


**PainWeek**

**The Regulatory Agency  
Will See You Now**

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Kevin L. Zacharoff, MD



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**PainWeek**

**Disclosures**

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Nothing to Disclose

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**Learning Objectives**

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- 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

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### 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



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### Regulatory Scrutiny?



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### The Facts

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**It's a Crowded Field** **The Facts**

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**Who Does What?** **The Facts**

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**Centers for Medicare and Medicaid (CMS)**

- **Oversee most of the regulations** related directly to the health care 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)

Nancy Green, Healthcare Regulation: Who Does What? December, 2014. <http://www.painweek.com/healthcare-regulation-who-does-what/> Accessed July 13, 2017.

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**Who Does What?** **The Facts**

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- **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 Green, Healthcare Regulation: Who Does What? December, 2014. <http://www.painweek.com/healthcare-regulation-who-does-what/> Accessed July 13, 2017.

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The Facts

**Who Does What?**

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- **The Joint Commission**
  - The Joint Commission **accredits and certifies nearly 21,000 health care 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

http://www.jointcommission.org/.../Accredited July 13, 2017.

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The Facts

**Who Does What?**

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- **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/.../Accredited July 13, 2017.

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The Facts

**Who Does What?**

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- **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**



http://www.oncdcp.gov/.../Accredited July 13, 2017.

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The Facts

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**Who Does What?**

- **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




Accounted July 13, 2017

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The Facts

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**Who Does What?**

- **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.




Accounted July 13, 2017

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The Facts

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**Who Does What?**

- **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




Accounted July 13, 2017

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The Facts

**Who Does What?**

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- **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 non-infectious diseases** is a founding member of the International Association of National Public Health Institutes



CENTERS FOR DISEASE CONTROL AND PREVENTION

http://www.cdc.gov/about/about\_cdc.html Accessed July 13, 2017.

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The Facts

**Who Does What?**

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- **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



U.S. FOOD & DRUG ADMINISTRATION

http://www.fda.gov/about/fda.html Accessed July 13, 2017.

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**So What?**

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**So What?** **The Facts**

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**America's Opioid Crisis**

The alarming spread of the opioid epidemic over heroin epidemic in two years over 10 years.

**Drug mortality 2016**

**Drug mortality 2017**

**A challenge for cities, counties and states**

The rise in opioid-related deaths is a challenge for cities, counties and states. The number of deaths has increased by 78% since 2010.

**78%**

2010-2017

**2010-2017**

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**So What?** **The Implications**

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**So What?** **The Implications**

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

Dear Arizona Physicians:

June 5, 2017 Governor Ducey declared a **state of emergency** in the opioid epidemic in response to the substance abuse epidemic. Ducey issued Executive Order 2017-04, Enhanced Surveillance Authority.

Attached please find a letter from Cara Crain, M.D., M.S., Director of the Department of Health Services, outlining the specific content of that new requirement related to reporting suspected opioid overdose 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 McCortney*  
Patricia McCortney, J.D.  
Executive Director  
Arizona Medical Board

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### So What?

### The Facts




**pennsylvania**  
DEPARTMENT OF HEALTH

**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. In-state 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.

States 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 cross-state 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.



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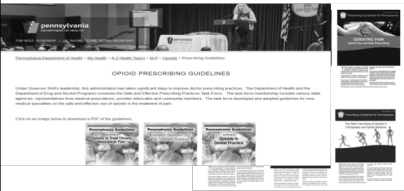

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### So What?

### The Implications



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### 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






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## The Role of Regulatory Agencies

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## 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 2016, 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.



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## 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



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The Implications

### The Role of Regulatory Agencies

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 non-pharmacologic 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


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The Implications

### The Role of Regulatory Agencies

- 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


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The Facts

### The Role of Regulatory Agencies

#### 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




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**The Role of Regulatory Agencies** The Implications

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- **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**)





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**The Role of Regulatory Agencies** The Implications





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



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**The Role of Regulatory Agencies** The Implications

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- **Guidelines**
  - **Non-pharmacologic** therapy and **non-opioid 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





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The Implications

### The Role of Regulatory Agencies

- Guidelines (Cont'd)
  - Lowest effective dosage
    - Reassess risk/benefit if  $\leq 50$  MME/day
    - Avoid or carefully justify  $\geq 90$  MME/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


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The Implications

### The Role of Regulatory Agencies

- 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**


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The Implications

### The Role of Regulatory Agencies

**Checklist for prescribing opioids for chronic pain**



**BEFORE**

**When considering long-term opioid therapy**

1. Do you have a valid clinical indication for chronic opioid therapy?
2. Have you reviewed the patient's history and current medications?
3. Do you have a valid clinical indication for chronic opioid therapy?
4. Have you reviewed the patient's history and current medications?
5. Have you reviewed the patient's history and current medications?

**WHEN INITIATING OR CHANGING OPIOID THERAPY**

1. Do you have a valid clinical indication for chronic opioid therapy?
2. Have you reviewed the patient's history and current medications?
3. Do you have a valid clinical indication for chronic opioid therapy?
4. Have you reviewed the patient's history and current medications?
5. Have you reviewed the patient's history and current medications?


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The Facts

**The Role of Regulatory Agencies**




**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



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The Facts

**The Role of Regulatory Agencies**



**Mission:**

- Update information since IOM Report1
- The evolving role of opioid analgesics
- Characterizing the epidemiology of the opioid epidemic
  - Evidence on strategies for addressing it



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The Facts

**The Role of Regulatory Agencies**



- 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



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The Facts

### The Role of Regulatory Agencies

**FDA U.S. FOOD & DRUG ADMINISTRATION**

Number of Overdose Deaths

Year

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The Implications

### The Role of Regulatory Agencies

- **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

**FDA U.S. FOOD & DRUG ADMINISTRATION**

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The Implications

### The Role of Regulatory Agencies

- **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

**FDA U.S. FOOD & DRUG ADMINISTRATION**

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December 19, 2018

HHS.gov

U.S. Department of Health & Human Services

FOR IMMEDIATE RELEASE  
December 15, 2018

Contact: ASH Press Office  
202-205-0143  
ashmedia@hhs.gov

**HHS recommends prescribing or co-prescribing naloxone to patients at high risk for an opioid overdose**

Asst. Brett P. Giroir, MD, assistant secretary for health and senior advisor for opioid policy, today released guidance... for healthcare providers and patients obtaining their naloxone – the opioid overdose reversal drug – can help save lives and should be prescribed to all patients at risk for opioid complications, including overdose.

"Given the scope of the opioid crisis, it's critically important that healthcare providers and patients discuss the risks of opioids and how naloxone should be used in the event of an overdose," said Adm. Giroir. "We have begun to see some encouraging signs in our response to the opioid crisis, but we know that more work is required to fully reverse the decades-long epidemic. Co-prescribing naloxone when a patient is considered to be at high risk of an overdose, is an essential element of our national effort to reduce overdose deaths and should be practiced widely."



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**The California Death Certificate Project**

- Investigators are going back **three years to identify any doctors who may have prescribed the drugs inappropriately when someone dies of an overdose death**, even if it was not the fatal dose, and send them letters
- A physician in San Francisco was sent a letter explaining that a patient he had treated died in 2012 from taking a toxic cocktail of methadone and Benadryl – and he was the doctor who wrote the patient's last prescription for methadone
- He had **two weeks to respond to the letter** with a written summary of the care he had provided, and a certified copy of the patient's medical record facing fines of \$1,000 per day if he didn't comply



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**Massachusetts Sends Warning to Prescribers**

- Letters went to physicians and others identified as having **prescribed opioids to a patient within 60 days of the patient's death – or to a patient who subsequently died from an opioid overdose**. U.S. Attorney Andrew Lelling said Thursday in a statement



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The Implications

**Conclusions**

- There are a lot of cooks in the kitchen...

- How does this affect clinical practice?

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**You Need to Know...**

The 660-Page Opioids Bill Is Now the Law. Here's What's in It.

By Billy Wynne, Glenn Joplin




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**Conclusions**

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



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

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Questions? \_\_\_\_\_

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