



**The Regulatory Agency
Will See You Now**



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Disclosures

Nothing to Disclose

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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



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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



significant
OTHER

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Regulatory Scrutiny?



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The Facts

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The Facts

It's a Crowded Field

Pain

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The Facts

Who Does What?

- 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 (CHIP)
 - Health Insurance Portability and Accountability Act (HIPPA)

Nancy Green, Healthcare Regulations: Who Does What? December, 2014. <http://www.painweek.com/cms>. Accessed July 13, 2017.

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The Facts

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

Nancy Green, Healthcare Regulations: Who Does What? December, 2014. <http://www.painweek.com/ahrq>. Accessed July 13, 2017.


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The Facts

Who Does What?

- 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



https://www.jointcommission.org/our-work/our-work/ Accessed July 13, 2017.


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The Facts

Who Does What?

- 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



https://www.ncqa.org/our-work/our-work/ Accessed July 13, 2017.


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The Facts

Who Does What?

- 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.oncdp.gov/our-work/our-work/ Accessed July 13, 2017.


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The Facts

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




PainWeek http://www.painweek.com/ Accessed July 13, 2017.

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The Facts

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.




PainWeek http://www.painweek.com/ Accessed July 13, 2017.

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The Facts

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



PainWeek http://www.painweek.com/ Accessed July 13, 2017.

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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



PainWeek <http://www.painweek.com> Accessed July 13, 2017.

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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



PainWeek <http://www.painweek.com> Accessed July 13, 2017.

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So What?



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So What? **The Facts**

America's Opioid Crisis
The stunning spread of the opioid pandemic and heroin epidemics in less than 10 years.

A challenge for cities, counties and states
The opioid epidemic is a public health crisis that is spreading across the United States.

78 states have declared a state of emergency

~130 deaths per day

25,324 (2014) **16,000** (2015)

HEROIN OVERDOSE DEATHS

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So What? **The Implications**

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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** in response to the state's **opioid epidemic**. Governor Ducey issued Executive Order 2017-04, **Enhanced Services**.

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

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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.



Health Information Systems | Health Information Systems | Health Information Systems | Health Information Systems | Accessed July 14, 2017.

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So What?

The Implications



Dear Patients:

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

As a result of A.D.H.S.'s declaration of emergency, the following regulations will be implemented to help reduce the number of opioid overdoses and deaths:

- **Prescription Opioids:**
 - 1. Increased oversight of controlled substances.
 - 2. Increased oversight of controlled substances.
 - 3. Increased oversight of controlled substances.
 - 4. Increased oversight of controlled substances.
- **Medication Assisted Treatment (MAT):**
 - 1. Increased oversight of controlled substances.
 - 2. Increased oversight of controlled substances.
 - 3. Increased oversight of controlled substances.
 - 4. Increased oversight of controlled substances.
- **Reverse Opioid Overdoses:**
 - 1. Increased oversight of controlled substances.
 - 2. Increased oversight of controlled substances.
 - 3. Increased oversight of controlled substances.
 - 4. Increased oversight of controlled substances.

Reporting System:

The reporting system will be implemented to help reduce the number of opioid overdoses and deaths.

Additional Information:

For more information, please contact the Arizona Department of Health Services at (602) 974-3333.



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NYS – PMP

The Implications



Internet System for Tracking Over-Prescribing



- 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 non-medical use




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So What? **The Implications**

ELECTRONIC PRESCRIBING
Revised: November 2014



NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement
www.health.ny.gov/bureauofnarcoticenforcement


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

A2: As of March 27, 2015, it will be mandatory for practitioners, including 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.

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So What? **The Implications**



Department of Health
ANDREW M. CUOMO
Governor

Department of Health
EDWARD A. ZICKEL, M.D., J.D.
Commissioner

Department of Health
SALLY DRESLER, 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 faculty DEA registration number, must complete at least three (3) hours of course work or training in pain management commencing on July 1, 2017. The course work or training must be completed July 1, 2017. An every three-year threshold, pursuant to Public Health Law § 2805(1)(c).

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;
- Alternative prescribing;
- Managing acute pain;
- Prescribing medication;
- Prevention, monitoring and signs of addiction;
- Responses to abuse and addiction; and
- End of life care.



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So What? **The Implications**




pennsylvania
DEPARTMENT OF HEALTH
PENNSYLVANIA 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 April 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 schedule II substance 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.**

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So What? **The Facts**



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.

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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 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 says it will "lead" HHS will release plan to address opioid drug-related overdose, death and dependence | www.washingtonpost.com/news/health/wp/2016/07/05/hhs-will-lead-hhs-will-release-plan-to-address-opioid-drug-related-overdose-death-and-dependence/ Accessed July 14, 2017

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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




Healthcare Research and Quality | <http://www.ahrq.gov/painmanagement/> Accessed July 14, 2017

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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

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/epahome/collecting-disposing-unwanted-medicines Accessed July 15, 2017

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The Role of Regulatory Agencies The Implications

HEADQUARTERS NEWS

https://www.dea.gov/pressroom/2016/10/04/16100411 Accessed July 15, 2017

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



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

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The Role of Regulatory Agencies The Facts





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

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The Role of Regulatory Agencies	The Implications
<ul style="list-style-type: none"> ▪ Consider treatment inappropriate including but <i>not limited to</i>: <ul style="list-style-type: none"> -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
	
<p>CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016</p>	
	

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The Role of Regulatory Agencies	The Implications
<ul style="list-style-type: none"> ▪ Guidelines <ul style="list-style-type: none"> - 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 Role of Regulatory Agencies

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



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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 Role of Regulatory Agencies

Checklist for prescribing opioids for chronic pain

For prescribers and patients. For more information, visit www.cdc.gov/painmanagement.

WHEN CONSIDERING LONG-TERM OPIOID THERAPY

1. Do you and your patient have a clear, well-defined goal of treatment?
2. Have you and your patient discussed the risks and benefits of long-term opioid therapy?
3. Do you and your patient have a clear understanding of the risks and benefits of long-term opioid therapy?
4. Do you and your patient have a clear understanding of the risks and benefits of long-term opioid therapy?
5. Do you and your patient have a clear understanding of the risks and benefits of long-term opioid therapy?

WHEN PRESCRIBING OPIOIDS FOR CHRONIC PAIN


1. Check the state Prescription Drug Monitoring Program (PDMP) for controlled substances.
2. Check the patient's medical history for conditions that may increase the risk of opioid-related harm.
3. Check the patient's current and past opioid use.
4. Check the patient's current and past use of benzodiazepines and other sedating medications.
5. Check the patient's current and past use of alcohol.
6. Check the patient's current and past use of other substances that may increase the risk of opioid-related harm.
7. Check the patient's current and past use of other substances that may increase the risk of opioid-related harm.
8. Check the patient's current and past use of other substances that may increase the risk of opioid-related harm.
9. Check the patient's current and past use of other substances that may increase the risk of opioid-related harm.
10. Check the patient's current and past use of other substances that may increase the risk of opioid-related harm.



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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

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


July 13, 2017



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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

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


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The Facts

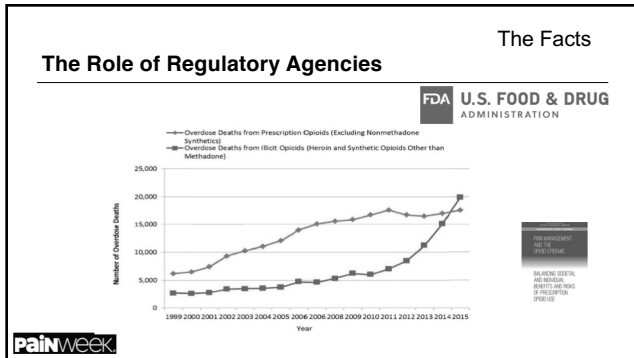
The Role of Regulatory Agencies



- 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 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 19, 2018

Contact: ASH Press Office
302-268-0142
ash@hhs.gov

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

Adm. Brett P. Giroir, MD, assistant secretary for health and senior advisor for opioid policy, today released [guidance](#) for healthcare providers and patients detailing how 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

California Doctors Alarmed As State Links Their Opioid Prescriptions to Deaths

January 18, 2018, 2:02 PM PST

Reported in the Orange County Register

Author: JENNIFER

Photo: KOLED



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The California Death Certificate Project

MEDPAGE TODAY

Pain Management • Opioids

Four Nurse Practitioners Accused in Calif. Death Certificate Project

— One surrendered license; another accused of coming to work "wobbly," "drugged," and "under the influence"

September 11, 2019

"Physicians and nurse practitioners are not the only healthcare professionals under investigation in California for involvement in patients' overdoses. The Osteopathic Medical Board of California is investigating two cases but has not yet filed any accusations. The Medical Board of California has also overseen investigations of 31 physician assistants; all but one of those cases are now closed."



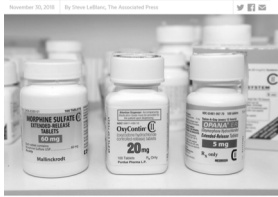
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Massachusetts Sends Warning to Prescribers

"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

Mass. U.S. Attorney Warning Doctors About Prescribing Opioids



Roxicodone, Oxycodone and Oxycodone are displayed for a photograph in Cambridge, California on Jan. 16, 2015. (DNA, Photo/USA)

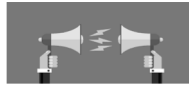


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Conclusions

The Implications

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

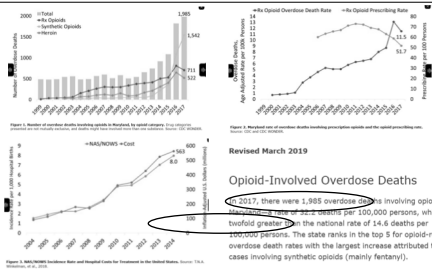


- How does this affect clinical practice?



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You Need to Know...



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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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