

Opioids and controlled substances



Joshua D. Lenchus, DO, RPh, FACP, SFHM

Past President, Florida Osteopathic Medical Association

Past President, Florida Medical Association

Clinical Professor, Orlando College of Osteopathic Medicine

Disclosure

- Aetna/CVS Health Medical Director, Medicare Advantage, Florida Market
- No financial or other material conflicts of interest
- Not representative of any institution or organization

Outline-1

- Pharmacology of opiates
- Epidemiology of opioid crisis
- Current standards, laws and rules on prescribing controlled substances*
- Proper prescribing of opiates

Outline-2

- Risks, diagnosis and treatment of opioid addiction*
- Prescribing emergency opioid antagonists*
- Alternatives to controlled substance prescribing*
 - Nonpharmacological therapies*
- Controlled substance disposal

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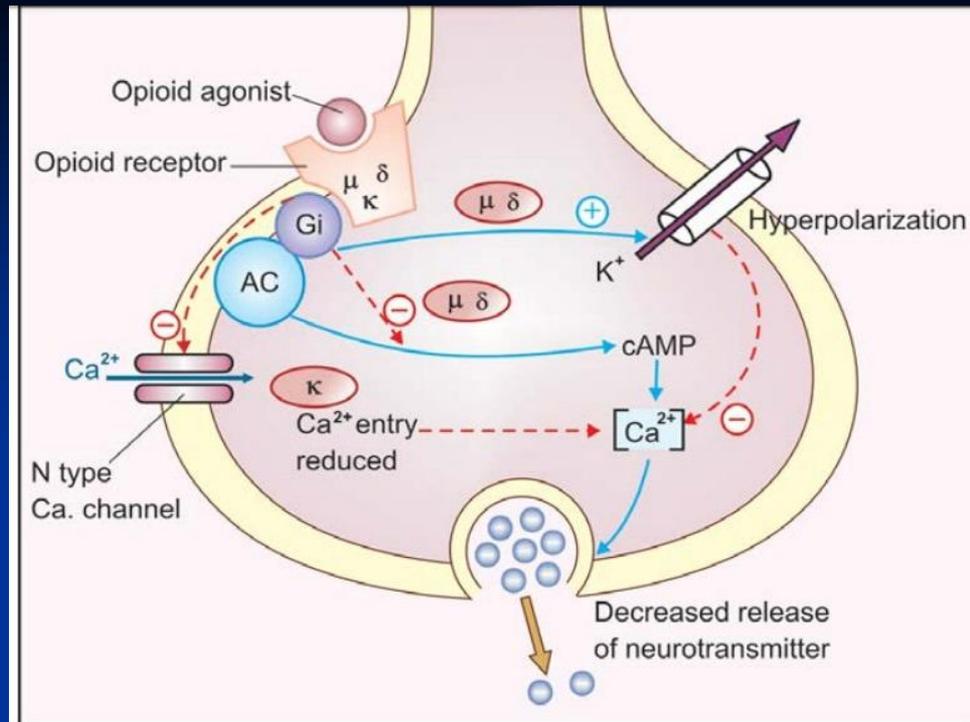


Fig. 34.1: Opioid receptor transducer mechanisms
 AC-Adenylyl cyclase; Gi-coupling protein; cAMP-Cyclic AMP

μ (<i>mu</i>)	κ (<i>kappa</i>)	δ (<i>delta</i>)
Analgesia (supraspinal μ_1 + spinal μ_2)	Analgesia (spinal κ_1) (Supraspinal- κ_3)	Analgesia (Spinal + Affective component of supraspinal)
Respiratory depression (μ_2)	Respiratory depression (lower ceiling)	Respiratory depression
Sedation	Dysphoria, psychotomimetic	Affective behaviour
Euphoria	Miosis (lower ceiling)	Reinforcing actions
Miosis	Sedation	Reduced g.i. motility
Reduced g.i. motility (μ_2)	Physical dependence (nalorphine type)	
Physical dependence (morphine type)	Reduced g.i. motility	

Opioid classification

Full agonist	Partial agonist	Agonist-antagonist	Antagonist
Morphine	Buprenorphine	Pentazocine	Naloxone
Fentanyl		Butorphanol	Naltrexone
Oxycodone		Nalbuphine	
Hydrocodone			
Methadone			

Opioid comparison

Medication	Onset (po)	Duration (po)	Equianalgesic dose
Fentanyl patch	12-24 hrs	72 hrs/patch	12.5mcg/hr; 0.1mg IV
Hydromorphone	15-30 mins	4-6 hrs	6 - 7.5mg po/1.5mg IV
Tapentadol	1.5 hrs (IR)	4 hrs	100mg po
Morphine IR	30-60 mins	3-6 hrs	30mg po/10mg IV
MS Contin [®]	30-90 mins	8-12 hrs	30mg po
Oxycodone IR	15-30 mins	4-6 hrs	20mg po
OxyContin [®]	1 hr	12 hrs	20mg po
Hydrocodone	30-60 mins	4-6 hrs	30mg po
Codeine	30-60 mins	4-6 hrs	200mg po/100–120mg IV
Meperidine	10-15 mins	2-4 hrs	300mg po/75-100mg IV

Opioid allergy

Phen-anthrenes	Phenyl-piperidines	Diphenyl-heptanes	Phenylpropyl amines
Buprenorphine	Fentanyl*	Methadone*	Tapentadol
Codeine	Meperidine	Propoxyphene	Tramadol*
Hydrocodone			
Hydromorphone*	Alfentanil		
Morphine	Remifentanil		
Oxycodone*	Sufentanil		
Oxymorphone*			

FENTANYL > HYDROMORPHONE > OXYMORPHONE >
 OXYCODONE > TRAMADOL

Controlled substance examples

C-II	C-III	C-IV	C-V
Higher dose of codeine, >90mg	Lower dose of codeine, <90mg	Tramadol	Lowest dose of codeine, <2mg/mL
Fentanyl	Anabolic steroids	Chloral hydrate	Robitussin-AC [®]
Hydrocodone	Lower dose of hydrocodone	Chlordiazepoxide	Lomotil [®]
Morphine	Ketamine	Clorazepate	Phenergan with codeine [®]
Oxycodone	Dronabinol	Carisoprodol	CBD oil (Epidiolex [®])
Methadone	Fiorinal	Meprobamate	
Amphetamine	Buprenorphine	Phentermine	
Pentobarbital	Cannabis???	Phenobarbital	

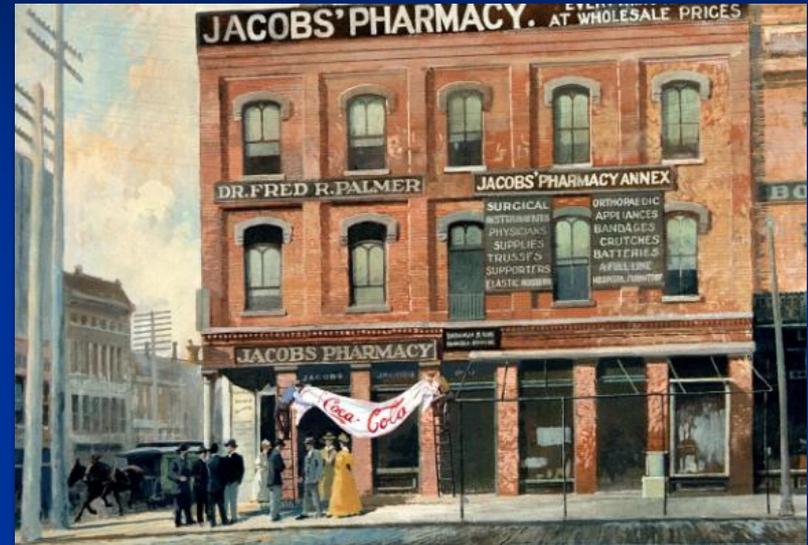
Marijuana

- CSA of 1970
 - Rescheduling efforts
 - 8-FA
 - Relative abuse potential
 - CAMU
 - Relative safety or ability to produce physical dependence
- Agriculture Improvement Act of 2018
- Rescheduling = regulations

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19th Century

- ▶ 1886: Coca-Cola™
- ▶ 1898: diacetylmorphine
- ▶ 1899: acetylsalicylic acid



20th Century

- ▶ 1906: Pure Food and Drug Law
- ▶ 1909: Opium Exclusion Act
- ▶ 1914: Harrison Narcotics Tax Act
- ▶ 1914 – 1918: WWI
- ▶ 1920 – 1970



This Photo by Unknown Author is licensed under CC BY-SA-NC

20th Century

- ▶ 1970: Controlled Substance Act (CSA)
- ▶ 1974: Narcotic Addict Treatment Act



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<https://crsreports.congress.gov/product/pdf/r/r45948>

<https://www.dea.gov/drug-information/csa>

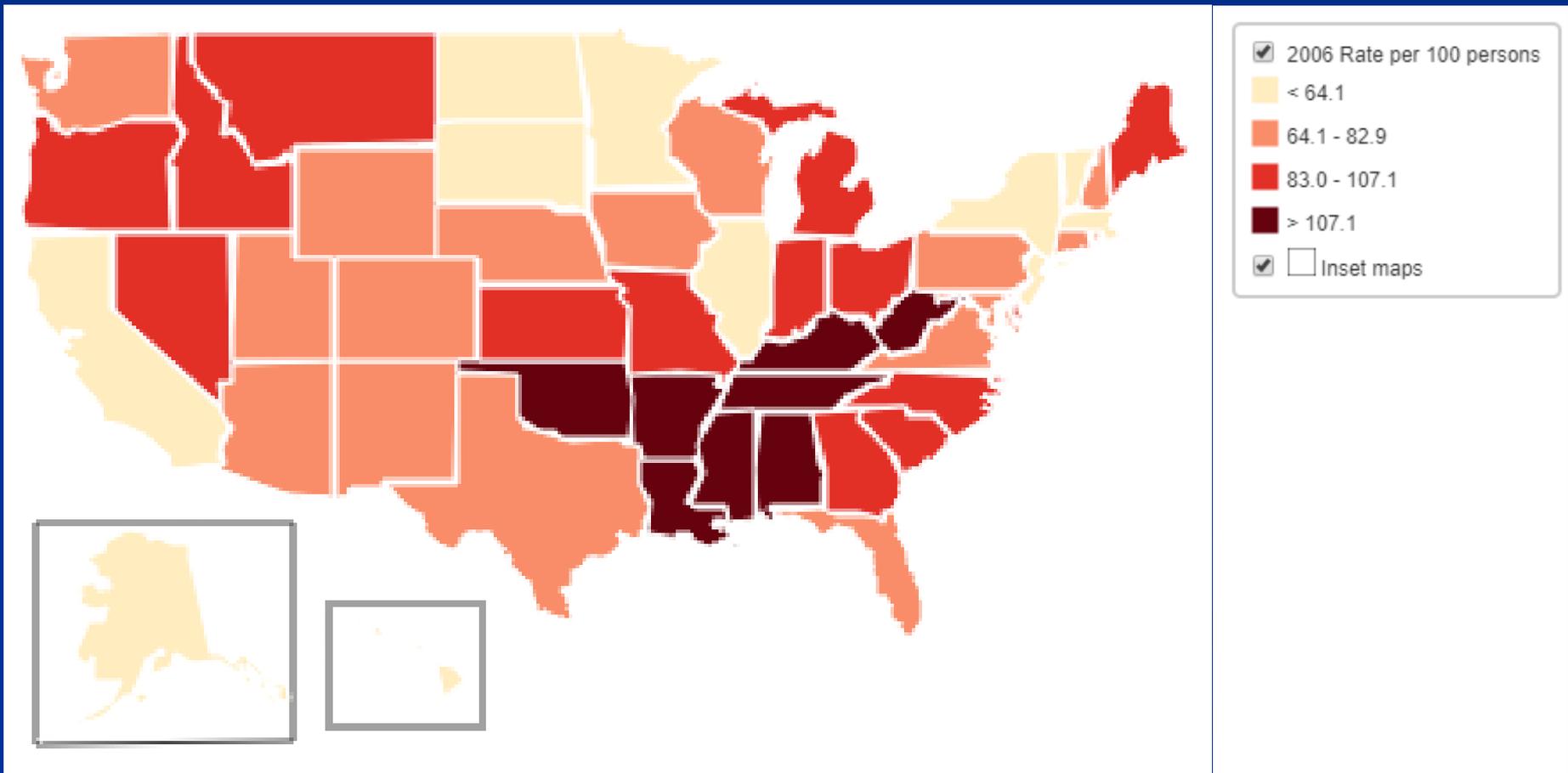
<https://www.govtrack.us/congress/bills/93/hr12503>

<https://www.buprenorphine-doctors.com/opioid-articles/what-is-data-2000/>

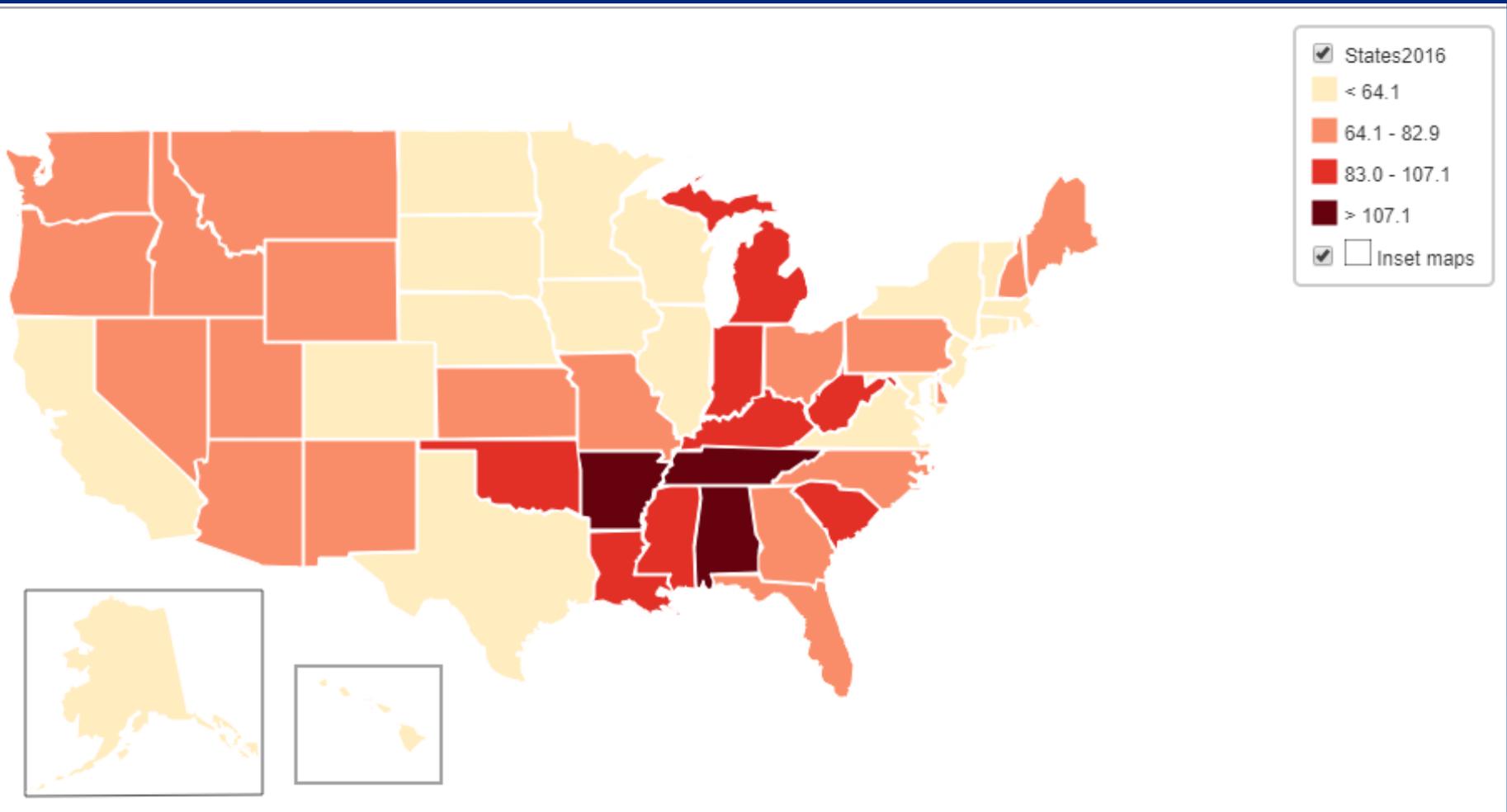
How did we get here?

- 1980s: opioids for non-malignant pain
- 1996: the 5th vital sign; Oxycontin released
- 2001: TJC weighs in
- 2006: HCAHPS pain questions
- 2024: 220 opioid-related OD deaths/day, US

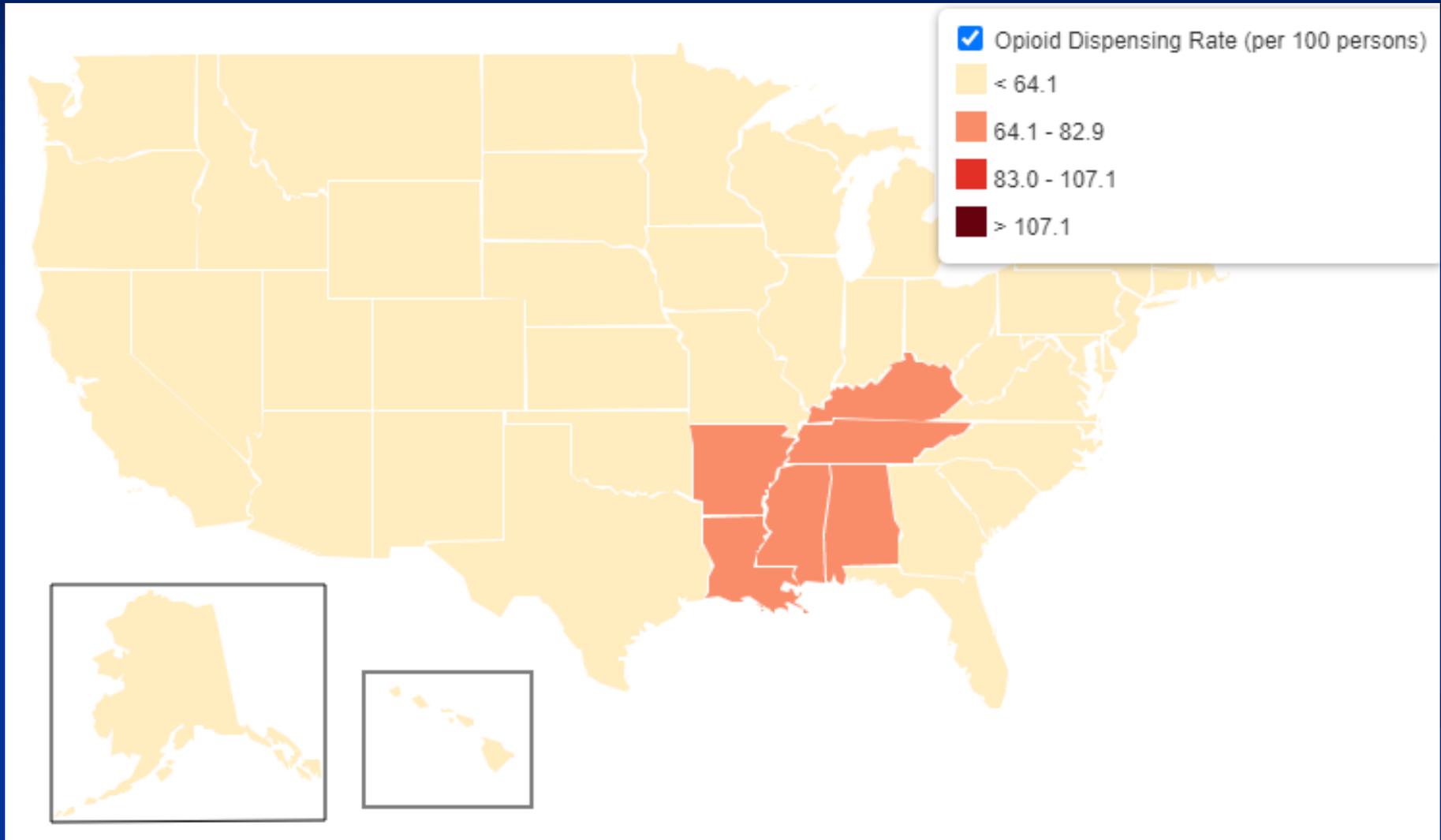
U.S. State Prescribing Rates, 2012



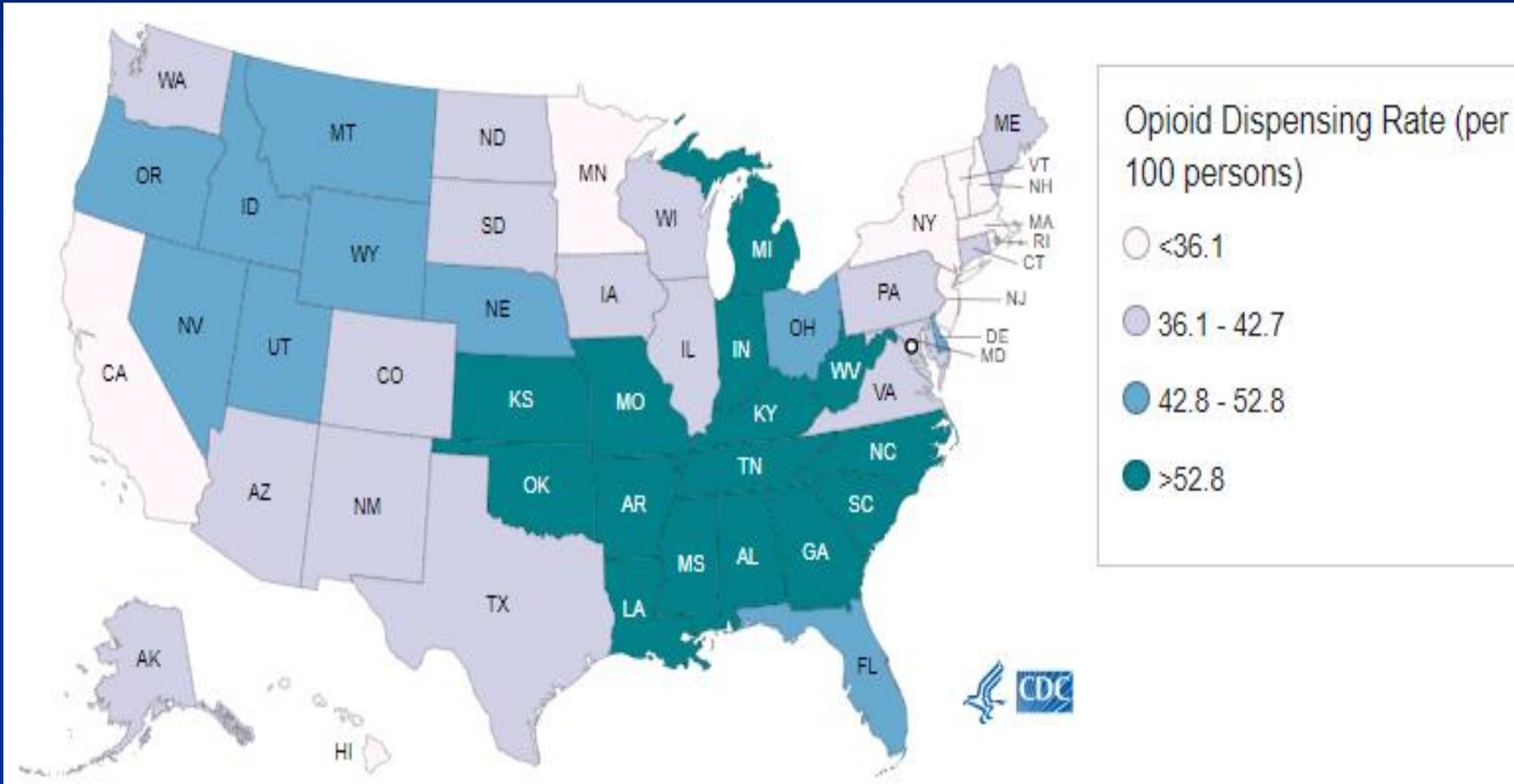
U.S. State Prescribing Rates, 2016



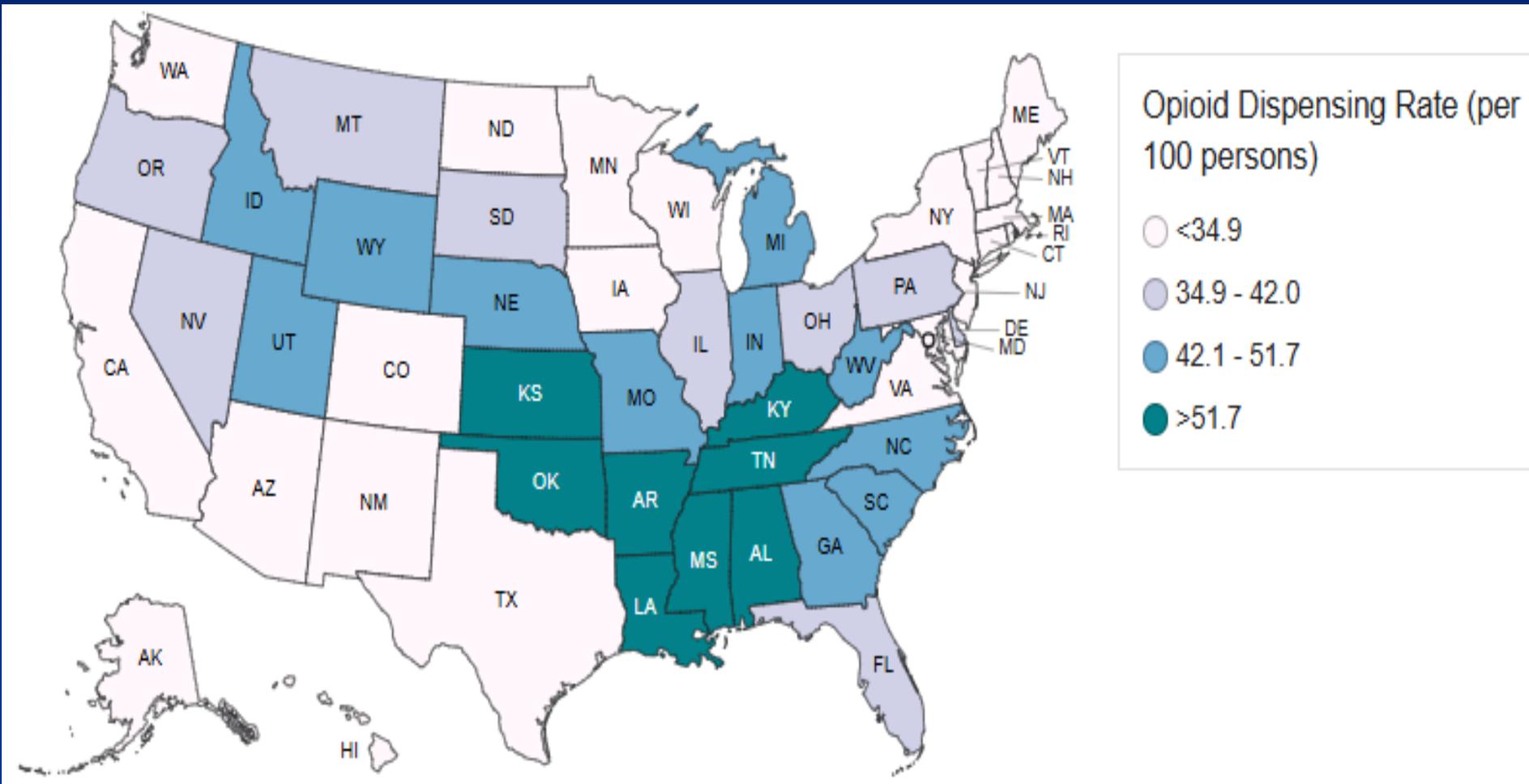
U.S. State Prescribing Rates, 2020



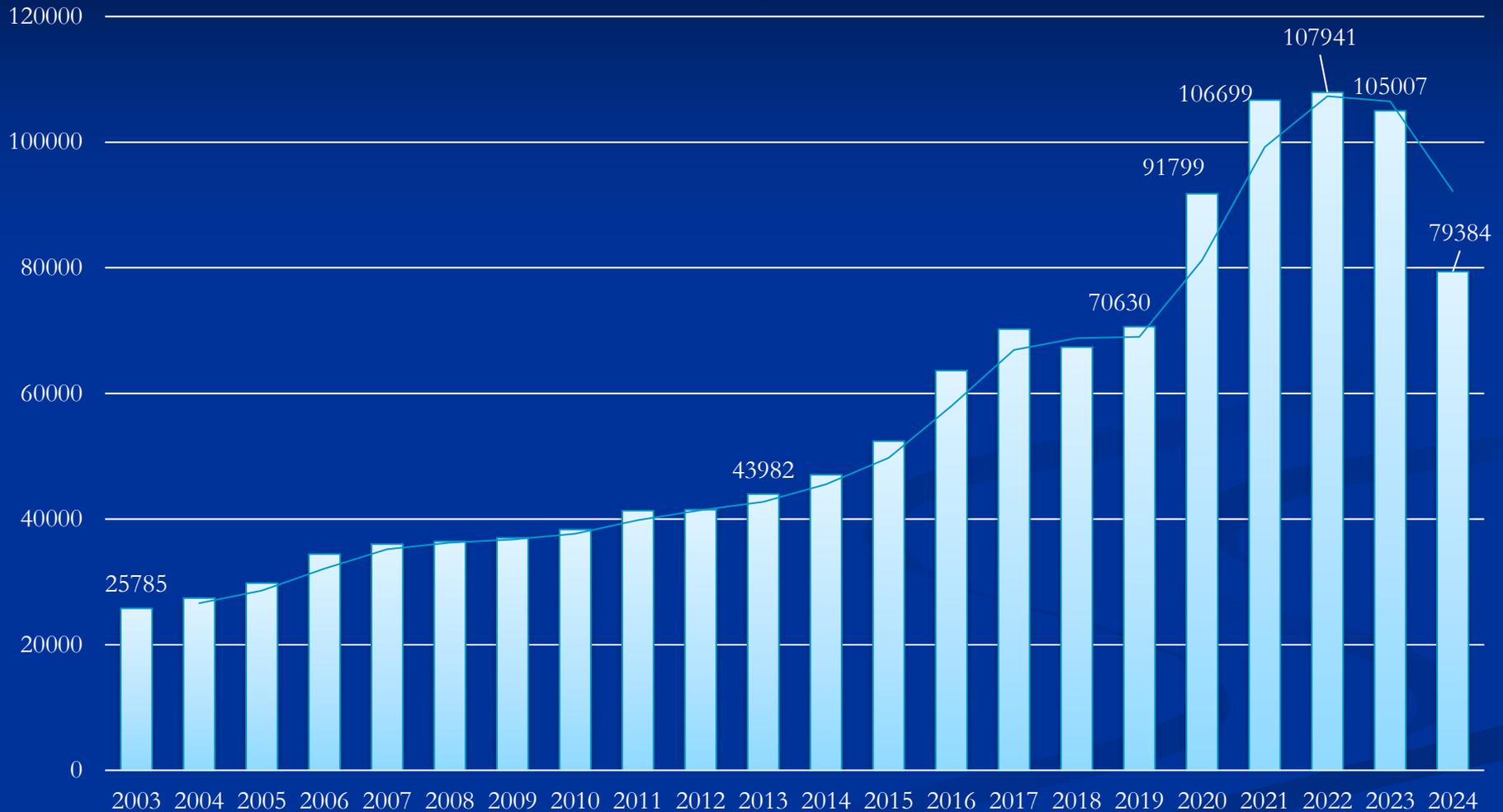
U.S. State Prescribing Rates, 2020



U.S. State Prescribing Rates, 2023



Age-adjusted drug overdose death rate: United States, 2003–2024



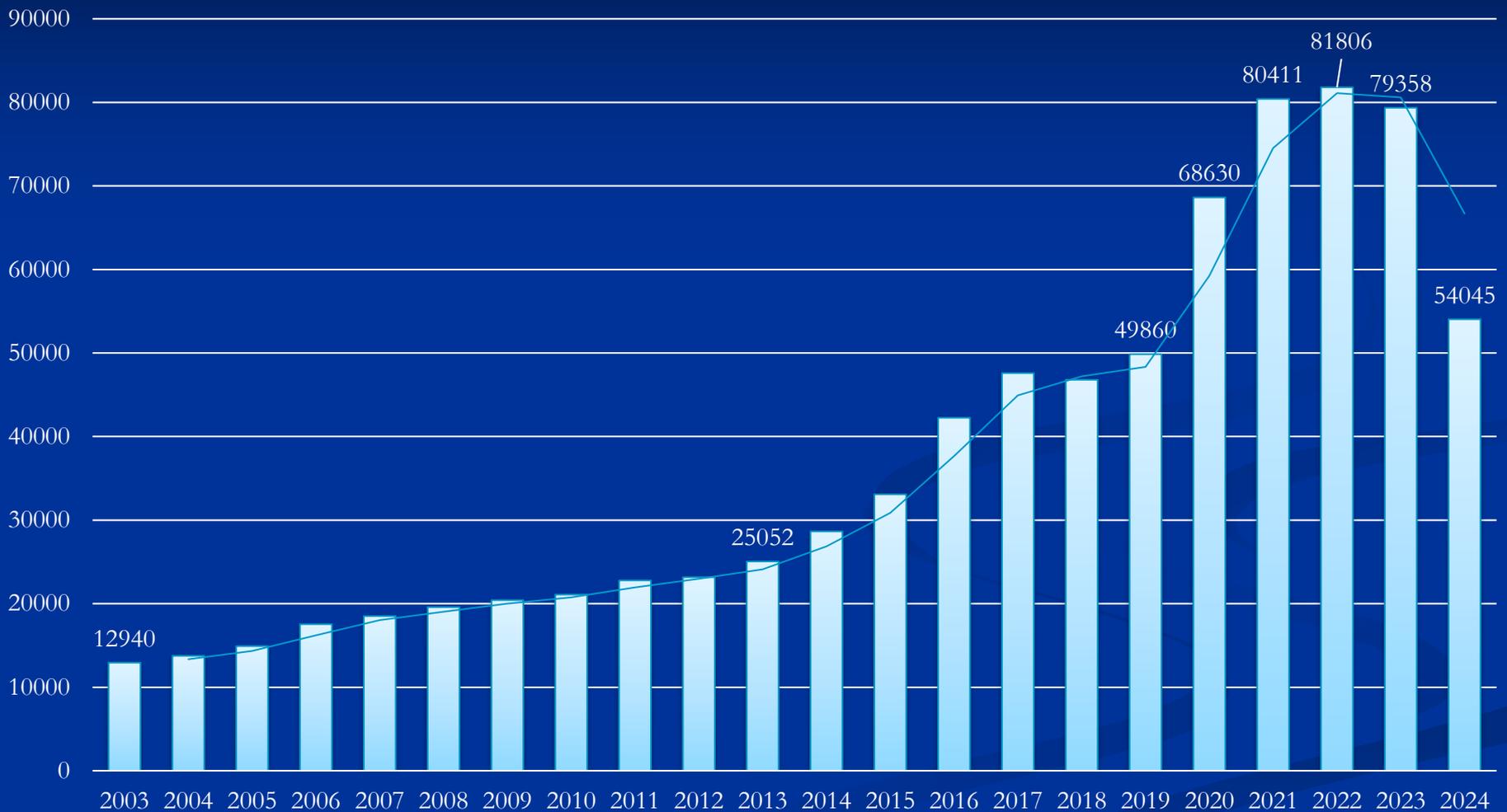
<https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Fig1>

<https://www.cdc.gov/nchs/data/databriefs/db549.pdf>

<https://www.overdoselifeline.org/news/2024-opioid-overdose-data-report-key-trends-and-insights/>

Garnett MF, Miniño AM. Drug overdose deaths in the United States, 2003–2023. NCHS Data Brief, no 522. Hyattsville, MD: National Center for Health Statistics. 2024. DOI: <https://dx.doi.org/10.15620/cdc/170565>.

Age-adjusted rate of drug overdose deaths involving opioids: United States, 2003–2024



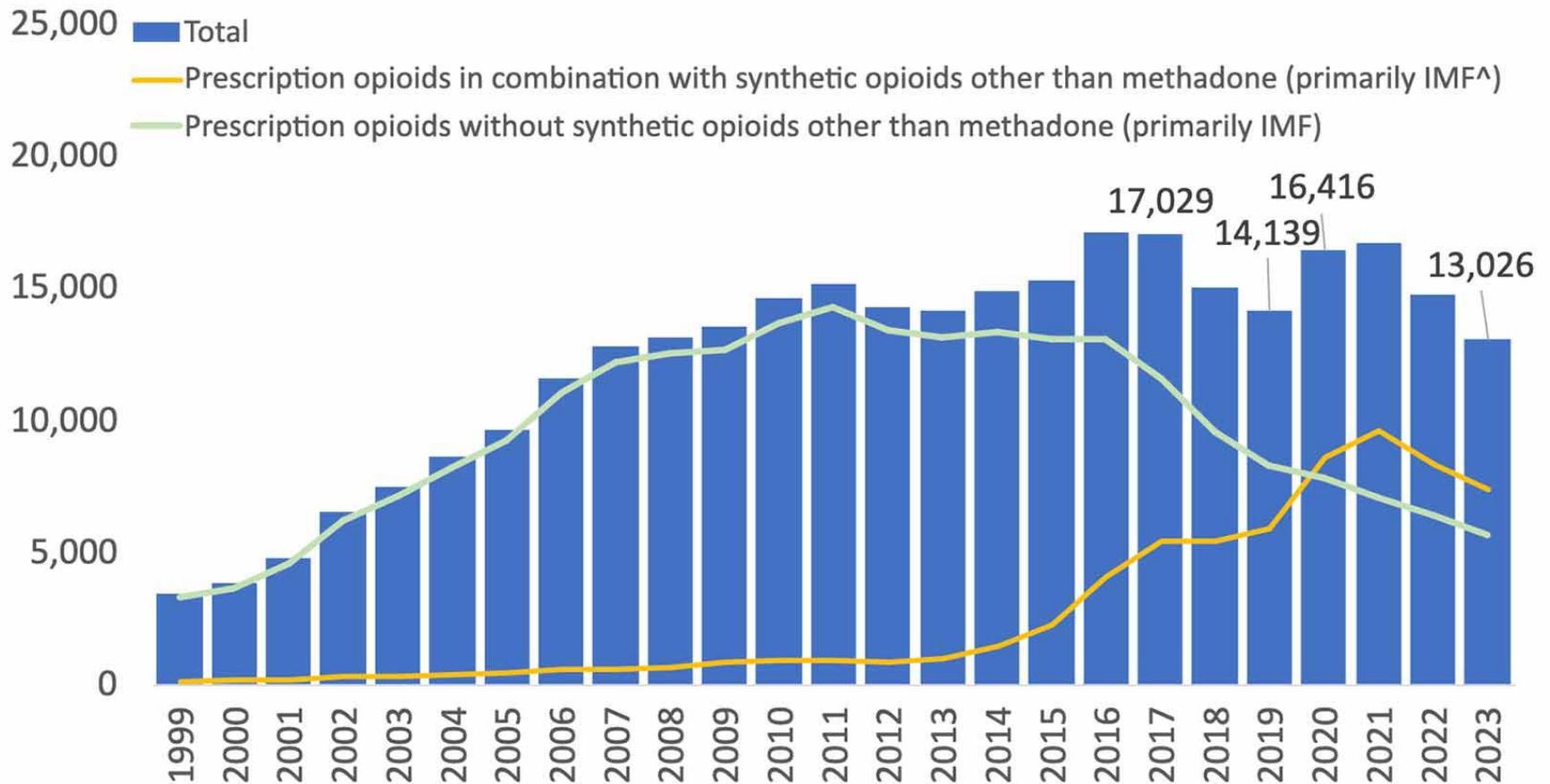
<https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Fig3>

<https://www.cdc.gov/nchs/data/databriefs/db549.pdf>

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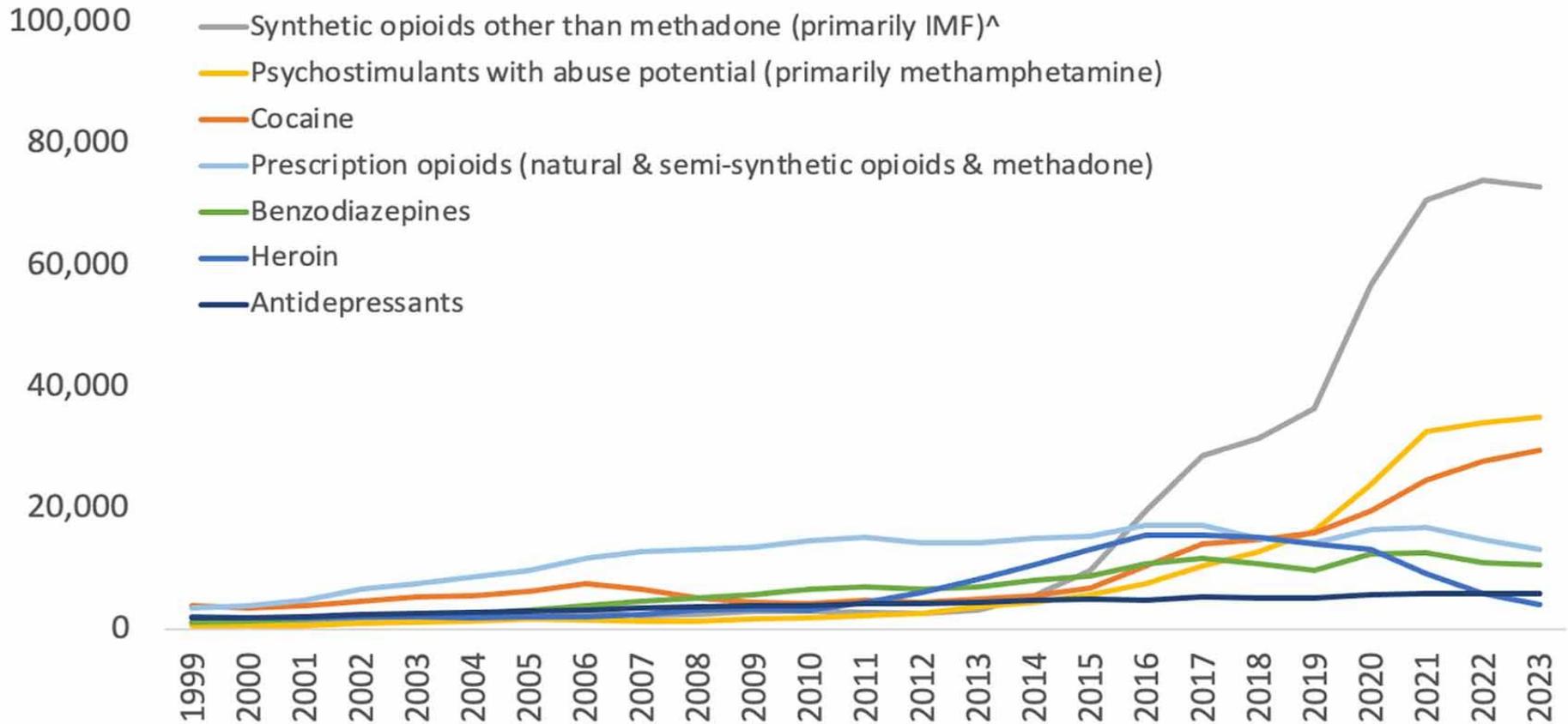
Garnett MF, Miniño AM. Drug overdose deaths in the United States, 2003–2023. NCHS Data Brief, no 522. Hyattsville, MD: National Center for Health Statistics. 2024. DOI: <https://dx.doi.org/10.15620/cdc/170565>.

Figure 4. U.S. Overdose Deaths Involving Prescription Opioids*, 1999-2023



*Among deaths with drug overdose as the underlying cause, the prescription opioid subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2) or methadone (T40.3). ^illicitly manufactured fentanyl. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2023 on CDC WONDER Online Database, released 1/2025.

Figure 2. U.S. Overdose Deaths*, Select Drugs or Drug Categories, 1999-2023



*Includes deaths with underlying causes of unintentional drug poisoning (X40–X44), suicide drug poisoning (X60–X64), homicide drug poisoning (X85), or drug poisoning of undetermined intent (Y10–Y14), as coded in the International Classification of Diseases, 10th Revision. ^Illicitly manufactured fentanyl. Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2023 on CDC WONDER Online Database, released 1/2025.

**Potentially Lethal
Dose of Fentanyl**



DEA

| Oxycodone**Popular Emoji
Drug Codes****| Xanax®****| Percocet®****| Adderall®**

Additional Threat: Access

Monitoring for suspicious text messages on social media or cash app posts could spark an important, and potentially life-saving, conversation.

**ONE
PILL CAN
KILL**

7-Hydroxymitragynine (7-OH)

Hiding in Plain Sight: 7-OH Products are Designed to Look Like Everyday Treats Like Gummies, Candies and Ice Cream.



Note: These images are select illustrative examples and do not represent the full scope of 7-OH products on the market. Consumers should read packaging and labels carefully to determine whether a product contains 7-OH.



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- C-II prescriptions do not have an expiration
 - Florida Rx must be filled within 1yr
 - No refills allowed
- C-III–V prescriptions expire 6mos post date written
 - Max of 5 refills within 6mos
- Physicians who write or dispense controlled substances for detoxification must be separately registered for that purpose
- Emergencies
- Partial fills

“Chronic nonmalignant pain”

The 2016 Florida Statutes

Title XXXII

REGULATION OF PROFESSIONS
AND OCCUPATIONS

Chapter 456

HEALTH PROFESSIONS AND
OCCUPATIONS: GENERAL PROVISIONS

View Entire
Chapter

456.44 **Controlled substance prescribing.—**

(1) DEFINITIONS.—As used in this section, the term:

(e) “Chronic nonmalignant pain” means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

Florida HB 21: 2018

- Signed by Gov. Scott on March 19, 2018
- Presently in full effect
- Impact on key areas
 - Prescription Drug Monitoring Program (PDMP)
 - Controlled substance prescribing
 - Pain management clinic registration
 - Continuing medical education

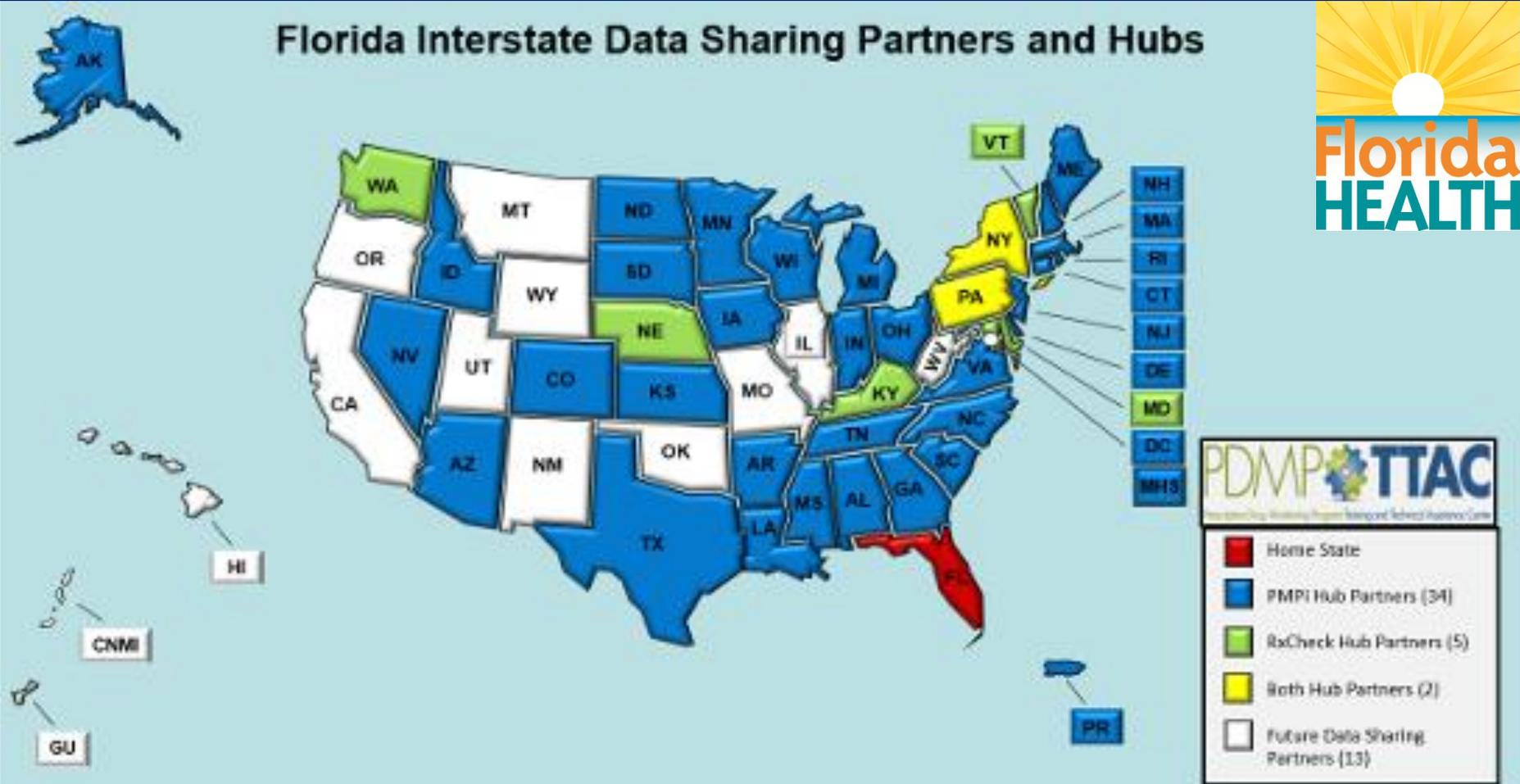
E-FORCSE

- Electronic - Florida Online Reporting of Controlled Substances Evaluation program: Florida's Prescription Drug Monitoring Program (PDMP)
- Created by the 2009 legislature, an initiative to encourage safer prescribing of controlled substances and to reduce drug abuse and diversion within the State
- Operational 9/1/11; Health care practitioner (HCP) access 10/17/11; law enforcement access 11/14/11
- Health Information Designs, Inc. developed a database that collects and stores prescribing and dispensing data for controlled substances in Schedules II, III, and IV
- PDMP purpose: to provide information to HCPs to guide their decisions in prescribing and dispensing controlled substances

PDMP Compatibility

<https://florida.pmpaware.net>

Florida Interstate Data Sharing Partners and Hubs



PDMP TTAC
Partnership for Prescription Monitoring
www.floridahealth.gov/pdmp-ttac

- Home State
- PMP Hub Partners (34)
- RxCheck Hub Partners (5)
- Both Hub Partners (2)
- Future Data Sharing Partners (13)

Updated December 27, 2024

PDMP: 7/1/18 – s. 893.055(8)

- Prescribers and dispensers, or their designees, must consult the PDMP before each time a CS, other than a C-V nonopioid, is prescribed or dispensed, for a patient 16 years or older, *except hospice* (7-1-19)
- Applies to ALL controlled substances
- Document reason for not consulting (cannot dispense more than 3d supply)
- Dispensing must be reported by next day's EOB

****Avoid downloading & printing information****

Controlled substance Rx: 7/1/2018

- Added treatment of acute pain to F.S.456.44
- Board authority: Rule 64B8-9.013 (2/21/19)
- Acute pain: “the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness.”
- <https://www.flrules.org/gateway/RuleNo.asp?ID=64B8-9.013>

Injury Severity Score

Body system
Head and neck
Face
Chest
Abdomen
Extremity, inc pelvis
External

Injury severity	Points
No injury	0
Minor	1
Moderate	2
Serious	3
Severe	4
Critical	5
Unsurvivable	6

- 3-day limit on C-II opioid
- Up to 7-day supply IF...
 - Medically necessary
 - “Acute pain exception” is written on Rx
 - Documents acute condition and lack of alternatives

Note that all 3 criteria must be met

- Emergency opioid antagonist
- “Nonacute pain”

Pain management clinic: 1/1/2019

- Pain management clinic registration
- Exempt entities
 - Clinic in which the majority of physicians there primarily provide surgical services
 - Clinic held by a publicly traded company whose most recent total quarterly assets exceed \$50M
 - Clinic affiliated with a medical school at which training is provided
- Certificate of exemption

CME: 1/31/2019

- DEA registrants/CS prescribers
 - 2-hour, board-approved, CME
 - Part of total required CME hours
 - For licensure renewal, since 1/31/2019
 - CE Broker
-
- All dentists (HB549, 7-1-19)
 - All podiatrists (HB17, 7-1-21)

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Purpose of issue of prescription

- Legitimate medical purpose
- Practitioner
- Usual course of practice

- Corresponding responsibility

s. 465.035: Dispensing of medicinal drugs pursuant to facsimile of prescription

- (1) It is lawful for a pharmacy to dispense medicinal drugs, including controlled substances authorized under subsection (2), based on receipt of an electronic facsimile of the original Rx if all of the following conditions are met:
 - In the course of the transaction the pharmacy complies with laws and administrative rules relating to pharmacies and pharmacists.
 - Except in the case of the transmission of a prescription by a person authorized by law to prescribe medicinal drugs:
 - The facsimile system making the transmission provides the pharmacy receiving the transmission with audio communication via telephonic, electronic, or similar means with the person presenting the prescription.
 - At the time of the delivery of the medicinal drugs, the pharmacy has in its possession the original prescription for the medicinal drug involved.
 - The recipient of the prescription shall sign a log and shall indicate the name and address of both the recipient and the patient for whom the medicinal drug was prescribed.
- (2) C-II as defined in s. 893.03(2) may be dispensed as provided in this section to the extent allowed by 21 C.F.R. s. 1306.11.



<https://www.justthinktwice.gov/true-stories/ryan-haight-18>

<https://abcnews.go.com/GMA/story?id=127762&page=1>

Telehealth Extension of COVID-19 PHE

(c) During the period May 12, 2023, through December 31, 2024, a Drug Enforcement Administration (DEA)-registered practitioner is authorized to prescribe schedule II–V controlled substances via telemedicine, as defined in 21 CFR 1300.04(i), to a patient without having conducted an in-person medical evaluation of the patient if all of the conditions listed in paragraph (e) of this section are met.

(e) A practitioner is only authorized to issue prescriptions for controlled substances pursuant to paragraphs (c) or (d) of this section if all of the following conditions are met:

- (1) The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;
- (2) The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3);
- (3) The practitioner is:
 - (i) Authorized under their registration under 21 CFR 1301.13(e)(1)(iv) to prescribe the basic class of controlled substance specified on the prescription; or
 - (ii) Exempt from obtaining a registration to dispense controlled substances under 21 U.S.C. 822(d); and
- (4) The prescription is consistent with all other requirements of 21 CFR part 1306.

s. 456.47: Use of telehealth to provide services

(2) PRACTICE STANDARDS.—

(b) A telehealth provider may use telehealth to perform a patient evaluation. If a telehealth provider conducts a patient evaluation sufficient to diagnose and treat the patient, the telehealth provider is not required to research a patient's medical history or conduct a physical examination of the patient before using telehealth to provide health care services to the patient.

(c) A telehealth provider may not use telehealth to prescribe a controlled substance listed in Schedule II of s. 893.03 unless the controlled substance is prescribed for the following:

- ❖ 1. The treatment of a psychiatric disorder;
- ❖ 2. Inpatient treatment at a hospital licensed under chapter 395;
- ❖ 3. The treatment of a patient receiving hospice services as defined in s. 400.601; or
- ❖ 4. The treatment of a resident of a nursing home facility as defined in s. 400.021.

(d) A telehealth provider and a patient may be in separate locations when telehealth is used to provide health care services to a patient.

(e) A nonphysician telehealth provider using telehealth and acting within his or her relevant scope of practice, as established by Florida law or rule, is not in violation of s. 458.327(1)(a) or s. 459.013(1)(a).

Counterfeit-proof Rx pads

- Controlled substance Rx must be written on a counterfeit-resistant pad produced by an approved vendor, or electronically prescribed
- Otherwise, risk of Rx rejection and confiscation

<http://www.floridashealth.com/mqu/counterfeit-proof.html>

http://www.deadiversion.usdoj.gov/ecommm/e_rx/faq/faq.html

<https://www.floridahealth.gov/licensing-and-regulation/counterfeit-proof-prescription-pad-vendors/faq.html>

http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0400-0499/0465/Sections/0465.035.html

Example

Dr. Stephen Strange, DO
177A Bleecker Street
New York City, Florida 33313
954-867-5309



Date: January 20, 2026

Patient Name: Peter Parker

DOB: 08/27/1992

Address: 1111 Center Lane, London, Florida 33312

Percocet (5/325)

Disp. # 10 (Ten)

Sig: Take one tab by mouth every 6 hours PRN post-op pain

No Refills

DEA # BS1838616

Signature

A handwritten signature in red ink that reads "Doctor Strange". The signature is written in a cursive, flowing style and is contained within a light gray rectangular box.

DEA 2010

- EPCS is born
- Dual factor authentication is required
 - Something you know: a knowledge factor
 - Something you have: a hard token
 - Something you are: biometric information
- Confirm identity
- Two-factor authentication issued
- Setting access control

<https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html>

https://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html

https://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/practitioners.htm

Opioid Prescribing Recommendations: Summary of 2016 CDC Guidelines

Determining when to initiate or continue opioids for chronic pain

- Opioids are not first-line or routine therapy
- Establish treatment goals before starting opioid therapy and a plan if therapy is discontinued
- Only continue opioid if there is clinically meaningful improvement in pain and function
- Discuss risks, benefits and responsibilities for managing therapy before starting and during treatment

Opioid selection, dosage, duration, follow-up and discontinuation

- Use immediate-release (IR) opioids when starting therapy
- Prescribe the lowest effective dose
- When using opioids for acute pain, provide no more than needed for the condition
- Follow up and review benefits and risks before starting *and* during therapy
- If benefits do not outweigh harms, consider tapering opioids to lower doses or taper and discontinue

Assessing risk and addressing harms of opioid use

- Offer risk mitigation strategies, including naloxone for patients at risk for overdose
- Review PDMP* data at least every 3 months and perform UDT** at least annually***
- Avoid prescribing opioid and benzodiazepines concurrently when possible
- Clinicians should offer or arrange MAT**** for patients with OUD†

*Prescription drug monitoring program

**Urine drug testing

***Some VA facilities may require more frequent testing

****Medication-assisted treatment

†Opioid use disorder



2022 updated guidelines, >18yoa

1. Determining whether or not to initiate opioids for pain
2. Selecting opioids and determining opioid dosages
3. Deciding duration of initial opioid prescription and conducting follow-up
4. Assessing risk and addressing potential harms of opioid use

Clinically meaningful improvement

- 30%+ improvement
- Assess and document
- Validated tools

- What is not CMI?

- Rx – CMI = inappropriate care

- Risks, diagnosis and treatment of opioid addiction
- Prescribing emergency opioid antagonists
- Alternatives to controlled substance prescribing
 - Nonpharmacological therapies
- Controlled substance disposal

Consequences

- Opioid use disorder
- Hyperalgesia/allodynia
- Addiction
- Withdrawal
- Toxicity/overdose
- Overdose treatment

Risks of Opioid Therapy

- Mortality (of all-causes)
 - **Hazard ratio (HR) 1.64** for long acting opioids for non-cancer pain
- Overdose deaths (unintentional)
 - **HR 7.18-8.9** for MED > 100 mg/d
- Opioid use disorder

For patients on long-term opioids (> 90 days)

 - **HR 15** for 1-36 mg/d MED
 - **HR 29** for 36-120 mg/d MED
 - **HR 122** for > 120 mg/d MED

*MED=Morphine Equivalent Daily Dose (in mg/d)

DSM-5 Criteria for OUD (Rx opioids)

(2 or more criteria)

DSM-5 Criteria	Example behaviors
Craving or strong desire to use opioids	Describes constantly thinking about opioids
Recurrent use in hazardous situations	Repeatedly driving under the influence
Using more opioids than intended	Repeated requests for early refills
Persistent desire/unable to cut down or control opioid use	Unable to taper opioids despite safety concern or family's concern
Great deal of time spent obtaining, using or recovering from the effects	Spending time going to different doctor's offices and pharmacies to obtain opioids
Continued opioid use despite persistent opioid-related social problems	Marital/family problems or divorce due to concern about opioid use
Continued opioid use despite opioid-related medical/psychological problem	Insistence on continuing opioids despite significant sedation
Failure to fulfill role obligations	Poor job/school performance; declining home/social function
Important activities given up	No longer active in sports/leisure activities

Original ORS

NARX SCORES			OVERDOSE RISK SCORE	ADDITIONAL RISK INDICATORS (3)
Narcotic	Sedative	Stimulant	740 (Range 000-999)	<ul style="list-style-type: none"> 1 >= 4 opioid or sedative dispensing pharmacies in any 90 day period in the last 2 years 1 >= 5 opioid or sedative providers in any year in the last 2 years 1 > 100 MME total and 40 MME/day average
791	551	000		
Explanation and Guidance			Explanation and Guidance	Explanation and Guidance

Updated ORS

UNINTENTIONAL OVERDOSE RISK SCORE MODEL i



710

NARX SCORES i

NARCOTICS	SEDATIVES	STIMULANTS
642	481	000
ACTIVE RX 2	ACTIVE RX 1	ACTIVE RX 0

[How should I use this information?](#)

KEY CONTRIBUTING FACTORS TO OVERDOSE RISK SCORE MODEL

Greater than six dispensations	Yes
Benzo - Narcotics overlap	60 Days
Number of high risk scripts	0
Number of pharmacies where narcotics/sedatives filled	3
Total days supply of short-acting drugs	240
Combination of Narcotic, and Sedative RX	9

One cohesive tile ensures scores and key contributing factors are always displayed together

Key Contributing Factors gives further insight into the how the ORS was derived

Refreshed display of ORS

Helps identify potential long-term opioid use

UNINTENTIONAL OVERDOSE RISK SCORE MODEL



[How should I use this information?](#)

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Benzo - Narcotics overlap	60 Days
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Number of pharmacies where narcotics/sedatives filled	3
Total days supply of short-acting drugs	240
Combination of Narcotic, and Sedative RX	9

Identifies overlapping prescriptions within a 90-day period

Helps identify potential history of opioid use disorder

Offers insight into multiple provider episodes

Helps identify potential multiple provider episodes

Offers insight into potential risk of adverse effects

Narx Scores help draw awareness to the presence of PDMP history

NARX SCORES

NARCOTICS	SEDATIVES	STIMULANTS
642	481	000
ACTIVE RX 2	ACTIVE RX 1	ACTIVE RX 0

Active Rxs for each Narx Score are easily seen below its respective section

Physical dependence vs. addiction

Physical Dependence

- Body is used to having a high level of opioid
- Abrupt discontinuation will result in withdrawal symptoms (nausea & vomiting, anxiety, etc.)

Addiction

- Uncontrollable craving and compulsive use, inability to control drug use
- There is no addiction without craving

Addiction is a chronic, progressive brain disease due to altered brain structure and function

Addiction

■ Definition

1. Tolerance
2. Withdrawal
3. Abuse
4. Helplessness
5. Compulsion
6. Isolation
7. Vicious circle of devastation

■ Dependence

■ Hyperalgesia

Addiction treatment

- Inpatient
 - Short term
 - Long term
 - Partial hospitalization
- Outpatient
 - Intensive programs
 - Clinics
- Medication-assisted treatment programs

Buprenorphine today: X the X-waiver

- MAT Act of 2021

<https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf>

<https://www.congress.gov/bill/117th-congress/senate-bill/445>

https://www.deadiversion.usdoj.gov/pubs/docs/MATE_Training_Letter_Final.pdf

<https://www.samhsa.gov/medications-substance-use-disorders/waiver-elimination-mat-act>

https://www.deadiversion.usdoj.gov/drug_chem_info/buprenorphine.pdf

MATE Act of 2021

1. All DEA-certificate holders
2. > 6/27/2023
3. One time only
4. \geq 8 hours training
5. Self-attestation
6. Training exceptions

➤ HB21 requirement?

<https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf>

<https://www.congress.gov/bill/117th-congress/senate-bill/445>

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https://www.deadiversion.usdoj.gov/drug_chem_info/buprenorphine.pdf

1. Do you hold a board certification in addiction psychiatry or addiction medicine from one of the following associations; American Board of Medical Specialties, American Board of Addiction Medicine, American Osteopathic Association?

Yes No

2. Have you graduated, in good standing, from an accredited school of allopathic medicine, osteopathic medicine, dental surgery, dental medicine, physician assistant, or advanced practice nursing in the United States during the 5-year period immediately preceding the date on which you first submitted a registration or renewal and the curriculum included not less than 8 hours of training?***

Yes No

- ***
- A. Treating and managing patients with opioid or other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder or
 - B. The safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid and other substance use disorders

3. Have you completed not less than 8 hours of training with one or more of the following from the approved training requirements?***

Yes No

- ***
- the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (ACCME) or the Commission for Continuing Education Provider Recognition (CCEPR)

You must be able to answer yes to at least one of the questions in order to continue.

[More Information](#)

Withdrawal Sx

- Rhinorrhea
- Diarrhea
- Yawning
- Anxiety
- Mydriasis
- Sneezing
- Lacrimation
- Vomiting
- Hyperventilation
- Hostility
- Piloerection

Clinical Opiate Withdrawal Scale

- Resting HR
- GI upset
- Sweating
- Tremor
- Restlessness
- Yawning
- Pupil size
- Anxiety/irritability
- Bone/joint aches
- Gooseflesh skin
- Runny nose/tearing

Score: 5-12 = mild; 13-24 = moderate;
25-36 = moderately severe; > 36 = severe

Withdrawal treatment

	Symptoms	OUD
Clonidine, lofexidine	X	
Naltrexone		X
Buprenorphine, methadone	X	X

- ❖ Clonidine, lofexidine: α_2 -agonists
- ❖ Naltrexone: mu receptor antagonist
- ❖ Buprenorphine: partial mu receptor agonist
- ❖ Methadone: mu receptor agonist
 - Opioid treatment program (OTP)

Opiate-induced constipation (OIC)

- At least 2 of the following criteria = Dx
 - < 3 BMs/wk
 - Hard/lumpy stools
 - Sensation of incomplete evacuation
 - Small stools
 - Sensation of anorectal obstruction
 - Straining with defecation
 - Bloating + abdominal pain relieved by BM
 - GERD

Opiate-induced constipation (OIC)

- Dietary and lifestyle interventions
- OTC medications
 - Stimulant laxatives: bisacodyl, senna
 - Stool softeners: docusate, mineral oil, Mg citrate
 - Enemas
- Prescription medications (PAMORAs)
 1. Naldemedine (Symproic)
 2. Naloxegol (Movantik)/Alvimopan (Entereg)
 3. Methylnaltrexone (Relistor)

Lubiprostone (Amitiza)/Prucalopride (Motegrity)

<https://www.uspharmacist.com/article/opioidinduced-constipation-clinical-guidance-and-approved-therapies>

Ouyang R, Li Z, Huang S, et al. *Efficacy and Safety of Peripherally Acting Mu-Opioid Receptor Antagonists for the Treatment of Opioid-Induced Constipation: A Bayesian Network Meta-analysis*. Pain Med. 2020 Jun 3. pii: 5850638. doi: 10.1093/pm/pnaa152.

- Risks, diagnosis and treatment of opioid addiction
- Prescribing emergency opioid antagonists
- Alternatives to controlled substance prescribing
 - Nonpharmacological therapies
- Controlled substance disposal

Overdose treatment

- Assess risk proactively
- Pale, clammy skin, miosis, vomiting, bradypnea, hypoventilation, limp, unarousable, coma
- BLS

Highest risk population

Patients who:

- Are receiving opioids at a dosage of ≥ 50 MME/d;
- Have respiratory conditions (i.e., COPD, OSA), regardless of opioid dose;
- Have been prescribed BZDs, regardless of opioid dose; OR
- Have a non-opioid substance use disorder, report excessive alcohol use, or have a mental health disorder, regardless of opioid dose.

<https://www.cdc.gov/stopoverdose/naloxone/index.html>

<https://www.hhs.gov/about/news/2018/12/19/hhs-recommends-prescribing-or-co-prescribing-naloxone-to-patients-at-high-risk-for-an-opioid-overdose.html>

<https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf>

Opioid antagonist

- Naloxone
- Pharmacokinetics
- Federal government guidelines
- Naloxone access law

OTC

<https://www.flsenate.gov/Session/Bill/2022/544/BillText/er/PDF>

<https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-naloxone-narcan-evzio>

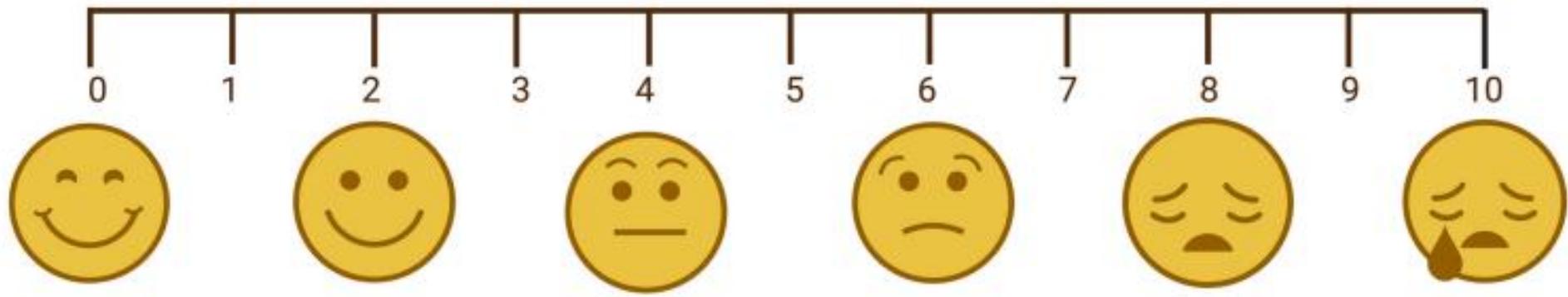
<https://www.hhs.gov/about/news/2018/12/19/hhs-recommends-prescribing-or-co-prescribing-naloxone-to-patients-at-high-risk-for-an-opioid-overdose.html>

- Risks, diagnosis and treatment of opioid addiction
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Face, Legs, Activity, Cry & Consolability (FLAAC)

Category	Scoring		
	0	1	2
 Face	No particular expression or smile, eye contact and interest in surroundings	Occasional grimace of frown, withdrawn, disinterested, worried look to face, eyebrows lowered, eyes partially closed, cheeks raised, mouth pursed	Frequent to constant frown, clenched jaw, quivering chin, deep furrows on forehead, eyes closed, mouth opened, deep lines around nose / lips
 Legs	Normal position or relaxed	Uneasy, restless, tense, increased tone, rigidity, intermittent flexion / extension of limbs	Kicking or legs drawn up, hypertonicity, exaggerated flexion / extension of limbs, tremors
 Activity	Lying quietly, normal position, moves easily and freely	Squirming, shifting back and forth, tense, hesitant to move, guarding, pressure on body part	Arched, rigid, or jerking, fixed position, rocking, side to side head movement, rubbing of body part
 Cry	No cry or moan (awake or asleep)	Moans or whimpers, occasional cries, sighs, occasional complaint	Crying steadily, screams, sobs, moans, grunts, frequent complaints
 Consolability	Calm, content, relaxed, does not require consoling	Reassured by occasional touching, hugging or talking to, distractible	Difficult to console or comfort

Wong-Baker FACES scale



Pain characteristics

	Nociceptive Pain		Neuropathic Pain
	Somatic Pain	Visceral Pain	
Origin	Superficial receptors	Visceral receptors	Nerves
Location and distribution	<ul style="list-style-type: none"> • Superficial (skin and subcutaneous tissue) • Well-localized • Not referred 	<ul style="list-style-type: none"> • Deep (e.g., from muscle/bone/fascia/periosteum) • Poorly localized • Often referred 	<ul style="list-style-type: none"> • Nerve structures (e.g., trigeminal nerve) • Radiating or specific
Transmission	A-delta-fibers	C-fibers	Dermatomal (periphery) or non-dermatomal (central)
Type of pain reported	Pinprick, sharp or stabbing	Pressure, sharp or ache	Tingling, prickling, lancinating or burning

Nonpharmacological

Hot/cold	Osteopathic manipulation
Physical therapy	Chiropractic medicine
Acupuncture	TENS
Biofeedback	Cognitive behavioral therapy
Exercise	Yoga
Music	Moxibustion
Pulsed radiofrequency	Mindfulness
Tai-chi	Laughter/humor

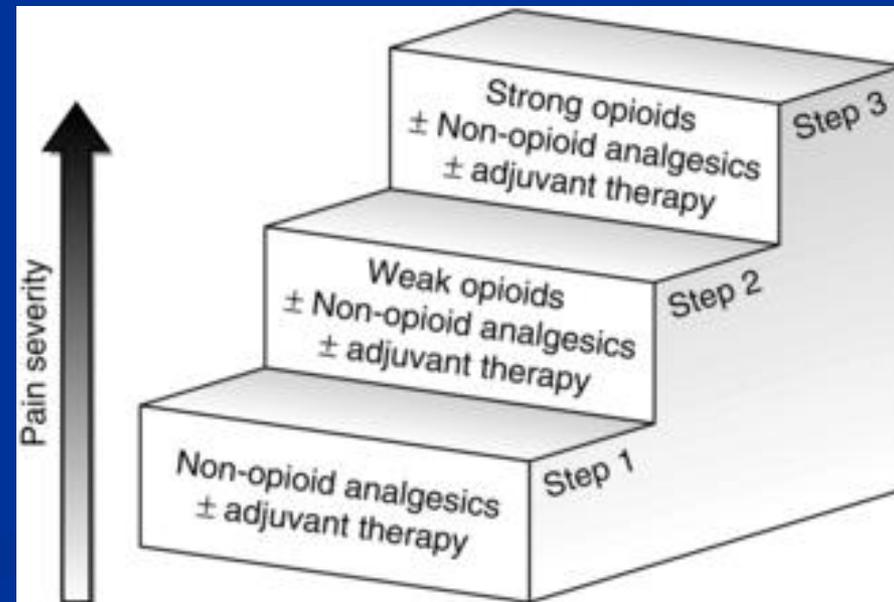
Colebaugh CA, et al. *J Pain*, published online Jan 13, 2023. doi:10.1016/j.jpain.2023.01.006.

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Nadlinda PG, et al. *Pain*, published online Oct 26, 2021, doi:10.1097/j.pain.0000000000002521.

Phased approach to analgesia

- Medications
 - Mild (1 – 4): acetaminophen or NSAIDs
 - Moderate (5 – 6): acetaminophen +/- NSAIDs +/- oral opioids
 - Severe (7 – 10): IV opioids
- Non-pharmacological interventions



Non-opioid alternatives

- Acetaminophen
- NSAIDs
- Antidepressants
- Anticonvulsants
- Anesthetics
- Corticosteroids
- Non-BZD muscle relaxers

Non-opioids

- Acetaminophen
 - 325-1000mg q4-6h (max 4g/d)
- NSAIDs
 - Diclofenac
 - 50mg q6-12h (max 150mg/d)
 - Ibuprofen
 - 600-800mg q6-8h (max 3.2g/d)
 - Naproxen (base)
 - 500mg q12h

Non-opioids

■ Gabapentinoids

■ Pregabalin

- 75-150mg q12h or 50-100mg q8h (max 300mg/d)

■ Gabapentin (IR)

- 300mg qd (d.1) – 300mg BID (d.2) – 300mg TID (d.3)
- Titrate up to max of 600mg q8h (1800mg/d)

■ Dexamethasone

- 4-8mg q8h

Analgesics for comorbidities

■ Renal impairment

Preferred	Caution	Avoid
Acetaminophen, fentanyl, buprenorphine	Hydromorphone, oxycodone, gabapentinoids, SNRIs	Morphine, codeine, tramadol, meperidine

- NSAIDs – short-term, close monitoring
- Altered pharmacokinetics
- Lipophilic agents
- Topicals

Analgesics for comorbidities

■ Hepatic dysfunction

Preferred	Caution	Avoid
Acetaminophen	Hydromorphone, oxycodone, fentanyl, gabapentinoids	Morphine, codeine, tramadol, meperidine, SNRIs, NSAIDs

- NSAIDs – no
- Decrease dose, longer frequency intervals
- Topicals (NSAIDs, lidocaine, capsaicin)

Odoma VA, Pitliya A, AlEdani E, Bhangu J, Javed K, Manshahia PK, Nahar S, Kanda S, Chatha U, Mohammed L. Opioid Prescription in Patients With Chronic Kidney Disease: A Systematic Review of Comparing Safety and Efficacy of Opioid Use in Chronic Kidney Disease Patients. *Cureus*. 2023 Sep 18;15(9):e45485. doi: 10.7759/cureus.45485. PMID: 37727840; PMCID: PMC10506738.

Soleimanpour H, Safari S, Shahsavari Nia K, Sanaie S, Alavian SM. Opioid Drugs in Patients With Liver Disease: A Systematic Review. *Hepat Mon*. 2016 Mar 6;16(4):e32636. doi: 10.5812/hepatmon.32636. PMID: 27257423; PMCID: PMC4887963.

Past, present, and future

- ERAS /pre-operative Rx
- IV acetaminophen (e.g., Ofirmev)
- Slow-release bupivacaine (e.g., Exparel)
- Different targets than opioid receptors
- Longer acting agents (i.e., Zilretta)
- Nerve fiber inactivation
- Novel combinations (i.e., Zynrelef)
- Sodium channel blockers (i.e., Journavx)
- Potassium channel blockers

Appropriate opioid use

1. Limit use for acute pain
2. May be used for moderate – severe refractory pain
3. Identify patients at risk of misuse
4. Reduce risk of overdose
5. Start low, go slow with short-acting meds
6. Co-prescribe naloxone
7. Discuss expectations
 - “Opioids are a time-limited trial”

Appropriate opioid use

8. Educate about opioid safety
9. Assess for misuse
10. Regular follow up
11. Consider non-opioids +/- adjunctive therapies
12. Taper or discontinue, when appropriate
13. Opioid disposal
14. OUD treatment, as relevant

Abuse-deterrent opioids

- **Hydrocodone:** Hysingla ER; Vantrela ER; Zohydro ER
- **Hydromorphone:** Exalgo
- **Morphine ER:** Morphabond; Arymo ER
- **Morphine ER/Naltrexone:** Embeda
- **Oxycodone IR:** Oxaydo; Roxybond
- **Oxycodone ER:** Oxycontin; Xtampza ER
- **Oxycodone ER/Naltrexone:** Targiniq ER; Troxyca ER

Bottom Line

- Individualized approach to patient and pain type
 - Review PDMP
 - Evaluate those at higher risk of misuse/abuse
- Discuss realistic analgesic expectations
- Multimodal analgesia + non-pharmacological tx
- Educate about storage, tapering, and disposal
- Monitor for efficacy and adverse effects
- Consider referral to pain management

In-house analgesia for OUD patients

TREAT

- Short-acting opioids
- Buprenorphine: partial agonist
 - Precipitated withdrawal
- Methadone: full agonist
 - No withdrawal
 - Jun 2025: Expanding Access to Methadone Treatment in Hospital Settings

Substance Abuse and Mental Health Services Administration. Expanding Access to Methadone Treatment in Hospital Settings. Publication No. PEP25-02007. Rockville, MD: Substance Abuse and Mental Health Services Administration. 2025. <https://library.samhsa.gov/sites/default/files/methadone-treatment-hospital-setting-pep25-02-007.pdf>

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South AM, et al. Beyond the Basics: How Should We Manage Acute Pain in Hospitalized Patients with OUD? *The Hospitalist*. Nov 2022; 15-17.

Inheriting chronic pain patients

- Review case with colleague
- Consider therapeutic bridge
- Develop care plan
- Assess for OUD
- Opioid stewardship

Tapering opioids: initiation

- Individualize
- Monitor and adjust
- Consolidate

- Regimens
 - 5 – 20% every 4wks
 - 10% weekly
 - 10% each month (chronic)
- Dose before frequency

<https://www.agencymeddirectors.wa.gov/Calculator/TaperDoseCalculator.html>

<https://www.rxfiles.ca/rxfiles/uploads/documents/Opioid-Taper-Template.pdf>

Tapering opioids: monitoring

- Weekly – monthly check
- CMI assessment – pain & function
- Non-opioids for pain
- Evaluate behavioral health conditions
- Monitor for withdrawal – treat prn
- Risk of overdose counseling
- Naloxone

- Risks, diagnosis and treatment of opioid addiction
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- Controlled substance disposal

Controlled substance disposal

- Small amounts
- Secure safely
- Safe disposal options



- Household trash (*not for controlled substances*)

- National Prescription Drug Take-Back Day
 - April and October annually
 - www.DEATakeBack.com

- DEA-authorized collectors
 - <https://apps.dea.gov/pubdispsearch/spring/main?execution=e1s1>
 - DEA Office of Diversion Control's Registration Call Center: 1-800-882-9539

- Flushing:
<https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm588196.pdf>

<https://takebackday.dea.gov/sites/default/files/NTBI%20XVI%20Totals.pdf>

Khan, et al. Risks associated with the environmental release of pharmaceuticals on the U.S. Food and Drug Administration "flush list". Sci Total Environ 2017 Dec 31;609:1023-1040.

<https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186188.htm>

Thank you

Joshua D. Lenchus, DO, RPh, FACP, SFHM

jlenchus@yahoo.com

954-817-5684 (cel)

Every Day is
Take Back Day



Clean them out.



Take them back.



All year long.



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