



Opioid Regulations in NYS



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Disclaimer

- ❑ Note: This lecture is for the sole purpose of providing information to the practitioner about the laws, rules and regulations that govern prescribing in New York State and is not a source of legal advice. The law is dynamic and changes frequently. Discrete facts should be verified before they are relied upon. For specific legal problems, practitioners should seek legal counsel.

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Objectives

- ☐ Discuss the present-day opioid epidemic nationally and in New York State
- ☐ List upcoming legislative issues and their potential on the prescribing and dispensing of controlled substances
- ☐ Describe the regulations affecting practitioner and pharmacist responsibilities concerning controlled substances
- ☐ Recognize the use of naloxone in the treatment of opioid overdose.

National Survey on Drug Use and Health (NSDUH) 2016

Substance Abuse and Mental Health Services Administration (SAMHSA)

- 28.6 million people aged 12 and older used an illicit drug in the past 30 days (10.6%)
 - 12-17 2.0 million (7.9%) (2014: 9.4%)
 - 18-25 8.0 million (23.2%) (2014: 22%)
 - ≥ 26 18.6 million (8.9%) (2014: 8.3%)



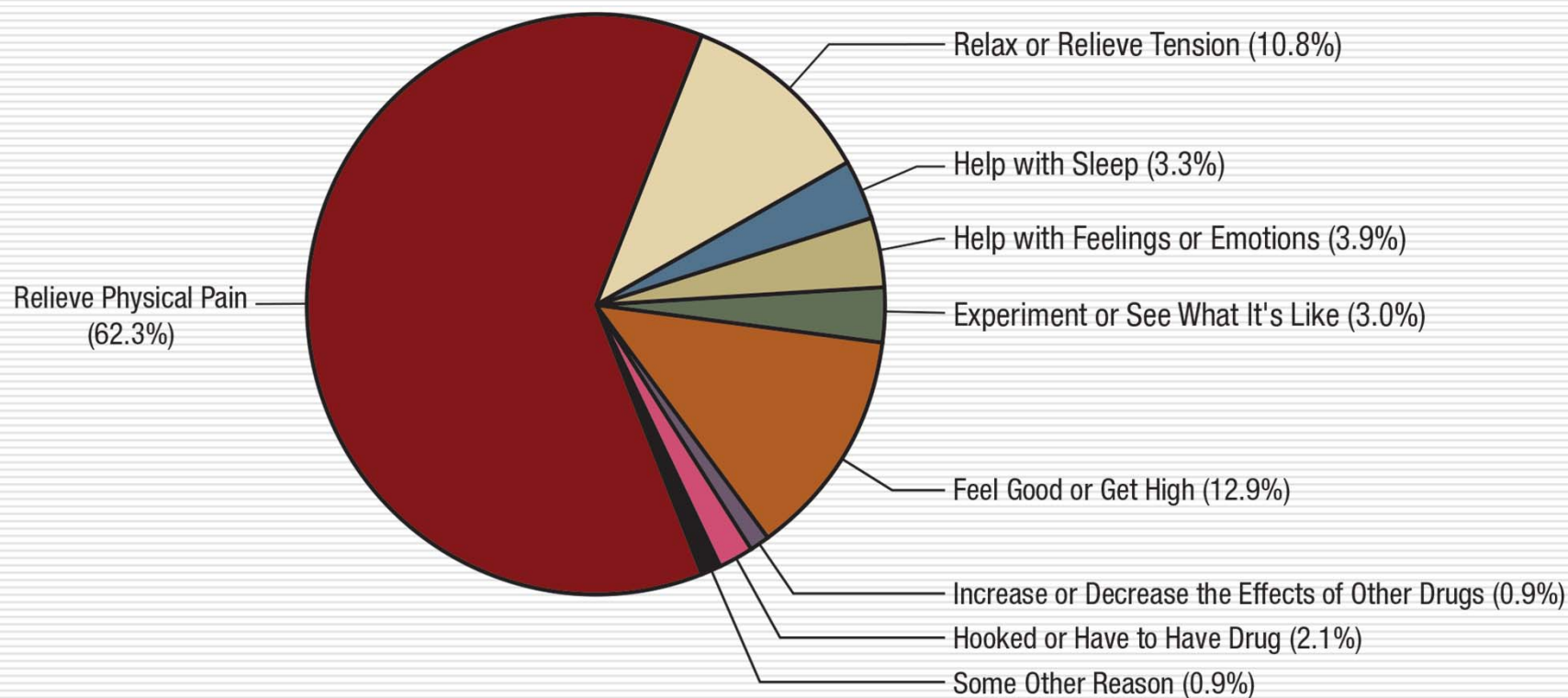
National Survey on Drug Use and Health (NSDUH) 2016

Substance Abuse and Mental Health Services Administration (SAMSA)

- 11.8 million people aged 12 and older misused opioids in the past year (4.4%)
 - 12-17 891,000 (3.6%)
 - 18-25 2.5 million (7.3%)
 - ≥ 26 8.4 million (4%)

NSDUH

Main Reason for the Most Recent Rx Pain Reliever Misuse

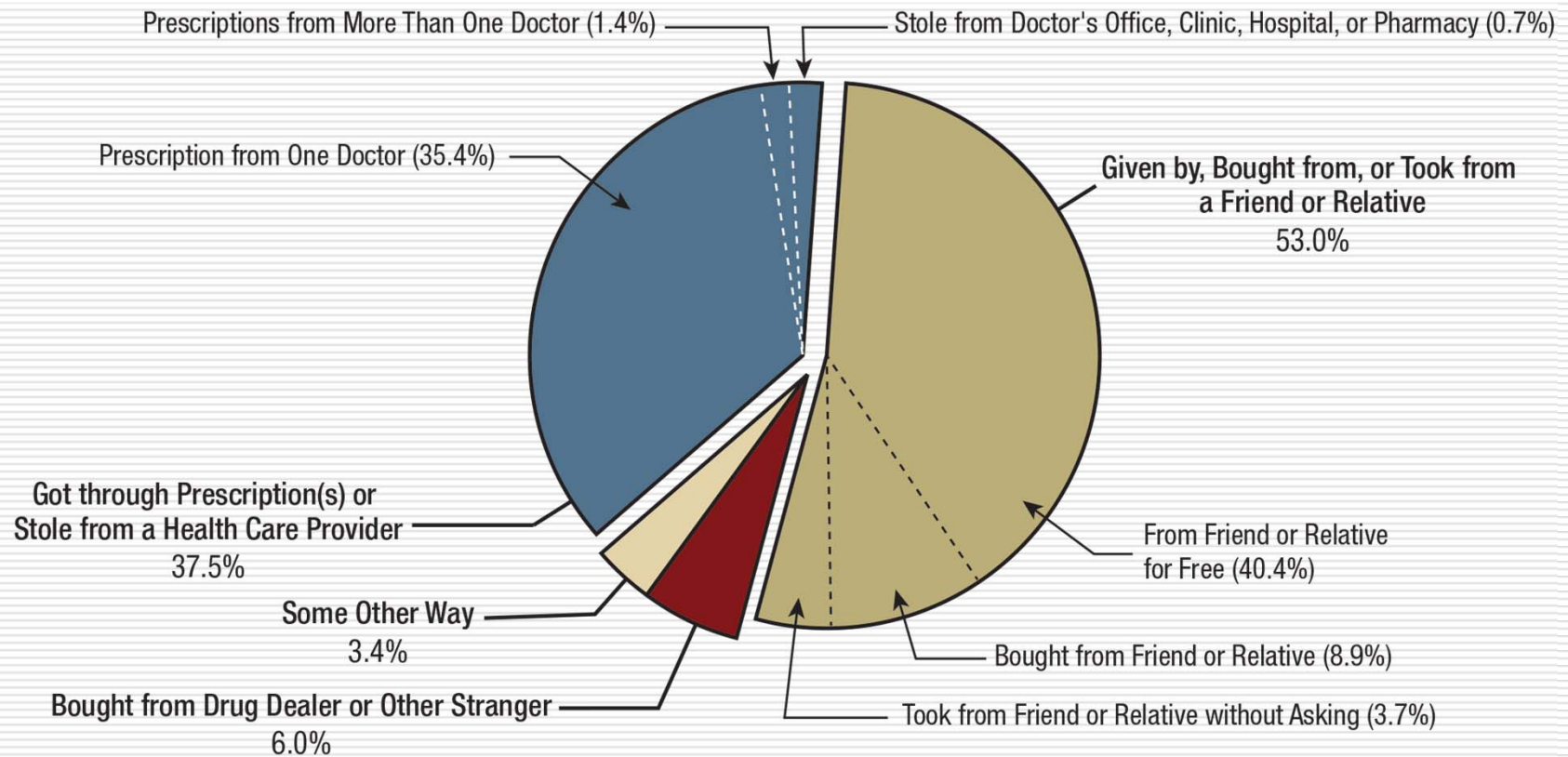


11.5 Million People Aged 12 or Older Who Misused Prescription Pain Relievers in the Past Year



NSDUH

Source of the Last Pain Reliever That was Misused

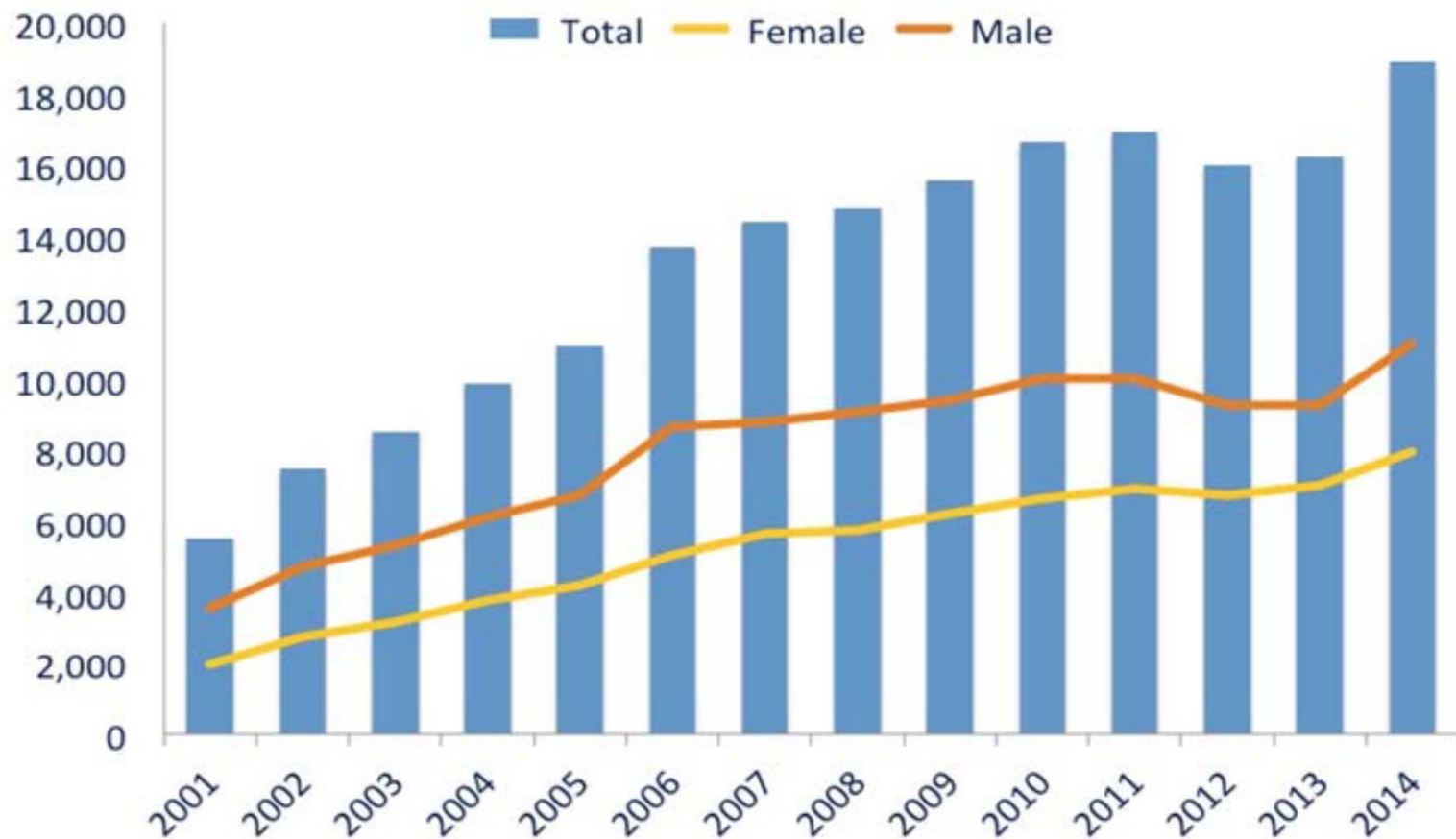


11.5 Million People Aged 12 or Older Who Misused Prescription Pain Relievers in the Past Year



National Overdose Deaths

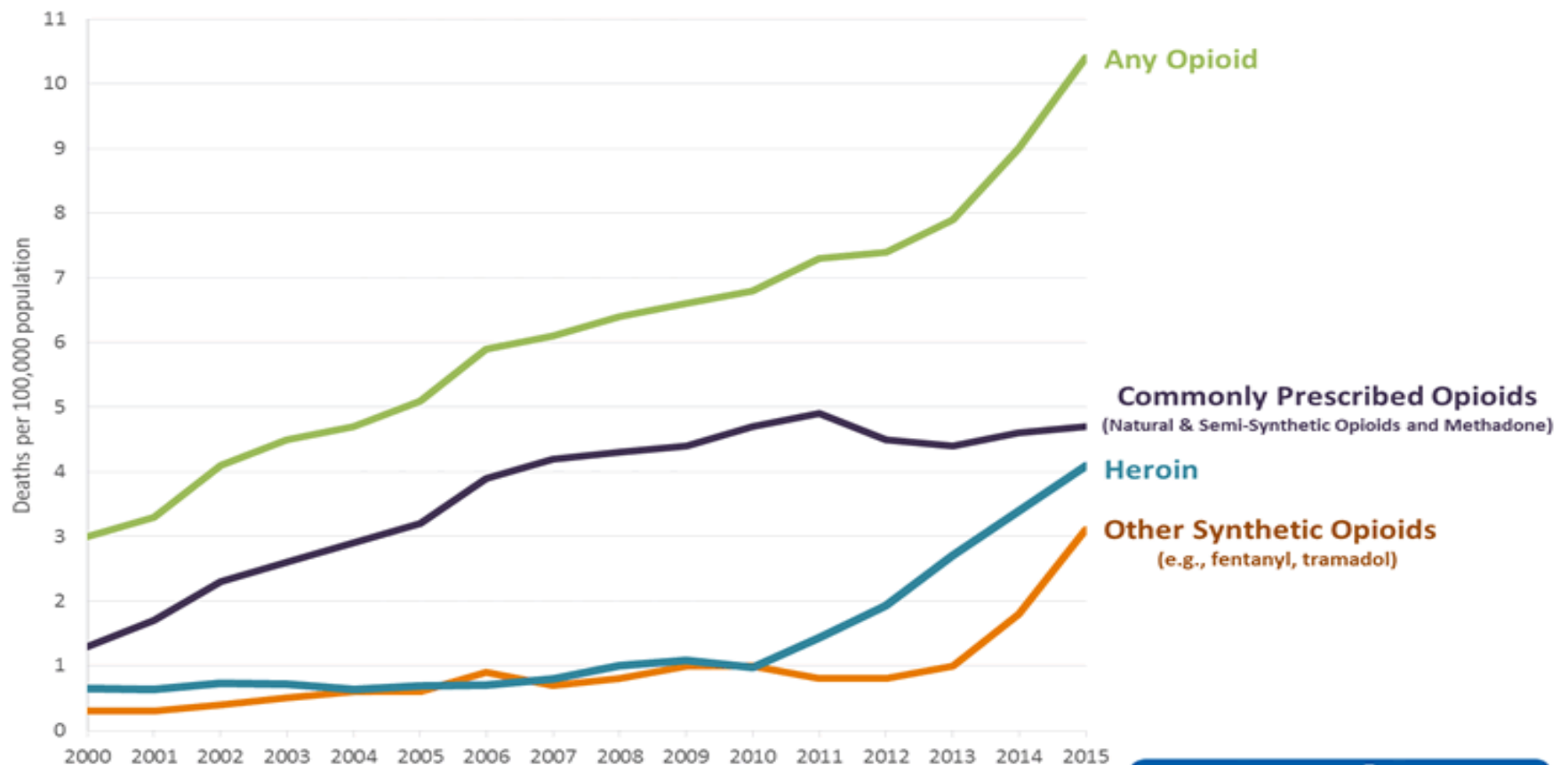
Number of Deaths from Prescription Opioid Pain Relievers



Source: National Center for Health Statistics, CDC Wonder

Overdose Deaths Involving Opioids

Overdose Deaths Involving Opioids, United States, 2000-2015



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2016. <https://wonder.cdc.gov/>.

www.cdc.gov
Your Source for Credible Health Information

Drug Overdose Deaths

- 52,898
 - The year ending January 2016
- 64,070
 - The year ending January 2017
 - Primarily due to illicitly manufactured fentanyl (~20,000)
- 188,000 deaths 1999-2015 (CDC)

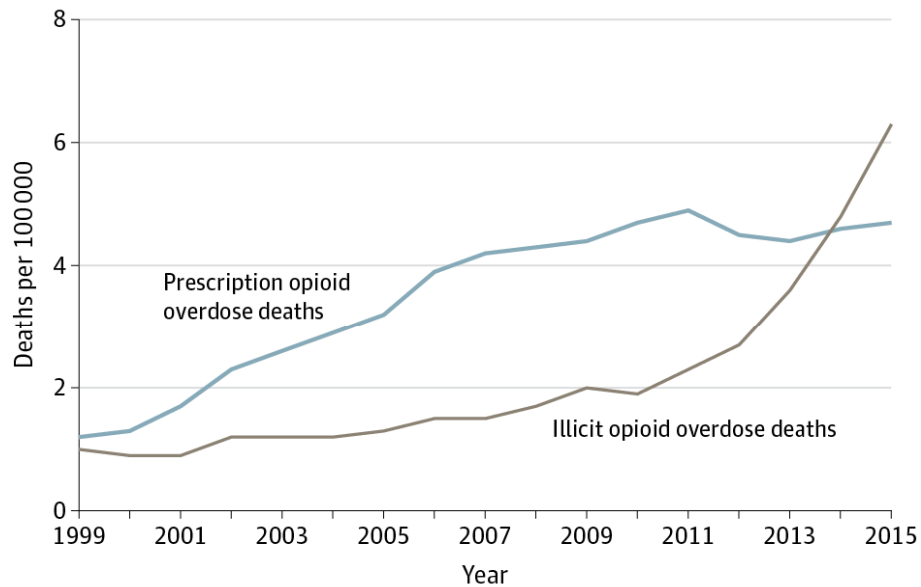
Underlying Factors in Drug Overdose Deaths

[Deborah Dowell, MD, MPH¹](#); [Rita K. Noonan, PhD¹](#); [Debra Houry, MD, MPH¹](#)

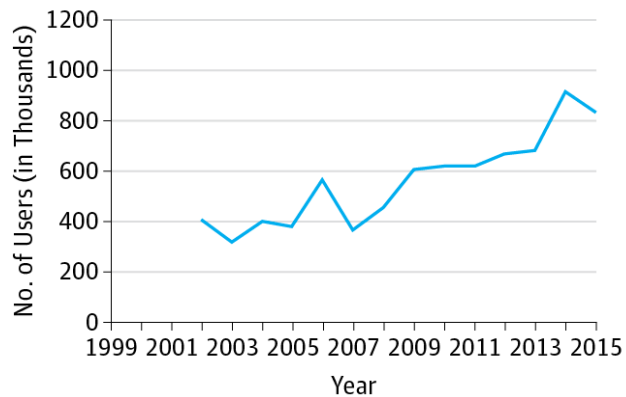
Author Affiliations [Article Information](#)

JAMA. Published online October 11, 2017. doi:10.1001/jama.2017.15971 Accessed 10/22/2017

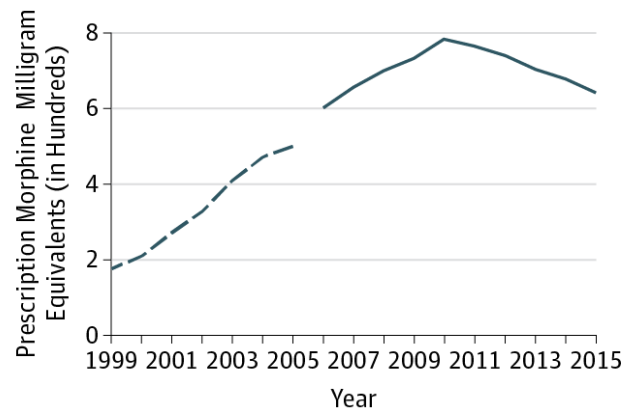
Age-adjusted opioid-related overdose deaths,^a
1999-2015



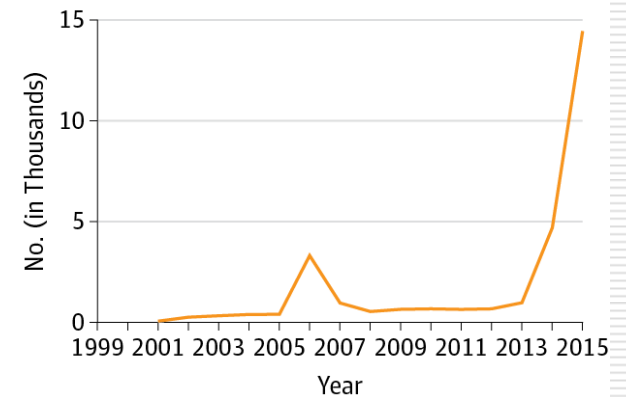
Past-year heroin use among
individuals aged ≥ 12 y,^b
2002-2015



Per capita prescription opioid sales,^c
1999-2015



Fentanyl drug reports,^d
2001-2015



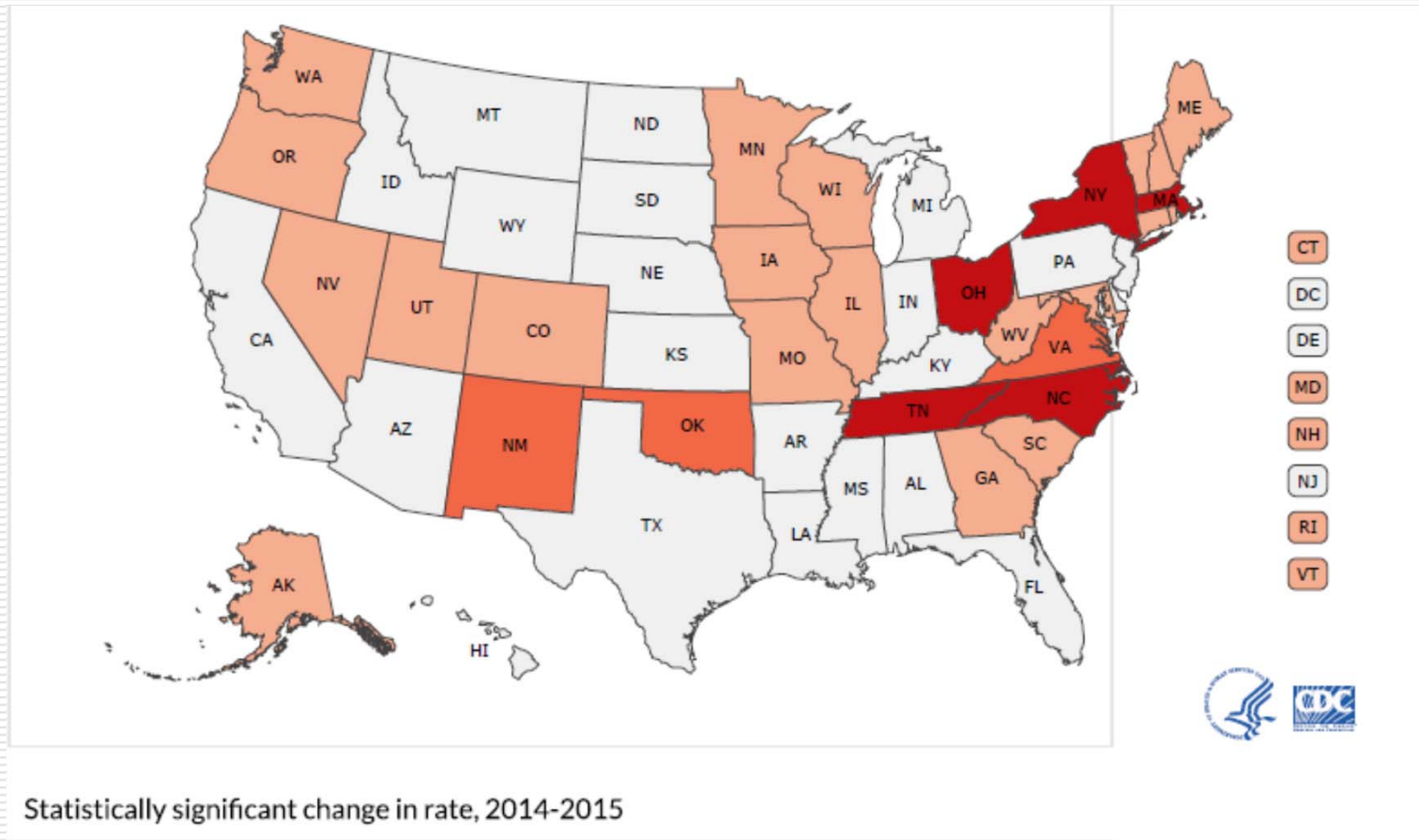
Underlying Factors in Drug Overdose Deaths

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Statistically Significant Changes in Drug Overdose Death Rates: Natural and Synthetic Opioids 2014-2015



NYS Drug Overdoses

- ❑ 1.4 million New Yorkers suffer from a substance abuse disorder
- ❑ Upstate NY had a 222% increase in admissions to OASAS certified treatment programs among 18-24 year old for heroin and other opioids (2014)
- ❑ 2015
 - 13.6 % increase in opioid death rate since 2014
 - 20 % increase in all drug overdose death rate

NYS Opioid Crisis: Statistics

- ❑ Nearly 80% of recent heroin uses started with opioid analgesics
- ❑ Heroin overdose is now the leading cause of accidental death in NYS

Jones, CM (2013). Heroin Use and Heroin Use Risk Behaviors among Nonmedical Users of Prescription Opioid Pain Relievers: United States, 2002-2004 and 2008-2010. Retrieved September 27, 2016, from <http://www.ncbi.nlm.nih.gov/pubmed/23410617>

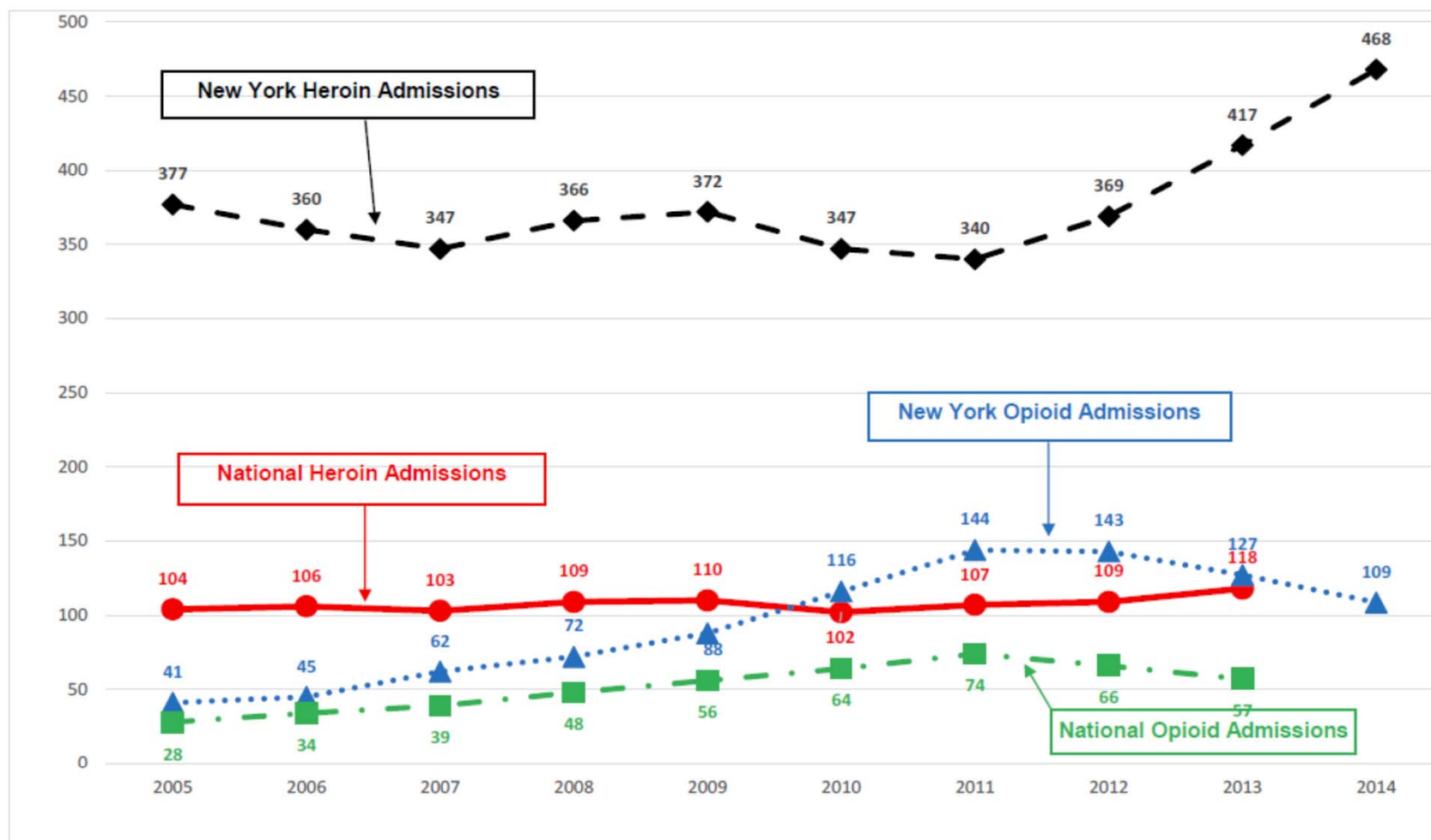


Prescription Opioid and Heroin Overdose Death Rates (Per 100,000 population)



Source: CDC, NCHS, Multiple Cause of Death on CDC WONDER Online Database, released 2015. Accessed at <http://wonder.cdc.gov/mcd-icd10.html> on December 9, 2015. Rates are age-adjusted by NCHS to facilitate comparisons over time or among groups, such as those living in different geographic areas. This type of measure eliminates differences that would be expected due to variations in age, such as higher or lower rates of heroin or opioid use.

Treatment Admission Rates for Heroin and Prescription Opioids, New York and U.S. (Individuals Aged 12 and Older, per 100,000 population)



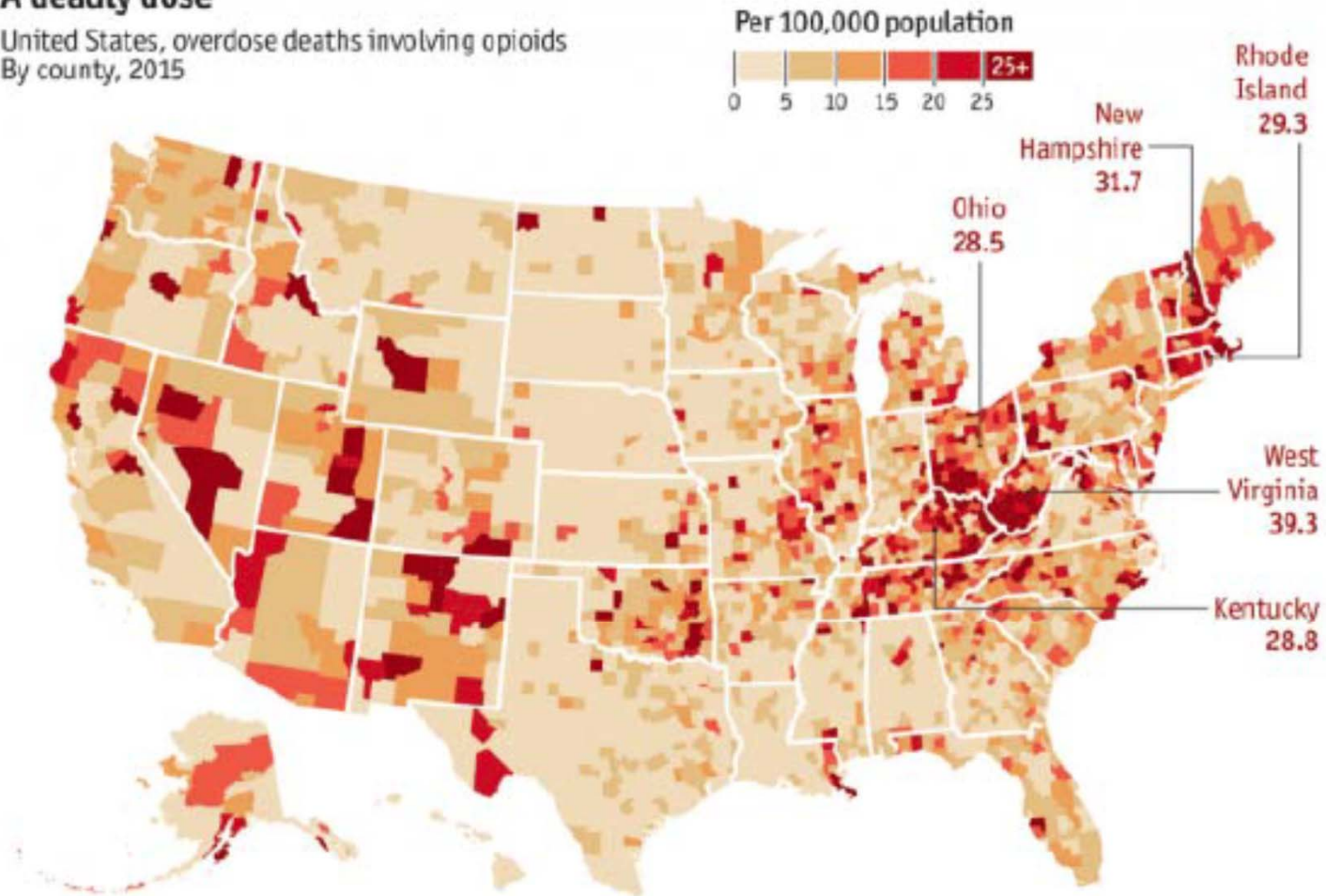
Sources: Rates are per 100,000 population aged 12 and older. Substance Abuse and Mental Health Services Administration (SAMHSA) 2014 Treatment Episode Data Set Substance Abuse Treatment Admissions Tables as of the 2nd Quarter of 2015 Quarter, available at http://www.samhsa.gov/data/sites/default/files/2014_TEDS_Substance_Abuse_Treatment_Admissions_Tables_as_of_2015_Q2/2014_TEDS_Substance_Abuse_Treatment_Admissions_Tables_as_of_2015_Q2.html, accessed on Dec. 3, 2015. Also see the SAMHSA Treatment Episode Data Set 2003-2013, available at http://www.dasis.samhsa.gov/dasis2/teds_pubs/2013_teds_rpt_st.pdf. National data are not available for 2014.

America's opioid epidemic is worsening

States are losing the battle against deadly drugs like heroin and fentanyl

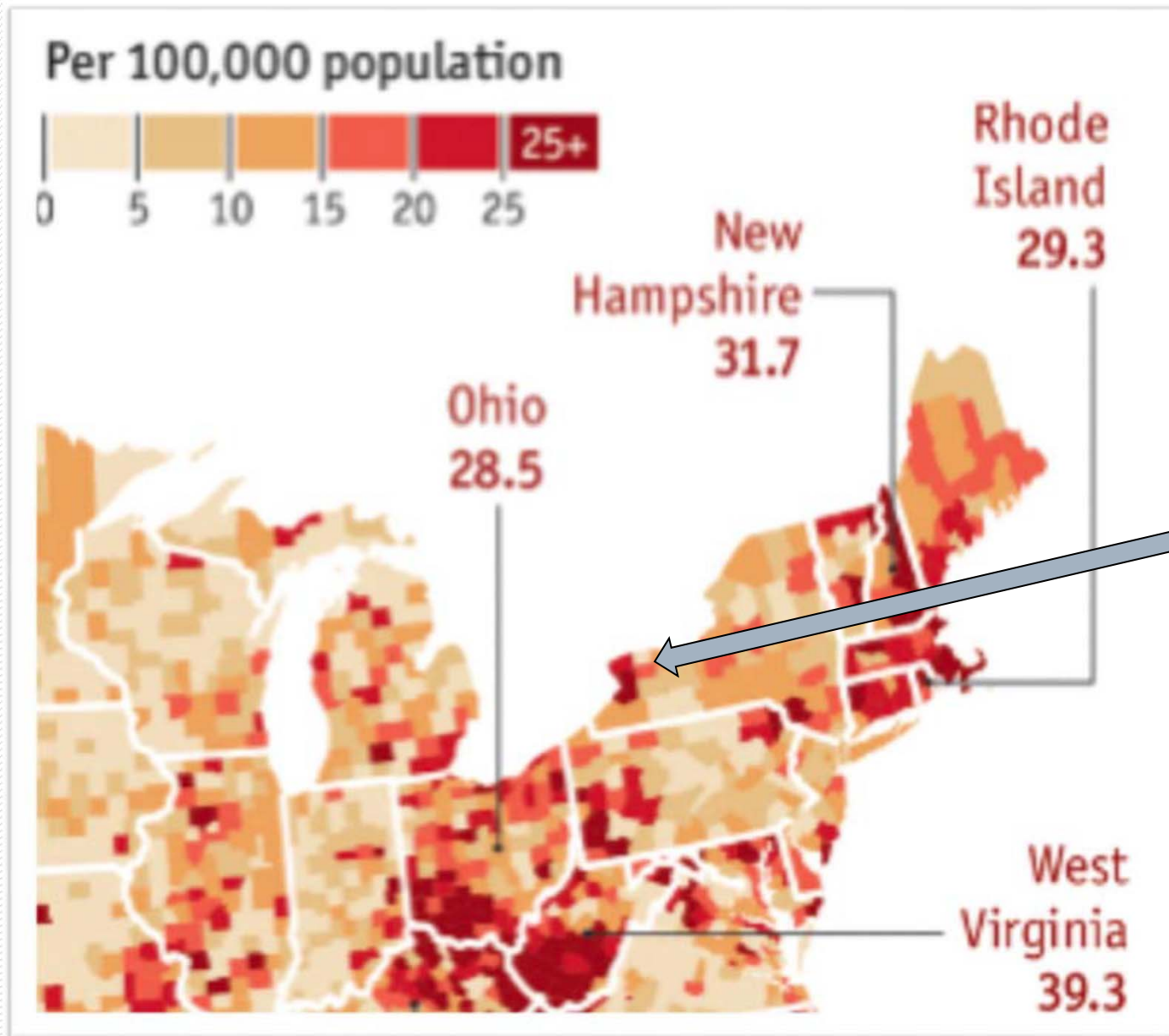
A deadly dose

United States, overdose deaths involving opioids
By county, 2015

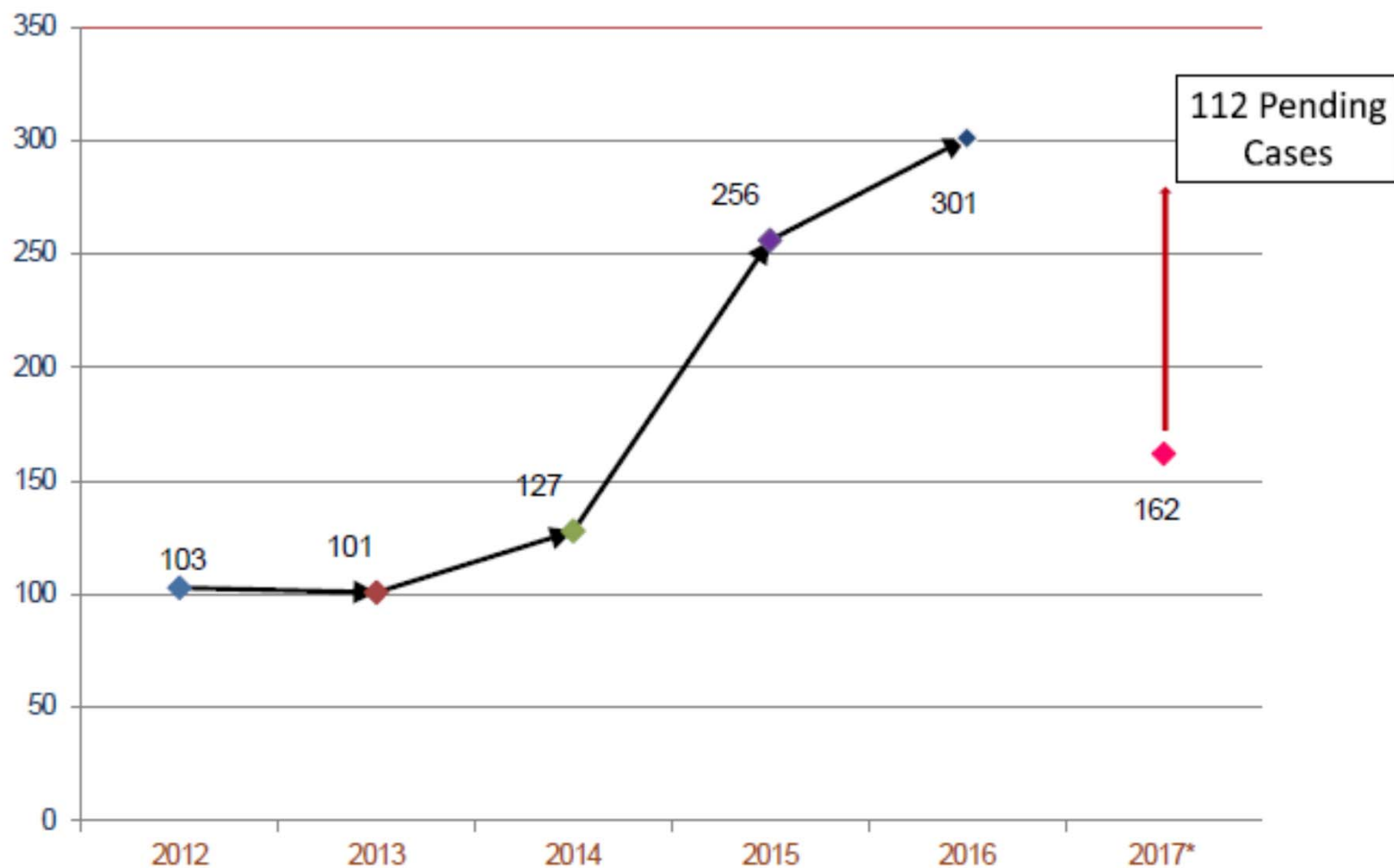


Source: Centres for Disease Control and Prevention

Economist.com The Economist March 6, 2017 Accessed 10/20/2017



2012 – 2017* OPIOID DEATHS ERIE COUNTY



SOURCE: ERIE COUNTY MEDICAL EXAMINERS OFFICE, *CLOSED CASES REPORTED THRU 10/10/2017

Courtesy of Cheryll Moore, RN, ECDOH

2015 CENSUS ESTIMATES FOR ERIE COUNTY, NEW YORK

	Number	Percent
Total Population	922,578	100
Race		
White	746,993	81.0
Black or African American	134,287	14.6
Asian or Pacific Islander	33,873	3.7
American Indian or Alaska Native	7,425	0.8
Ethnicity		
Hispanic or Latino	48,141	5.2
Not-Hispanic or Latino	874,437	94.8
Gender		
Female	475,707	51.6
Male	446,871	48.4
Age		
15-19	60,096	6.5
20-29	134,337	14.6
30-39	109,246	11.8
40-49	111,837	12.1
50-59	137,219	14.9
60-69	109,082	11.8
70+	105,941	11.5

2017 Opioid Statistics

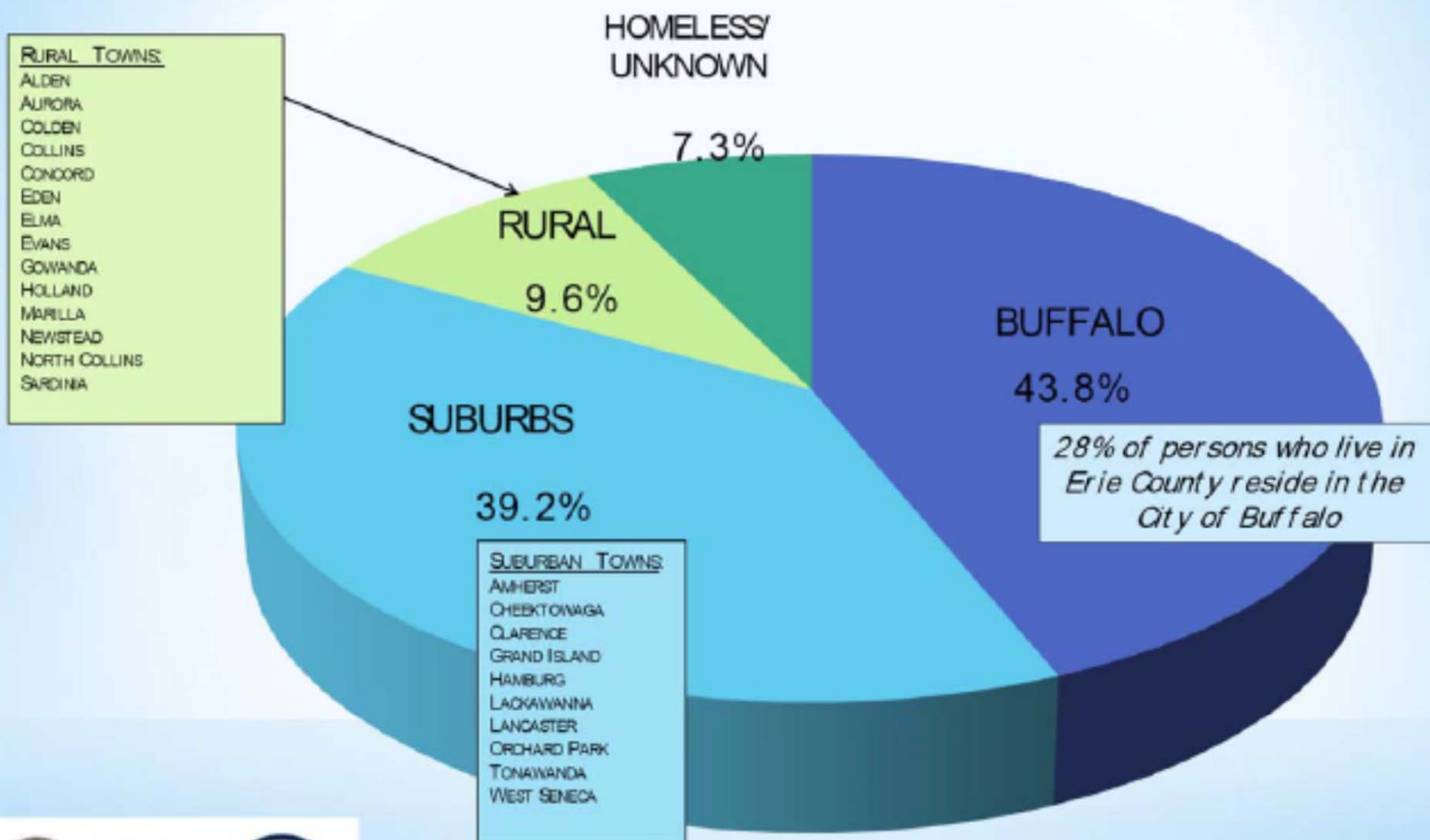
83% of Opioid Deaths are White
10% of Opioid Deaths are Black

76% of Opioid Deaths are Male

59% of Opioid Deaths are
between 20-39 years of age

2016 ERIE COUNTY OPIOID DEATHS BY RESIDENCE

N=296



SOURCE: ERIE COUNTY MEDICAL EXAMINERS OFFICE, CLOSED CASES REPORTED THRU 8/7/2017

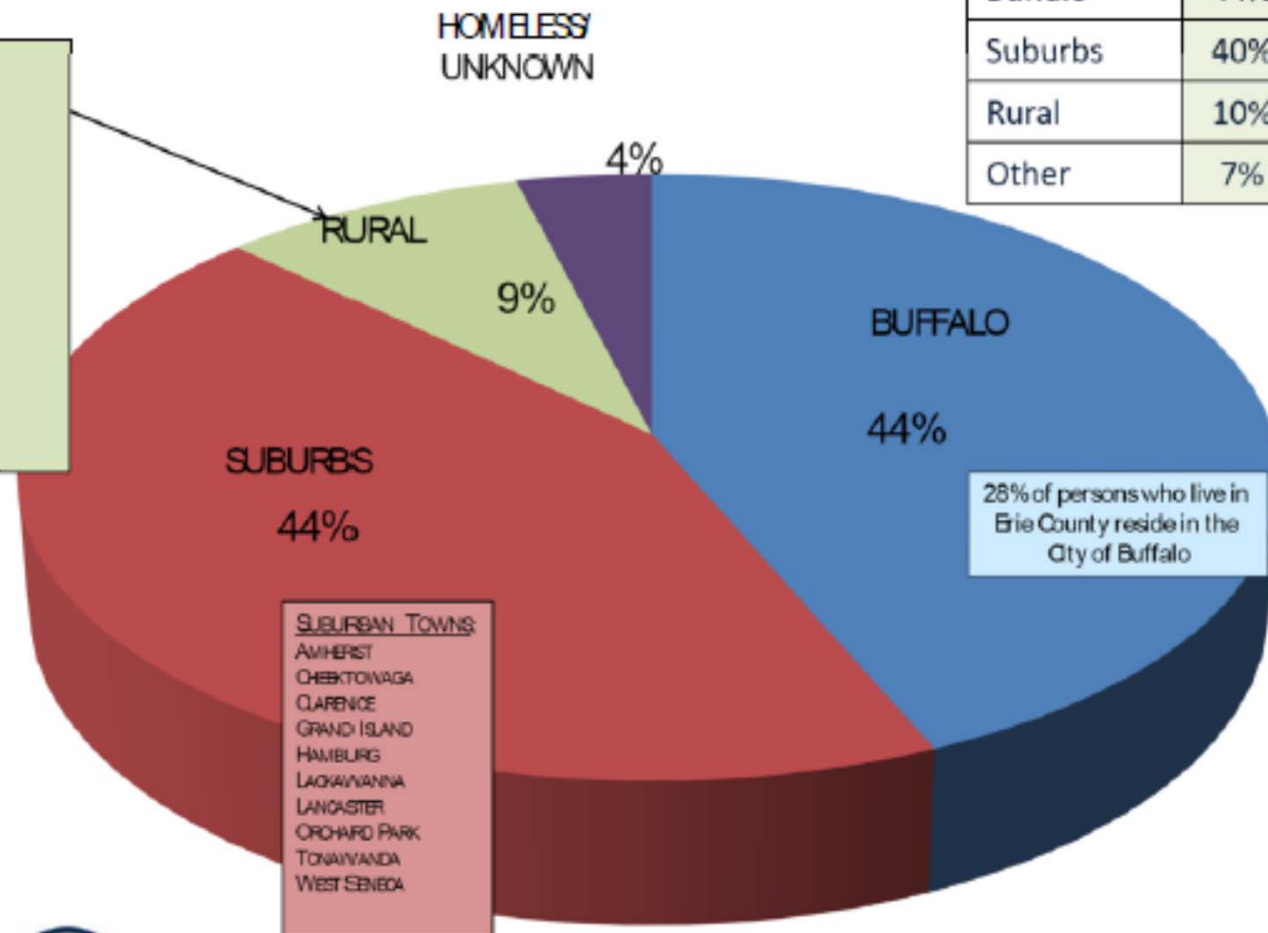
Courtesy of Cheryll Moore, ECDOH

2017* ERIE COUNTY OPIOID DEATHS BY RESIDENCE

N=161 (112 Pending)

Residence	2016	2017
Buffalo	44%	44%
Suburbs	40%	44%
Rural	10%	9%
Other	7%	4%

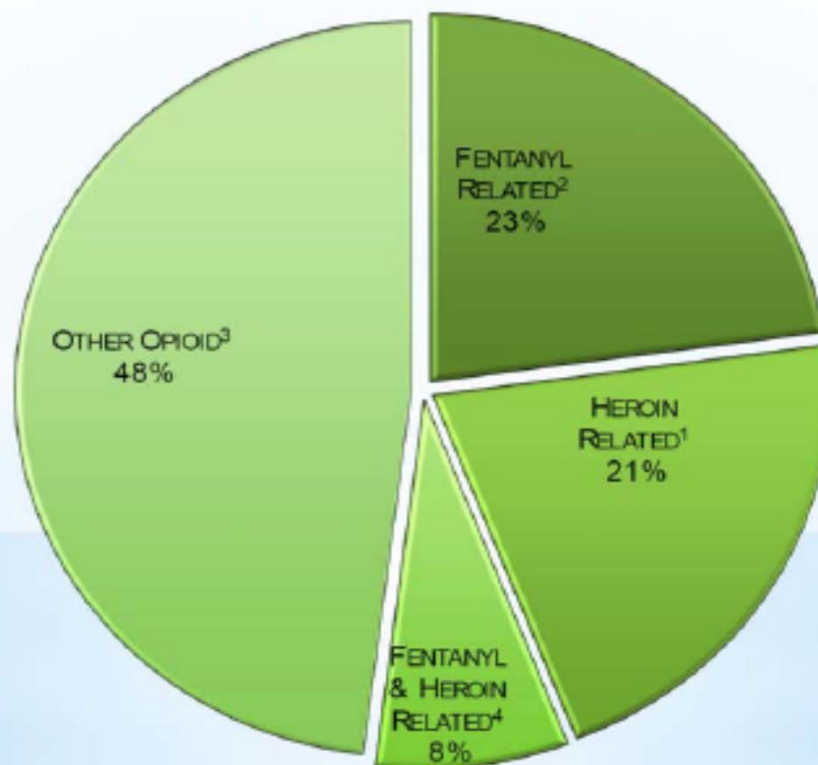
- RURAL TOWNS:**
- ALDEN
 - AURORA
 - COLDEN
 - COLLINS
 - CONCORD
 - EDEN
 - ELMA
 - EVANS
 - GOWANDA
 - HOLLAND
 - MARILLA
 - NEWSTEAD
 - NORTH COLLINS
 - SARDINIA



SOURCE: ERIE COUNTY MEDICAL EXAMINERS OFFICE, *CLOSED CASES REPORTED THRU 10/10/2017

Courtesy of Cheryl Moore, ECDOH

ERIE COUNTY OPIOID RELATED DEATHS BY TYPE OF OPIOID



2014
N=127



Erie County
Department of
Health



Public Health
Prevent. Promote. Protect.

¹ NO FENTANYL; POSSIBLE OTHER DRUGS INVOLVED

² NO HEROIN; POSSIBLE OTHER DRUGS INVOLVED

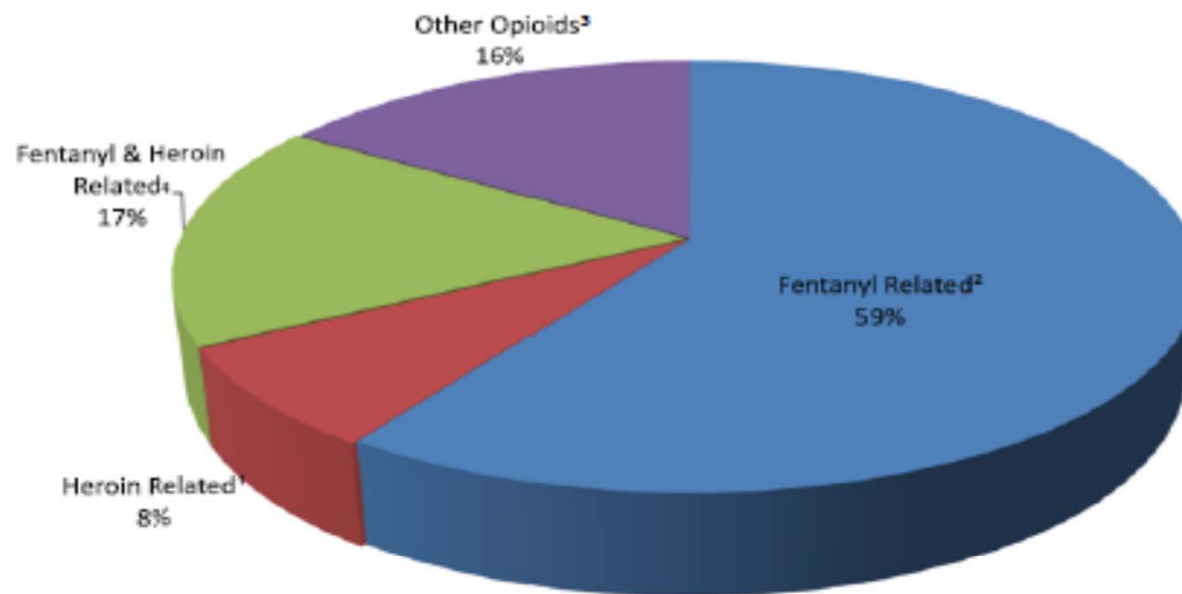
³ NO FENTANYL OR HEROIN; POSSIBLE OTHER DRUGS INVOLVED

⁴ POSSIBLE OTHER DRUGS INVOLVED

SOURCE: ERIE COUNTY MEDICAL EXAMINERS OFFICE, CLOSED CASES

2016 ERIE COUNTY OPIOID RELATED DEATHS BY TYPE OF OPIOID

2016
N=301



¹ NO FENTANYL; POSSIBLE OTHER DRUGS INVOLVED

² NO HEROIN; POSSIBLE OTHER DRUGS INVOLVED

³ NO FENTANYL OR HEROIN; POSSIBLE OTHER DRUGS INVOLVED

⁴ POSSIBLE OTHER DRUGS INVOLVED



Erie County
Department of
Health



Public Health
Prevent. Promote. Protect.

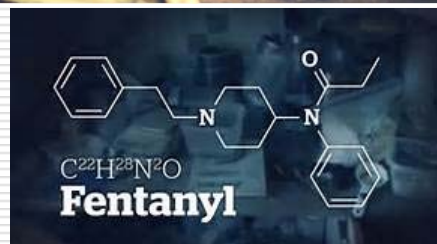
SOURCE: ERIE COUNTY MEDICAL EXAMINERS OFFICE, *CLOSED CASES REPORTED THRU 9/18/2017

*This is U-47700, Once a Lab Experiment
(1973 Upjohn) , Now a Killer Opioid*



<http://www.wsj.com/articles/this-is-u-47700-once-a-lab-experiment-now-a-killer-opioid-1478269461>: accessed 11/4/2016

Fentanyl et al (CHINA WHITE)



Analogs include:

- Acetylalphamethylfentanyl
- Acetyl fentanyl
- Alfentanil
- Alphamethylfentanyl
- Alphamethylthiofentanyl
- Betahydroxy-fentanyl
- Beta-hydroxy-3methylfentanyl
- Fentanyl
- 3-methylfentanyl
- 3-methylthio-fentanyl
- Parafluoro-fentanyl
- Remifentanil
- Sufentanil
- Thiofentanyl
- Carfentanil

<http://www.wsj.com/articles/this-is-u-47700-once-a-lab-experiment-now-a-killer-opioid-1478269461>: accessed 11/4/2016

<http://www.emcdda.europa.eu/publications/drug-profiles/fentanyl>: accessed 11/10/2016

Why Carfentanil is Deadly



<https://www.statnews.com/2016/09/29/fentanyl-heroin-photo-fatal-doses/> Accessed 10/20/2017

Buprenorphine Federal

- ❑ Physicians may see 30 patients initially
 - Must have training
 - Must have a DEA number with "X"
- ❑ Physicians may see up to 100 patients
 - After one year with DEA number with "X"

Federal Register July 8, 2016

- ☐ Physicians may now have up to 275 patients
 - Must have 100 patients prior
 - Additional credentials
 - ☐ Board certified in addiction medicine or psychiatry by
 - American Board of Addiction Medicine or
 - American Board of Medical Specialties
 - ☐ Certified by
 - American Society of Addiction Medicines
 - Be practicing in a qualified practice setting

Buprenorphine S8137/A10725

Office of Alcoholism and Substance Abuse Services (OASAS)

- ❑ Every insurance policy must provide for prescription drugs for the treatment of a substance use disorder shall include immediate access, without prior authorization, to a 5-day emergency supply of prescribed medication associate with the management of opioid withdrawal and/or stabilization
 - Subject to copay or coinsurance

Buprenorphine S8137/A10725

Office of Alcoholism and Substance Abuse Services (OASAS)

- ☐ No additional copays/coinsurance
 - When patient is prescribed up to a 30-days supply in the same 30 day period in which they received the emergency 5-days supply

Treatment of Heroin and Opioid Addictions s8139/ §3309-a

- ❑ Passed and signed by Governor
- ❑ Requires all practitioners who treat humans are allowed to prescribe controlled substances and who have a DEA #
 - ❑ Must complete 3 hours of mandatory coursework on pain management, palliative care and addiction every 3 years

FREQUENTLY ASKED QUESTIONS ABOUT

MANDATORY PRESCRIBER EDUCATION

June 2017



**Department
of Health**

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement

1-866-811-7957

www.health.ny.gov/professionals/narcotic



University at Buffalo

School of Pharmacy and Pharmaceutical Sciences

- ☐ Prescriber Training Program
- ☐ Free to all prescribers
- ☐ \$20 for pharmacists/technicians
- ☐ <https://www.pharm.buffalo.edu/CE/>
- ☐ Part I
- ☐ Part II

Treatment of Heroin and Opioid Addictions s8139/ §3309-a

- Practitioners may not prescribe more than a 7-day's supply pf any CII, CIII or CIV
 - Initial consultation
 - Acute pain
 - This rule does not apply to chronic, cancer, hospice or end of life care.

Copays

- ❑ Proportional between the copayment for a 30-days supply and the amount of drugs the patient was prescribed OR
- ❑ Equivalent to the copayment for a full 30-days supply of the opioid drug

Pharmacy Required Information Sheet

Controlled Substances October 22, 2016

- ☐ Every patient dispensing for controlled substance the pharmacist must provide the patient with information about the
 - ☐ 1. Dangers of misuse and potential risk for addiction to prescription controlled substances
 - ☐ 2. The physical and behavior warning signs of addiction
-

Pharmacy Required Information Sheet Controlled Substances October 22, 2016

- ☐ 3. Available alcohol and drug addiction treatment resources
- ☐ 4. Proper disposal guidelines for unused prescription controlled substances
- ☐ <https://www.health.ny.gov/publications/12022.pdf>

Comprehensive Addiction and Recovery Act of 2016

Some provisions

- ☐ Availability of naloxone in pharmacies
- ☐ Law enforcement carrying naloxone
- ☐ NP's and PA's for buprenorphine prescribing
- ☐ Incentivize states to address opioid epidemic
- ☐ Partial filling of CII's
 - Not allowed by NYS yet.



DEA Red Flags

□ Remember:

- Use your professional judgment
- Although the DEA stresses the law, we must take care of the patient
- Do not look at all patients with suspicion as most prescriptions are for legitimate use.
- These flags are not stop signs

Corresponding Responsibility

21 U.S.C. § 829

- ❑ *"A pharmacist also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription.*
- ❑ *The person knowingly filling such a purported prescription, as well as the person using it, shall be subject to the penalties provided for violations of the provisions of law related to controlled substances."*

United States v. Kershman, 555 F.2d 198 [United States Court Of Appeals, Eighth Circuit, 1977]

- *A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription...*
- *The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin.*

DEC Wants Pharmacies to Have Take-Back Capabilities

- ❑ Must have a DEA-compliant collection box
- ❑ Can take back any pharmaceutical
 - Not syringe/needles
 - Not illicit



Courtesy NYS DEC

Pharmacy Collector

- ☐ Must have your DEA registration modified
 - voluntary
 - No fee
- ☐ “Authorized Collector”
- ☐ Note: Authorized collectors may NOT perform take-back programs
 - Only law enforcement
 - May partner with law enforcement

Authorized Collector

- ☐ Community pharmacies
- ☐ Hospitals
- ☐ Long term care facilities
- ☐ May take back CII-CV
- ☐ May also take back non-controls
- ☐ Must be securely locked, substantially constructed container.
 - Securely fastened to a permanent structure
 - ☐ Floor

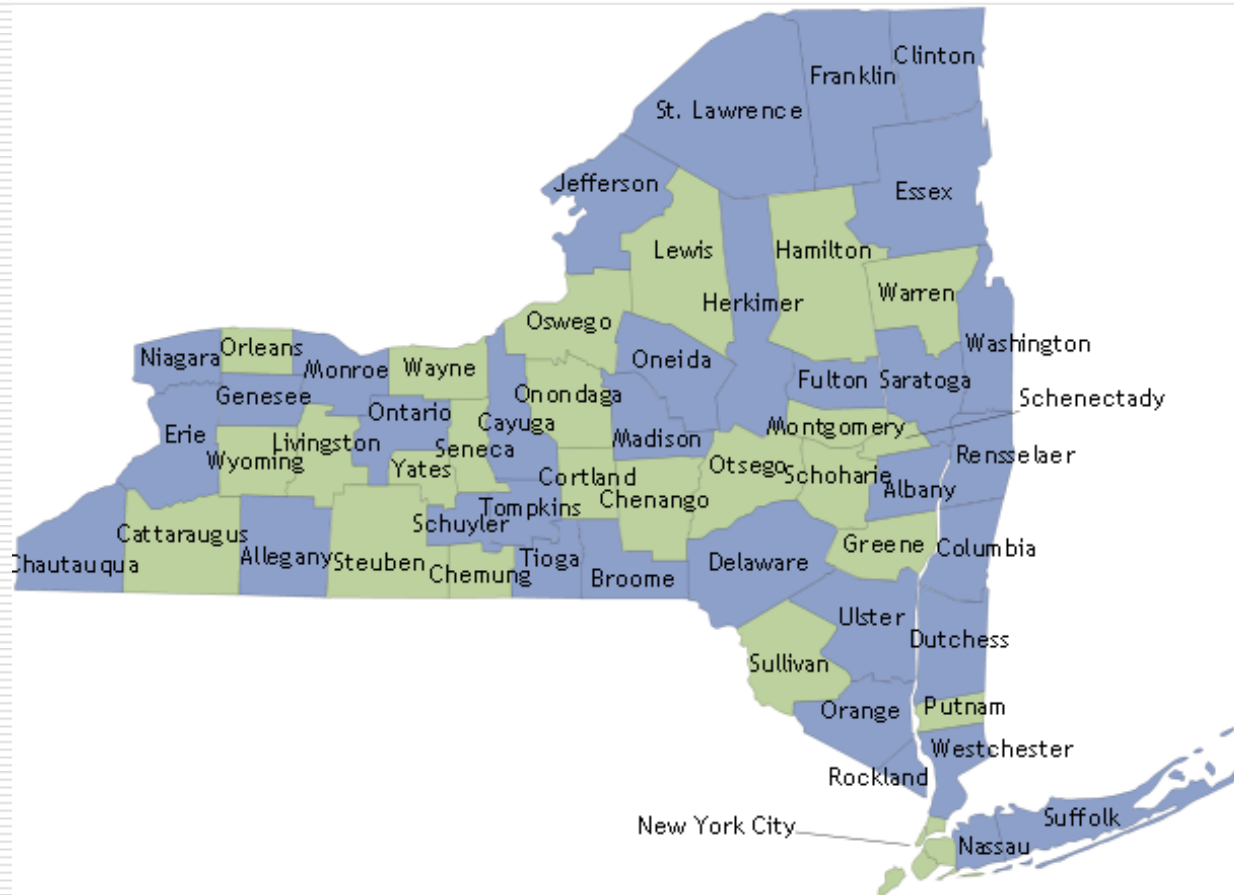
Receptacles

- ❑ Must have sign that clearly states CII-CV and non-controls
 - Other items not accepted
 - Syringes/needles not accepted.
 - Illicit drugs may not be accepted



Drug Disposal

List of Sites in NYS: Interactive



https://www.health.ny.gov/professionals/narcotic/medication_drop_boxes/

Drug Take Back Twice a Year October and April



DRUG ENFORCEMENT ADMINISTRATION

**National Prescription Drug
TAKE BACK DAY**

**Saturday, October 28th
10 a.m. – 2 p.m.**

**Turn in your unused or expired
prescription medication
for safe disposal.**

Click here
for a collection
site near you.

dispose

unused
Rx

For more information, please visit www.dea.gov.

The poster features a blue and white color scheme. At the top, a blue banner contains the text 'DRUG ENFORCEMENT ADMINISTRATION'. Below this, the title 'National Prescription Drug TAKE BACK DAY' is prominently displayed, with 'TAKE BACK DAY' in large, bold, red letters. The date and time, 'Saturday, October 28th 10 a.m. – 2 p.m.', are in blue. A red instruction line reads 'Turn in your unused or expired prescription medication for safe disposal.' To the right, a link is provided: 'Click here for a collection site near you.' The central graphic shows three pills: two blue capsules, one labeled 'dispose' in blue, and one white round tablet labeled 'unused Rx' in black. A faint, large 'DEA' seal is visible in the background. The bottom of the poster has a blue banner with the text 'For more information, please visit www.dea.gov.'

Drug Disposal



NYS Department of Environmental Conservation
NYS Education Department



IMPORTANT MESSAGE

Help Protect New York's Waters

Don't Flush Unwanted Household Medications or Pour Them Down the Drain

Return to collection events where available
or
Mix with something undesirable such as coffee grounds, cat litter or dirt
Tape up containers
Toss in your garbage



For full instructions or designated collection events visit:
www.dontflushyourdrugs.net

Opioid Overdose Prevention Programs 80.138 / §3309

- ☐ Programs must meet standards
 - Training, record-keeping, reporting
- ☐ Complete refresher training at least every 2 years

Opioid Overdose Prevention Programs

80.138 / §3309

- ☐ May be dispensed to anyone who requests it
 - No prescription
 - State-wide standing order
- ☐ Harm Reduction Coalition:
“Dispensing Naloxone”



University at Buffalo

School of Pharmacy and Pharmaceutical Sciences

- You must have received training to dispense naloxone
- <http://pharmacy.buffalo.edu/academic-programs/continuing-education/events/dispensing-naloxone.html>

Dispensing Naloxone: Label

- ☐ Name of recipient/patient
- ☐ Prescriber Name: Sharon Stancliff MD
- ☐ Naloxone formulation and concentration
- ☐ Date Dispensed
- ☐ Refills: 5 (recommended)
- ☐ "Dispensed per standing order"
- ☐ "Use as directed"
- ☐ "Trained opioid overdose responder"

Naloxone Atomizer

Narcan

Evzio



2mg, 4mg



Erie County DOH at
www.2erie.gov

NYSDOH Naloxone costs

- Beginning on August 9, 2017, New York State will cover up to \$40 of the cost of co-payments for naloxone at pharmacies with a physician standing order through a new overdose response initiative, the Naloxone Co-payment Assistance Program (N-CAP).

Opioid Crisis Looms Over Job Market, Worrying Employers And Economists

- ❑ Addiction leads to more unemployment
- ❑ Employers have a difficult time finding drug-free applicants

The Link Between Opioids and Unemployment

- ❑ A new study finds that as the jobless rate rises, so do drug overdoses
- ❑ "...as the unemployment rate increases by one percentage point in a given county, the opioid-death-rate rises by 3.6 percent, and emergency-room visits rise by 7 percent."

'It's like a tsunami': Opioid epidemic pushes kids into foster care



Halli Lavner, a director with Baker Victory Services, speaks with a child at the Nelson Cottage in Lackawanna, which serves as a temporary shelter for children in need of emergency foster care services. (Mark Mulville/Buffalo News)

Buffalo News: October 22, 2017



YOU ARE NEVER ALONE

We are here to help.


If you are thinking of suicide or
having a mental health crisis
call our 24 hour hotline

716-834-3131

If you are struggling with addiction call
24 hours a day to get help

716-831-7007



 University at Buffalo
School of Pharmacy and
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