The Regulatory Agency
Will See You Now

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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 known as:
  - Regulatory authority
  - Regulatory body
  - Regulator

Regulatory Scrutiny?

The Facts
It’s a Crowded Field

Who Does What?

• 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)

Who Does What?

• 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
### Who Does What? The Facts

<table>
<thead>
<tr>
<th>The Joint Commission</th>
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<tbody>
<tr>
<td>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.</td>
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<tr>
<th>The National Committee for Quality Assurance (NCQA)</th>
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<tbody>
<tr>
<td>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:</td>
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<td>- Large employers</td>
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<tr>
<td>- Policymakers</td>
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<tr>
<td>- Healthcare providers</td>
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<tr>
<td>- Patients</td>
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<td>Health plans</td>
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<th>The Office of National Drug Control Policy (ONDCP)</th>
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<td>Works to reduce drug use and its consequences by leading and coordinating the development, implementation, and assessment of US 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.</td>
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Who Does What? The Facts

• The Environmental Protection Agency (EPA)
  – Mission is to protect human health and the environment
  – Plays an integral role in US 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

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 illegally 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 US

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

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

So What?
So What?

The Implications

Governor Ducey Declares Statewide Health Emergency In Opioid Epide

News Release

Large numbers of deaths from the Arizona Department of Health Services show in 2016, 92,000 deaths took place as a result of drug overdoses — an average of more than two people per day. The best evidence from studies in other countries indicates many of these individuals have had a history of prior treatment for substance use disorders.

As a result, a number of recommendations have been made:

- Prevention and treatment of opioid addiction
- Increased access to naloxone
- Increased access to medication-assisted treatment
- Increased availability of mental health services
- Increased availability of substance use disorder treatment
- Increased availability of opioid overdose reversal medications
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NYS – PMP

Internet System for Tracking Over-Prescribing

- Effective August 27th, 2018, all prescribers are required to consult the Prescribed 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 non-medical use
So What? The Facts

Pennsylvania Prescription Drug Monitoring Program New Sharing Bots with 11 Other States and D.C.

So What? The Implications

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
    • CMS requirement for prescribers
**The Role of Regulatory Agencies**

- 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
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

The Role of Regulatory Agencies

Proposes new measures to assess potentially inappropriate use of opioids:
- As a part of an initiative to assess 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

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 PMPs
**The Role of Regulatory Agencies**

**Collecting and Disposing of Unwanted Medicines**

- Guidelines for disposal
- Take-back events or programs

**The Implications**

**The Role of Regulatory Agencies**

- 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 quasars 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 Facts**

- 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

• 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

• 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

The Role of Regulatory Agencies

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

MMWR
Mortality and Morbidity Weekly Report
March 15, 2016
The Role of Regulatory Agencies

- Guidelines (Cont'd)
  - Lowest effective dosage
    - Reassess risk/benefit if ≥ 50 MME/day
    - Avoid or carefully justify ≥ 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

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

The Role of Regulatory Agencies
The Role of Regulatory Agencies

- **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

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\(^1\) Science Advisory Committee on Opioid-Related Health Risks and Harm Reduction, National Institutes of Health, 2019

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- 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

![Graph showing data]

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**

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### Hot Off the Press...

**The Implications**

- **2018 Arizona Opioid Epidemic Act January 2018**
  - 812 people died of drug overdoses in 2018
  - 5,202 people sought treatment for opioid addiction
  - 455 people were admitted to treatment facilities
  - 6,000,000+ people were at risk
  - 75% of people entering treatment are successful
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 they had the diagnosis and it was not identified by PCP

Hot Off the Press...

The Implications

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

3,429
86%

Hot Off the Press...

Case 1

Merrick, doctor wants pain pill case tossed

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

- 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 her "play" included social drinking in addition
- A few years later husband develops cancer, and cancer pain
- Her 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?
“Cure sometimes, treat often, comfort always.”
— Hippocrates

Questions?