Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Crisis

October 13, 2021 | 1:00-5:00 p.m. ET

October 14, 2021 | 1:00-4:05 p.m. ET

FDA U.S. FOOD & DRUG ADMINISTRATION | Duke MARGOLIS CENTER for Health Policy

Welcome & Introduction | Day 1

Mark McClellan, MD, PhD

Director, Duke-Margolis Center for Health Policy

Agenda: Day 1

Presentations:

- Opening Remarks from FDA
- The Current Landscape of the Evolving Opioid and Addiction Crisis
- Selected FDA Actions in Response to the Opioid Crisis
- Prescription Opioid Utilization Patterns in the U.S.

Panel Discussions:

- Assessing the Landscape of Federal, State, and Health System Prescriber Education Requirements
- Examining the Potential Role of Prescriber Education in Helping to Address the Current Opioid Crisis

Agenda: Day 2

Panel Discussions:

- Considerations for the Future Role of Federally Mandated Prescriber Education in Alleviating the Current Opioid Crisis
- Next Steps

Statement of Independence

The Robert J. Margolis, MD, Center for Health Policy is part of Duke University, and as such it honors the tradition of academic independence on the part of its faculty and scholars. Neither Duke nor the Margolis Center take partisan positions, but the individual members are free to speak their minds and express their opinions regarding important issues.

For more details on relevant institutional policies, please refer to the Duke Faculty Handbook, including the Code of Conduct and other policies and procedures. In addition, regarding positions on legislation and advocacy, Duke University policies are available at http://publicaffairs.duke.edu/government.

Virtual Meeting Reminders

- Attendees are encouraged to contribute throughout the meeting with questions in the Zoom Q&A function.
- Panelists should go on video during their panel discussion
- Presenters should provide a verbal prompt when they'd like to advance the slides

Opening Remarks from FDA

Patrizia Cavazzoni

U.S. Food and Drug Administration

The Current Landscape of the Evolving Opioid and Addiction Crisis

Wilson Compton

National Institute on Drug Abuse

The U.S. Overdose Crisis

Wilson M. Compton, M.D., MPE
Deputy Director, NIDA

National Institute on Drug Abuse

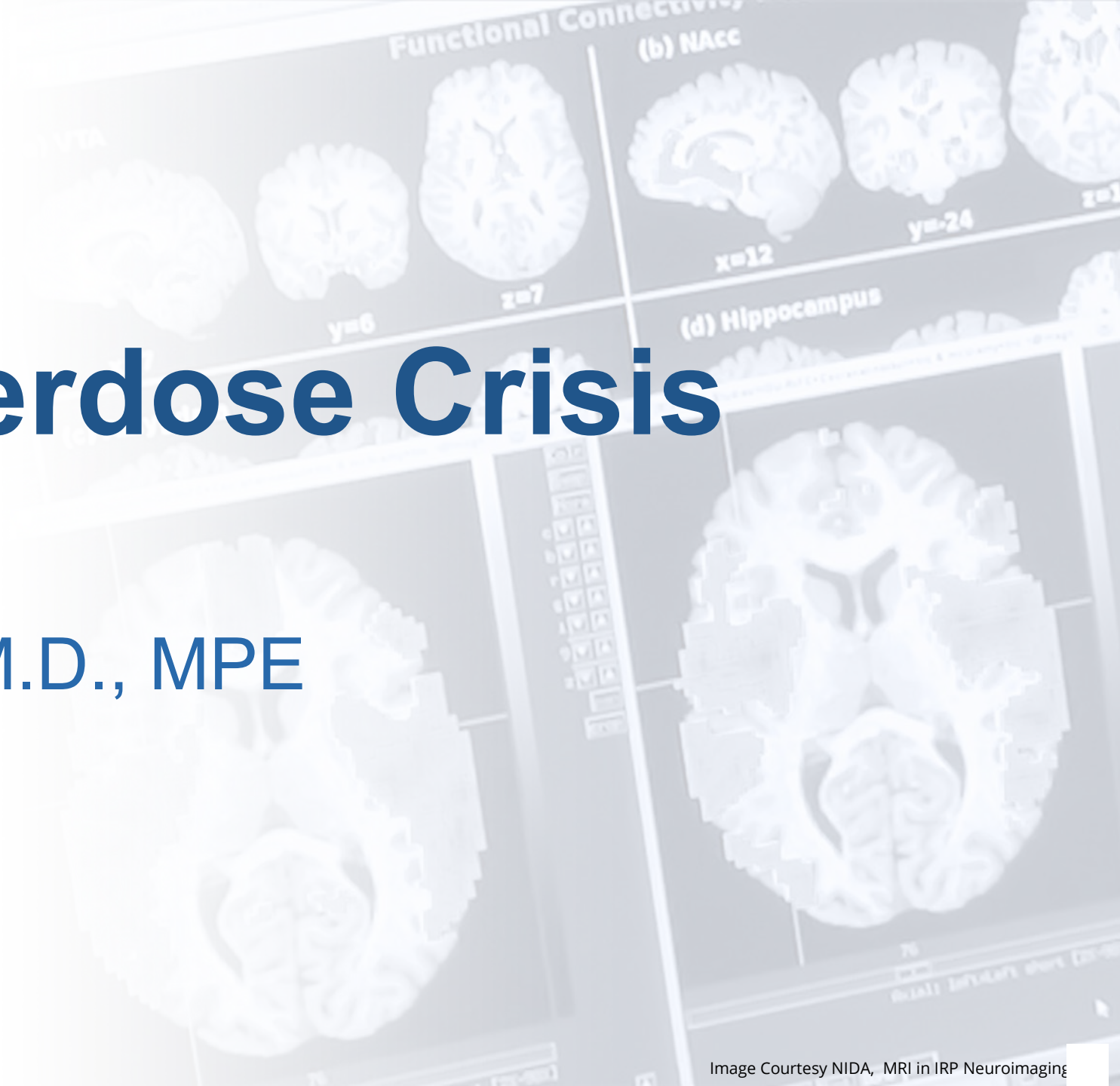
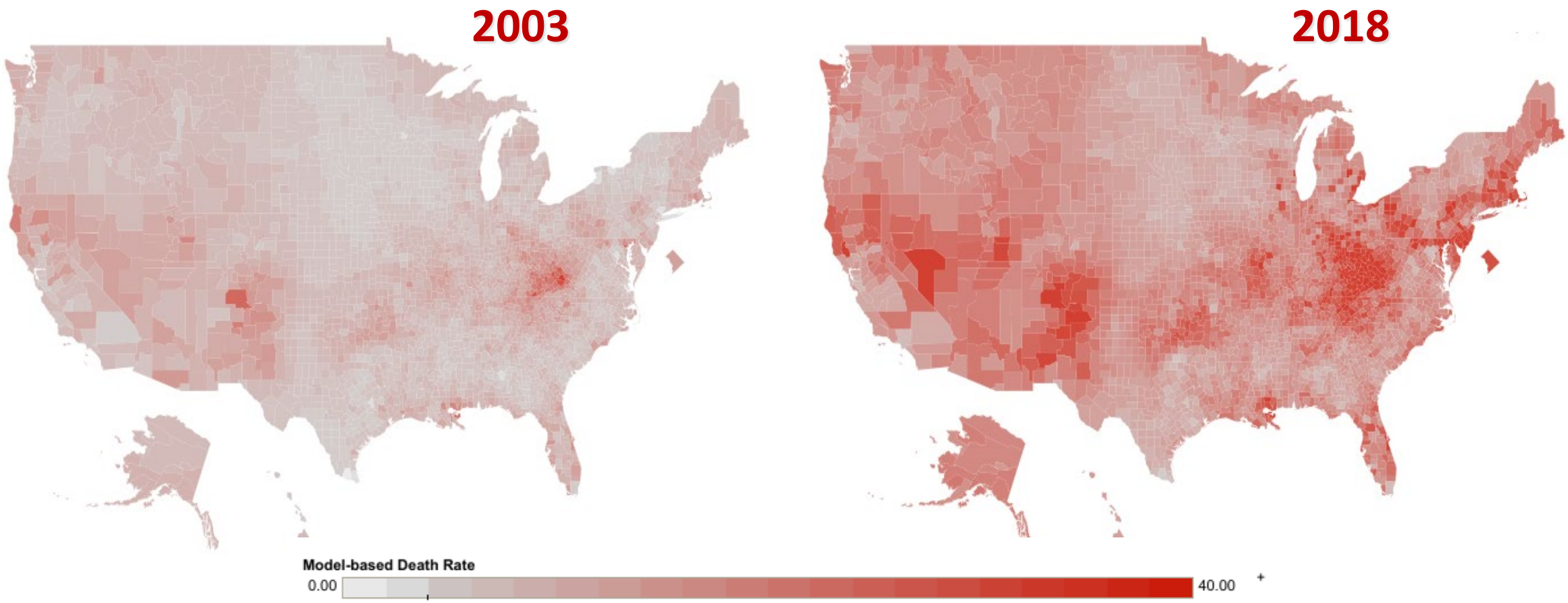


Image Courtesy NIDA, MRI in IRP Neuroimaging

Virtually *All U.S. Regions* Have Increased Drug Overdoses *But Rates Vary*

Estimated Age-adjusted Death Rates per 100,000 for Drug Poisoning by County



National Center for Health Statistics, National Vital Statistics System, mortality data https://www.cdc.gov/nchs/data-visualization/drug-poisoning-mortality/

U.S. Drug Overdose Deaths

70,630 Deaths in 2019

49,860 from Opioids (Prescription and Illicit)

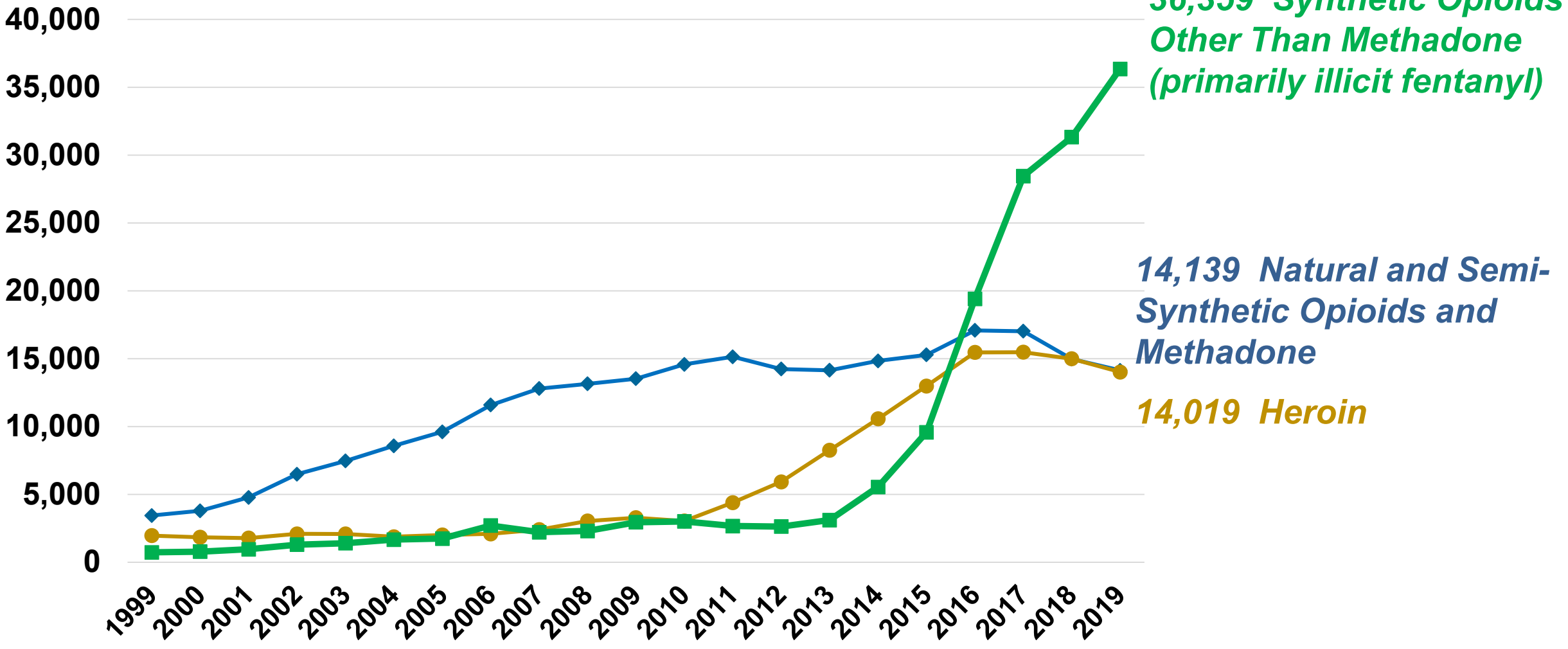
93,398 Deaths in 2020

69,769 from Opioids (Prescription and Illicit)

National Center for Health Statistics, National Vital Statistics System, mortality data

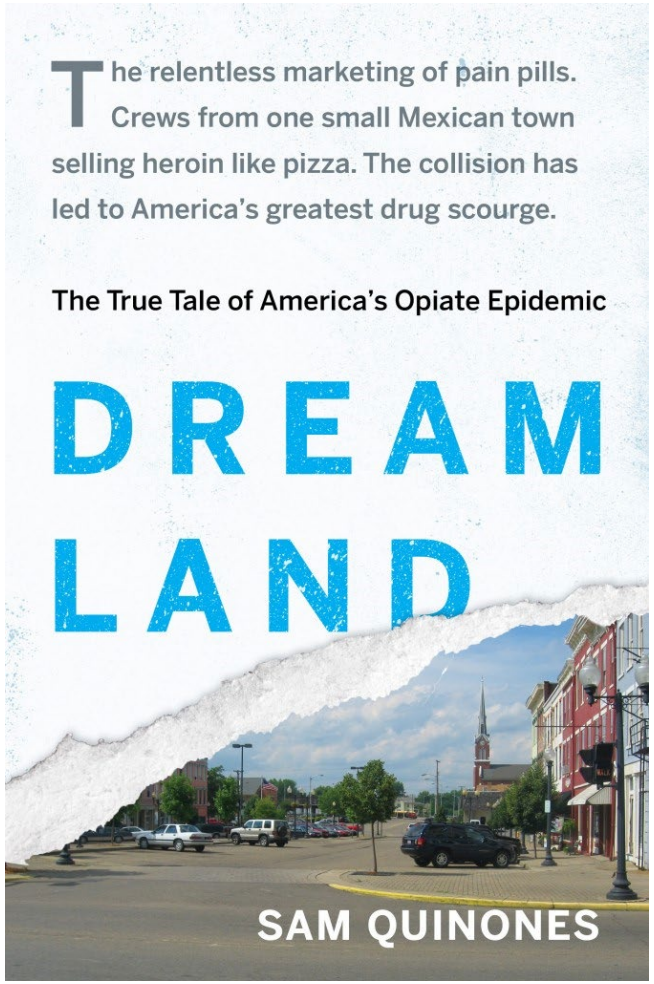
Evolution of Drivers of Overdose Deaths:

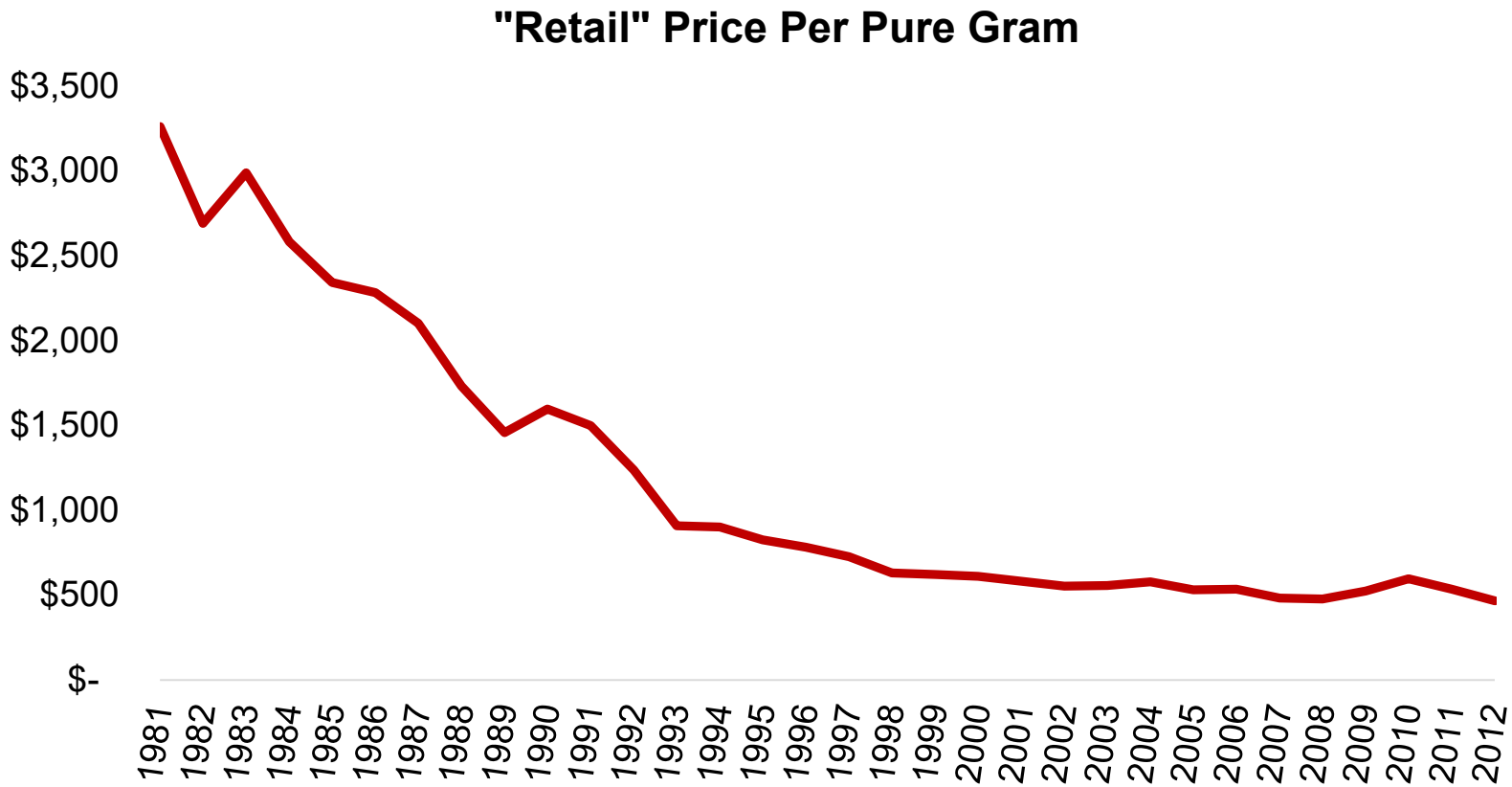
Analgesics ➡ Heroin ➡ "Fentanyl"



See: Compton WM & Jones CM, Ann NY Acad Sci, 2019;
Updated for 2019 from WONDER Database

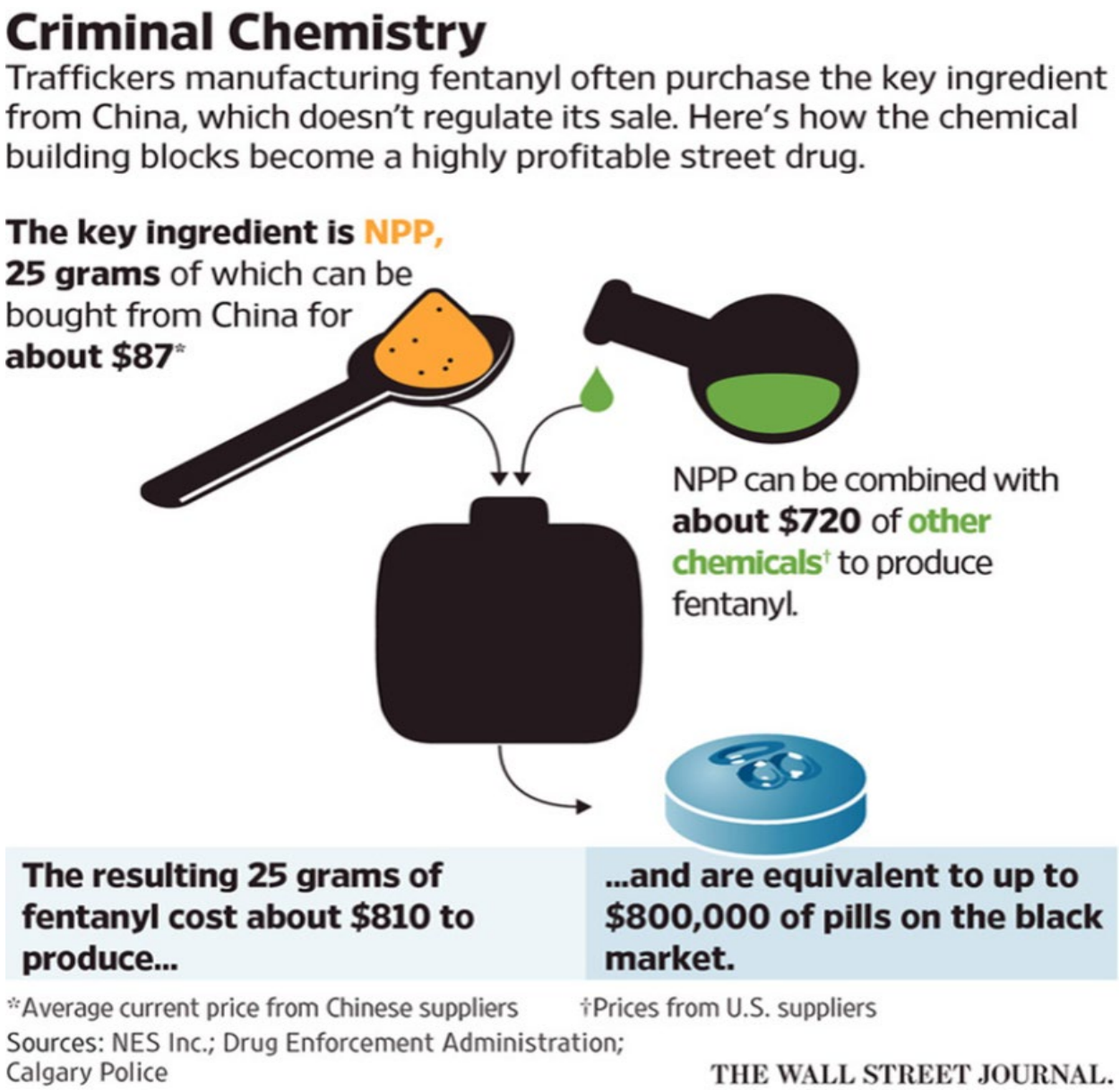
ECONOMICS: Heroin Increases Due to Lower Price and Greater Availability





National Drug Control Strategy--Data Supplement 2016. https://obamawhitehouse.archives.gov/sites/default/files/ondcp/policy-and-research/2016_ndcs_data_supplement_20170110.pdf

ECONOMICS: CHEAP Fentanyl Precursor Chemicals



September 27, 2021

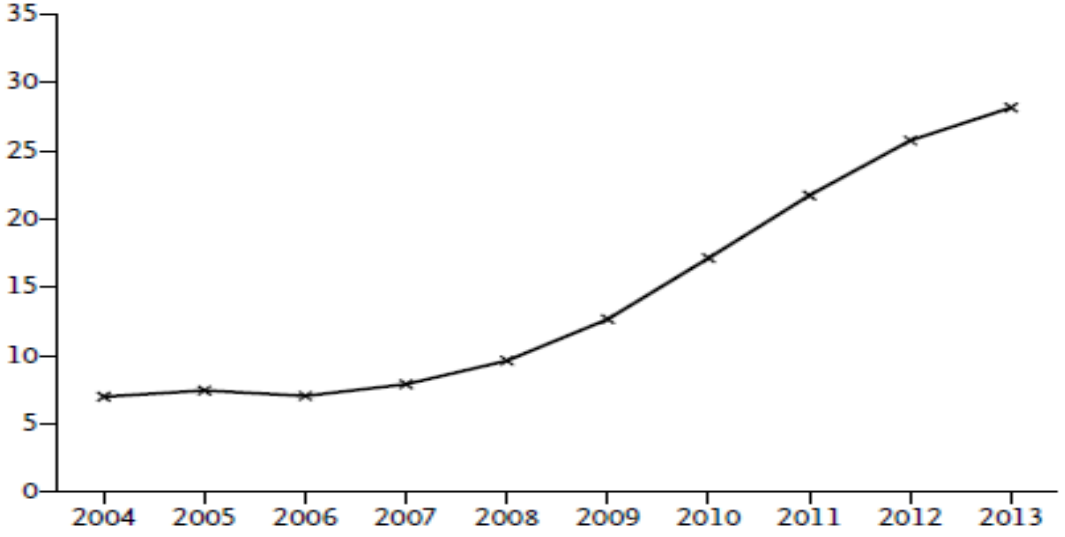
DEA Issues Public Safety Alert on Sharp Increase in Fake Prescription Pills Containing Fentanyl and Meth

DEA Warns that International and Domestic Criminal Drug Networks are Flooding the United States with Lethal Counterfeit Pills

https://www.dea.gov/press-releases/2021/09/27/dea-issues-public-safety-alert

Opioid Use and Misuse During Pregnancy

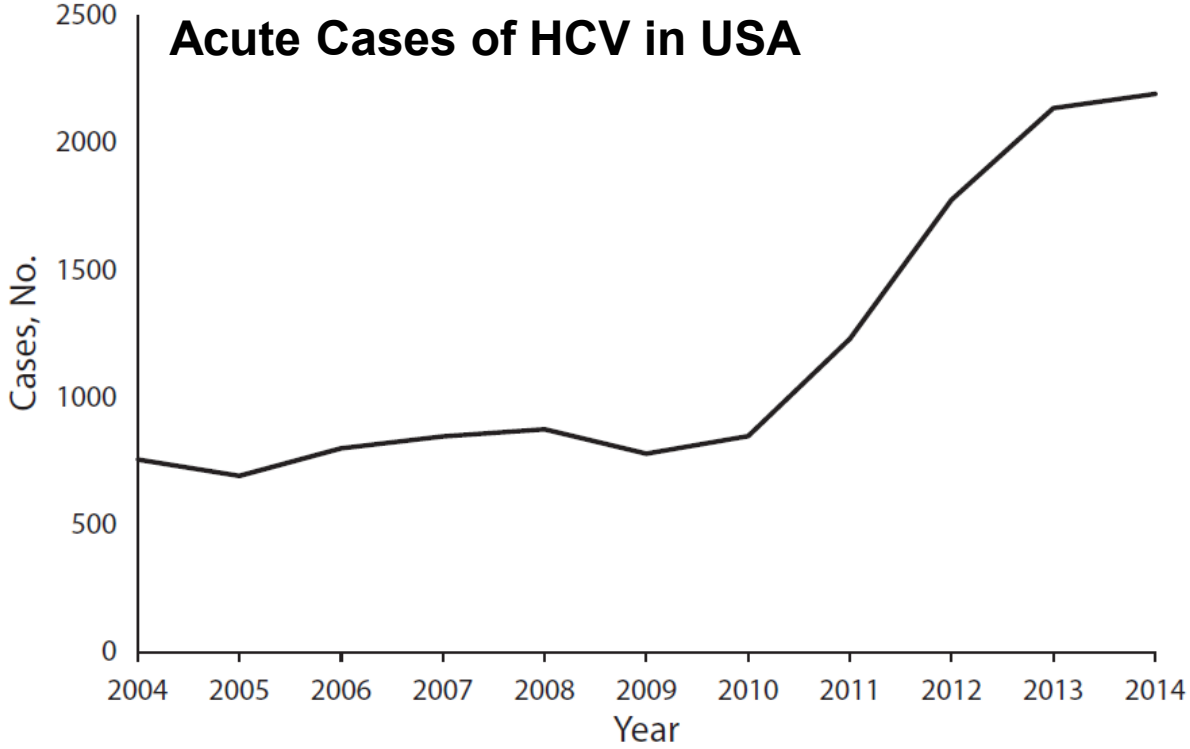
NICU Admissions for Neonatal Abstinence Syndrome NAS *(Number per 1000 Admissions)*



17% of pregnant women are prescribed an opioid during pregnancy

VN Tolia, SW Patrick, SW Patrick, et al.,NEJM 2015;372:2118-2126.

Rising rates of HCV

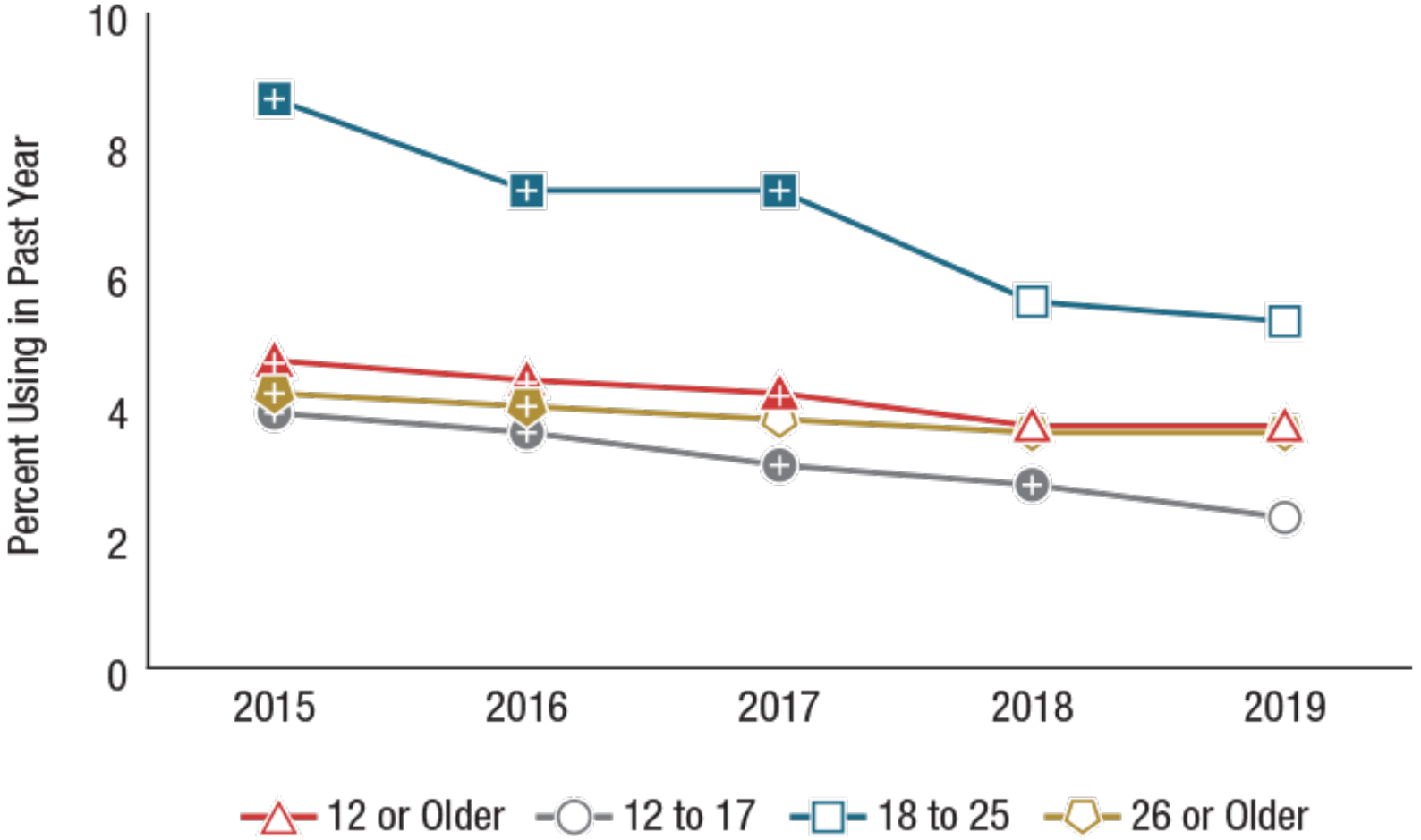


JE Zibbell, AK Asher, RC Patel, et al. Am J Public Heath 2018;108:175-181

HIV (and Hepatitis C) Outbreak Linked to Oxymorphone Injection Use in Indiana, 2015

PJ Peters, P Pontones, KW Hoover, et al. NEJM. 2016;375:229-239

Past Year Opioid Misuse among People Aged 12 or Older: 2015-2019



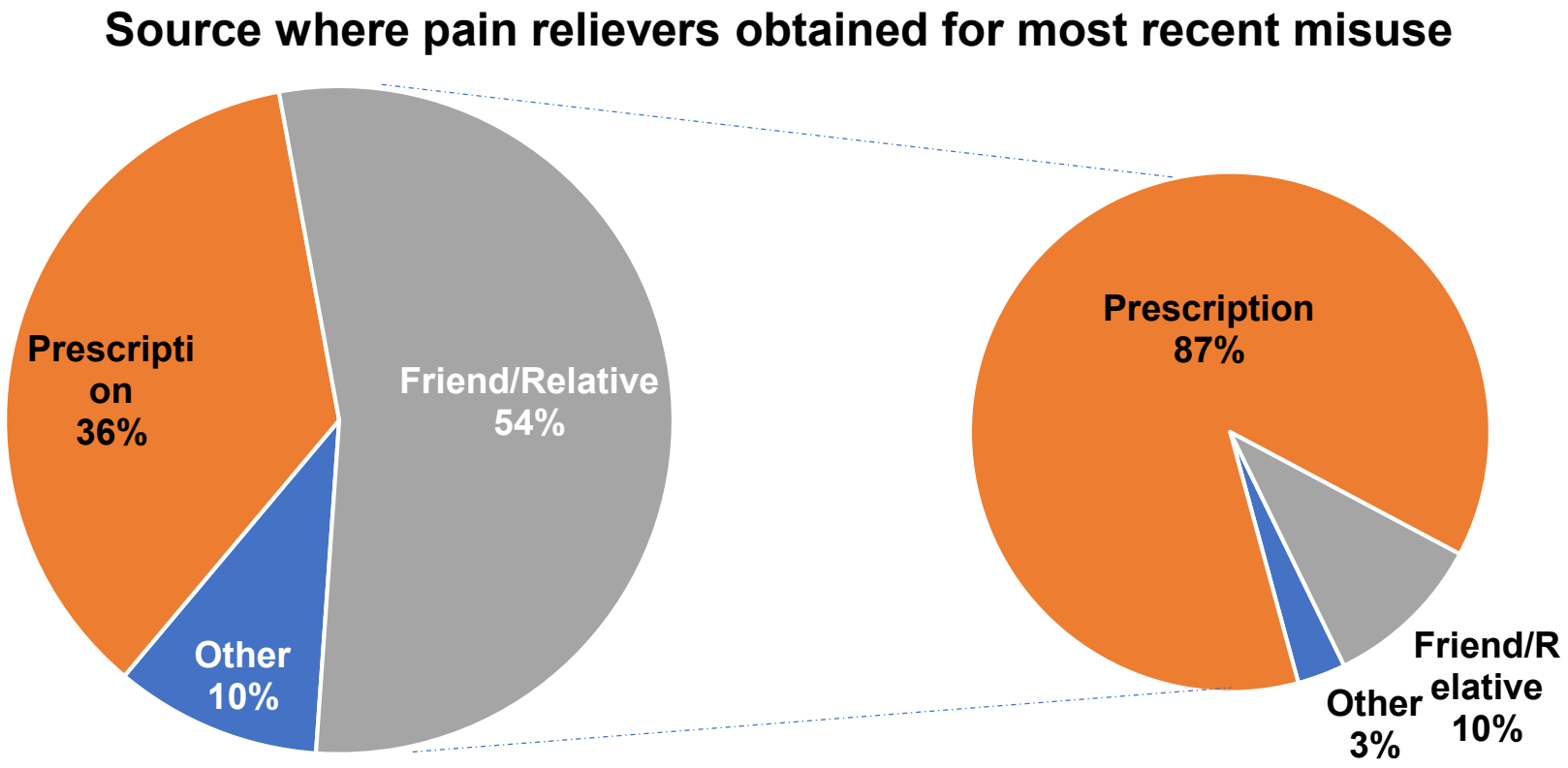
Age	2015	2016	2017	2018	2019
12 or Older	4.7+	4.4+	4.2+	3.7	3.7
12 to 17	3.9+	3.6+	3.1+	2.8+	2.3
18 to 25	8.7+	7.3+	7.3+	5.6	5.3
26 or Older	4.2+	4.0+	3.8	3.6	3.6

Note: *Misuse includes any use outside of legitimate medical recommendations. Also, the most frequently cited reason for misuse was because of pain.*

+ Difference between this estimate and the 2019 estimate is statistically significant at the .05 level.

Direct and Indirect Pathways from Prescriptions to Misuse

People misusing analgesics, directly and indirectly, obtain them by prescription.



B Han, WM Compton, C Blanco, et al. Annals of Internal Medicine. 2017;67(5):293-301;

Adolescent Exposure to Prescription Opioids Associated with Future Opioid Misuse

6,220 12th graders followed up to age 23:

Legitimate opioid use before high school graduation is independently associated with a 33% increase in the risk of future opioid misuse after high school.

Richard Miech, Lloyd Johnston, Patrick M. O'Malley, Katherine M. Keyes and Kennon Heard
Pediatrics November 2015, 136 (5) e1169-e1177; DOI: https://doi.org/10.1542/peds.2015-1364

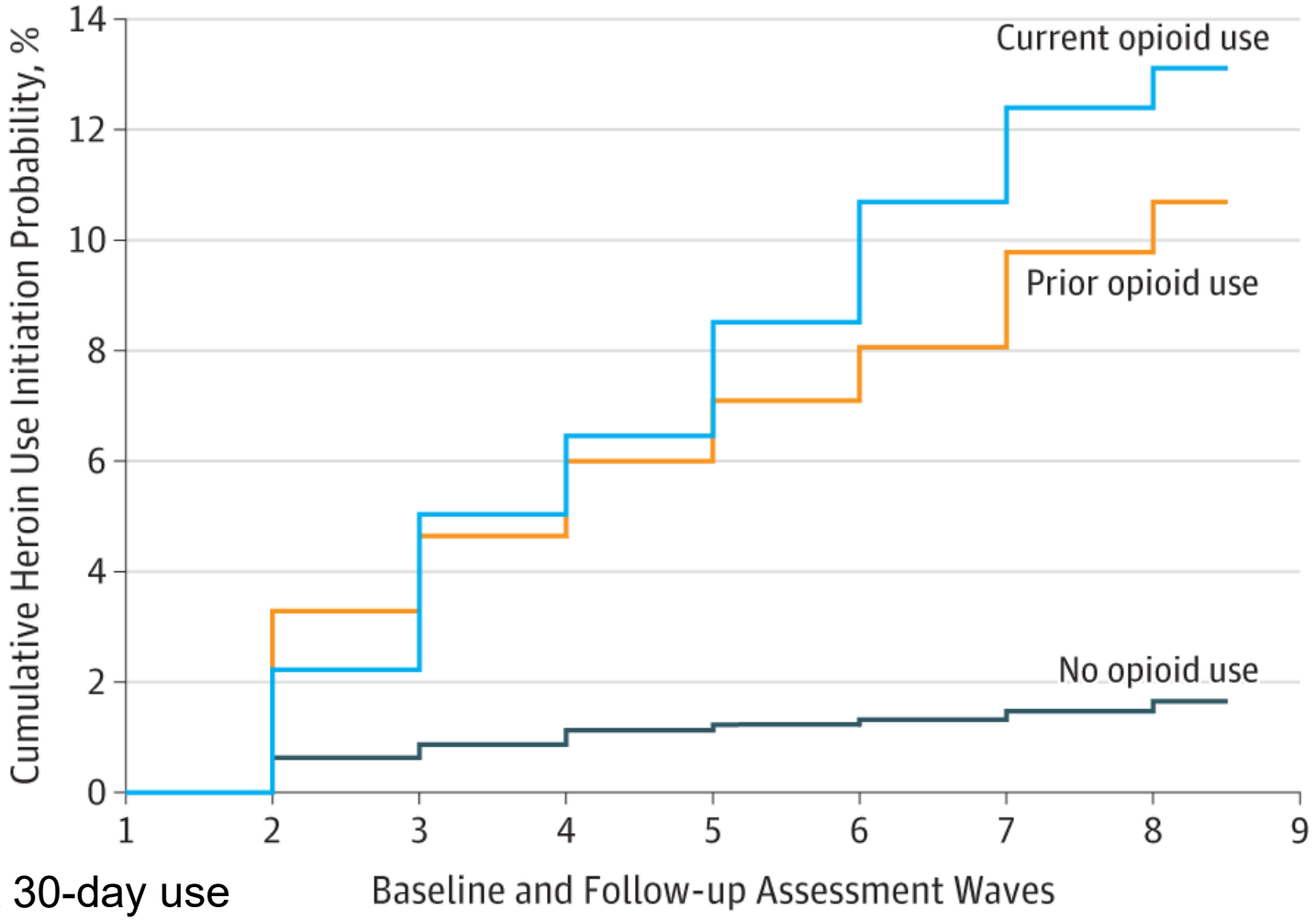
11,012 12th graders followed up to 35:

Adolescents who reported <u>nonmedical</u> prescription opioid use (with subsequent nonmedical or medical use) had greater odds of any heroin use in adulthood than population controls.

McCabe SE, Boyd CJ, Evans-Polce RJ, McCabe VV, Schulenberg JE, Veliz PT. Pills to Powder: A 17-Year Transition From Prescription Opioids to Heroin Among US Adolescents Followed Into Adulthood. J Addict Med. 2021 May-Jun 01;15(3):241-244.

Association of Nonmedical Prescription Opioid Use With Subsequent Heroin Use Initiation in Adolescents

Estimated Hazard Curves for Heroin Use Initiation by Nonmedical Prescription Opioid Use Status in Preceding Waves, across semiannual assessments from fall 9th grade, 2013 to spring 12th grade, 2017.



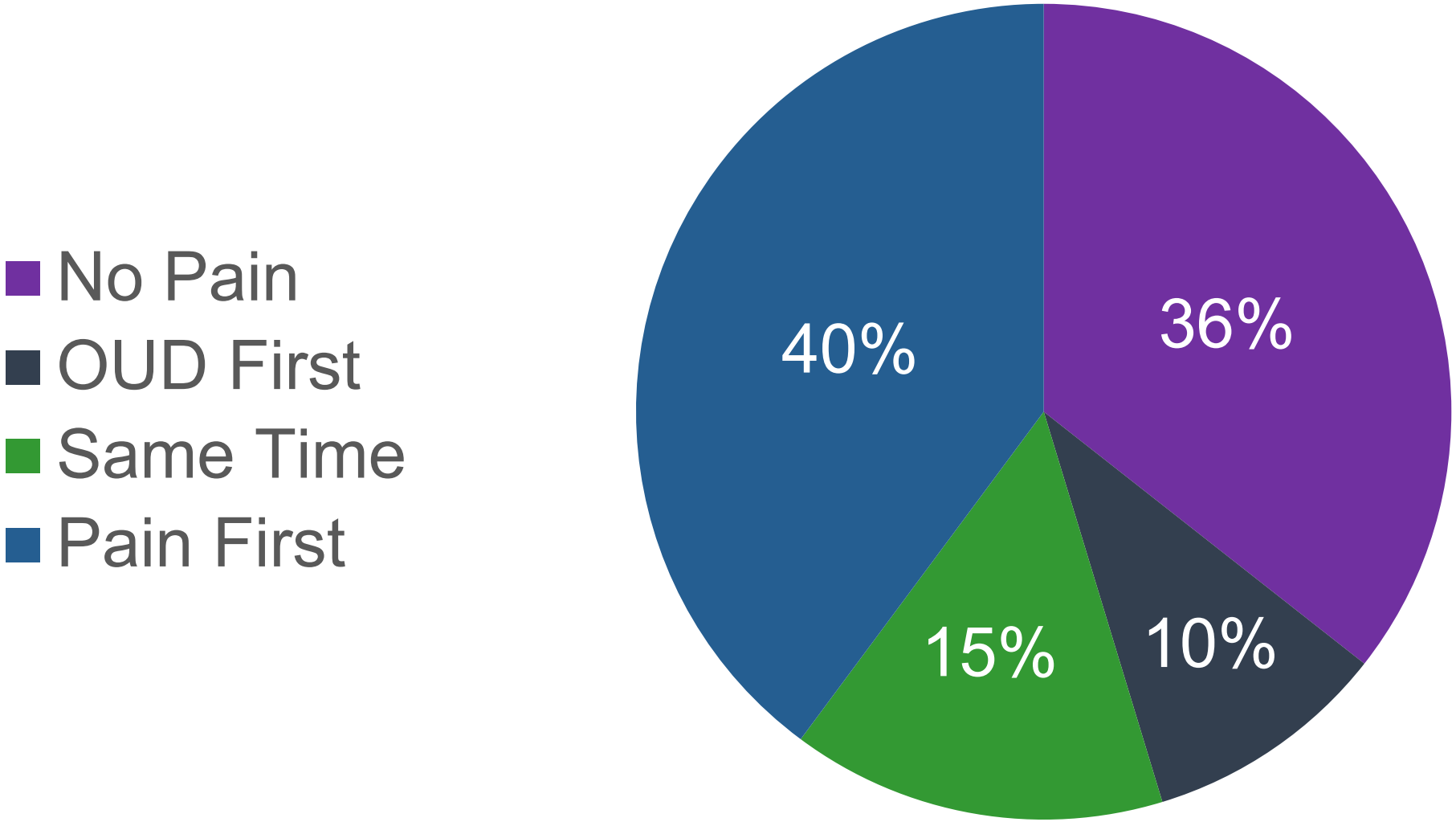
No use = no past 6-month use

Prior use = past 6-month use without past 30-day use

Current use = past 30-day use.

Kelley-Quon LI, Cho J, Strong DR, Miech RA, Barrington-Trimis JL, Kechter A, Leventhal AM. JAMA Pediatr. 2019;173(9):e191750

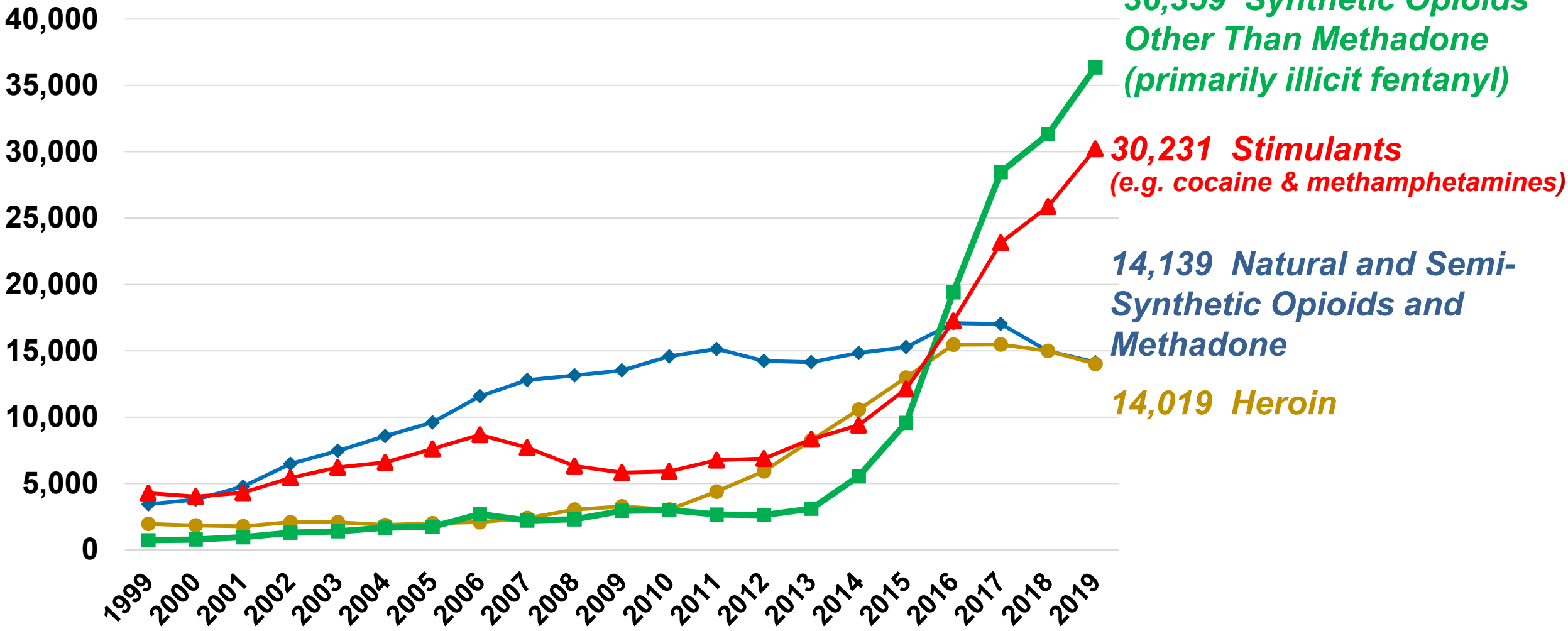
Majority of OUD Patients Have Comorbid Pain Conditions



Hser Y, et al. J Substance Abuse Treatment. 2017; 77:26-30

Evolution of Drivers of Overdose Deaths:

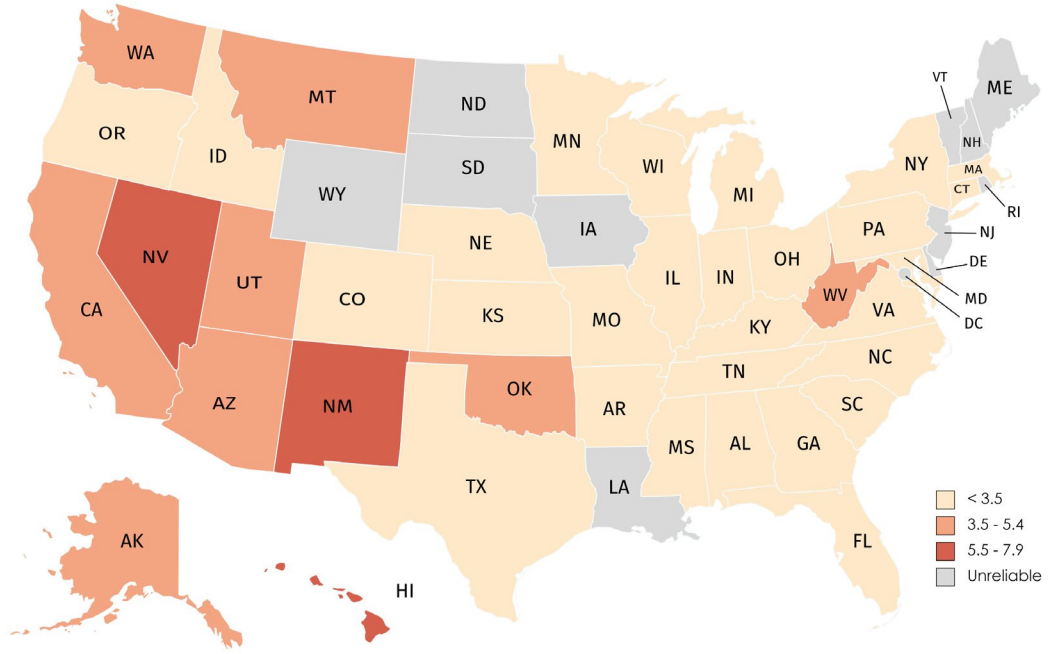
Analgesics → Heroin → "Fentanyl" → Stimulants



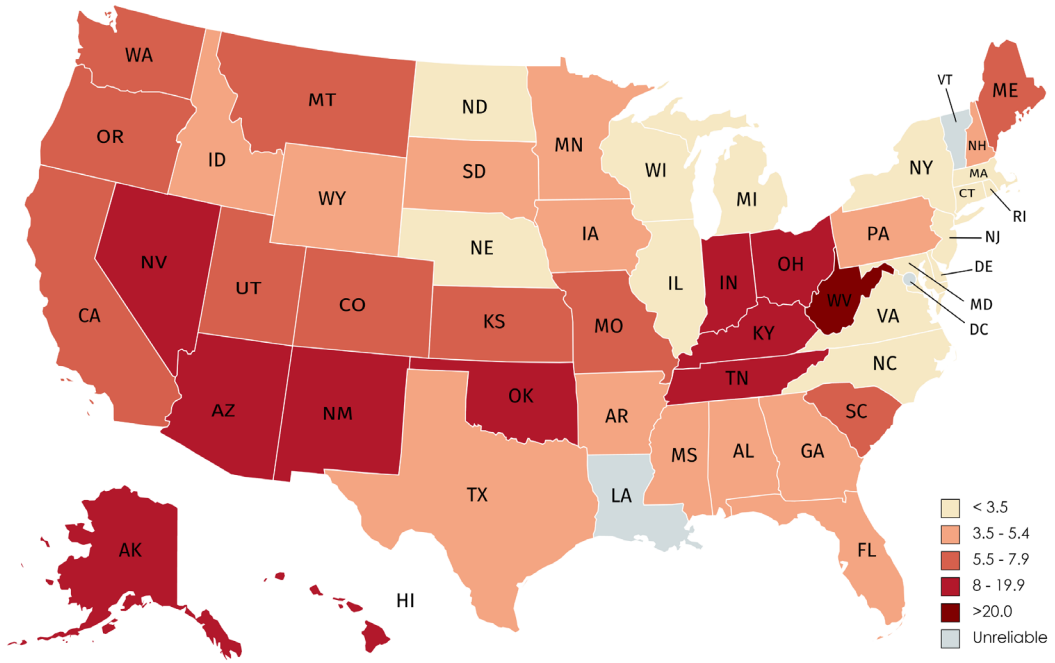
See: Compton WM & Jones CM, Ann NY Acad Sci, 2019;
Updated for 2019 from WONDER Database

U.S. overdose deaths involving methamphetamine* age-adjusted rates/100k persons

2015



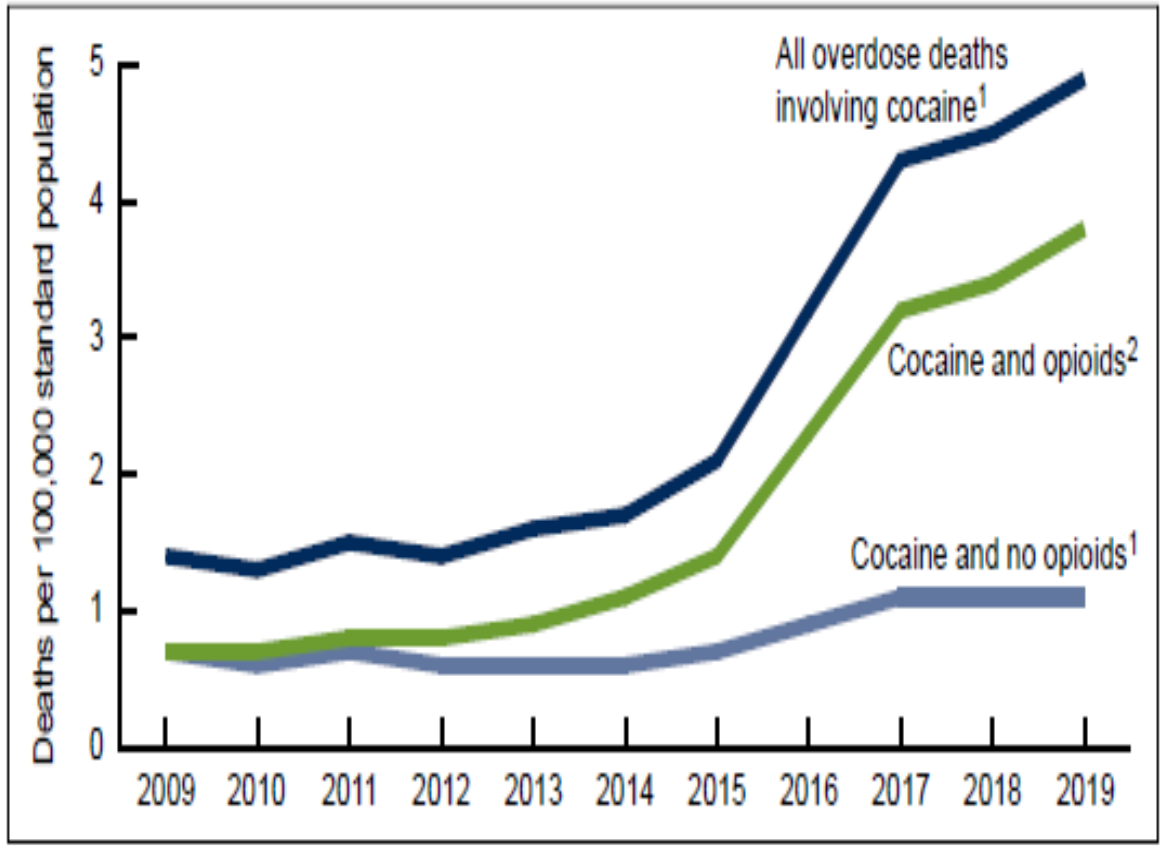
2019



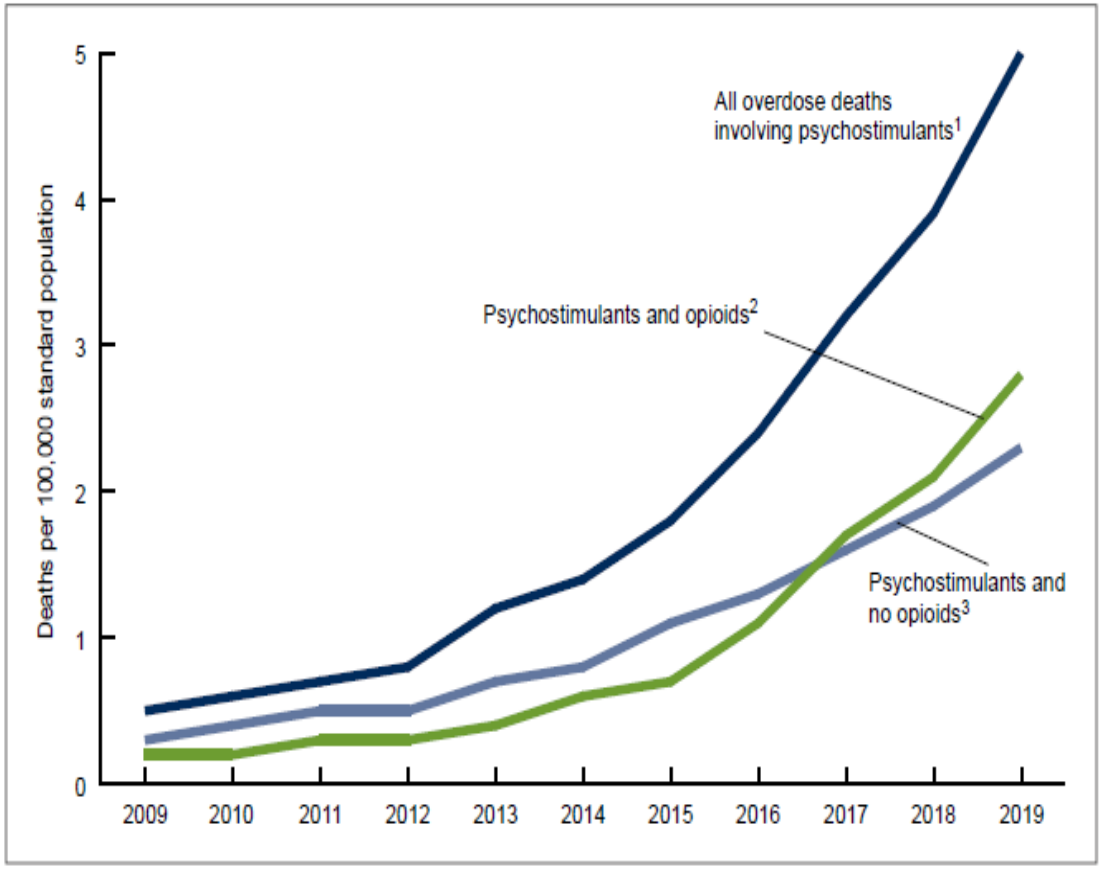
*Psychostimulants With Abuse Potential ICD-10 code (T43.6). This category is dominated by methamphetamine-involved overdose deaths.
Source: CDC, National Center for Health Statistics. Multiple Cause of Death 1999-2019 on CDC WONDER Online Database, released in 2020.

Age-Adjusted Rates of Overdose Deaths Involving Cocaine and Psychostumulants* with Concurrent Involvement of Opioids

Cocaine

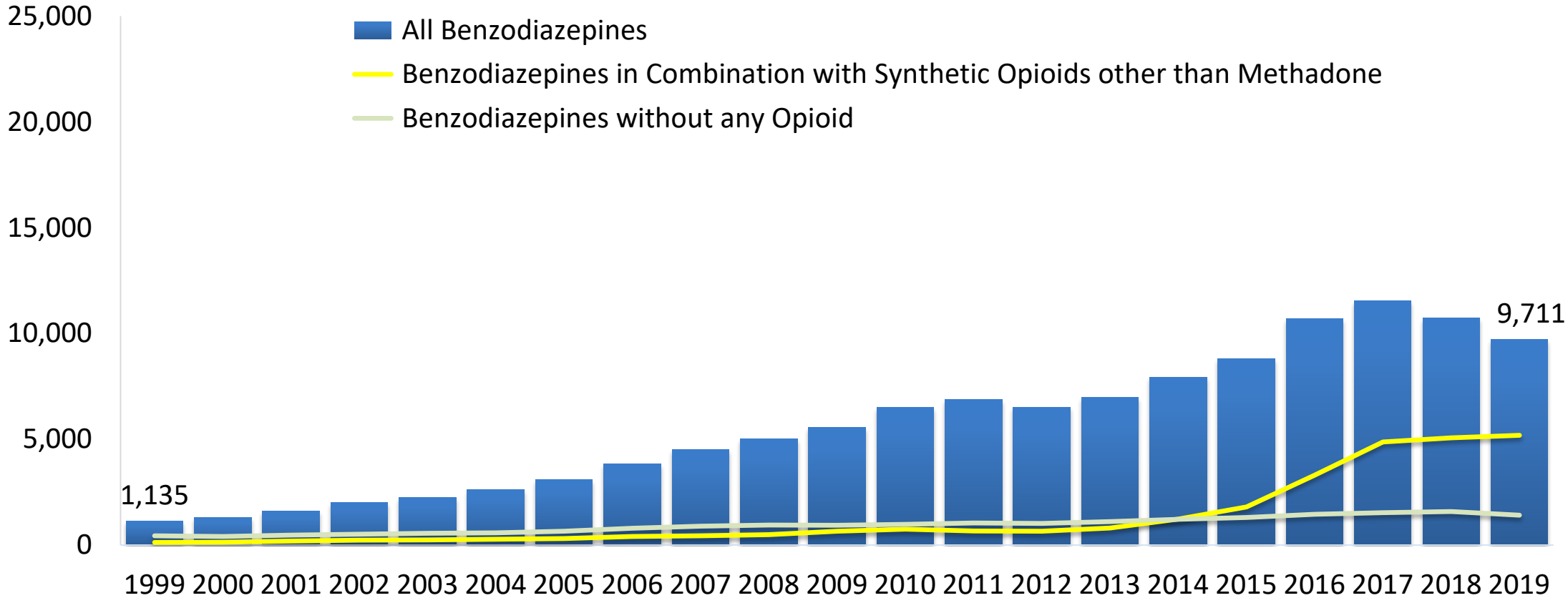


Psychostimulants*



* Predominantly Methamphetamine

National Drug Overdose Deaths Involving Benzodiazepines, by Opioid Involvement, All Ages, 1999-2019



*Among deaths with drug overdose as the underlying cause, the benzodiazepine category was determined by the T402.2 ICD-10 multiple cause-of-death code. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2019 on CDC WONDER Online Database, released 12/2020.

Polydrug Use: Key Concepts

- **Strong Relationships Across Substances** — one of the strongest predictors of virtually any substance use is the use of other substances.
- **Addictive Substances Share Common Neurobiological Features** — Reward, Dependence and Relapse stages have common brain substrates, apparently regardless of the substance involved

Note that for Overdose Death Data, the substances listed are not mutually exclusive and many deaths involve multiple substances making causal determinations difficult

Solutions toward *Responsible Prescribing*: Guidance

Opioid Prescribing Guidelines March 2016

- Intended for primary care providers
- Applies to patients >18 years old in chronic pain outside of end-of-life care
- *Focuses on:*
  - 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

Patient-Centered Reduction or Discontinuation of Long-term Opioid Analgesics: *The HHS Guide for Clinicians*

Focuses on:

1. Criteria for reducing or discontinuing opioid therapy
2. Considerations prior to deciding to taper opioids
3. Ensuring patient safety prior to initiating taper
4. Shared decision-making with patients
5. Rate of opioid taper
6. Opioid withdrawal management
7. Behavioral health support
8. Challenges to tapering

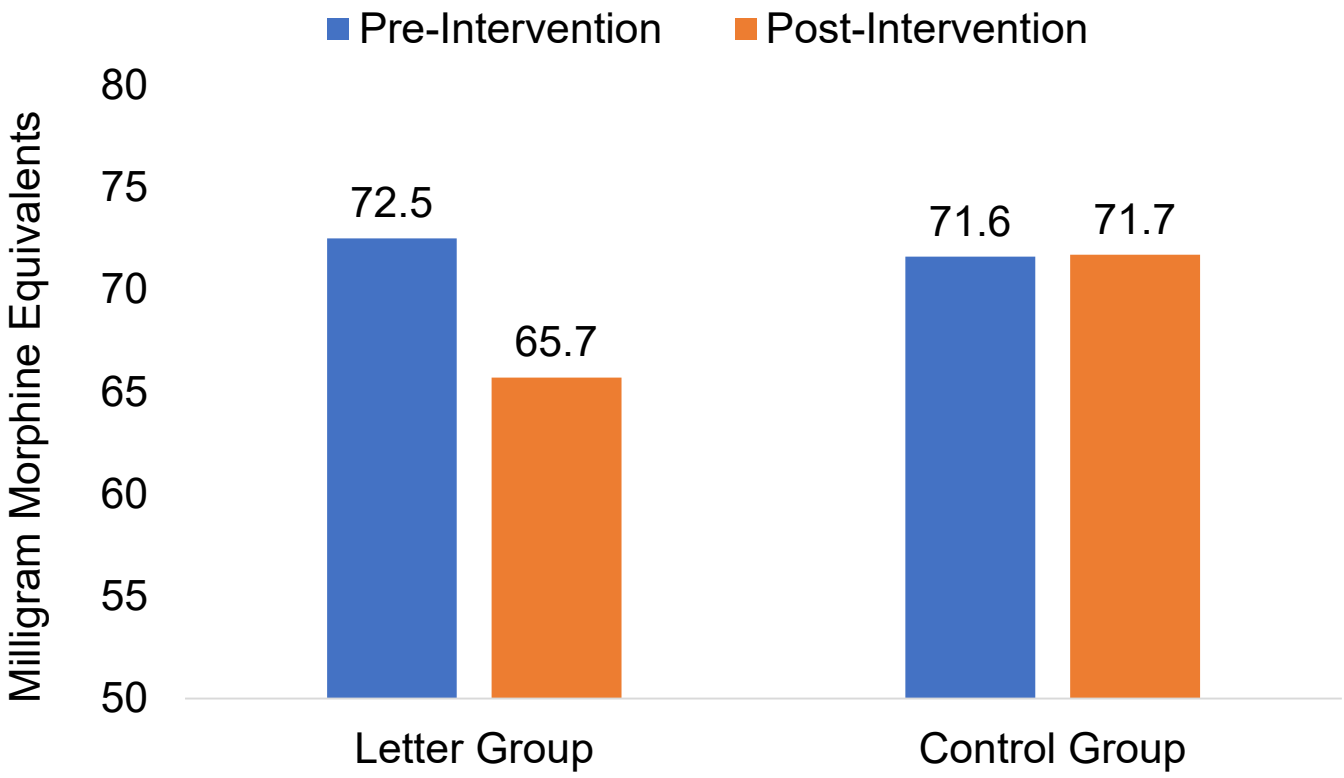
Dosage changes, particularly rapid reductions in dose, can harm patients or put them at risk if not made in a thoughtful, deliberative, collaborative, and measured manner.

D Dowell, WM Compton, BP Giroir. 2019;322(19):1855–1856

Medical Examiner Letter Reduces Subsequent Prescribing

Randomized trial of 861 clinicians prescribing to 170 OD decedents

- Intervention group received notification of their patients' deaths and a safe prescribing injunction from their county's medical examiner; control group did not.
- Milligram morphine equivalents in prescriptions filled by patients of letter recipients decreased by 9.7% (95% confidence interval: 6.2 to 13.2%; P < 0.001) over 3 months after intervention; also, fewer opioid initiates and fewer high-dose opioid prescriptions.



JN Doctor, A Nguyen, R lev, et al. Science. 2018;361(6402):588-590.

NIDAMED: Resources for Medical & Health Professionals

NIDAMED's mission is to develop and disseminate science-based resources for health professionals and those in training about screening for, addressing, and treating substance use disorder and addiction.

Stay Up to Date with NIDAMED

Health Professions Education

Discipline Specific Resources Page

Opioid Crisis & Pain Management

Marijuana and Other Drugs

Screening, Prevention, & Treatment

Screening
Get validated tools for screening for and discussing substance use from adolescence into adulthood.

Prevention
Get tips and resources to help keep patients safe.

Treatment
Discover research-based treatment options for your patients.

Science to Medicine: Peer to Peer
Hear how clinicians are operationalizing research to improve patient care across practice settings, including FQHCs.

More from NIDAMED

For Patients
Access educational materials on substance use and addiction to share in your practice.

Clinical Trials Network
Read about how clinicians and scientists are working together to implement research findings.

Drugabuse.gov/NIDAMED

NIDAMED

Naloxone Distribution

Naloxone Saves Lives

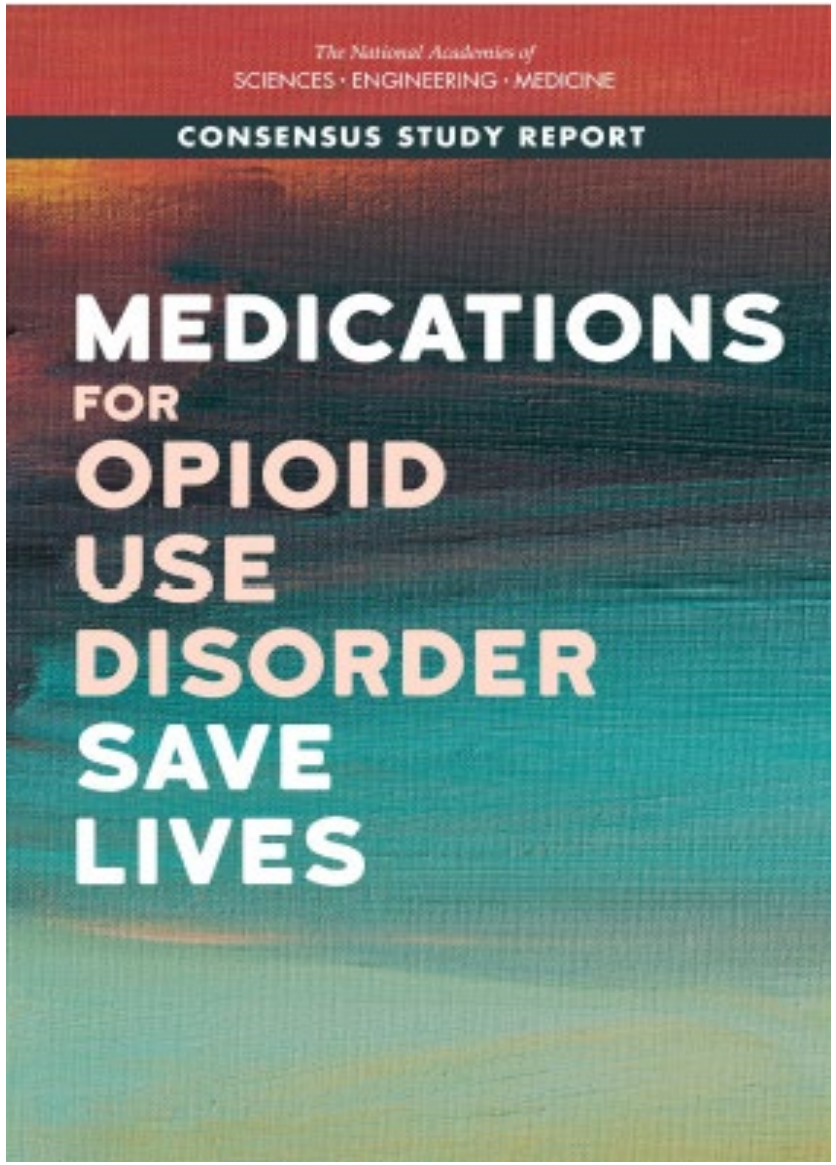
- Direct intervention to save lives
  - Nasal spray and Auto-injector formulations
- Next steps
  - Longer acting agents to address fentanyl risks?
  - Respiratory stimulation?
  - Device development?

Surgeon General's Advisory on Naloxone and Opioid Overdose, April 5, 2018

I, Surgeon General of the United States Public Health Service, VADM Jerome Adams, am emphasizing the importance of the overdose-reversing drug naloxone.

For patients currently taking high doses of opioids as prescribed for pain, individuals misusing prescription opioids, individuals using illicit opioids such as heroin or fentanyl, health care practitioners, family and friends of people who have an opioid use disorder, and community members who come into contact with people at risk for opioid overdose, knowing how to use naloxone and keeping it within reach can save a life.

Given counterfeits and contamination, outreach may need to include those who use cocaine, methamphetamine or pills obtained illicitly.



2019
Study Sponsors
National Institutes of Health
Substance Abuse and Mental Health Services Administration

Medications for Opioid Use Disorder are underutilized

Barriers include:

- **Misunderstanding and stigma** toward drug addiction, individuals with OUD, and the medications to treat it.
- **Inadequate education and training** of the professionals responsible for working with people with OUD, including treatment providers and law enforcement and other criminal justice personnel.
- **Current regulations** around methadone and buprenorphine, such as waiver policies, patient limits, restrictions on treatment settings, and other policies that are not supported by evidence or employed for other medical disorders.
- The **fragmented system of care** for people with OUD and current financing and payment policies.

Intersection of the SARS-CoV-2 Pandemic and Addiction

'Opioid overdoses are skyrocketing': as Covid-19 sweeps across US an old epidemic returns

The pandemic is creating the social conditions – no jobs, isolation, despair – that helped enable the opioid crisis to emerge in the first place. Now it's back

Search The Guardian US edition

'There was nothing to help me': how the pandemic has worsened opioid addiction

US treatment centers have shut down or turned away patients amid as they struggle to adhere to Covid-19 safety protocols

abc7 EYEWITNESS NEWS

I-TEAM

Drug overdose deaths spike amid COVID-19 pandemic

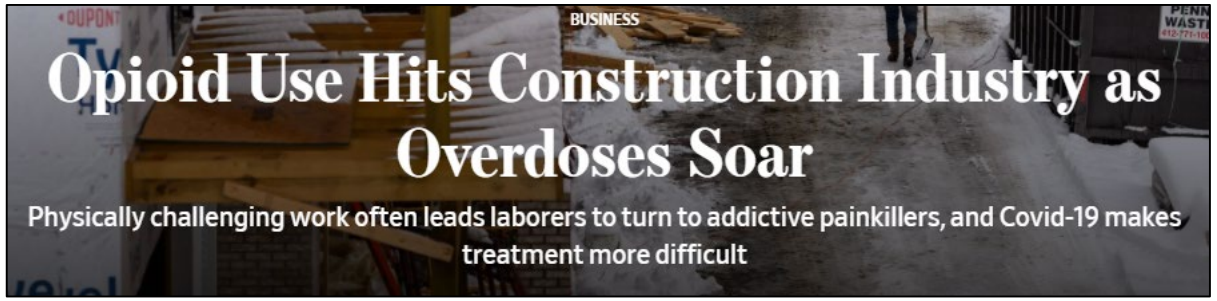
By Chuck Goudie and Barb Markoff, Christine Tressel, Ross Weidner, Jonathan Fagg

Wednesday, February 10, 2021

THE OTHER EMERGENCY

Covid-19 is undoing a decade of progress on the opioid epidemic

THE WALL STREET JOURNAL.



U.S.

The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic

Overdose deaths rise as job losses and stress from Covid-19 destabilize people struggling with addiction

Structural and Social Challenges for SUD During COVID-19

- Stress and Stigma
- Limited medication access and limited peer-support groups/social connection
- Social distancing increases likelihood of opioid overdoses happening with no observers who can administer naloxone
- Job losses
- Housing instability/homelessness
- Incarceration (>50% of U.S prisoners have SUD) and prison populations are at greatest risk SARS-CoV-2 transmission

SUD Services Have Shifted During the Pandemic

- Increased use of telemedicine
- Establishment of mental health hot lines
- Deployment of virtual support meetings
- Expansion of take-home medicines for MOUD
- Buprenorphine prescribing via Telehealth
- Release of non-violent offenders with SUD from jails and prisons(might improve their outcomes)
- Development of web-based educational material that can be used to help in rehabilitation

Increased Overdose Death Rates During COVID-19 Pandemic

12-months ending June 2019 compared to 12-months ending May 2020

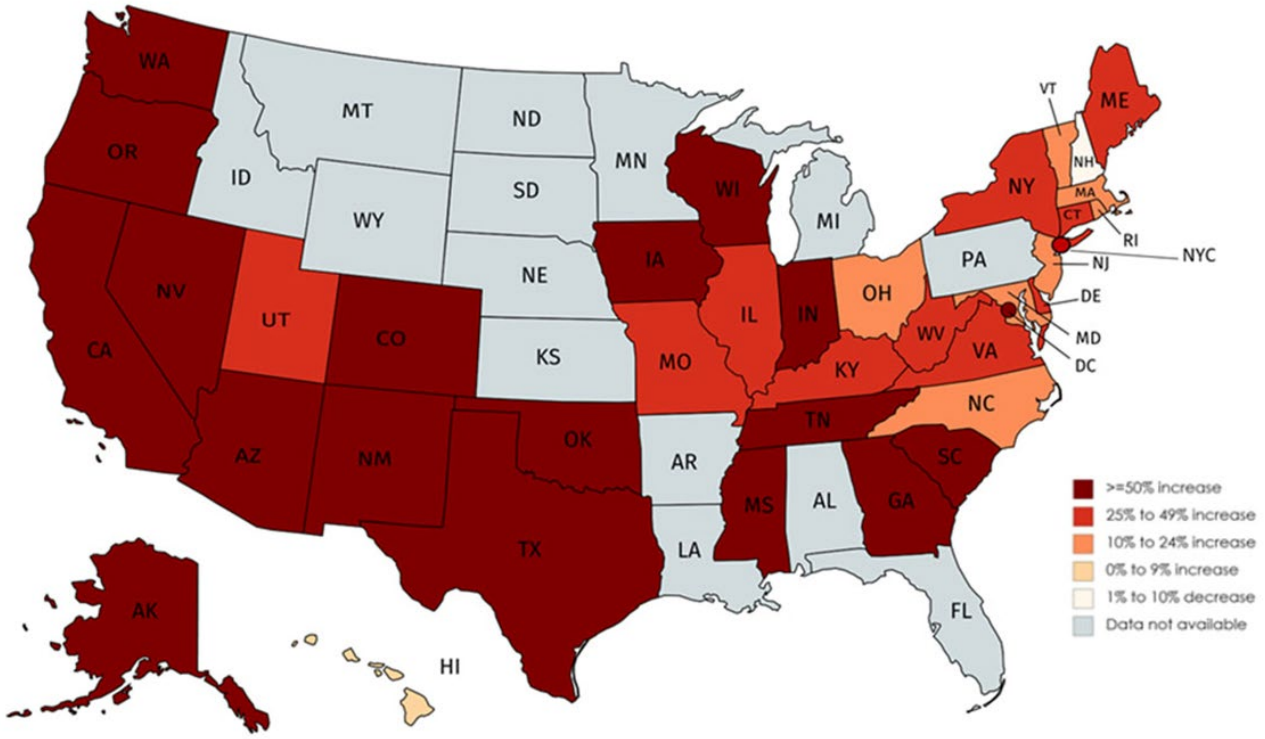
April 15, 2021 THE WALL STREET JOURNAL.

U.S.

Fentanyl Has Spread West and Overdoses Are Surging

More than twice as many people died from drug overdoses as from Covid-19 in San Francisco last year

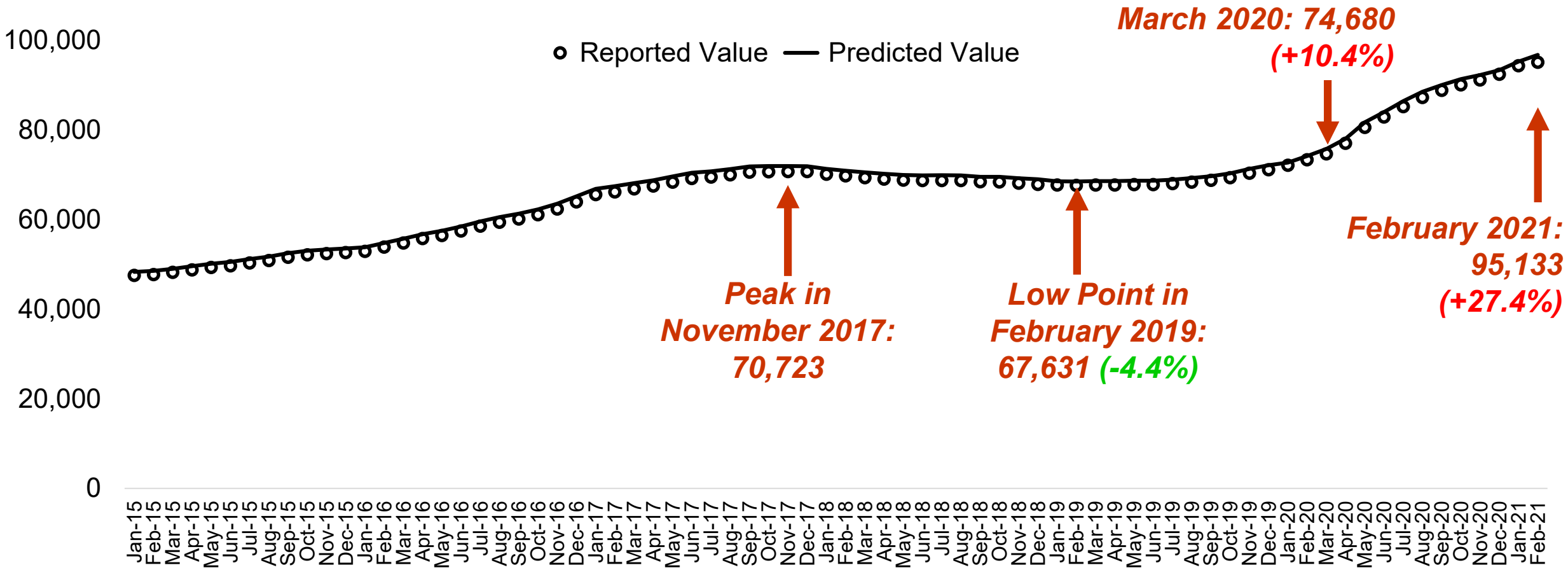
- 98.0% - 10 western states
- 35.4% - 12 southern states & DC
- 32.1% - 6 midwestern states
- 21.1% - 8 northeastern states & NYC



CDC Health Alert Network Advisory December 17, 2020, https://emergency.cdc.gov/han/2020/han00438.asp

Recent Increases in Overdose Deaths

12 month ending provisional counts (*reported values*) of drug-involved overdose deaths in the U.S.



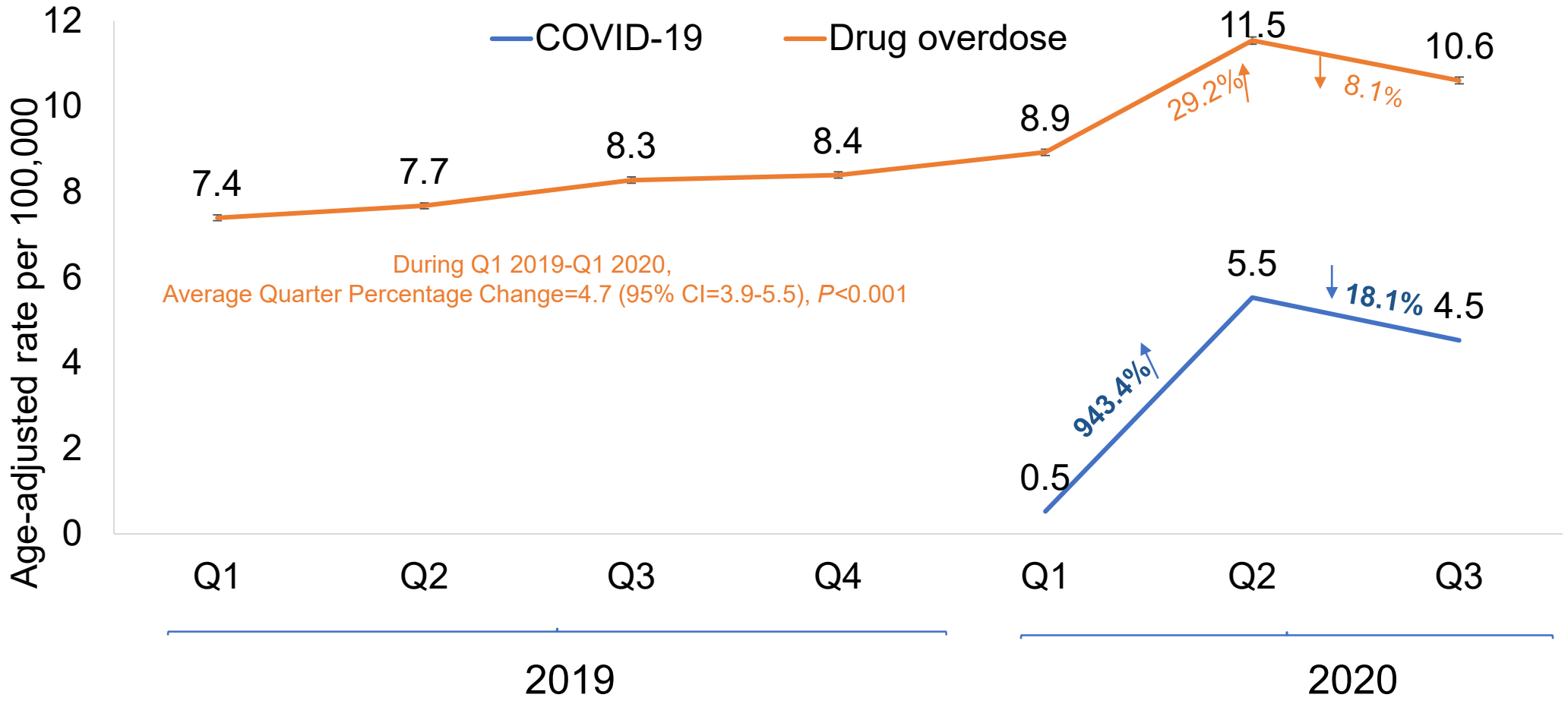
NCHS Provisional Drug Overdose Death Counts: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm, *September 19, 2021*

Drug-involved Overdose Deaths* Continue to Increase

	ALL DRUGS	HEROIN	NAT & SEMI SYNTHETIC	METHADONE	SYNTHETIC OPIOIDS (mainly illicit fentanyl)	COCAINE	OTHER PSYCHO-STIMULANTS (mainly meth)
2/2020*	74,234	14,172	12,288	2,791	39,361	17,000	17,434
8/2020*	88,598	14,495	13,451	3,436	52,561	19,868	22,287
2/2021*	96,801	12,859	13,806	3,770	60,857	20,231	26,128
Percent Change 2/20-2/21	**30.3%**	**-9.3%**	**12.4%**	**35.1%**	**54.6%**	**19.0%**	**49.9%**

*NCHS Provisional drug-involved overdose death counts are PREDICTED VALUES, 12 months ending in select months.
https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Age-adjusted Rates Of COVID-19 Or Drug-overdose Deaths For People Aged 15-54 In USA For 2019-2020



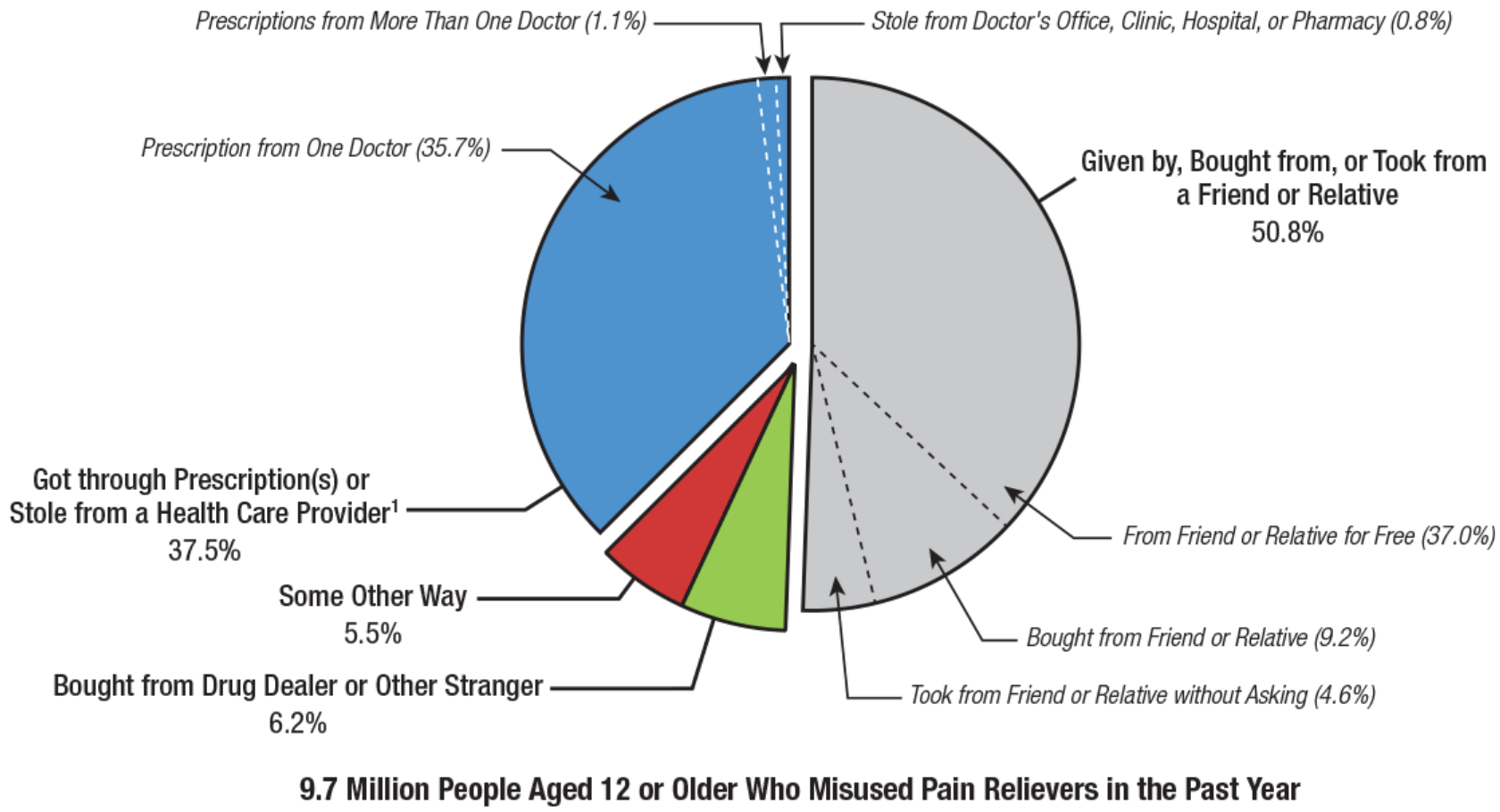
NIDA analysis of data from the NCHS, National Vital Statistics System

Summary

- The landscape of substance use and consequences undergoes dynamic shifts over time, related to: user behaviors, purveyor behaviors, drug factors, and multiple environmental influences.
- The U.S. Overdose Epidemic has accelerated during the COVID-19 public health emergency.
- Prescription opioid-involved overdose deaths increased during the pandemic
- Fentanyl-related overdoses have markedly increased.
- Polydrug use is common (especially stimulants).

Extra Slides

Source Where Pain Relievers Were Obtained for Most Recent Misuse among People Aged 12 or Older Who Misused Pain Relievers in the Past Year: 2019

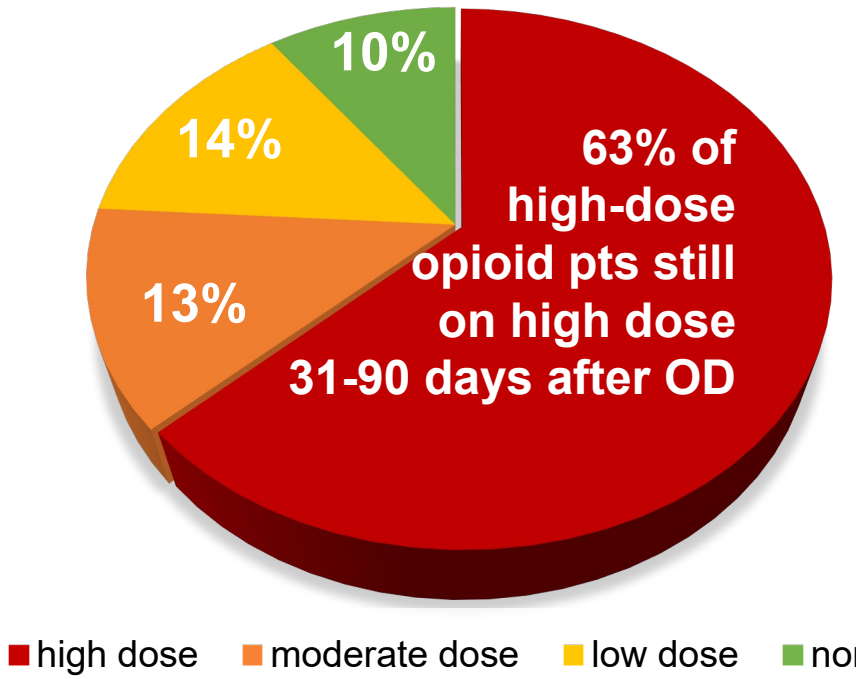


Note: Respondents with unknown data for the Source for Most Recent Misuse or who reported Some Other Way but did not specify a valid way were excluded.

[1] The percentages from the subcategories do not add to the total percentage for the category due to rounding.

Doctors Continued to Prescribe Opioids for 91% of Overdose Patients

In a **2-year follow-up of 2,848 commercially insured patients who had a nonfatal opioid overdose** during long-term opioid therapy :



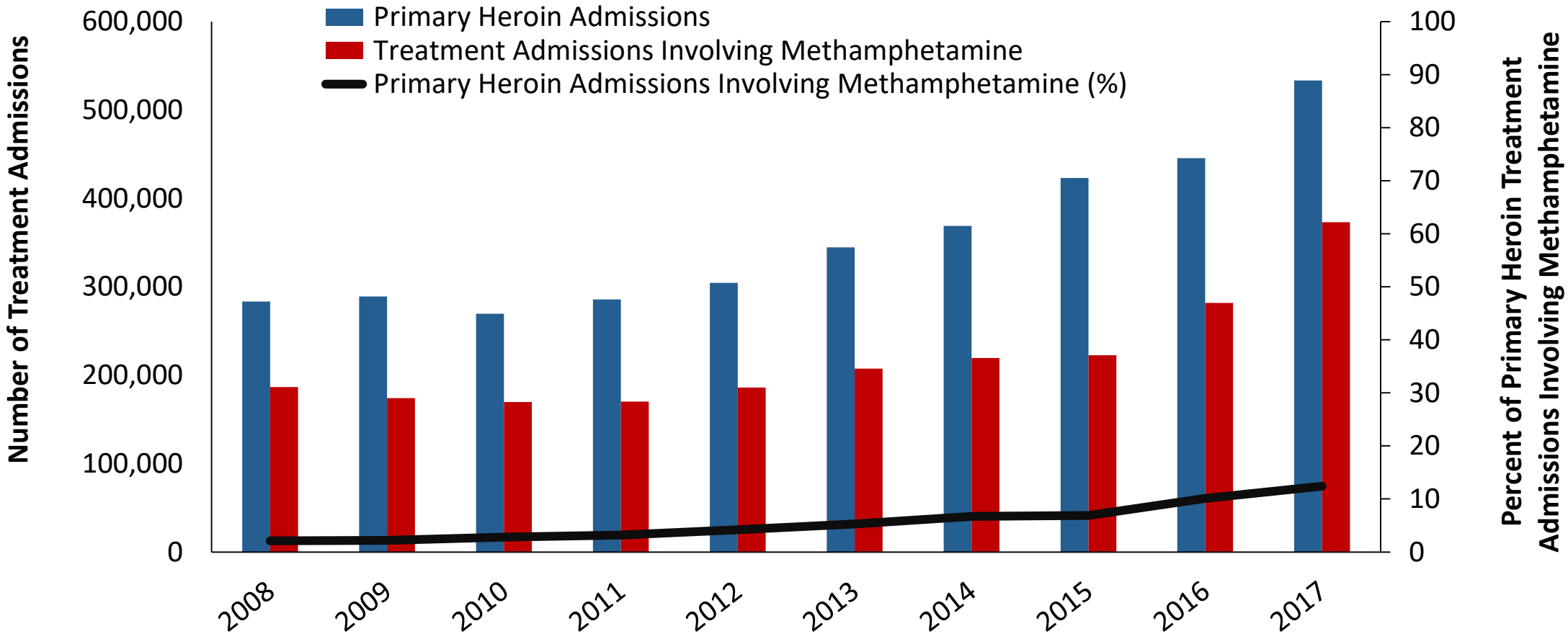
17%
of high- dose patients overdosed again within two years

- **33-39% of those with active opioid prescriptions during follow-up were also prescribed benzodiazepines.**

MR Larochelle, JM Liebschutz, F Zhang, et al. *Ann Intern Med*. 2016;164(1):1-9.

Methamphetamine (and other stimulants): An Emerging Issue

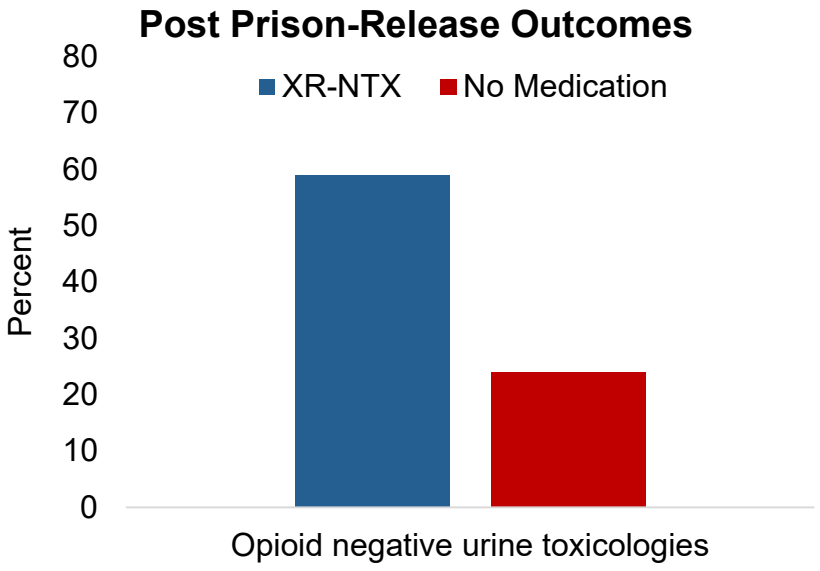
Heroin and Methamphetamine Treatment Admission in the U.S.



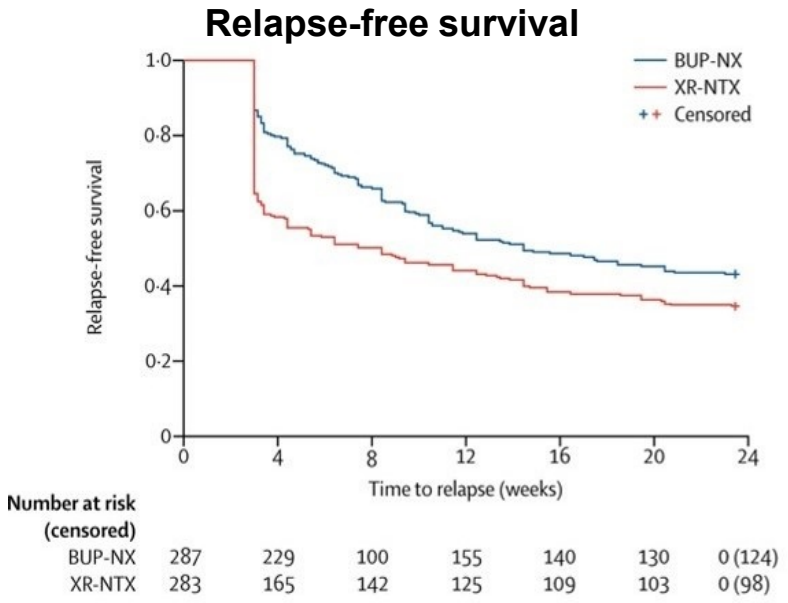
CM Jones, N Underwood, W Compton. *Addiction* 2019;(2):347-353

Science = *Solutions*: Improving Addiction Treatment

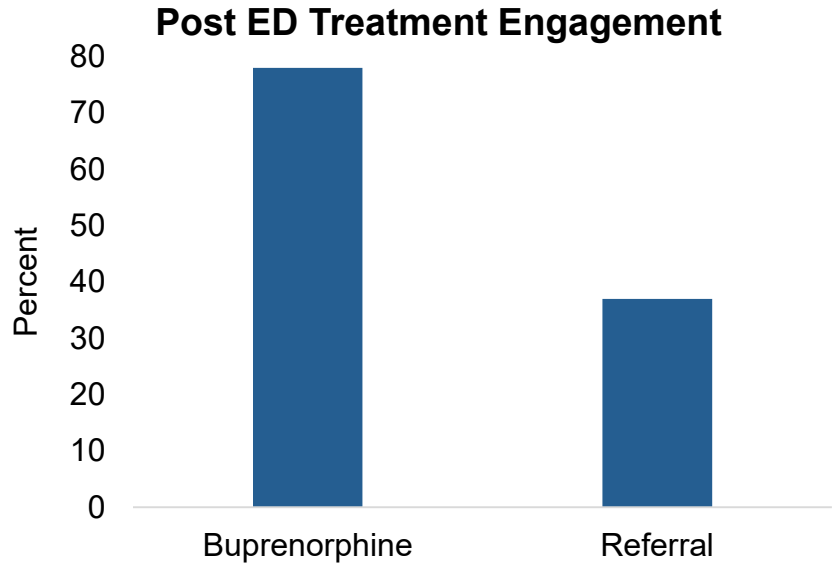
- Initiating buprenorphine treatment in the emergency department improves treatment engagement and reduces illicit opioid use
- Extended-release naltrexone initiated in criminal justice settings lowers relapse rates and overdoses
- BUP-Nx more effective the XR-Naltrexone overall but appear equally safe and effective after induction



JD Lee, et al., *Addiction.* 2015;100:1008-1014
and NEJM. 2016;374:1232-1242

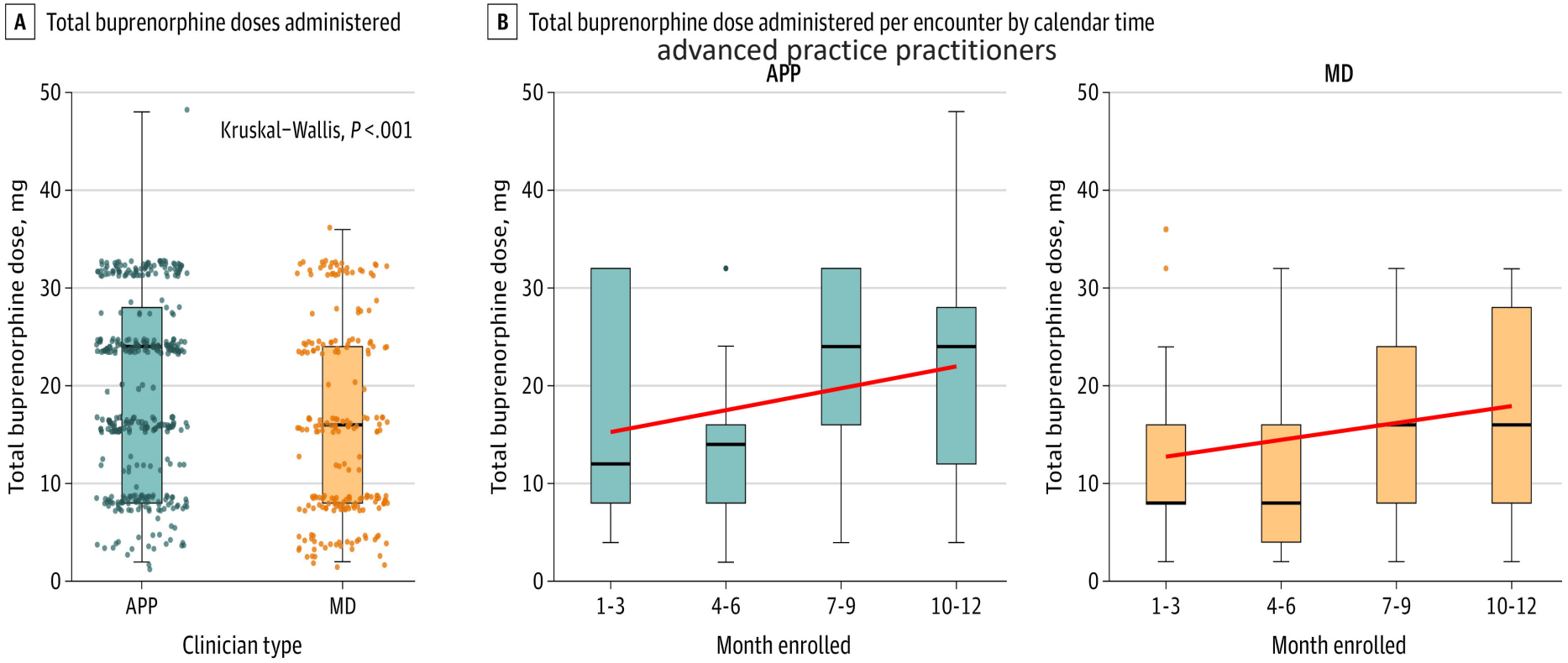


JD Lee, et al., The Lancet. *2018*;(391)10119:309-318.



G D'Onofrio, PG O'Connor, MV Pantalon, et al.
JAMA. 2015;313(16): 1936-44

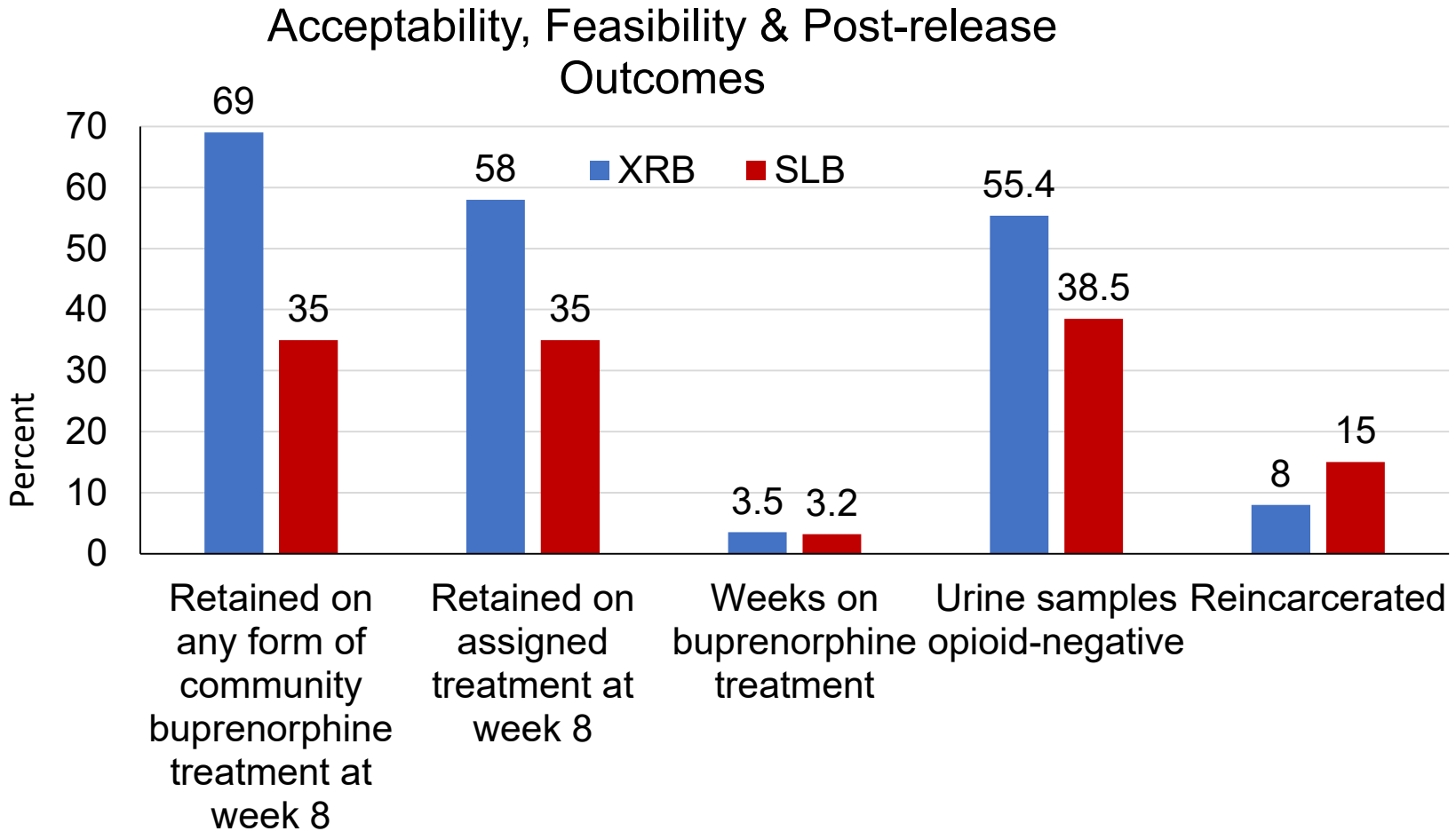
CTN: ED-administered, High-dose Buprenorphine >12 mg) May Enhance OUD Treatment Outcomes



High-dose Buprenorphine induction was safe and well tolerated in untreated OUD patients (n=391). No cases of respiratory depression or sedation. 5 cases of precipitated w/d were not associated with dose.

AA Herring, AA Vosooghi, J Luftig, et al. JAMA Network Open. 2021;4(7):e2117128

Extended-Release vs Daily Buprenorphine in Adults (n=52) with OUD at Time of Release From Jail



- XR-Bup was acceptable and had fewer in-jail clinic visits and increased treatment retention when compared with daily Bup treatment.
- These results support wider use and further study of XR-Bup in correctional and reentry OUD treatment.

JD Lee, M Malone, R McDonald, et al., JAMA Network Open. 2021;4(9):e2123032

Treating Stimulant Use Disorder

ADAPT-2 Trial Results Deliver a Breakthrough in Long Search for Methamphetamine Use Disorder Medication

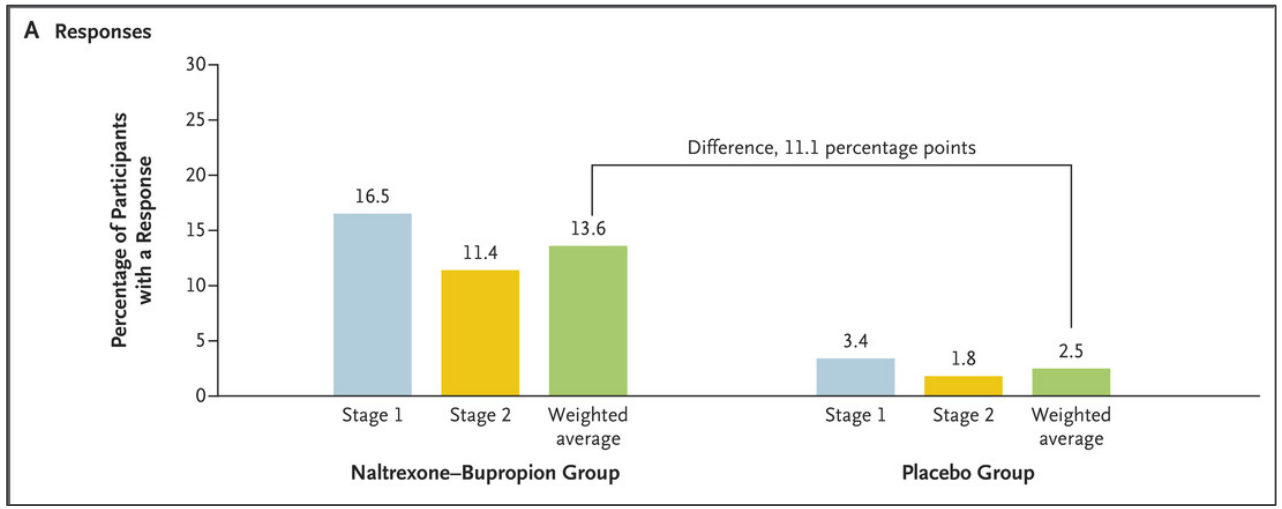
- No FDA approved medications for stimulant use disorder or overdose
- Contingency management is the most effective treatment but is challenging to implement and underutilized
- NIDA prioritizing investment in development of medications to treat stimulant use disorders

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

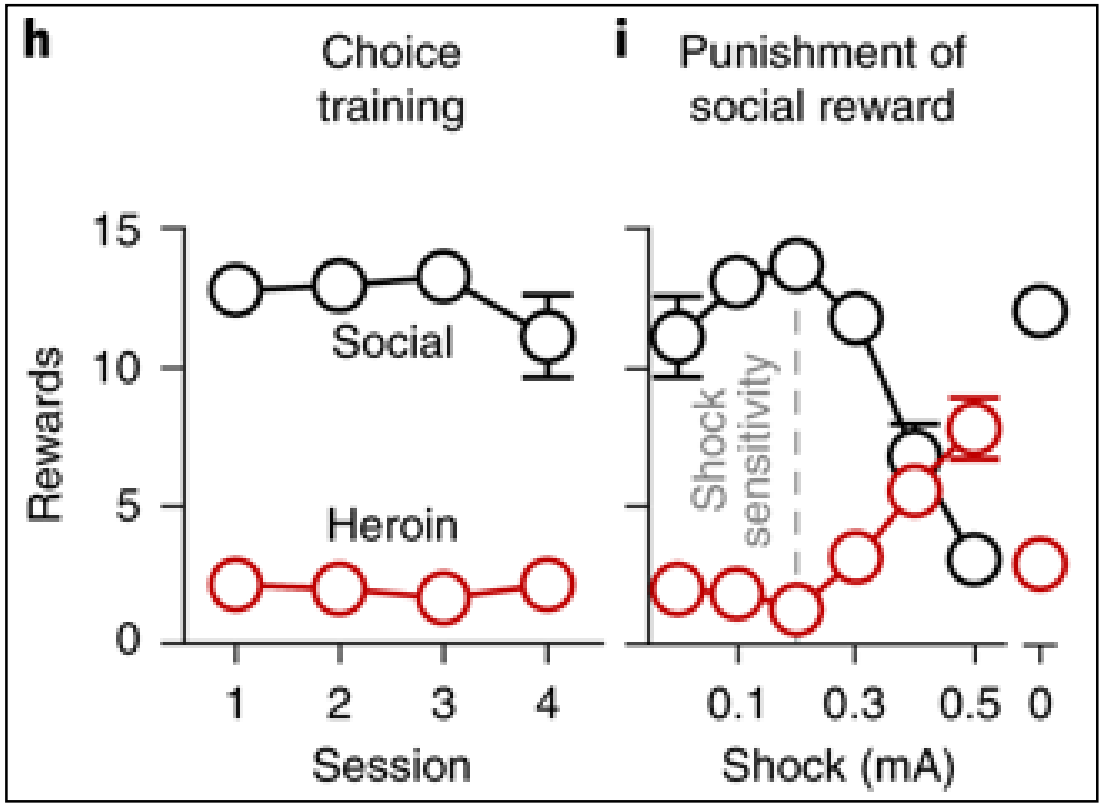
Bupropion and Naltrexone in Methamphetamine Use Disorder

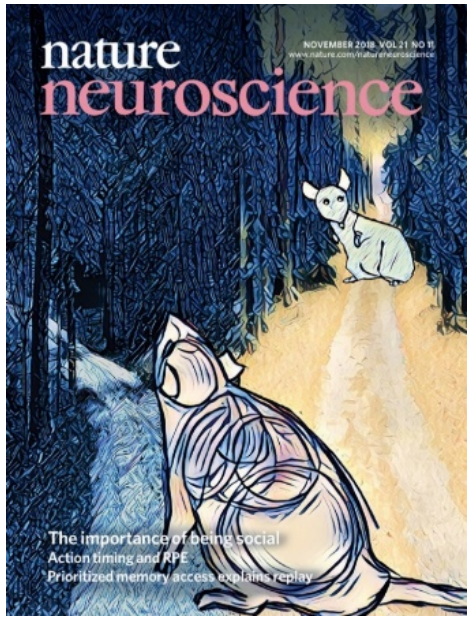
M.H. Trivedi, R. Walker, W. Ling, A. dela Cruz, G. Sharma, T. Carmody, U.E. Ghitza, A. Wahle, M. Kim, K. Shores-Wilson, S. Sparenborg, P. Coffin, J. Schmitz, K. Wiest, G. Bart, S.C. Sonne, S. Wakhlu, A.J. Rush, E.V. Nunes, and S. Shoptaw

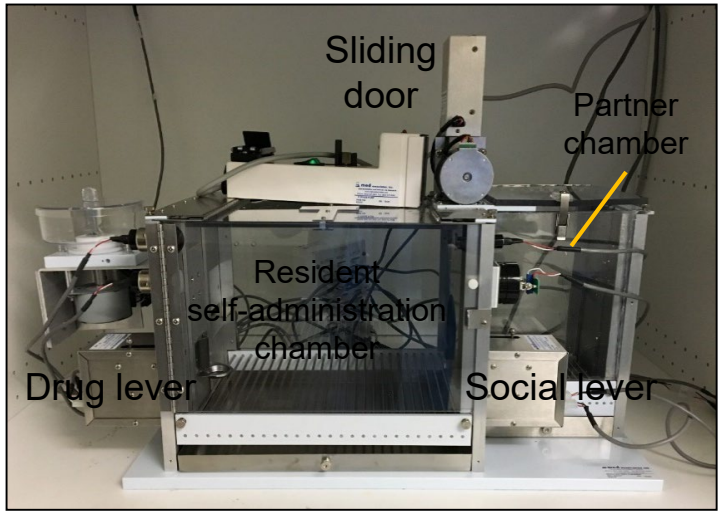


Social Interaction Preferred Over Drug

Drug preference increases when social reward is punished







M Venniro, M Zhang, D Caprioli, et al. Nature Neuroscience. 2018; 21:1520-1529

Selected FDA Actions in Response to the Opioid Crisis

Doris Auth

U.S. Food and Drug Administration

FDA's Actions to Educate Prescribers on Pain Management and Safe Use of Opioids

Doris Auth, Pharm.D.
Deputy Director, Division of Risk Management
OSE/CDER/FDA

Duke Margolis Meeting Oct 13-14

Outline

- Risk management actions to address opioid crisis
- Background on Risk Evaluation and Mitigation Strategies (REMS) and restricted distribution operations
- REMS for opioid analgesics
  - Rationale for 2012 Extended-Release and Long-Acting REMS "ER/LA REMS"
  - Rationale for 2018 modification to the Opioid Analgesic REMS "OA REMS"
- REMS assessment results and challenges
- Impact of REMS with mandatory prescriber education for all opioid analgesics

Risk mitigation approaches

Labeling

a. **Boxed warning**
b. Contraindications
c. Warnings and Precautions
d. Medication Guide

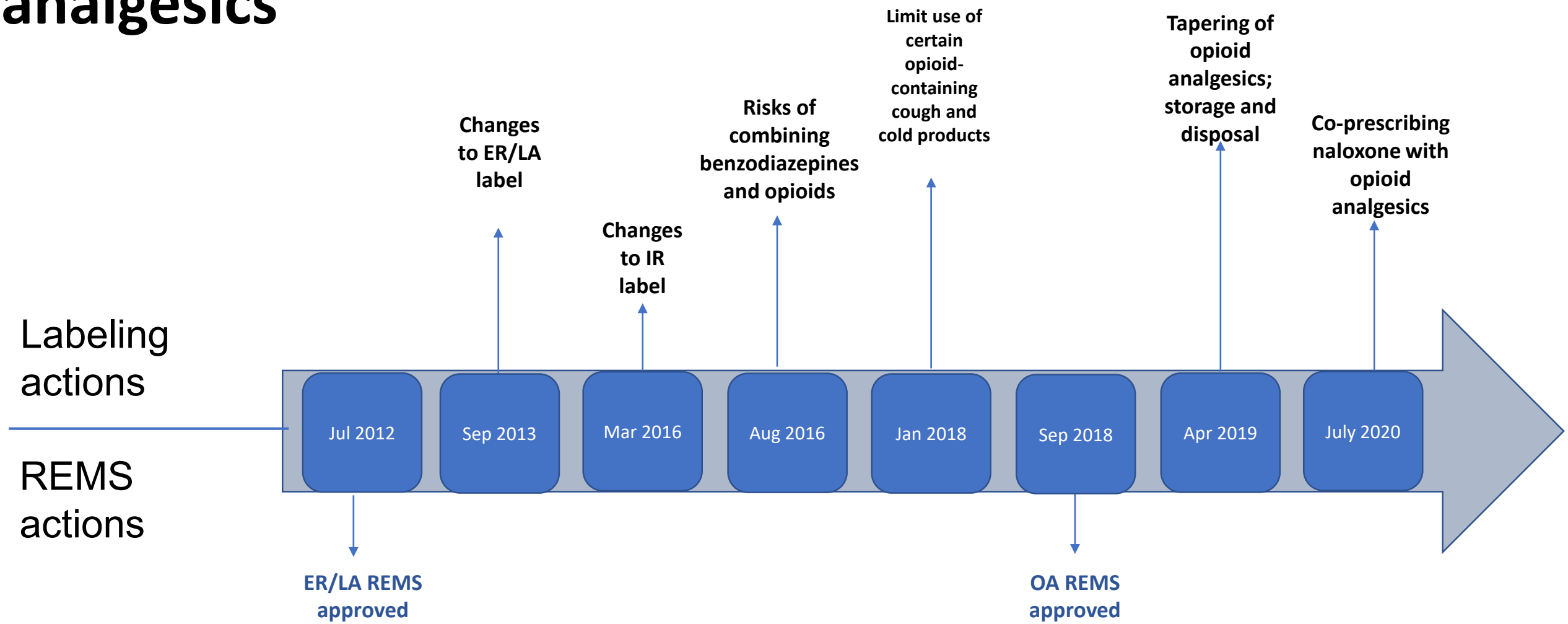
Risk Evaluation and Mitigation Strategy (REMS)

a. Drug safety programs that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the drug outweigh its risks.

b. FDA has the authority to require a REMS before approval or post approval if FDA becomes aware of new safety information.

Timeline of selected FDA opioid risk mitigation actions

Selected FDA actions to mitigate risks of opioid analgesics



FDA Opioid timeline at:
https://www.fda.gov/drugs/information-drug-class/timeline-selected-fda-activities-and-significant-events-addressing-opioid-misuse-and-abuse, accessed September 22, 2021

RISK EVALUATION AND MITIGATION STRATEGIES (REMS) BACKGROUND

When determining need for REMS the following must be considered

- The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug;
- The expected benefit of the drug with respect to the disease or condition;
- The seriousness of the disease or condition that is to be treated with the drug;
- Whether the drug is a new molecular entity;
- The expected or actual duration of treatment with the drug; and
- The estimated size of the population likely to use the drug.

FD&C Act, Section 505-1(a)(1)

REMS include one or more of the following elements

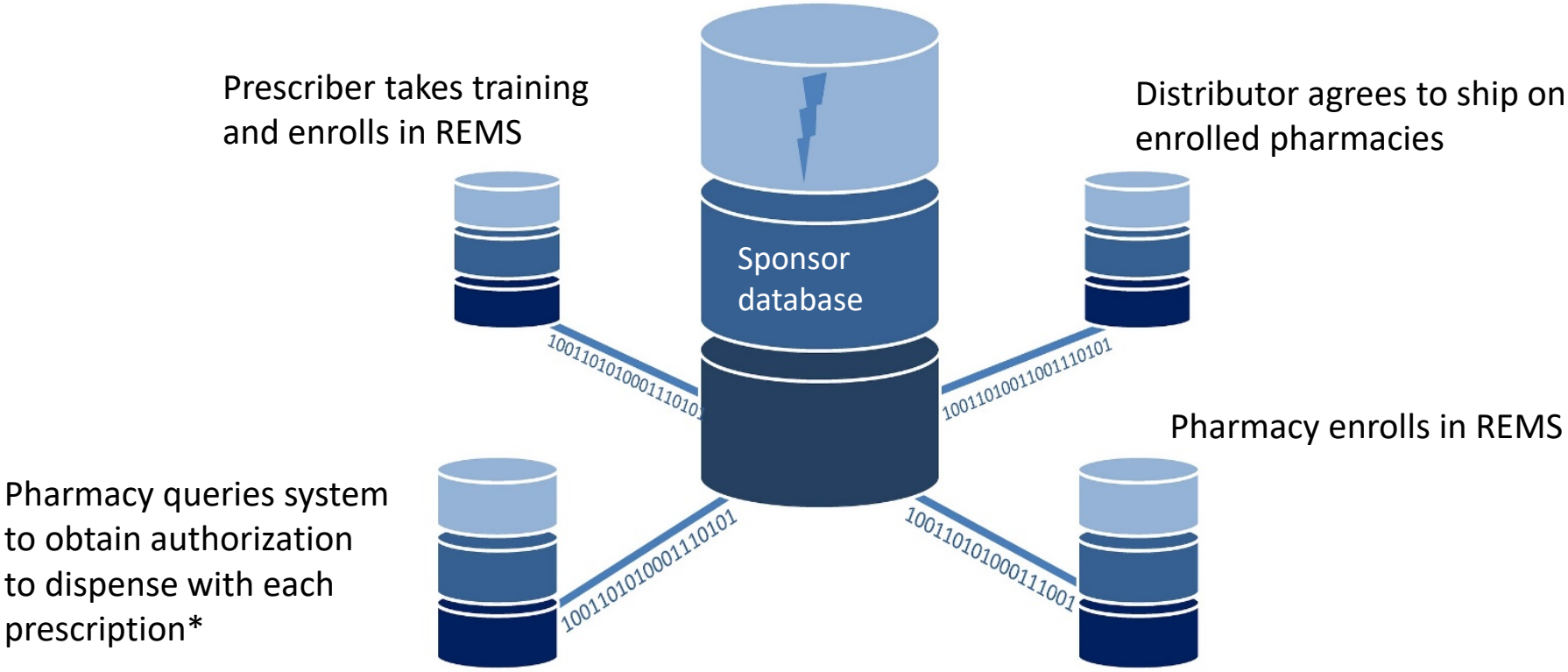
- Medication Guide
- Communication Plan*
- Certain packaging and safe disposal requirements for drugs that pose a serious risk of abuse or overdose
- Elements to Assure Safe Use
- Implementation system
- Timetable for Submission of Assessments

*Communication plans are targeted to prescribers and professional organizations

Additional key points about REMS

- Drug sponsors design, develop and implement REMS programs, FDA review REMS and approves them
- Drug sponsors are required to conduct and submit assessments of the REMS and FDA reviews them to determine if the REMS is meeting its goals
- REMS programs can be designed for a single drug or a class of drugs
- REMS with ETASU are to be designed so they are not *unduly* burdensome on patient access to the drug, and to the extent practicable, minimize the burden on the healthcare delivery system
  - If certification and education is mandatory for prescribers, a system must be in place to ensure that no drugs are dispensed when written by non-certified prescribers

Current Operations for REMS with required prescriber education



*Obtaining authorization within pharmacy workflow currently not available

EXTENDED-RELEASE AND LONG-ACTING OPIOID ANALGESIC REMS (ER/LA REMS)

2012-2018

History of the ER/LA REMS development

- During 2009 and 2010, FDA sought stakeholder input on a REMS for opioids
  - Potential REMS requirements considered included mandatory prescriber education, enrollment of patients, and patient-prescriber agreements
- FDA determined the REMS would include:
  - Prescriber education only – limit REMS burden; education was to aid in patient selection and counseling and inform prescribers about how to recognize the potential for and evidence of addiction, dependence, and tolerance
  - ER/LA opioid analgesics – riskier products due to the higher concentration of opioids per dosage form
  - Education required to be made available by the manufacturers, but prescribers not required to complete it in order to prescribe - limit burden on healthcare system and avoid impact on patient access for patients with legitimate pain control needs
    - As mandatory prescriber education was not required, there was no core set of knowledge that all prescribers of opioid analgesics had in common.

Goal of the ER/LA REMS

- To reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of extended-release or long-acting (ER/LA) opioid analgesics while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death

ER/LA REMS approved July 9, 2012

- Manufacturers required to make education available
  - Through grants to CE providers; content independent of manufacturers and must be based on FDA blueprint
  - CE Programs typically 2-3 hours in duration
  - Post-CE knowledge assessment required for credit and to be counted as "completer" for the REMS
- Specific training targets outlined
- REMS assessment focused on
  - evaluation of prescriber and patient knowledge,
  - surveillance of events of interest,
  - and drug utilization trends

Public discussion of the ER/LA REMS assessment findings

- **In 2016** the 36-month ER/LA REMS assessment was the subject of a joint meeting of the Drug Safety and Risk Management and the Anesthetic and Analgesic Drug Products Advisory Committees to obtain input on whether:
  - the REMS is meeting its goals
  - there are alternative methodologies for evaluating the program
  - the FDA educational blueprint should be revised and/or expanded;
  - to expand the REMS program to include IR opioid analgesics; and
  - whether additional modifications should be made to the REMS

*https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm486856.htm

Advisory Committee recommendations for modifying the ER/LA REMS

- The REMS should be expanded to include the immediate-release opioid analgesics
- The focus of the education should be expanded to include pain management and risk/benefit of different treatments
- Training should be expanded to entire health care team, not only prescribers
- The training should be mandatory for prescribers; most preferred this be implemented either through DEA registration or state licensure
  - 2017 FDA public meeting explored mandatory education with similar recommendation

Advisory Committee recommendations on evaluating the impact of the REMS

- Improve survey sampling
- Clarify expectations for drug utilization changes
  - Reducing the number of opioid analgesic prescriptions is not helpful without some evaluation of whether the prescribing is appropriate or inappropriate; the committee struggled with how to define appropriate prescribing
- Link drug utilization and patient outcomes data to completion of REMS educational program
  - To understand if/how education directly affects prescriber behavior and patient outcomes
  - *Most CE providers do not collect information on individual prescribers that would be necessary for linking*

Modified Opioid Analgesic REMS (OA REMS)

2018-present

The **Modified** Opioid Analgesics REMS was approved in September 2018

- Includes all IR, ER, and LA opioid analgesics intended for use in outpatient settings
- The primary component of the OA REMS is education that is targeted to prescribers, pharmacists, nurses and other providers involved in treatment and monitoring of patients with pain
- Same process as ER/LA REMS via grants from manufacturers to accredited CE providers with content based on a revised FDA blueprint; content is independent of the companies that fund the CE

The education under the modified Opioid Analgesics REMS remains voluntary for prescribers and is not required to prescribe or dispense the drug

Goal of the OA REMS

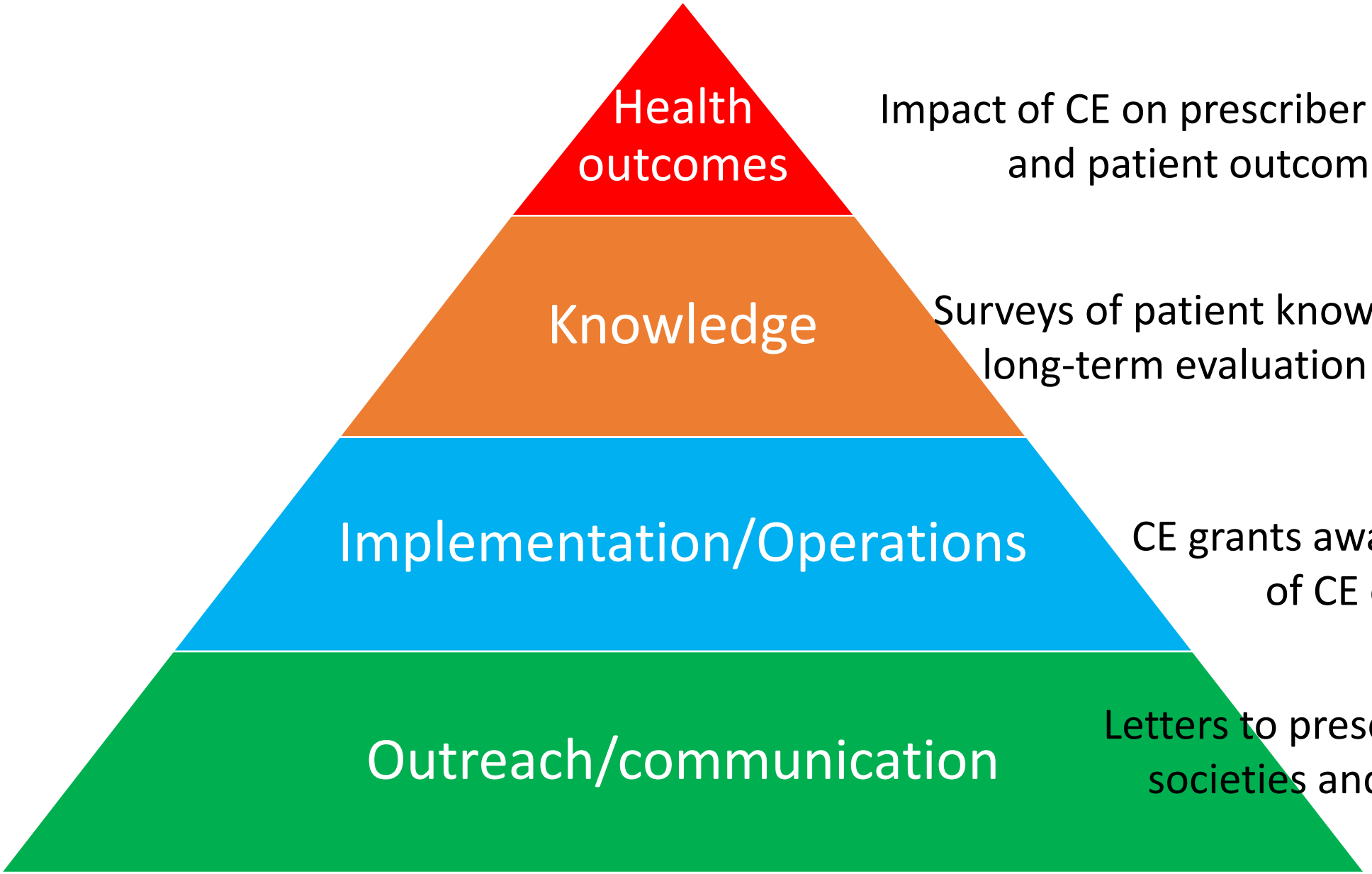
The goal of the Opioid Analgesic REMS is to educate prescribers and other healthcare providers (including pharmacists and nurses) on the treatment and monitoring of patients with pain. The education provided through the REMS program is based on the Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint"). Through better education, the healthcare team will have an improved understanding of how to manage pain and the role of opioid analgesics along with nonpharmacologic and non-opioid analgesics in pain management. The education will also provide information about the risks of opioids and use of other therapies which is intended ***to assist healthcare providers in reducing adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse.***

The REMS will accomplish this goal by:

- **Ensuring that training based on the FDA Blueprint is effective** in educating prescribers and other healthcare providers involved in the treatment and monitoring of patients in pain (including pharmacists and nurses) about recommended pain management practices and appropriate use of opioid analgesics.
- **Informing patients about their roles and responsibilities regarding their pain treatment plan**, including the risks of opioid analgesics and how to use and store them safely, as outlined in the Medication Guides and Patient Counseling Guide for opioid analgesics.

OPIOID ANALGESIC REMS ASSESSMENT

OA REMS assessment categories



Impact of CE on prescriber behavior and patient outcomes

Surveys of patient knowledge; pre/post and long-term evaluation of CE completers

CE grants awarded and number of CE completers

Letters to prescribers, professional societies and licensing boards

REMS assessments – additional data collected

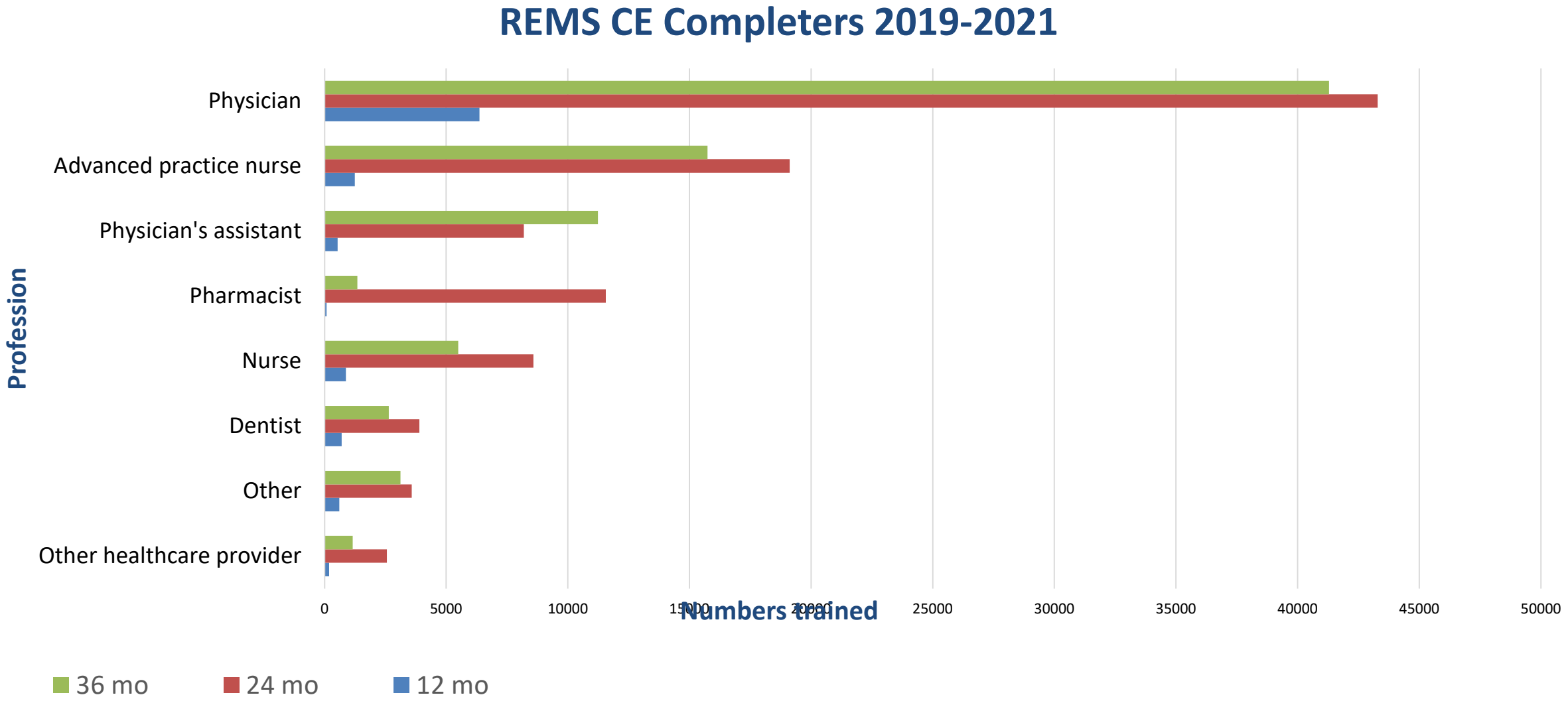
- Landscape analysis
  - An evaluation of concurrent educational interventions (states and health system requirements)
  - Summary of major legislative and policy changes
- National data on opioid misuse, abuse, overdose, addiction, and death
  - Mortality data, poison center call data, emergency department visits, national survey data
- National drug utilization trends/patterns
  - Opioid analgesics by drug, prescriber specialty, concomitant benzodiazepines and other CNS depressants
- Evaluation of prescribers' key influences on opioid prescribing

REMS CE Learner Metrics: CE Completers*

REMS	Dates	Completers
ER/LA	2/28/13-7/18/2020	161,543
OA	3/1/19-5/15/2021	193,406
Total		354,949

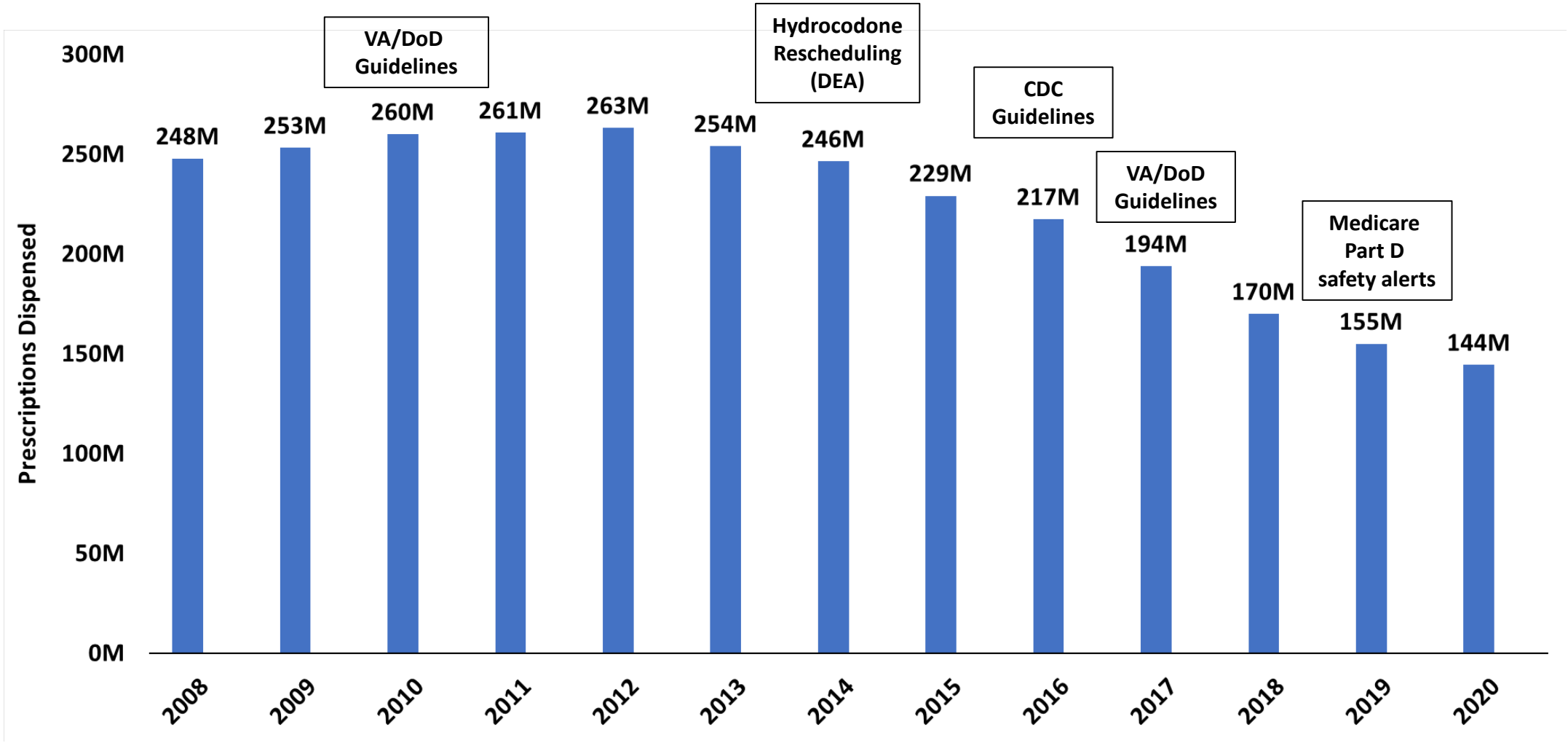
*Completer: an individual that has completed all components of an educational activity and meets the CE provider's criteria for passing

OA REMS assessment results- CE completers



Challenges in assessing the impact of the OA REMS on prescriber behavior and patient outcomes

Selected* non-FDA Federal Interventions



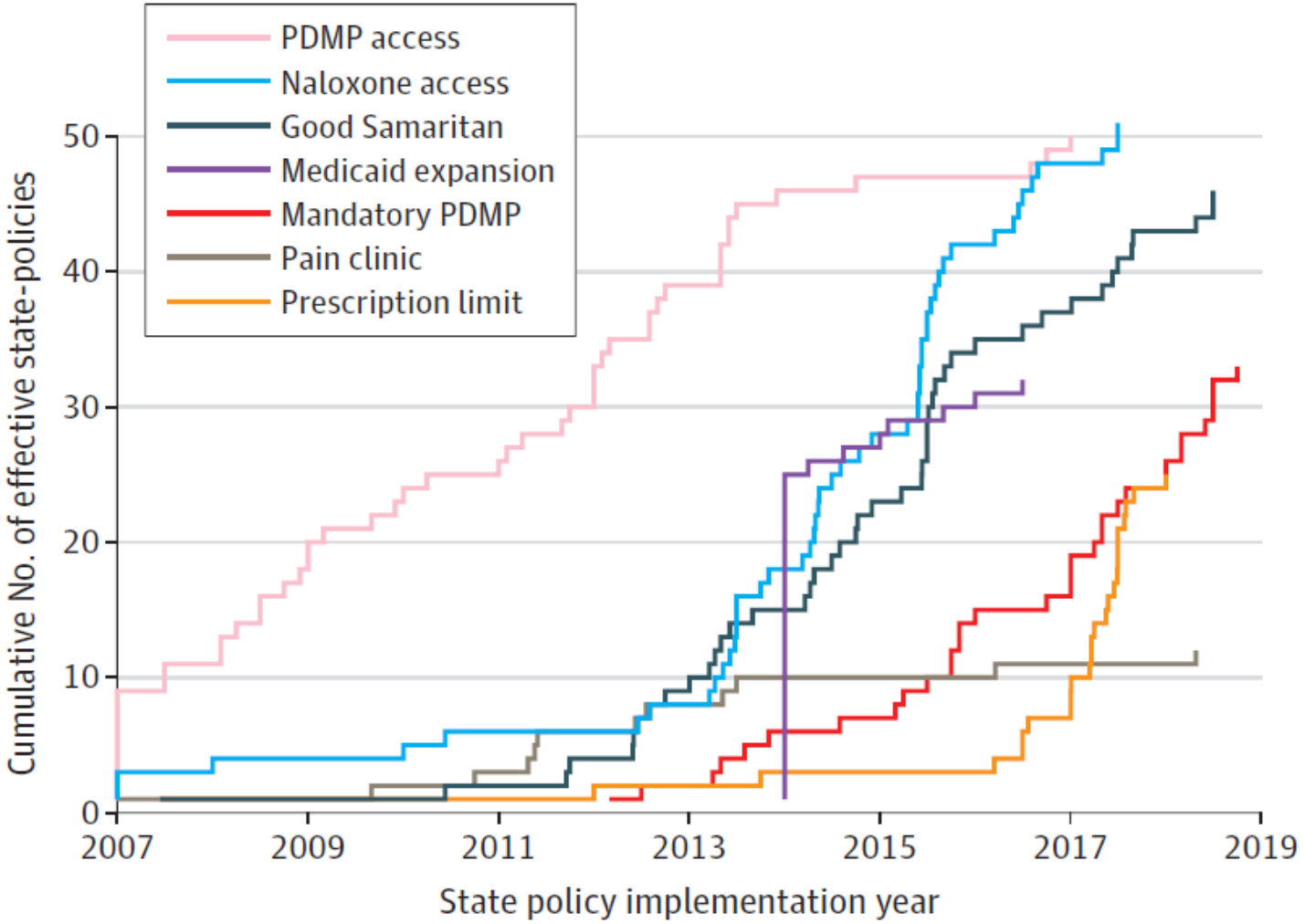
Nationally Estimated Number of Opioid Analgesic Prescriptions Dispensed from U.S. Outpatient Pharmacies, 2008–2020.

Source: IQVIA, National Prescription Audit™. 2008-2020. Data extracted July 2021. Data included opioid analgesics only, excluding opioid-containing cough-cold products or products labeled for treating opioid use disorder. Any changes over time must be interpreted in the context of the changes in methodology between 2016 and 2017 and between 2018 and 2019. Outpatient pharmacies included both retail and mail-order pharmacies.

* Only selected major federal interventions are noted on this figure. This is not a comprehensive list of interventions targeting opioid analgesic prescribing.

State-level Interventions

Implementation of State Policies from 2007 to 2018



Over 40 states require some CE on opioid prescribing, pain management, controlled substance, and/or substance use disorder for licensure—requirements vary by state.

Source: Lee et al 2021 JAMA Open Network; 4(2):e2036687

Challenges in assessing the impact of the OA REMS on prescriber behavior and patient outcomes

1. Many concurrent interventions (including other educational programs)
2. Voluntary CE subject to self-selection bias
3. Identifying meaningful, measurable outcomes
   - "Appropriate" prescribing for individual patients, clinical scenarios
   - Other pain management best practices (e.g., multi-modal approach)
   - Patient-centered outcomes (e.g., pain, function, opioid-related AEs/overdose)
   - Broader public health impacts

Requiring prescriber education under the OA REMS

Modifying the OA REMS to include mandatory prescriber education will require

- Defining clear, measurable outcomes
- Verifying prescriber education status with each dispense
  - Development of database to capture multiple stakeholder types (e.g., pharmacist, prescriber, distributor)
  - Pharmacists query database prior to each dispense; pharmacist taken out of workflow

Mandatory prescriber education under a REMS

Will Impact:

- 980,000 opioid prescribers 2020*
- 88,000 retail pharmacies
  - 144.3 million prescriptions**
- 41.2 million patients***

In comparison – annual impact of largest REMS:

- *20,000 prescribers*
- *50,000 pharmacies*
  - *2,050,000 prescriptions*
- *530,000 patients*

*Source: Source: 36-month Opioid Analgesics REMS Assessment, submitted September 2021, page 1113. REMS data based upon IQVIA Xponent database. Data did not include opioid analgesics covered under another REMS program, such as transmucosal immediate-release fentanyl.
**Source: IQVIA National Prescription Audit™. Data year 2020, extracted Sept 2021. Estimated opioid analgesic prescriptions dispensed from U.S. outpatient retail and mail-order pharmacies.
***Source: Total Patient Tracker™. Data year 2020, extracted Sept 2021. Estimated number of patients who received opioid analgesic prescriptions dispensed from U.S. outpatient retail pharmacies.

BACKUP SLIDES REMS PRESENTATION

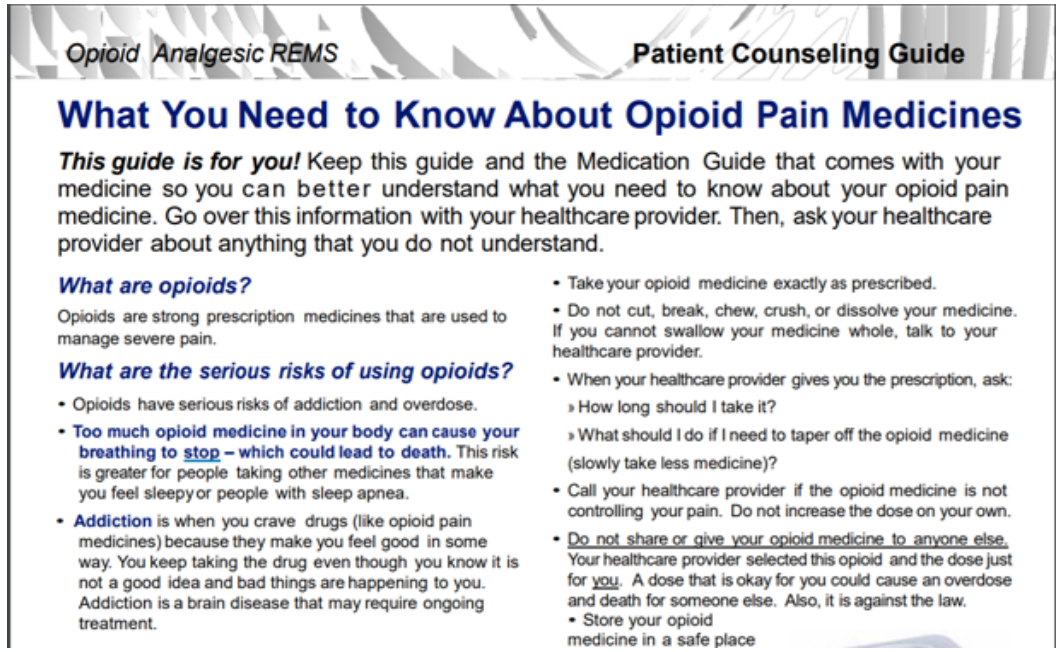
Product labels for immediate release and extended-release and long-acting opioid analgesics

IR Opioid Label (Roxicodone)

ERLA Opioid Label (MS Contin)

Patient materials

- Product-specific Medication Guides
- Patient Counseling Document



Opioid Analgesic REMS **Patient Counseling Guide**

What You Need to Know About Opioid Pain Medicines

This guide is for you! Keep this guide and the Medication Guide that comes with your medicine so you can better understand what you need to know about your opioid pain medicine. Go over this information with your healthcare provider. Then, ask your healthcare provider about anything that you do not understand.

What are opioids?

Opioids are strong prescription medicines that are used to manage severe pain.

What are the serious risks of using opioids?

- Opioids have serious risks of addiction and overdose.
- **Too much opioid medicine in your body can cause your breathing to stop – which could lead to death.** This risk is greater for people taking other medicines that make you feel sleepy or people with sleep apnea.
- **Addiction** is when you crave drugs (like opioid pain medicines) because they make you feel good in some way. You keep taking the drug even though you know it is not a good idea and bad things are happening to you. Addiction is a brain disease that may require ongoing treatment.
- Take your opioid medicine exactly as prescribed.
- Do not cut, break, chew, crush, or dissolve your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider.
- When your healthcare provider gives you the prescription, ask:
  - How long should I take it?
  - What should I do if I need to taper off the opioid medicine (slowly take less medicine)?
- Call your healthcare provider if the opioid medicine is not controlling your pain. Do not increase the dose on your own.
- Do not share or give your opioid medicine to anyone else. Your healthcare provider selected this opioid and the dose just for you. A dose that is okay for you could cause an overdose and death for someone else. Also, it is against the law.
- Store your opioid medicine in a safe place

Blueprint overview

ER/LA REMS

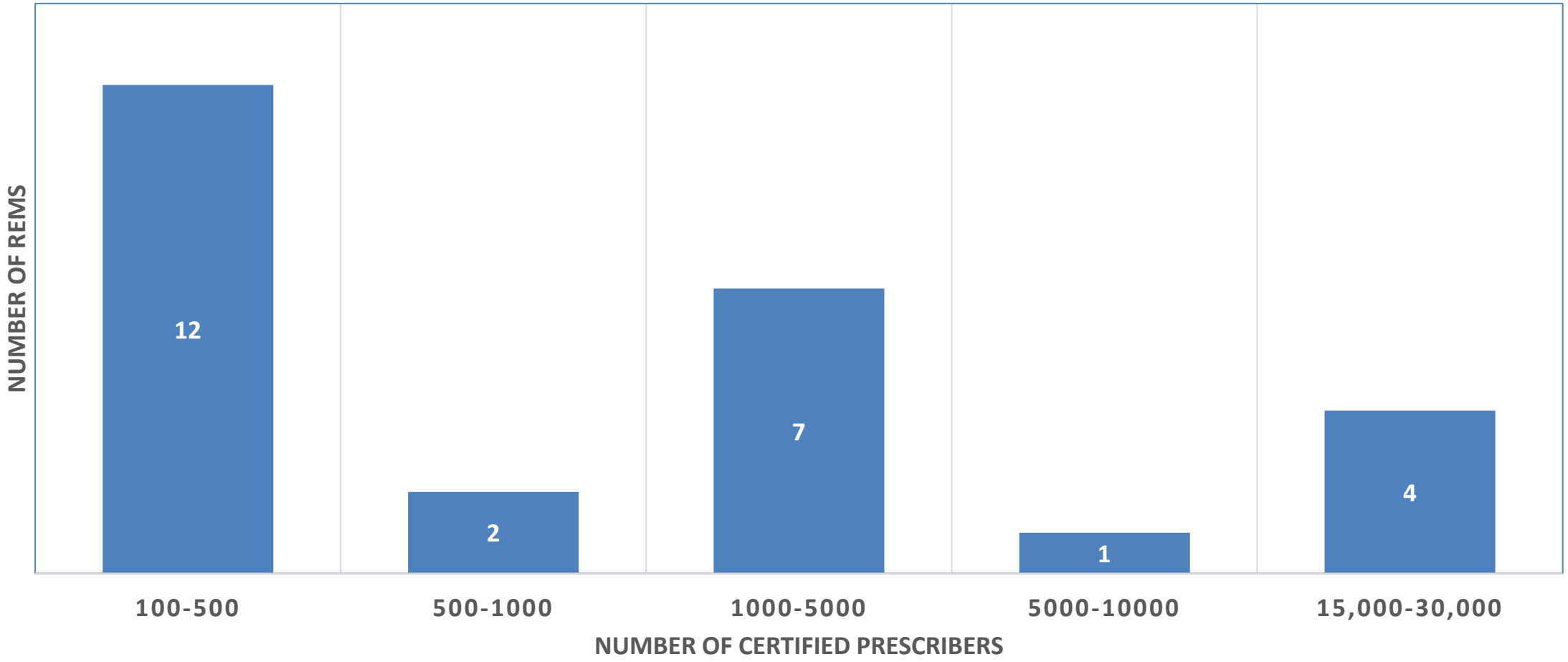
- Assessing Patients for Treatment with ER/LA OA Therapy
- Initiating Therapy, Modifying Dosing, and Discontinuing ER/LA OA
- Managing Therapy with ER/LA OA
- Counseling Patients and Caregivers about Safe Use of ER/LA OA
- General Drug Information for ER/LA Opioid analgesics
- Specific Drug Information for ER/LA Opioid analgesics

Opioid Analgesic REMS

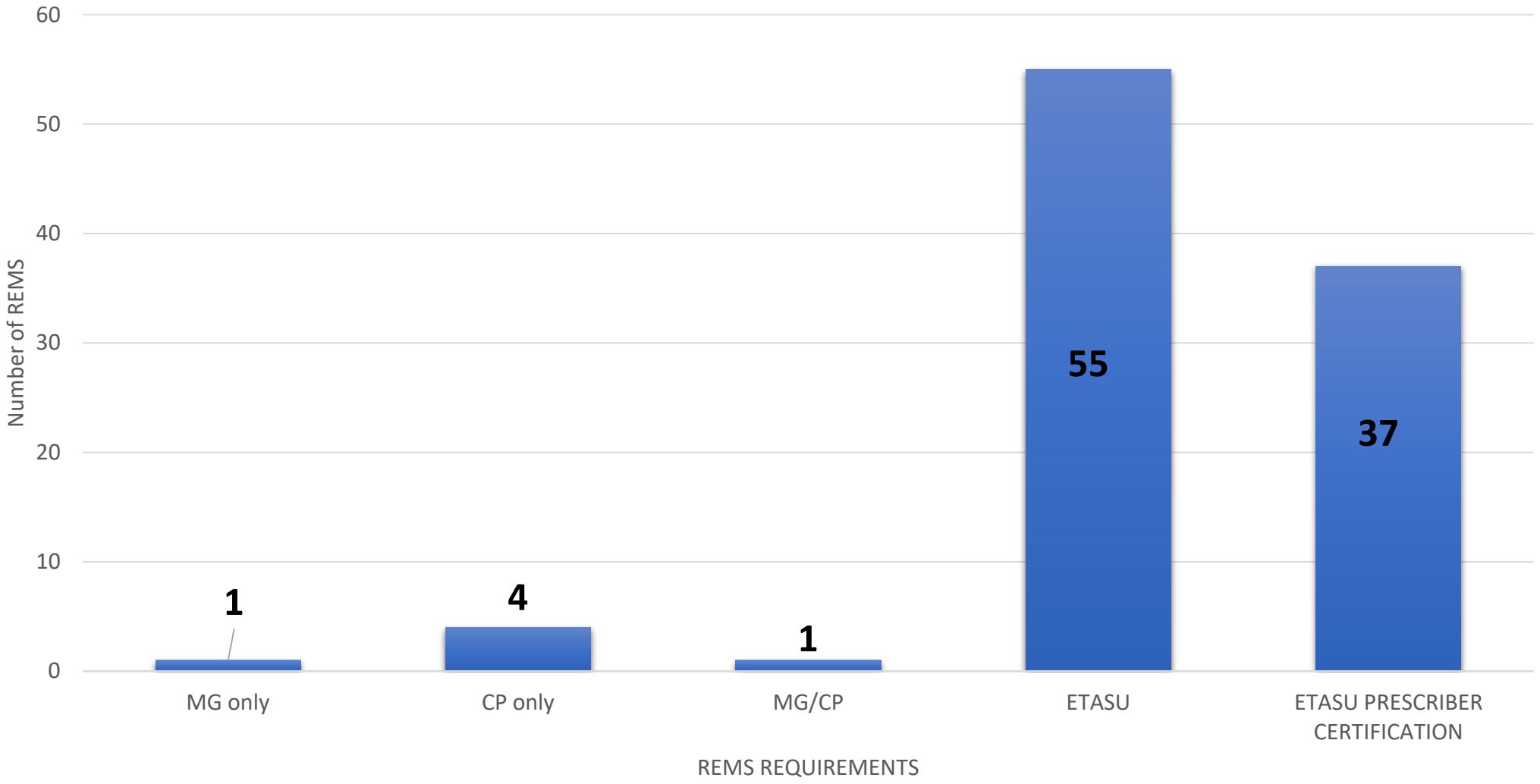
- The Basics of Pain Management
- Creating the Pain Treatment Plan
- General Principles of Pharmacologic Analgesic Therapy
- Managing Patients on Opioid Analgesics
- Addiction Medicine Primer

https://www.fmda.org/2017/Blueprint%20Opioid%20LA.ER%20REMS%20as%20of%201.20.2017.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf

Prescriber participation: REMS with prescriber certification requirements



CURRENTLY APPROVED REMS AND REQUIREMENTS



REMS@FDA accessed 9/16/21


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Prescription Opioid Utilization Patterns in the U.S.

Corinne Woods

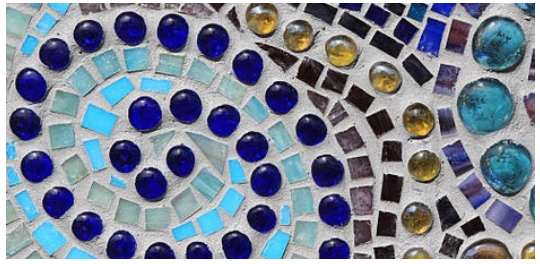
U.S. Food and Drug Administration

Prescription Opioid Utilization Patterns in the U.S.

Corinne Woods, RPh, MPH
Team Lead, Drug Utilization Team
Division of Epidemiology II, OPE/OSE/CDER/FDA
Duke-Margolis Meeting October 13-14

Objectives and Outline

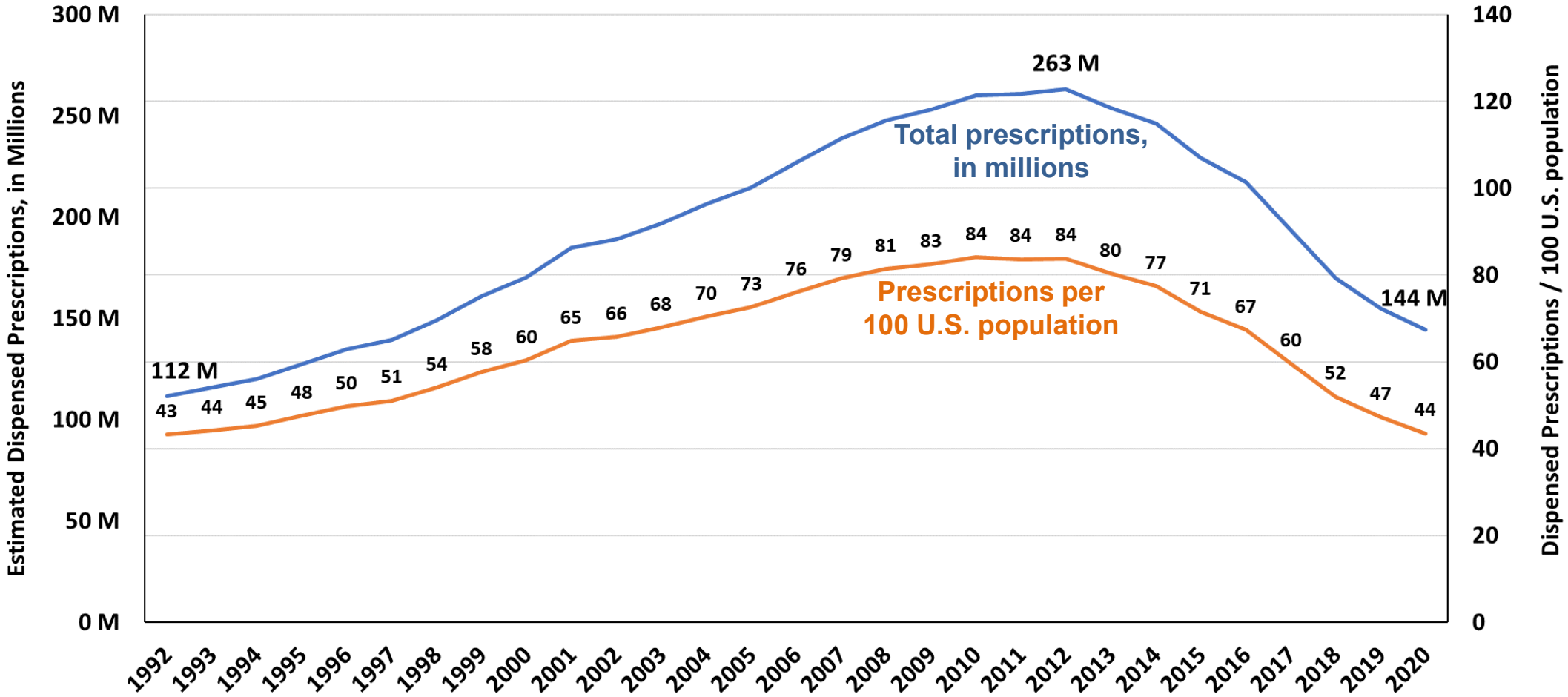
- Examine different facets of U.S. opioid analgesic utilization
  - Utilization patterns over time
  - Patient demographics
  - Prescription and patient characteristics
  - Prescriber specialties
  - Concomitant benzodiazepine prescriptions
- Describe use of buprenorphine for opioid use disorder



Dispensed Opioid Analgesic Prescriptions

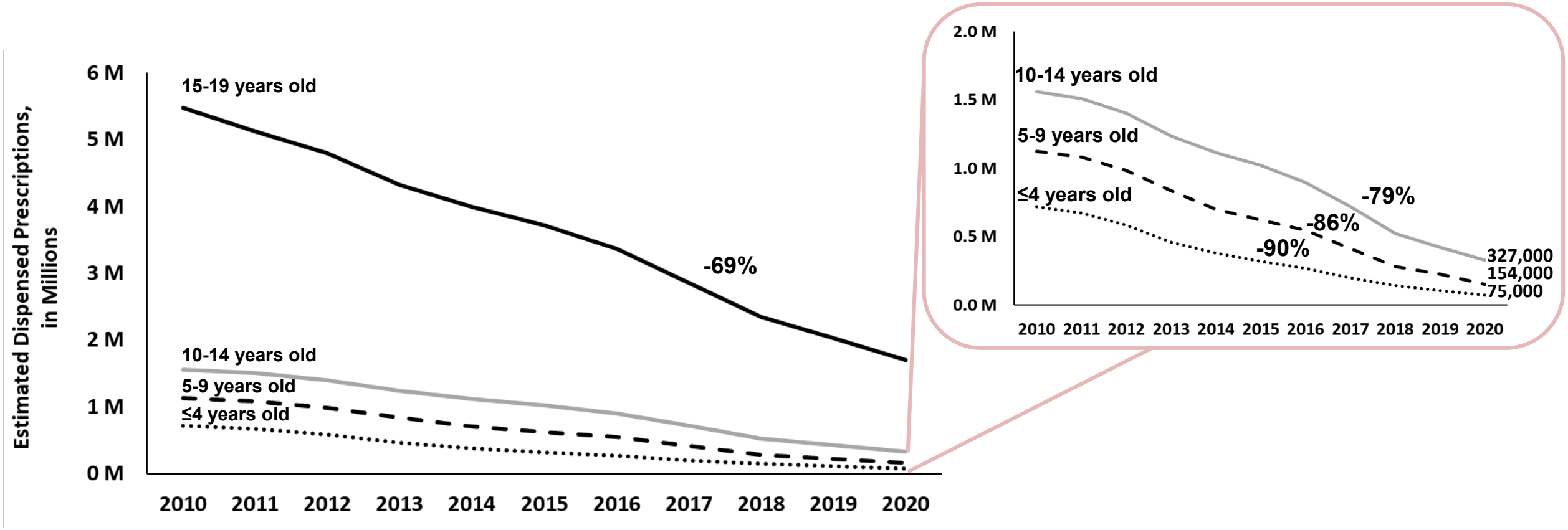
Patients with Opioid Analgesic Prescriptions

Large Declines in Opioid Analgesic Prescriptions



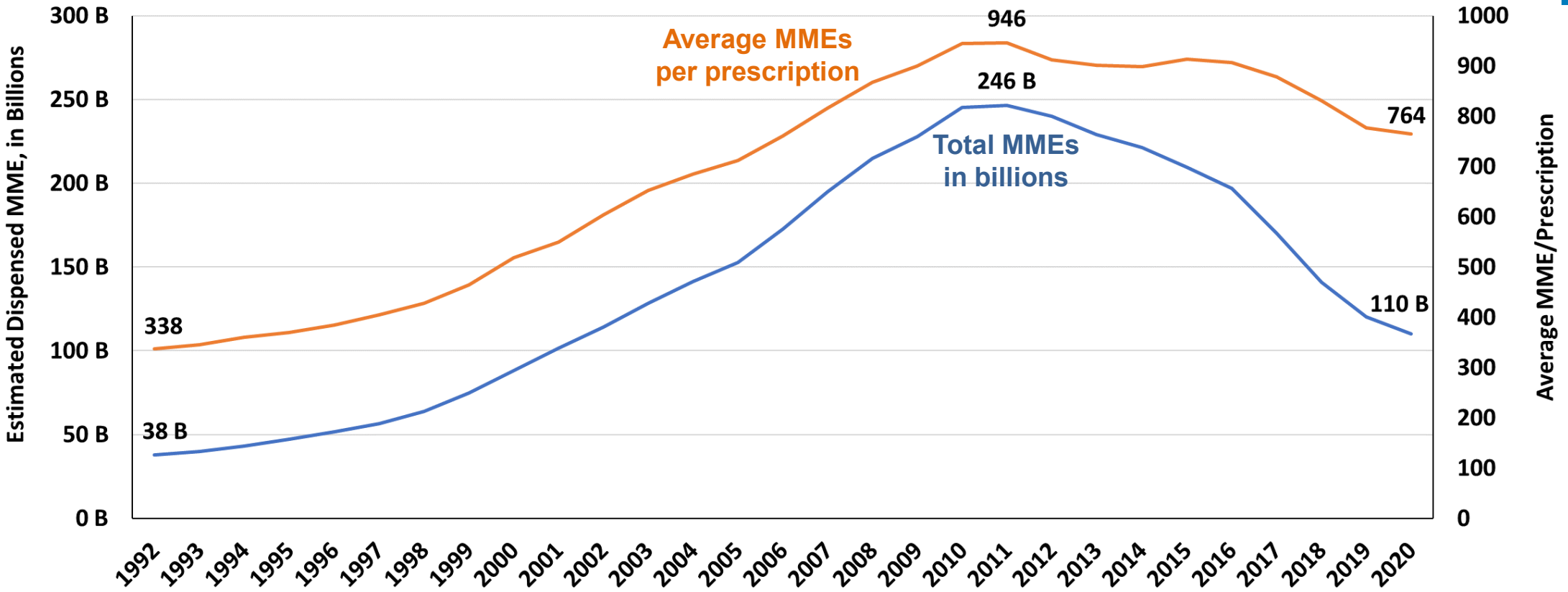
Estimated opioid analgesic prescriptions dispensed from U.S. outpatient pharmacies, total and per 100 U.S. population, 1992–2020.
Source: IQVIA, National Prescription Audit™, time period 1992-2020. Data extracted July 2021. M = millions. Outpatient pharmacies included retail and mail-order pharmacies. Data included opioid analgesics only, excluding cough-cold products and medications to treat opioid use disorder. Any changes over time must be interpreted in the context of the changes in methodology, specifically during two trend breaks between 2016 and 2017 and between 2018 and 2019.

Steeper Opioid Analgesic Prescription Declines Among Younger Patients



Estimated opioid analgesics prescriptions dispensed to patients 19 years old or younger from U.S. outpatient retail pharmacies, 2010–2020.
Source: IQVIA National Prescription Audit™, time period 2010-2020. M = millions. Data included opioid analgesics only, excluding injectable products, cough/cold products, medications labeled for opioid use disorder, and prescriptions written by veterinarians. Any changes over time must be interpreted in the context of the changes in methodology, specifically during two trend breaks between 2016 and 2017 and between 2018 and 2019.

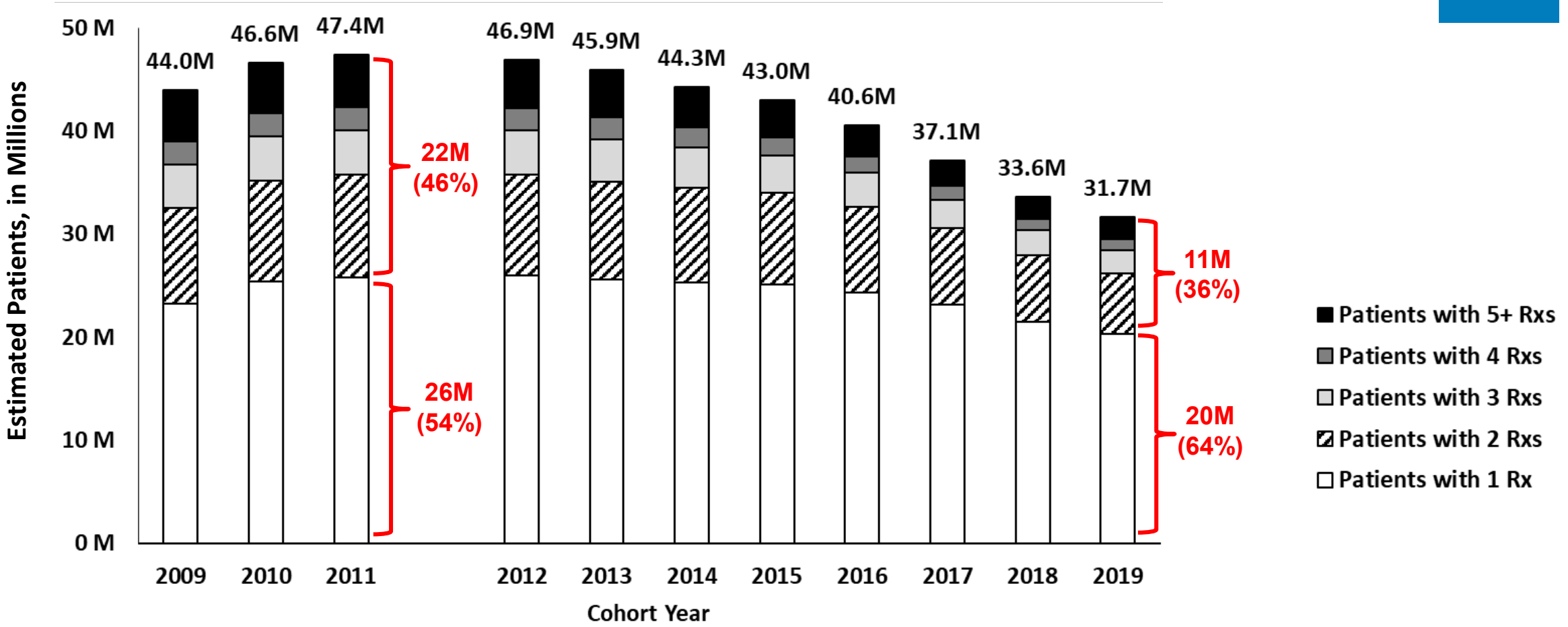
Smaller Declines in Morphine Milligram Equivalents (MMEs) per Prescription



Estimated morphine milligram equivalents (MMEs) dispensed from U.S. outpatient pharmacies, total and average per prescription, 1992–2020.
Sources: IQVIA, National Prescription Audit™, time period 1992-2020. Data extracted August 2021. B = billions. MME conversion factor sources: CDC File of National Drug Codes for Opioid analgesics, and Linked Oral Morphine Milligram Equivalent Conversion Factors, 2020 Version. Atlanta, GA: Centers for Disease Control and Prevention; 2021. Available upon request at https://www.cdc.gov/drugoverdose/resources/data.html, and other sources. MME are oral morphine milligram equivalents, sometimes represented as "OME". Outpatient pharmacies included retail and mail-order pharmacies. Data included opioid analgesics only, excluding cough-cold products and medications to treat opioid use disorder. Any changes over time must be interpreted in the context of the changes in methodology, specifically during two trend breaks between 2016 and 2017 and between 2018 and 2019.

Declines in New Outpatient Starts of Opioid Analgesics:

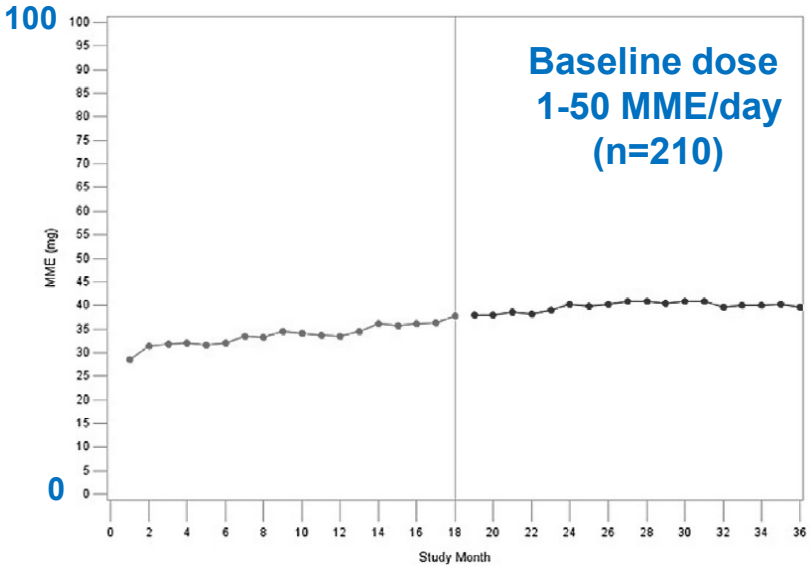
Steeper declines in Patients with >1 Rx a Year

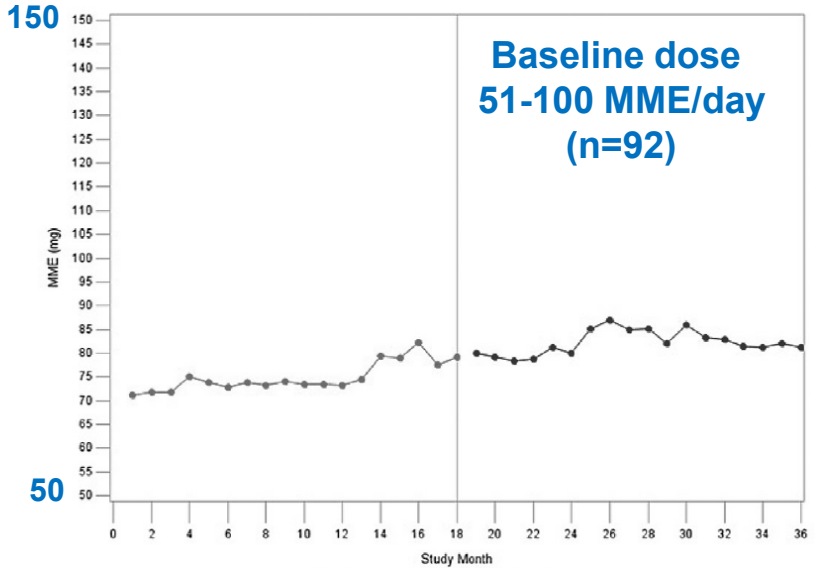


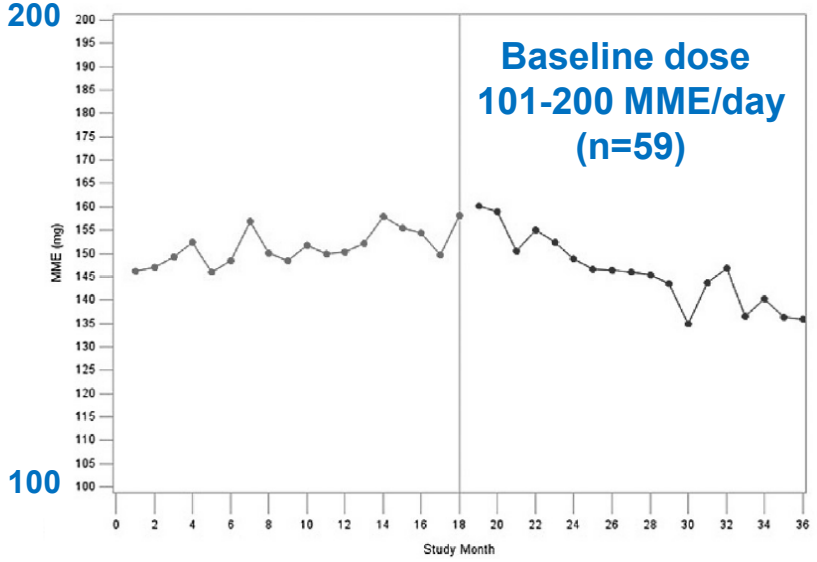
Estimated patients receiving an incident opioid analgesic prescription dispensed from U.S. outpatient retail pharmacies, by total number of opioid analgesic prescriptions received within a year, 2009–2019.

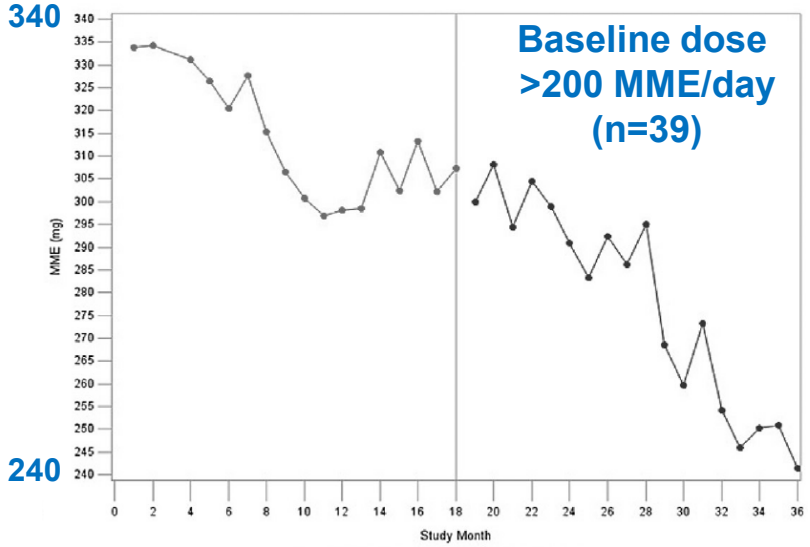
Source: Symphony Health Integrated Dataverse (IDV®), time period 2009-2019. M = millions, Rx = prescription(s). Incident opioid analgesic prescription was defined as the patient's first opioid analgesic prescription with no opioid analgesic prescriptions in the previous twelve months. Cohort year refers to the calendar year in which the patient received the incident opioid analgesic prescription. Each patient group is mutually exclusive. Patients with one prescription are counted separately from patients with two prescriptions; they are not counted multiple times across the groups.

Chronic Use: Largest Dose Decreases in Patients on Highest Opioid Analgesic Doses









Source: Salas et al. *Int J Drug Policy.* 2021;97:103308. MME = morphine milligram equivalent. Y-axes represent monthly averages of patients' daily MME. X-axes represent 30-day periods starting 9/15/14, with the line at 18 months representing the 3/15/2016 CDC publication: Dowell et al. *JAMA*. 2016; 315(15):1624-45. Chronic use defined as opioid therapy from 9/15/14 (month 0) to 9/14/17 (end of month 36).

New Outpatient Starts: Declines in Total MME per Prescription

Patients starting any opioid analgesic*

	2016	2017	2018	2019	2020
Total patients	**37.2 M**	**33.9 M**	**30.1 M**	**28.8 M**	**26.1 M**
Mean MME per prescription	215	206	181	160	156
Median MME per prescription	135	125	108	100	100
25th percentile	80	75	75	60	60
75th percentile	225	225	200	150	150

Number of morphine milligram equivalents (MMEs) dispensed to patients in their first outpatient opioid analgesic prescription and no outpatient opioid prescriptions in the previous 12 months, 2016–2020.
Source: 36-month Opioid Analgesics (OA) REMS Assessment, submitted Sept 2021, page 990. REMS data based upon IQVIA LRx database. Data included patients with an incident opioid analgesic prescription in the outpatient setting only.
* Data extracted from OA REMS and excluded opioid analgesics covered under another REMS program, such as transmucosal immediate-release fentanyl.

Declines in New Outpatient Starts of Opioid Analgesics and Initial Tablets Dispensed

	Patients starting tablet/capsule opioid analgesics				
	2016	**2017**	**2018**	**2019**	**2020**
Total patients	**36.0 M**	**32.8 M**	**29.2 M**	**28.1 M**	**25.5 M**
Mean tablets/capsules per prescription	31	30	27	23	23
Median tablets/capsules per prescription	20	20	20	20	18
25th percentile	15	15	12	12	12
75th percentile	30	30	30	30	28

Number of tablets or capsules dispensed to patients in their first outpatient opioid analgesic prescription and no outpatient opioid prescriptions in the previous 12 months, 2016–2020.

Source: 36-month Opioid Analgesics REMS Assessment, submitted Sept 2021, page 992. REMS Assessment data based upon IQVIA LRx database. M = millions. Data included patients with an incident opioid analgesic tablet or capsule prescription in the outpatient setting only. Data did not include prescriptions for opioid analgesics covered under another REMS program, such as transmucosal immediate-release fentanyl.

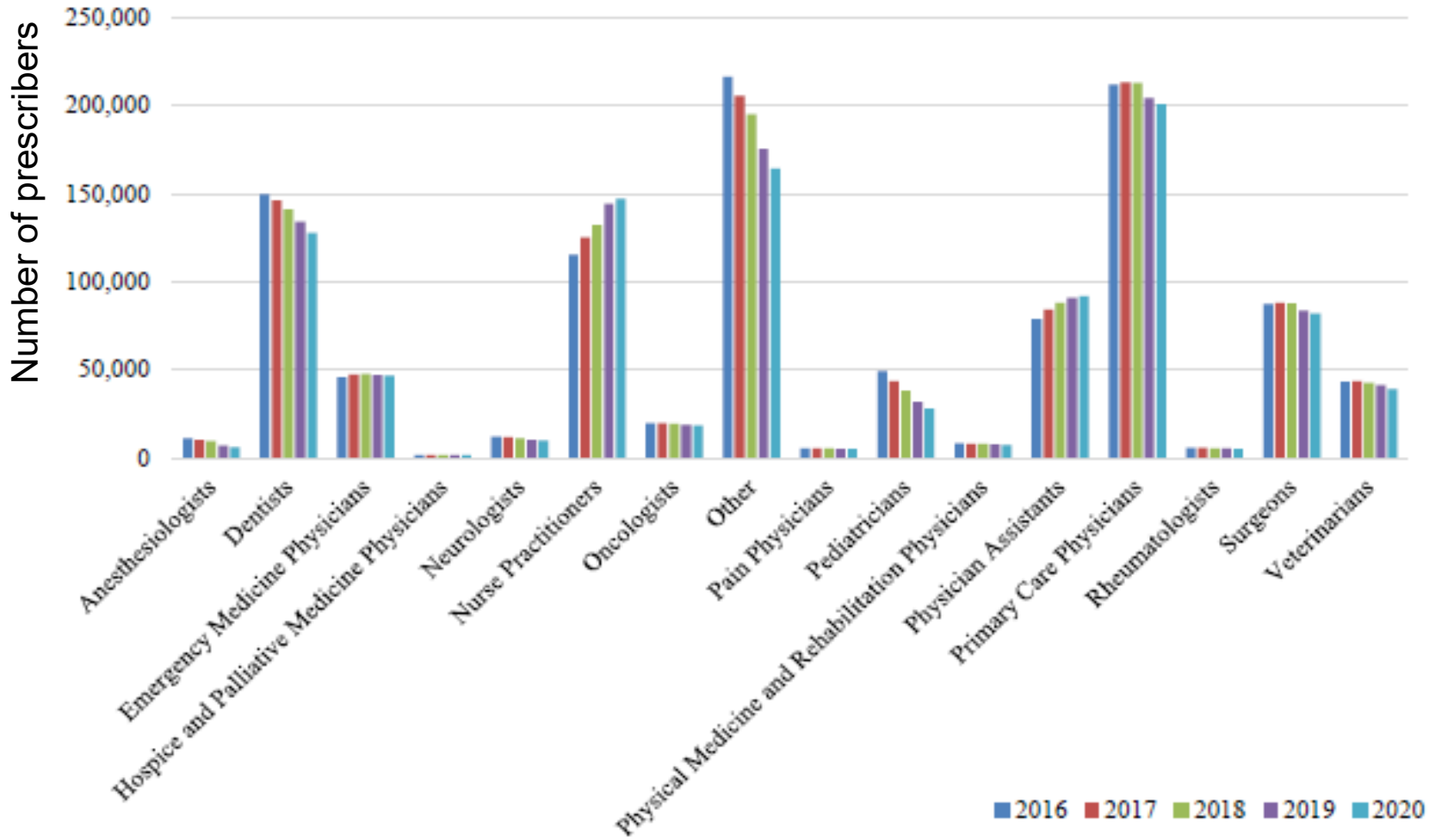
Excess Opioid Analgesics Common After Surgical Procedures

- FDA review* of published studies examining patient-reported outpatient opioid use after surgical procedures
  - Use varied widely across procedure types and within the same procedure type
  - Most studies reported that 50-70% of tablets went unused
  - Many factors were associated with reported opioid use, such as:
    - Preoperative opioid use
    - Opioid use in hospital and pain level at discharge
    - Tobacco use
    - Patient counseling and pain management education

* Mallama et al. *Pain Med.* 2021; doi: 10.1093/pm/pnab244.

Prescriber Specialties

Number of Prescribers of Opioid Analgesics, by Specialty/Type



Annual number of unique prescribers who prescribed at least one opioid analgesic (OA) covered under the OA REMS program, 2016–2020.
Source: 36-month Opioid Analgesics REMS Assessment, submitted September 2021, page 1113. REMS Assessment data based upon IQVIA Xponent database. Data did not include opioid analgesics covered under another REMS program, such as transmucosal immediate-release fentanyl. Primary care physicians included general practice, preventive medicine, family medicine, geriatric medicine, and internal medicine.

Majority of New Outpatient Opioid Analgesic Starts:

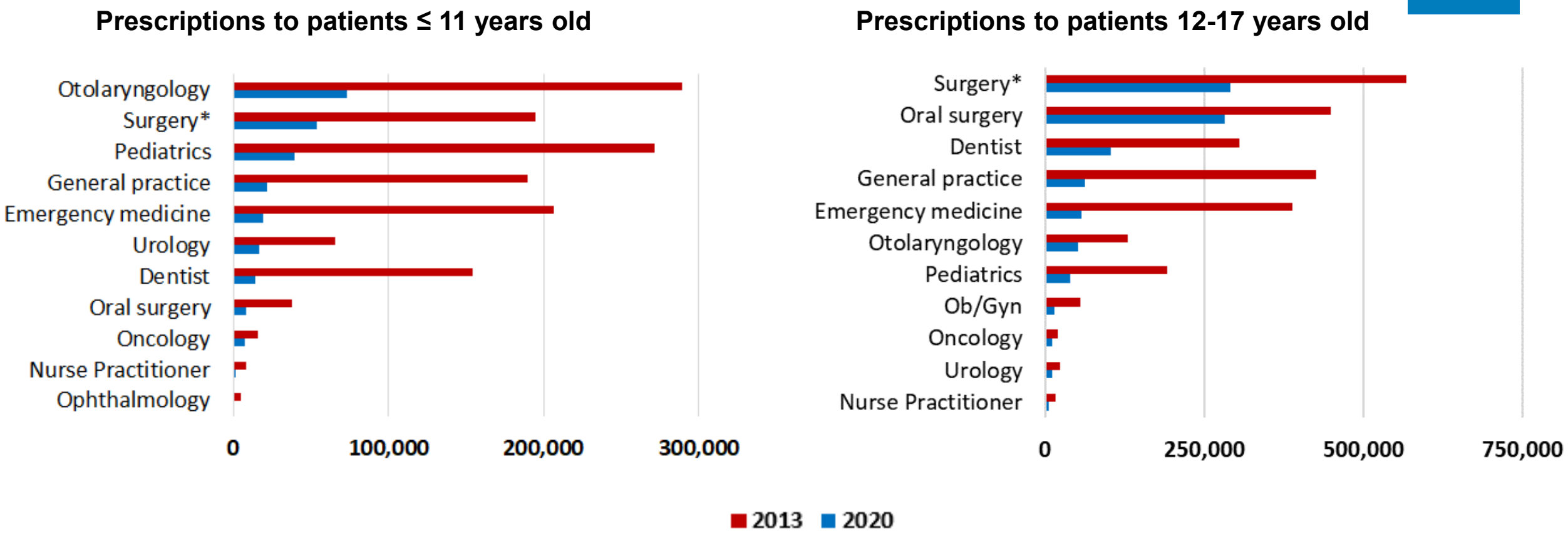
Primary Care, Mid-Level Practitioners, Dentists, and Surgeons

	2016	2017	2018	2019	2020	2020 share
Total patients	**1,060,883**	**1,059,219**	**1,045,831**	**1,007,657**	**980,820**	**100%**
Primary Care Physicians	212,141	213,614	213,091	204,401	201,011	21%
Nurse Practitioners	115,527	125,272	132,373	144,313	147,229	15%
Dentists	149,600	146,431	141,148	134,216	127,989	13%
Physician Assistants	78,953	84,274	87,948	90,964	92,031	9%
Surgeons	87,447	88,255	87,884	83,707	81,963	8%
Emergency Medicine Physicians	45,730	47,100	47,741	46,803	46,741	5%
Veterinarians	42,963	43,475	42,480	41,200	39,118	4%
Pediatricians	49,060	43,526	38,284	31,652	27,901	3%
Oncologists	19,686	19,656	19,392	18,650	18,248	2%
Neurologists	11,956	11,644	11,250	10,217	9,706	1%
Physical Medicine and Rehabilitation	8,017	7,966	7,866	7,507	7,261	1%
Anesthesiologists	11,020	10,155	9,301	7,006	6,028	1%
Pain Physicians	5,070	5,129	5,092	5,002	4,918	1%
Rheumatologists	5,641	5,524	5,368	5,111	4,885	1%
Hospice and Palliative Medicine	1,295	1,324	1,347	1,312	1,292	<1%
Other Prescribers	216,777	205,874	195,266	175,596	164,499	17%

66%

Prescriber specialty for patients' first outpatient opioid analgesic prescriptions and no outpatient opioid prescriptions in the previous 12 months, 2016-2020. Source: 36-month Opioid Analgesics REMS Assessment, submitted Sept 2021, p. 1137. REMS data based upon IQVIA Xponent database. Primary care physicians included general practice, preventive medicine, family medicine, geriatric medicine, and internal medicine. Data did not include opioid analgesics covered under another REMS program, such as transmucosal immediate-release fentanyl.

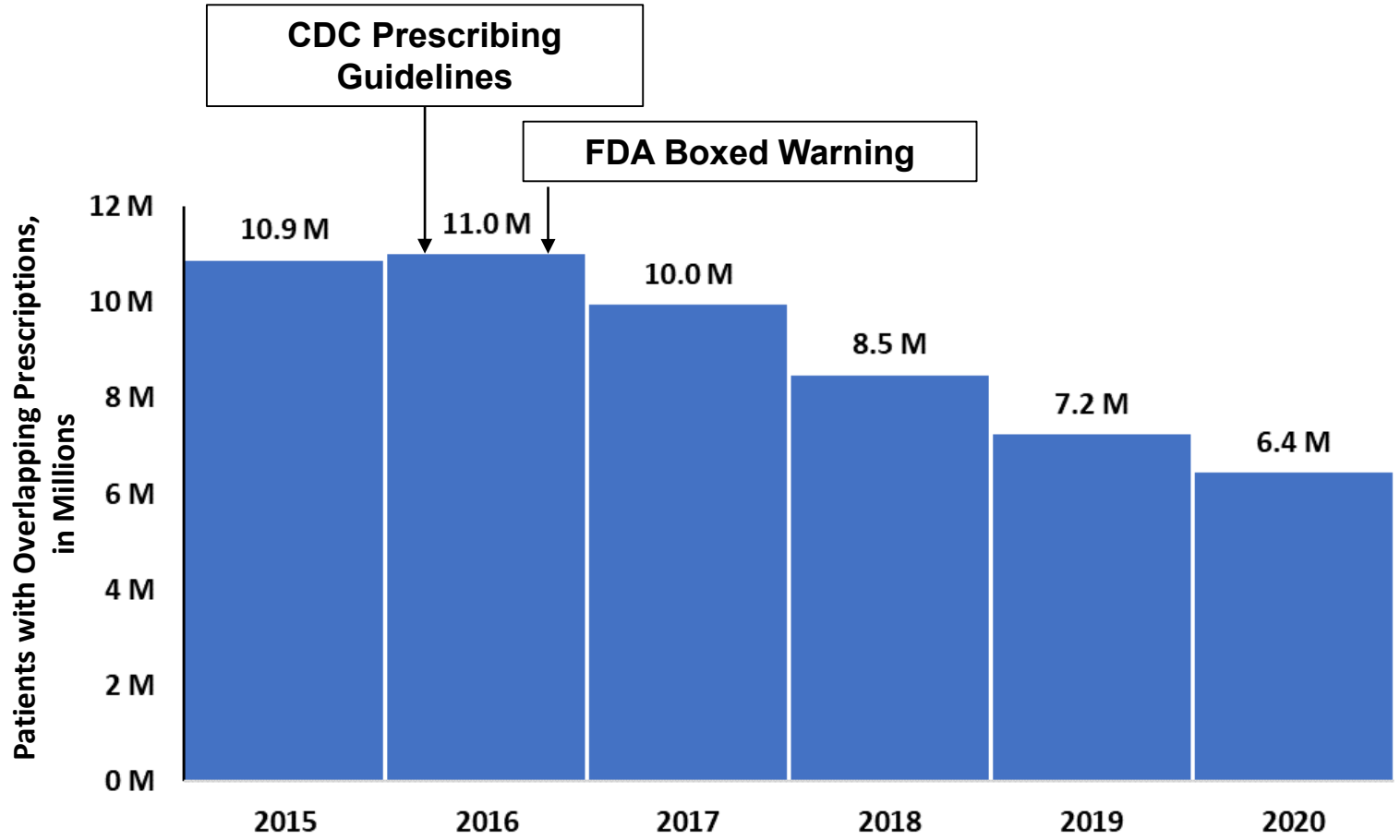
Declines in Prescriptions to Pediatric Patients Across Specialties



Estimated opioid prescriptions, by top prescriber groups, dispensed to pediatric patients from U.S. outpatient retail pharmacies, 2013 and 2020.
Source: Symphony Health Metys™, time period 2013 and 2020. Data extracted September 2021. Data excluded injectable products, cough/cold products, medications labeled for opioid use disorder, and prescriptions written by veterinarians. Physician assistants were captured under their practice specialty, such as general practice or pediatrics. General practice included family medicine and internal medicine.
* Surgery specialty group excluded oral and maxillofacial surgeons.

Benzodiazepine Use With Opioid Analgesics

Declines in Patients with Overlapping Opioid Analgesic and Benzodiazepine Prescriptions, but Still Prevalent

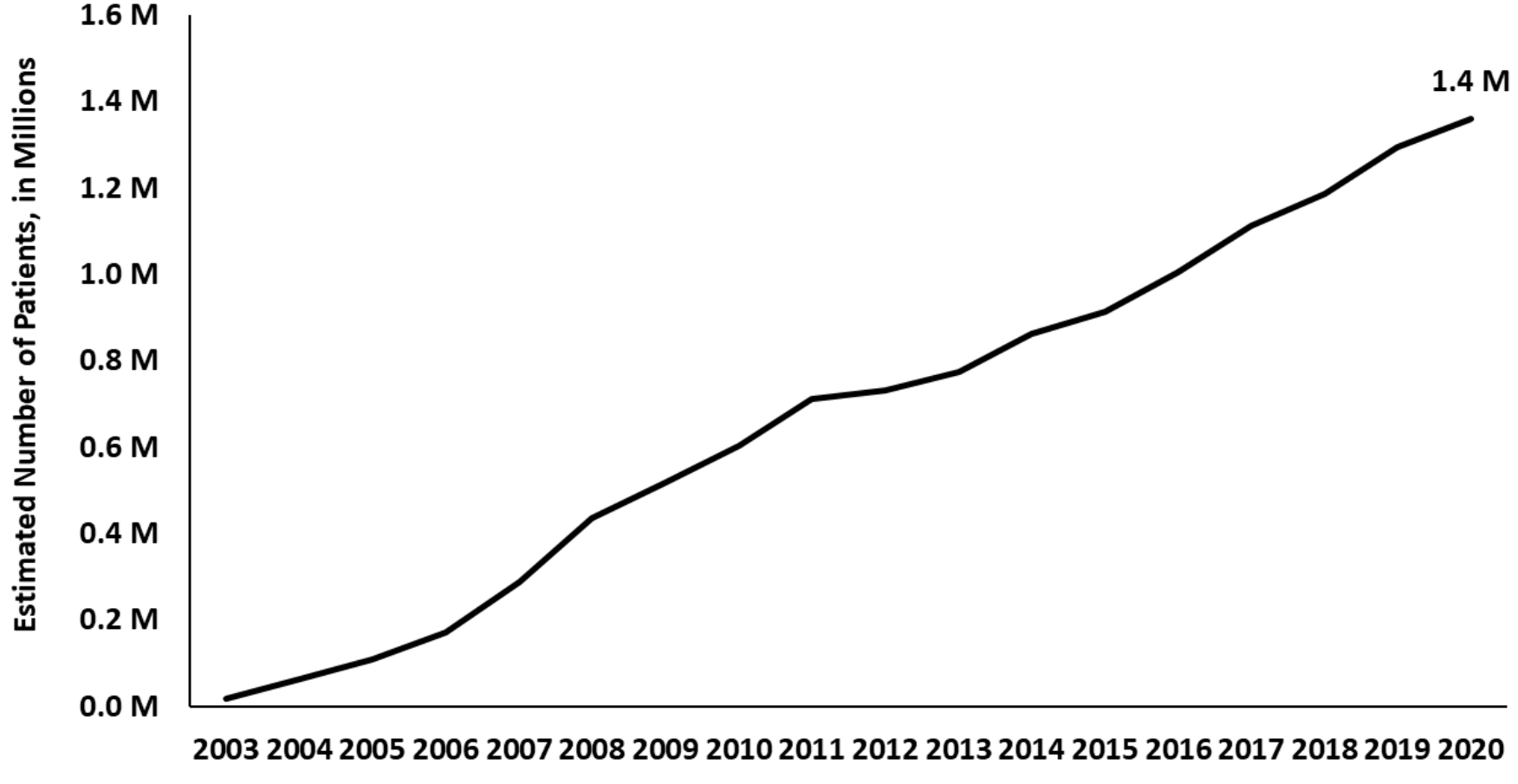


Estimated number of patients with overlapping prescriptions for opioid analgesics and oral benzodiazepines dispensed from U.S. outpatient retail pharmacies, 2015–2020.

Source: Symphony Health's IDV® (Integrated Dataverse), time period 2015-2020. Data extracted June 2021. M = millions. Opioid analgesics included oral, transdermal, and transmucosal formulations and excluded cough/cold products, migraine products, and products labeled for opioid use disorder. Based on dispensed prescription data, overlap was defined as at least 1 day supply of an opioid analgesic prescription overlapping with an oral benzodiazepine prescription.

Buprenorphine for Opioid Use Disorder

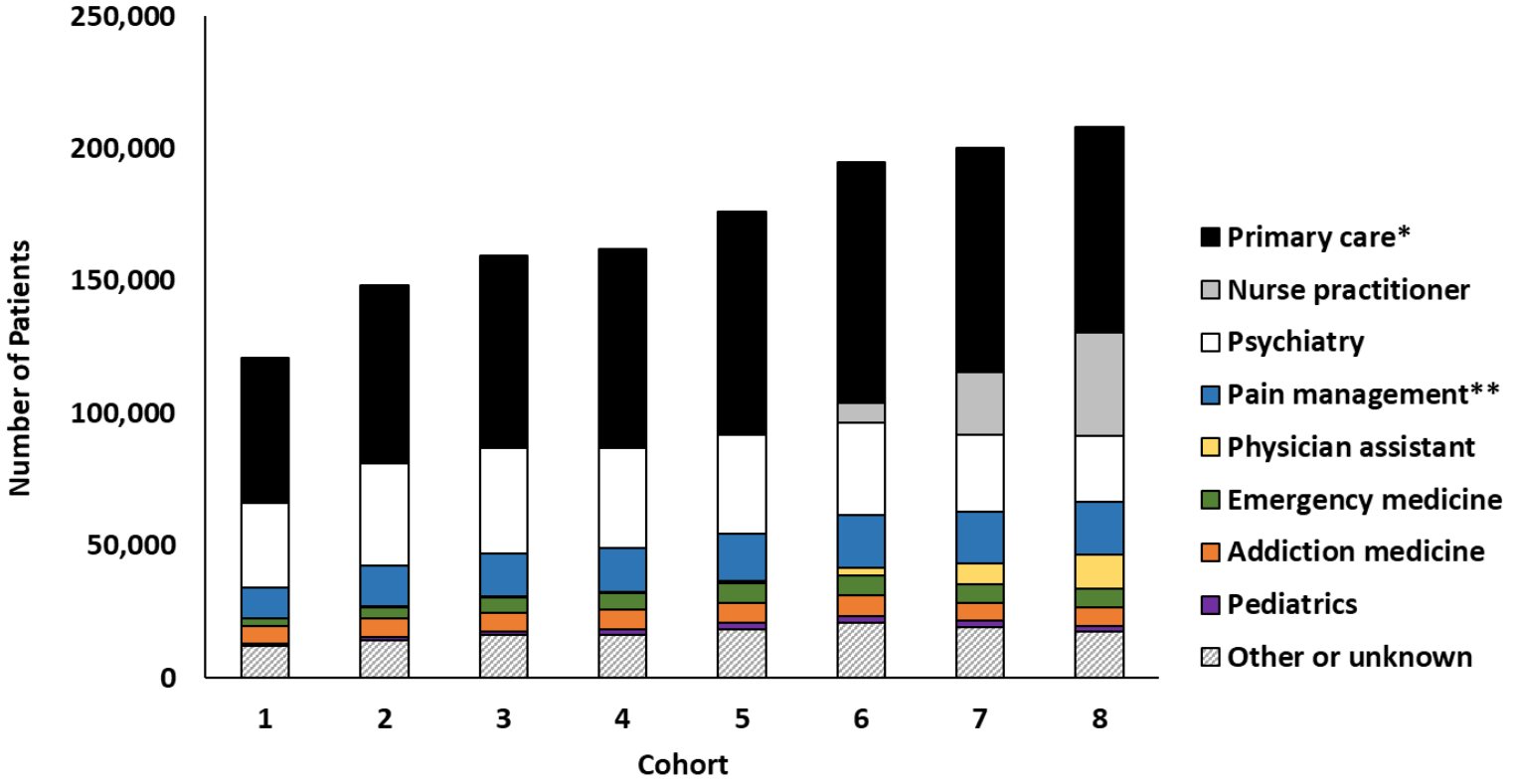
Increase in Patients Receiving Buprenorphine Labeled for Opioid Use Disorder



Estimated unique number of patients with buprenorphine prescriptions labeled for opioid use disorder dispensed from U.S. outpatient retail pharmacies, annually, 2003–2020.

Source: IQVIA Total Patient Tracker™, time period 2003-2020. Data extracted Aug 2020 (2003-2019) and Mar 2021 (2020). M = millions.

Primary Care Most Commonly Starting Patients on Buprenorphine Therapy for Opioid Use Disorder



Specialty of health care practitioner who prescribed patients' first transmucosal buprenorphine product labeled for opioid use disorder over time.
Source: 9th BTOD REMS Assessment, submitted August 2021, Excel file, *Demographics* tab, final population. Cohort 1 Jan 2011 – Dec 2011. Cohort 2 Feb 2013 – Jan 2014. Cohort 3 Feb 2014 – Jan 2015. Cohort 4 Feb 2015 – Jan 2016. Cohort 5 Feb 2016 – Jan 2017. Cohort 6 Feb 2017 – Jan 2018. Cohort 7 Feb 2018 – Jan 2019, Cohort 8 Feb 2019 – Jan 2020.
* Primary care included internal medicine, family medicine, and general practice.
** Pain management included anesthesiology, physical medicine, and pain medicine.

In Summary

- Recent decreases in opioid analgesic utilization patterns:
  - Large decrease in dispensed prescriptions
  - Steep decrease in prescriptions for pediatric patients
  - Less of a decrease in average MMEs per prescription
  - Fewer patients starting therapy
  - Fewer patients receiving longer courses of therapy
  - Decreased daily dose among patients with high-dose, chronic use
  - Overlapping benzodiazepine use has declined but still prevalent
- Primary Care, surgeons, dentists among top prescribers
  - Increasing role of mid-level practitioners
- More patients are getting buprenorphine for opioid use disorder
  - Patients are frequently started by primary care practitioners
  - Increasing role of mid-level practitioners

Additional Points to Consider

- Dispensing data provide high-level, mosaic view
  - Appropriate use depends upon individual benefit-risk considerations
  - No single threshold can identify risk for all patients and all situations
- Excessive opioid prescribing has undoubtedly played a role in the opioid crisis
  - But contribution and impact of OA prescribing continues to evolve
  - No consensus definition of excessive opioid prescribing
- Potential unintended consequences of efforts to reduce opioid prescribing:
  - Inadequate pain control
  - Acute opioid withdrawal
  - Mental distress
  - Substitution of illicit substances

Active Areas of Research and Policy in Opioid Prescribing and Pain Management

- Evidence-based guidelines for acute/post-surgical pain
  - FDA-commissioned NASEM evidence framework for condition-specific acute-pain guidelines
  - FDA-supported development of dental pain guidelines based on NASEM framework
- Non-opioid and multimodal/multidisciplinary pain management
- Opioid tapering: best practices and patient outcomes
- Identification and management of substance use disorders in patients with pain
  - Reducing stigma and expanding access to evidence-based treatment
- Other research


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Assessing the Landscape of Federal, State, and Health System Prescriber Education Requirements

- **Kathy Chappell,** American Nurses Credentialing Center
- **Blake Fagan**, Mountain Area Health Education Center
- **Adriane Fugh-Berman,** Georgetown University Medical Center
- **Graham McMahon**, Accreditation Council for Continuing Medical Education
- **Lisa Robin,** Federation of State Medical Boards
- **Kristine Schmit**, Centers for Disease Control and Prevention

FDA Prescriber Education: Impact on Nursing and the Interprofessional Health Care Team

Kathy Chappell, PhD, RN, FNAP, FAAN
Senior Vice President
Accreditation, Certification, Measurement, Institute for Credentialing Research and Quality Management, and Advanced Practice Initiatives

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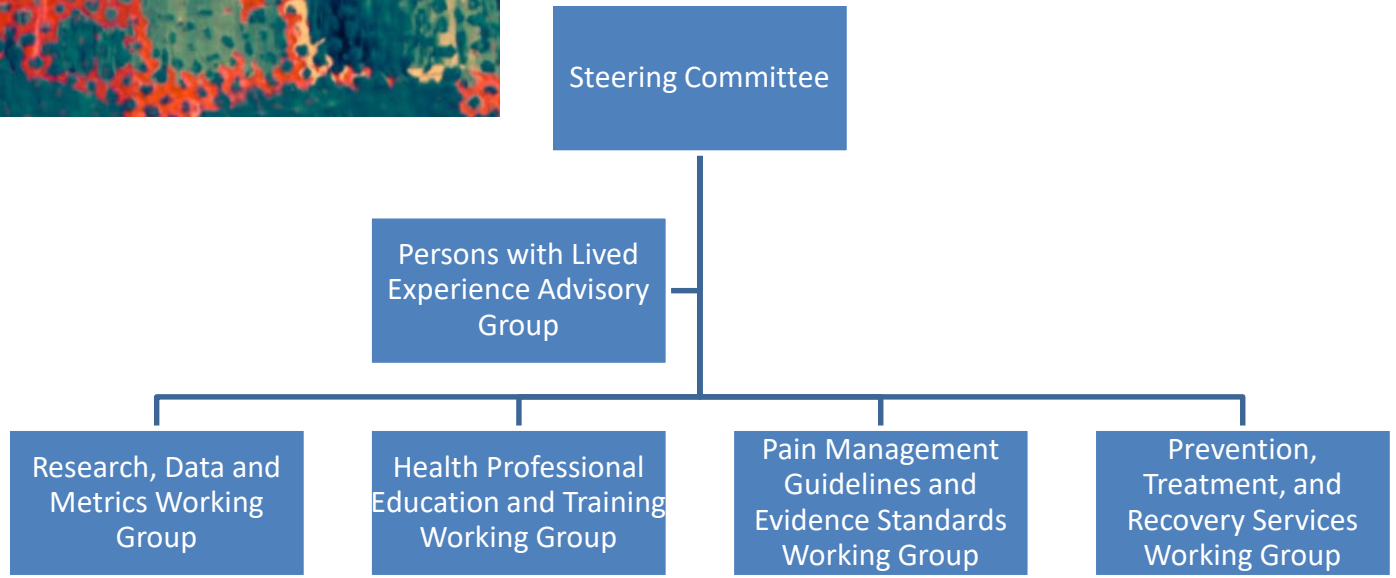
Nursing Context

- Prescribers subject to regulation by state nurse practice act
  - APRN (CNP, CRNA, CNM, CNS)
- Non-prescribers
  - RN
  - LPN
  - CNA

➢ ~ 5,000,000 nurses practicing within the United States (~ 500K APRNs)

Current Work

Launched in 2019



Health Professional Education and Training Working Group

- Mission: Collaboratively develop a harmonized interprofessional, patient and family-centered approach for the continuum of health professions' education that addresses acute and chronic pain management and substance use disorders (including prevention, screening, intervention, treatment, and long-term recovery).
- Special publication on professional practice gaps, existing regulatory requirements and policy standards, and actionable priorities needed to strengthen coordination and collaboration across the health education system (publication expected in November 2021).
  - Key priorities moving forward include:
    - establish minimum core competencies for all health care professionals in pain management and SUDs, and support evaluating and tracking of health care professionals' competence;
    - align accreditors' expectations for interprofessional collaboration in education for pain management and SUDs;
    - foster interprofessional collaboration among licensing and certifying bodies to optimize regulatory approaches and outcomes;
    - unleash the capacity for continuing education to meet health professional learners where they are; and
    - create partnerships among organizational stakeholders such as health care organizations and regulatory agencies to harmonize practice improvement initiatives.

Professional Practice Gaps

- Literature review and validation survey
- 6 professions: medicine (MD and DO); nursing (RN and APRN); PA; dentistry; pharmacy
- Gaps:
  - 40% knowledge
  - 30% attitudes and biases
  - 26% lack of available tools and resources

System Issues (Themes)

- Lack of insurance coverage
- Regulatory restrictions
- Lack of referral resources
- Lack of institutional guidelines
- Lack of data interoperability
- Patient/family logistic challenges

Core Competencies for HCP

Core Competency Domains

- Developed a core competency framework, which identifies a foundational set of abilities that all health professionals, regardless of profession or level, should have competency in to deliver high quality and safe pain and/or SUD care

- Overarching goals are to:
  - utilize a public health approach that sets a minimum standard of competence for all practicing clinicians; and
  - provide an implementable framework that can used to develop specific competencies across professions and/or specialties as needed

- Framework is centered around patient and family care, and describes three broad dimensions of performance that collectively reflect competence in health professionals: 1) Core Knowledge, 2) Collaboration, 3) Clinical Practice

Strategies for Success

- Align education with HCP learning needs and gaps
- Use an interprofessional, team-based approach
- Engage patients/families in the work
- Address system barriers that prevent HCPs and patients/families from delivering and/or accessing care
- Evaluate impact not “time in seat”

Thank you

Kathy.chappell@ana.org

Mandatory CME Must Be Industry-Free

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PharmedOUT.ORG

Disclosure: Adriane Fugh-Berman is a paid expert witness at the request of plaintiffs in litigation regarding pharmaceutical and medical device marketing practices.

Industry-funded CME is always marketing

World Medical and Health Policy

Continuing Medical Education and the Marketing of Fentanyl for Breakthrough Pain: Marketing Messages in an Industry-Funded CME Module on Breakthrough Pain

Margaret Infeld, Alicia Bell, Clare Marlin, Stephanie Waterhouse, Nicole Uliassi, and Adriane Fugh-Berman

ORIGINAL RESEARCH

Marketing Messages in Continuing Medical Education (CME) Modules on Binge-Eating Disorder (BED)

Jinhyun Jung, BS and Adriane Fugh-Berman, MD

Viewpoint

Editor's choice
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Hypoactive sexual desire disorder: inventing a disease to sell low libido

Antonie Meixel,[1] Elena Yanchar,[1] Adriane Fugh-Berman[2]

Pain Physician 2021; 24:E529-E538 • ISSN 2150-1149

Thematic Analysis

Increase your Confidence in Opioid Prescribing: Marketing Messages in Continuing Medical Education Activities on ER/LA Opioids

Benjamin Goodwin, MS[1], Hwa-Pyung (David) Lim, MS[2], Judy Butler, MS[3], Daniel Paglia, MS[4], Matthew T. Dempsey, MS[3], Bonnie O'Connor, PhD[5], and Adriane Fugh-Berman, MD[6]

Messaging may be subtle…

FEATURE

Check for updates

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http://dx.doi.org/10.1136/bmj.n1273
Published: 4 June 2021

ESSAY

Industry-funded medical education is always promotion—an essay by Adriane Fugh-Berman

Virtual Mentor
Ethics Journal of the American Medical Association
June 2006, Volume 8, Number 6: 412-415.

Op-Ed
"This may sting a bit": cutting CME's ties to pharma
by Adriane Fugh-Berman, MD, and Sharon Batt, MA

Quotes from anonymous pharma executive

“CME contributions are commercial decisions…” representing “a focus on a particular business objective…”

“The sales and marketing divisions dominate deliberations and distribution of CME cash.”

"Friendly institutions, as defined by access and volume, are more likely to receive grants than those that favor another company’s products. "

"Grants may also be made in support of programs including particular KOLs [key opinion leaders] whose opinions resonate with the promotional plan…"

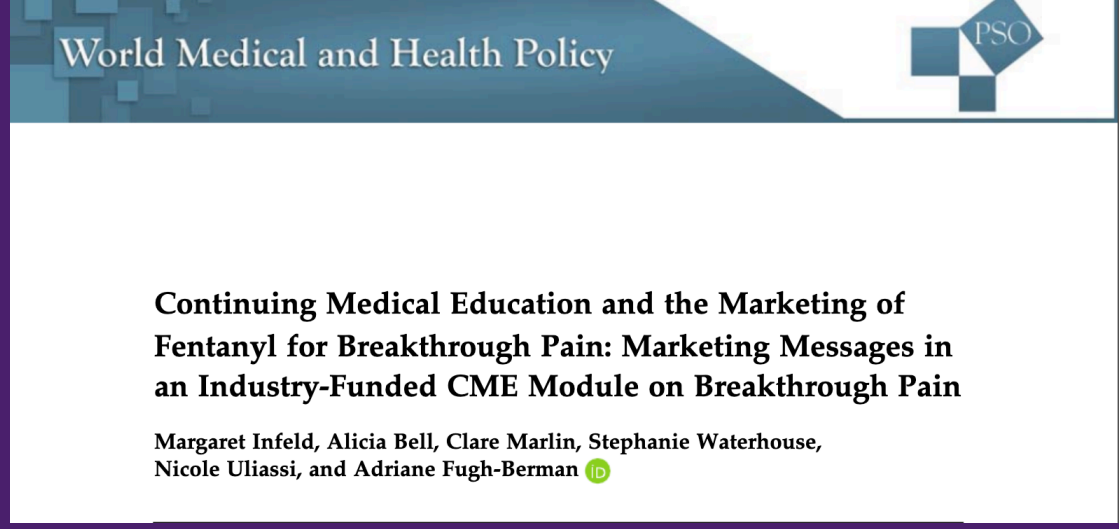
"Similarly, those known for positions antithetical to the company’s promotional plan are less likely to be supported.”

Ridgeway J. Mother Jones, 2010

Industry-funded CME is designed to

- Increase awareness of what industry calls “disease states”
- Encourage off-label use
- Minimize perceived risks of targeted drugs
- Exaggerate harms of competing therapies.

Take-home messages in readers of industry-funded and non-industry-funded education modules on opioids

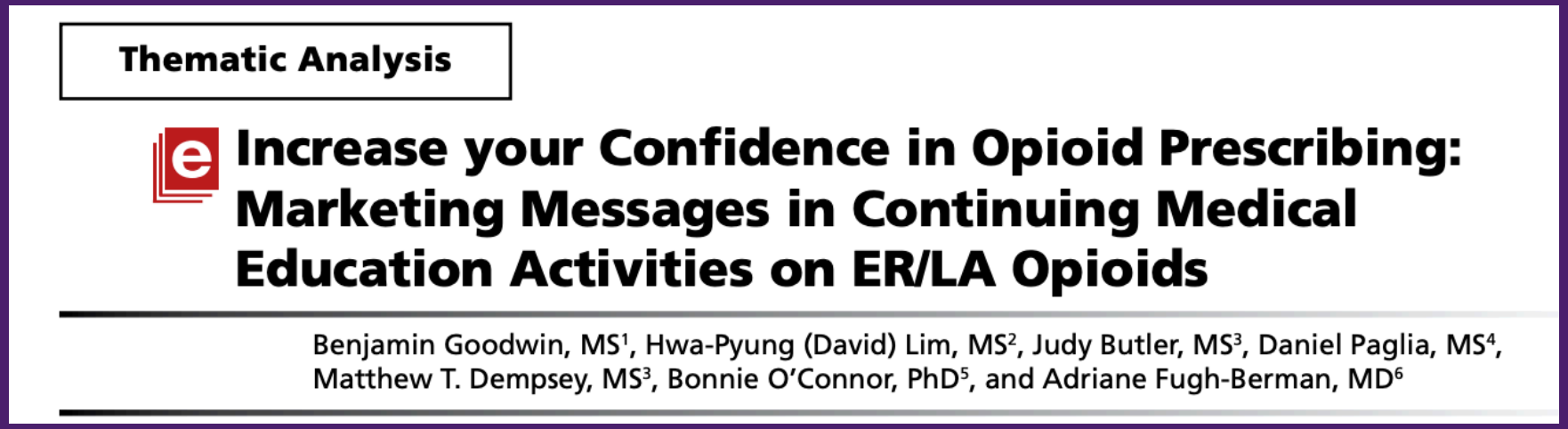


Non-industry-funded:

- “There’s not great evidence supporting efficacy of analgesic long-term use for treating chronic pain.”
- “Long-term treatment with opioids only shows little effectiveness.”
- “Opioid use to treat chronic pain and non-cancer pain is debated.”

Industry-funded:

- “Pain Management is almost universally managed with opioids.”
- “Opioids are great for treating pretty much any kind of pain.”



PharmedOut utilized systematic narrative thematic analysis to identify and elucidate major teaching points within all internet-based REMS CME activities available on RPC's ER-LA-OPIOID REMS website in July 2018.

Goodwin et al. Pain Physician Journal, 2021, 24: E529-E538.

Marketing messages in REMS-compliant CME on opioids

1. Chronic pain is a common, under-treated problem.
2. Chronic pain is a chronic disease.
3. Opioids are an appropriate treatment for chronic pain.
4. ER/LAs are more appropriate than IR opioids for chronic pain.
5. Tolerance is normal, expected, and beneficial.
6. “Opioid rotation” can maximize analgesia and minimize adverse effects.
7. There is no population for whom opioids are absolutely contraindicated or inappropriate.
8. Screening and monitoring tools are effective for preventing opioid-related problems.
9. Opioid related adverse effects, such as respiratory depression and addiction, are due only to misuse and abuse.
10. Addiction, overdose, and death are due to street drugs such as heroin and fentanyl, not prescription opioids.

Goodwin et al. Pain Physician 2021, 24: E529-E538.

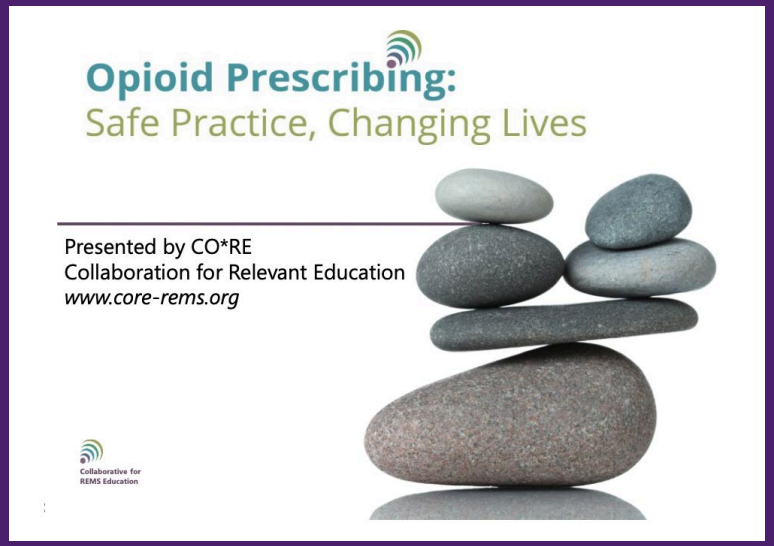
Quotes from REMS-compliant CME on Opioids

"This module is designed to help increase your confidence in opioid prescribing."[1]

"You can never go wrong with opioids if you start low and go slow"[2]

"Now you can still treat people with opioids even if they have a high risk, but you would monitor them differently"[2]

"So, uh, older adults are at higher risk for respiratory depression. Doesn't mean you can't use an opioid"[2]



1. Get Smart: Assessing Patients for treatment with opioid analgesic therapy (Postgraduate Institute for Medicine)
2. Opioid prescribing: Safe Practice, changing lives. (American Society of Addiction Medicine)

Misinformation in REMS-compliant CME

Every activity presented opioid therapy as an efficacious or the most efficacious treatment for chronic pain

In Fact…

No evidence supports the efficacy of long-term opioid therapy for chronic nonmalignant pain.[1,2]

"Tolerance to and dependence on opioids are normal physiological responses to long-term treatment"

"Opioid-tolerant patients also develop tolerance to many opioid side effects, like drowsiness and respiratory depression" [3]

In Fact…

Opioid tolerance does not protect against harms

"a trial of several opioids [is needed] …to find an acceptable balance between the analgesia and tolerability"[4]

"The key point is that, in any given patient, the absence of benefit or side effects with one opioid does not predict similar responses to another opioid"[3]

In Fact…

No reliable evidence supports opioid rotation.[5]

3. Get Smart: Assessing Patients for treatment with opioid analgesic therapy: Postgraduate Institute for Medicine
4. Scope of Pain: Safe and Competent Opioid Prescribing

Scope of Pain REMS: Mary Williams case study

"Mary Williams, a 42-year-old receptionist and mother of three, has a complicated medical record: She's obese and diabetic, has a history of alcoholism, and smokes a pack a day. Substance abuse problems run in the family. She takes short-acting opioids every few hours for her lower back pain and neuropathy, but she's still uncomfortable, so she goes back to the clinic. Should the doctor keep prescribing opioids?"

Lurie, J. Doctors Receive Opioid Training, Big Pharma Funds It. What Could Go Wrong? Mother Jones. April 27, 2018.

CASE STUDY **Mary Williams: Presentation**

Mary Williams, a 42-year-old woman, presents to a new practice for the first time to obtain a new prescription, at a higher dose, of her opioid analgesic medication. She has brought in her previous medical records for review and explains that her previous primary care provider moved out of state, leaving her with barely enough medication to last her 1 more week.

Her past medical history includes type 2 diabetes mellitus for 8 years (hemoglobin A1C 7.4%), painful diabetic neuropathy for 2 years, spinal stenosis with chronic low back pain, hypertension, obesity, tobacco use disorder, and a remote history of alcohol use disorder. Her current medications are metformin 1000 mg twice daily, lisinopril 10 mg once daily, hydrochlorothiazide 12.5 mg once daily, and aspirin 81 mg once daily.

For pain, Mary is currently taking oxycodone 5 mg/acetaminophen (APAP) 325 mg 1 to 2 tablets every 4 to 6 hours and gabapentin 300 mg 3 times daily. In the past, her pain has been treated with nonsteroidal anti-inflammatory drugs (NSAIDs), APAP, tricyclic antidepressants (TCAs), tramadol, and APAP with codeine. However, none of these medications provided adequate pain relief and some had intolerable side effects (eg, upset stomach with NSAIDs; dry mouth with TCAs).

The social history reveals that Mary, who is a part-time (20 hours/week) receptionist in a law office, is married to the manager of a hardware store and has 3 children aged 6, 12, and 15 years. She reports that she was an "alcoholic" but has been in recovery for the past 10 years. Although she tried marijuana in high school, she denies any recent history of illicit drug use. She continues to smoke, about 1 pack/day for the past 25 years. Her family history is unremarkable, other than that her mother died from complications of alcoholic cirrhosis.

Mary reports that she usually takes 4 to 8 oxycodone/APAP tablets per day, but 8 tablets provide the best pain relief, making it possible for her to go to work. Her previous prescription was limited to 150 tablets/month (up to 5 tablets/day) because her previous primary care provider feared that dose escalation would cause Mary to become addicted: she is careful not to run out of her medication because, when she does, she experiences nausea, vomiting, and diarrhea due to physical dependence.

Scope of Pain: Safe and Competent Opioid Prescribing. Boston, MA: Boston University School of Medicine.

PharmedOut supports mandatory REMS for physicians, dentists, and other prescribers but ONLY if it is entirely free of industry influence.

Industry-free CME means:

- No direct or indirect funding from any company that makes FDA-regulated products
- Planners, faculty, content developers and speakers must have no financial relationships with any company that makes FDA-regulated products
- The accreditor takes no pharma funding

ASSESSING THE LANDSCAPE OF FEDERAL, STATE, AND HEALTH SYSTEM PRESCRIBER EDUCATION REQUIREMENTS

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President and CEO, ACCME


ACCME


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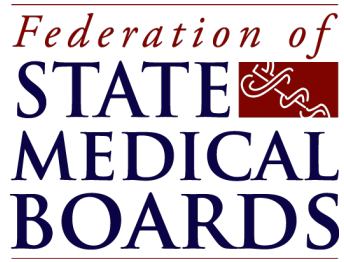
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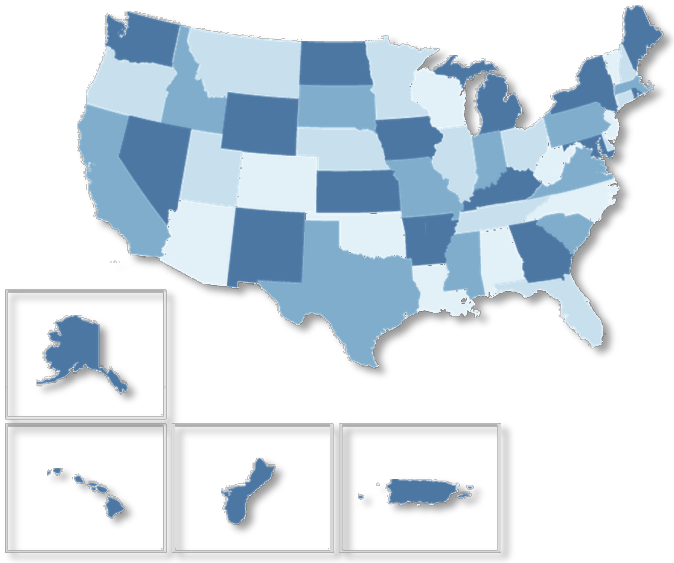
ACCME

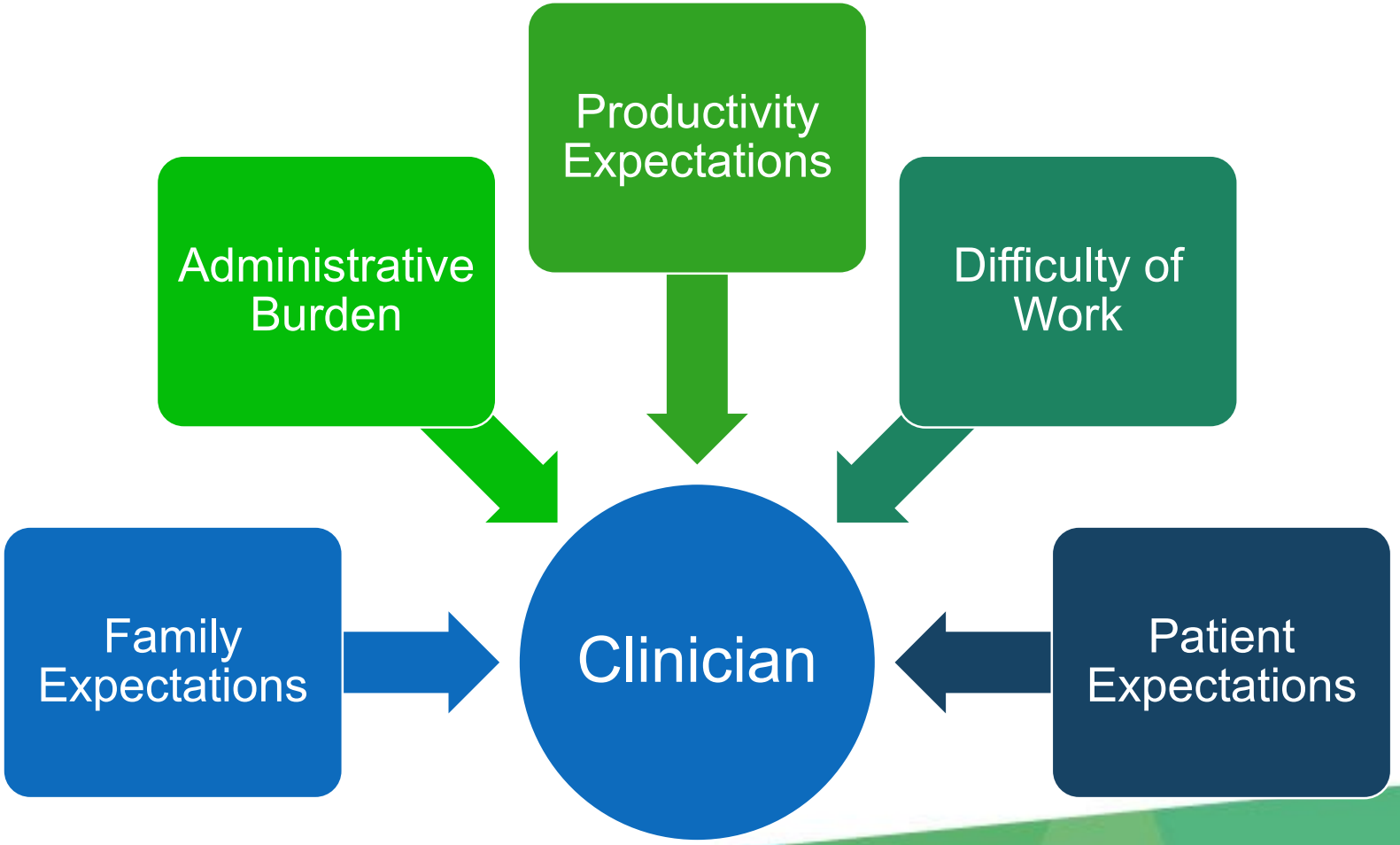
ACCME'S ROLES AND FUNCTIONS

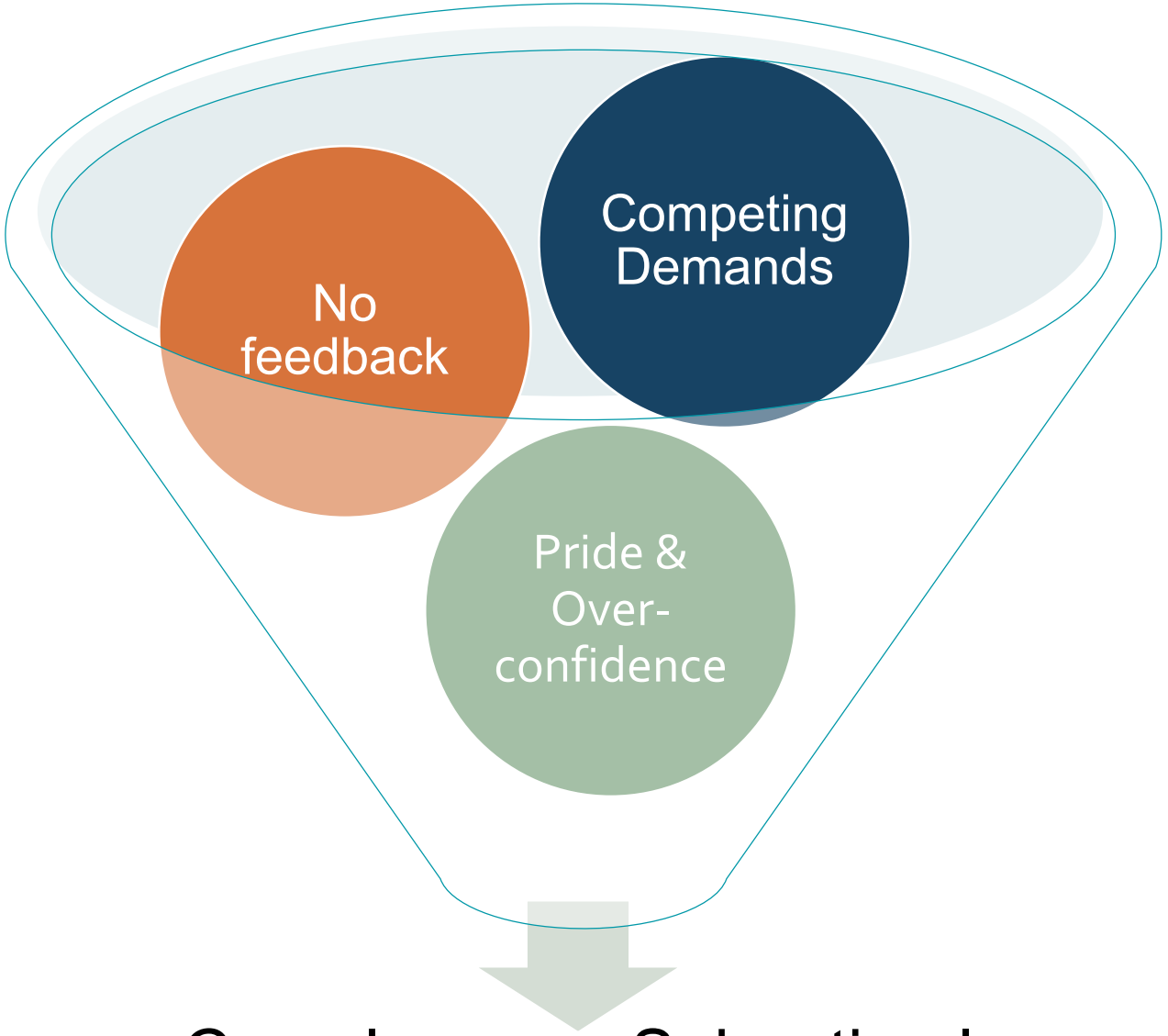
Accrediting Body



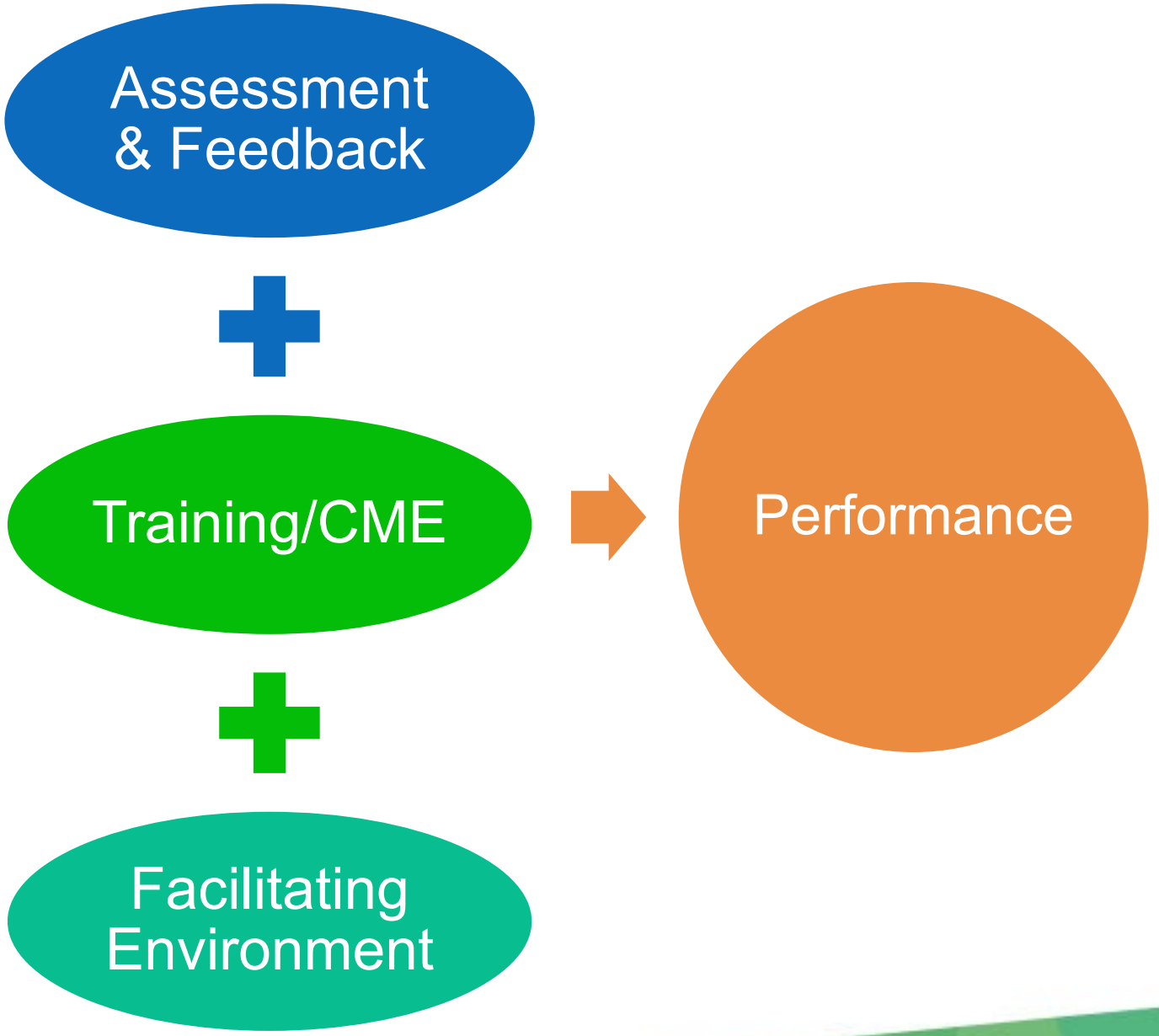
- Voluntary system of self-regulation
- Sets the national standard for high-quality continuing medical education (CME)
- Accredits 1,720 health care organizations that deliver CME to a local, national, or international community of learners
- Manages and shares provider, activity, and learner completion data for the system
- Supports and educates providers of CME

Changing Environment





Complacency, Suboptimal Performance & Errors


Assessment & Feedback
Training/CME
Facilitating Environment
Performance

Benefits of a Constructive Learning Environment for Professionals

Patient safety

Best practices

Intellectual growth

Build teams

Create community

Satisfaction

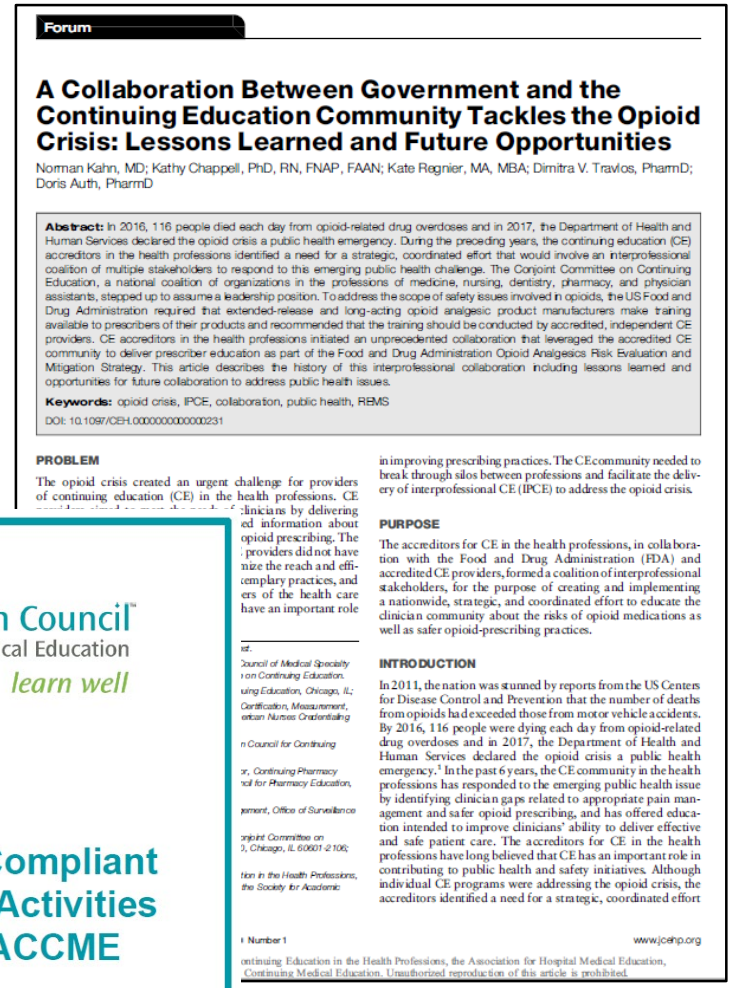
Retention

Less Burnout

IN SUPPORT OF THE CURRENT OPIOID ANALGESIC REMS

ACCME, ANCC and ACPE…

- Ensured activities remain balanced and protected from industry bias;
- Encouraged modifications to the FDA blueprint to be more inclusive of pain and non-medication alternatives;
- Created the independent grant review committee to recommend educationally effective proposals to the RPC;
- Asked FDA to require RPC transparency in funding, grant allocations
- Collected the activity and learner data – for the Opioid Analgesic REMS (2019 - current)
  - **208 OA REMS-compliant Activities**
  - **185,854 Learners Successfully Completing the Activities**
- Audited activities to ensure compliance with REMS and accreditation requirements.



Forum

A Collaboration Between Government and the Continuing Education Community Tackles the Opioid Crisis: Lessons Learned and Future Opportunities

Norman Kahn, MD; Kathy Chappell, PhD, RN, FNAP, FAAN; Kate Regnier, MA, MBA; Dimitra V. Travlos, PharmD; Doris Auth, PharmD

Abstract: In 2016, 116 people died each day from opioid-related drug overdoses and in 2017, the Department of Health and Human Services declared the opioid crisis a public health emergency. During the preceding years, the continuing education (CE) accreditors in the health professions identified a need for a strategic, coordinated effort that would involve an interprofessional coalition of multiple stakeholders to respond to this emerging public health challenge. The Conjoint Committee on Continuing Education, a national coalition of organizations in the professions of medicine, nursing, dentistry, pharmacy, and physician assistants, stepped up to assume a leadership position. To address the scope of safety issues involved in opioids, the US Food and Drug Administration required that extended-release and long-acting opioid analgesic product manufacturers make training available to prescribers of their products and recommended that the training should be conducted by accredited, independent CE providers. CE accreditors in the health professions initiated an unprecedented collaboration that leveraged the accredited CE community to deliver prescriber education as part of the Food and Drug Administration Opioid Analgesics Risk Evaluation and Mitigation Strategy. This article describes the history of this interprofessional collaboration including lessons learned and opportunities for future collaboration to address public health issues.

Keywords: opioid crisis, IPCE, collaboration, public health, REMS

DOI: 10.1097/CEH.0000000000000231

PROBLEM

The opioid crisis created an urgent challenge for providers of continuing education (CE) in the health professions. CE

clinicians by delivering ed information about opioid prescribing. The providers did not have nize the reach and effi- emplary practices, and ers of the health care have an important role

in improving prescribing practices. The CE community needed to break through silos between professions and facilitate the delivery of interprofessional CE (IPCE) to address the opioid crisis.

PURPOSE

The accreditors for CE in the health professions, in collaboration with the Food and Drug Administration (FDA) and accredited CE providers, formed a coalition of interprofessional stakeholders, for the purpose of creating and implementing a nationwide, strategic, and coordinated effort to educate the clinician community about the risks of opioid medications as well as safer opioid-prescribing practices.

INTRODUCTION

In 2011, the nation was stunned by reports from the US Centers for Disease Control and Prevention that the number of deaths from opioids had exceeded those from motor vehicle accidents. By 2016, 116 people were dying each day from opioid-related drug overdoses and in 2017, the Department of Health and Human Services declared the opioid crisis a public health emergency.[1] In the past 6 years, the CE community in the health professions has responded to the emerging public health issue by identifying clinician gaps related to appropriate pain management and safer opioid prescribing, and has offered education intended to improve clinicians' ability to deliver effective and safe patient care. The accreditors for CE in the health professions have long believed that CE has an important role in contributing to public health and safety initiatives. Although individual CE programs were addressing the opioid crisis, the accreditors identified a need for a strategic, coordinated effort

Council of Medical Specialty on Continuing Education.
uing Education, Chicago, IL;
Certification, Measurement, erican Nurses Credentialing
n Council for Continuing
r, Continuing Pharmacy ncil for Pharmacy Education,
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onjoint Committee on), Chicago, IL 60601-2100;
tion in the Health Professions, the Society for Academic

Number 1 www.jcehp.org

ontinuing Education in the Health Professions, the Association for Hospital Medical Education, Continuing Medical Education. Unauthorized reproduction of this article is prohibited.

Accreditation Council for Continuing Medical Education

learn well

Opioid REMS-Compliant Accredited CE Activities Reported to ACCME

2021 Update

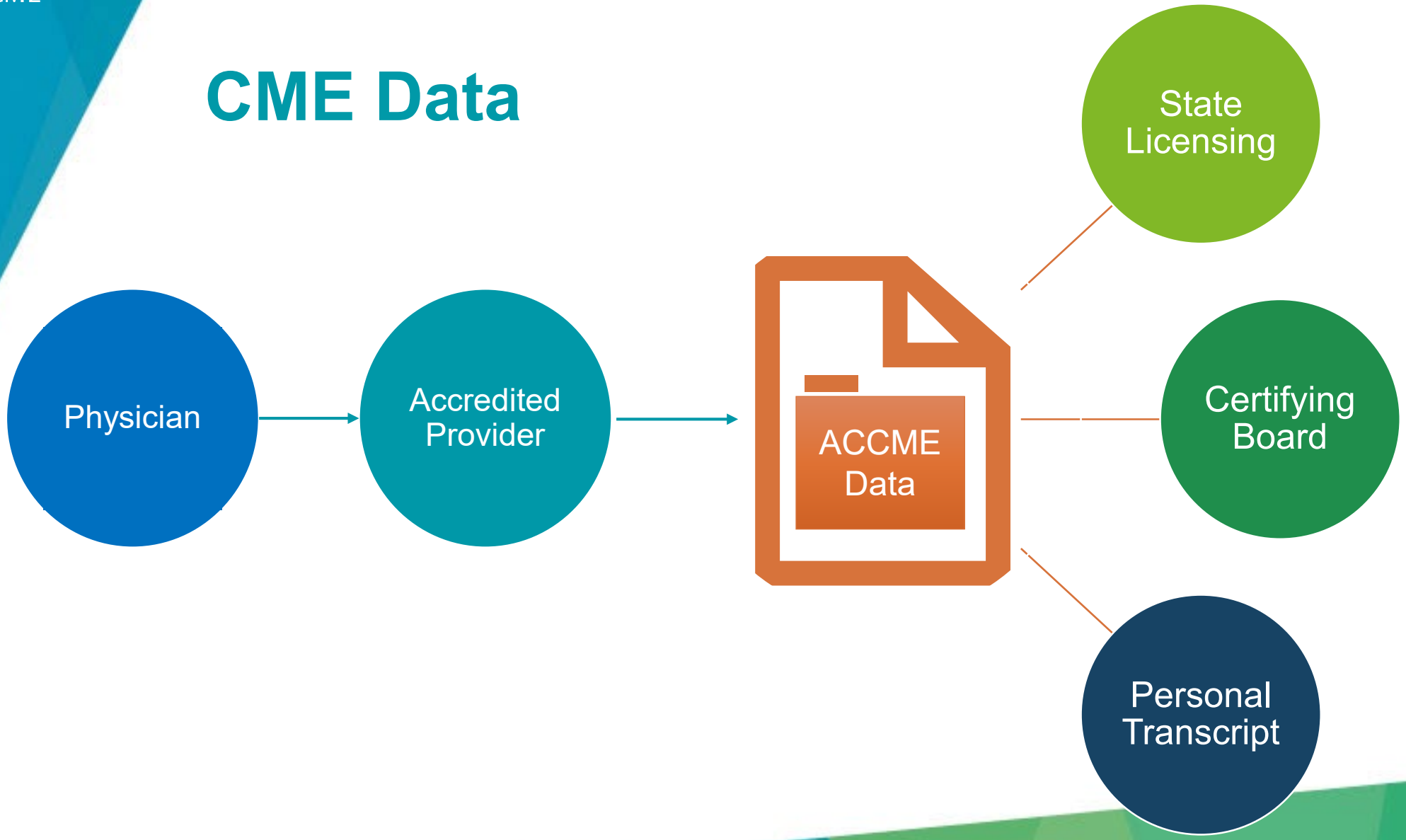
401 N. Michigan Ave., Suite 1850 | Chicago, IL 60611 | Phone: 312-527-9200 | www.accme.org

https://journals.lww.com/jcehp/Abstract/2019/03910/A_Collaboration_Between_Government_and_the.11.aspx
https://www.accme.org/sites/default/files/2021-09/926_20210922_Opioid%20REMS%20Compliant%20Accredited%20CE%20Activities%20Reported%20to%20ACCME.pdf

Mandates & Adult Learning

- Education is a powerful and effective tool to drive and facilitate change and improve patient outcomes.
- While general mandates will create compliance, such mandates generate counterproductive psychological resistance and cynicism, and would not be expected to create learning, skill development or a change in behavior.
- Mandates for education and certification that are *prerequisites to a desirable privilege* or opportunity and considered *highly relevant to practice* would, in contrast, be expected to have a positive impact and engagement, especially if the education can be tailored to individual competency gaps, is efficient, and educationally effective (longitudinal, practiced with feedback, reinforced, reminded etc.).

CME Data


Physician
Accredited Provider
ACCME Data
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Certifying Board
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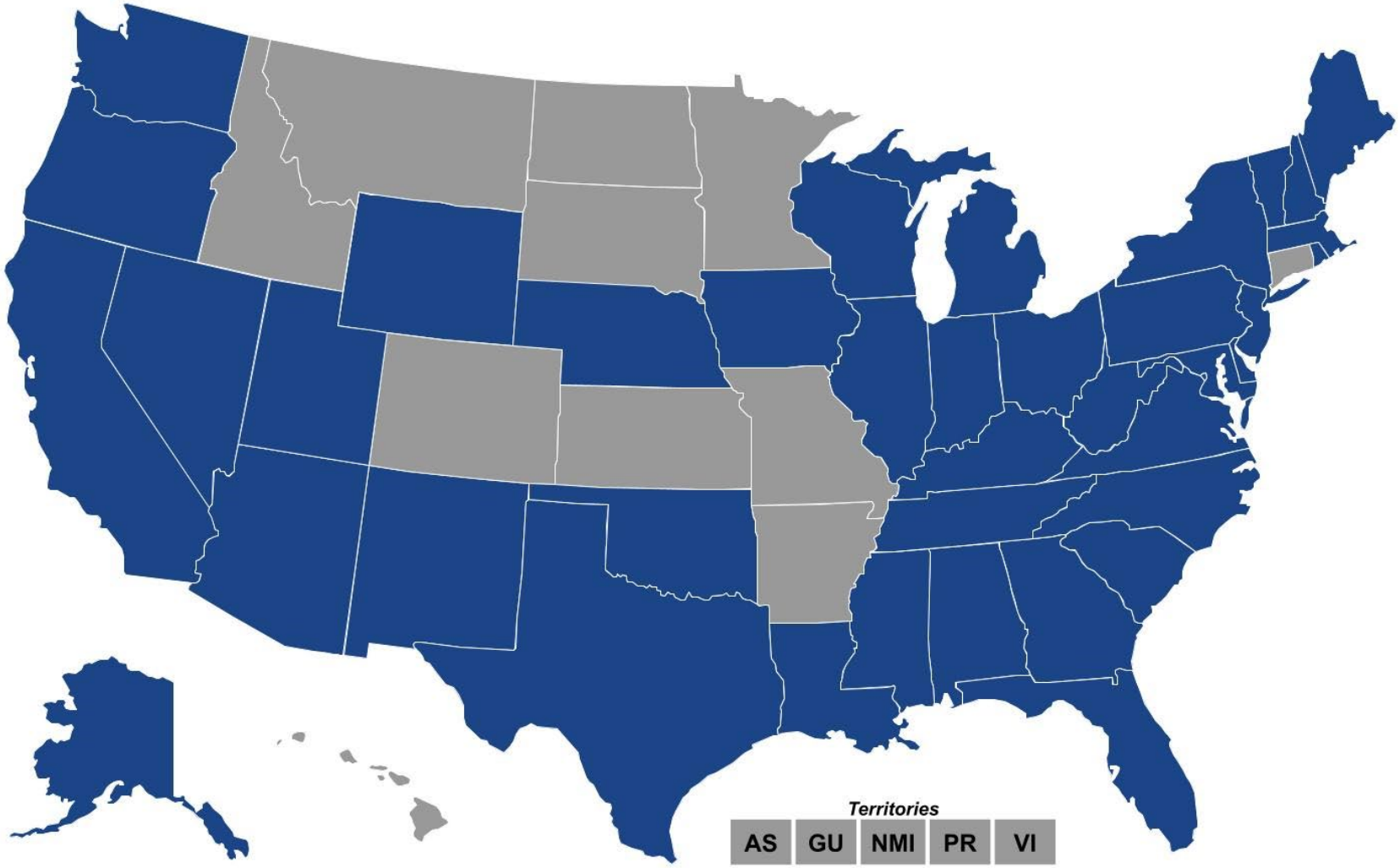
Federation of State Medical Boards (FSMB)

- ✓ Founded in 1912, we are the national, non-profit organization that represents all 70 of the state medical and osteopathic boards across the United States
- ✓ State medical boards **protect the public** through the licensing, disciplining and regulation of 1 million+ physicians, PAs, and other health care professionals
- ✓ FSMB **supports state medical boards** through education, assessment, research and advocacy and promotes regulatory best practices across states

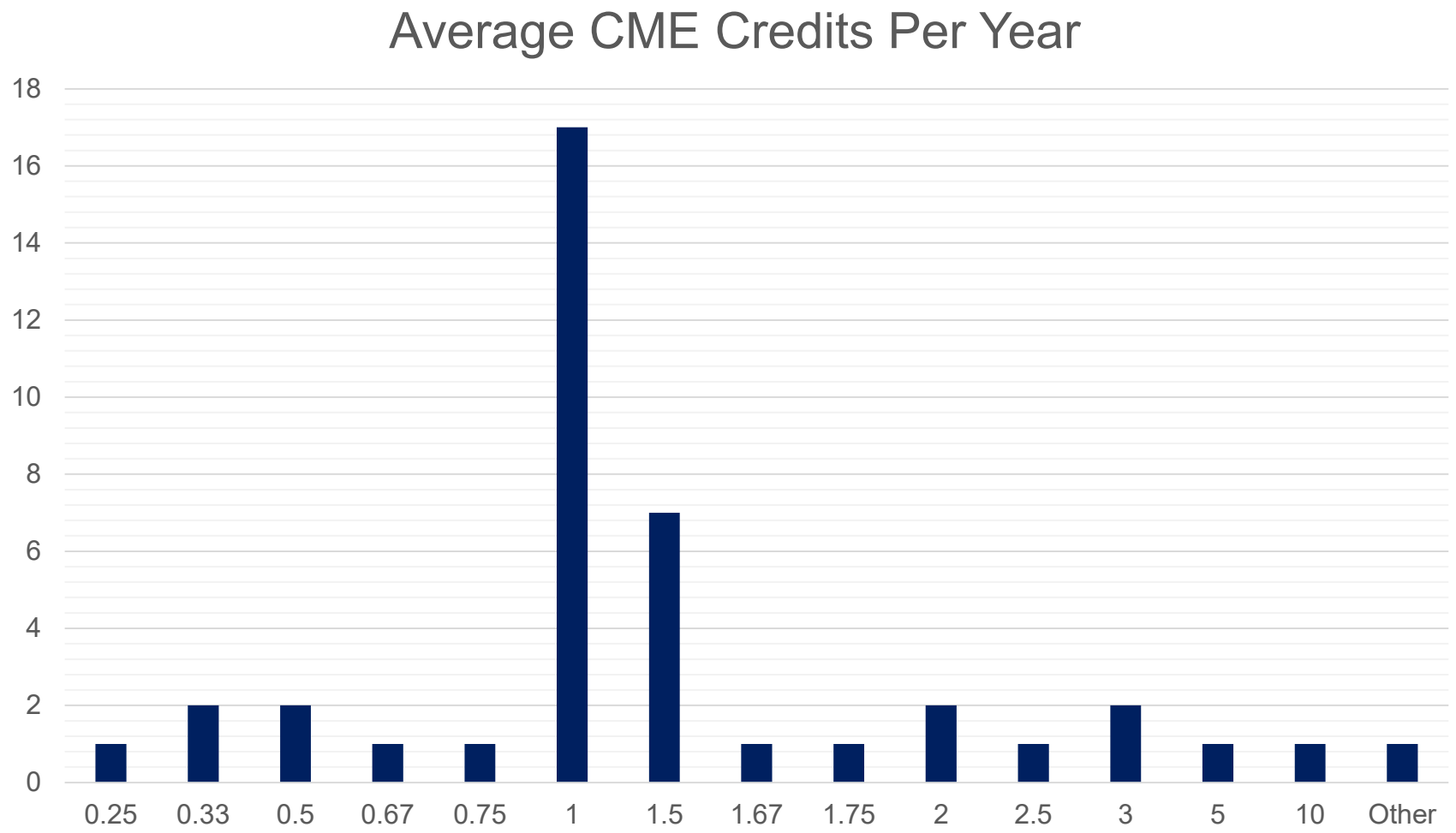
States Requiring Opioid Related CME



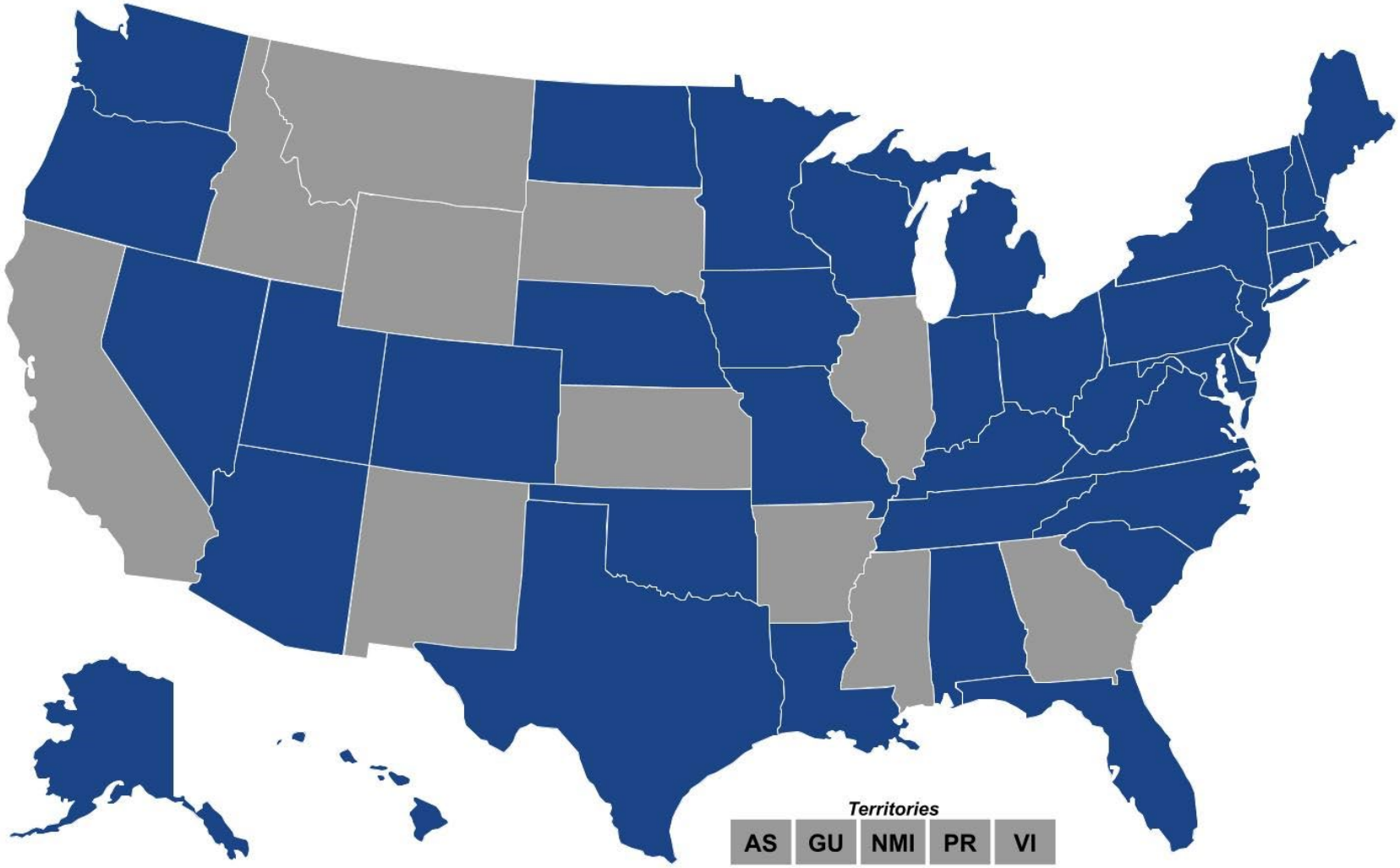
Content Specific Requirements

- ✓ Best Practices for Opioid/Controlled Substance Prescribing
- ✓ Pain Management and Opioid Use and Addiction
- ✓ Pain Management and the Appropriate Care and Treatment of the Terminally Ill
- ✓ Recognition of Substance Use Disorders
- ✓ Effective Use of PDMP
- ✓ Federal and State Laws Related to Prescribing Controlled Substances
- ✓ Drug Diversion

Hour Specific Requirements



States Limiting Opioid Prescriptions



Lisa Robin
Chief Advocacy Officer
Federation of State Medical Boards
lrobin@fsmb.org

Resources for Implementing the *CDC Guideline for Prescribing Opioids for Chronic Pain*

Kristine Schmit, MD, MPH
Medical Epidemiologist
Division of Overdose Prevention
Centers for Disease Control and Prevention

FDA Public Workshop
October 13-14, 2021

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 65 / No. 1
March 18, 2016

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

Continuing Education Examination available at http://www.cdc.gov/mmwr/cme/conted.html.

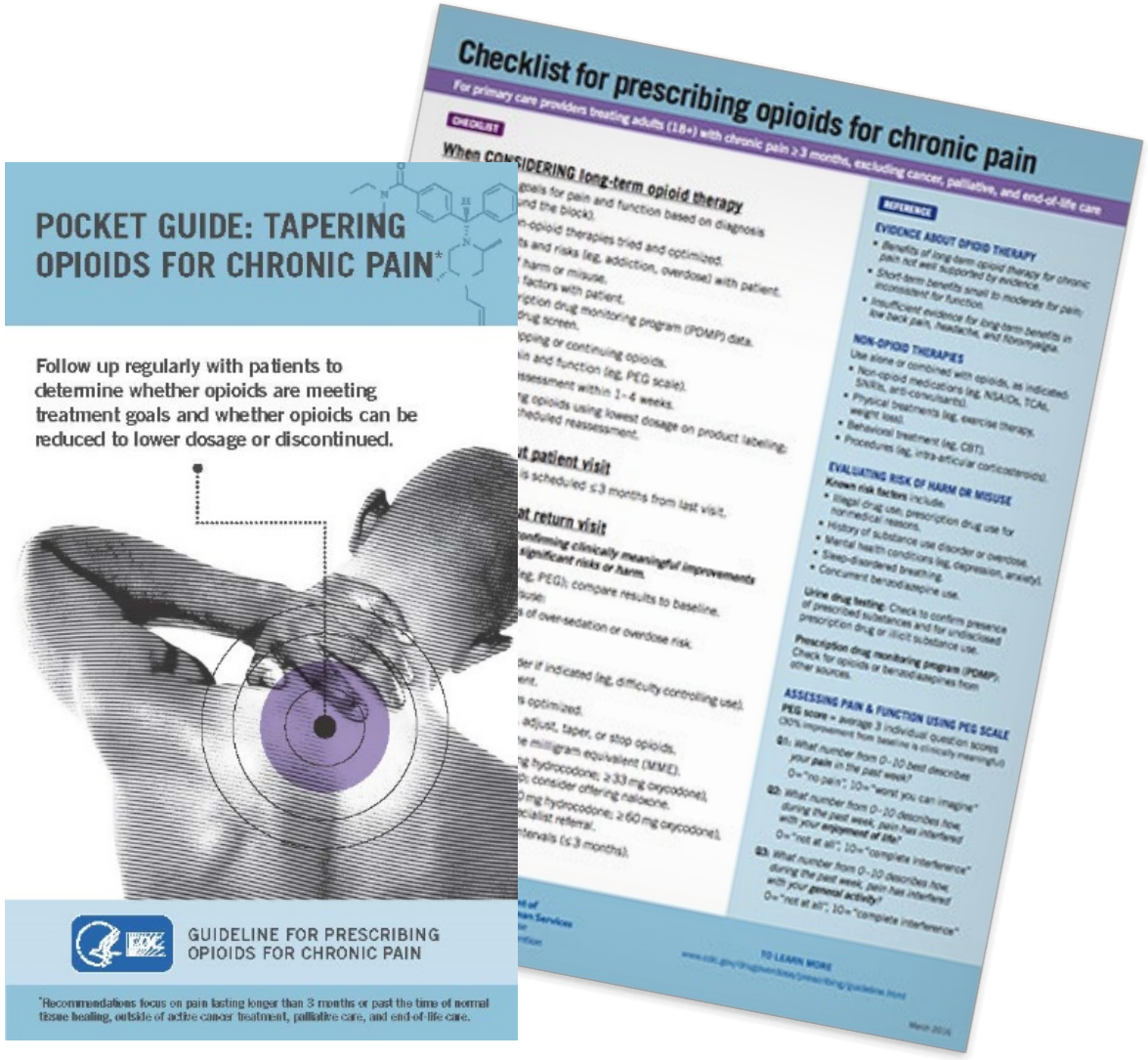
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

- Primary care providers
- Patients 18 years or older with chronic pain
- Outpatient settings
- Outside of active cancer, palliative, and end of life care

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

www.cdc.gov

Guideline Resources: Clinical Tools



- **Checklist**
- **Pocket Guides**
- **Fact sheets**
  - Assessing Benefits and Harms of Opioid Therapy
  - Non-opioid Treatments
  - Prescription Drug Monitoring Programs
  - Calculating Total Daily Dose of Opioids for Safer Prescribing

https://www.cdc.gov/opioids/providers/prescribing/clinical-tools.html

Guideline Resources: Clinical Tools

- **Mobile App –**

“Prescribe with Confidence”

- Features include:
  - MME Calculator
  - Prescribing Guidance
  - Motivational Interviewing

https://www.cdc.gov/opioids/providers/prescribing/app.html

Guideline Resources: Videos

- Help improve communication between prescribers and patients
- Can easily feature in trainings

https://www.cdc.gov/opioids/providers/prescribing/videos.html

Guideline Resources: Online training modules & webinars

Clinical Outreach and Communication Activity (COCA) Free Webinars

1. Overview of Guideline
2. Nonopioid Treatments for Chronic Pain
3. Assessing Benefits and Harms of Opioid Therapy
4. Dosing and Titration of Opioids
5. Opioid Use Disorder—Assessment and Referral
6. Risk Mitigation Strategies
7. Effective Communication with Patients

https://www.cdc.gov/drugoverdose/training/index.html

Guideline Resources: Online training modules & webinars

Interactive Training Series for Healthcare Providers

https://www.cdc.gov/drugoverdose/training/index.html

Guideline Resources: Where to Find

https://www.cdc.gov/drugoverdose/prescribing/resources.html

https://www.cdc.gov/opioids/providers/training/index.html

https://www.cdc.gov/opioids/healthcare-admins/index.html

Thank you

The findings and conclusions in this presentation are those of the presenter and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Discussion Questions

- Have prescriber education efforts at the federal, state, and health system levels generally provided prescribers with the training and information needed to safely prescribe opioid analgesics? How have prescriber education efforts generally supported or aligned with other policy efforts to reduce risks related to opioid prescribing?
- Are there overlaps or redundancies in requirements that may lead to unnecessary, burdensome, or duplicative requirements for prescribers?
- What can we learn about implementation of prescriber education from existing educational programs at the federal, state, and health system levels in pain management, in opioid risk reduction, and in the treatment of opioid use disorder?

Break

We will be back momentarily.

The next panel will begin at 3:55 p.m. (U.S. Eastern Time)

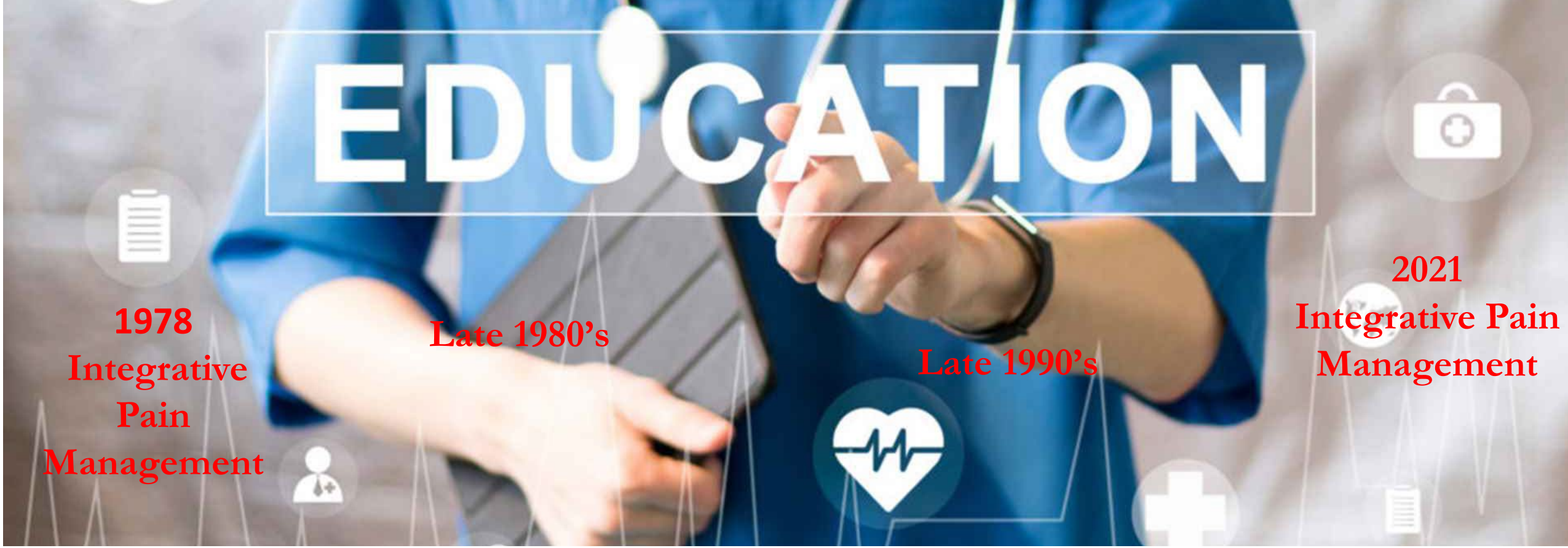
Examining the Potential Role of Prescriber Education in Helping to Address the Current Opioid Crisis

- **Theresa Campo**, American Association of Nurse Practitioners
- **Penney Cowan**, World Patients Alliance
- **David Fiellin**, Yale School of Medicine
- **Erin Krebs,** Minneapolis Veterans Affairs Health Care System
- **Mary Lynn McPherson**, University of Maryland Center to Advance Chronic Pain Research

Examining the Potential Role of Prescriber Education in Helping to Address the Current Opioid Crisis

World Patients Alliance

www.worldpatientsalliance.org



REMS Education for HCP

The REMS focus was <u>not</u> on helping a person manage pain with a combination of therapies, but on prescribing.

REMS Education for HCP

- Time provider has to spend with patient to do a complete initial assessment is not enough
- Payers control how HCP would practice medicine

My Goals

Regaining control of my life in spite of chronic pain means:

1. Improve Quality of Life
2. Improve function
3. Reduce Suffering

REMS Education for HCP

- Expectations of both provider and person living with pain
- Focus on the balanced approach to pain management
- Team approach with patient at the center of the team

Discussion Questions

- How can prescriber education programs be improved to support appropriate opioid prescribing, better pain management, and recognition and management of OUD?
- What are the current knowledge gaps or important clinical challenges related to safe opioid prescribing and pain management more generally?
- How could improved prescriber education address those challenges to achieve better outcomes for patients and make a positive impact on the opioid crisis?

Closing Remarks | Day 1

Mark McClellan, MD, PhD

Director, Duke-Margolis Center for Health Policy

Thank You!

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Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Crisis

October 13, 2021 | 1:00-5:00 p.m. ET

October 14, 2021 | 1:00-4:05 p.m. ET

FDA U.S. FOOD & DRUG ADMINISTRATION | Duke MARGOLIS CENTER *for* Health Policy

Welcome and Introduction | Day 2

Mark McClellan

Duke-Margolis Center for Health Policy

Overview: Day 1

Presentations:

- Opening Remarks from FDA
- The Current Landscape of the Evolving Opioid and Addiction Crisis
- Selected FDA Actions in Response to the Opioid Crisis
- Prescription Opioid Utilization Patterns in the U.S.

Panel Discussions:

- Assessing the Landscape of Federal, State, and Health System Prescriber Education Requirements
- Examining the Potential Role of Prescriber Education in Helping to Address the Current Opioid Crisis

Agenda: Day 2

Panel Discussions:

- Considerations for the Future Role of Federally Mandated Prescriber Education in Alleviating the Current Opioid Crisis
- Next Steps

Statement of Independence

The Robert J. Margolis, MD, Center for Health Policy is part of Duke University, and as such it honors the tradition of academic independence on the part of its faculty and scholars. Neither Duke nor the Margolis Center take partisan positions, but the individual members are free to speak their minds and express their opinions regarding important issues.

For more details on relevant institutional policies, please refer to the Duke Faculty Handbook, including the Code of Conduct and other policies and procedures. In addition, regarding positions on legislation and advocacy, Duke University policies are available at http://publicaffairs.duke.edu/government.

Virtual Meeting Reminders

- Attendees are encouraged to contribute throughout the meeting with questions in the Zoom Q&A function.
- Panelists should go on video during their panel discussion
- Presenters should provide a verbal prompt when they'd like to advance the slides

Considerations for the Future Role of Federally Mandated Prescriber Education in Alleviating the Current Opioid Crisis

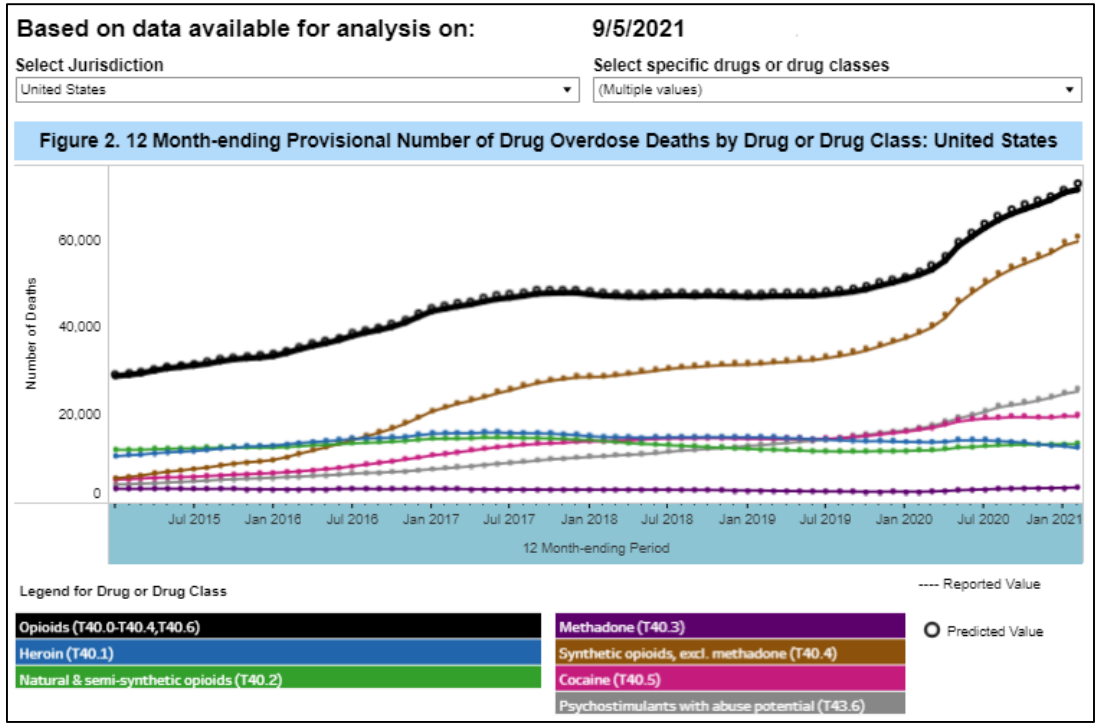
- **Bobby Mukkamala,** American Medical Association
- **Elyse Powell,** North Carolina Department of Health and Human Services
- **Anuradha Rao-Patel**, North Carolina Medical Board
- **Steve Singer**, Accreditation Council for Continuing Medical Education

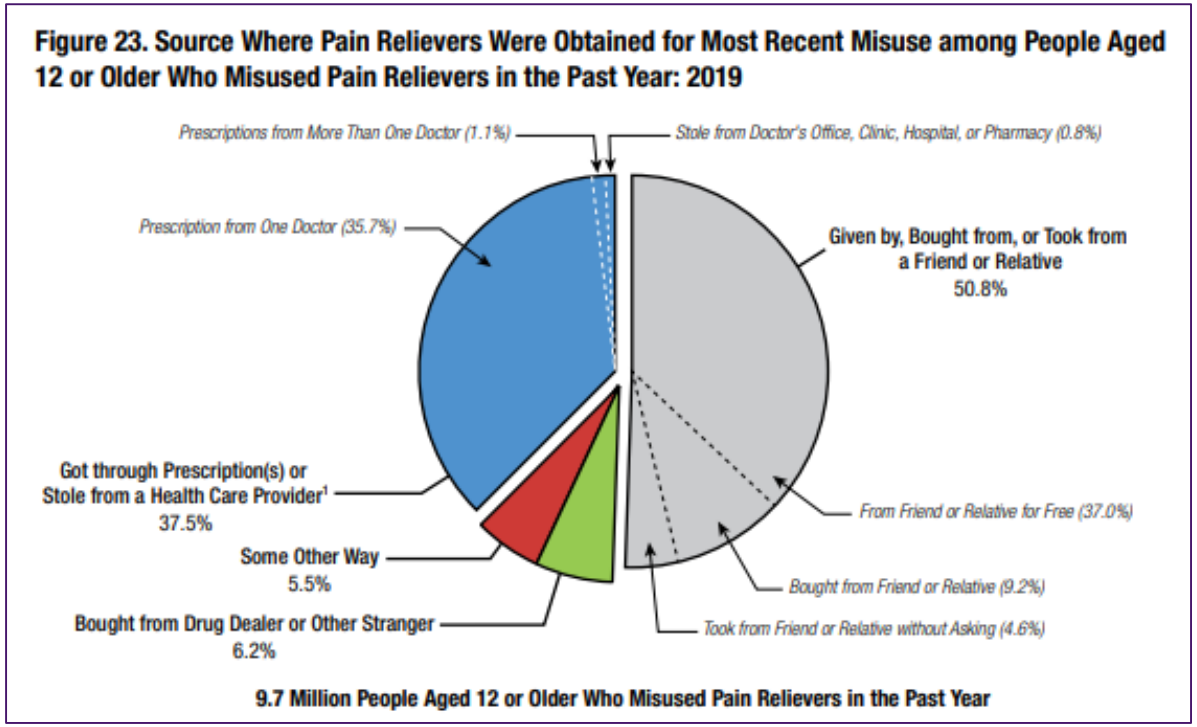
American Medical Association discussion concerning mandatory REMS as a proposal for addressing the nation's drug overdose epidemic

Bobby Mukkamala, MD
Chair, AMA Board of Trustees
Chair, AMA Substance Use and Pain Care Task Force

October 14, 2021

Drivers of America's drug overdose epidemic





MORNING CONSULT

BARRIERS TO RECEIVING TREATMENT

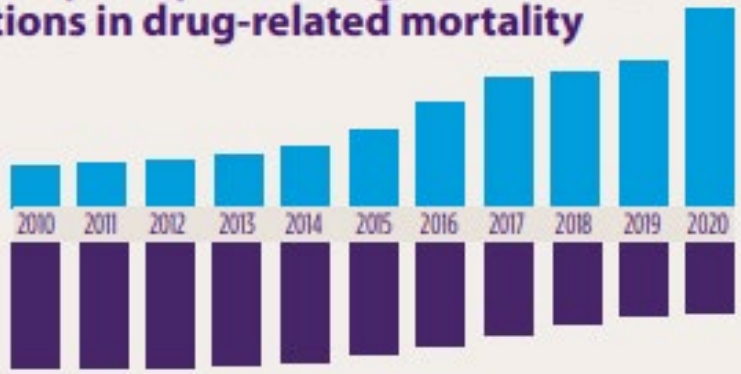
Adults are most likely to say cost of help or treatment (51%), availability of providers who are taking patients regardless of insurance (41%), and availability of providers taking patients within their insurance network (39%) are large obstacles to seeking help, treatment or counseling.

Most common policy responses to epidemic

Reductions in opioid prescribing have not led to reductions in drug-related mortality

Overdose deaths:
94,134*

Opioid prescriptions:
143,390,951[1]
(44.4% decrease since 2011)



*Provisional data for the 12-month period Jan. 2020–Jan. 2021
https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Harm reduction and other community-based organizations **distributed more than 3.7 million doses of naloxone between 2017–2020.**[5]

During the COVID-19 pandemic, the number of **individuals filling a naloxone prescription from retail pharmacies decreased more than 26%.**[6]

44.4% decrease in opioid prescriptions from 257.9M in 2011 to 143.4M in 2020[1]

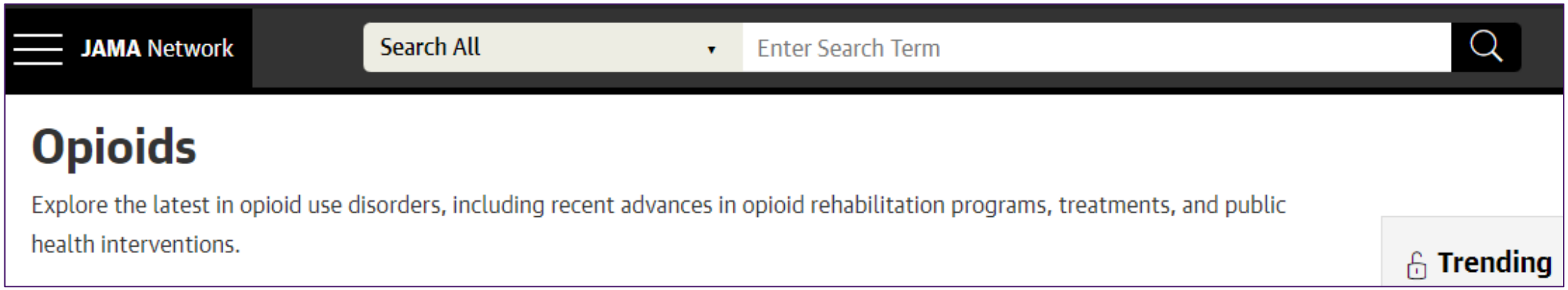
910.6M

61.5M

Increase in PDMP use and **2.7B queries** since 2014[2]

106,000+ physicians and health care professionals certified to prescribe buprenorphine in-office—a nearly 70,000 increase since 2017.[3] Yet, millions with a substance use disorder (SUD) remain without access to evidence-based care.

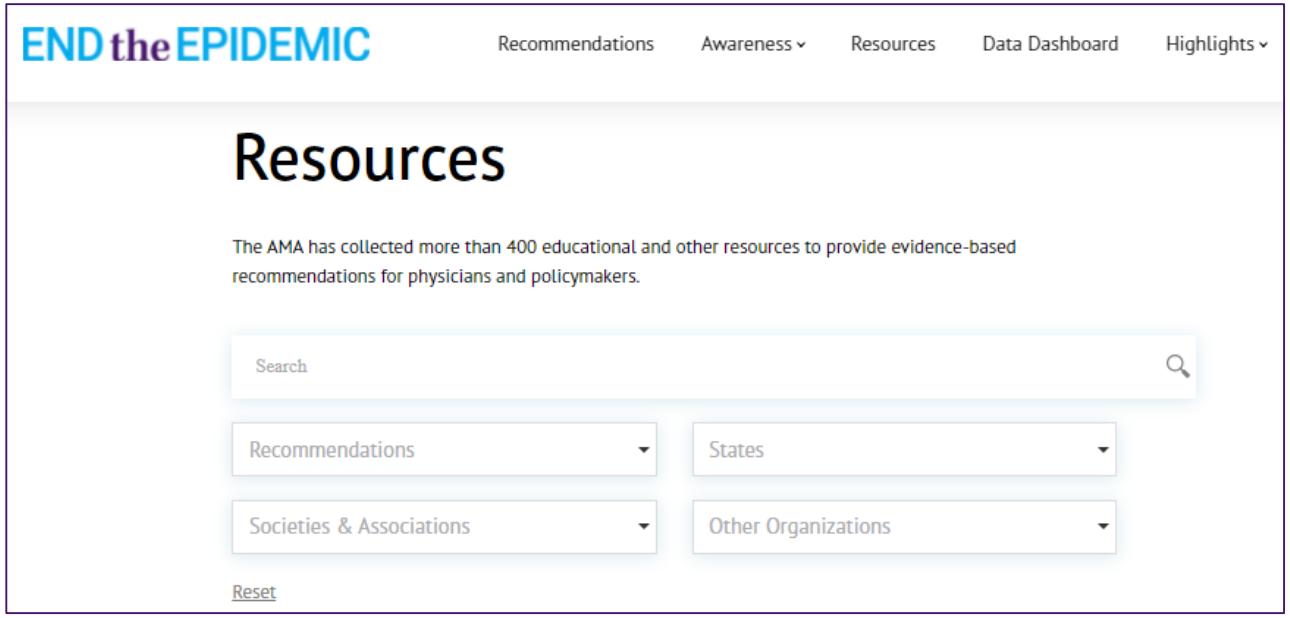
AMA strongly supports voluntary education



In 2018, more than

700,000 PHYSICIANS

and other health care professionals completed continuing medical education trainings and accessed other educational resources provided by the AMA, and state and specialty medical societies. These materials included opioid prescribing, pain management, screening for substance use disorders, and related areas.[4]



Focus efforts on evidence-based solutions

- Support GME programs to hire core faculty in pain medicine and addiction medicine and psychiatry
- Urge naloxone manufacturers to submit OTC applications
- Review labeling for buprenorphine to account for the need for higher doses in response to illicit fentanyl
- Increase research efforts for medications to treat substance use disorders related to methamphetamine and cocaine
- Support revisions to the 2016 CDC Guideline to remove arbitrary thresholds
- Build broad stakeholder support to help destigmatize medications for pain and for substance use disorders

Physicians' powerful ally in patient care



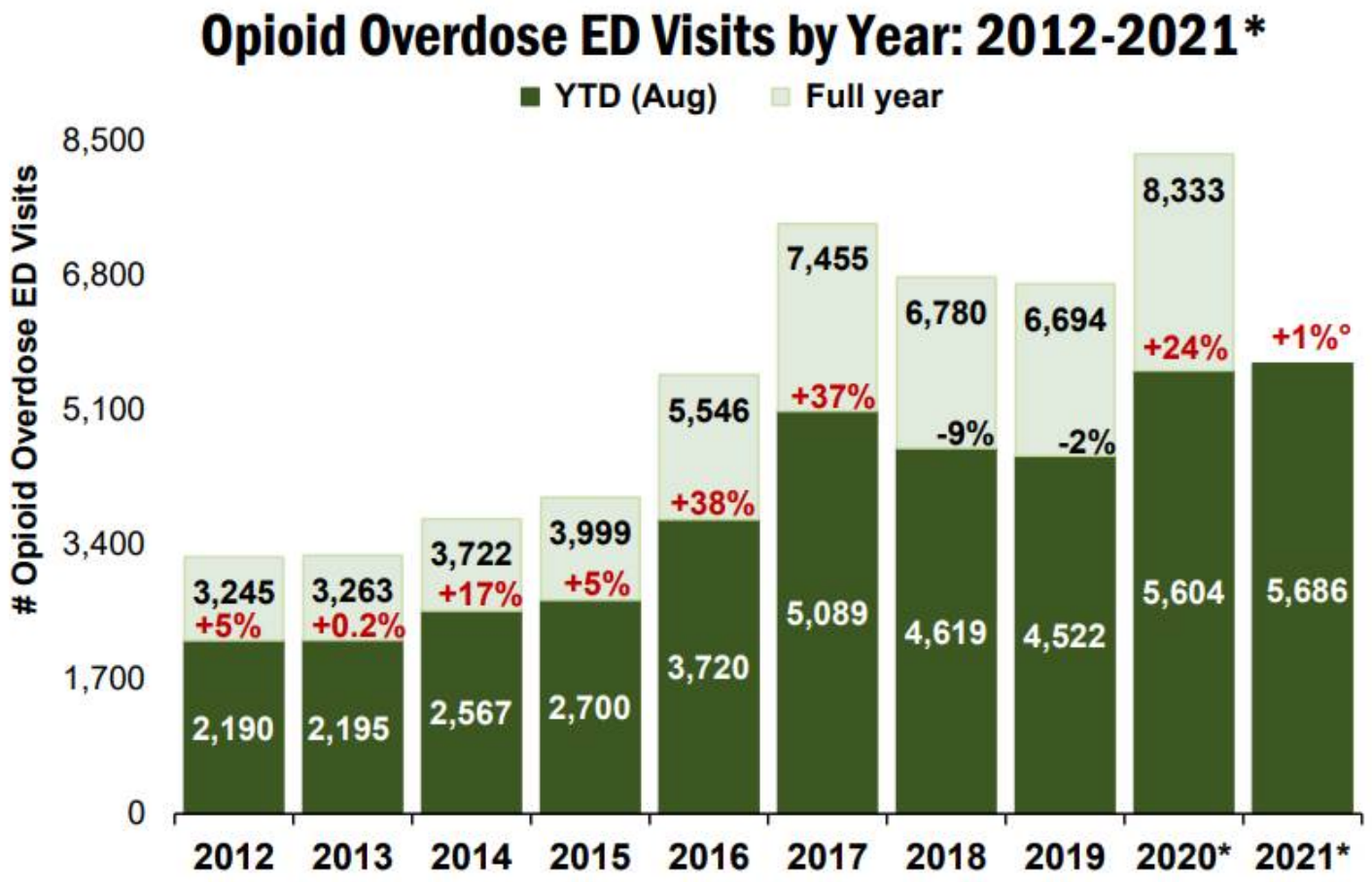


Considerations for the Future Role of Federally Mandated Prescriber Education in Alleviating the Current Opioid Crisis

Elyse Powell, Ph.D

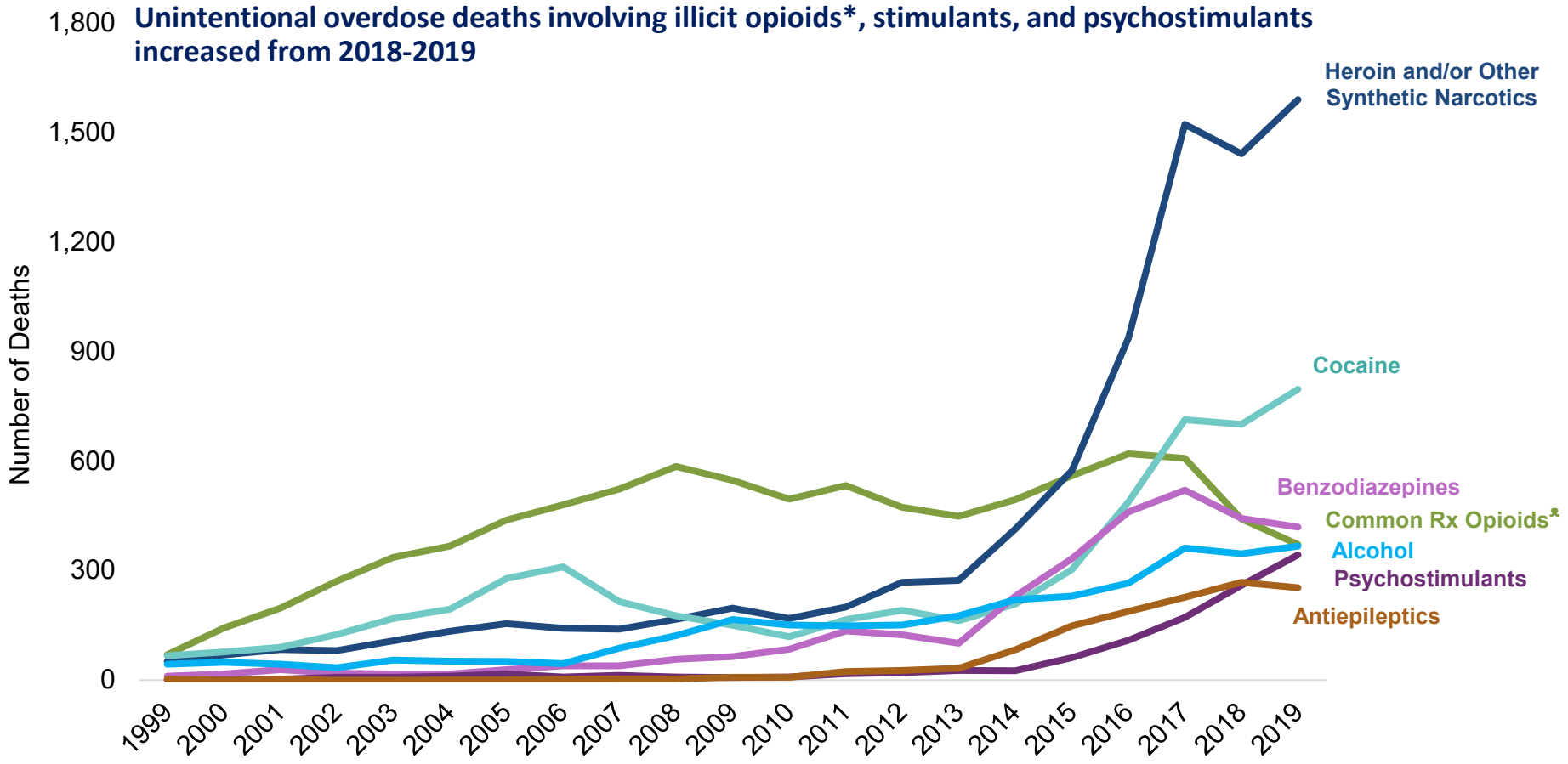
NC State Opioid Coordinator

North Carolina experienced a surge in overdoses during COVID similar to national trends



Percent change: YTD total compared to YTD total of previous year; °There are known data quality gaps for May-June 2021 that are impacting the shown trends. Interpret the data for

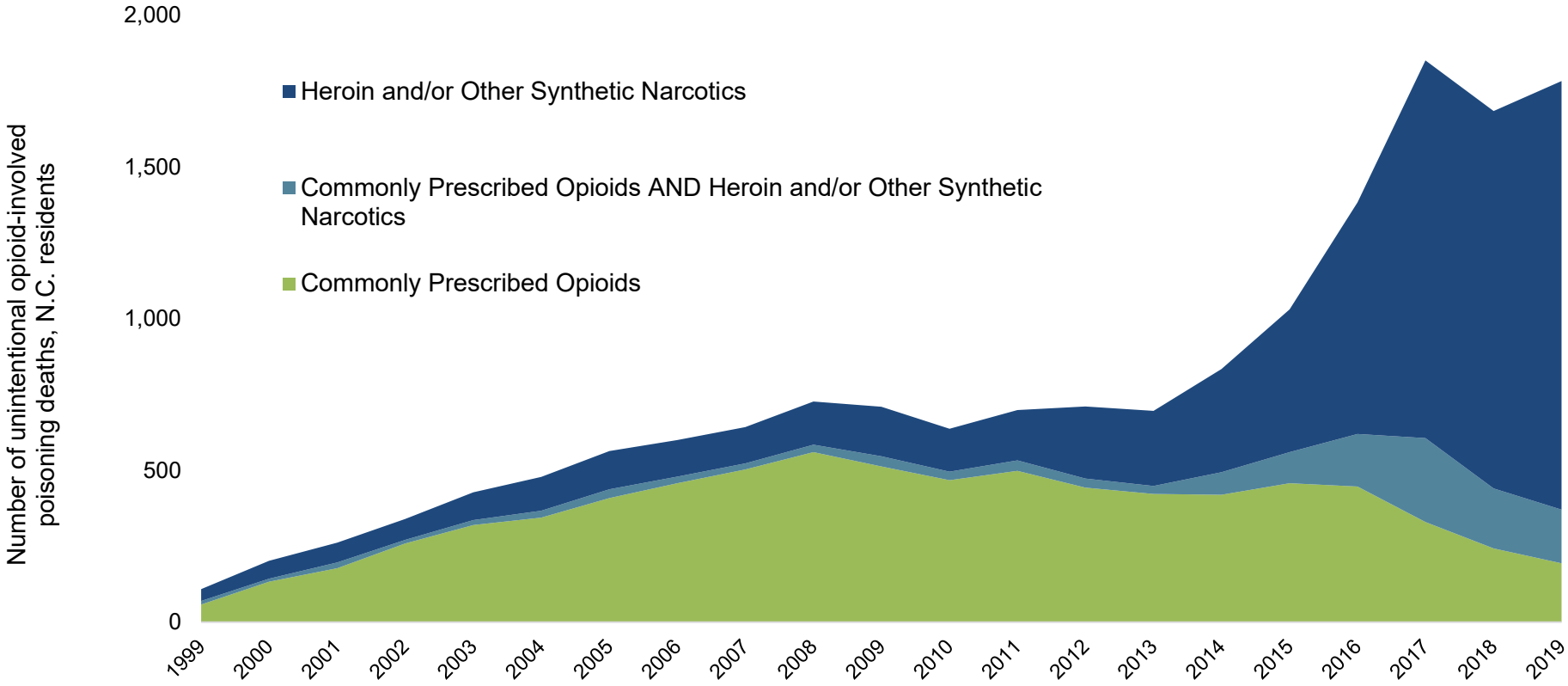
Deaths involving stimulants and psychostimulants are increasing



*Heroin and/or Other Synthetic Narcotics (mainly illicitly manufactured fentanyl and fentanyl analogues); *Commonly Prescribed Opioid Medications

Technical Notes: These counts are not mutually exclusive; If the death involved multiple substances it can be counted on multiple lines;
Unintentional medication, drug, alcohol poisoning: X40-X45 with any mention of specific T-codes by drug type; limited to N.C. residents
Source: Deaths-N.C. State Center for Health Statistics, Vital Statistics, 1999-2019
Analysis by Injury Epidemiology and Surveillance Unit

Illicit opioids* were involved in approximately 78% of unintentional opioid overdose deaths



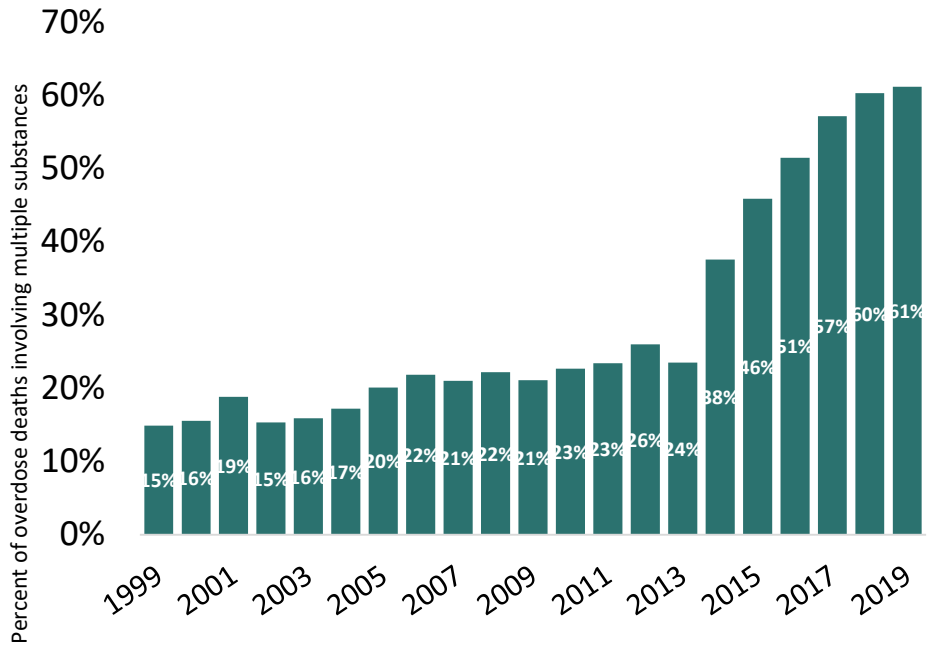
*Heroin and/or Other Synthetic Narcotics (mainly illicitly manufactured fentanyl and fentanyl analogues)

Technical Notes: Cases with only an Opium (T40.0) or only Other and Unspecified Narcotics (T40.6) code are excluded; Unintentional medication and drug poisoning: X40-X44 and any mention of T40.1 (Heroin), T40.2 (Other Opioids), T40.3 (Methadone),T40.4 (Other synthetic opioid) and/or T40.6 (Other/unspecified narcotics); Limited to N.C. residents
Source: Deaths-N.C. State Center for Health Statistics, Vital Statistics, 1999-2019
Analysis by Injury Epidemiology and Surveillance Unit

Most overdose deaths involve multiple substances

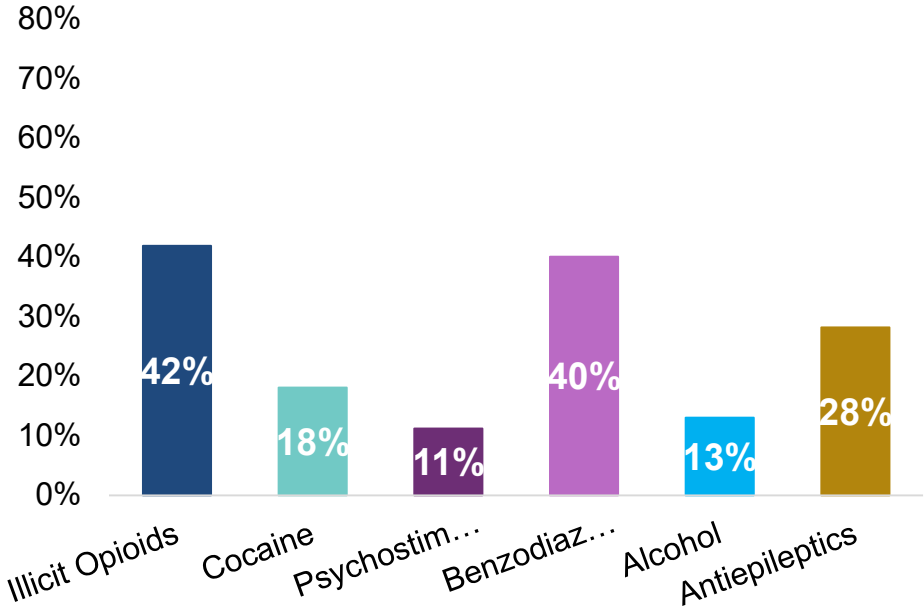
Even prior to COVID, there has been an accelerating trend toward polysubstance use

61% of overdose deaths involve multiple substances



Source: NC State Center for Health Statistics, Vital Statistics, 1999-2019
Detailed technical available from NC DHHS

82% of prescription opioid deaths involve multiple substances



Technical Notes: These categories are not mutually exclusive; If the death involved multiple substances, it can be counted on multiple bars
Source: Deaths-N.C. State Center for Health Statistics, Vital Statistics, 2019
Analysis by Injury Epidemiology and Surveillance Unit

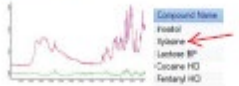
XYLAZINE

NORTH CAROLINA SURVIVORS UNION
NCSU
THE COMMUNITY VOICE

XYLAZINE, A VETERINARY TRANQUILIZER, IS SHOWING UP IN HEROIN AND FENTANYL.

To keep our people safe, we got a machine that
what's in drug samples.

When people came to us with really bad sympto
used our drug checking machine and identified a
substance called **xylazine**.



This substance has been showing up in the drug
other places, too. **In Philly, 1 out of every 3 peo**
fatally overdosed in 2020 had xylazine in their s

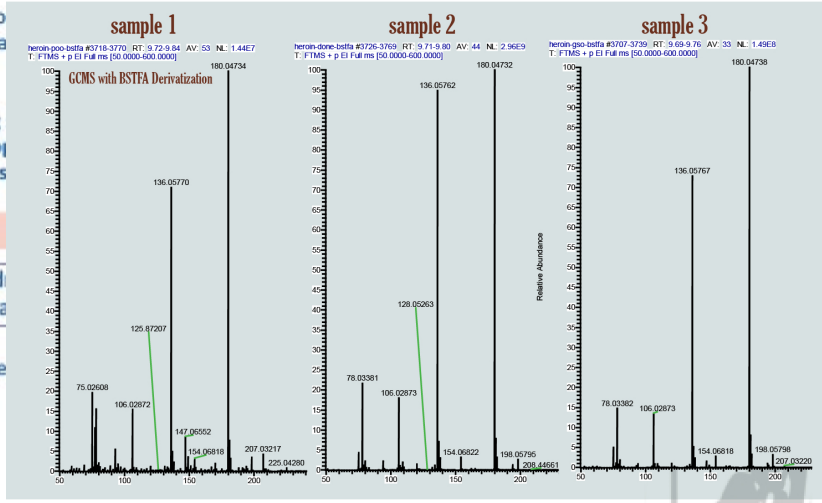
WHAT WE KNOW

Xylazine can be very dangerous. If you think you have been using this d
seeking medical attention can make the difference between life and dea

- Xylazine causes central nervous system depression. You may experience a low blood pressure, slowed breathing, and a slowed heart rate.
  - ➜ **Tip: Go slow. Use with a friend if you can.**
- Xylazine can cause painful skin ulcers.
  - ➜ **Tip: Keep wounds clean. Ask us for help if you're worried.**
- Naloxone works on opioids. It may work on xylazine, but the evidence is unclear.
  - ➜ **Tip: Always use naloxone in the event of an overdose.**
- Xylazine may make people out of breath and feel really tired.
  - ➜ **Tip: Come talk to us if you are experiencing either of these symptoms.**

Vitamins in heroin? Why that's not so great

UNC CHEMISTRY MASS SPECTROMETRY LAB



$C_9H_{13}NO_2Si$

Niacin showed up in 3 Greensboro street samples in December - along with heroin, fentanyl, and fillers.

Pandemic-time drugs are weird!

Niacin is called Vitamin B3, and is found in tuna and peanuts. But, it's showing up in dope. So, **drink extra water** if you feel:

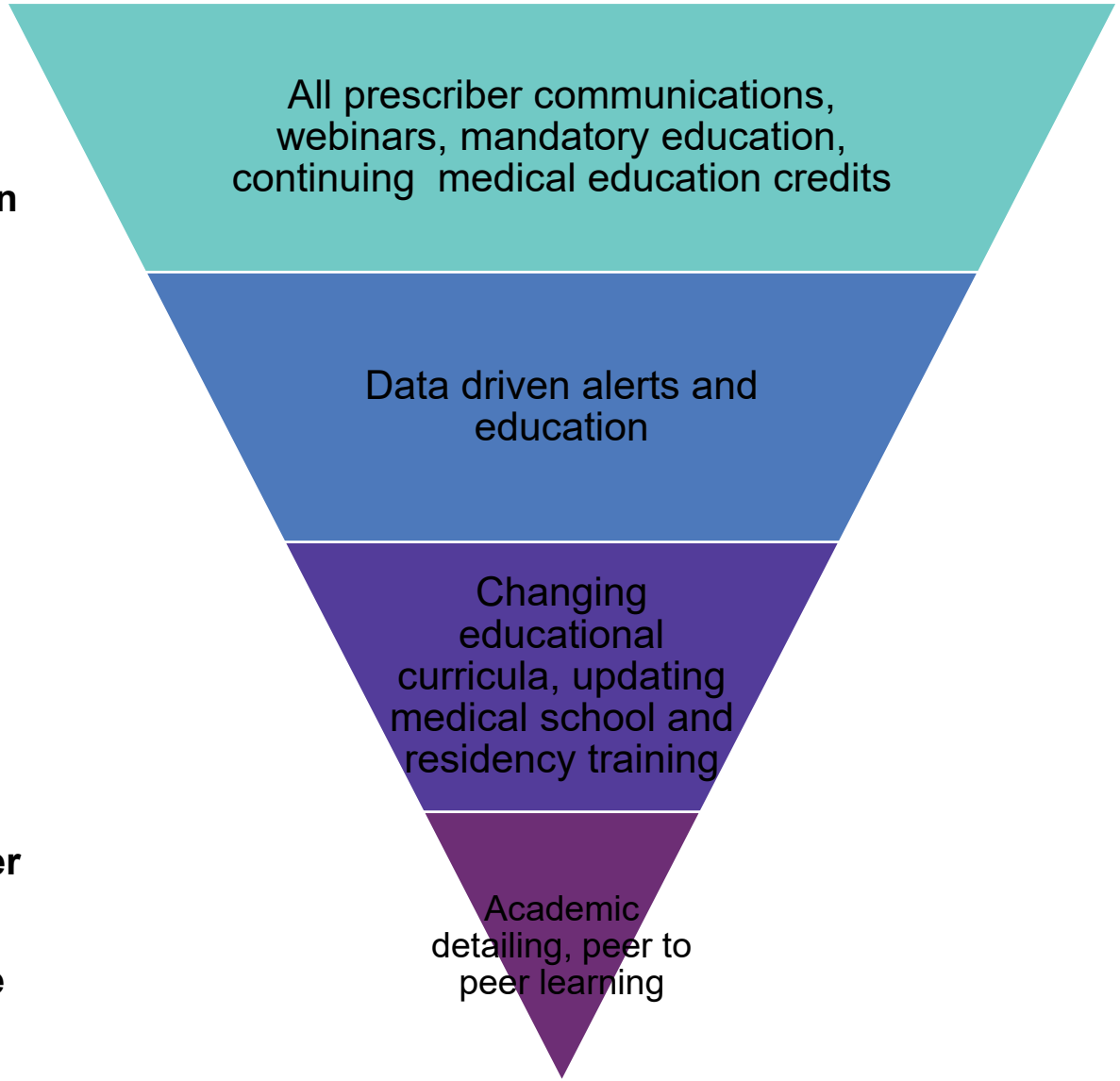
Flushing 😳 Itching 🤦
Fast Heartbeat ❤️ Nausea 🤮
Dizzy 🌪️

Jan 29, 2021
OpioidData.org

Opioid and Substance Use Action Plan

The Opioid and Substance Use Action Plan broadens its focus to include **polysubstance use** and **centers equity and lived experience**

- **All provider communications**
  - **Implemented the STOP Act, including mandatory checking of PDMP**
  - **Launched NC Dental Opioid Action Plan**
  - **Trained more than 4,000 prescribers in safe opioid prescribing and pain treatment**
- **Data driven outreach**
  - **Leveraging NC's PDMP to refer prescribers to the appropriate professional/licensing boards**
- **Updating the curricula for medical school, residency, and APP training**
  - **Launched an MAT Residency Training program which trained more than 1,500 prescribers, and incorporated MAT training into over 29 residency and APP programs**
  - **4 of NC's 5 medical schools now provide MAT training as part of the standard curricula**
- **Peer to Peer learning**
  - **Established an opioid prescribing academic detailing pilot**



Lessons learned from NC's provider education efforts

- Identifying **the correct message** from **the correct messenger** is critical for behavior change
- Both very broad and very deep educational efforts involve important trade offs
- **Changing educational curricula yield long term gains.** Pain management and addiction treatment should be a standard component of clinical provider training
- **PDMPs** are an underutilized tool to shape educational efforts

North Carolina's approach: Engaging medical professionals on opioids topics

Anuradha Rao-Patel, MD

Board Member

Presented Oct. 14, 2021

NORTH CAROLINA MEDICAL BOARD

North Carolina Medical Board
3127 Smoketree Court| Raleigh, NC 27604
www.ncmedboard.org | info@ncmedboard.org
800.253.9653

The role of the regulator

Impartial

Does not advocate, like a professional society

No direct hand in patient care – that's the job of the individual medical professional

Disciplinary authority – we enforce standards of care but do NOT set them

Licensing powers – we ensure applicants meet all requirements for licensure in NC

So how to engage?

Tools in NCMB's toolbox

- Notice/slideshow image on the NCMB home page
- Article in the NCMB newsletter
- Social media posts
- Dedicated resource page with helpful links, documents, videos and other resources
- Podcast episode
- Outreach to NCMB stakeholders
- Development of original education/new resources

North Carolina's CS CME mandate

- 2015-2016 budget session law called on boards that license CS prescribers to implement opioid CME requirements
- NCMB requirement:
  - Physicians – 3 hours of CS CME per 3-year CME cycle
  - PAs – 2 hours per 2-year CME cycle
- Effective July 1, 2017
- ALL controlled substances prescribers subject to mandate (not just opioid prescribers)

Supporting NCMB's requirement

- For the first time in its history, NCMB developed original CME
- Partnered with Wake AHEC to obtain grant money for program
- Two components:
  - Free recorded webinar (1 hour) on responsible opioid prescribing
  - Free live opioid panel discussion (2 hours) presented at locations statewide

Impact?

43%

Thank you!

SUPPORTIVE EDUCATIONAL ENGAGEMENT

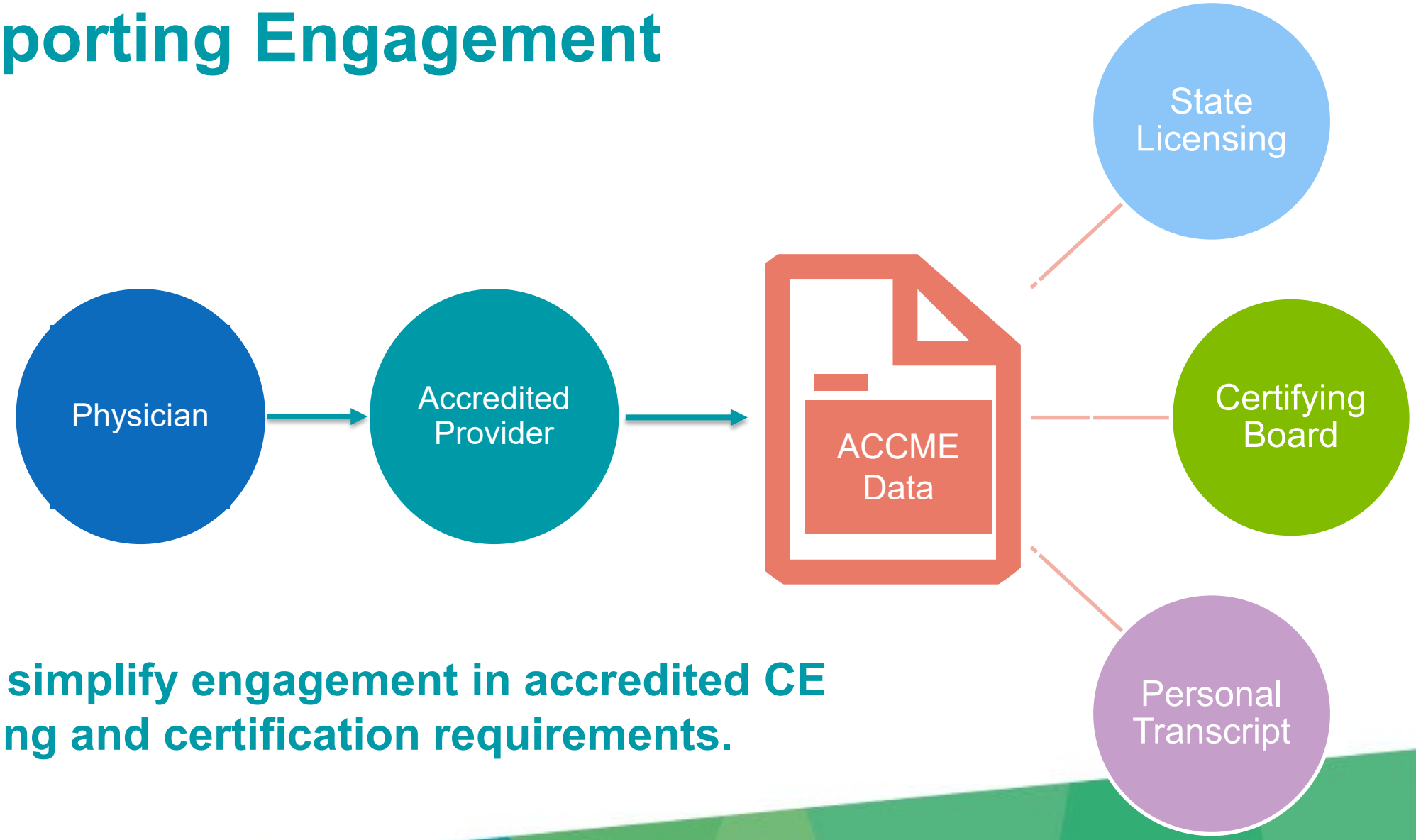
Steve Singer, PhD

Vice President of Education and Outreach

Accreditation Council™
for Continuing Medical Education

learn well

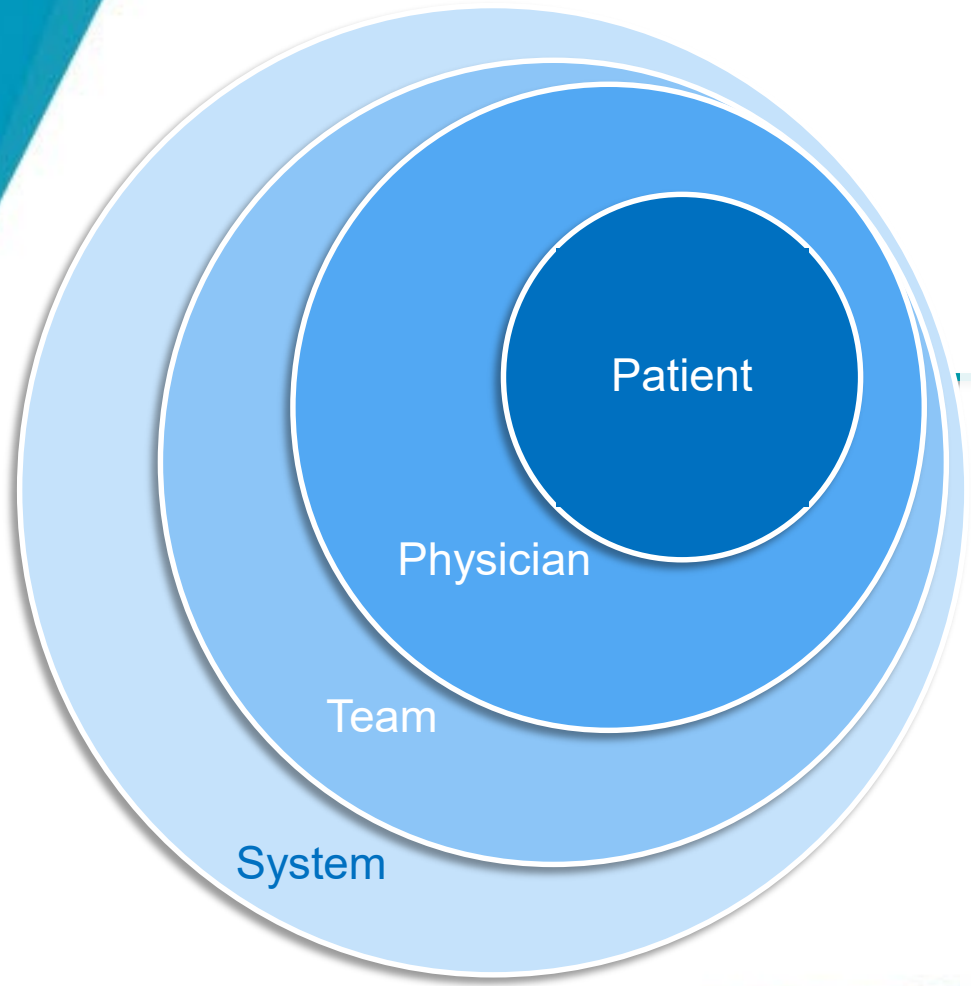
Supporting Engagement



Partnership to simplify engagement in accredited CE to meet licensing and certification requirements.

EMBRACING COMPLEXITY

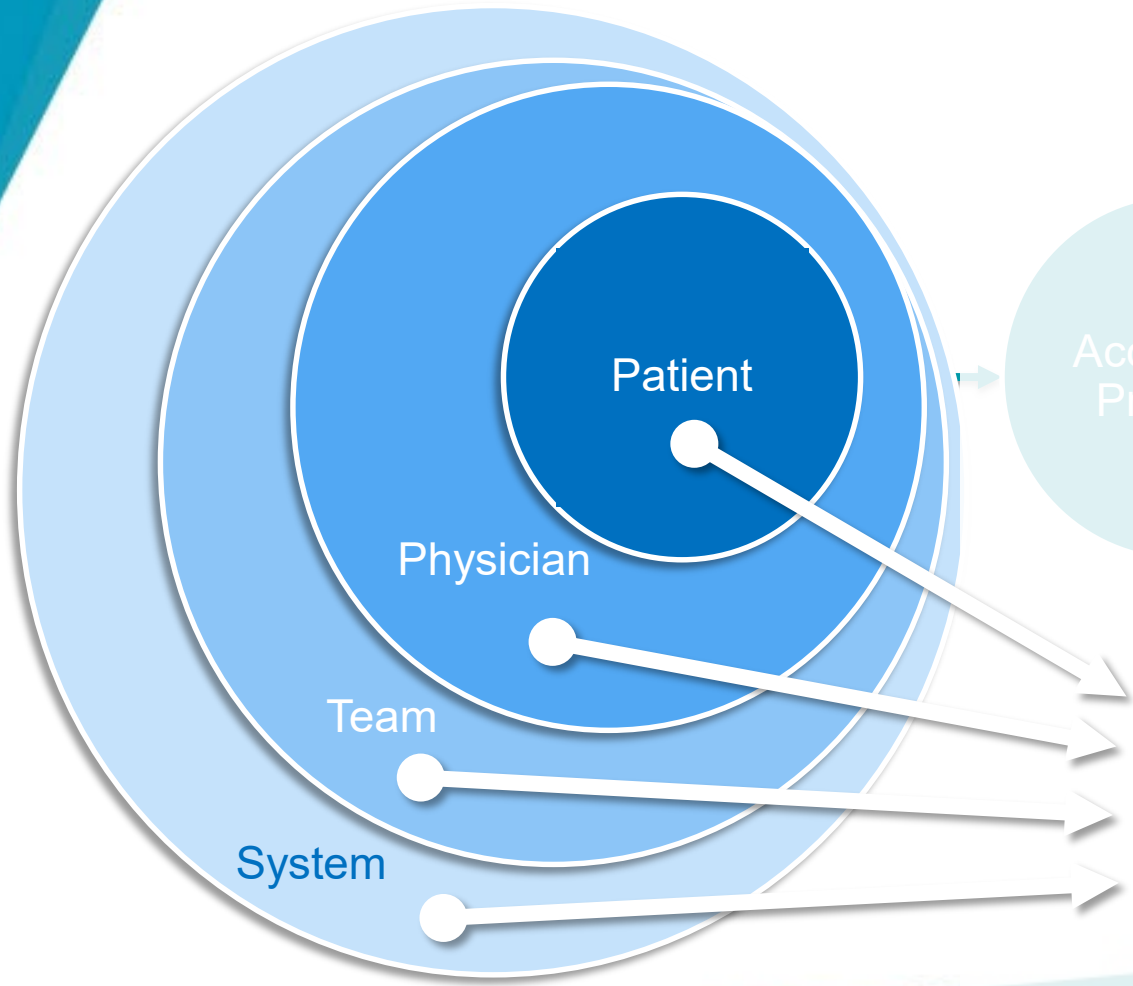
Supporting Engagement



Recognize the heterogeneity of the local environments in which health professionals work…

EMBRACING COMPLEXITY

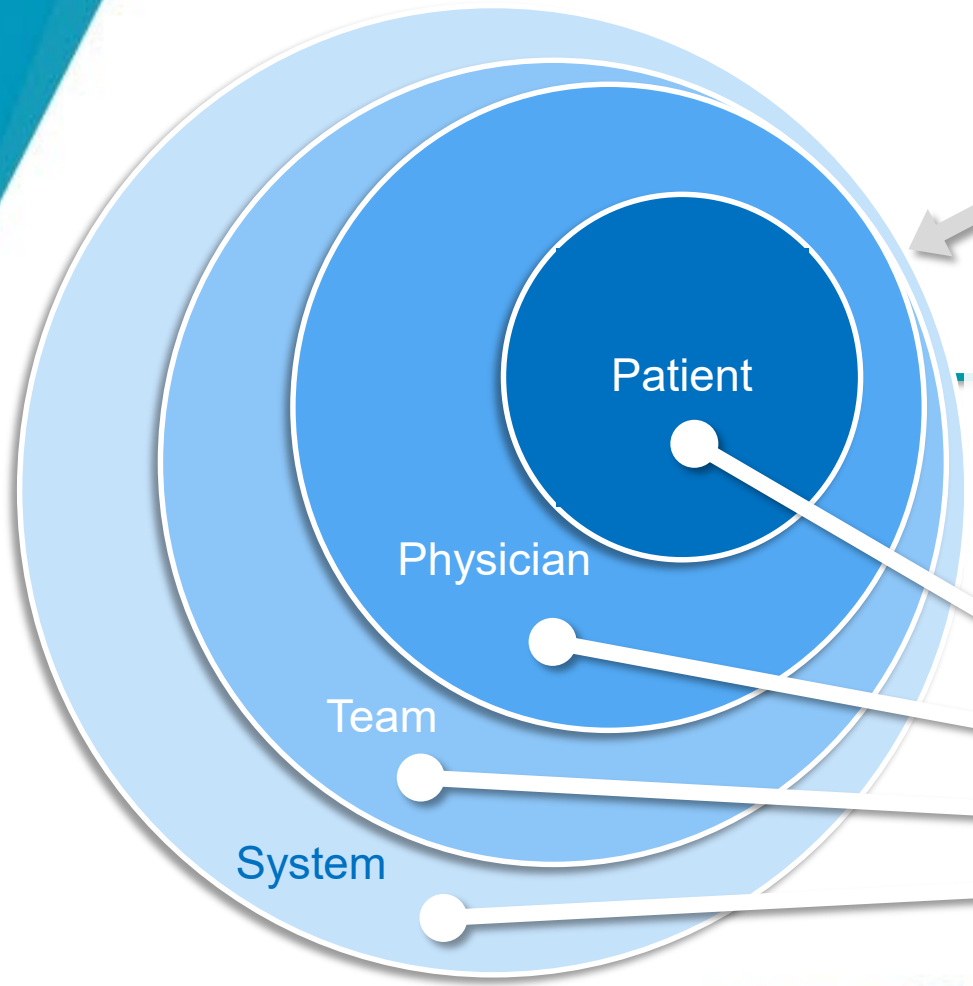
Supporting Engagement



Identify and address gaps and educational needs to support continuous improvement unique to setting, practice and patient population.

EMBRACING COMPLEXITY

Supporting Engagement



Gaps and needs inform evolving competencies and educational priorities, supported by regulations.

Identify and address gaps and educational needs to support continuous improvement unique to setting, practice and patient population.

CURRENT EDUCATIONAL ENGAGEMENT

Educational Activities in the ACCME System 2014 - 2018

	# of accredited CE providers	# of Activities	# of learner participants
OA REMS COMPLIANT[1]	109	892	395,663
TOTAL BY KEYWORD[2] opioid, opiates, naloxone, methamphetamine, substance use, substance abuse, SUD, addiction, medication assisted treatment, methadone, buprenorphine, pain, pain management	**1,492**	**25,257**	**4,513,802**

1. Opioid Analgesic (OA) REMS data summarized in Kahn, N. et al. J Contin Educ Health Prof. Winter 2019;39(1):58-63.

2. Based on keyword search of activity titles and descriptions in ACCME's Program and Activity Reporting System (PARS) as of January 20, 2020.

ACCME learn well

LOOKING FORWARD

How Can We Be More Impactful?

- Create a more flexible blueprint
- Incorporate evolving science
- Recognize team participation
- Assess outcomes vs completions
- Involve patients in designing/teaching CE
- Improve coordination
- Build awareness
- Identify and disseminate effective practices via CE research
- Promote innovation in educational approaches and ed. technology

NATIONAL ACADEMY of MEDICINE

HOME ABOUT PROGRAMS PUBLICATIONS NEWS EVENTS MEMBER HOME

ACCME learn well

ACCME

NAM ACTION COLLABORATIVE ON ADDRESSING THE OPIOID EPIDEMIC

Health Professional Education and Training Working Group

MISSION Collaboratively develop a harmonized interprofessional, patient and family-centered approach for the continuum of health professions' education that addresses acute and chronic pain management and substance use disorders (including prevention, screening, intervention, treatment, and long-term recovery).

SPECIAL PUBLICATION on professional practice gaps, existing regulatory requirements and policy standards, and actionable priorities needed to strengthen coordination and collaboration across the health education system (publication expected in November 2021).

ACCME

NATIONAL ACADEMY OF MEDICINE – SPECIAL PUBLICATION

Key Priorities

- Establish **minimum core competencies** for all health care professionals in pain management and SUDs, and support evaluating and tracking of health care professionals' competence;
- Align accreditors' expectations for **interprofessional collaboration** in education for pain management and SUDs;
- Foster interprofessional collaboration among licensing and certifying bodies to **optimize regulatory approaches** and outcomes;
- Unleash the capacity for **continuing education to meet health professional learners where they are**;
- Facilitate collaboration to **harmonize practice improvement initiatives**.

THANK YOU!

Follow ACCME on Social Media

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Contact us: info@accme.org

ACCME
learn well

Discussion Questions

- How might federally mandated prescriber education via a REMS benefit patients and prescribers? Conversely, what undue burdens might it place on providers and health systems and what barriers to access might it create for patients?
- What would appropriate program goals be for a mandatory prescriber education program through REMS? How would these goals complement the aims of other federal, state, and health system interventions?
- What logistical challenges might arise for FDA, health systems, and providers if prescriber education were federally mandated under a REMS? How could these and other stakeholders work to mitigate those challenges?

Break

We will be back momentarily.

The next panel will begin at 2:45 p.m. (U.S. Eastern Time)

Next Steps

- **Stefan Kertesz**, University of Alabama Birmingham
- **Kate Nicholson**, National Pain Advocacy Center
- **Daniel Pace**, American Academy of PAs
- **Friedhelm Sandbrink,** Veterans Health Administration
- **David Tauben**, University of Washington (Professor Emeritus)

Mandating REMS Prescriber Education Doesn't Fit the Problem or Today's Context:

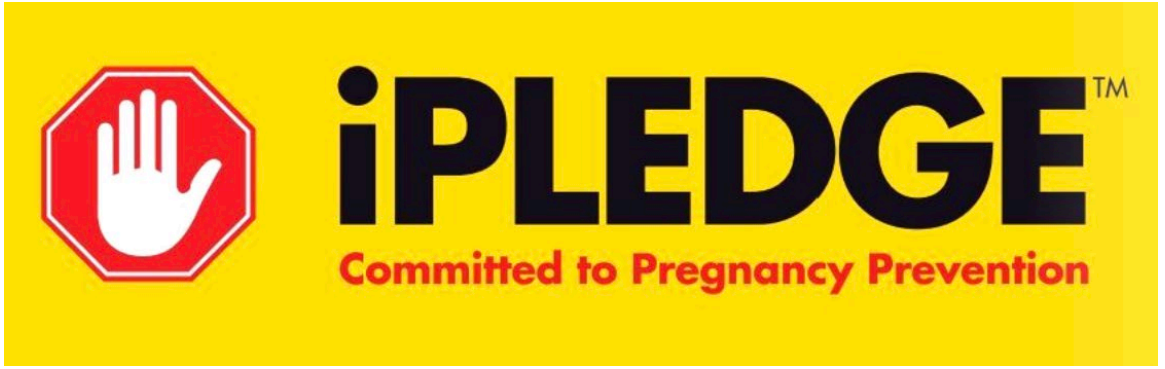
Stefan G. Kertesz, MD, MSc

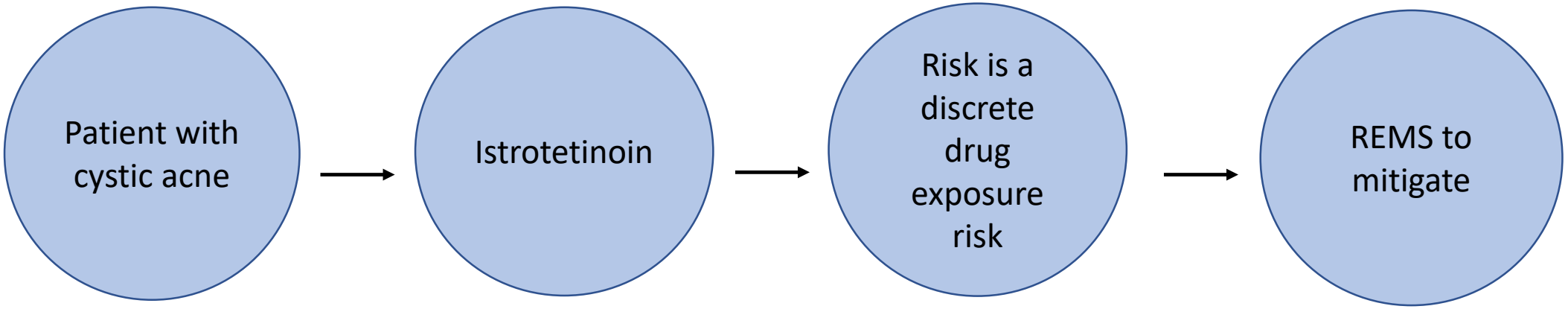
University of Alabama at Birmingham, Birmingham VA Medical Center

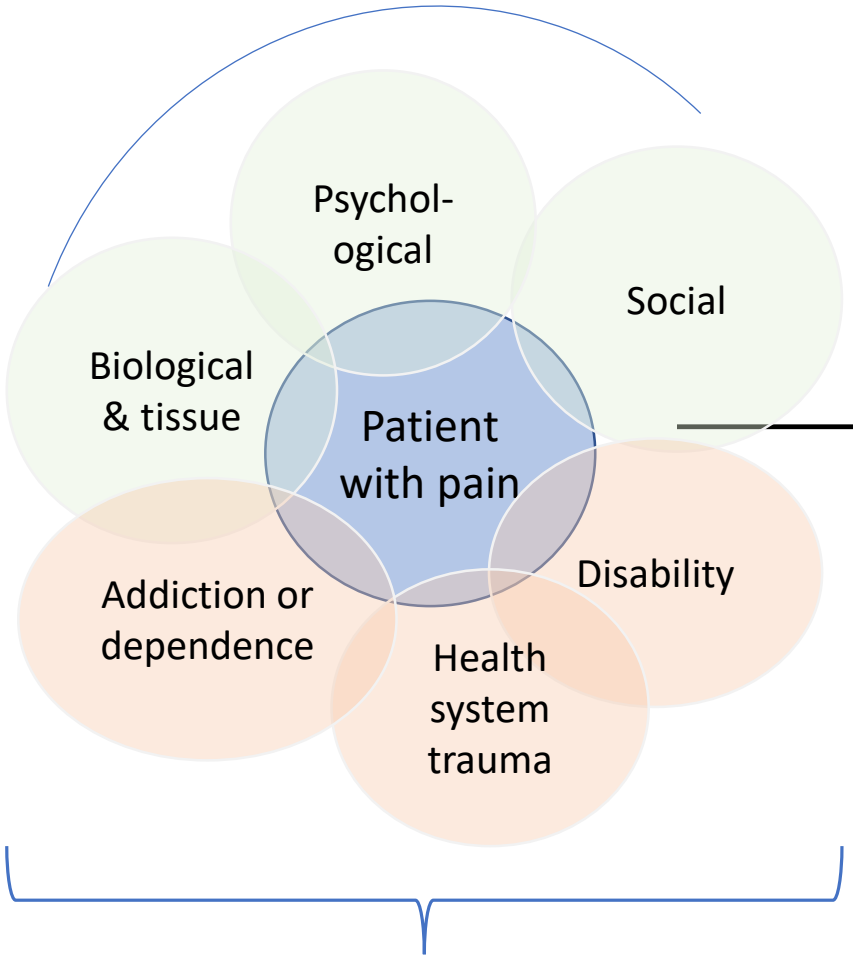
Views are my own and not those of the US Dept of Veterans Affairs

I have no pharma or opioid litigation interests

A REMS prototype







Not taught, which makes the Rx discussion myopic

Non-opioid

Rx opioid

Physical modalities

Other choices

Risk only partly Rx factors (VA data)

OD crisis

Collective reckoning

Regulation

Metrics

DEA/prison

Scientific disputes

No safety or ethical account for "cut off" patients

Does REMS expansion mitigate?

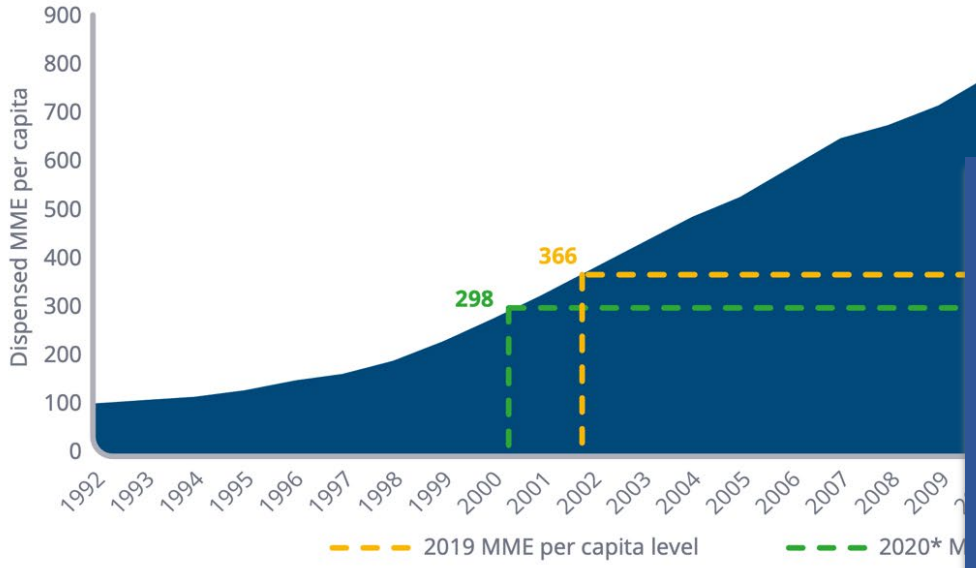
VA data on risk:
Oliva, 2017 doi: 10.1037/ser0000099

LONG-TERM TRENDS

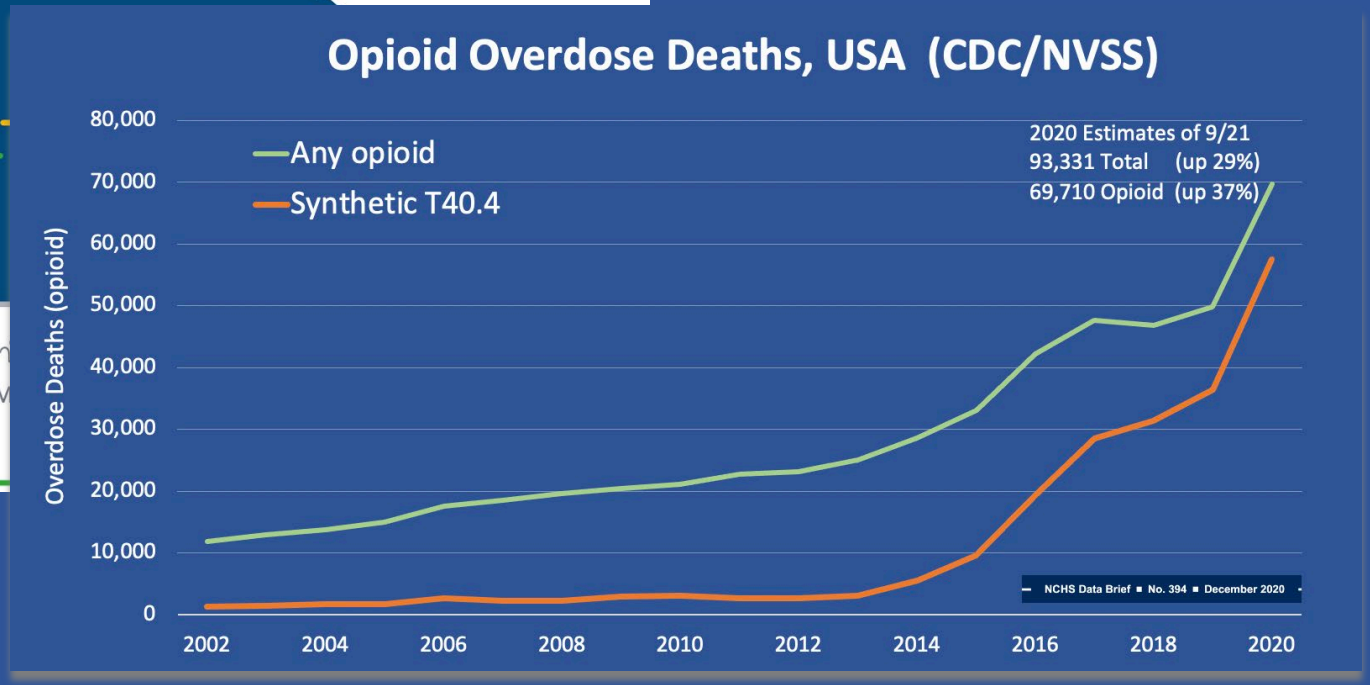
A change of course in prescribing began in 2011

Continued declines have brought normalized per capita prescription opioid use below the 2001 level

Exhibit 2: Prescription Opioid Use in Morphine Milligram Equivalents (MME) per Capita, 1992–2020*



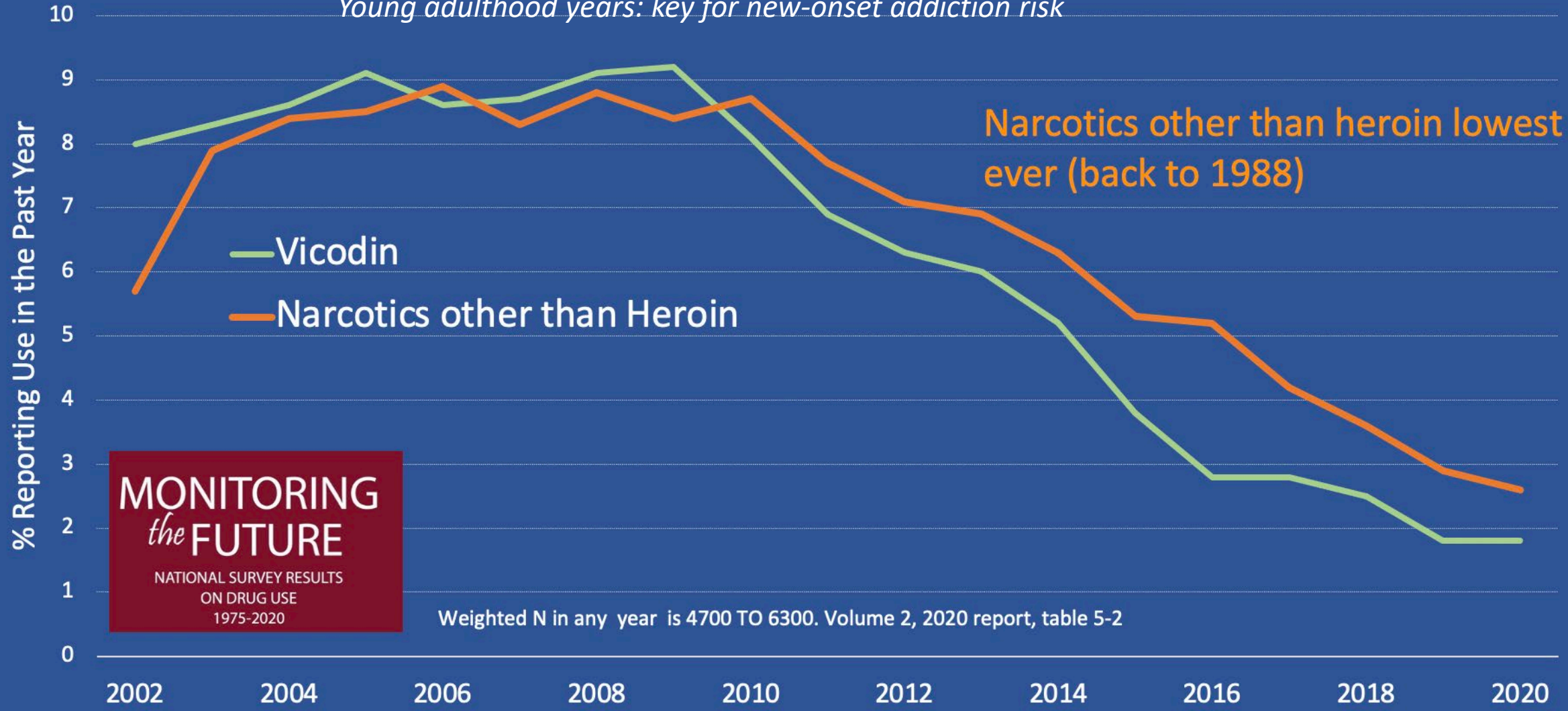
Source: IQVIA Xponent, Mar 2020; IQVIA National Prescription Audit; IQVIA Institute, Nov 2020



Stefan Kertesz, MD, 2021

Past-year misuse of opioids (ages 19-30), Monitoring the Future

Young adulthood years: key for new-onset addiction risk



Stefan Kertesz, MD, 2021

Conclusions

- The context is an enduring prescription reduction
  - Today's reductions highly incentivized, often abrupt and unsafe for some patients
  - Patients with chronic pain often wind up without someone to care for them
- Medical schools **should** train in pain, disability, addiction, rehabilitation
  - They are not required to
  - Mandatory REMS don't fit this problem and they may incentivize abandonment

- Resources:
  - Kertesz, Gordon, *Addiction. 2019; Jan;114(1):* 10.1111/add.14394
  - My TEDx: *We need to measure the opioid crisis differently* (on YouTube, 11/23,19)

ADDICTION SSA SOCIETY FOR THE STUDY OF ADDICTION TEDx

Will mandatory REMS benefit or burden providers and patients?

Kate M. Nicholson, JD

President, National Pain Advocacy Center

Patient Care

- Half of clinics unwilling to take on patients who use opioids.(Lagisetty et al. 2021)

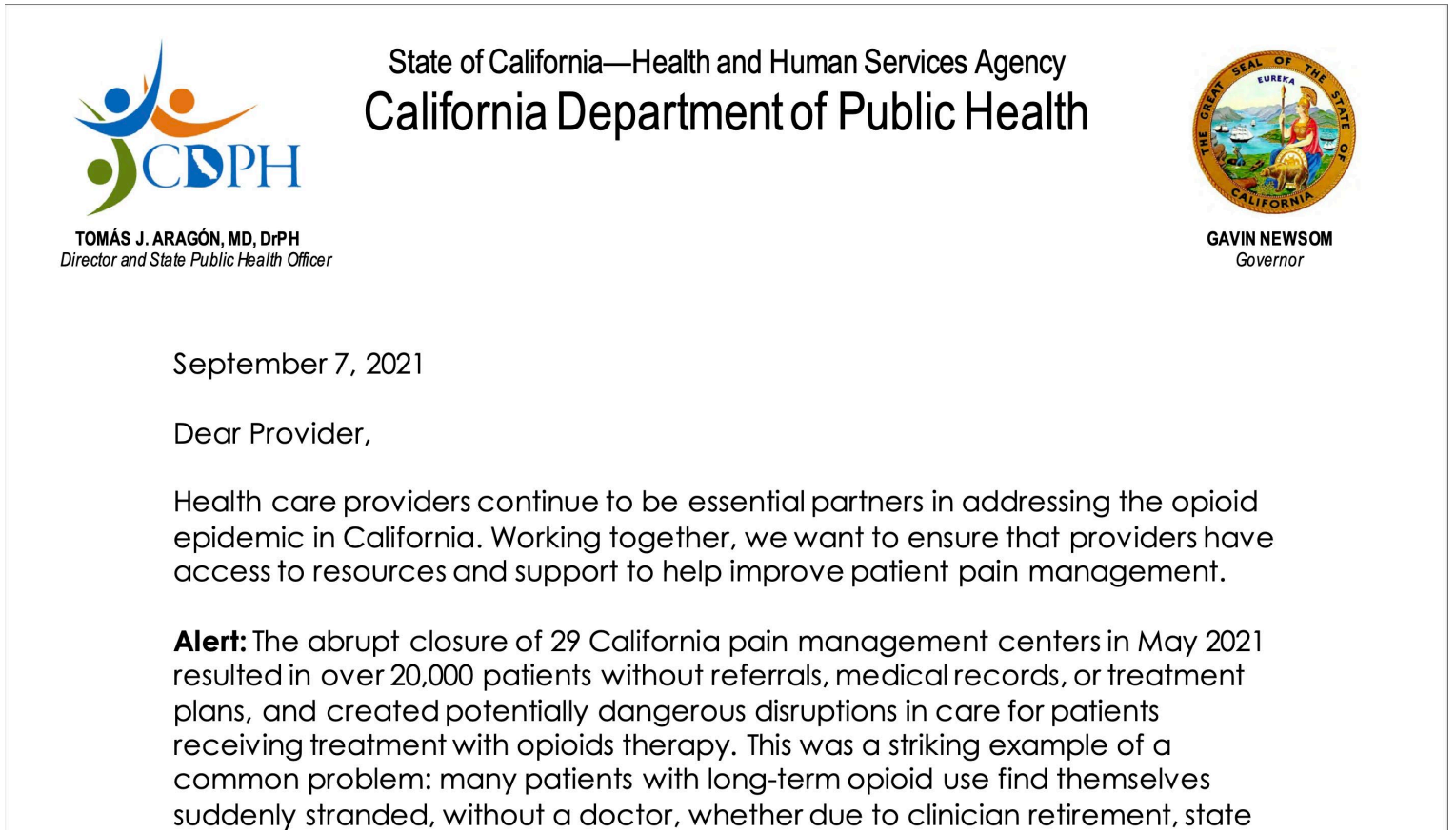
- 81% are reluctant to do so. (Quest Diagnostics/Ctr for Addiction 2019)

- Between 8 and 13 million Americans take opioids long term (Kroenke et al 2019; Mojtabai 2017)

Pain Patients Who Take Opioids Can't Get in the Door at Half of Primary Care Clinics

"Secret shopper" study finds stigma is highest against those who say their last doctor stopped prescribing opioids to them.

Increasing Recognition of the Problem



State of California—Health and Human Services Agency
California Department of Public Health

TOMÁS J. ARAGÓN, MD, DrPH
Director and State Public Health Officer

GAVIN NEWSOM
Governor

September 7, 2021

Dear Provider,

Health care providers continue to be essential partners in addressing the opioid epidemic in California. Working together, we want to ensure that providers have access to resources and support to help improve patient pain management.

Alert: The abrupt closure of 29 California pain management centers in May 2021 resulted in over 20,000 patients without referrals, medical records, or treatment plans, and created potentially dangerous disruptions in care for patients receiving treatment with opioids therapy. This was a striking example of a common problem: many patients with long-term opioid use find themselves suddenly stranded, without a doctor, whether due to clinician retirement, state

Tapering

- Discontinuation often happens abruptly (in 24 hours) Mark & Parish 2019
- Discontinuation in patients stable on opioids on the rise; occurs abruptly Neprash 2021
- Changing dose puts patients at 3-fold increased risk of death Glanz, Binswanger et al. 2019
- Increase risk of death in tapering in primary care settings James, et al. 2019
- Increased risk of overdose and mental destabilization Agnoli et al. 2021
- Heightened risk of death in veterans. Oliva et al. 2020. Another recent study found association with suicide after OSI. Tibbins, Cowan 2021
- Tapering associated with termination of care Perez at al. 2020

Benefits v. Burdens

Is it responsive to the current crisis?

Is it measurable?

Does it overlap other efforts?

What may be the unintended consequences?

Burden > Benefit?

One more mandatory requirement may drive providers from medication management and impede access to care.

Next Steps:

Pain & Opioid Education for Primary Care & Specialty Prescribers

David Tauben, MD, FACP

Emeritus Clinical Professor
University of Washington
Depts. Medicine and Anesthesia & Pain Medicine

tauben@uw.edu

Disclosures

Financial

- ***UpToDate*® authorship and receipt of royalties based on user access of sections: "Evaluation of Chronic Non-Cancer Pain Management"; "Approach to Management of Chronic Non-Cancer Pain"; "Pharmacological Management of Chronic Non-Cancer Pain"**

Non-financial continuing participatory support of:

- **CDC Injury Health-related Equity across the Lifespan (iHeal); Collaborative Opioid Taper after Trauma Study**
- **Human Resources and Services Administration (HRSA), Advanced Nursing Education Workforce (ANEW) Program Enhancing APRN Workforce Competencies: "Combatting the Opioid Crisis in Rural and Underserved WA State Correctional Facilities", Washington State Department of Corrections**
- **Washington State Health Care Authority: UW TelePain & UW Pain and Opioid Hotline**

NIH Pain Consortium
Centers of Excellence in Pain Education
CoEPE

Centers Excellence
AMERICAN PAIN SOCIETY
Award Recipient 2010

UW Medicine
PAIN MEDICINE

Personal Perspectives

- **30^{+} years of Primary Care Practice** ***(community-based internal medicine)***
- **26^{+} years Pain Specialty certification** ***(ABPM)***
- **12 years as Pain Medicine educator** ***(U Washington School of Medicine)***
- **Participated in nation's first state-wide opioid guidelines (2007-), CDC webinars series, "TelePain" regional HCP mentoring, REMS CE activities, opioid stewardship implementation, …**

- ✓ **Pain is HARD for *everyone:* patients and families, communities, providers, health systems, payors, policy-makers…**
- ✓ **Inadequate education at all levels and across professions: pre-licensure, residency, and practicing HCPs**
- ✓ **Insufficient research (= funding) in Pain, absent dedicated institute at NIH**

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PAIN MEDICINE

Some Key Points

1. Chronic Pain is best managed with non-drug and non-opioid treatments.
2. Current Pain education is insufficient for trainees and practicing clinicians.
3. Pain and OUD are entangled, confounded, and face stigma and disparities.
4. Simply attending a course or passing an exam *does not translate* into practice competencies.
5. Introducing/sustaining HCP prelicensure courses occurs within complex and tightly guarded and already overloaded curriculum.
6. Many potential curricular platforms, content, structures are available.
7. Disincentives occur when mandatory training is prerequisite for prescribing.
8. High value of patient education and effective public and policy outreach.
9. Critical role for improved credentialing exams, licensing and practice guidelines.
10. Sustained funding and dissemination needed, without industry conflict.

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PAIN MEDICINE

Education Content and Delivery Recommendations

Improve Pain Care and Reduce Prescription Opioid Misuse and Abuse

1. Bio-psycho-social assessment and outcomes tracking guides effective treatment
2. Emphasize access to non-drug and non-opioid pain management treatment strategies
3. Increase inter-professional pre-licensure training and access
4. Differentiate indications for opioids across a range of Pain types and OUD
5. Acknowledge bias and disparities of Pain and OUD diagnosis and care
6. Reach beyond prescribers (patients, families, schools, community, policy-makers)

Curriculum Design, Delivery, and Implementation

1. Interprofessional, Integrated, and Implemented across a range of platforms
2. Content and performance expectations determined by health profession educational organizations *(e.g., AAMC)*, education/licensing/certification *(e.g., NBME, ABMS, MOCAs)*
3. Necessary and sufficient funding for research, development and dissemination
4. Not a *"one off":* outcomes and new science requires revisions and updates
5. Exclude industry stakeholders from content development and approvals

UW Medicine
PAIN MEDICINE

Summary “Next Steps”

1. **Design and disseminate sustainable interprofessional range of educational options that guide indications for safe and effective use of opioids for Pain Management, including assessment and care of Opioid Use Disorder.**
2. **Improve HCP’s pain management and addiction competencies, and hence *willingness to treat both*.**
3. **Engage expert health sciences educators, credentialing licensing boards, and specialty certification/recertification examiners**
4. **Define measures, evaluate outcomes, and identify sustainable funding model for continuing educational process improvement.**
5. **Promote public and private payors support for expanded access to multidisciplinary/interprofessional providers of Pain and OUD care.**

UW Medicine
PAIN MEDICINE

Discussion Questions

- Would making prescriber education mandatory via a REMS be an effective response to the current opioid crisis? What unmet needs do you think it could address?
- How would the effectiveness and impact of a mandatory prescriber education program be measured?
- What lessons can we learn from the implementation of the broad range of existing prescriber education programs and requirements? How can these lessons inform decision-making regarding the future of the Opioid Analgesic REMS?
- What would an ideal national prescriber education system look like? What practical challenges might arise in creating such a system, and how can FDA and other stakeholders mitigate those challenges?
- What could be unintended consequences of mandatory opioid prescriber education through a REMS, and are there ways to identify and address them?

Closing Remarks | Day 2

Mark McClellan, MD, PhD

Director, Duke-Margolis Center for Health Policy

Thank You!

Contact Us

healthpolicy.duke.edu

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dukemargolis@duke.edu

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