Shortcuts to Safer Opioid Prescribing

Deborah Dowell, M.D., M.P.H., Tamara Haegerich, Ph.D., and Roger Chou, M.D.

able. Unfortunately, some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations. A consensus panel has highlighted these inconsistencies,[1] which

able. Unfortunately, some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations. A consensus panel has highlighted these inconsistencies,[1] which

from a physician's practice. The panel also noted the potential for misapplication of the recommendations to populations outside the scope of the guideline. Such misapplication has been reported for patients with pain associated with cancer,[3] surgical procedures,[4] or acute sickle cell crises. There have also been reports of misapplication of the guideline's dosage thresholds to opioid agonists for treatment of opioid use disorder. Such actions are likely to result in harm to patients.

or coverage.[5] This recommendation also does not apply to dosing for medication-assisted treatment for opioid use disorder. The CDC based the recommendation on evidence of dose-dependent harms of opioids and the lack of evidence that higher dosages confer long-term benefits for pain relief. However, we know little about the benefits and harms of reducing high dosages of opioids in patients who are physically dependent on them.

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Recent Developments – Unintended Consequences

USA TODAY

Pain patients left in anguish by doctors 'terrified' of opioid addiction, despite CDC change

Ken Alltucker and Jayne O'Donnell, USA TODAY Published 3:54 p.m. ET June 24, 2019 | Updated 4:55 p.m. ET June 30, 2019

Last month, the CDC clarified its position, saying the response to the opioid crisis went too far. In a New England Journal of Medicine editorial, a panel of experts cited examples such as inflexible thresholds on dosages, abrupt tapering and misapplication of the guidelines for people with cancer, sickle cell disease or recovering from surgery.

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Recent Developments – HHS Pain MGMT Best Practices Inter-Agency Task Force

- The Task Force was convened by HHS in conjunction with US Dept. of Defense, Dept. of Veterans Affairs, and Office of Natl. Drug Control Policy to address acute and chronic pain in light of the ongoing opioid crisis

discussion of risks between providers and patients (shared decision making).[1] Although the CDC Guideline was not intended to be model legislation, at least 28 states have gone beyond the guidelines and enacted legislation related to opioid prescription limits. As a result, such unintended consequences have led health care providers to limit or not provide pain treatment due in part to concerns and undue burdens of investigation and prosecution by drug enforcement.[18] Furthermore, many states and organizations have implemented the guideline without recognizing that the intended audience was PCPs; have used legislation to override what should be medical decision making by health care professionals; and have applied them to all physicians, dentists, NPs, and PAs, including pain specialists.[479–482] Some stakeholders have interpreted the guideline as intended to broadly

a seven-day supply is rarely necessary.[128] Various health insurance plans, retail pharmacies, and local and state governments are implementing the CDC Guideline as policy, limiting the number of days a patient can receive prescription opioids even when the seriousness of the injury or surgery may require opioids for adequate pain management for a longer period. A more even-handed approach would balance addressing opioid overuse with the need to protect the patient-provider relationship by preserving access to medically necessary drug regimens and reducing the potential for unintended consequences.[487]

requirements.[487] In essence, clinicians should be able to use their clinical judgement to determine opioid duration for their patients while considering risk assessment recommendations as discussed in Section 3.1: Risk Assessment. Safe opioid stewardship involves a proper history and examination, periodic reevaluation, and risk assessment, with a focus on measurable outcomes, including function, QOL, and ADLs.

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Recent Developments – State Prescription Standards

- As of October of 2018, at least 33 states have enacted legislation related to opioid prescription limits
  - National Conference of State Legislatures. Prescribing policies: States confront opioid overdose epidemic, http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx
- Ohio is an example of a rather aggressive state approach to the opioid crisis:
  - In general, the rules subject the prescribing of opioid analgesics for acute pain to strict parameters:
    - No more than a seven (7) day supply can be prescribed for adults;
    - No more than a five (5) day supply can be prescribed for minors and only with the written consent of parent/guardian;
    - Providers may prescribe opioids in excess of the days' supply limit only if they document the specific circumstances in the patients' medical record;
    - Subject to various other exceptions in Ohio's rules, the total MED or a Rx for the treatment of acute pain cannot exceed 30 MED per day.
      - O.A.C. 4731-11-13

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Compliance Approach

- Treatment of pain is still good medicine
- Traditional compliance process can be applied to opioid and controlled substance issues

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Compliance Approach

- Risk assessment
  - Majority of government focus on clinical setting and prescriptions
    - DEA is largely focused on prescribing decisions
    - Traditional hospital-based diversion still exists
  - Review where your organization touches on controlled drugs
    - Pharmacy, prescribing, administration, disposal
    - Clinics, off site departments, ASCs, hospital
  - Review types of controlled substances and volume

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Compliance Approach

- Risk assessment, cont.
  - Optics of high level dosages (MME or otherwise)
  - Optics of concurrent prescribing/dispensing of opioids and benzodiazepines (among other "combinations")
  - Elephant in the room:
    - Continuing treatment of long-term chronic pain patients?
    - Lack of SUD treatment options?
    - Lack of reimbursement for non-opioid treatment

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Compliance Approach

- Policy and procedure review
  - Review policy and procedures
  - Update to reflect changes in law or environment
  - Mock DEA inspection
- Data review
  - Look for outliers or unexpected data
  - By prescriber; by location; by drug type
  - Use PDMP data, if possible or other public data

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Compliance Approach

- Education
  - Training of staff
  - Education available for prescribers
  - Consider a physician champion
  - Encouragement of prescribers
    - CME is likely necessary as standard of care is changing

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Compliance Approach

- Document plan to address any issues identified (i.e., corrective action)
  - Many prescribing issues involve professional judgment
  - Lack of bright lines makes substantive review difficult, but enforcement risk exists
  - Engage experts if needed
  - Document efforts and plans
    - Can be patient specific

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Legal Risk Can Be Mitigated

- Physician/Pharmacist concerns about their personal exposure are real and appropriate
  - Encourage open dialogue
  - Recognize that professional opinions can differ
- Organizational support is essential
  - Assist physicians in providing quality care in a changing environment
  - Assist with documentation
  - Assist with difficult cases
  - Assist with education

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Legal Risk Can Be Mitigated

- Key elements
  - Develop policy on use of opioid analgesics to treat chronic pain
  - Review and assess current patients with chronic pain and current prescription practices
  - Have a clear process to **document** basis for high dose prescriptions
  - Consider additional clinical education

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Legal Risk Can Be Mitigated

Chronic Pain Patient		
Right Checks	**Right Chart Note**	**Right Prescription**
Patient chart reviewed and contains: ☐ Current PDMP confirming no unknown prescriptions or other physician prescribing opioids ☐ Urinalysis dated within __ days confirming presence of prescribed opioids and lack of others or illicit drugs ☐ Treatment plan and informed consent	Note from today's encounter contains: ☐ Current 5As of pain management ☐ Risk of abuse, addiction or referral for substance abuse treatment ☐ Statement addressing risk of diversion ☐ Statement addressing titration or discontinuation of opioid ☐ Statement addressing need for or compliance with pain contract	Today's prescription reviewed: ☐ Today's prescription is no more morphine equivalents than prior prescription ☐ Prescription for no more than 30 day period ☐ No prescription for benzodiazepines or carisporodol

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Resource Materials

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Legal Risk Can Be Mitigated

- Systems and protocols that increase clinician efficiency
  - Patient evaluation: initially and periodically
    - Assessment of risk and function
    - Depression and anxiety screening
    - Screening for addiction
  - Treatment planning and risk mitigation
    - Patient agreements with periodic updating
    - PDMP checks: initially and at least every 3 months; establish delegates, as permitted
    - UDT: initially and at least annually (frequency commensurate with risk)
    - Naloxone (Narcan) prescribing/dispensing

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Legal Risk Can Be Mitigated

- Systems and protocols that increase clinician efficiency *(continued)*
  - Patient education:
    - Expectations
    - Risks, benefits, alternatives
    - Safe use, storage and disposal
    - Titration to low dose may be necessary
  - Documentation
    - Means to easily document best practices in EMR
    - Cues to include clinical rationale, especially when prescribing/dispensing outside of guidelines
    - Pharmacist documentation of resolution of Rx "red flag(s)" when dispensing/documentation of refusal to dispense

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Chronic Pain Policy

- Concise, practical and readable
  - Physician involvement is critical
- Significant discretion on standards
  - Record basis for potentially controversial standards
- Issues to address
  - New patient intake
    - Geographic limits; prior treatment; medical history
  - Criteria for use of treatment agreement

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Chronic Pain Policy

- Issues to address
  - Use of treatment plan, goals and schedule for re-evaluation
    - Including assessment of non-opioid options
  - Monitoring safeguards (set your own)
    - PDMP review
    - Urine drug testing
    - Evidence of diversion or dependence
    - Documentation expectations and support process
  - Response to suspected diversion

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Chronic Pain Policy

- Issues to address
  - Objective clinical standards, such as
    - Maximum dosages and combination of drugs
    - Use of short acting and long acting drugs
    - Heroin and illicit drug use
    - Evidence of injury or pain
  - Standards for referral to pain specialist
  - Standards for referral to substance abuse treatment
  - Process for lost prescriptions

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Chronic Pain Policy

- Issues to address
  - Standards for tapering
    - Expected timelines
    - Standards for exceptions (if any)
  - Issues/cases to be addressed by informal peer review
  - Patient noncompliance and termination
    - Consistency is important
- Create policy and ensure it is followed

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Legal Risk Can Be Mitigated

- Foster an environment where clinical guidelines are seen and used as practice supports, not practice constraints
- Education: institution-wide
  - Clinicians:
    - Safe prescribing/dispensing, guidelines, rationale
    - Non-pharmacologic and non-opioid treatments
    - If possible, include situation-specific recommendations
  - Patients: appropriate expectations

Meeker et al. Effects of behavioral Interventions on Inappropriate Antibiotic Prescribing Among Primary Care Practices. JAMA. 2016;315(6):562-570
Hill MV et al. An Educational Intervention Decreases Opioid Prescribing After General Surgical Operations. Ann Surg 2017 PAP
Scully RE et al. Defining Optimal Length of Opioid Pain Medication Prescription After Common surgical Procedures. JAMA Surgery. JAMA Surg. doi:10.1001/jamasurg.2017.3132. Published online September 27, 2017.

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