Opioids and controlled substances

Joshua D. Lenchus, DO, RPh, FACP, SFHM
President, Florida Osteopathic Medical Association
Speaker of the House, Florida Medical Association

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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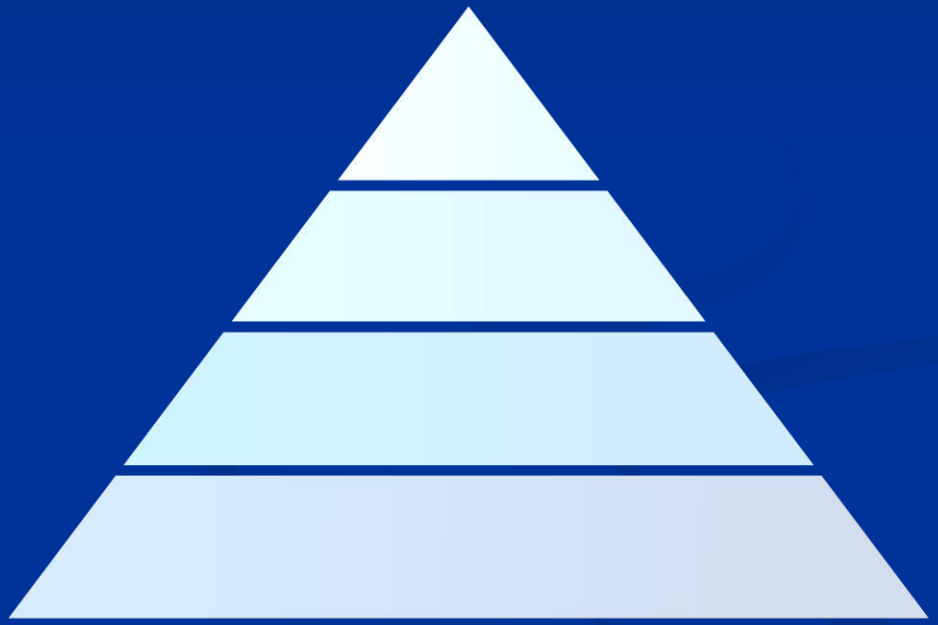
Definitions

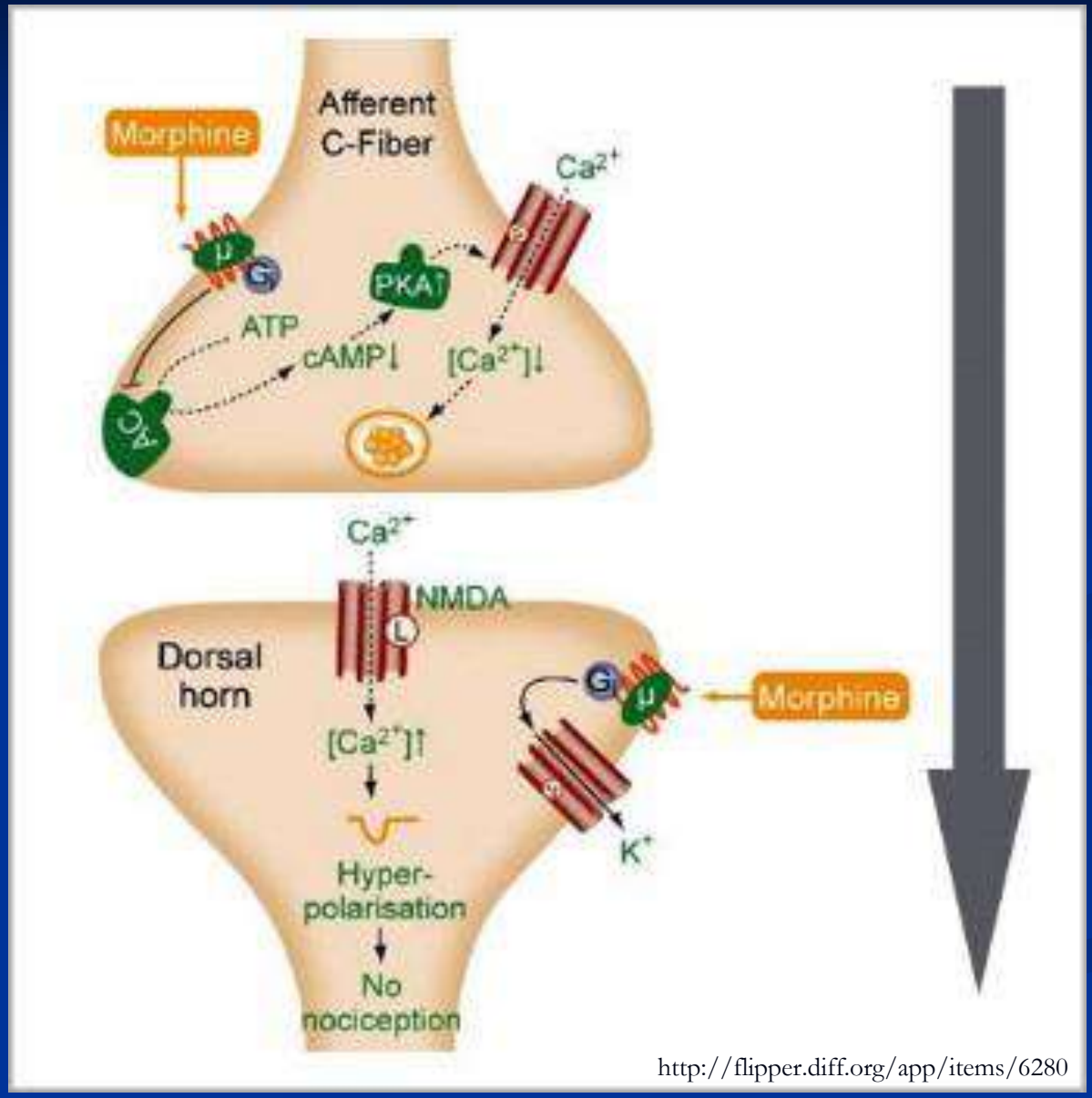
- Opiate
- Opioid
- Narcotic
- Controlled substance



Morpheus: God of Dreams

- Winged creature
- Many siblings
- Communicator
- Dream: human form
- Hypnos
- “In the arms of Morpheus”

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	Duration	Equianalgesic dose
Fentanyl patch	12-24 hrs	72 hrs/patch	
Hydromorphone	15-30 mins	4-6 hrs	7.5mg po
Methadone	30-60 mins	> 8 hrs	
Morphine IR	30-60 mins	3-6 hrs	30mg po
MS Contin®	30-90 mins	8-12 hrs	30mg po
Kadian®	30-90 mins	12-24 hrs	30mg po
Oxycodone IR	10-15 mins	4-6 hrs	20mg po
Oxycodone CR	1 hr	12 hrs	20mg po
Hydrocodone	30-60 mins	4-6 hrs	30mg po
Codeine	30-60 mins	4-6 hrs	200mg po
Meperidine	10-15 mins	2-4 hrs	300mg po

Opioid allergy

Phenanthrenes	Piperidine/ phenylpiperadine	Deiphenylheptanes
Morphine	Fentanyl*	Methadone*
Hydromorphone*	Meperidine	Propoxyphene
Oxymorphone*		
Codeine		
Hydrocodone		
Oxycodone*		

Controlled substance examples

C-II	C-III	C-IV	C-V
Codeine	Lower dose of codeine	Tramadol	Lowest dose of codeine
Fentanyl	Anabolic steroids	Chloral hydrate	Robitussin-AC®
Hydrocodone	~~Lower dose of hydrocodone~~	Chlordiazepoxide	Lomotil®
Morphine	Ketamine	Clorazepate	Phenergan with codeine®
Oxycodone	Dronabinol	Carisoprodol	
Methadone	GHB	Meprobamate	
Amphetamine		Phentermine	
Pentobarbital		Phenobarbital	

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Why are we talking about this?

- Statistics
- Leading cause of injury death
- Headlines
- Legislation

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.

Source: Centers for Disease Control and Prevention

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.

JANE PORTER
HERSHEL JICK, M.D.
Boston Collaborative Drug
Surveillance Program
Waltham, MA 02154 Boston University Medical Center

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

Russell K. Portenoy and Kathleen M. Foley

Pain Service, Department of Neurology, Memorial Sloan-Kettering Cancer Center, and Department of Neurology, Cornell University Medical College, New York, NY 10021 (U.S.A.)

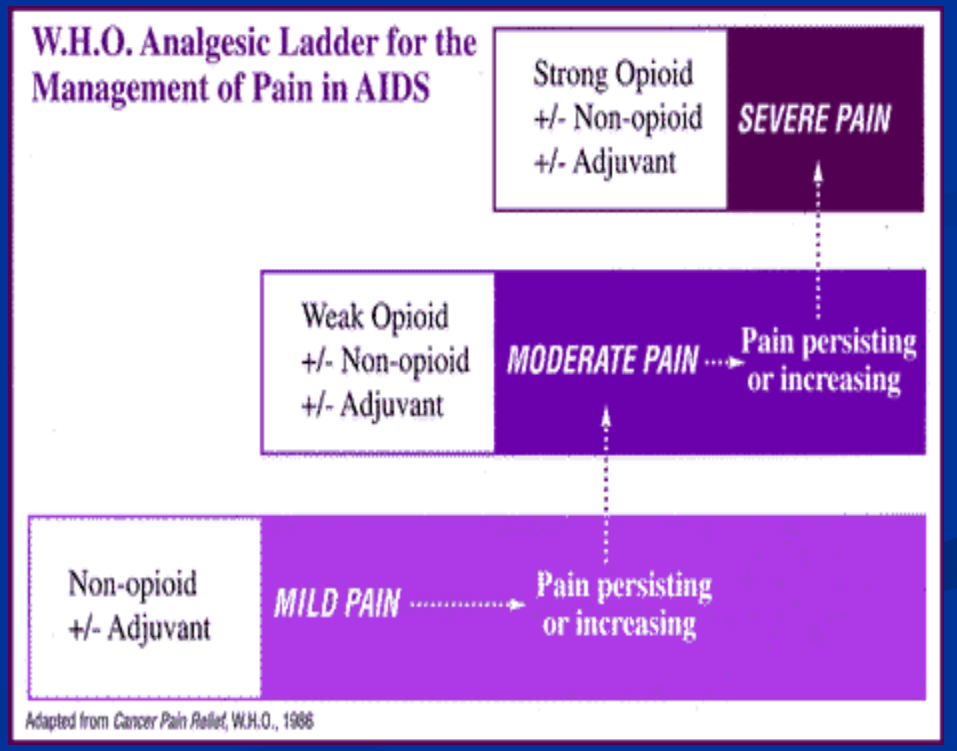
(Received 10 June 1985, accepted 28 October 1985)

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
- 1998: FSMB protection
- 2001: TJC weighs in
- 2004: failure to treat is punishable
- 2007: Purdue is guilty of misbranding



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

Multiple Contributing Elements

- Annual volume of opioid prescriptions steadily on the rise throughout the 1990's
- Aggressive marketing by opioid manufacturers
- Rise of internet sales
- Birth of pill mills
- Low prescriber awareness / low public awareness
- Initially weak regulatory environment
- Pain as a vital sign
- HCAHPS pain question

Source of pain relievers for non-medical use, users aged 12 or older: 2012-2013

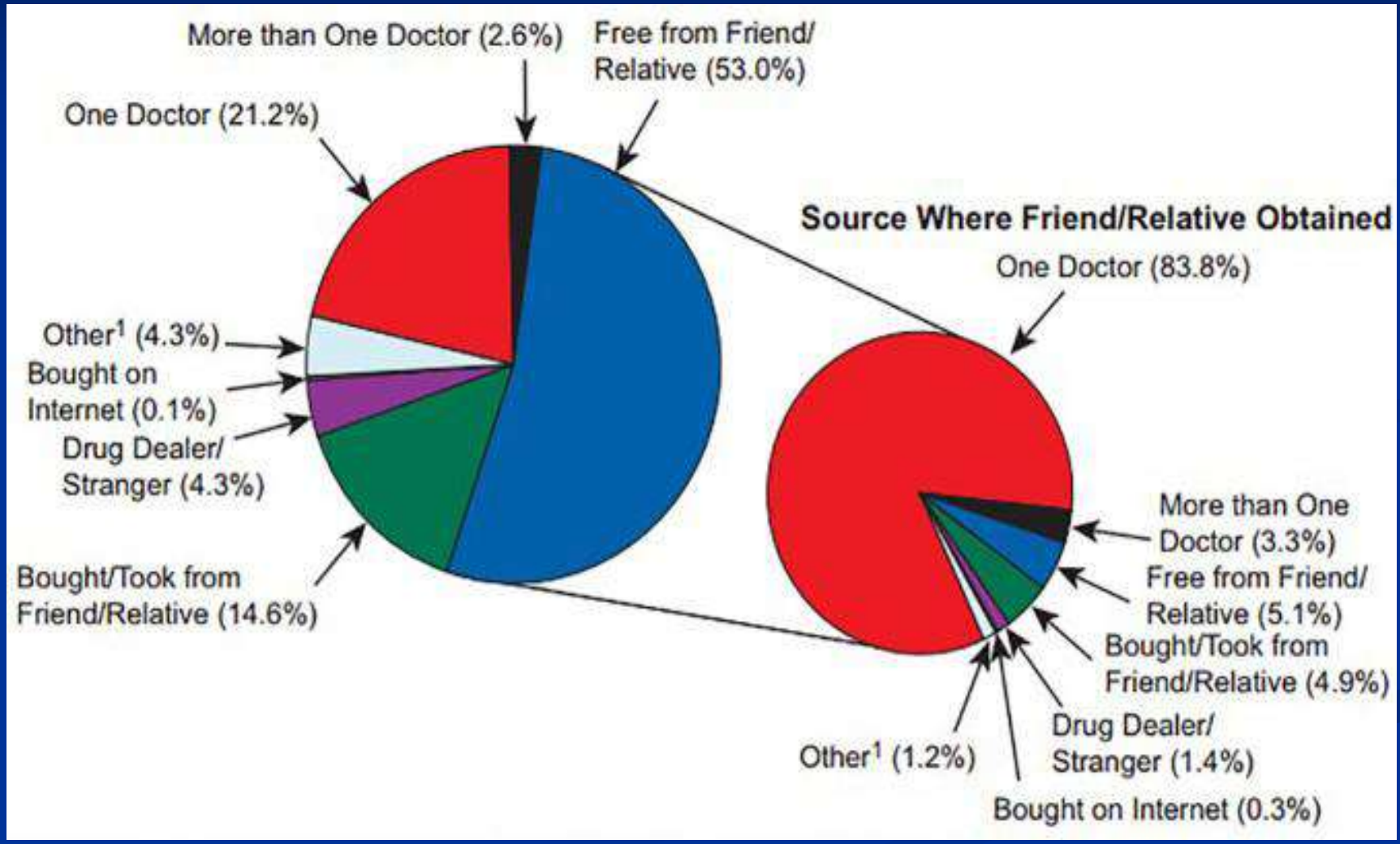
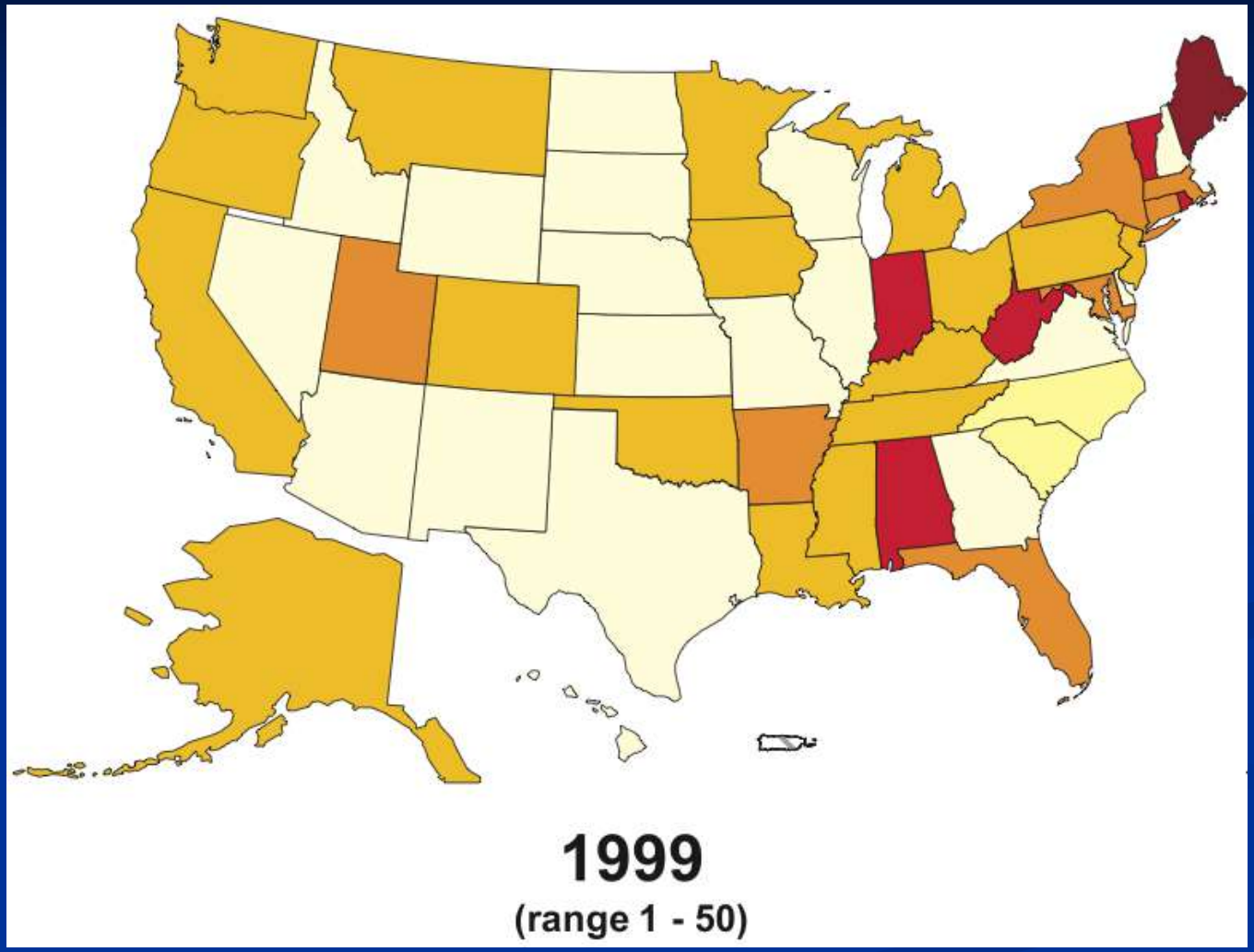
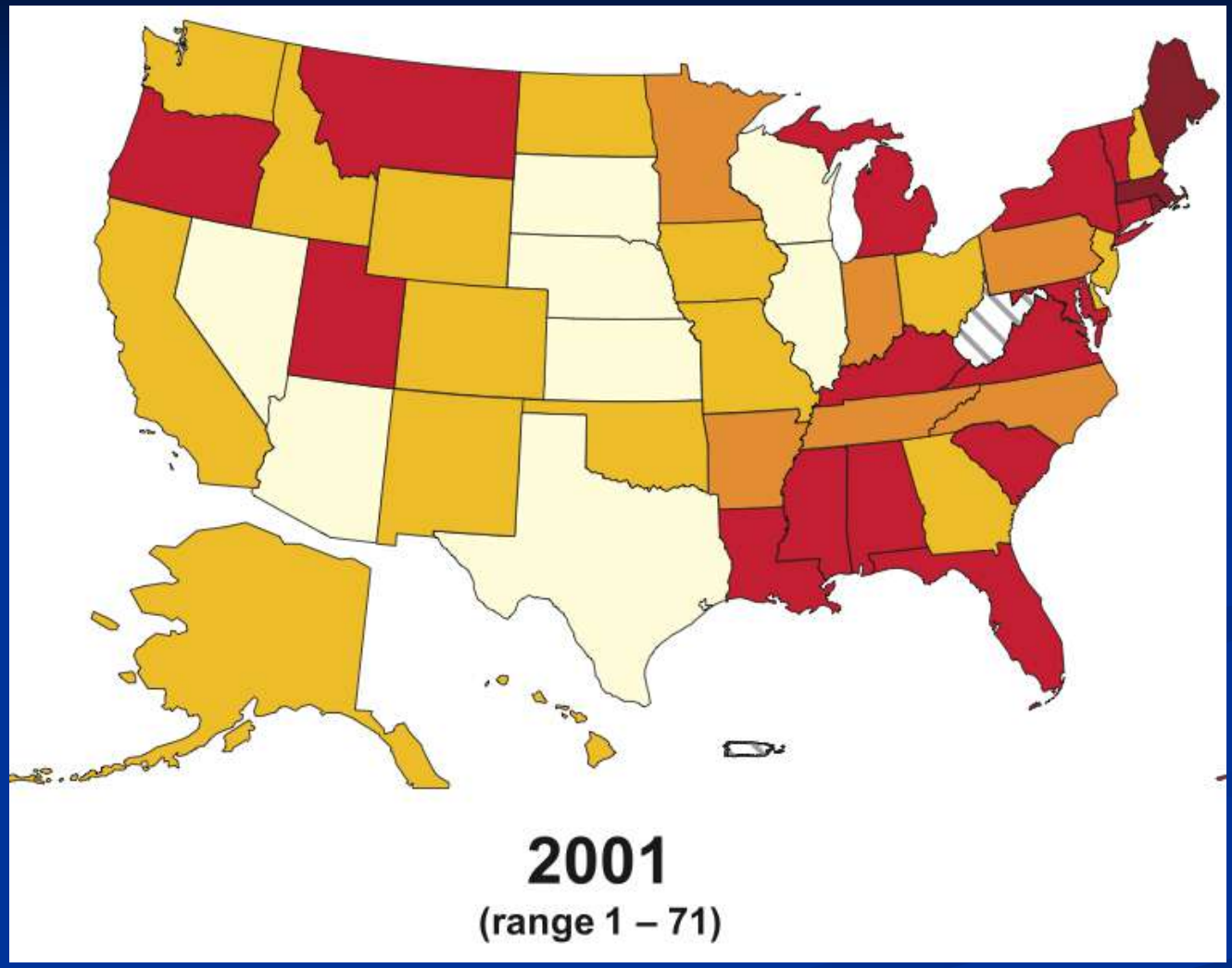


Image from SAMHSA, as cited in Tetrault and Butner, 2015.

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

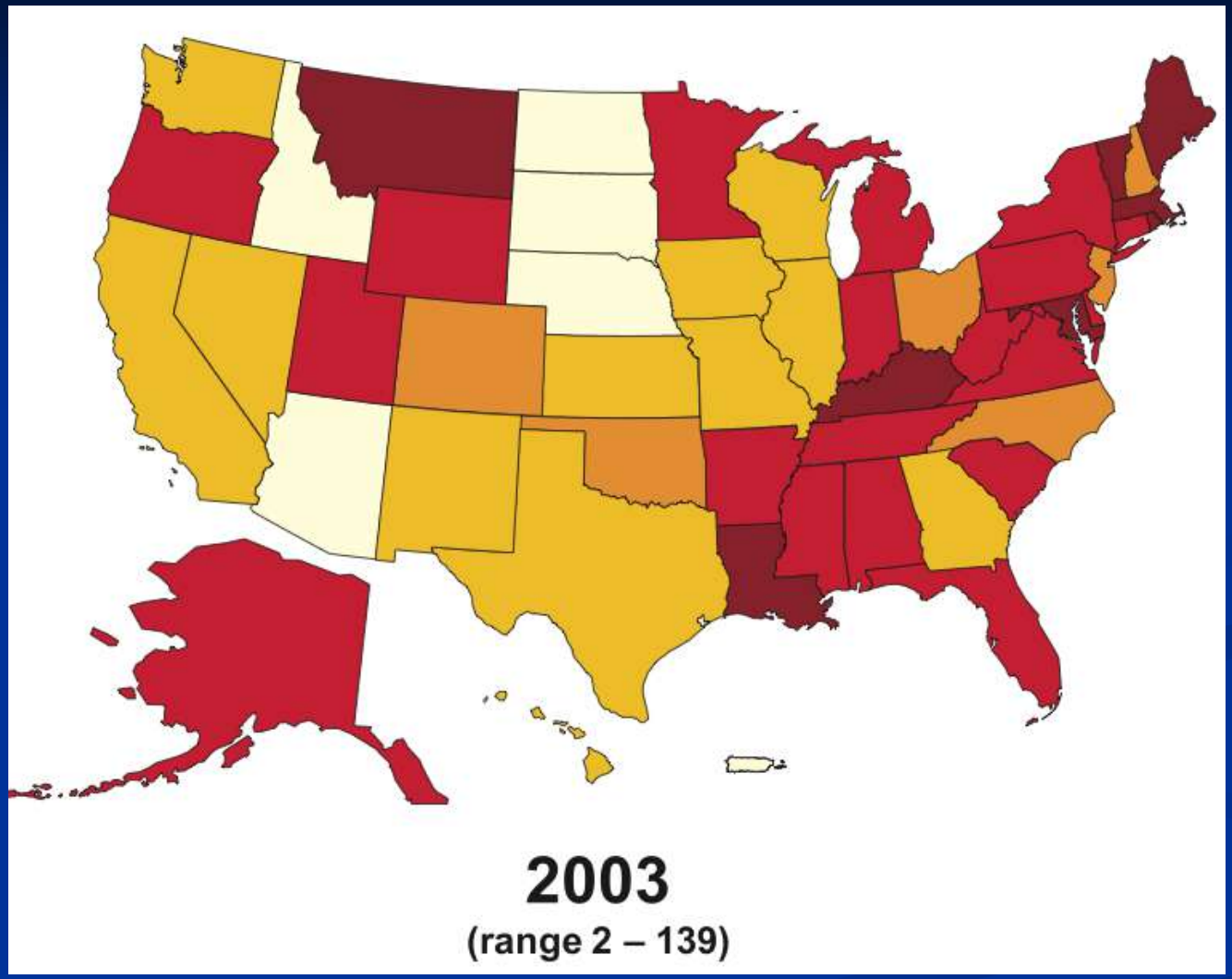


SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.



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

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



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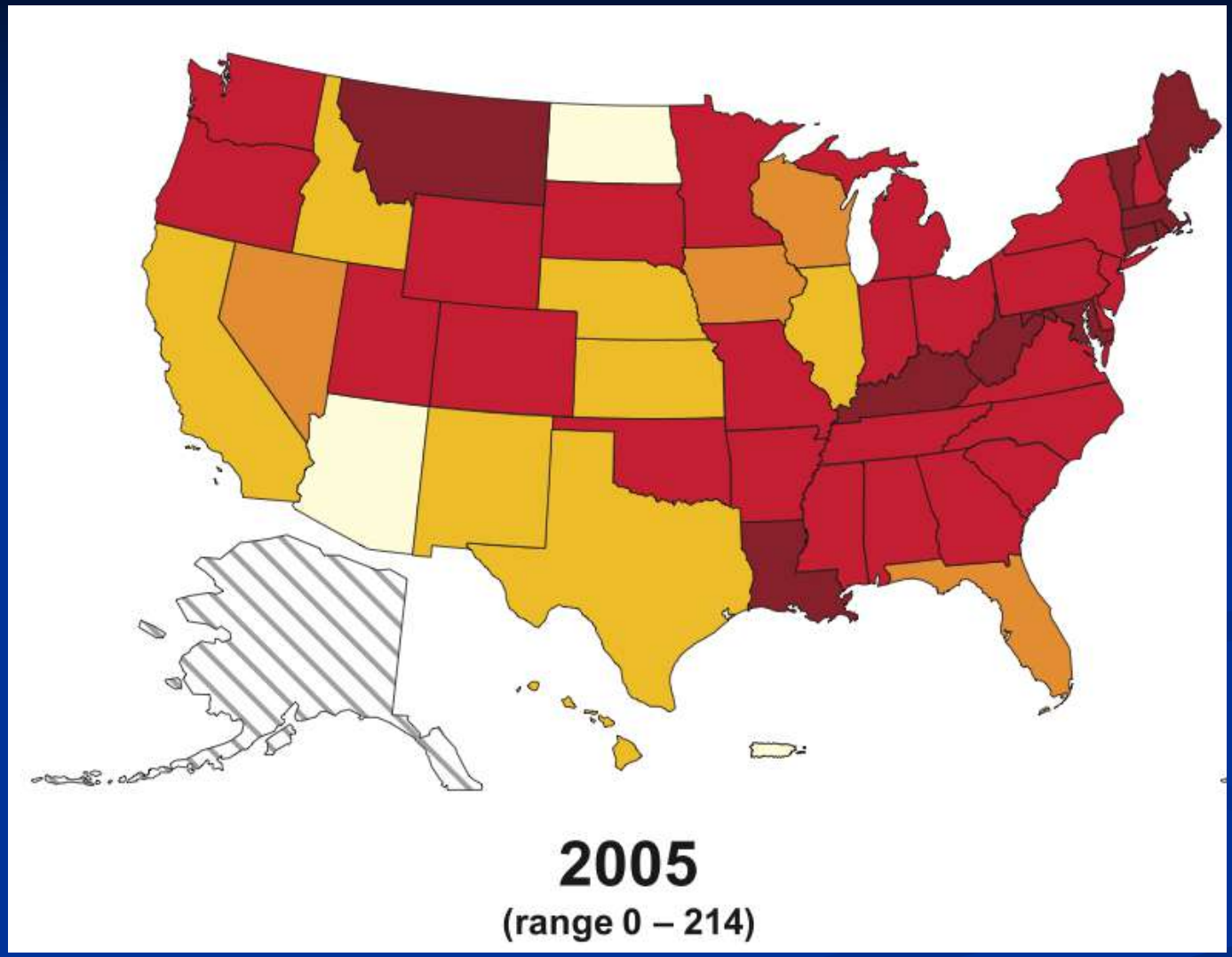
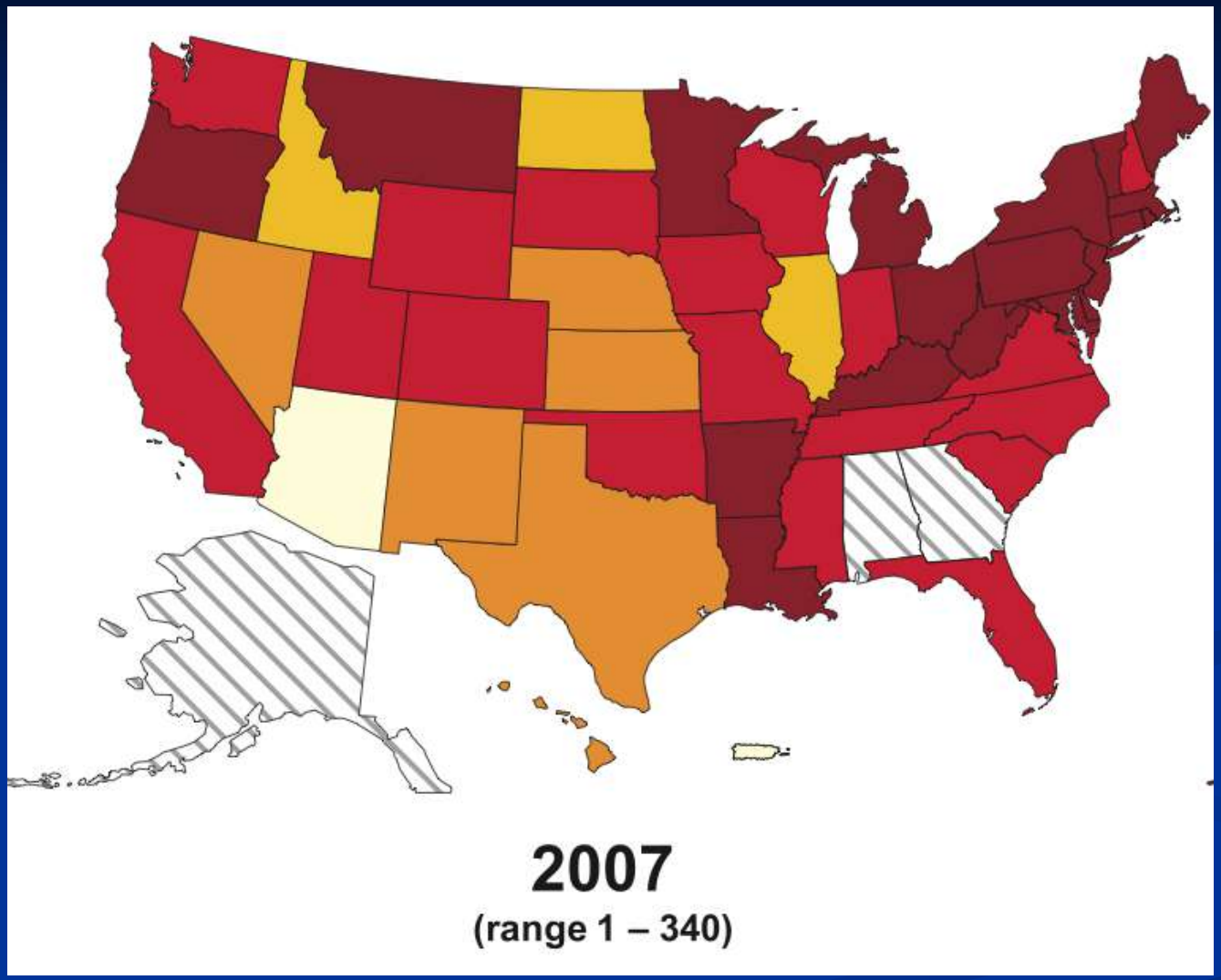


2005

(range 0 – 214)

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

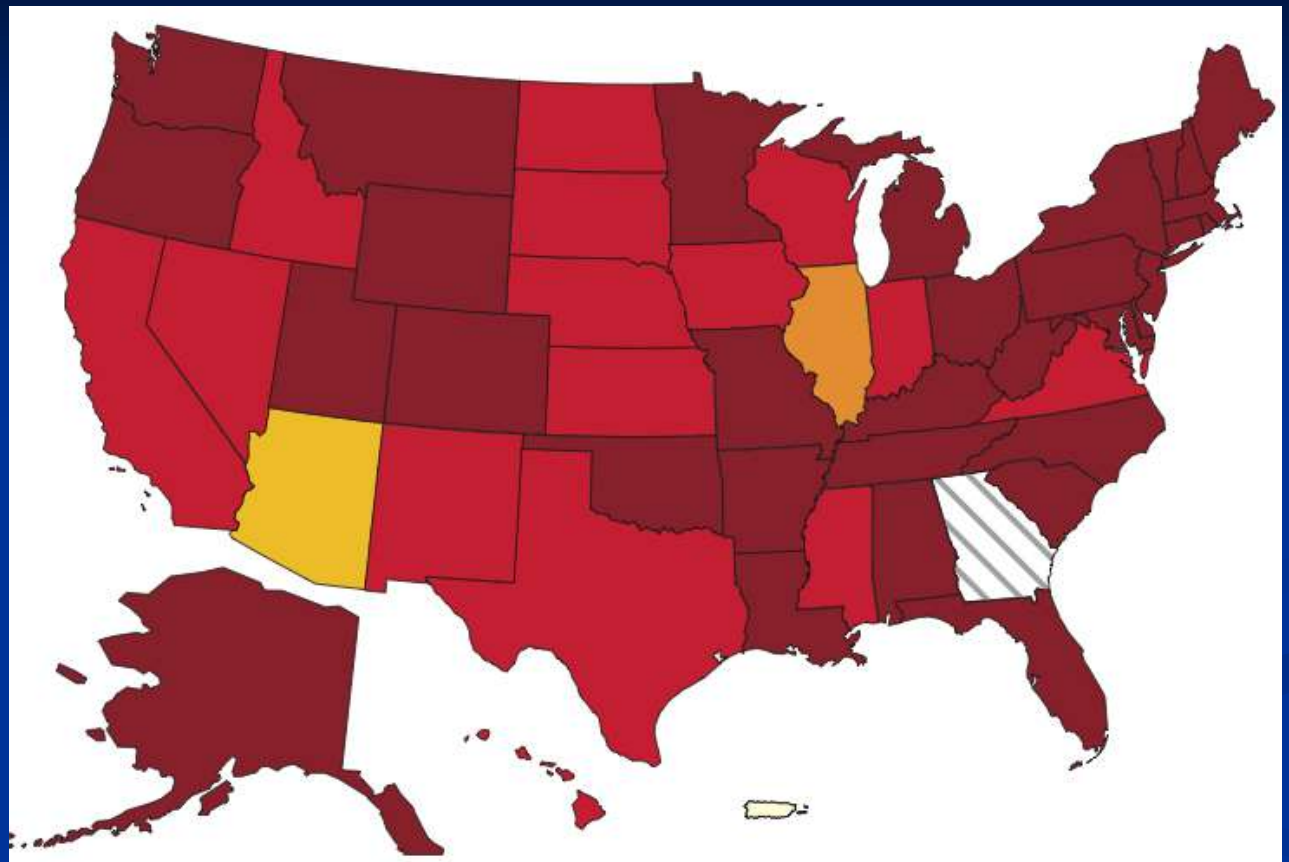
SOURCE: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS). Data received through 11.03.10.



2007
(range 1 – 340)

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

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



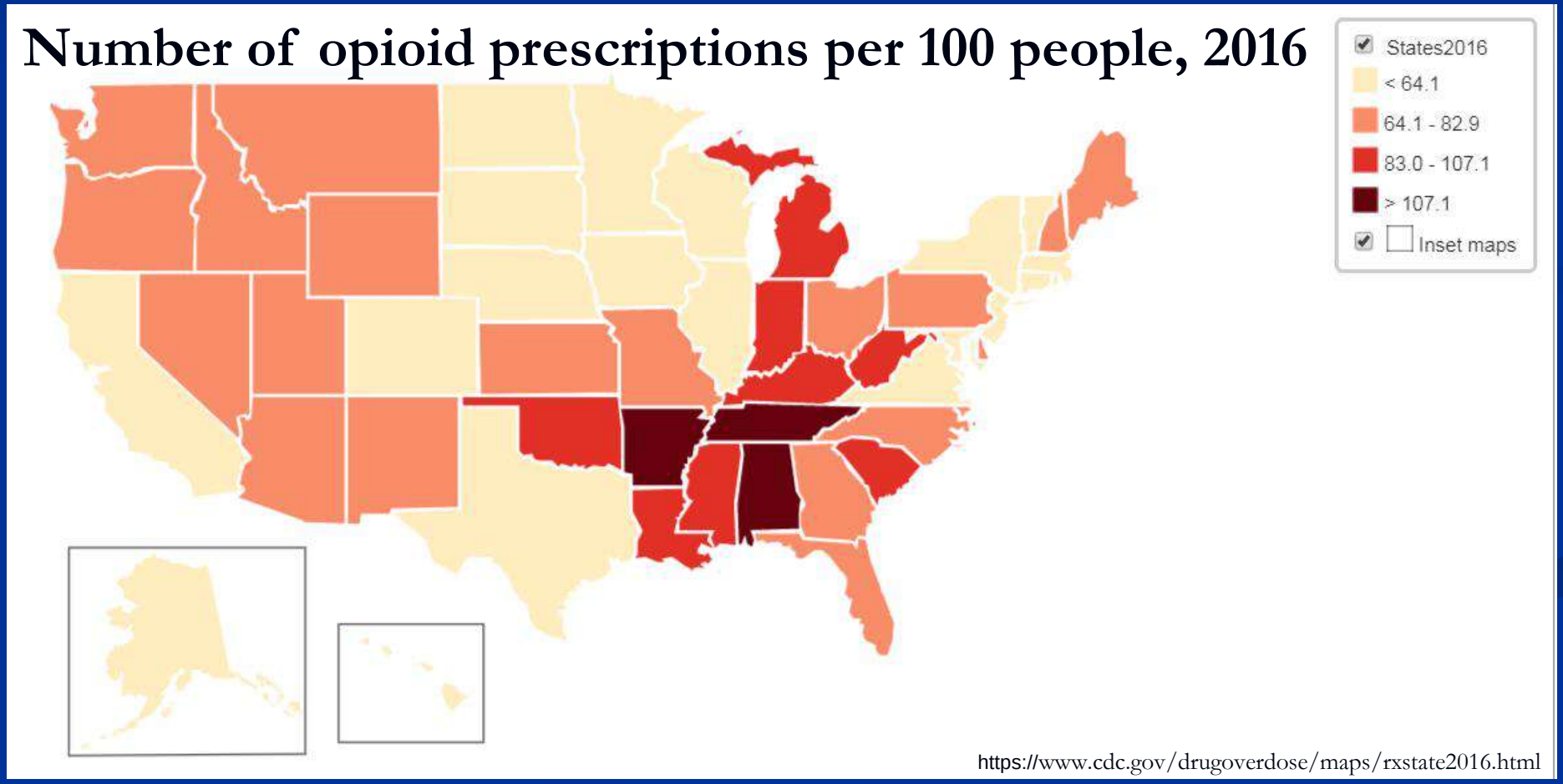
2009

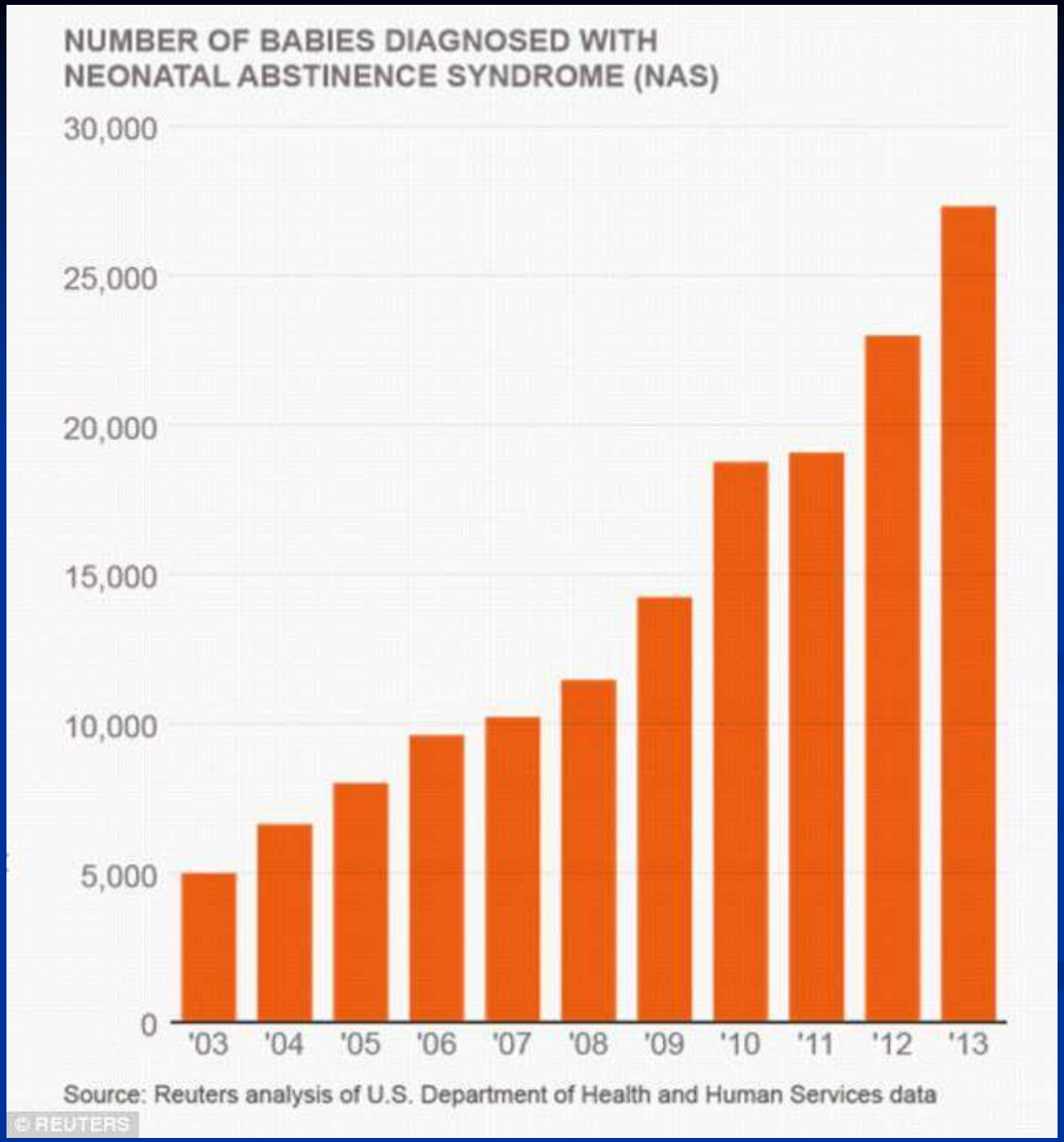
(range 1 – 379)

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

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

Some states have more opioid prescriptions per person than others




NUMBER OF BABIES DIAGNOSED WITH NEONATAL ABSTINENCE SYNDROME (NAS)
30,000
25,000
20,000
15,000
10,000
5,000
0
'03
'04
'05
'06
'07
'08
'09
'10
'11
'12
'13
Source: Reuters analysis of U.S. Department of Health and Human Services data
© REUTERS

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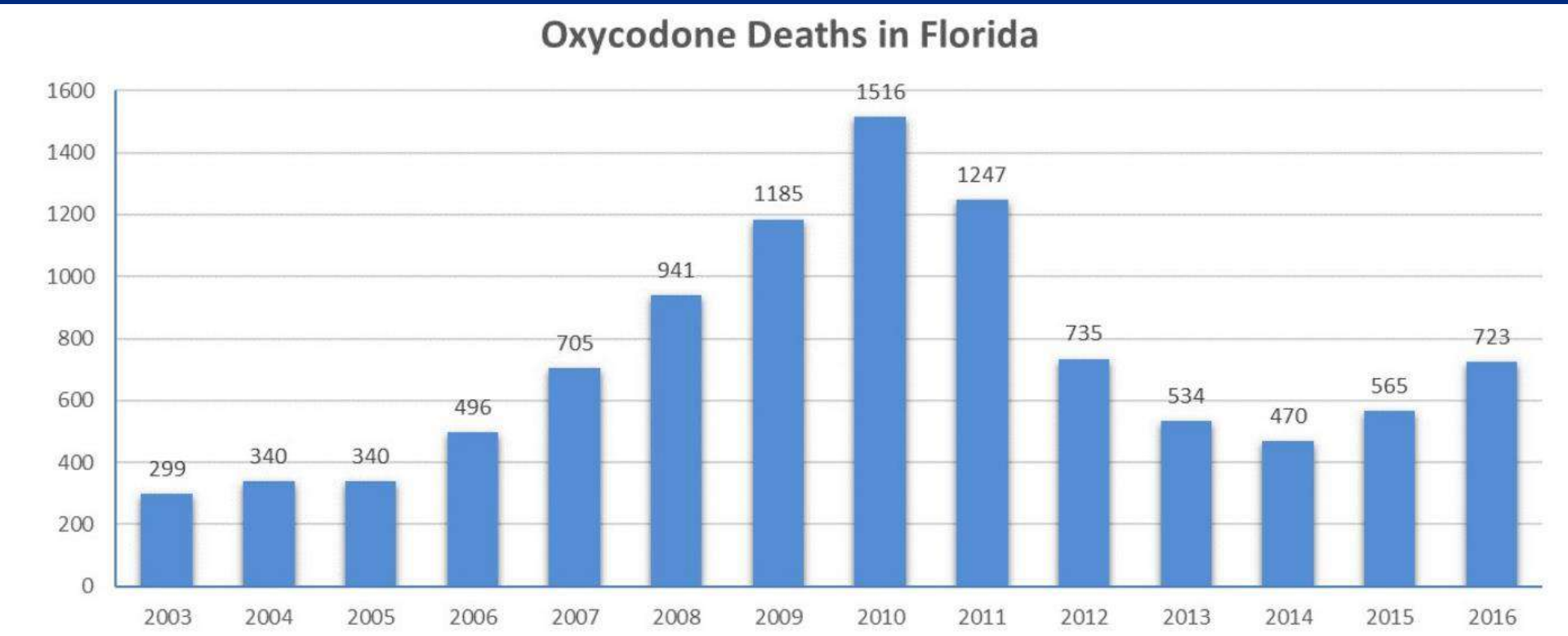


Source: Drugs Identified in Deceased Persons by Florida Medical Examiners 2016 Annual

Drug overdose deaths

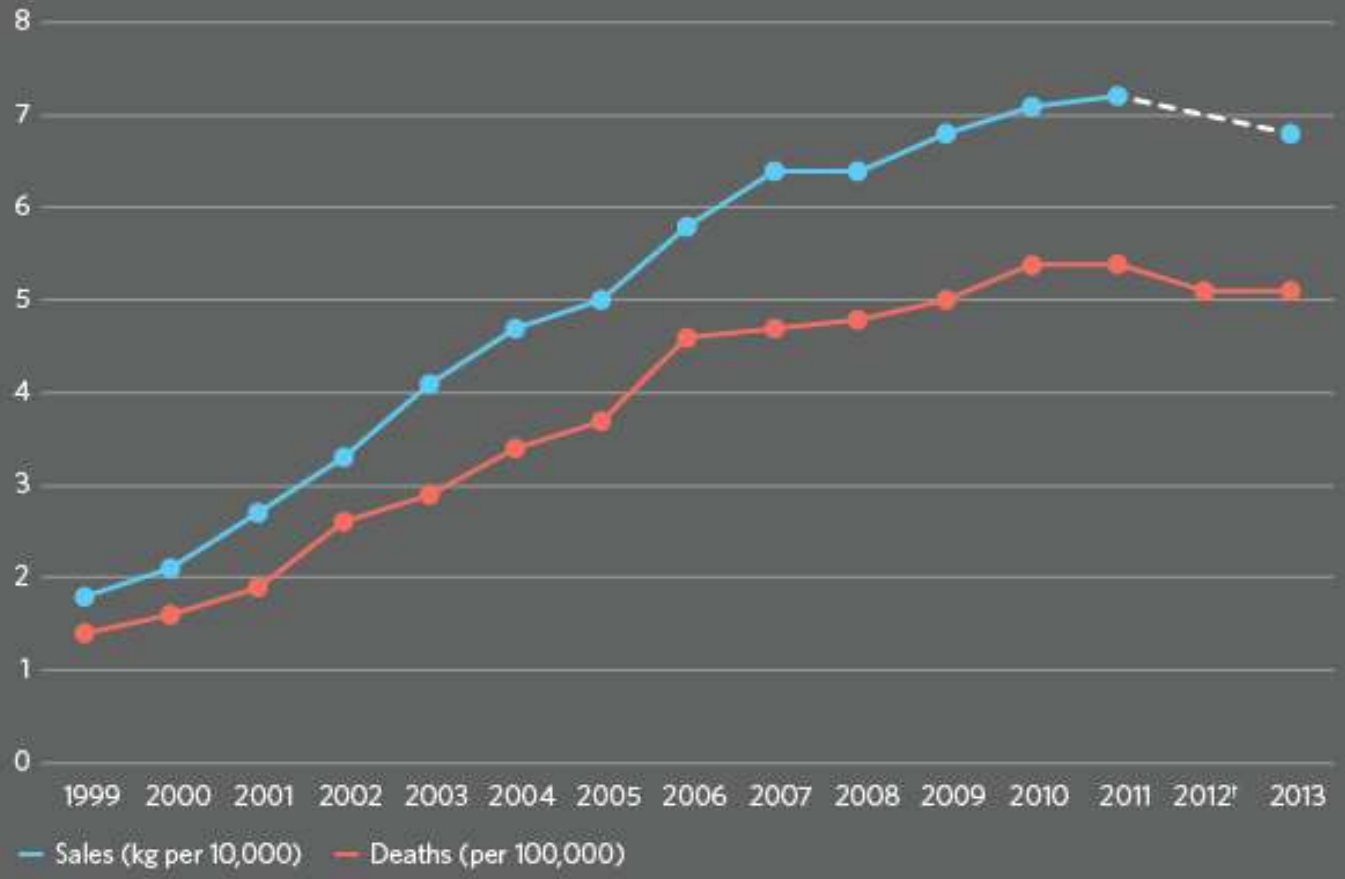
	2016	2017	% change
US	696,602	825,016	18
Florida	48,380	65,428	35

USA	2016	2017	% change
Cocaine	101,860	152,650	50
Heroin	173,183	191,315	10
Semi-synthetic opioids	163,138	177,901	9
Opioids	452,369	554,974	23
Psychostimulants	80,589	109,652	36
Synthetic opioids	170,776	302,130	77

CDC, National Center for Health Statistics, National Vital Statistics System,

Painkiller Sales and Overdose Deaths

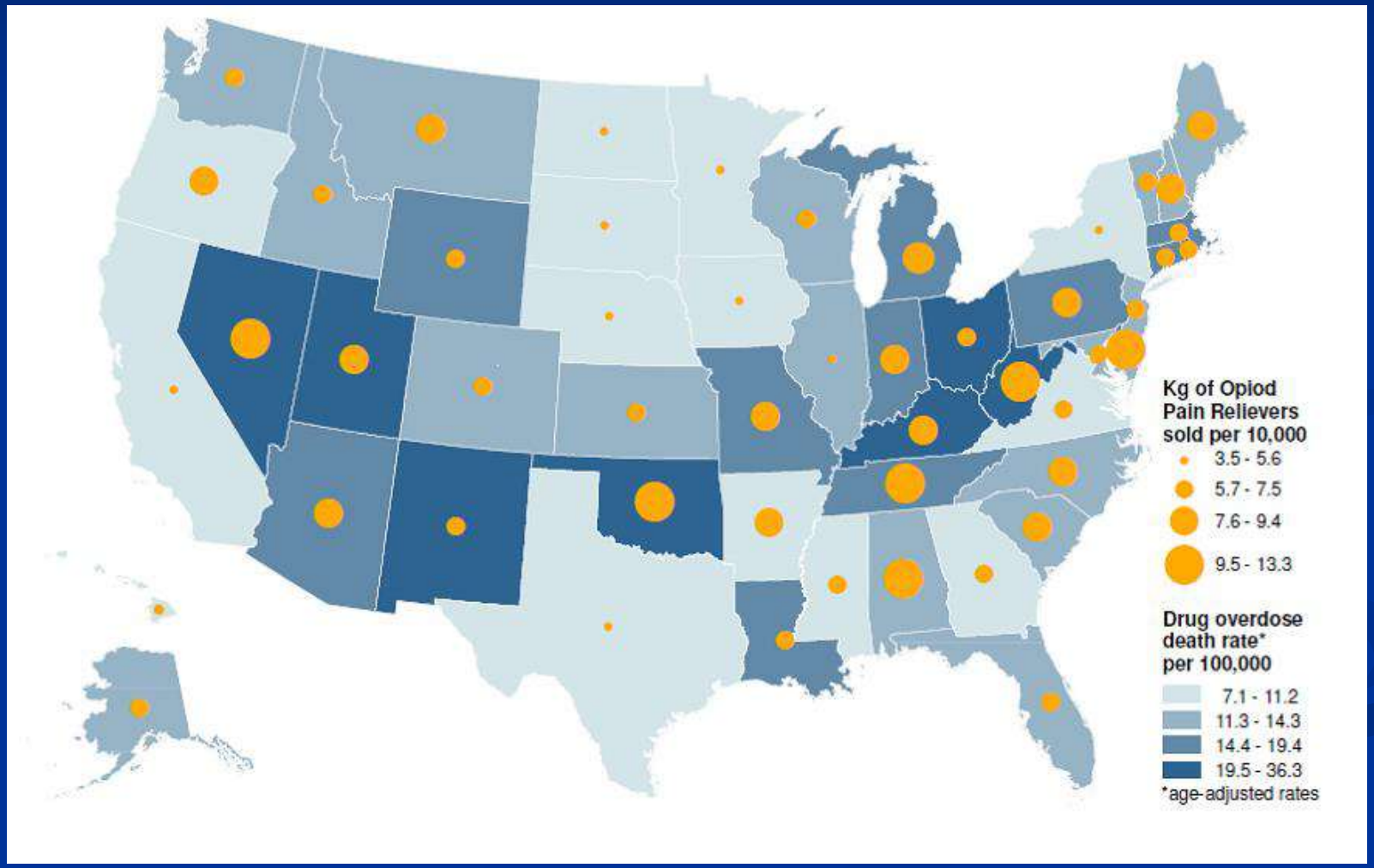
The nation's rising overdose death rate from painkillers such as Vicodin, Percocet and OxyContin closely parallels an increase in opioid prescription sales over the past 15 years.



† Sales data is unavailable for 2012.

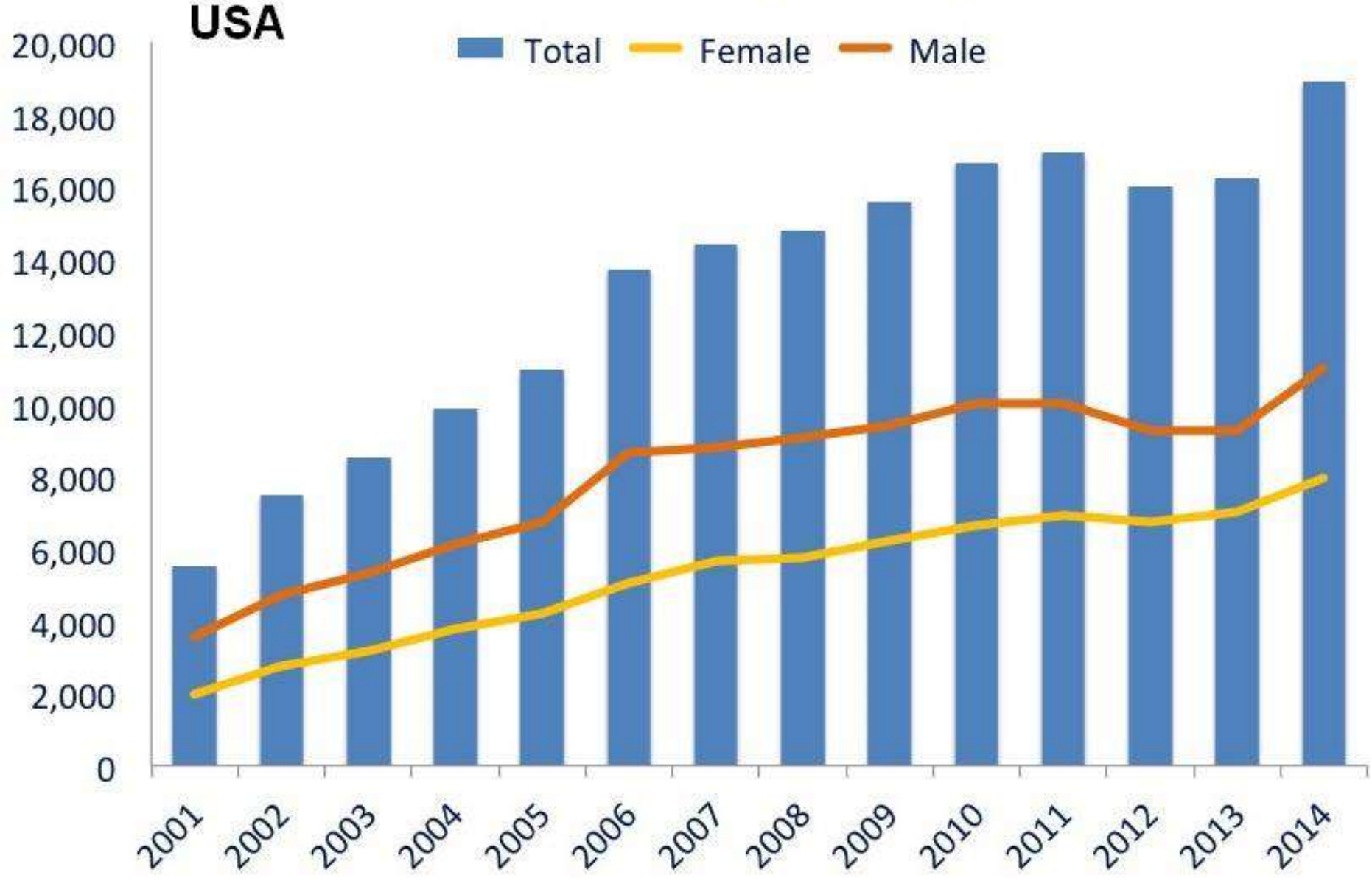
Source: U.S. Drug Enforcement Administration and Centers for Disease Control and Prevention

Relationship Between Opioid Prescribing and Drug Overdose Death Rates



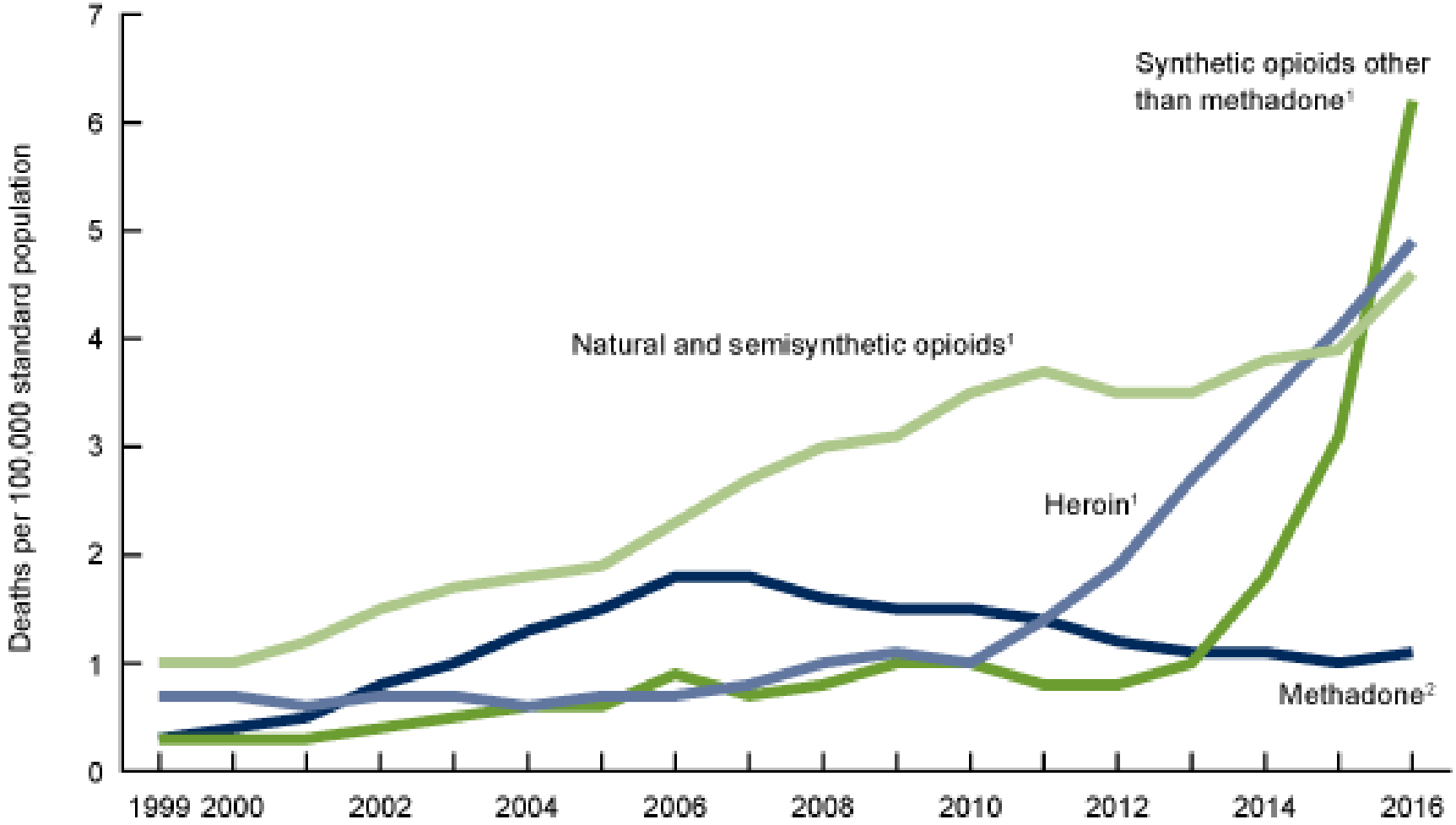
Source: Death rate, 2008, CDC/NVSS. Opioid pain reliever sales rate, 2010, DEA's ARCOS

Number of Deaths from Prescription Opioid Pain Relievers



Source: National Center for Health Statistics, CDC Wonder

Age-adjusted drug overdose death rates, by opioid category: US, 1999–2016



https://www.cdc.gov/nchs/products/databriefs/db294.htm

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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

“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

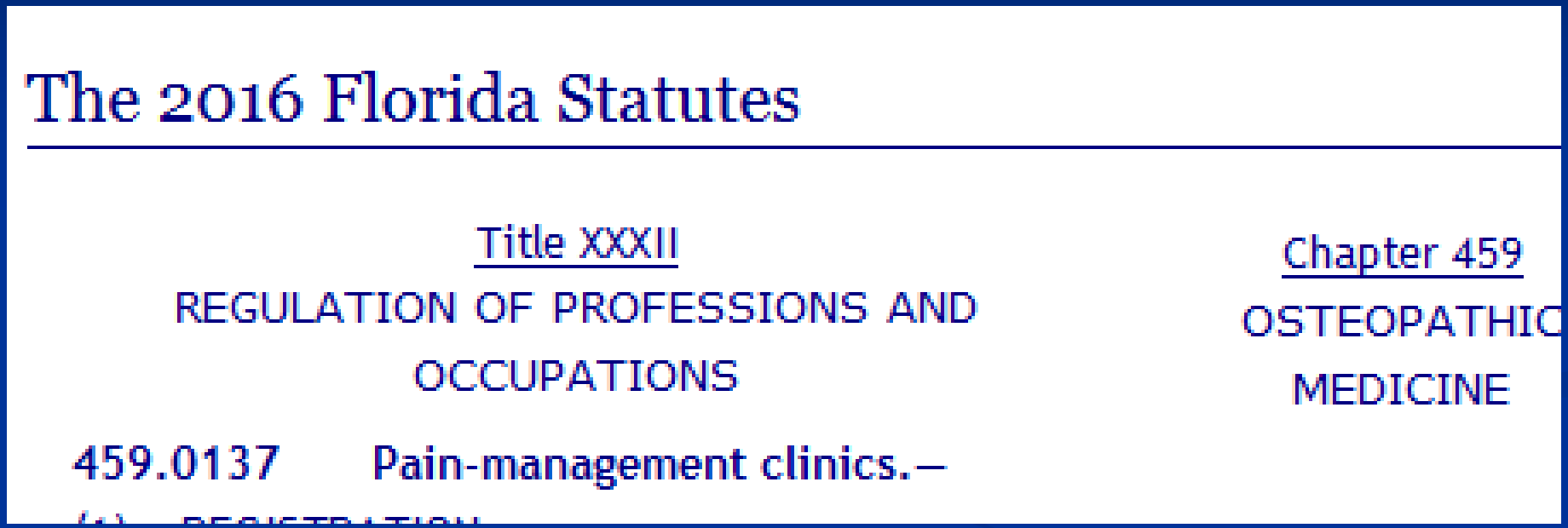
456.44 Controlled substance prescribing.—

(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.

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

Pain Management Clinics



The 2016 Florida Statutes

Title XXXII
REGULATION OF PROFESSIONS AND OCCUPATIONS

Chapter 459
OSTEOPATHIC MEDICINE

459.0137 Pain-management clinics.—

http://www.leg.state.fl.us/statutes/index.cfm?mode=View%20Statutes&SubMenu=1&App_mode=Display_Statute&Search_String=459.0137&URL=0400-0499/0459/Sections/0459.0137.html

Training requirements

64B15-14.0051 Training Requirements for Physicians Practicing in Pain Management Clinics.

Effective July 1, 2012, physicians who have not met the qualifications set forth in subsections (1) through (6), below, shall have successfully completed a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or a pain medicine residency that is accredited by ACGME or the AOA. Prior to July 1, 2012, physicians prescribing or dispensing controlled substance medications in pain management clinics registered pursuant to Section 459.0137(1), F.S., must meet one of the following qualifications:

(1) Board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) and holds a sub-specialty certification in pain medicine; or a Certificate of Added Qualification in Pain Management by the American Osteopathic Association;

(2) Board certification in pain medicine by the American Board of Pain Medicine (ABPM);

(3) Successful completion of a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or a pain medicine residency that is accredited by the ACGME or the AOA;

(4)(a) Successful completion of a residency program in physical medicine and rehabilitation, anesthesiology, neurology, neurosurgery, or psychiatry approved by the ACGME or the AOA;

(b) Successful completion of a residency program in family practice, internal medicine, or orthopedics approved by the AOA; or

(c) Current Certificate of Added Qualification approved by the AOA in hospice, palliative medicine or geriatric medicine.

(5) Current staff privileges at a Florida-licensed hospital to practice pain medicine or perform pain medicine procedures;

(6) Three (3) years of documented full-time practice, which is defined as an average of 20 hours per week each year, in pain-management and attendance and successful completion of 40 hours of in-person, live-participatory AMA Category I or AOA Category IA CME courses in pain management that address all the following subject areas:

(7) Upon completion of the 40 hours of CME set forth above, physicians qualifying under subsection (6) above, must also document the completion of 15 hours of in-person, live participatory AMA Category I or AOA Category IA CME in pain management for every year the physician is practicing pain management.

Rulemaking Authority 459.0137(4) FS. Law Implemented 459.0137 FS. History–New 11-8-10, Amended 3-16-11, 3-26-12, 7-3-12.

Regulatory/Agency Actions

- 2014-17: Approval of a new formulations of naloxone for community use, including autoinjector and intranasal products
- Development of abuse deterrent (AD) opioid formulations
- Much more…

http://www.fda.gov

- Jun 10, 2015 – FL HB751, Emergency Treatment and Recovery Act
- Jan 1, 2016 – CDC Morbidity & Mortality Weekly Report (MMWR): Increases in Drug and Opioid Overdose Deaths -- United States 2000-2014
- Mar 16, 2016 – CDC Guideline for Prescribing Opioids for Chronic Pain
- Jul 7, 2016 – National Governors Association: Finding Solutions to the Prescription Opioid and Heroin Crisis: A Roadmap for States
- Jul 22, 2016 – US S.524, Comprehensive Addiction and Recovery Act

https://www.whitehouse.senate.gov/imo/media/doc/CARA%20Conference%20Report%20Summary.pdf

http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/_documents/MMWR-Jan-2016.pdf

https://www.nga.org/cms/finding-solutions-to-the-prescription-opioid-and-heroin-crisis-a-road-map-for-states

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm

http://www.cdc.gov/drugoverdose/prescribing/guideline.html

May 3, 2017

FLORIDA | Board of Pharmacy

Home | Licensing | Renewals | Resources | Meetings

State of Emergency Issued

Posted in Latest News on *May 3, 2017*.

Original Post: May 3rd @ 3:20pm

Dear Florida Pharmacists and Pharmacies:

Today following Governor Scott's Executive Order declaring the opioid epidemic a state of emergency in Florida, Dr. Philip, State Surgeon General, declared a public health emergency and issued a naloxone standing order for emergency responders.
http://ww10.doh.state.fl.us/pub/bop/2.%20Executive%20Order%20-%205.19.17.pdf

http://floridaspharmacy.gov/latest-news/state-of-emergency-issued/

Florida HB 21

- Signed by Gov. Scott on March 19, 2018
- Mostly effective 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

As of September 30, 2018-

- Dispensing records uploaded: > 250M
- Total registrants: 95,796
- Number that have queried: 71,726
- Total reports requested: > 40M

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

Registration, 9-30-18

License type	Total licensees (no.)	Registered users (no.)	Registered users (%)
ARNP	25,740	7,223	28.1
DN	14,283	4,882	34.2
ME	75,729	33,256	43.9
OPC	3,332	32	0.96
OS	9,120	4,995	54.8
PA	8,687	3,565	41
PO	1,904	756	39.7
PS	31,606	14,423	45.6
Pres designee	---	17,718	---
Disp designee	---	8,537	

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

PDMP: 7/1/2018

- E-FORCSE remains intact
- Prescriber or dispenser (or designee) must consult the database for all patients 16 or older
- Applies to **ALL** controlled substances, not just opioids
- 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 rule-making
- 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."

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