Grand Rounds: The Prescription Opioid Epidemic

Tim Gronniger MPP
Shari Ling MD
Lemeneh Tefera MD

Centers for Medicare & Medicaid Services

November 3rd, 2015

CENTERS FOR MEDICARE & MEDICAID SERVICES

Grand Rounds: The Prescription Opioid Epidemic

Tim Gronniger MPP

Deputy Chief of Staff
CMS Administrator

Director of Delivery System Reform

Centers for Medicare & Medicaid Services

November 3rd, 2015

What can you do to help our system achieve the goals of Better Care, Smarter Spending, and Healthier People?

- **Eliminate** patient harm
- **Focus** on better care, smarter spending, and better health for the patient population you serve
- **Engage** in accountable care and other alternative contracts that move away from fee-for-service to model based on achieving better outcomes at lower cost
- **Invest** in the quality infrastructure necessary to improve
- **Focus** on data and performance transparency
- **Research** to inform policy and implementation research
- **Test** new innovations and scale successes rapidly
- **Relentlessly pursue** improved health outcomes

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Grand Rounds: The Prescription Opioid Epidemic

Shari Ling MD

Deputy Chief Medical Officer

Centers for Medicare & Medicaid Services

Center for Clinical Standards and Quality

November 3rd, 2015

The Problem

- Prescription drugs, especially opioid analgesics—a class of prescription drugs used to treat both acute and chronic pain such as hydrocodone, oxycodone, codeine, morphine, and methadone, have increasingly been implicated in drug overdose deaths over the last decade.
- Deaths related to heroin have also sharply increased since 2010, with a 39 percent increase between 2012 and 2013. Among drug overdose deaths in 2013, approximately 37 percent involved prescription opioids.
- Given these alarming trends, it is time for a sustainable response to prevent and treat opioid use disorders

News

FOR IMMEDIATE RELEASE
March 26, 2015

Contact: HHS Press Office
202-690-6343

HHS takes strong steps to address opioid-drug related overdose, death and dependence

Evidence-based, bipartisan efforts focus on prescribing practices and treatment to reduce prescription opioid and heroin use disorders

U.S. Health and Human Services Secretary Sylvia M. Burwell today announced a targeted initiative aimed at reducing prescription opioid and heroin related overdose, death and dependence. Deaths from drug overdose have risen steadily over the past two decades and currently outnumber deaths from car accidents in the United States. The President's FY 2016 budget includes critical investments to intensify efforts to reduce opioid misuse and abuse, including $133 million in new funding to address this critical issue.

The Secretary's efforts focus on three priority areas that tackle the opioid crisis, significantly impacting those struggling with substance use disorders and helping save lives.

1. **Providing training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions** and address the over-prescribing of opioids.
2. **Increasing use of naloxone**, as well as continuing to support the development and distribution of the life-saving drug, to help reduce the number of deaths associated with prescription opioid and heroin overdose.
3. **Expanding the use of Medication-Assisted Treatment (MAT)**, a comprehensive way to address the needs of individuals that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

Addressing the opioid crisis is a top priority for the department and the Secretary is committed to bipartisan solutions and evidence-informed interventions to turn the tide against opioid drug-related overdose and misuse.

"Opioid drug abuse is a devastating epidemic facing our nation. I have seen firsthand, in my home state of West

Grand Rounds: The Prescription Opioid Epidemic

Lemeneh Tefera MD

Medical Officer

Quality Measurement and Value-Based Incentives Group

Centers for Medicare & Medicaid Services

November 3rd, 2015

CMS Part D Opioid Policy in Action: Overutilization Monitoring System (OMS)

- **January 2013:** Policy focused on medication safety AND maintaining appropriate medication access
- **July 2013:** CMS provides sponsors quarterly reports.
  - **Sponsors** required to review each case & provide outcome to CMS
- **February 2014:** CMS enhanced the Medicare Advantage Prescription System (MARx) which identifies high opioid utilizers
  - **MARx** system alerts a new sponsor when a MARx-flagged beneficiary enrolls in a new Part D plan

Overutilization Monitoring System (OMS): 2011 through 2014 - http://go.cms.gov/1MCLWHO

Year	Total Part D Enrollees	Total Part D Enrollees Utilizing Opioids	% Part D Enrollees Utilizing Opioids	Beneficiaries Identified as Potential Opioid Overutilizers	Difference in Overutilizers 2013-2014	Change in Absolute Number Part D Utilizing Opioids	Difference in Absolute Number 2013-2014
2011	31,483,841	10,049,914	31.9%	29,404		-	-
2013	37,842,632	11,794,908	31.2%	25,347	- 4,057	+1,744,994*	-
2014	39,982,962	12,308,735	30.8%	21,838	- 3,509	+513,827	-1,231,167

26% decrease

70% decrease

- From 2011 thru 2014, there was a 26% decrease or 7,500 fewer Medicare Part D beneficiaries identified by the OMS as potential opioid overutilizers
- From 2013 thru 2014, the total number of enrollees utilizing opioids increased at a slower rate
- Please see today's press release for more details http://go.cms.gov/1MCLWHO

CMS Part D Provider Enrollment Policy:

- **June 2015** CMS requires Part D prescribers to enroll in Medicare or record of opting out of Medicare
- Projected to save $1.62 billion dollars
- Helps combat fraud and abuse
- Empowers CMS to revoke Medicare privileges for abusive prescribing practice & patterns

CMS Policy in Action: QIN-QIOs

- Quality Innovation Network & Quality Improvement Organizations

  (QIN-QIOs) focused on patient safety
- Focused on opioid medication safety and decreasing Adverse Drug Events related to opioids
- Encouraging care coordination and communication
- To learn more, interested providers can contact their local QIN-QIO

  http://qioprogram.org/about/why-cms-has-qios

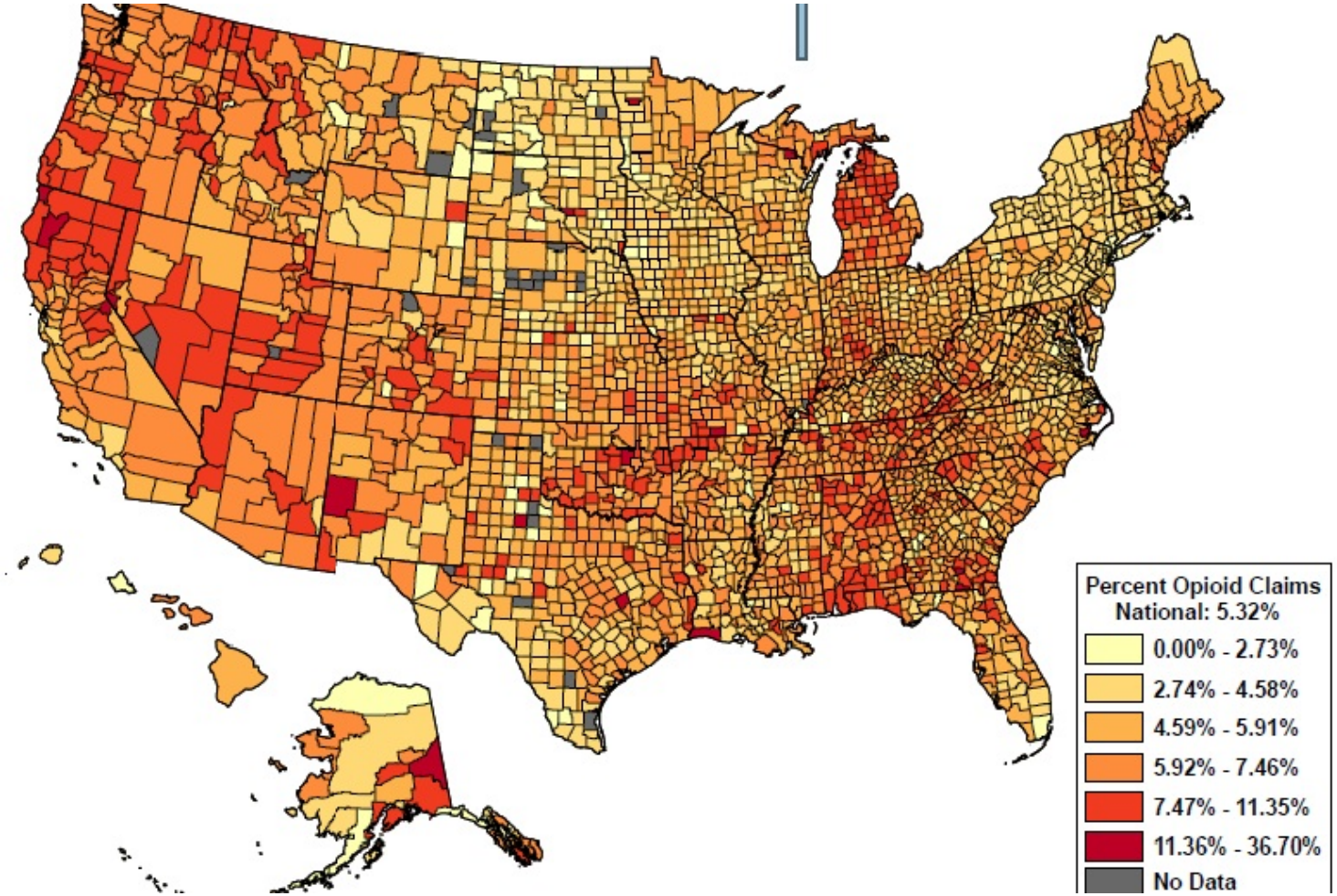
CMS Distributing Information:

- April 30, 2015 - public release of new datasets detailing prescribing information from 2013

- Prescription Drug Events Standard Analytic Files
  - Final action claims submitted
  - Sources: Medicare Advantage Prescription Drug (MA-PD) plans and Stand alone Prescription Drug Plans (PDPs)
  - Provider identity (NPI)
  - Total # of prescriptions dispenses (original and refills)
  - Total drug cost (amounts paid by Part D plan, Medicare beneficiary, other subsidies and other 3rd-party payers)

CMS Policy in Action: Nov 2015
New Interactive Part D Opioid Heat Map

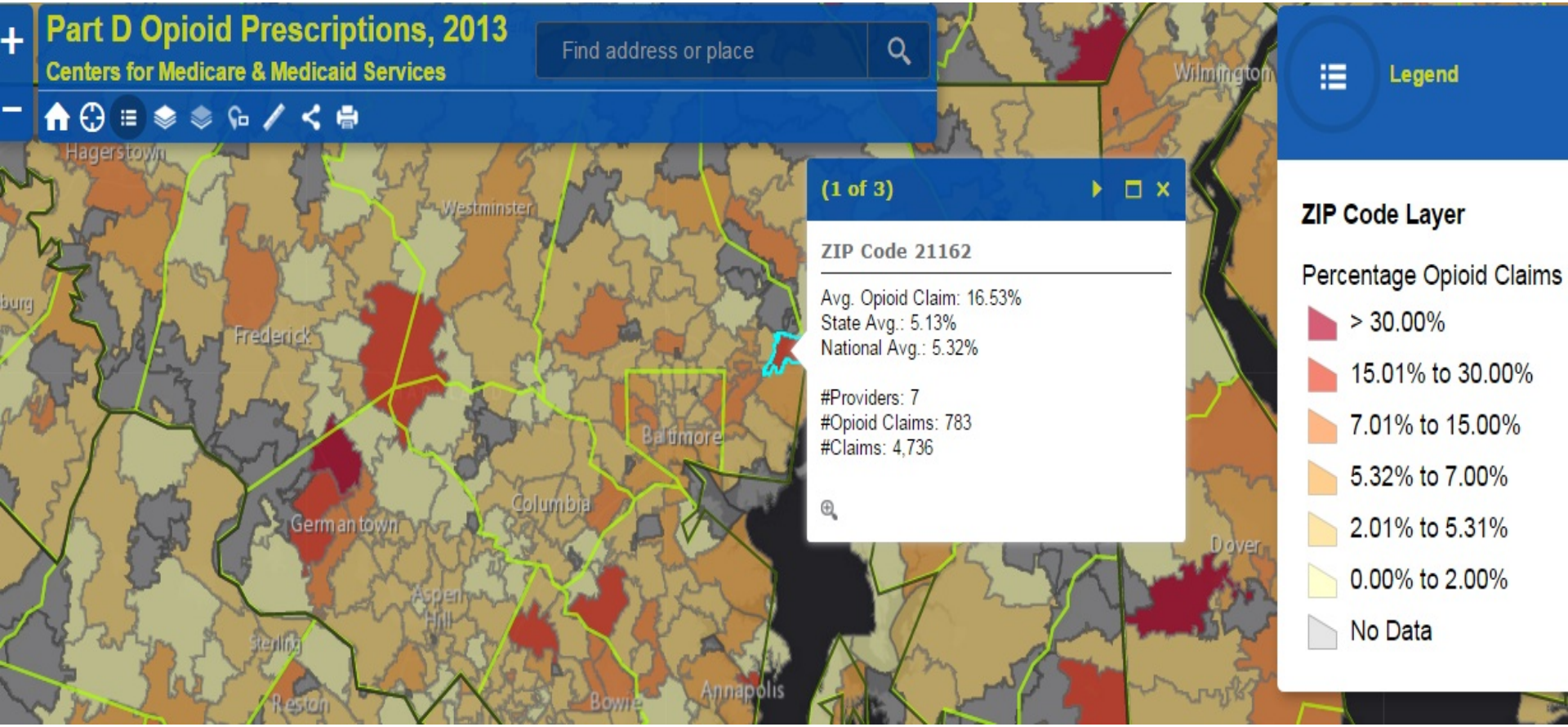
http://go.cms.gov/opioidheatmap



CMS Policy in Action:

Interactive Part D Opioid Prescriptions Heat Map (2013)

http://go.cms.gov/opioidheatmap



Grand Rounds Speakers:

Knox Todd, M.D.

Professor and Chair, Department of Emergency Medicine

The University of Texas MD Anderson Cancer Center, Houston, TX

Caleb Alexander, M.D.

Associate Professor of Epidemiology and Medicine

Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Andrew Kolodny, M.D.

Chief Medical Officer

Phoenix House, New York, NY

Grant Baldwin, Ph.D.

Director of the Division of Unintentional Injury Prevention

Centers for Disease Control and Prevention, Atlanta, GA

The Honorable Richard Frank, Ph.D.

Assistant Secretary for Planning and Evaluation

Department of Health and Human Services, Washington, D.C.

Pain, Opioids and the Emergency Department-

Knox Todd MD MPH
Professor and Chair
Department of Emergency Medicine
The University of Texas MD Anderson Cancer Center

ED Pain Management Trends

- High pain prevalence
  - Two-thirds of visits
- Past emphasis on undertreatment
  - The Joint Commission, patient satisfaction
- Prescription opioid abuse
  - US epidemic
- Room for improvement
  - Risk assessment, PDMP, storage and disposal
- Opportunities?
  - Non-opioid analgesics, naloxone for high risk patients, buprenorphine/naloxone induction

Cordell WH, Keene KK, Giles BK, et al. The high prevalence of pain in emergency medical care. *Am J Emerg Med*. 2002;20:165-169.
Todd KH, Ducharme J, Choiniere M, et al. Pain in the emergency department: results of the Pain and Emergency Medicine Initiative (PEMI) multicenter study. *J Pain*. 2007;8:460-466.

Emergency Physicians Must Balance

- Pain relief
  - primary responsibility of emergency physicians
- Harm reduction
  - address the prescription opioid misuse epidemic

ED Opioid Prescribing

- In 2012, among 289 million opioid prescriptions, Emergency Medicine accounted for 4%

Levy B, Paulozzi L, Mack KA, Jones CM. Trends in Opioid Analgesic–Prescribing Rates by Specialty, U.S., 2007–2012.
American Journal of Preventive Medicine. 2015;49(3):409-13.

ED Opioid Prescribing

- 19 EDs surveyed
- 17% of patients received prescription at discharge
- 15 pills per prescription

Hoppe JA, Nelson LS, Perrone J, et al. Opioid Prescribing in a Cross Section of US Emergency Departments. Ann Emerg Med. 2015;66:253-9.

Opioid Prescribing Rates 2007-2012

- PM&R +12%
  Pain Medicine +9%
- FP/GP/IM +5 to 6%
- ----------
- Surgery -4%
- Dentistry -6%
  Emergency Medicine -9%

Hoppe JA, Nelson LS, Perrone J, et al. Opioid Prescribing in a Cross Section of US Emergency Departments. Ann Emerg Med. 2015;66:253-9.

Risky Pills vs Risky Patients

Risky Pills

- Departmental policies limiting prescribing
- Waiting room signage
  - Concern about discouraging treatment
  - Potential EMTALA violation?
- Ban opioid prescribing
  - Not very practical

Risky Patients

- ID patients at higher risk for misuse
- Utilize risk assessment tools
- Incorporate PDMP data
- Countermeasures to limit harm

ED Best Practices and Targets

- Best practices
  - Appropriate prescribing
  - Individualized risk assessment
  - Storage and disposal
- Targets
  - Specialty societies (ACEP, ABEM)
  - EMR industry
  - Practice management industry
    - Employs significant proportion of practicing emergency physicians

ED Opportunities

- Increased use of non-opioid therapies
  - Local therapies, regional anesthesia, gabapentinoids, intravenous therapies (NSAIDs, acetaminophen, ketamine, lidocaine)
- Naloxone prescriptions for high-risk patients
- ED-initiated buprenorphine/naloxone treatment for opioid dependence

Dwyer K, Walley AY, Langlois BK, et al. Opioid education and nasal naloxone rescue kits in the emergency department. *West J Emerg Med*. 2015;16:381-4.
D'Onofrio G, O'Connor PG, Pantalon MV, Chawarski MC, Busch SH, Owens PH, et al. Emergency department-initiated buprenorphine/naloxone treatment for opioid dependence: a randomized clinical trial. *JAMA*. 2015;313:1636-44.

www.EMpainLine.org

To get more information on ED pain management

http://www.empainline.org/

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SCHOOL of PUBLIC HEALTH

G. Caleb Alexander, MD, MS
Associate Professor of Epidemiology and Medicine
Johns Hopkins Bloomberg School of Public Health,
Baltimore, MD

November 3, 2015

Protecting Health, Saving Lives—*Millions at a Time*

What is the top selling drug in the U.S.?

A. Aripiprazole (Abilify®)

B. Sildafenil (Viagra®)

C. Hydrocodone/APAP (Vicodin®)

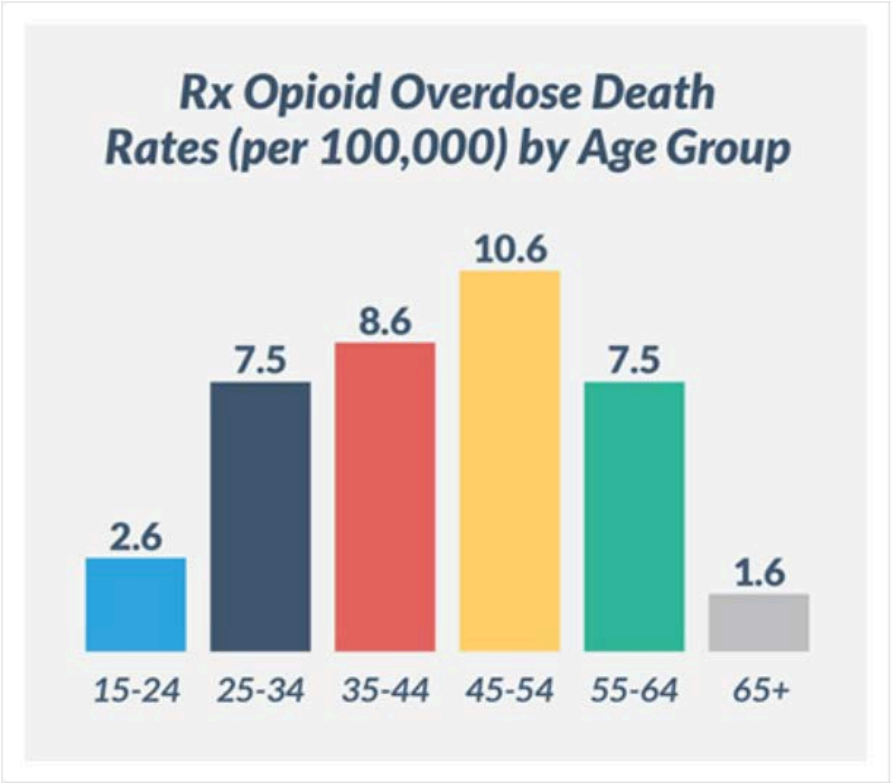
D. Atorvastatin (Lipitor®)

E. Esomeprazole (Nexium®)

F. Etanercept (Enbrel®)

Prescription Opioid Overdose Death Rates (per 100,000) by Age Group-

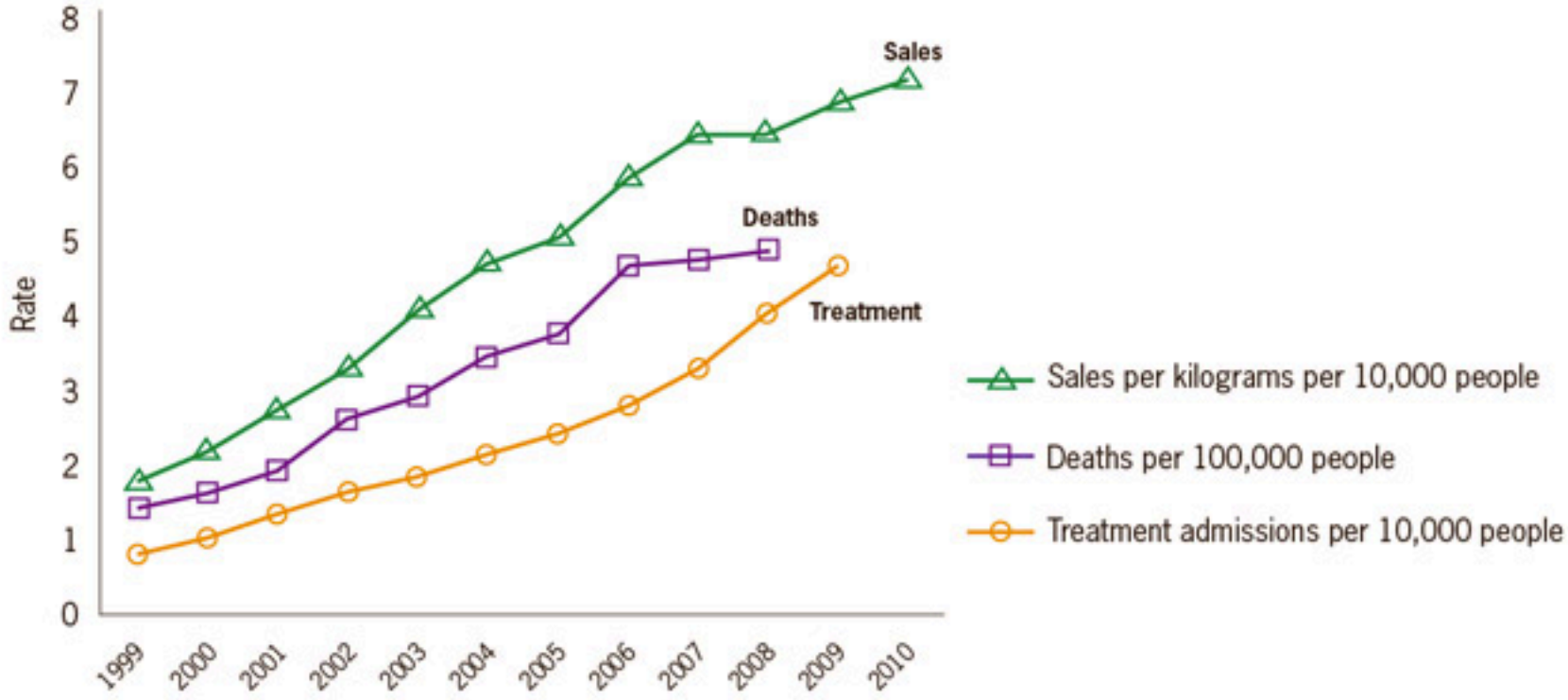
http://www.cdc.gov/drugoverdose/data/overdose.html



http://www.cdc.gov/drugoverdose/data/overdose.html

Rates of Prescription Opioid Sales, Death and Substance Abuse Treatment Admissions, 1999-2010.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.html



SOURCES: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009

CDC. MMWR. 2011.

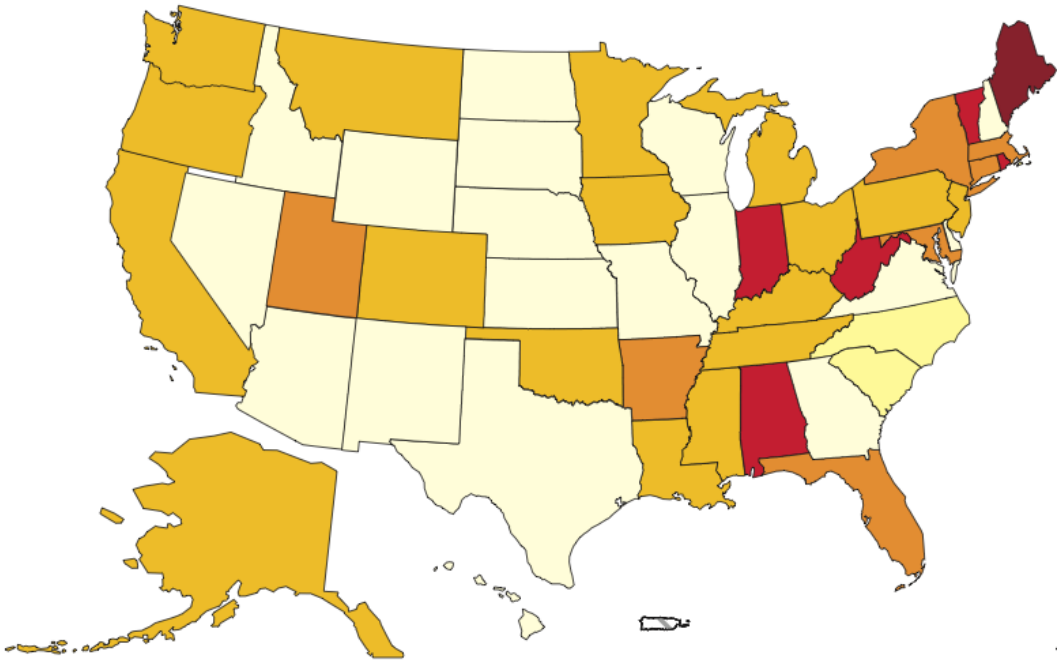
The Opioid Addiction Epidemic: *How it Happened*

Andrew Kolodny, M.D.

Chief Medical Officer, Phoenix House Foundation Inc.
Executive Director, Physicians for Responsible Opioid Prescribing
Senior Scientist, Heller School for Social Policy and Management, Brandeis University
Research Professor, Global Institute of Public Health, New York University

Primary non-heroin opiates/synthetics admission rates, by State- 1999 (per 100,000 population aged 12 and over)

http://www.samhsa.gov/data/sites/default/files/2010_Treatment_Episode_Data_Set_State/2010_Treatment_Episode_Data_Set_State_Tables.html



1999

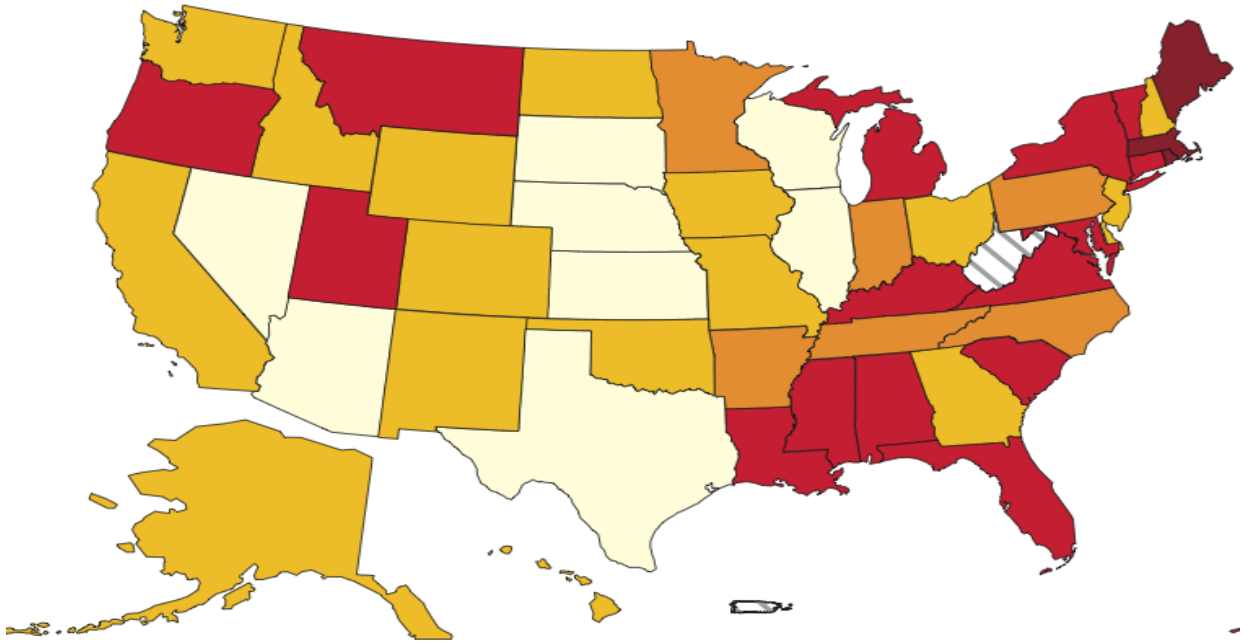
(range 1 - 50)

< 8	15 - 18	45 or more
8 - 14	19 - 44	Incomplete data

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

Primary non-heroin opiates/synthetics admission rates, by State- 2001

http://www.samhsa.gov/data/sites/default/files/2010_Treatment_Episode_Data_Set_State/2010_Treatment_Episode_Data_Set_State_Tables.html



2001

(range 1 – 71)

< 8

8 - 14

15 - 18

19 - 44

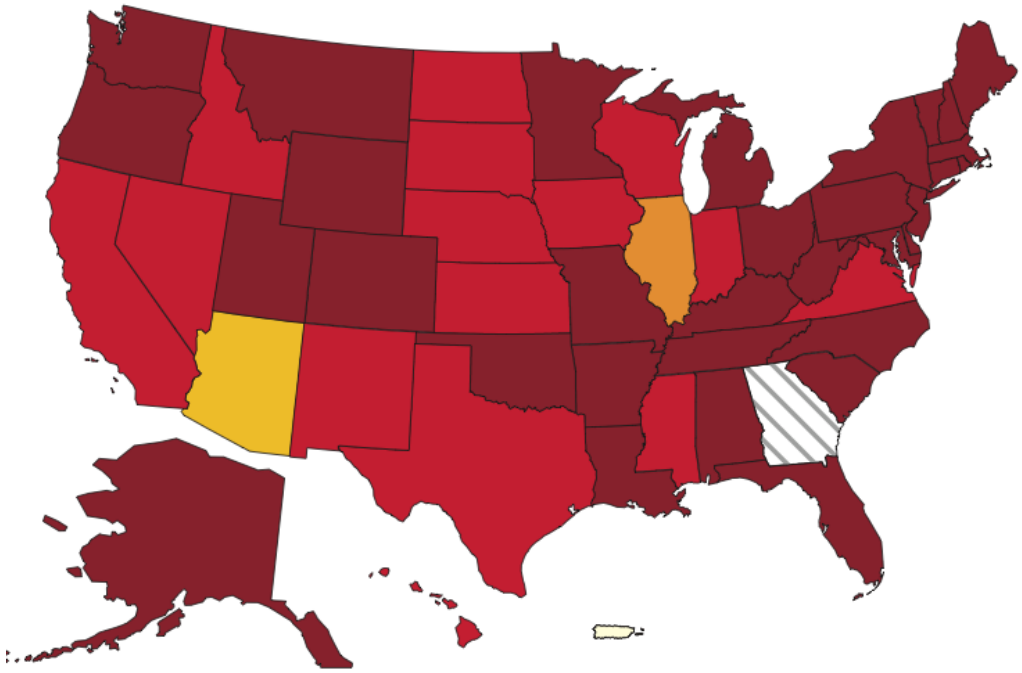
45 or more

Incomplete data

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

Primary non-heroin opiates/synthetics admission rates, by State- 2009

http://www.samhsa.gov/data/sites/default/files/2010_Treatment_Episode_Data_Set_State/2010_Treatment_Episode_Data_Set_State_Tables.html



2009

(range 1 – 379)

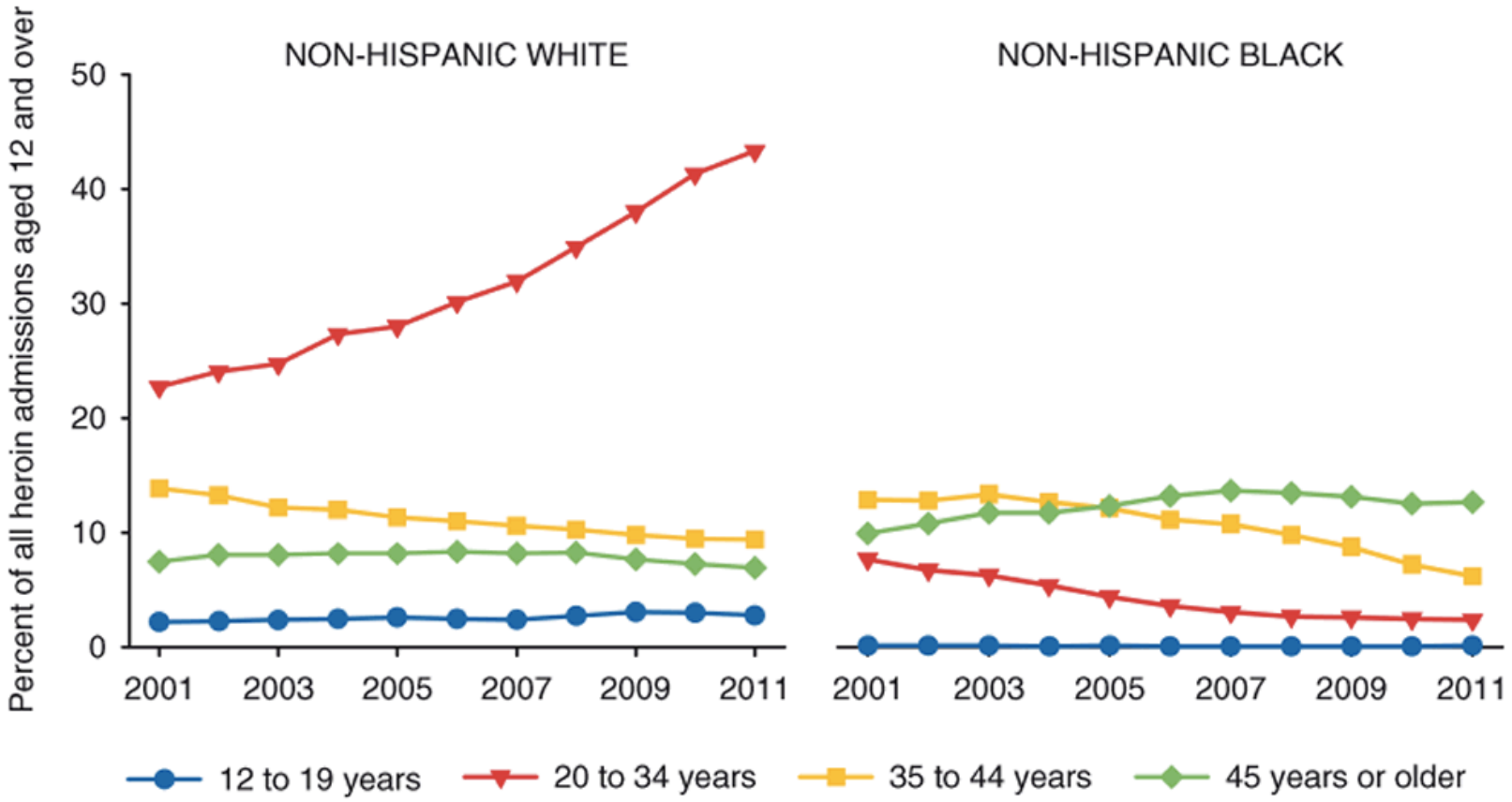
< 8	15 - 18	45 or more
8 - 14	19 - 44	Incomplete data

SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.

Heroin admissions, by age group & race/ethnicity: 2001- 2011

http://wwwdasis.samhsa.gov/dasis2/TEDS%20Pubs/2010_teds_rpt_natl.pdf

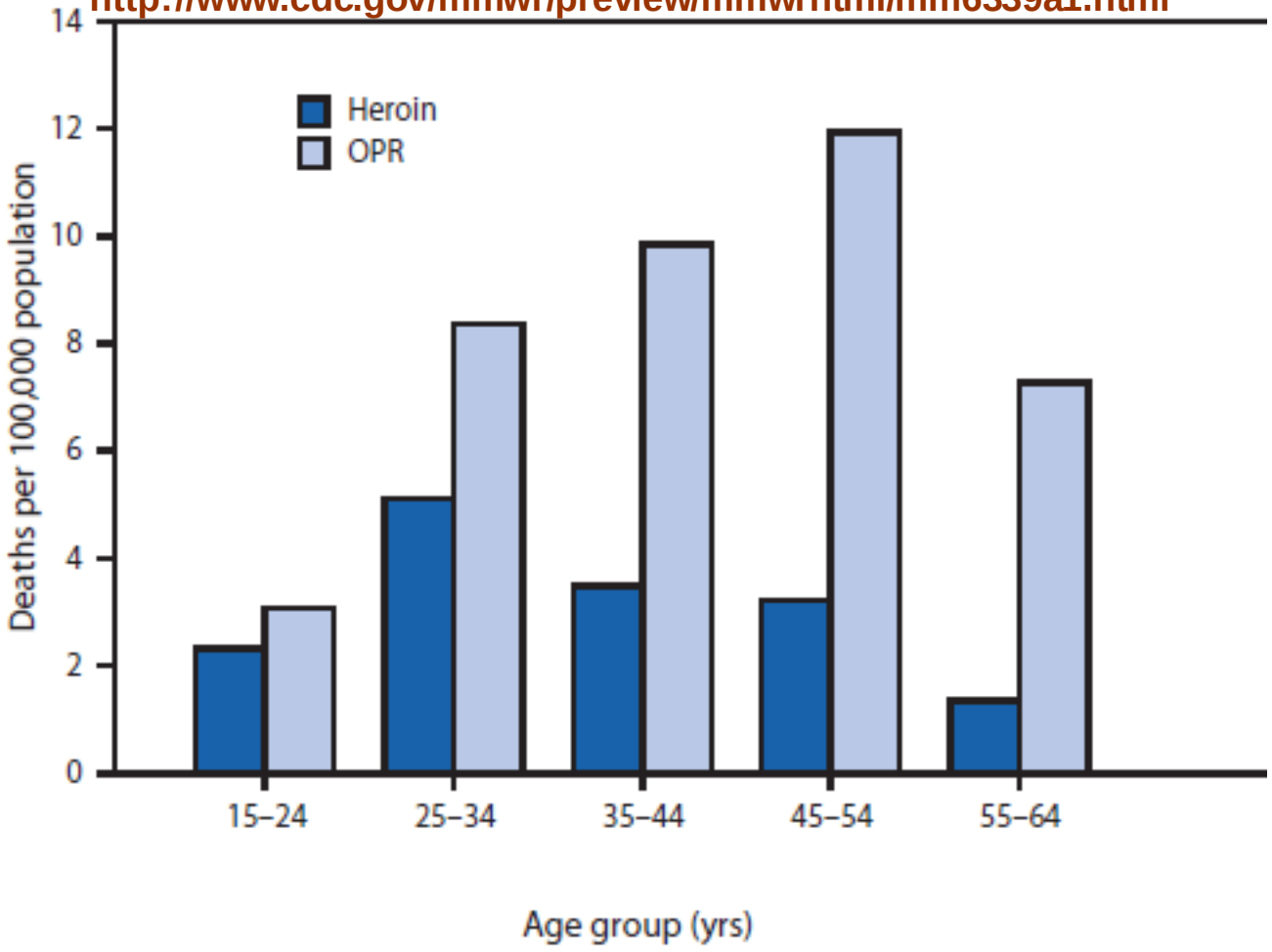
Figure 21. Heroin admissions aged 12 and older, by age group and race/ethnicity: 2001-2011



SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 10.10.11.

Death rates from overdoses of heroin or prescription opioid pain relievers (OPRs), by age group

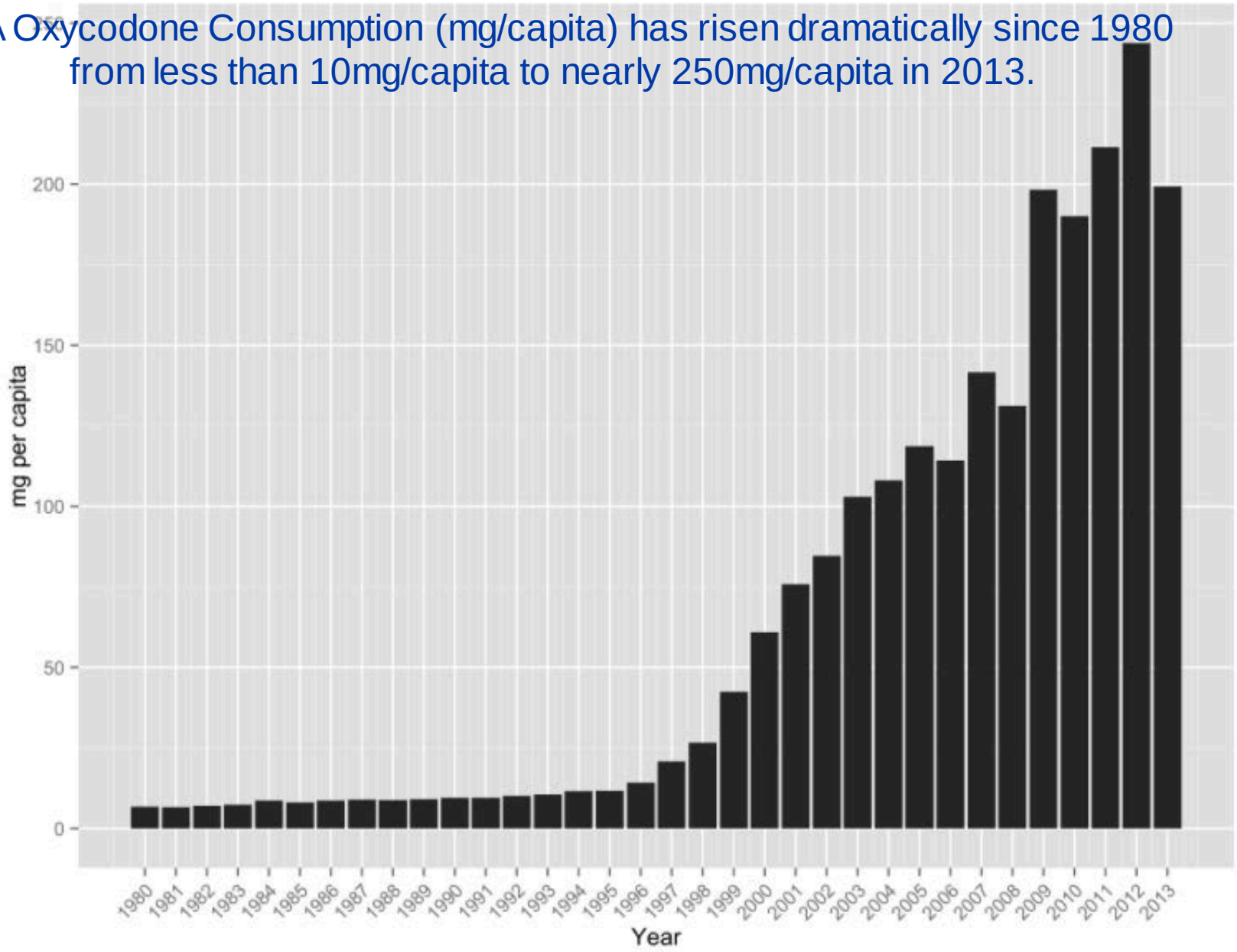
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6339a1.html



SOURCE: CDC. *Increases in Heroin Overdose Deaths — 28 States, 2010 to 2012* MMWR. 2014, 63:849-854

United States of America
Oxycodone Consumption (mg/capita) 1980–2013

USA Oxycodone Consumption (mg/capita) has risen dramatically since 1980 from less than 10mg/capita to nearly 250mg/capita in 2013.

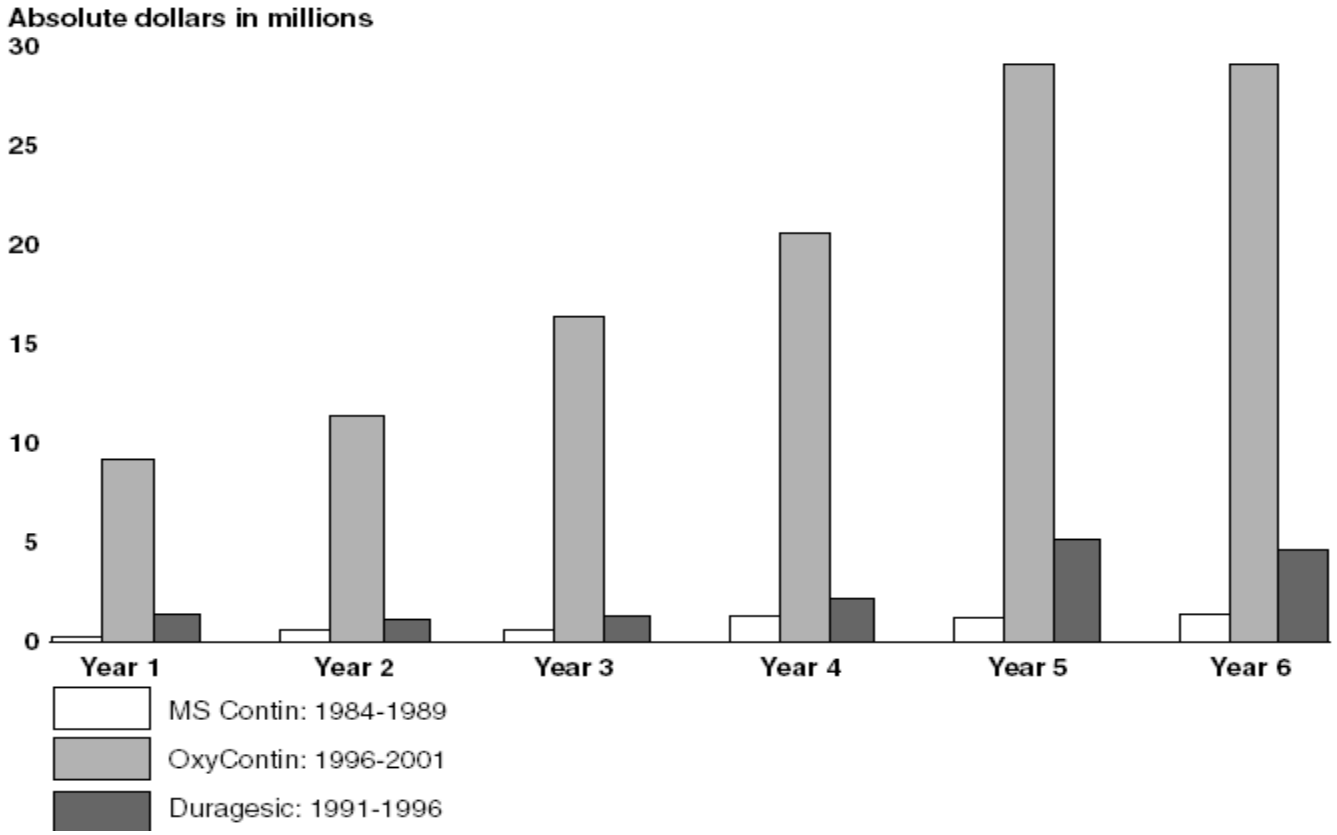


Sources: International Narcotics Control Board; World Health Organization population data

Dollars Spent Marketing OxyContin (1996-2001)

http://www.gao.gov/new.items/d04110.pdf

Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales



Source: United States GAO Report: OxyContin Abuse and Diversion and Efforts to Address the Problem. 2003

Industry-funded "educational" messages

- Physicians are needlessly allowing patients to suffer because of "opiophobia."
- Opioid addiction is rare in pain patients.
- Opioids can be easily discontinued.
- Opioids are safe and effective for chronic pain.

Industry-funded organizations campaigned for greater use of opioids

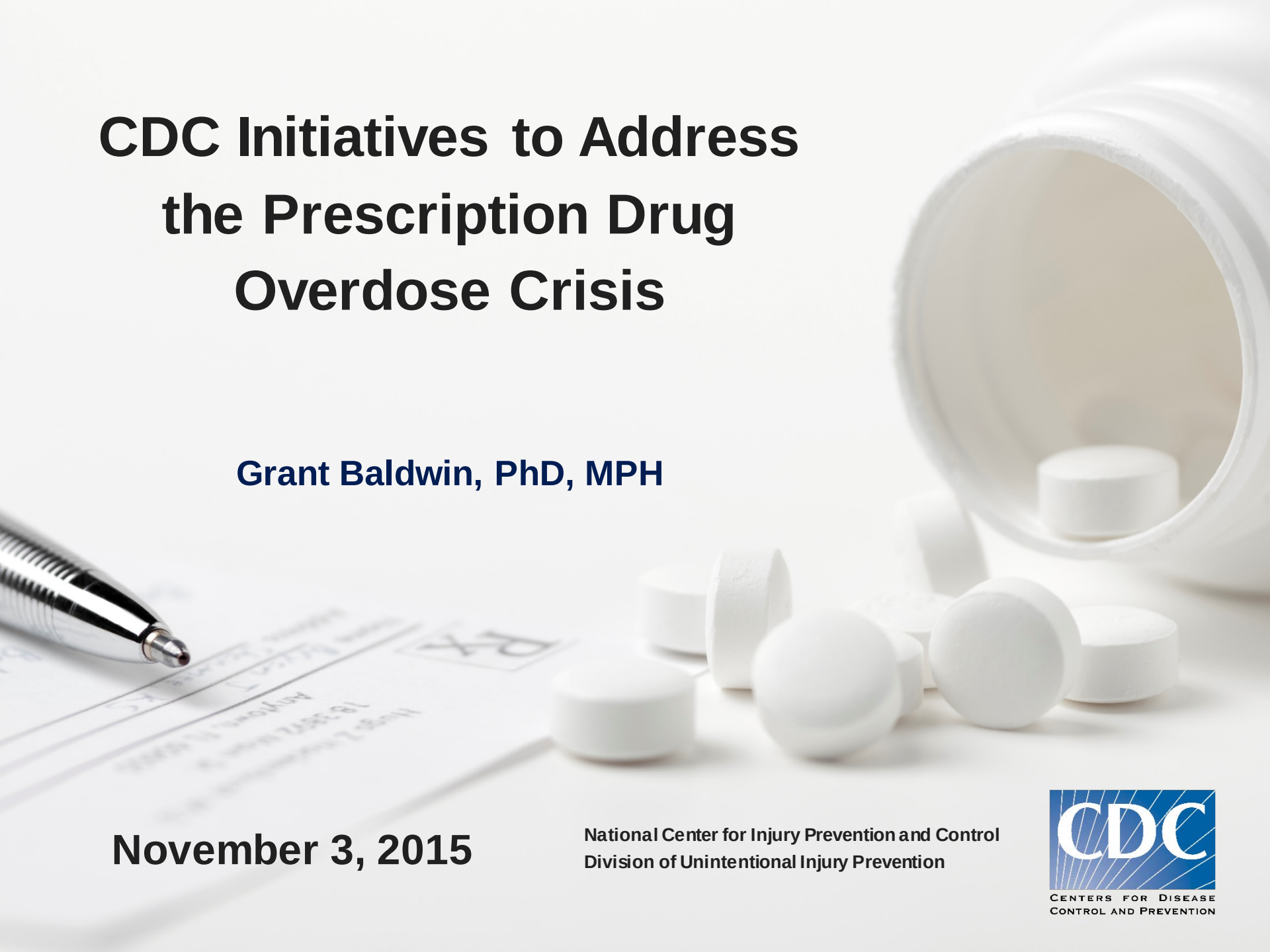
- Pain Patient Groups
- Professional Societies
- The Joint Commission
- The Federation of State Medical Boards

How to end the epidemic:

- Prevent new cases of opioid addiction with more cautious prescribing
- Expand access to opioid addiction treatment- especially buprenorphine

CDC Initiatives to Address the Prescription Drug Overdose Crisis

Grant Baldwin, PhD, MPH



November 3, 2015

National Center for Injury Prevention and Control
Division of Unintentional Injury Prevention

CDC
Centers for Disease Control and Prevention

Three Pillars of CDC's Work

- **Improve data** quality and track trends
- **Strengthen state efforts** by scaling up effective public health interventions
- **Supply healthcare providers with resources** to improve patient safety




Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Surveillance Summaries / Vol. 64 / No. 9
October 16, 2015
Controlled Substance Prescribing Patterns — Eight States, 2013
Prescription Behavioral Surveillance System
BJA
Bureau of Justice Assistance
U.S. Department of Justice
FDA
CDC
Centers for Disease Control and Prevention
Brandeis

Improving the quality & timeliness of opioid overdose surveillance

WHAT WE'RE DOING

- Generate near real-time surveillance of emergency department visits related to drug overdoses
- Improve surveillance of EMS transports related to drug overdoses

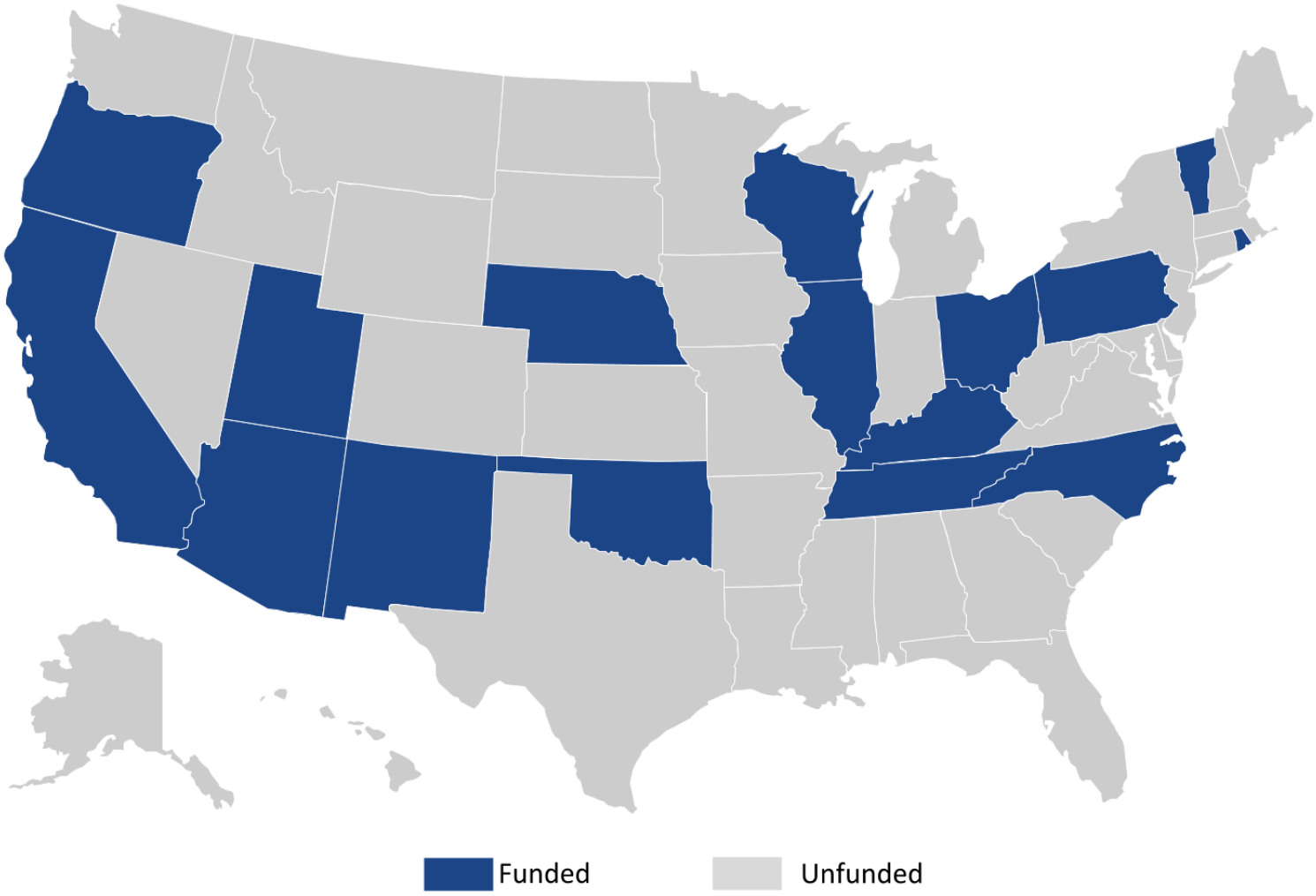
WHY WE'RE DOING IT

- An early warning of large increases or decreases of drug overdoses to better target prevention efforts
- Better understand changing demographic patterns of drug overdoses

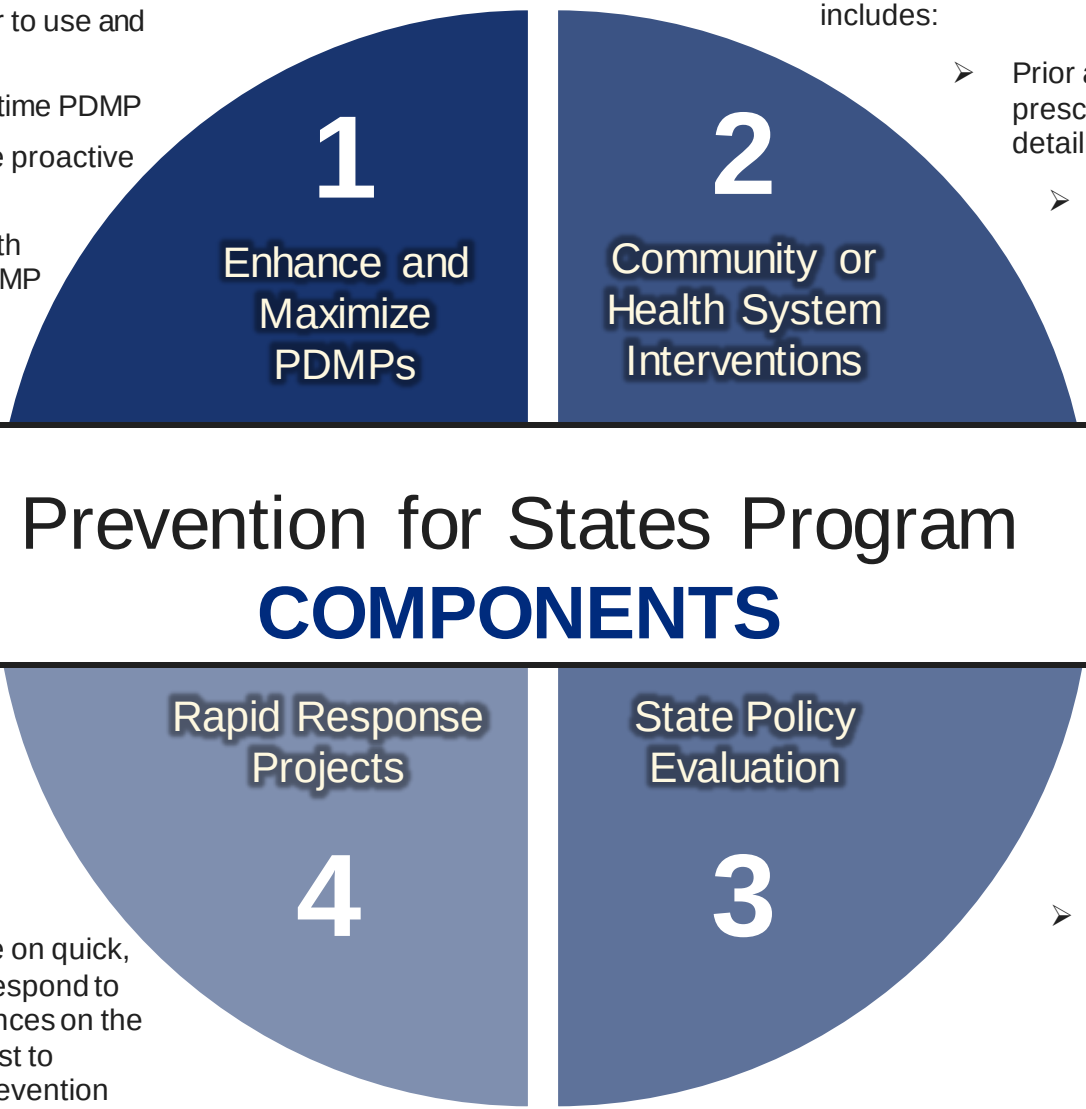
Prevention for States (PfS)

- Provides states guidance and resources to prevent prescription drug overdoses by addressing problematic opioid prescribing
- Builds on the success of the Prevention Boost – Funding Opportunity
- 16 states funded with average award ranging from $750K to $1M
- Funding to states with high burden and readiness to act
- Focus on high impact, data driven activities and give states flexibility to tailor their work

Prevention for States (PfS)
Funded Programs



Prevention for States Program
COMPONENTS



- Move toward universal PDMP registration and use
- Make PDMPs easier to use and access
- Move toward a real-time PDMP
- Expand and improve proactive reporting
- Conduct public health surveillance with PDMP

- Implement or improve opioid prescribing interventions for insurers, health systems, or pharmacy benefit managers. This includes:
  - Prior authorization, prescribing rules, academic detailing, CCPs, PRRs,
  - Enhance adoption of opioid prescribing guidelines

- Allow states to move on quick, flexible projects to respond to changing circumstances on the ground and move fast to capitalize on new prevention opportunities.

- Build evidence base for policy prevention strategies that work like pain clinic laws and regulations, or naloxone access laws

Prevention for States METRICS

Short-term:

- **Reduced barriers to PDMP registration and use**
- **Shorter PDMP data collection interval**
- **Implementation of opioid management programs**

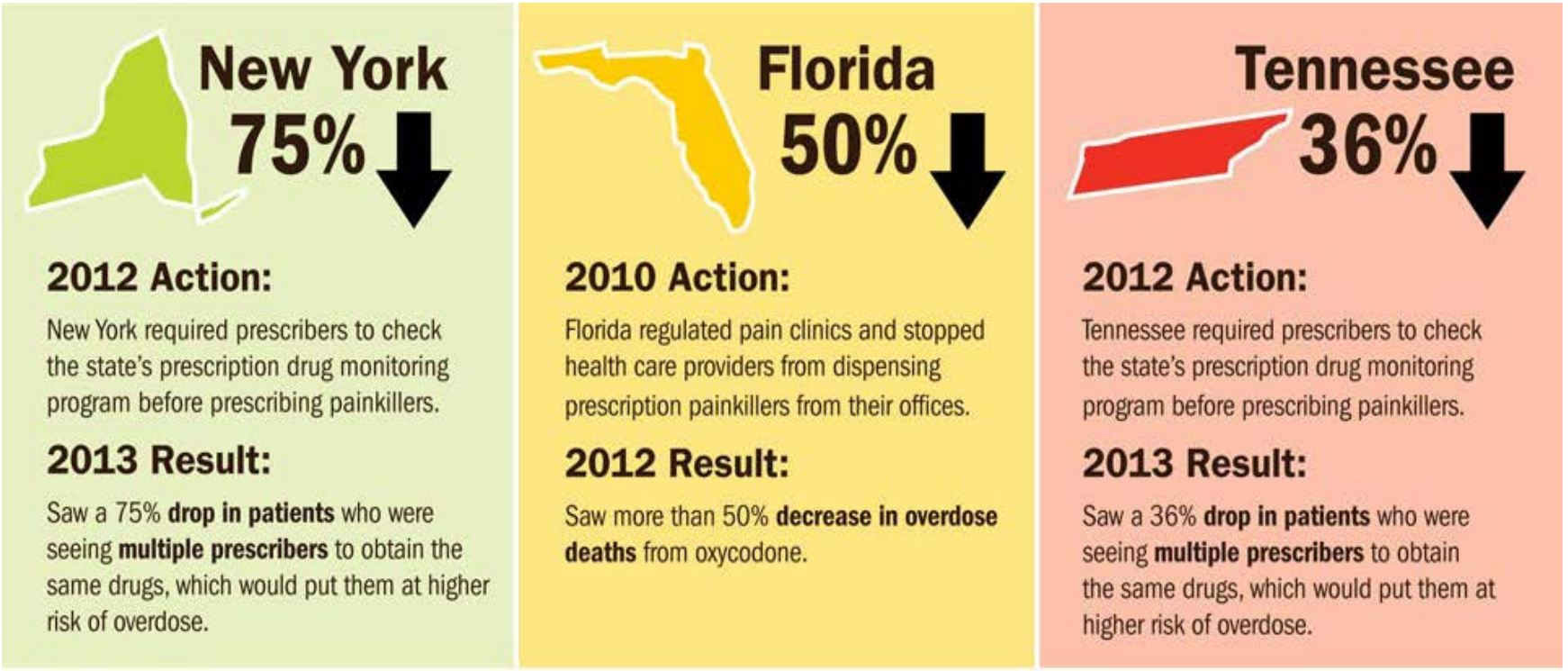
Intermediate-term:

- **Increased use of PDMPs**
- **Decreased rate of high-dose opioid prescribing and problematic drug combinations**
- **Decreased rate of multiple providers for prescriptions**

Long-term:

- **Decreased drug overdose death rate - including Rx opioids and heroin**

State-based interventions are improving outcomes



SOURCES: NY, TN: PDMP Center of Excellence at Brandeis University, 2014. FL: Vital Signs Morbidity and Mortality Weekly Report, July 1, 2014.

CENTERS FOR DISEASE CONTROL AND PREVENTION

Opioid Prescribing Guidelines for Chronic Pain

Outside of Active Cancer, Palliative, & End-of-life Care

PRIMARY CARE

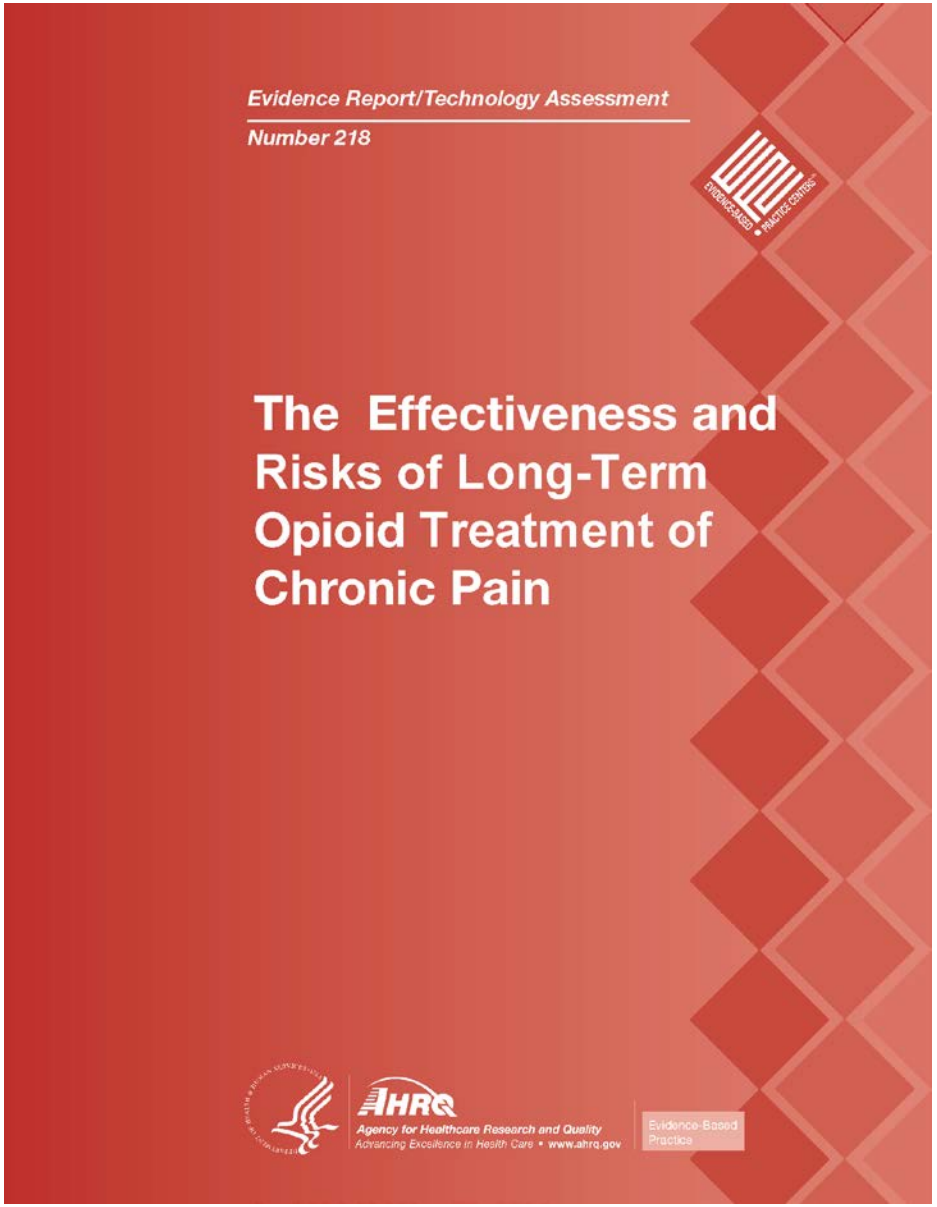
Current Guideline Landscape

- **Gaps**
  - Incorporate new evidence
  - Use rigorous processes
  - Avoid conflicts of interest
  - Focus on primary care
- **CDC Common Data Elements**

Leveraging AHRQ

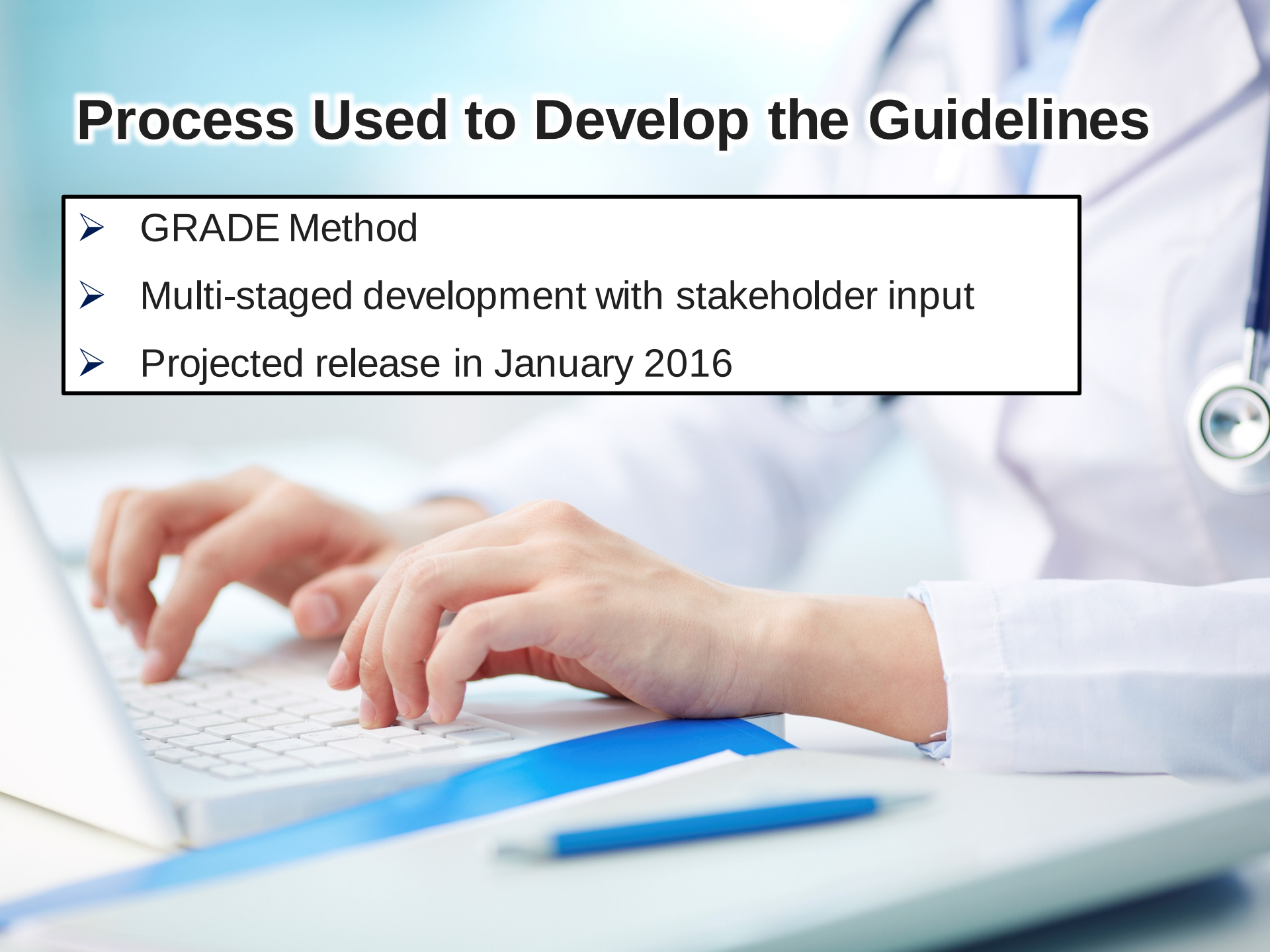
Systematic Review

Sept 2014



Process Used to Develop the Guidelines

- GRADE Method
- Multi-staged development with stakeholder input
- Projected release in January 2016



Clinical Practices Addressed in the Guidelines

- Determining when to initiate or continue opioids for chronic pain
- Opioid selection, dosage, duration, follow-up, and discontinuation
- Assessing risk and addressing harms of opioid use

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

Special thanks to Kristen Sanderson for her help preparing this presentation

Secretary's Opioid Initiative Overview

Richard G. Frank

Office of the Assistant Secretary for Planning and Evaluation
US Department of Health and Human Services

November 3, 2015

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Assistant Secretary for Planning and Evaluation

Challenge by the Numbers

- Drug overdose death rates have increased five-fold since 1980
- Among drug overdose deaths, approx. 37% (16,235) involved prescription opioids
- Chronic non-medical use of prescription opioids (200 or more days) has increased 75% since 2002
- Deaths from heroin overdoses increased by 39% from 2012 to 2013 and are approx. 19% (8,257) of all drug overdose related mortality

Initiative Goals

1) Decrease opioid overdoses and overdose-related mortality

2) Decrease prevalence of opioid dependence

Three Priority Areas

PRESCRIPTION OPIOIDS

1) **Opioid prescribing practices** to reduce opioid use disorders and overdose
   - Improve clinical decision making to reduce inappropriate prescribing
   - Enhance prescription monitoring and health IT to support appropriate pain management
   - Support data sharing to facilitate appropriate prescribing

HEROIN AND PRESCRIPTION OPIOIDS

2) **Naloxone** development, access, and distribution
   - Accelerate development and availability of new naloxone formulations and products
   - Identify and disseminate best practice naloxone delivery models and strategies
   - Expand utilization of naloxone

3) **Medication assisted treatment (MAT)** to reduce opioid use disorders and overdose
   - Support research that informs effective use and dissemination of MAT and accelerates development of new treatment medications
   - Increase access to clinically effective MAT services

Increasing Access to MAT

Policy Balance:

- Ensuring quality of care
- Minimizing the risk of diversion
- Meaningfully expanding capacity for MAT

Data Puzzle:

- A few specialists hit the limit but most waivered physicians do not
- Roughly 10-20% of patients treated with buprenorphine-based MAT receive counseling and testing

Grand Rounds Panel Discussion:

The Honorable Richard Frank, PhD

Assistant Secretary for Planning and Evaluation

Department of Health and Human Services, Washington, D.C.

Grant Baldwin, PhD

Director of the Division of Unintentional Injury Prevention , CDC , Atlanta, GA

Shari Ling, MD

Deputy Chief Medical Officer, CMS

Lemeneh Tefera, MD

Medical Officer, CMS

Knox Todd, MD

Professor and Chair, Department of Emergency Medicine

The University of Texas MD Anderson Cancer Center, Houston, TX

Caleb Alexander, MD

Associate Professor of Epidemiology and Medicine

Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Andrew Kolodny, MD

Chief Medical Officer, Phoenix House, New York, NY

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Concluding Remarks: The Prescription Opioid Epidemic

Centers for Medicare & Medicaid Services

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