Opioids and controlled substances

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Disclosure

- 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 Florida statistics regarding M&M of controlled substance-related deaths
- Current standards, laws and rules on prescribing controlled substances*
- Proper prescribing of opiates
- Risks, diagnosis and treatment of opioid addiction*

Outline-2

- Prescribing emergency opioid antagonists*
- Alternatives to controlled substance prescribing*
  - Nonpharmacological therapies*
- Physician liability for overprescribing controlled substances
- Controlled substance disposal

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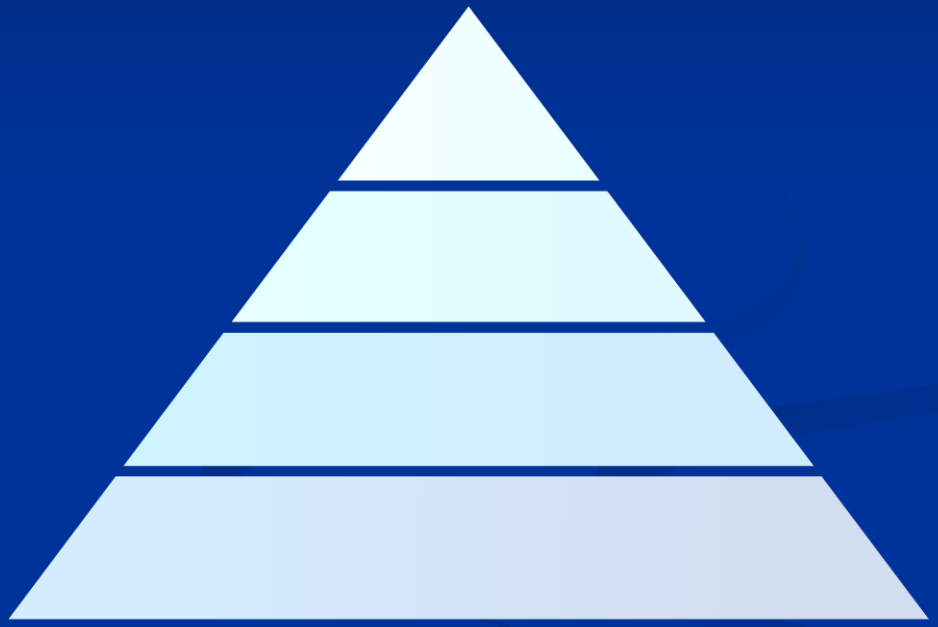
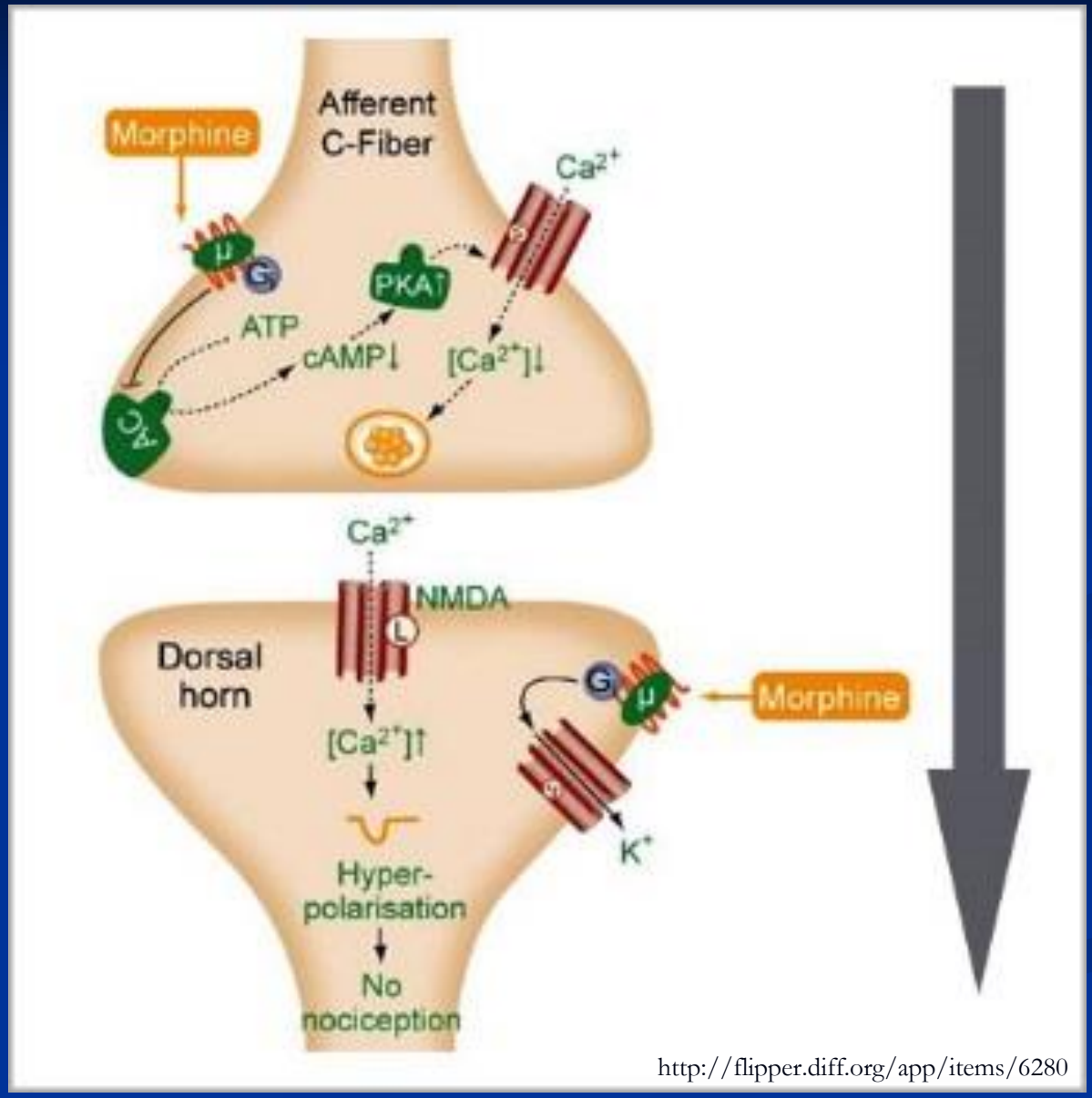
Definitions

- Opiate
- Opioid
- Narcotic
- Controlled substance



Mechanism of action



http://flipper.diff.org/app/items/6280

https://www.nps.org.au/australian-prescriber/articles/opioids-mechanisms-of-action

Receptor activity

Mu	Delta	Kappa
Analgesia	Analgesia with fewer adverse effects	Mild analgesia
Sedation		
Euphoria		Dysphoria
Respiratory depression		Less respiratory depression
Constipation		
Physical dependence		Decreased dependence

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

Phenanthrenes	Phenylpiperidines	Phenylheptylamines
Morphine	Fentanyl*	Methadone*
Hydromorphone*	Meperidine	Propoxyphene (d/c'd)
Oxymorphone*	Diphenoxylate	
Codeine	Loperamide	
Hydrocodone		
Oxycodone*		
Buprenorphine		

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	GHB	Meprobamate	
Amphetamine	Buprenorphine	Phentermine	
Pentobarbital		Phenobarbital	

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PAST
IN THE PAST.

From 1999 to 2013,

the amount of prescription opioid pain relievers prescribed & sold in the U.S. nearly

QUADRUPLED.

1999 2013

Yet there has not been an overall change in the amount of pain that Americans report.

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

History

- 1803: scientist discovers morphine
- 1874: chemist synthesizes diacetylmorphine
- 1898: pharmaceutical commercialization
- 1914: Harrison Narcotics Tax Act
- 1924: Anti-Heroin Act
- 1973: graduate student discovers opioid receptor

https://www.history.com/topics/crime/history-of-heroin-morphine-and-opiates

https://www.washingtonpost.com/national/health-science/candace-b-pert-neuroscientist-who-discovered-opiate-receptor-dies-at-67/2013/09/18/c84ef128-1eda-11e3-8459-657e0c72fec8_story.html?utm_term=.54b42d75de3f

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

N Engl J Med. 1980 Jan 10;302(2):123.

Pain, 25 (1986) 171–186
Elsevier

PAI 00878

Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases

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(Received 10 June 1985, accepted 28 October 1985)

Summary

Thirty-eight patients maintained on opioid analgesics for non-malignant pain were retrospectively evaluated to determine the indications, course, safety and efficacy of this therapy. Oxycodone was used by 12 patients, methadone by 7, and levorphanol by 5; others were treated with propoxyphene, meperidine, codeine, pentazocine, or some combination of these drugs. Nineteen patients were treated for four or more years at the time of evaluation, while 6 were maintained for more than 7 years. Two-thirds required less than 20 morphine equivalent mg/day and only 4 took more than 40 mg/day. Patients occasionally required escalation of dose and/or hospitalization for exacerbation of pain; doses usually returned to a stable baseline afterward. Twenty-four patients described partial but acceptable or fully adequate relief of pain, while 14 reported inadequate relief. No patient underwent a surgical procedure for pain management while receiving therapy. Few substantial gains in employment or social function could be attributed to the institution of opioid therapy. No toxicity was reported and management became a problem in only 2 patients, both with a history of prior drug abuse. A critical review of patient characteristics, including data from the 16 Personality Factor Questionnaire in 24 patients, the Minnesota Multiphasic Personality Inventory in 23, and detailed psychiatric evaluation in 6, failed to disclose psychological or social variables capable of explaining the success of long-term management. We conclude that opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse.

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
- 2021: 207 opioid-related OD deaths/day, US

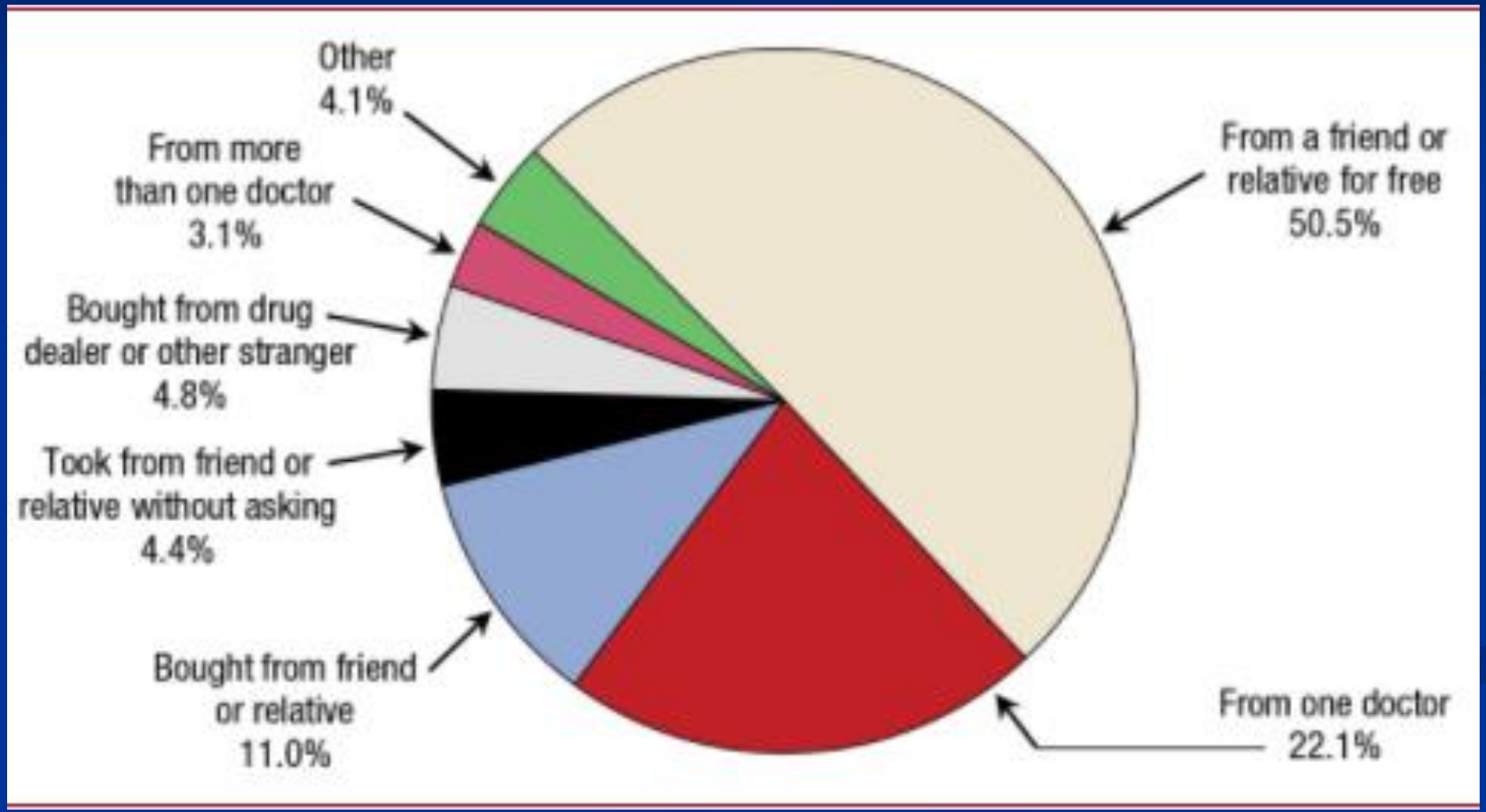
https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm

CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2018. https://wonder.cdc.gov.

http://www.nytimes.com/2007/05/10/business/11drug-web.html

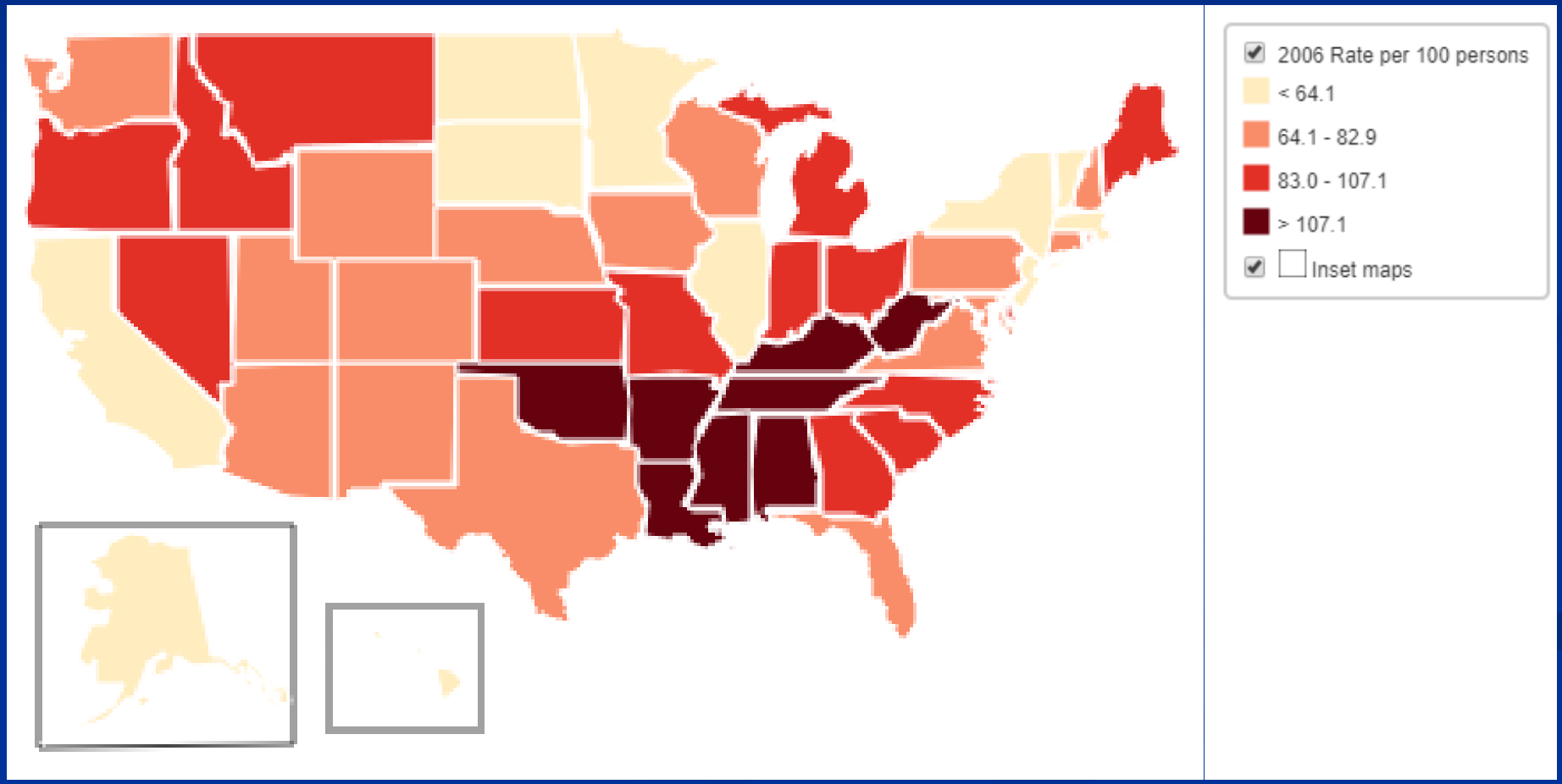
https://www.cdc.gov/drugoverdose/deaths/prescription/maps.html

Source of Rx pain relievers for nonmedical use among users 12yoa+, 2013 and 2014



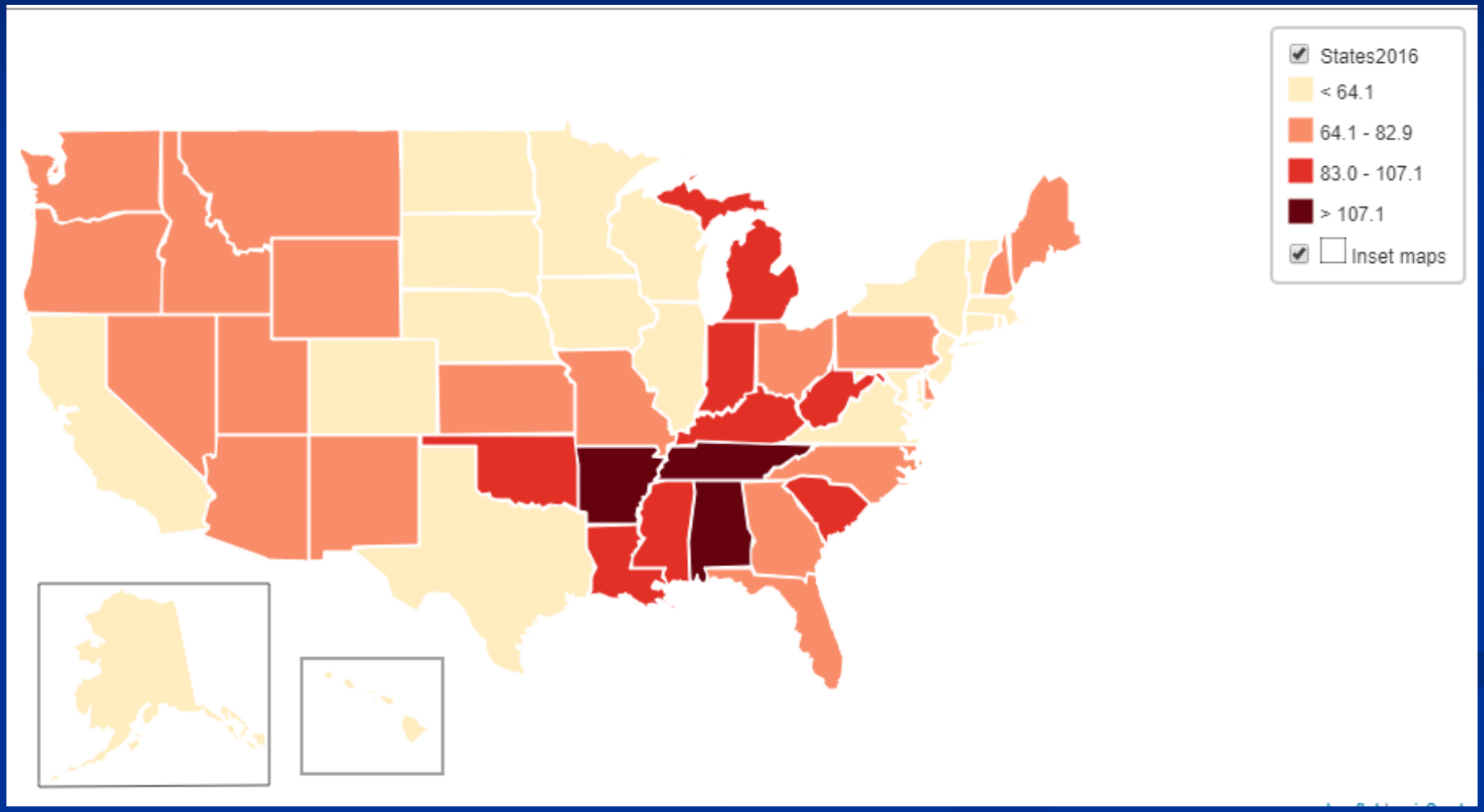
SAMHSA, Center for Behavioral Health Statistics and Quality, National Surveys on Drug Use and Health (NSDUHs), 2013 and 2014.
https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html

U.S. State Prescribing Rates, 2012



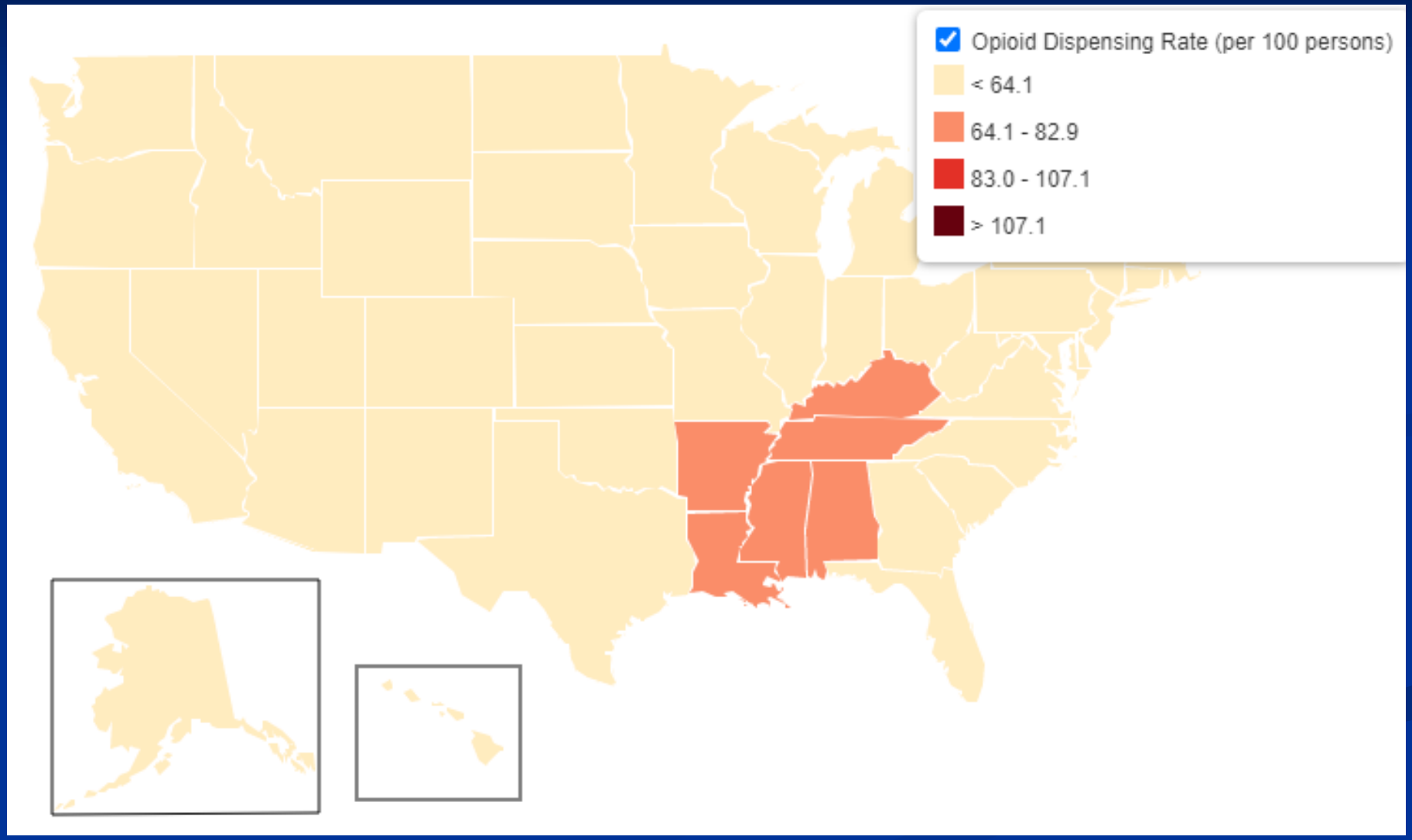
https://www.cdc.gov/drugoverdose/maps/rxstate2006.html

U.S. State Prescribing Rates, 2016



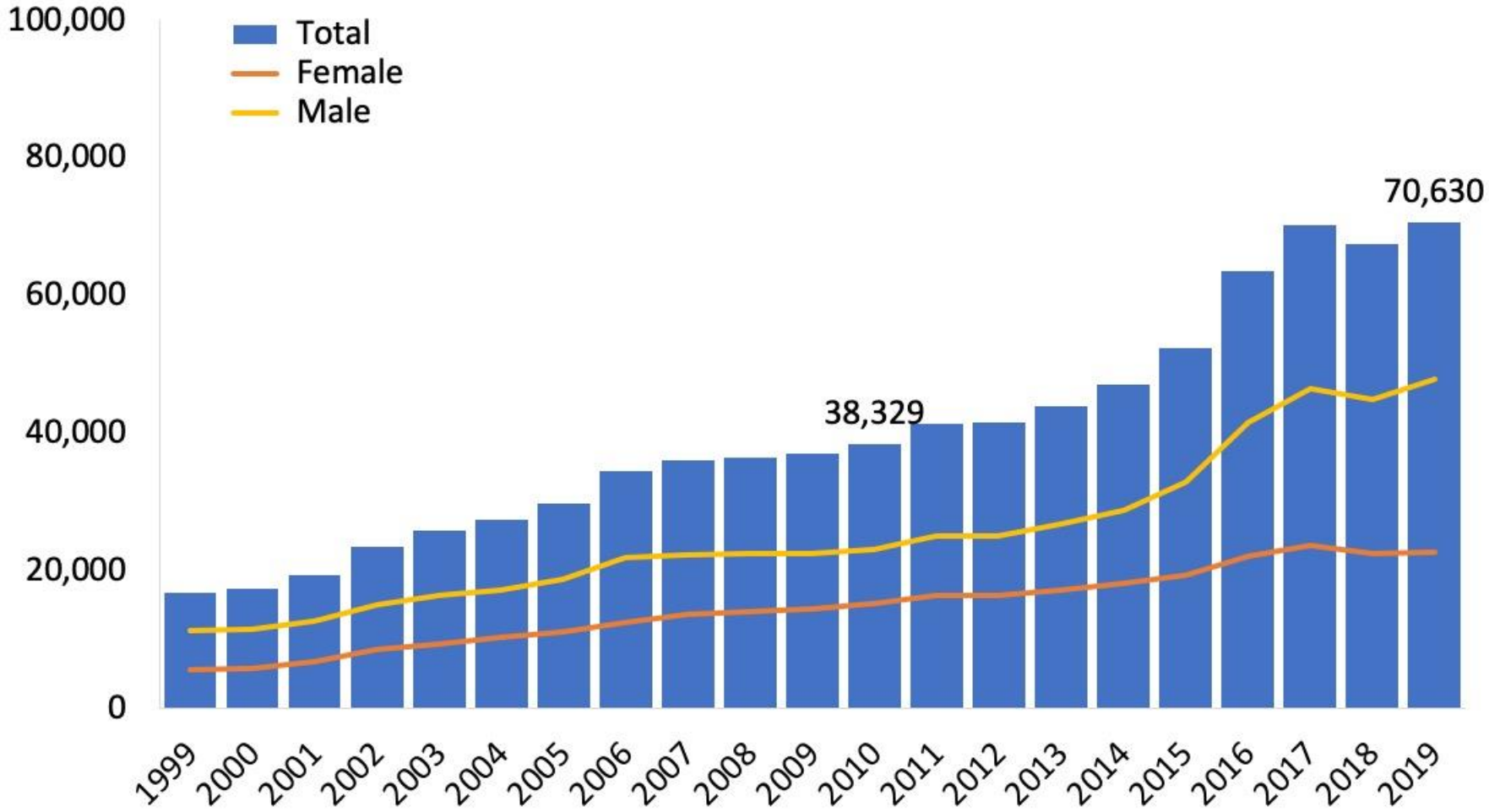
https://www.cdc.gov/drugoverdose/maps/rxstate2016.html

U.S. State Prescribing Rates, 2020



https://www.cdc.gov/drugoverdose/rxrate-maps/state2020.html

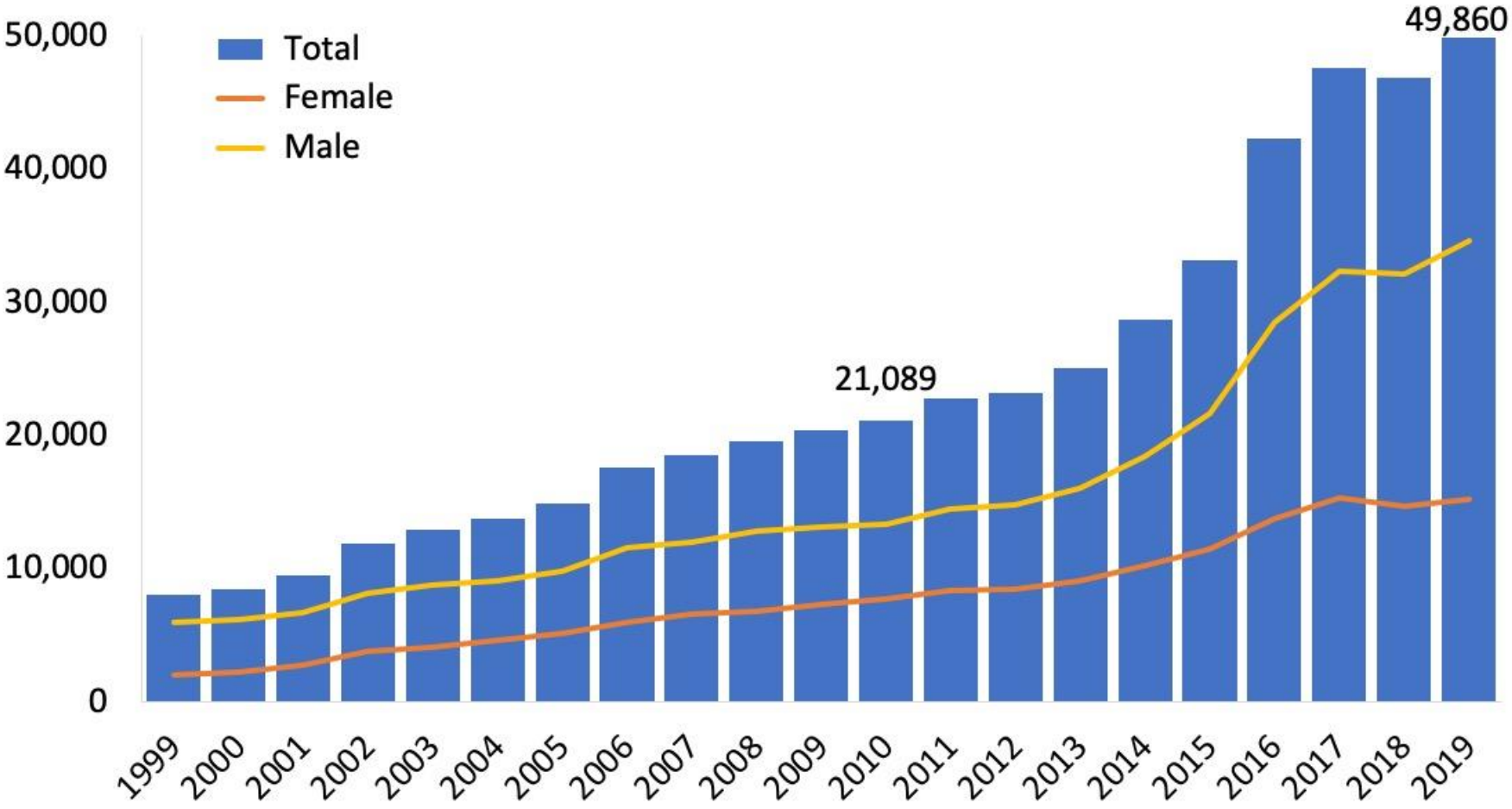
Figure 1. National Drug-Involved Overdose Deaths*
Number Among All Ages, by Gender, 1999-2019



*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.
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.

https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates

Figure 3. National Drug Overdose Deaths Involving Any Opioid, Number Among All Ages, by Gender, 1999-2019



https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates

*Among deaths with drug overdose as the underlying cause, the any opioid subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2), methadone (T40.3), other synthetic opioids (other than methadone) (T40.4), or heroin (T40.1). 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.


NOW!
←Past Future →

Sobering statistics

- 21 – 29% of those Rx opioids misuse them
- 8 – 12% develop OUD
- 4 – 6% who misuse Rx opioids => heroin
- ~80% of heroin users first misused Rx opioids

- 80% post-op opioids go unused
- 3 – 10% chronic users post-op

- $78.5B/yr in economic cost, 2018

https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis

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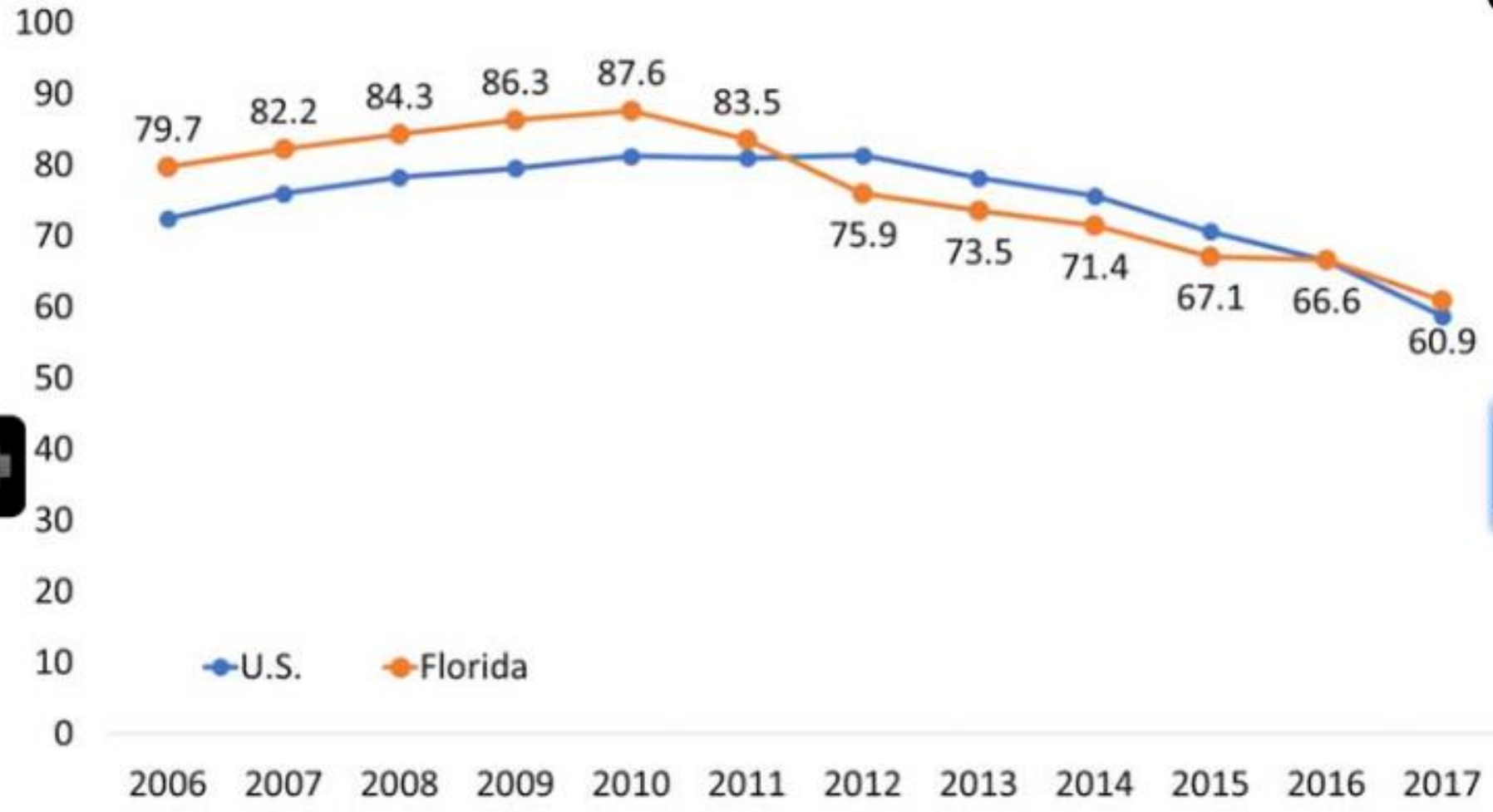
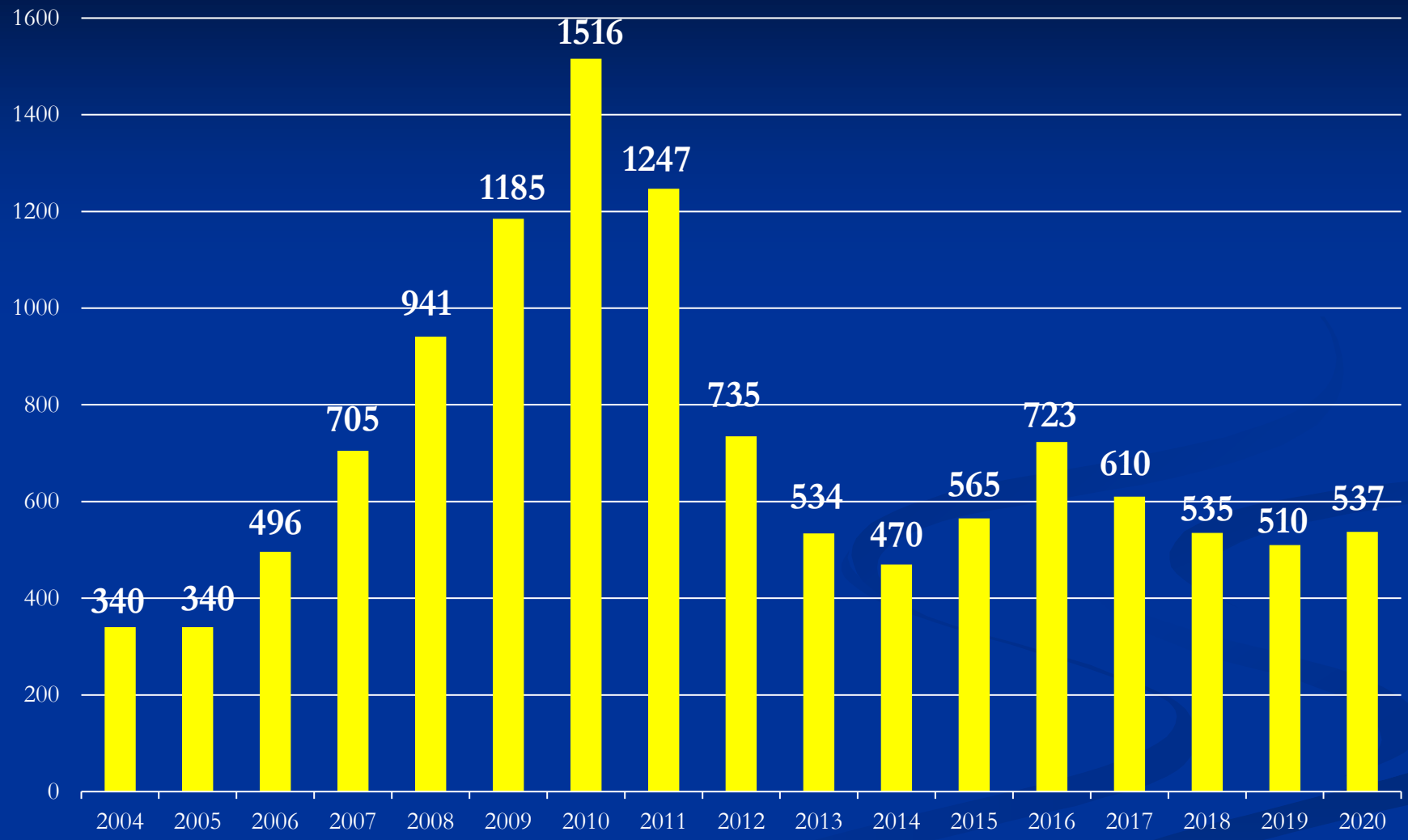


Figure 2. The U.S. and Florida opioid prescribing rate per 100 persons. Source: CDC and IQVIA Xponent 2006–2017.

https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/florida-opioid-summary

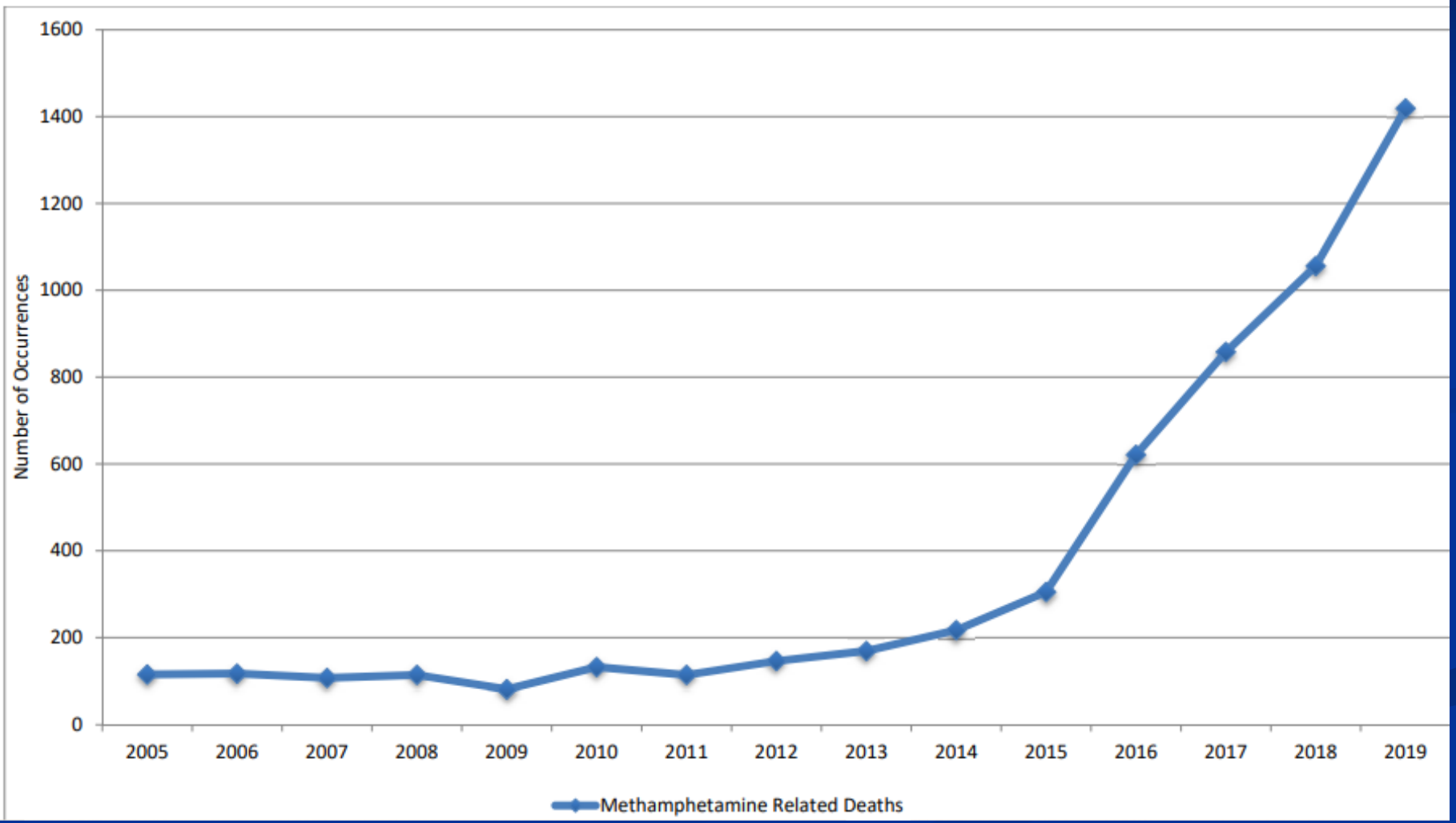
Oxycodone deaths in Florida



http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2020-Annual-Drug-Report-FINAL.aspx

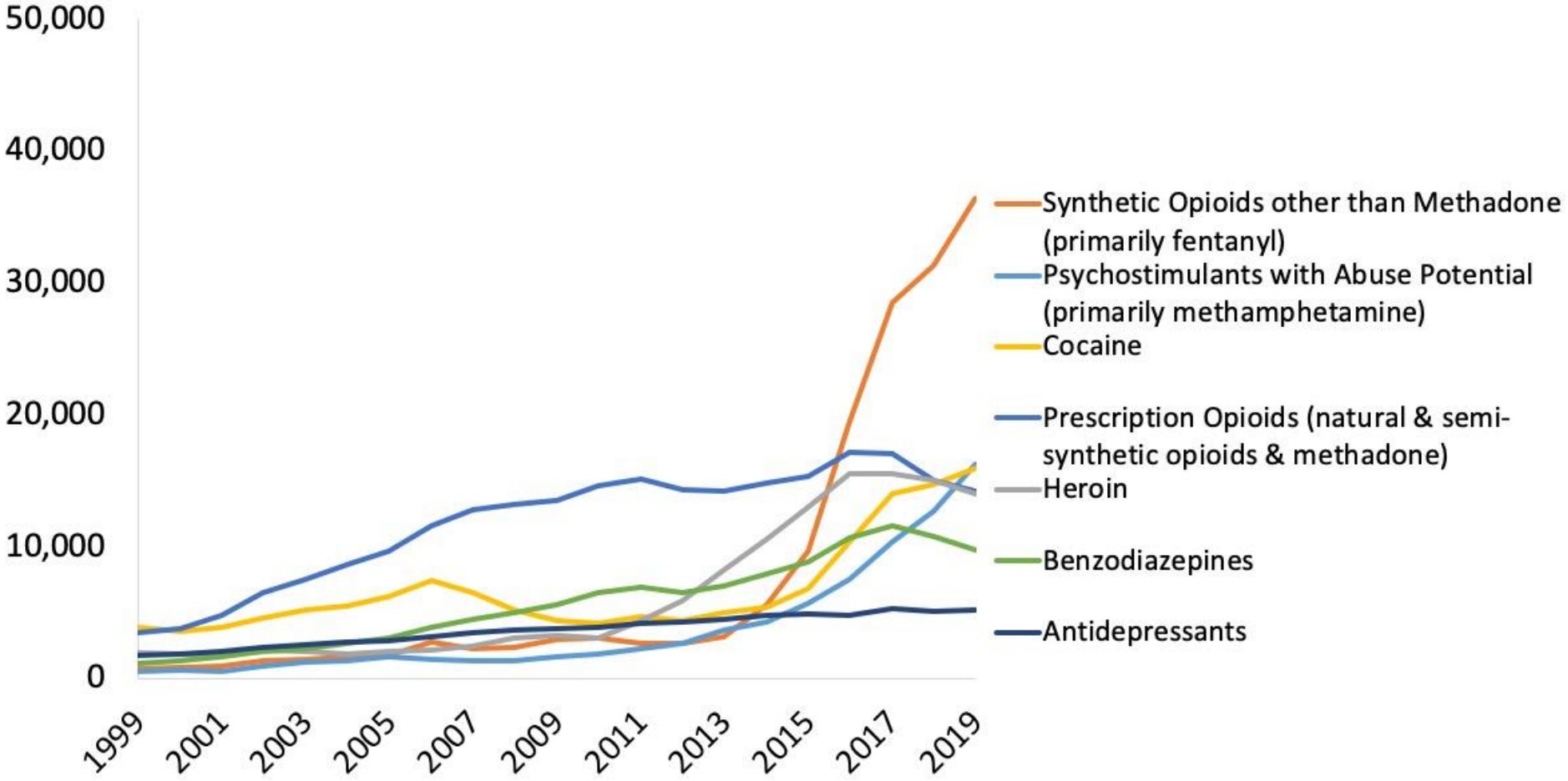
Historical Overview of Methamphetamine Occurrences

(Present and Cause)
2005 to 2019



https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2019-Annual-Drug-Report

Figure 2. National Drug-Involved Overdose Deaths*, Number Among All Ages, 1999-2019



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https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates

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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

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=0800-0899/0893/Sections/0893.04.html

In The News…

- Jan 1 2018: TJC requires opioid stewardship
  - Designate a leader
  - Engage patients
  - Identify and monitor high-risk patients
  - Facilitate PDMP access
  - Screen patients
  - Non-pharmacological pain management
  - Identify treatment programs
  - Conduct PI activities

“Chronic nonmalignant pain”

The 2016 Florida Statutes

Title XXXII	Chapter 456	View Entire Chapter
REGULATION OF PROFESSIONS AND OCCUPATIONS	HEALTH PROFESSIONS AND OCCUPATIONS: GENERAL PROVISIONS	

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.

http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0456/Sections/0456.44.html

Florida HB 21: 2018

- Signed by Gov. Scott on March 19, 2018
- Presently in full effect (mostly as of July 1, 2018)

- 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

Florida's PDMP: https://florida.pmpaware.net

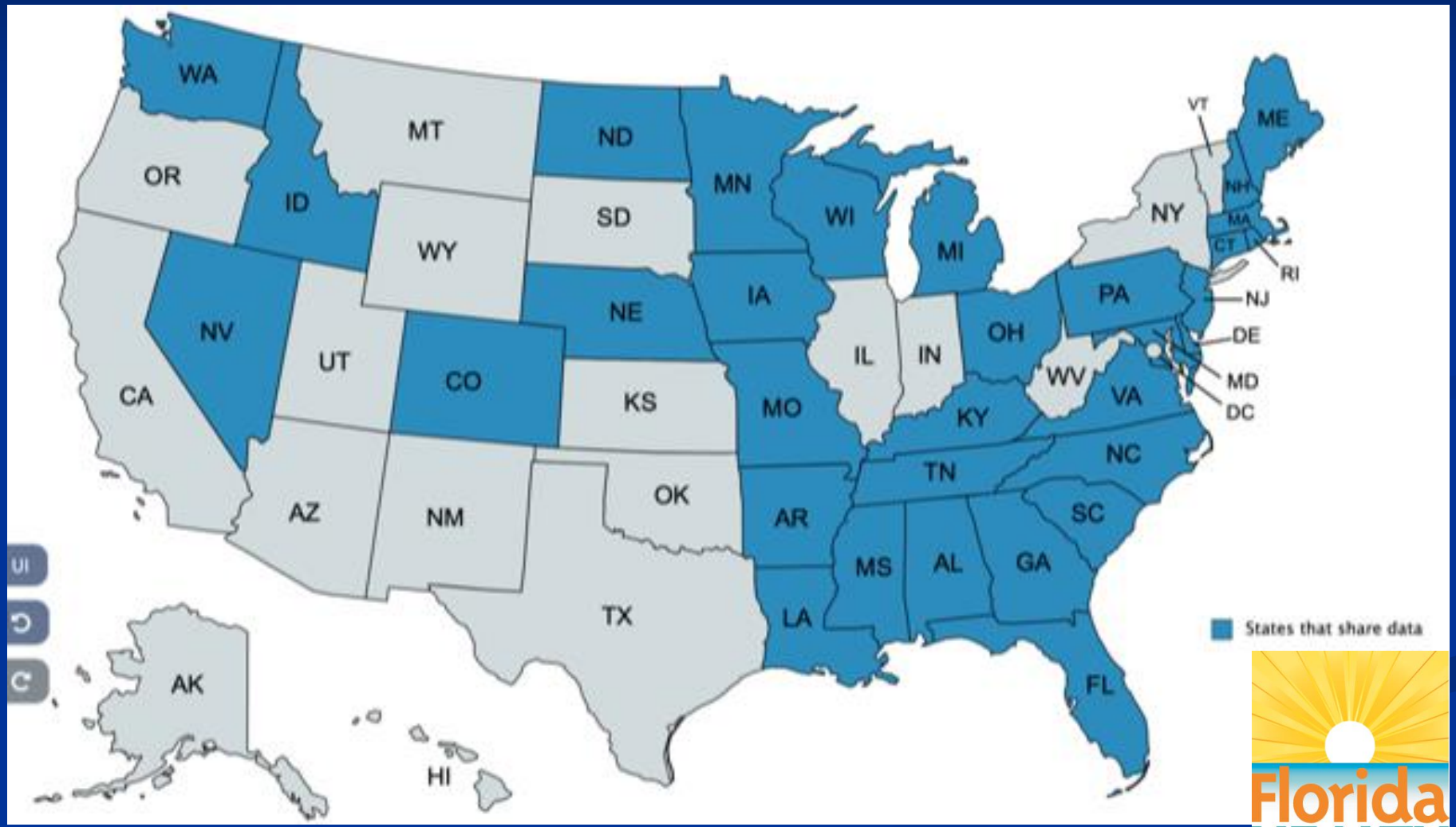
By the end of 2020 –

- Dispensing records uploaded: > 260M
- Total registrants: 131,314
- Total reports requested: 110M

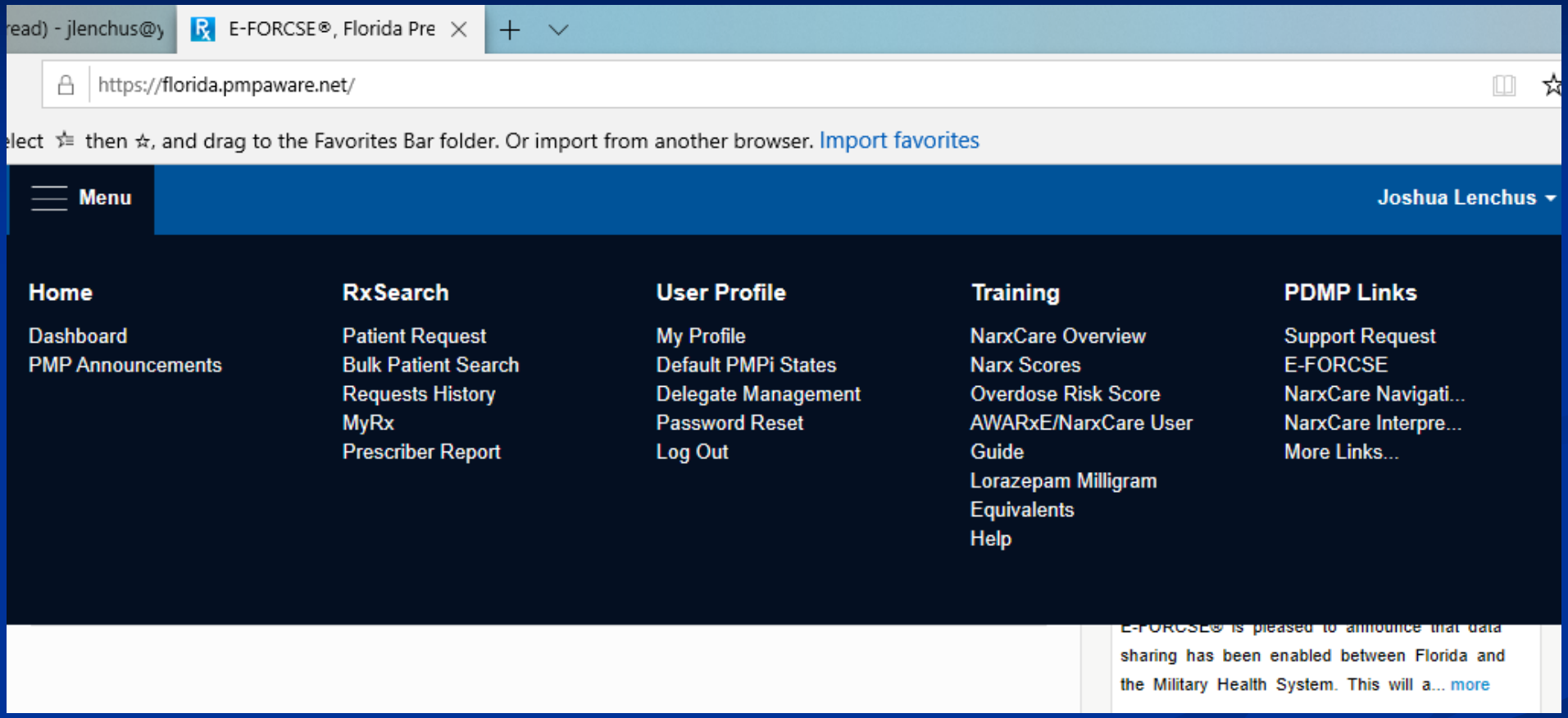
http://www.floridahealth.gov/statistics-and-data/e-forcse/funding/2017Dec31Dashboard.pdf

PDMP Compatibility

https://florida.pmpaware.net



Florida HEALTH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https://florida.pmpaware.net/
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Menu
Joshua Lenchus
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PMP Announcements
RxSearch
Patient Request
Bulk Patient Search
Requests History
MyRx
Prescriber Report
User Profile
My Profile
Default PMPi States
Delegate Management
Password Reset
Log Out
Training
NarxCare Overview
Narx Scores
Overdose Risk Score
AWARxE/NarxCare User Guide
Lorazepam Milligram Equivalents
Help
PDMP Links
Support Request
E-FORCSE
NarxCare Navigati...
NarxCare Interpre...
More Links...
sharing has been enabled between Florida and the Military Health System. This will a... more

Registration, 12-31-21

License type	Total licensees (no.)	Registered users (no.)	Registered users (%)
ARNP	42,498	15,077	35
DN	16,254	7,595	47
ME	87,980	45,769	52
OPC	3,645	76	2
OS	11,569	7,609	66
PA	11,337	6,050	53
PO	2,023	1,135	56
PS	34,825	20,289	58

http://www.floridahealth.gov/statistics-and-data/e-forcse/health_care_practitioners/_documents/quarterly-dashboard2018Sept30.pdf

PDMP: 7/1/2018

- Prescribers and dispensers, or their designees, must access and consult the PDMP before each time a controlled substance, other than a C-V nonopioid, is prescribed or dispensed, but not ordered, for a patient age 16 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

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=0800-0899/0893/Sections/0893.055.html

http://www.hidesigns.com/assets/files/flpdms/2016/Training_Guide_for_Florida_Practitioners_and_Pharmacists_-_Designee_Update_Final.pdf

http://www.flsenate.gov/Session/Bill/2018/21/BillText/er/PDF

https://flpdm-ph.hidinc.com/fllogappl/bdflpdmqlog/pmqhome.html

https://www.drugs.com/schedule-5-drugs.html

Florida Medical Association brief on HB 21

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

http://www.flsenate.gov/Session/Bill/2018/21/BillText/er/PDF

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

http://www.trauma.org/archive/scores/iss.html

- 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"

http://www.flsenate.gov/Session/Bill/2018/21/BillText/er/PDF

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

http://www.floridahealth.gov/licensing-and-regulation/pain-management-clinics/applications-and-forms/index.html

http://www.flsenate.gov/Session/Bill/2018/21/BillText/er/PDF

CME: 1/31/2019

- DEA registrants
- Controlled substance prescribers
- 2-hour, board-approved, CME
- Part of biennial license renewal
- Within the number of CE hours required by law
- Failure to complete course = no license renewal
- During each license renewal cycle since 1/31/19
- Submit confirmation of course completion
- All dentists (HB549, 7-1-19)

http://www.flsenate.gov/Session/Bill/2018/21/BillText/er/PDF

October 24, 2018: SUPPORT for Patients and Communities Act

- $8.5B appropriation

- Expands recovery centers
- Curbs drug shipments
- Lifts treatment restrictions
- Frees new painkiller research
- Changes Medicare and Medicaid provisions

- MISSING: provider education, labeling opioid bottles with risk

Comparison of select provisions in the House, Senate, and final opioid packages

	PROVISION	HOUSE	SENATE	**FINAL BILL**
MEDICARE AND DRUG PROVISIONS	Changes provider reimbursements to incentivize the use of non-opioid drugs for post-surgical pain	✓	X	**X**
	Requires CMS to test a bundled payment model to expand Medicare coverage for opioid treatment programs	✓	✓	**✓**
	Improves providers' ability to prescribe medication-assisted therapy drugs by expanding physician authorization	✓	✓	**✓**
	Establishes grant programs to incentivize hospitals and emergency departments to use opioid alternatives	✓	✓	**✓**
	Provides the National Institutes of Health authority to direct more funding toward opioid alternative research	✓	✓	**✓**
	Allows CMS to waive limits on telemedicine reimbursement for substance abuse and related mental health disorders	✓	X	**✓**
	Mandates electronic prescribing in Medicare Part D for controlled substance prescriptions	✓	✓	**✓**
	Requires Part D plans to establish drug management programs for beneficiaries with substance abuse risk	✓	X	**✓**
	Establishes a demonstration initiative to encourage providers to use certified e-health records	✓	✓	**✓**
	Allows Medicare Part D plans to suspend payments to pharmacies under investigation for fraud	✓	X	**✓**
	Allows CMS to identify Part D enrollees with histories of opioid overdoses and add them to monitoring systems	X	✓	**✓**
	Requires a review of opioid prescriptions and screening for abuse disorder in the initial Medicare preventive exam	✓	✓	**✓**

Comparison of select provisions in the House, Senate, and final opioid packages

	PROVISION	HOUSE	SENATE	**FINAL BILL**
MEDICAID PROVISIONS	Allows Medicaid to pay for opioid-related residential treatment at large facilities by removing Institutes for Mental Disease exclusion	✓	X	✓
	Allows Medicaid to pay for residential pediatric recovery centers for infant care	X	✓	✓
	Requires Medicaid and Medicaid managed care plans to implement safety limits for opioid prescriptions and refills	✓	X	✓
	Establishes a demonstration program to expand provider capacity for substance abuse treatment	✓	X	✓
	Ensures CHIP coverage for substance abuse disorder services for children and pregnant women	✓	X	✓
	Extends 90 percent federal Medicaid match for "health homes" that treat opioid addiction	✓	X	✓
	Expands Medicaid availability for juvenile inmates and adult inmates during the 30 days prior to release	✓	X	✓

Comparison of select provisions in the House, Senate, and final opioid packages

	PROVISION	HOUSE	SENATE	FINAL BILL
OTHER PROVISIONS	Increases FDA and U.S. Customs funding and authority to prevent illegal shipping of manufactured opioids	✗	✓	✓
	Clarifies the FDA's post-market drug authorities to consider reduced efficacy over time	✗	✓	✓
	Establishes a $10 million annual grant program to establish or operate comprehensive opioid recovery centers	✓	✓	✓
	Reauthorizes and extends grants for the comprehensive opioid abuse grant program, worth $330 million annually	✓	✗	✓
	Reauthorizes the Office of National Drug Control Policy, the High-Intensity Drug Trafficking program and other DOJ programs	✗	✓	✓
OFFSETS	Increase number of months employer-sponsored plans must cover end-stage renal disease services before Medicare coverage begins	✓	✗	✗
	Require employer group plans to report prescription drug coverage to determine primary payer situations in Medicare	✓	✗	✓
	Institute medical loss ratios for state Medicaid managed care plans that currently do not have such ratios	✓	✗	✓

Source: Congress.gov; Capital Alpha Partners; ML Strategies

By Tucker Doherty, POLITICO Pro DataPoint

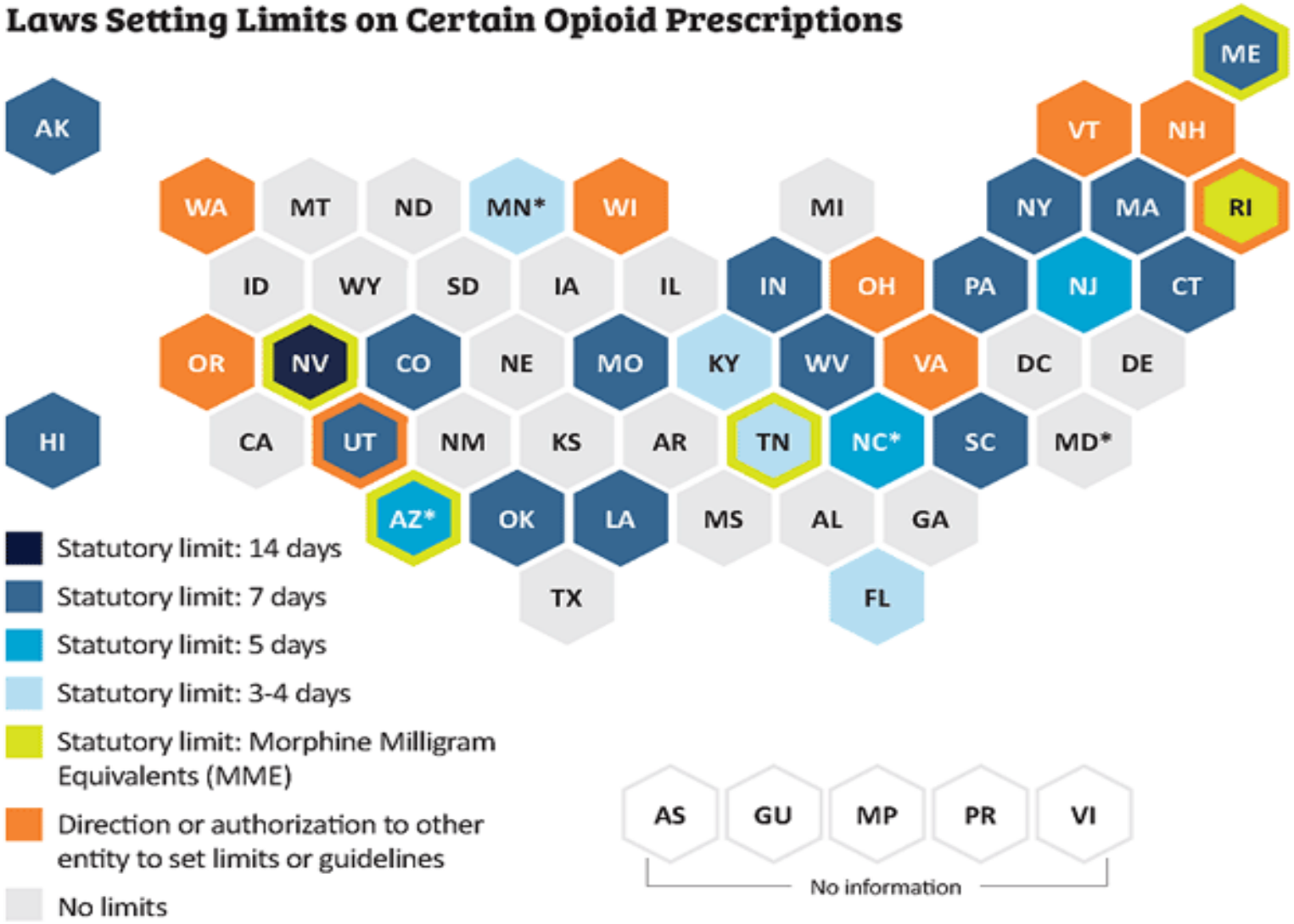
- Jan 1, 2019: CMS addresses opioid crisis
  - Hard safety edit at pharmacy
  - 90 MME threshold
  - Encourage drug management program

Medicare Prescription Drug Coverage

- Also called Part D
- Provides outpatient prescription drugs
- All Medicare beneficiaries are eligible
  - Can have Part A ***and/or*** Part B
- Coverage for Part D is provided by:
  - Prescription Drug plans (PDP's), also known as stand alone plans
  - Medicare Advantage Prescription Drug Plans (MAPD's)

10

Laws Setting Limits on Certain Opioid Prescriptions

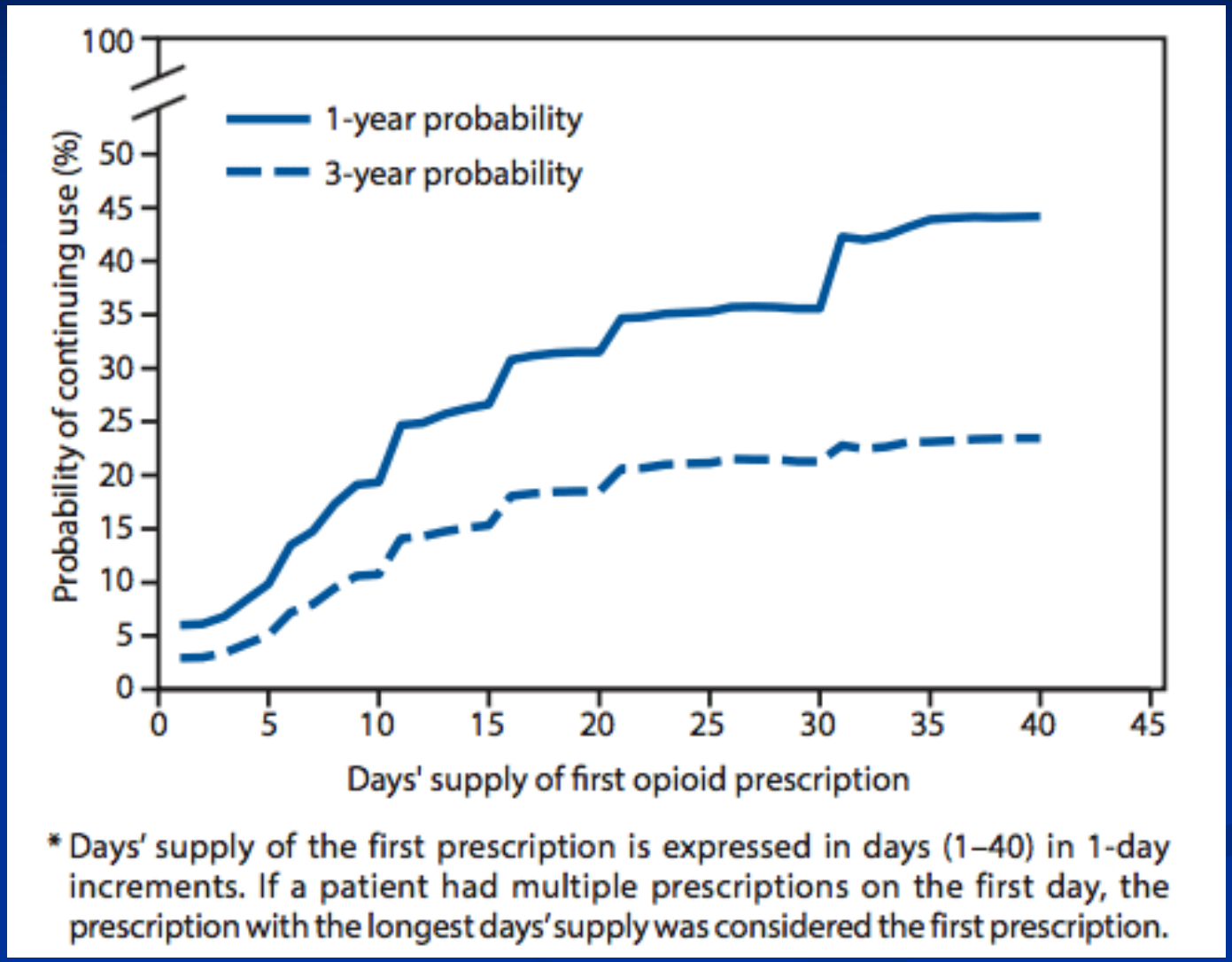


*** Note:** The map displays the state's primary opioid prescription limit and does not include additional limits on certain providers or in certain settings. Arizona allows prescriptions up to 14 days following surgical procedures and North Carolina allows up to seven days for post-operative relief. Maryland requires the "lowest effective dose." Minnesota's limit is for acute dental or ophthalmic pain. The map also does not reflect limits for minors that exist in at least eight states.

Source: NCSL, StateNet

http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx

When does dependence begin?

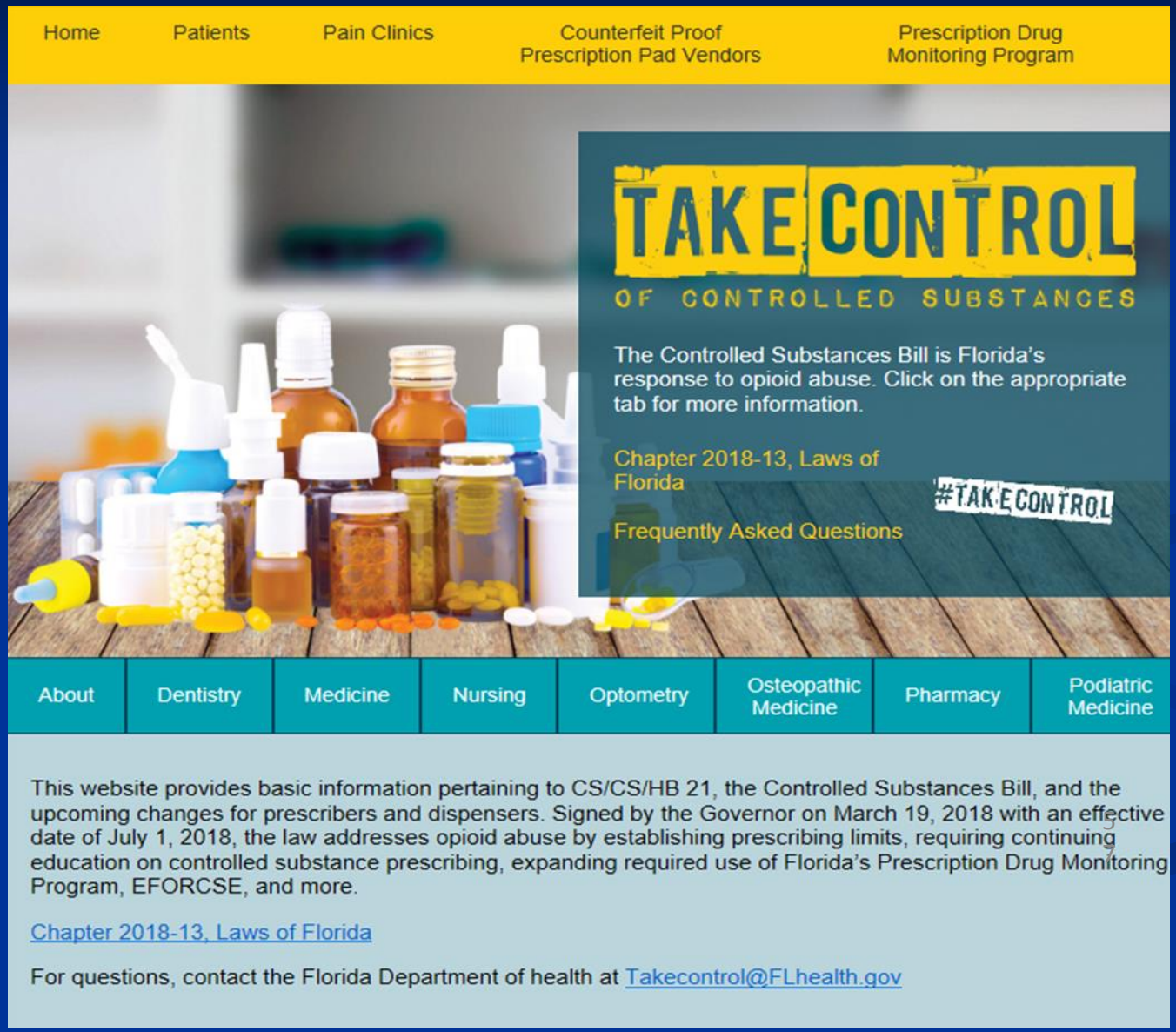


* Days' supply of the first prescription is expressed in days (1–40) in 1-day increments. If a patient had multiple prescriptions on the first day, the prescription with the longest days' supply was considered the first prescription.

http://www.newsweek.com/cdc-opiate-addiction-572498

https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm

www.flhealthsource.gov/FloridaTakeControl



- Pharmacology of opiates
- Epidemiology of opioid crisis
- Current Florida statistics regarding M&M of controlled substance-related deaths
- Current standards, laws and rules on prescribing controlled substances
- Proper prescribing of opiates
- Risks, diagnosis and treatment of opioid addiction

Purpose of issue of prescription

- Legitimate medical purpose
- Practitioner
- Usual course of practice

- Corresponding responsibility

Title 21 CFR, Part 1306 – Prescriptions, 1306.04, US DOJ, DEA

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/ecomm/e_rx/faq/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. Ali Ababwa
1234 Main Street
Anytown, Florida 33312
867-555-5309

Date: January 1, 2022

Patient Name: Jasmine Akrabah DOB: 08/27/1992

Address: 1111 Center Lane, Anytown, Florida 33312

Percocet (5/325)

Disp. # 10 (Ten)

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

No Refills

DEA # BA1222103

Signature 

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

SUPPORT Act of 2018

- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act
  - Section 2003
  - EPCS under Medicare Part D
  - Jan 1, 2021

https://www.congress.gov/bill/115th-congress/house-bill/6/text

https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2022-medicare-physician-fee-schedule-final-rule

EPCS in Florida: 2015

- Schedule II – V medications MAY be e-Rx
  - Review medication history
  - Electronic generation of the Rx
  - Electronic transmission of the Rx to a pharmacy

http://www.flsenate.gov/Laws/Statutes/2015/408.0611

http://www.flsenate.gov/Laws/Statutes/2015/456.42

64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education

Florida CS/HB 831: 2019

- Applies to ALL prescription medications
- Effective: 1/1/20
- Implement: license renewal or 7/1/21, earliest:

  - PAs & ½ MDs: 1/31/20
  - Dentists: 2/28/20
  - DOs & DPMs: 3/31/20
  - Other ½ MDs: 1/31/21
  - Optometrists: 2/28/21
  - APRN, group 1: 4/30/20
  - APRN, group 2: 7/31/20
  - APRN, group 3: 4/30/21

- Exceptions

http://flsenate.gov/Session/Bill/2019/831

Exceptions

1. Same entity
2. Unable to transmit
3. DOH waiver
4. Impractical & adversely impact patient's health
5. Research protocol
6. Rx elements can't be included electronically
7. Hospice/nursing home patient
8. Comparing drug prices

http://flsenate.gov/Session/Bill/2019/831

Florida CS/CS/HB 451: 2019

- Non-opioid alternatives: effective 7/1/2019

1. Inform the patient/rep of available alternatives
2. Discuss advantages and disadvantages
3. Provide DOH pamphlet: http://www.floridahealth.gov/programs-and-services/non-opioid-pain-management/_documents/alternatives-facts-8.5x11-eng.pdf
4. Document alternatives considered

- 2020 exceptions: HB 743

https://www.flsenate.gov/Session/Bill/2020/743/BillText/er/PDF

http://www.floridahealth.gov/programs-and-services/non-opioid-pain-management/index.html

https://www.flsenate.gov/Session/Bill/2019/451/BillText/er/PDF

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

Clinically meaningful improvement

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

- What is not CMI?

- Rx – CMI = inappropriate care

https://www.medscape.com/viewarticle/813875_2

- Pharmacology of opiates
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- Current standards, laws and rules on prescribing controlled substances
- Proper prescribing of opiates
- Risks, diagnosis and treatment of opioid addiction

Consequences

- Opioid use disorder
- Addiction
- Addiction treatment
- 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

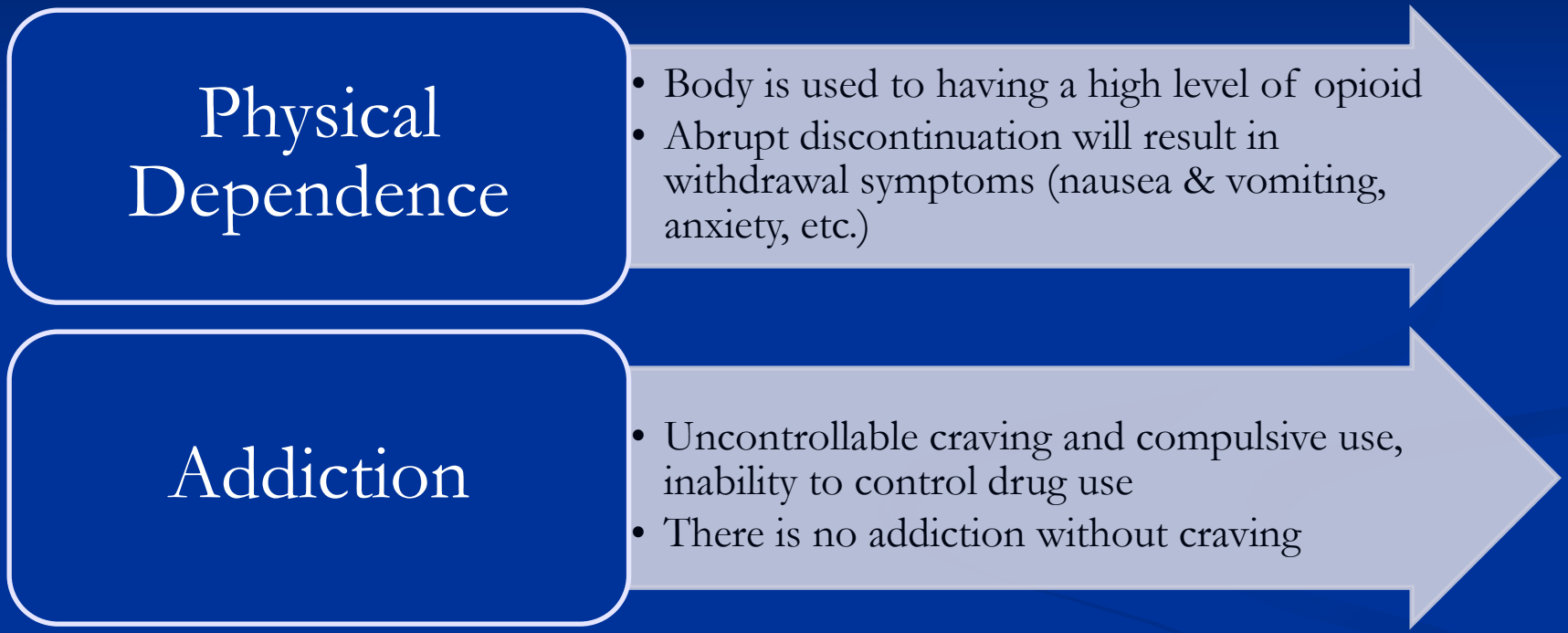
Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16—45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf

Physical dependence vs. addiction



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

Kosten, T. R., & George, T. P. (2002). The Neurobiology of Opioid Dependence: Implications for Treatment. *Science & Practice Perspectives*, *1*(1), 13–20.

Addiction

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

http://www.medscape.com/viewarticle/562216_4

American Society of Addiction Medicine. (2011). Public Policy Statement: Definition of Addiction. Chevy Chase, MD.

Addiction treatment

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

http://www.samhsa.gov/medication-assisted-treatment

MAT

- Component of comprehensive treatment

- Methadone
- Buprenorphine

- Naltrexone/naloxone?

http://store.samhsa.gov/product/Cl inical-Use-of-Extended-ReleaseInjectable-Naltrexone-in-theTreatment-of-Opioid-UseDisorder-A-Brief-Guide/SMA14- 4892R

	Buprenorphine/Naloxone*	Methadone
Treatment setting	Office-based	Specially licensed OTP
MOA	Partial opioid agonist*	Opioid agonist
FDA-approved?	Yes	Yes
Reduces cravings?	Yes	Yes
OUD classification?	Mild—Moderate	Mild/Moderate/Severe
Candidates	None/few failed attempts	Many failed attempts
Recommended for those using ongoing short-acting opioids?	No	Yes
Psychosocial intervention recommendations	Addiction-focused MM	Individual counseling and/or contingency management

https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner/new-practice-guidelines-faqs
http://www.opioidprescribing.com/ naloxone_module_1-landing
http://www.pcssmat.org
https://www.samhsa.gov/medication-assisted-treatment/practitioner-resources/DATA-program-data
http://buprenorphine.samhsa.gov/

Withdrawal

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

Clinical Opiate Withdrawal Scale

Clonidine v lofexidine

https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf

Opiate-induced constipation (OIC)

- Dietary and lifestyle interventions
- OTC medications
  - Stimulant laxatives: bisacodyl, senna
  - Stool softeners: docusate, mineral oil, Mg citrate
  - Enemas
- Prescription medications
  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.

- Prescribing emergency opioid antagonists
- Alternatives to controlled substance prescribing
  - Nonpharmacological therapies
- Physician liability for overprescribing controlled substances
- Controlled substance disposal

Overdose treatment

- Assess risk proactively
- Bradypnea, hypoventilation, miosis, coma
- BLS

Naloxone

- Injectable (Narcan)
- Autoinjectable (Evzio)
- Nasal spray (Narcan, naloxone)

- Active monitoring

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

- Prescribing emergency opioid antagonists
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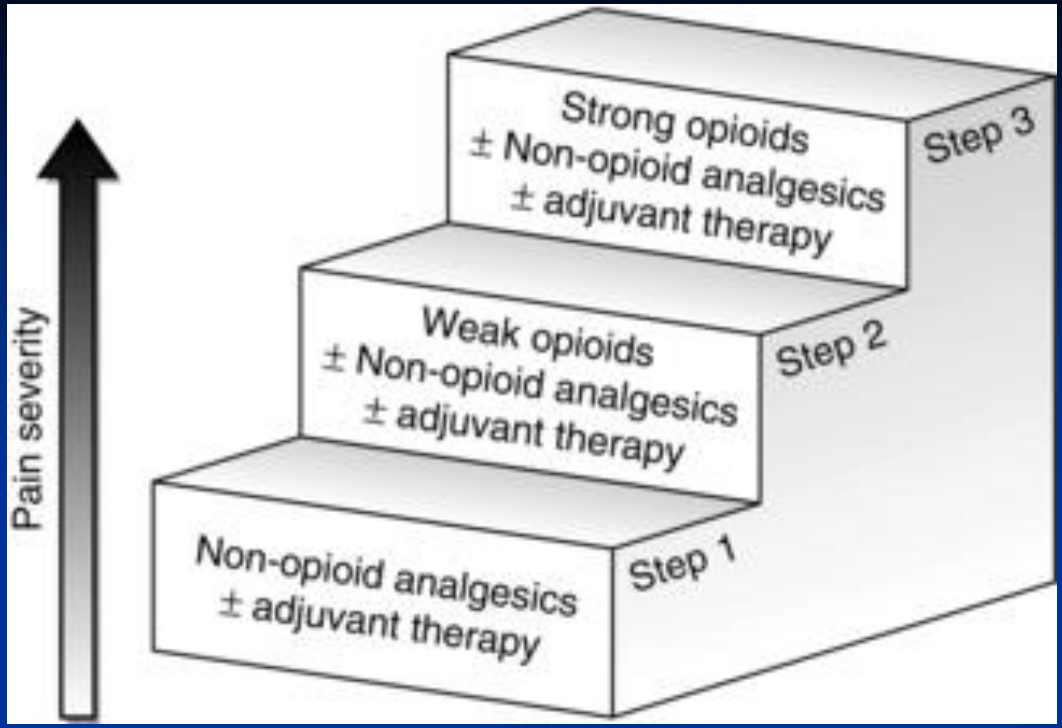
The Future

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



JAMA. 2018;320(23):2448-2460.

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

JAMA. May 15, 2018;319(19):2036-2037.

Next generation

- ERAS /pre-operative Rx
- IV acetaminophen
- Slow-release bupivacaine
- Different targets than opioid receptors
- Longer acting agents
- Nerve fiber inactivation
- Novel combinations
- Generic naloxone
- OTC naloxone

- Nonpharmacological
  - Heat/cold
  - Osteopathic manipulation
  - Physical therapy
  - Chiropractic
  - Acupuncture
  - TENS?
  - Biofeedback
  - Cognitive behavioral therapy
  - Exercise

Timing is everything

- Low back pain
  - 40%-60% less likely to use opioids over 2 years if PT seen within 2 weeks of onset
    - Childs et al 2015; Fritz et al 2013
- Neck pain
  - 41% less likely to receive opioid therapy for neck pain in the next 12 months
    - Horn et al, 2018
- Knee pain
  - 33% less likely over 12 months
    - Stevans et al 2017

- Prescribing emergency opioid antagonists
- Alternatives to controlled substance prescribing
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- Minimum penalty for 1st violation
  - 6mo license suspension, probation + $10,000 fine
- Minimum penalty for 2nd violation
  - 1yr license suspension, probation + $10,000 fine
- Maximum penalty for either offense
  - License revocation + $10,000 fine

- Failure to check the PDMP
  - 1st offense
    - Non-disciplinary citation from DOH
  - 2nd + offense
    - Subject to discipline from respective Board

- Prescribing emergency opioid antagonists
- Alternatives to controlled substance prescribing
  - Nonpharmacological therapies
- Physician liability for overprescribing controlled substances
- Controlled substance disposal

Controlled substance disposal

- Small amounts
- Secure safely
- Safe disposal options
  - Veterans Health Administration
  - Return to pharmacist or prescriber?

Medication disposal

- Take-back programs
  - April and October annually
  - https://www.deadiversion.usdoj.gov/drug_disposal/takeback/
- DEA-authorized collectors
  - https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1
  - DEA Office of Diversion Control's Registration Call Center: 1-800-882-9539
- Household trash (***not for controlled substances***)
- 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

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Additional references

- American Society of Addiction Medicine Opioid Addiction 2016 Facts & Figures http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf
- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1
- Medication Assisted Treatment http://www.samhsa.gov/medication-assisted-treatment, http://pcssmat.org/
- National Institute on Drug Abuse (NIDA) https://www.drugabuse.gov/
- Schuckit MA. Treatment of Opioid Use Disorders. *NEJM* (07/28/16) Vol. 375, No. 4, P. 357 http://www.nejm.org/doi/full/10.1056/NEJMra1604339#t=article
- Substance Abuse and Mental Health Services Administration. *Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders.* Treatment Improvement Protocol (TIP) Series 54. HHS Publication No. (SMA) 12-4671. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2011
- Drug disposal: https://www.deadiversion.usdoj.gov/drug_disposal/index.html
- National Academy of Medicine: https://nam.edu/wp-content/uploads/2017/09/First-Do-No-Harm-Marshaling-Clinician-Leadership-to-Counter-the-Opioid-Epidemic.pdf

Table 1. Recommendations for physical, psychosocial, and mind-body approaches for the management of osteoarthritis of the hand, knee, and hip

Intervention	Joint		
	Hand	Knee	Hip
Exercise			
Balance training			
Weight loss			
Self-efficacy and self-management programs			
Tai chi			
Yoga			
Cognitive behavioral therapy			
Cane			
Tibiofemoral knee braces		(Tibiofemoral)	
Patellofemoral braces		(Patellofemoral)	
Kinesiotaping	(First carpometacarpal)		
Hand orthosis	(First carpometacarpal)		
Hand orthosis	(Other joints)		
Modified shoes			
Lateral and medial wedged insoles			
Acupuncture			
Thermal interventions			
Paraffin			
Radiofrequency ablation			
Massage therapy			
Manual therapy with/without exercise			
Iontophoresis	(First carpometacarpal)		
Pulsed vibration therapy			
Transcutaneous electrical nerve stimulation			

Strongly recommended
Conditionally recommended
Strongly recommended against
Conditionally recommended against
No recommendation

https://www.rheumatology.org/Portals/0/Files/Osteoarthritis-Guideline-Early-View-2019.pdf

Table 2. Recommendations for the pharmacologic management of osteoarthritis of the hand, knee, and hip

Intervention	Joint		
	Hand	Knee	Hip
Topical nonsteroidal antiinflammatory drugs			
Topical capsaicin			
Oral nonsteroidal antiinflammatory drugs			
Intraarticular glucocorticoid injection			
Ultrasound-guided intraarticular glucocorticoid injection			
Intraarticular glucocorticoid injection compared to other injections			
Acetaminophen			
Duloxetine			
Tramadol			
Non-tramadol opioids			
Colchicine			
Fish oil			
Vitamin D			
Bisphosphonates			
Glucosamine			
Chondroitin sulfate			
Hydroxychloroquine			
Methotrexate			
Intraarticular hyaluronic acid injection	(First carpometacarpal)		
Intraarticular botulinum toxin			
Prolotherapy			
Platelet-rich plasma			
Stem cell injection			
Biologics (tumor necrosis factor inhibitors, interleukin-1 receptor antagonists)			

Strongly recommended
Conditionally recommended
Strongly recommended against
Conditionally recommended against
No recommendation

https://www.rheumatology.org/Portals/0/Files/Osteoarthritis-Guideline-Early-View-2019.pdf