PAINWEEK®

The Regulatory Agency Will See You Now

Kevin L. Zacharoff, MD

Disclosures

Nothing to Disclose

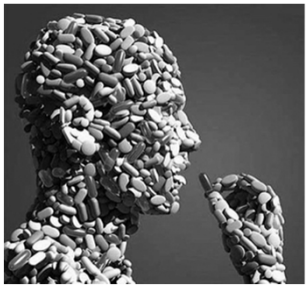
Learning Objectives

- **Identify pain treatment-related regulatory agencies**
- **Discuss the changing role of regulatory agencies in today's pain management environment**
- **Review similarities and differences between regulatory approaches to prescribing practices**
- **Discuss the negotiation between regulatory forces and practical clinical aspects of managing patients with chronic pain**

What is a Regulatory Agency?

- A regulatory agency is a **public authority or government agency** responsible for exercising some kind of autonomous authority over some area of human activity in a regulatory or supervisory capacity
  - Also know as:
    - **Regulatory authority**
    - **Regulatory body**
    - **Regulator**

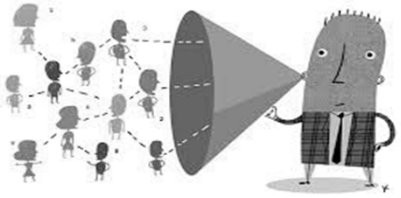
Regulatory Scrutiny?



The Facts

It's a Crowded Field

The Facts



Who Does What?

The Facts

- **Centers for Medicare and Medicaid (CMS)**
  - **Oversee most of the regulations** related directly to the healthcare system
  - Provides government-subsidized medical coverage through a number of programs:
    - Medicare
    - Medicaid
    - State Children's Health Insurance Program (SCHIP)
    - Health Insurance Portability and Accountability Act (HIPPA)

CMS.gov
Centers for Medicare & Medicaid Services

Nancy Grimm. Healthcare Regulations: Who Does What? December, 2014. http://www.yourtrainingprovider.com/blog_main/bid/203291/health-care-regulation-who-does-what. Accessed July 13, 2017.

Who Does What? The Facts

- **The Agency for Healthcare Research and Quality (AHRQ)**
  - Conducts research
  - Develops education
  - Generates measures and data
  - Goals include:
    - **Reducing costs**
    - **Improving safety**
    - Decreasing medical errors

Nancy Grimm. Healthcare Regulations: Who Does What? December, 2014. http://www.yourtrainingprovider.com/blog_main/bid/203291/health-care-regulation-who-does-what. Accessed July 13, 2017.

Who Does What? The Facts

- **The Joint Commission**
  - The Joint Commission **accredits and certifies nearly 21,000 healthcare organizations** and programs in the United States
  - Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards

The Joint Commission

https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx . Accessed July 13, 2017.

Who Does What?

The Facts

- **The National Committee for Quality Assurance (NCQA)**
  - **Helps to build consensus around important healthcare quality issues** and to decide what's important, how to measure it, and how to promote improvement by working with:
    - Large employers
    - Policymakers
    - Healthcare providers
    - Patients
    - Health plans

NCQA
Measuring quality.
Improving health care.

http://www.ncqa.org/newsroom/details/ncqa-seeks-publics-help-on-new-and-revised-measures?ArtMID=11280&ArticleID=66&tabid=2659. Accessed July 13, 2017.

Who Does What?

The Facts

- **The Office of National Drug Control Policy (ONDCP)**
  - **Works to reduce drug use and its consequences** by leading and coordinating the development, implementation, and assessment of U.S. drug policy
  - In addition to its vital ongoing work, ONDCP also provides administrative and financial support to the **President's Commission on Combating Drug Addiction and the Opioid Crisis**

https://www.whitehouse.gov/ondcp/about. Accessed July 13, 2017.

Who Does What?

The Facts

- **The Environmental Protection Agency (EPA)**
  - Mission is to **protect human health and the environment**
  - Plays an integral role in U.S. policies concerning natural resources, human health, economic growth, energy, transportation, agriculture, industry, and international trade
  - Ensuring that federal laws **protecting human health and the environment** are enforced fairly and effectively

https://www.epa.gov/aboutepa. Accessed July 13, 2017.

Who Does What?

The Facts

- **The Drug Enforcement Administration (DEA)**
  - Enforces controlled substances laws and regulations as they pertain to the manufacture, distribution, and dispensing of **legally produced** controlled substances
  - Brings criminal and civil justice actions against organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for **illicit traffic** in the U.S.

https://www.dea.gov/about/mission.shtml. Accessed July 13, 2017.

Who Does What?

The Facts

- **The Federation of State Medical Boards (FSMB)**
  - Represents the **70 state medical and osteopathic regulatory boards** (state medical boards)
  - Supports its member boards as they fulfill their mandate of protecting the public's health, safety and welfare through the proper **licensing**, **disciplining**, and **regulation** of physicians and, in most jurisdictions, other healthcare professionals

https://www.fsmb.org/about-fsmb/fsmb-overview. Accessed July 13, 2017.

Who Does What?

The Facts

- **The Centers for Disease Control and Prevention (CDC)**
  - Main goal is to **protect public health and safety** through the **control and prevention of disease**, injury, and disability in the US and internationally
  - Focuses mainly on infectious disease, food borne pathogens, environmental health, occupational safety and health, health promotion, injury prevention and educational activities designed to improve the health of United States citizens
  - **Researches and provides information on noninfectious diseases** is a founding member of the International Association of National Public Health Institutes

https://www.cdc.gov/about/organization/cio.htm. Accessed July 13, 2017.

Who Does What?

The Facts

- **The Food and Drug Administration (FDA)**
  - Responsible for **protecting the public health** by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices
  - Ensures the safety of our nation's food supply, cosmetics, and products that emit radiation

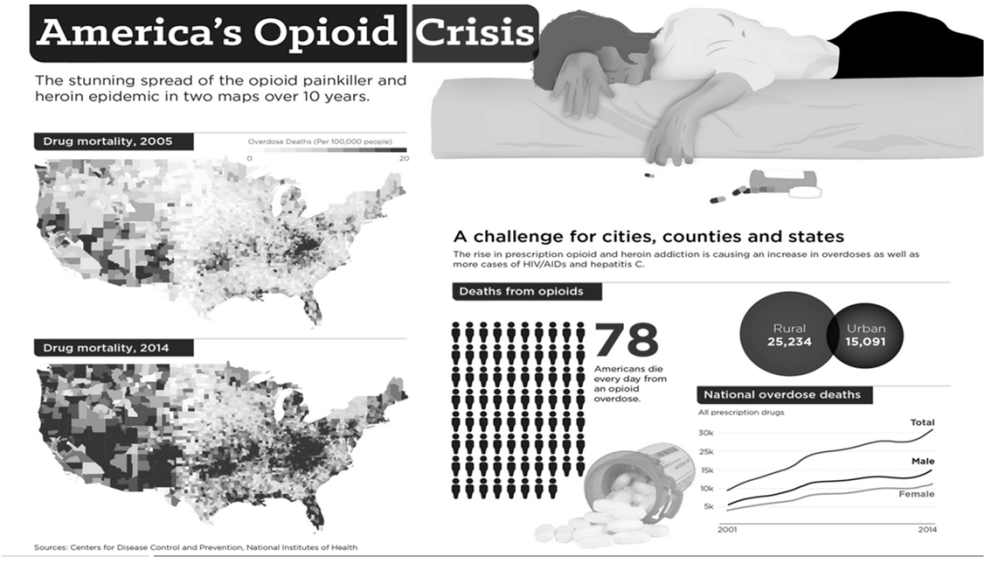
FDA U.S. FOOD & DRUG ADMINISTRATION

https://www.fda.gov/AboutFDA/WhatWeDo/default.htm, Accessed July 13, 2017.

So What?

So What?

The Facts



So What?

The Implications

So What?

The Implications

This is an important message from the Board delivered to your registered primary email address

Dear Arizona Physicians:

On June 5, 2017, Governor Ducey declared a **state of emergency** due to the opioid epidemic. Today, in response to this statewide emergency, Governor Ducey issued Executive Order 2017-04, *Enhanced Surveillance Advisory*.

Attached please find a link to a letter from Cara Christ, M.D. M.S., Director of the Department of Health Services, informing the medical community of the new requirements related to reporting suspected opioid overdoses and deaths.

This is one of the first steps in gathering important data to assist in assessing the problem and devising strategies to combat this serious health epidemic.

Very truly yours,

Patricia McSorley, J.D.
Executive Director
Arizona Medical Board

So What?

The Implications

Governor Ducey Declares Statewide Health Emergency In Opioid Epidemic

June 5, 2017

News Release

Newly released data from the Arizona Department of Health Services shows in 2016, 790 Arizonans died from opioid overdoses — an average of more than two people per day. The trend shows an alarming increase of 74 percent over the past four years. Today's declaration by the governor directs the Arizona Department of Health Services to rapidly respond to this public health emergency.

- prevent prescription opioid drug abuse through appropriate prescribing practices,
- develop guidelines to educate healthcare providers on responsible prescribing practices,
- expand access to treatment, especially Medication Assisted Treatment (MAT), and
- reverse overdoses through the distribution of naloxone.

https://azgovernor.gov/governor/news/2017/06/governor-ducey-declares-statewide-emergency-opioid-epidemic . Accessed July 14, 2017.

The Implications

Dear Partner,

On June 5, 2017, Arizona Governor Doug Ducey declared a Public Health State of Emergency due to the opioid epidemic. The declaration directs Arizona Department of Health Services to lead the statewide emergency response.

Pursuant to A.R.S. §36-782, an Enhanced Surveillance Advisory has been issued to track opioid morbidity and mortality. **Required reporting within 24 hours of the items below will go into effect June 15, 2017.**

Required Reporters	Health condition to be reported	Reporting System
Healthcare professionals licensed under A.R.S. Titles 32 and 36	• Suspected opioid overdoses • Suspected opioid deaths • Neonatal abstinence syndrome	**MEDSIS** **Training:** www.azhealth.gov/opioidtraining **New Account:** MedsisHelpDesk@siren.az.gov
Administrators of a healthcare institution or correctional facility	• Suspected opioid overdoses • Suspected opioid deaths • Neonatal abstinence syndrome	**MEDSIS** **Training:** www.azhealth.gov/opioidtraining **New Account:** MedsisHelpDesk@siren.az.gov
Emergency Medical Services/Ambulance agencies (first response agencies, ground and air ambulance agencies)	• Suspected opioid overdoses • Suspected opioid deaths • Naloxone doses administered	**AZ-PIERS** **Training:** www.azhealth.gov/opioidtraining **New Account:** Anne.Vossbrink@azdhs.gov
Law enforcement officers	• Suspected opioid overdoses • Suspected opioid deaths • Naloxone doses administered	**AZ-PIERS** **Training:** www.azhealth.gov/opioidtraining **New Account:** Anne.Vossbrink@azdhs.gov
Medical examiners	• Suspected opioid deaths	**MEDSIS** **Training:** www.azhealth.gov/opioidtraining **New Account:** MedsisHelpDesk@siren.az.gov
Pharmacists	• Naloxone doses dispensed	**Prescription Drug Monitoring Program (PDMP)** **Training:** https://azpa.learningexpressce.com/index.cfm?fa=view&eventID=8362 **New Account:** https://pharmacypmp.az.gov/

NYS – PMP

The Implications

- ***I*nternet *S*ystem for *T*racking *O*ver-*P*rescribing**
  - Effective **August 27th, 2013**, most prescribers are required to consult the **Prescription Monitoring Program (PMP) Registry** when writing prescriptions for Schedule II, III, and IV controlled substances
  - The registry provides practitioners with direct, secure access to view dispensed controlled substance prescription histories for their patients
  - The PMP is available 24 hours a day/7 days a week via an application on the Health Commerce System (HCS) at https://commerce.health.state.ny.us
  - Reports include all controlled substances that were dispensed in New York State and reported by the pharmacy/dispenser for the past six months
  - This information allows practitioners to better evaluate their patients' treatment with controlled substances and determine whether there may be abuse or nonmedical use

So What?

The Implications

ELECTRONIC PRESCRIBING

Revised: November 2016

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement
1-866-811-7957
www.health.ny.gov/professionals/narcotic

Q2: Is Electronic Prescribing mandatory for New York State practitioners?

A2: As of March 27, 2016 it will be mandatory for practitioners, excluding veterinarians, to issue electronic prescriptions for controlled and non-controlled substances. Electronic prescribing of controlled substances will require additional security features and registration of the certified software application with the Bureau of Narcotic Enforcement.

So What?

The Implications

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Mandatory Prescriber Education Guidance

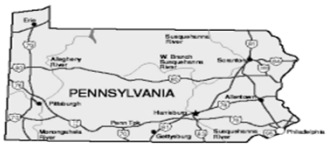
Prescribers licensed under Title Eight of the Education Law in New York to treat humans and who have a DEA registration number to prescribe controlled substances, as well as medical residents who prescribe controlled substances under a facility DEA registration number, must complete at least three (3) hours of course work or training in pain management, palliative care, and addiction. The course work or training must be completed by July 1, 2017, and once every three years thereafter, pursuant to Public Health Law (PHL) §3309-a(3).

The course work or training may be live or online.

The course work or training must include the following eight (8) topics:

- New York State and federal requirements for prescribing controlled substances;
- Pain management;
- Appropriate prescribing;
- Managing acute pain;
- Palliative medicine;
- Prevention, screening and signs of addiction;
- Responses to abuse and addiction; and
- End of life care.

So What? The Implications



pennsylvania
DEPARTMENT OF HEALTH
PRESCRIPTION DRUG MONITORING PROGRAM

In case you missed it – New PA PDMP requirements for prescribers.

New legislative changes to the Pennsylvania Prescription Drug Monitoring Program (PA PDMP) went into effect on Jan. 1, 2017.

Here is what you need to know:

- **Prescribers** must now query the PA PDMP **each time** a patient is prescribed an opioid drug product or benzodiazepine by the prescriber. There are exceptions for emergency departments and for patients who are admitted to a health care facility, and these can be found on our website's Frequently Asked Questions (FAQ) page.
- **Dispensing practitioners** must now submit data to the PA PDMP no later than the close of the subsequent business day (Monday through Friday) after dispensing the controlled substance, as opposed to the previous requirement of within 72 hours.

So What? The Facts

pennsylvania
DEPARTMENT OF HEALTH
PRESCRIPTION DRUG MONITORING PROGRAM

Pennsylvania Prescription Drug Monitoring Program Now Sharing Data with 11 Other States and D.C.

The Pennsylvania Prescription Drug Monitoring Program (PA PDMP) has now connected with 11 other states in an effort to foster data sharing among PDMPs. Interstate sharing of data helps prescribers and pharmacists get a more complete picture of their patients' controlled substance prescription histories, regardless of which state they filled their prescription in.

Users of the PA PDMP can now see if their patients have filled controlled substance prescriptions in: Connecticut; Illinois; Louisiana; Massachusetts; New Jersey; New York; Ohio; Texas; Virginia; West Virginia; and Washington D.C. Additionally, a one-way sharing connection has been established with Maryland, enabling their program users to search the PA PDMP. The PA PDMP Office invites all other states to begin sharing data, and anticipates that Pennsylvania will connect with more state PDMPs in the upcoming weeks.

So What?

The Implications

Pennsylvania Department of Health > My Health > A-Z Health Topics > M-P > Opioids > Prescribing Guidelines

OPIOID PRESCRIBING GUIDELINES

Under Governor Wolf's leadership, this administration has taken significant steps to improve doctor prescribing practices. The Department of Health and the Department of Drug and Alcohol Programs convenes the Safe and Effective Prescribing Practices Task Force. The task force membership includes various state agencies, representatives from medical associations, provider advocates and community members. The task force developed and adopted guidelines for nine medical specialties on the safe and effective use of opioids in the treatment of pain.

Click on an image below to download a PDF of the guidelines.

http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Pages/Prescribing-Guidelines.aspx#.WWkCxVGQvHs. Accessed July 14, 2017.

So What?

The Implications

- **Maine**
  - **January 1, 2017**
    - Mandatory check of PDMP
    - Limits on opioid prescribing for acute and chronic pain
  - **July 1, 2017**
    - Mandatory electronic prescribing
    - Patients with active prescriptions in excess of 100 morphine milligram equivalents must be tapered
  - **December 31, 2017**
    - CME requirement for prescribers

www.maine.gov/dhhs/samhs/osa/help/Documents/SessionB_Smith.pdf . Accessed July 15, 2017.

The Role of Regulatory Agencies

The Role of Regulatory Agencies

The Facts

January 5, 2017

Centers for Medicare & Medicaid Services (CMS)
Opioid Misuse Strategy

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) OPIOID MISUSE STRATEGY 2016

CMS has made attacking this devastating epidemic a top priority and is providing help and resources to clinicians, beneficiaries, and families. This is an ongoing CMS strategy, as part of the HHS Opioid Initiative launched in March 2015, to combat misuse and promote programs that support treatment and recovery support services. The CMS effort includes four priority areas:

1. *Implement more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion;*
2. *Expand naloxone use, distribution, and access, when clinically appropriate;*
3. *Expand screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment; and*
4. *Increase the use of evidence-based practices for acute and chronic pain management.*

HHS.gov News. (2016). HHS takes strong steps to address opioid-drug related overdose, death and dependence. http://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html. Accessed July 14, 2017

The Role of Regulatory Agencies

The Facts

- **Supporting the Department of Health and Human Services Initiative**
  - Increasing the evidence base with **research and data**
  - Investing ~$12 million over next 3 years to explore how to best support rural primary care practices using medication-assisted therapy and overcoming educational barriers

https://www.ahrq.gov/professionals/systems/primary-care/opioids/index.html. Accessed July 14, 2017

The Role of Regulatory Agencies

The Implications

A complimentary publication of The Joint Commission

Issue 49, August 8, 2012

SAFE USE OF OPIOIDS IN HOSPITALS

- **Create and implement policies and procedures for the ongoing clinical monitoring of patients receiving opioid therapy**
- **Create and implement policies and procedures that allow for a second level review by a pain management specialist or pharmacist**
- **Track and analyze opioid-related incidents**
- **Use information technology to monitor prescribing**
- **Advise clinicians who prescribe pain medications to use both pharmacologic and nonpharmacologic alternatives**
- **Educate and assess the understanding of staff**
- **Educate and provide written instructions to patients on opioids**
- **Assess the organization's need for training based on the analysis of reported adverse events, near misses and staff observations**

The Role of Regulatory Agencies

The Implications

- **Proposes new measures to assess potentially inappropriate use of opioids:**
  - Assesses whether health plan members 18 years and older receive:
    - Long-term opioids at high dose
    - Opioids from multiple prescribers or multiple pharmacies
    - Long-term, high-dose opioids from multiple prescribers and multiple pharmacies

http://www.ncqa.org/newsroom/details/ncqa-seeks-publics-help-on-new-and-revised-measures?ArtMID=11280&ArticleID=66&tabid=2659 . Accessed July 14, 2017

The Role of Regulatory Agencies

The Facts

President's Commission on Combating Drug Addiction and the Opioid Crisis

- **Mission**
  - To study the scope and effectiveness of the Federal response to **drug addiction** and the **opioid crisis** and to make recommendations to the President for improving that response including
    - Availability of **addiction treatment** and **drug reversal**
    - Best practices for prevention including **education and PDMPs**

https://www.whitehouse.gov/ondcp/presidents-commission/mission. Accessed July 15, 2017

The Role of Regulatory Agencies

The Implications

Collecting and Disposing of Unwanted Medicines

What to do with Unwanted or Expired Medicines

- Guidelines for **disposal**
- **Take-back** Events or Programs

https://www.epa.gov/hwgenerators/collecting-and-disposing-unwanted-medicines. Accessed July 15, 2017

The Role of Regulatory Agencies

The Implications

HEADQUARTERS NEWS

October 04, 2016
Contact: DEA Public Affairs
(202) 307-7977

https://www.dea.gov/divisions/hq/2016/hq100416.shtml. Accessed July 15th 2017

DEA Reduces Amount of Opioid Controlled Substances to be Manufactured in 2017

- **The United States Drug Enforcement Administration (DEA) has reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in 2017 by 25 percent or more**
- **The purpose of quotas are to provide for the adequate and uninterrupted supply for legitimate medical need of the types of schedule I and II controlled substances that have a potential for abuse, while limiting the amounts available to prevent diversion**

The Role of Regulatory Agencies — The Facts

Federation of STATE MEDICAL BOARDS

MODEL POLICY ON THE USE OF
OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

Adopted as policy by the House of Delegates of the Federation of State Medical Boards in July 2013

- **To provide state medical boards with an updated guideline for assessing physicians' management of pain**
- **To determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations**

The Role of Regulatory Agencies — The Implications

- **Consider treatment inappropriate including but *not limited to:***
  - Inadequate attention paid to **initial assessment and risk determination**
  - **Inadequate monitoring** of potential for aberrant drug-related behaviors and use of available tools
  - Inadequate attention to **patient education and informed consent**
  - Unjustified **dose escalation**
  - Excessive reliance on opioid analgesics (particularly **high doses**)

The Role of Regulatory Agencies

The Implications

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

The Role of Regulatory Agencies

The Implications

- **Guidelines**
  - **Nonpharmacologic** therapy and **nonopioid** pharmacologic therapy are preferred for chronic pain
  - Before starting opioid therapy for chronic pain, clinicians should **establish treatment goals** with all patients
  - Discuss known **risks, benefits, and responsibilities** with patients
  - **Immediate-release opioids** first

The Role of Regulatory Agencies

The Implications

- **Guidelines (cont'd)**
  - **Lowest effective dosage**
    - Reassess risk/benefit if **≥50 MME/day**
    - Avoid or carefully justify **≥90 MMD/day**
  - In acute pain, **lowest effective dose, lowest quantity**
  - **Re-evaluate risk/benefit** in 1-4 weeks, then every 3 months
  - Utilize strategies that **mitigate risk**
    - **Opioid risk assessment**
    - **Naloxone**

The Role of Regulatory Agencies

The Implications

- **Guidelines (cont'd)**
  - Check the **PDMP**
  - **Urine drug testing** before initiation
    - At least annually
  - Avoid concurrent opioids and **benzodiazepines**
  - Offer or arrange for evidence-based treatment for patients with **opioid use disorder**

The Role of Regulatory Agencies

The Implications

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

- ☐ Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- ☐ Check that non-opioid therapies tried and optimized.
- ☐ Discuss benefits and risks (eg, addiction, overdose) with patient.
- ☐ Evaluate risk of harm or misuse.
  - Discuss risk factors with patient.
  - Check prescription drug monitoring program (PDMP) data.
  - Check urine drug screen.
- ☐ Set criteria for stopping or continuing opioids.
- ☐ Assess baseline pain and function (eg, PEG scale).
- ☐ Schedule initial reassessment within 1–4 weeks.
- ☐ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

If RENEWING without patient visit

- ☐ Check that return visit is scheduled ≤3 months from last visit.

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- ☐ Assess pain and function (eg, PEG); compare results to baseline.
- ☐ Evaluate risk of harm or misuse:
  - Observe patient for signs of over-sedation or overdose risk.
    - If yes: Taper dose.
  - Check PDMP.
  - Check for opioid use disorder if indicated (eg, difficulty controlling use).
    - If yes: Refer for treatment.
- ☐ Check that non-opioid therapies optimized.
- ☐ Determine whether to continue, adjust, taper, or stop opioids.
- ☐ Calculate opioid dosage morphine milligram equivalent (MME).
  - If ≥ 50 MME /day total (≥ 50 mg hydrocodone; ≥ 33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
  - Avoid ≥ 90 MME /day total (≥ 90 mg hydrocodone; ≥ 60 mg oxycodone), or carefully justify; consider specialist referral.
- ☐ Schedule reassessment at regular intervals (≤ 3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores. (30% improvement from baseline is clinically meaningful)

Q1: *What number from 0–10 best describes your **pain** in the past week?*
0="no pain", 10="worst you can imagine"

Q2: *What number from 0–10 describes how, during the past week, pain has interfered with your **enjoyment of life**?*
0="not at all", 10="complete interference"

Q3: *What number from 0–10 describes how, during the past week, pain has interfered with your **general activity**?*
0="not at all", 10="complete interference"

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

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

March 2016

The Role of Regulatory Agencies

The Facts

FDA U.S. FOOD & DRUG ADMINISTRATION

PAIN MANAGEMENT AND THE OPIOID EPIDEMIC

BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE

July 13, 2017

Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse

The Role of Regulatory Agencies

The Facts

- **Mission:**
  - **Update information** since IOM Report[1]
  - The **evolving role** of opioid analgesics
  - Characterizing the **epidemiology of the opioid epidemic**
    - **Evidence** on strategies for addressing it

1. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Institute of Medicine, 2011.

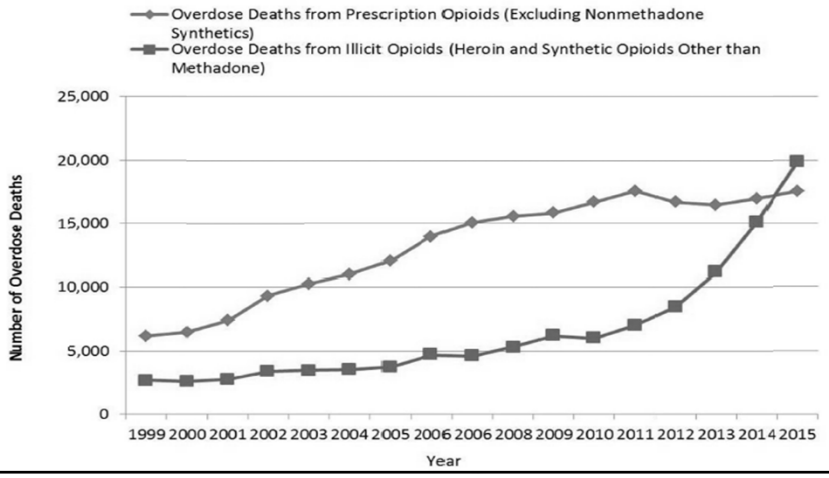
The Role of Regulatory Agencies

The Facts

- **Identify actions to be taken by FDA and other agencies and organizations**
  - Specifically **incorporating individual and societal considerations into its risk/benefit analysis** framework for approval and post-market surveillance
- **Identify research questions** that need to be addressed to assist the FDA in implementing this framework

The Role of Regulatory Agencies

The Facts



The Role of Regulatory Agencies

The Implications

- **Recommendations**
  - **Invest in research** to better understand pain and opioid use disorder
  - **Consider potential effects of policies and programs** for opioid analgesics on illicit markets
  - Improve **reporting**, invest in **data**, provide **transparency**
  - **Incorporate public health considerations** into FDA decision-making

The Role of Regulatory Agencies

The Implications

- **Recommendations (cont'd)**
  - Strengthen **post-approval oversight**
  - **Review currently approved** opioid analgesics
  - Establish **comprehensive educational materials** for patients and healthcare providers
  - **Facilitate reimbursement** for comprehensive approaches
  - **Improve PDMP** use and data

The Role of Regulatory Agencies

The Implications

- **Recommendations (cont'd)**
  - **Evaluate impact** of patient and public **education**
  - **Expand education and treatment for opioid use disorder**
  - Remove barriers to **insurance coverage** for Tx of opioid use disorder
  - **Leverage pharmacists**
  - Improve access to **naloxone**

Things May be Changing

The Implications

TAKE 5
Pain: The 5th Vital Sign

October 2000

Revised Edition

Geriatrics and Extended Care Strategic Healthcare Group
National Pain Management Coordinating Committee
Veterans Health Administration
810 Vermont Avenue NW
Washington, DC 20420

J Gen Intern Med. 2006 Jun; 21(6): 607–612.
doi: 10.1111/j.1525-1497.2006.00415.x
PMCID: PMC1924634

Measuring Pain as the 5th Vital Sign Does Not Improve Quality of Pain Management

Richard A Mularski, MD, MSHS,[1,2] Foy White-Chu, MD,[3] Devorah Overbay, MS, RN,[4] Lois Miller, PhD, RN,[4] Steven M Asch, MD, MPH,[1,2] and Linda Ganzini, MD, MPH[5,6]

Opioid Crisis: Scrap Pain as 5th Vital Sign?

— Groups call on JC and CMS to re-evaluate policies that could lead to opioid overprescribing

by Kristina Fiore
Associate Editor, MedPage Today

CAHPS® Hospital Survey

JUL 06 | MORE ON PHARMACY

To combat opioid epidemic, HHS moves to remove pain management questions from HCAHPS surveys

Many clinicians report feeling pressure to overprescribe opioids because scores on the pain management questions are tied to Medicare payments. **Susan Morse,** *Associate Editor*

Hot Off the Press…

The Implications

- **2018 Arizona Opioid Epidemic Act January 2018**

Real lives. Real people. Between June 2017 - January 2018:

812 Arizonans **died** of a suspected opioid overdose

5,202 Arizonans suffered a suspected **overdose** on opioids

455 Arizona **babies** were **born addicted** to opioids

A potent drug mis-prescribed, overprescribed, and misused.

6,000,000+ The amount of opioids that **four doctors** wrote over a **12-month period** in a county with a population of **200,000 people.**

75% The percentage of **heroin users** in treatment that **started with painkillers**, according to a 2014 study by the Journal of the American Medical Association.

Hot Off the Press…

The Implications

- **The Plan**
  - Targeting **Pill Mills**
  - Increasing **oversight and accountability**
  - Holding manufacturers accountable
    - Purdue Pharma
  - Good Samaritan law to protect naloxone administrator
  - Prescriber education
    - 20% of Primary Care Physicians consider themselves well-prepared to identify high-risk patients
    - 40% of patients claim that the had the diagnosis and it was not identified by PCP

Hot Off the Press…

The Implications

- **Limiting opioid doses prescribed**
  - <90 MME/day for nonexpert clinicians
  - 5-day limits for first prescription for acute pain
  - The use of Red Caps
  - Access to naloxone

3,429 Naloxone doses administered outside of the hospital by emergency medical services, law enforcement, and others from June 2017 through January 2018.

86% The percentage of patients who survived an overdose received Naloxone pre-hospital.

Case 1

Merrick doctor wants pain pill case tossed

Attorney: Belfiore, patients victims of pharmaceutical industry

Posted January 5, 2017

By Erik Hawkins

- **A Merrick doctor under indictment for allegedly writing illegal prescriptions** for patients is asking a federal judge to dismiss the case against him and go after those he thinks are really at fault — the pharmaceutical companies who promoted the drugs while downplaying their risks
- Wrote 5,000 prescriptions for 600,000 pain pills between January 2010 and March 2013
- According to federal officials, 5,000 is "an extremely high number of oxycodone prescriptions and oxycodone pills issued by a sole family practitioner, especially in light of the defendant's specialty area: **general family medicine and dermatology."**

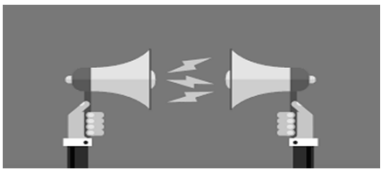
Case 2

A former opioid addict's story

- **50-year-old woman formerly enjoyed a successful career as a consultant for a pharmaceutical company**
  - "My husband and I worked hard and played hard"
    - Much of the "playing" included alcohol leading to alcoholism
  - A few years later husband develops cancer, and cancer pain
  - His opioid analgesics became an opportunity for this woman to start abusing them
  - She started to ask physicians she knew for prescriptions
  - "I would say, 'these doctors treating my husband don't know what they're doing, so could you help me out and write a script for him?'" she recalls. "I had worked with these doctors for many years, and they trusted me. They'd write me anything until they eventually started to catch on."

Conclusions

- **There are a lot of cooks in the kitchen…**

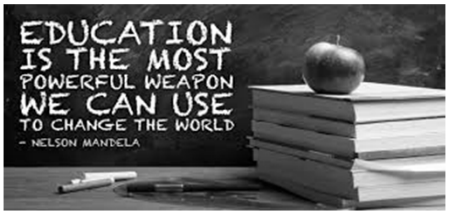


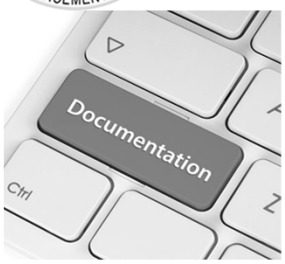
- **How does this affect clinical practice?**

Conclusions

- Start with **state-level requirements**
- Think **DEA**
- Pro-active **education**
- Discussion
- Consider **societal** outcomes
- Documentation

State Requirements





DISCUSSION

"Cure sometimes, treat often, comfort always."
— Hippocrates

PAINWEEK®

Questions?