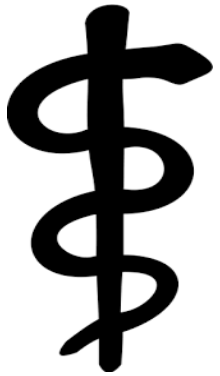
Michael Baron, MD, MPH, DFASAM
Medical Director
Physician's Health Program
11/9/2020

Opioid Prescribing: Progress and Pitfalls



Disclosure

Dr. Baron has no financial relationships to disclose.

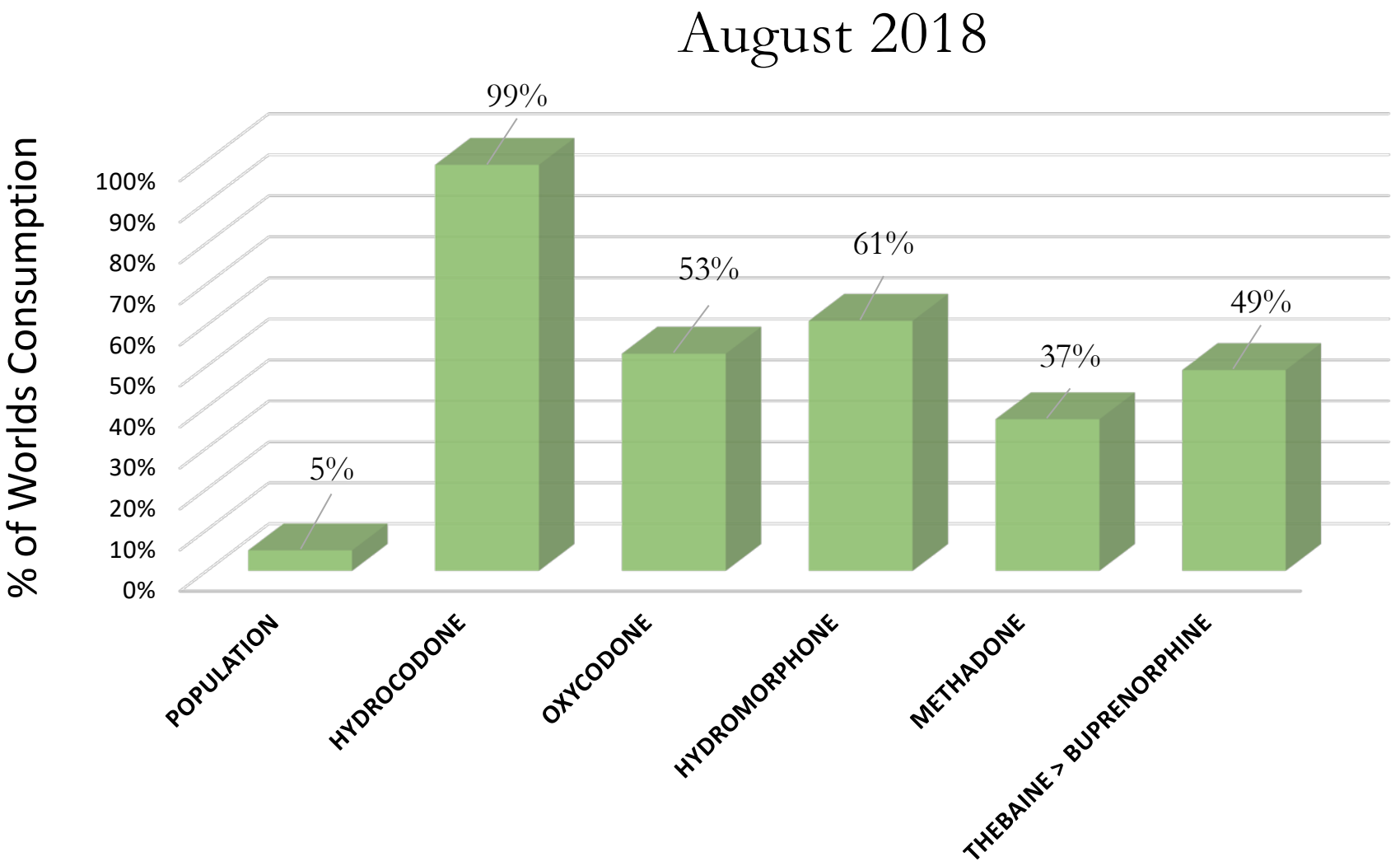
Board Certified in Anesthesiology, Psychiatry (MOC) and Addiction Medicine (MOC).

4/2010 – 1/2017	TN Board of Medical Examiners.
6/2014 – 1/2017	Chair - Controlled Substance Monitoring Database Committee (TN-PMP).
2/2017 -	Medical Director: Tennessee Medical Foundation - Physician's Health Program.
10/2018 -	Medical Director: Nashville - Davidson County Drug Court – DC4

Objectives

1. Review the causes for the Opioid Epidemic
2. Discuss and review the reasons for rising Over-Dose rates.
3. Familiarize with MME Rx and controlled prescription rates.
4. Review the intended and unintended consequences of pain and prescription legislation.

USA's Appetite for Opioids



International Narcotic Control Board

Opioid Consumption

How did we get here?

Opioid Consumption

- 5th vital sign:
- Pain assessed in all patients:
- Industry promotion:
- Evidenced Based Medicine:

AMA Consensus Statement, 1940

"The use of narcotics in terminal cancer is to be condemned if it can possibly be avoided. Morphine and terminal cancer are in no way synonymous."

Medical Clinics of North America, May 1999

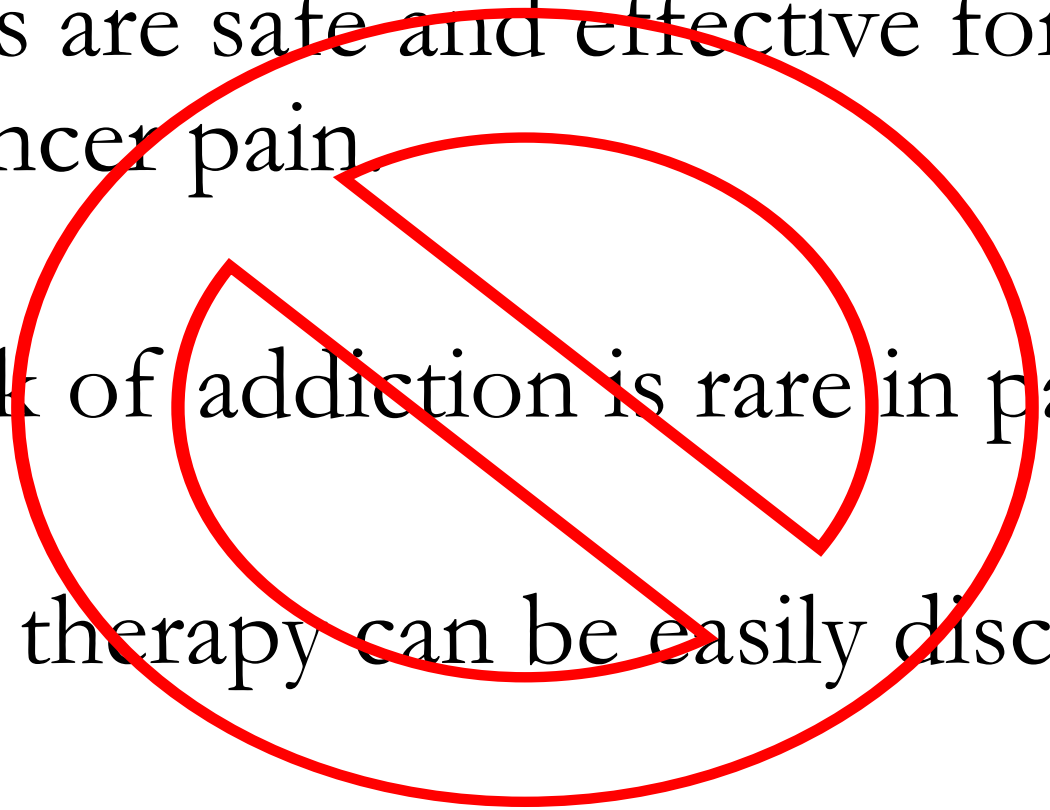
"In deciding whether opioids are indicated …, it is more appropriate to determine whether opioids reduce pain, improve function in valued life roles, and result in overall enhancement of well-being, without posing unacceptable risks or side effects, than to make the decision based solely on a diagnosis."

Industry Told Us

Opioids are safe and effective for chronic, non-cancer pain.

The risk of addiction is rare in pain patients.

Opioid therapy can be easily discontinued



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.

17,000 U per square meter daily). Patients who had complete remissions (except for three over 60 years of age) received central-nervous-system therapy (2400 rads to the skull, with five intrathecal injections of methotrexate or arabinosyl cytosine, or both). During complete remission, they were given 6-mercaptopurine (70 mg per square meter daily), methotrexate (25 mg per square meter each week), and courses of vincristine and prednisone every three to four months.

Results are shown in Table 1. They do not support the suggestion by Dr. Bitran that in adults with acute lymphoblastic anemia, T-cell leukemia has a poorer prognosis than B-cell disease. However, because of the limited number of cases and the short follow-up, the present data are far from definitive. More information on this point is needed. The identification of prognostic factors in acute lymphoblastic anemia in adults is critical, not only for the choice of induction therapy but also because young adults with an established poor prognosis could profit from allogeneic-marrow transplantation during the first remission. Therefore, we suggest that for the time being it may be wiser to base prognosis on more established criteria, such as age and blast-cell count in the blood.[2]

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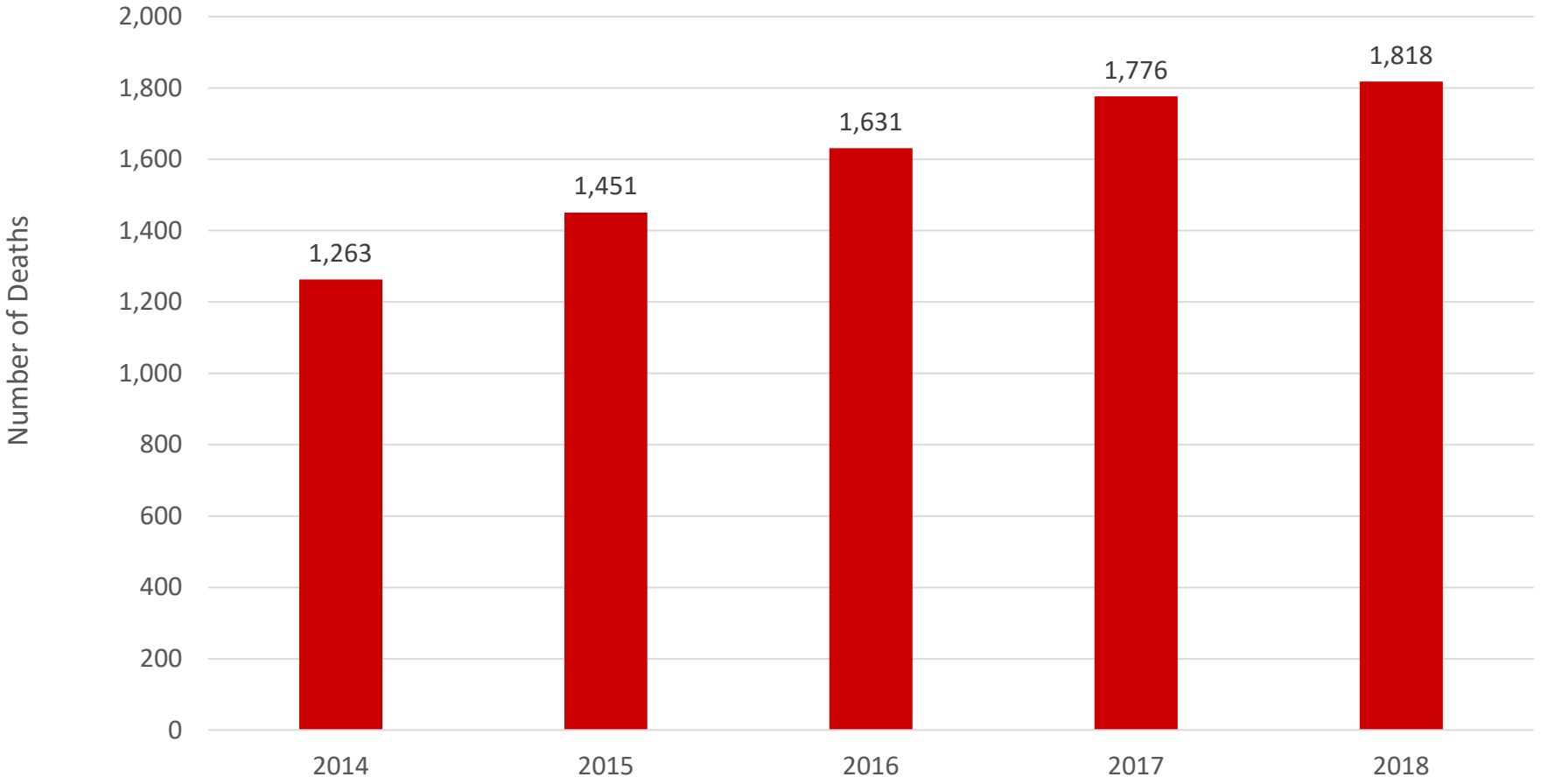
1. Bitran JD. Prognostic value of immunologic markers in adults with acute lymphoblastic leukemia. N Engl J Med. 1978; 299:1317.

Porter J & Jick, H (1980) Correspondence. *New England Journal of Medicine*, 302.2, 123.

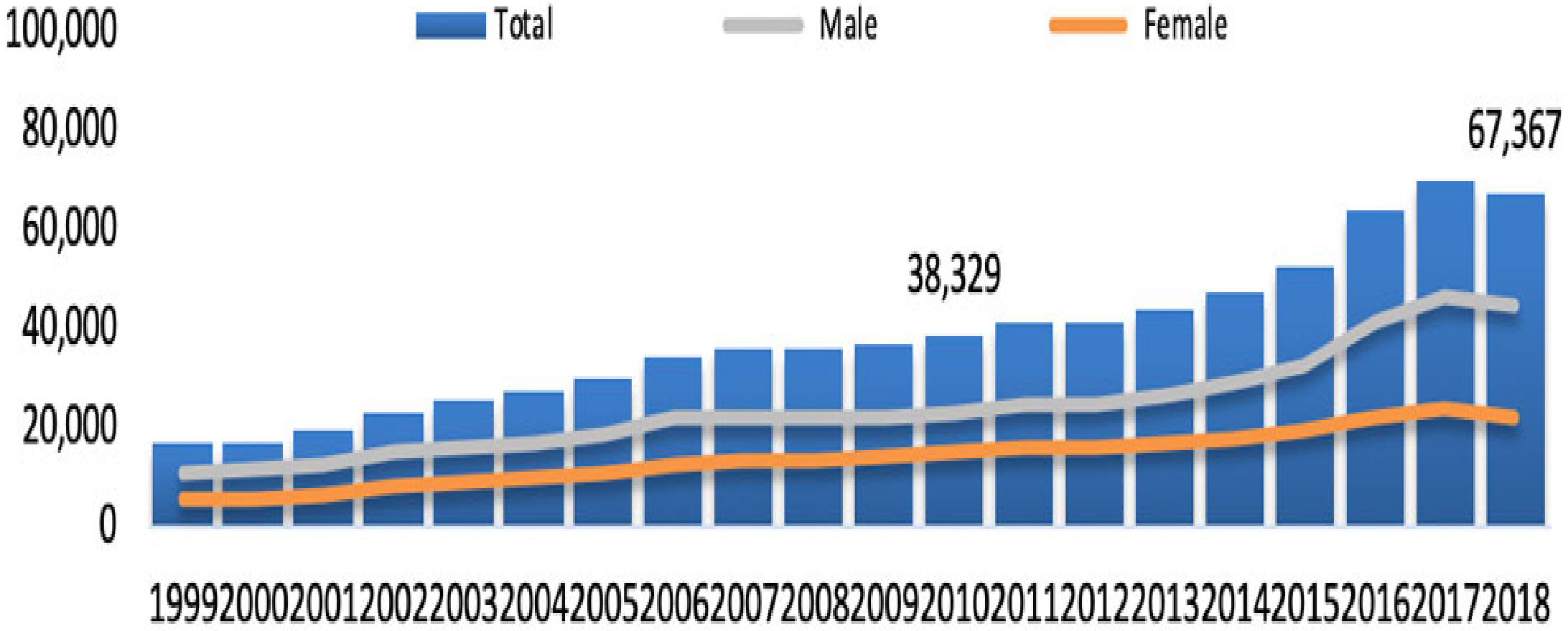
Drug Overdose Deaths in Tennessee



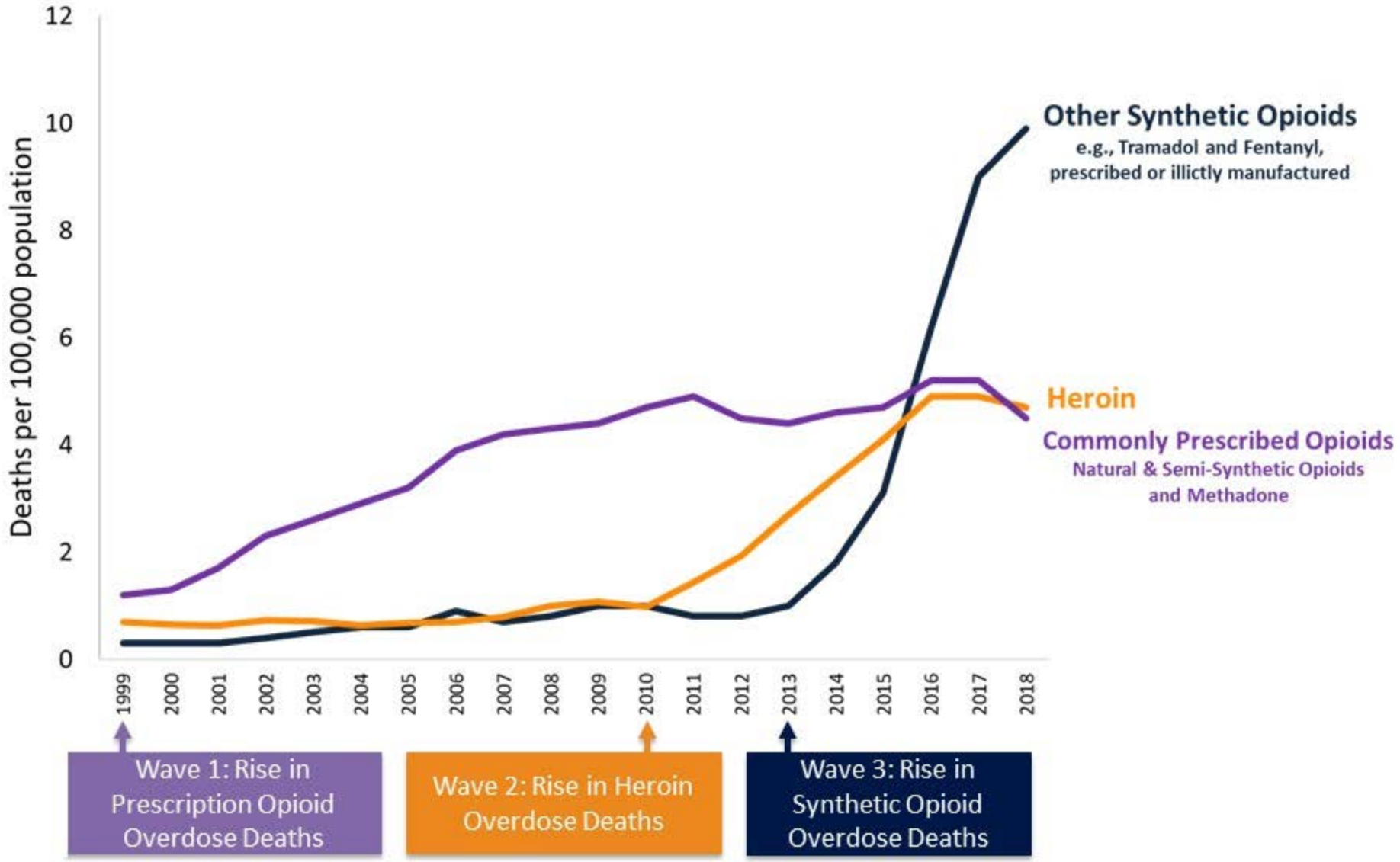
Source: Tennessee Department of Health, Office of Informatics and Analytics

National Drug Overdose Deaths

Number Among All Ages, by Gender, 1999-2018

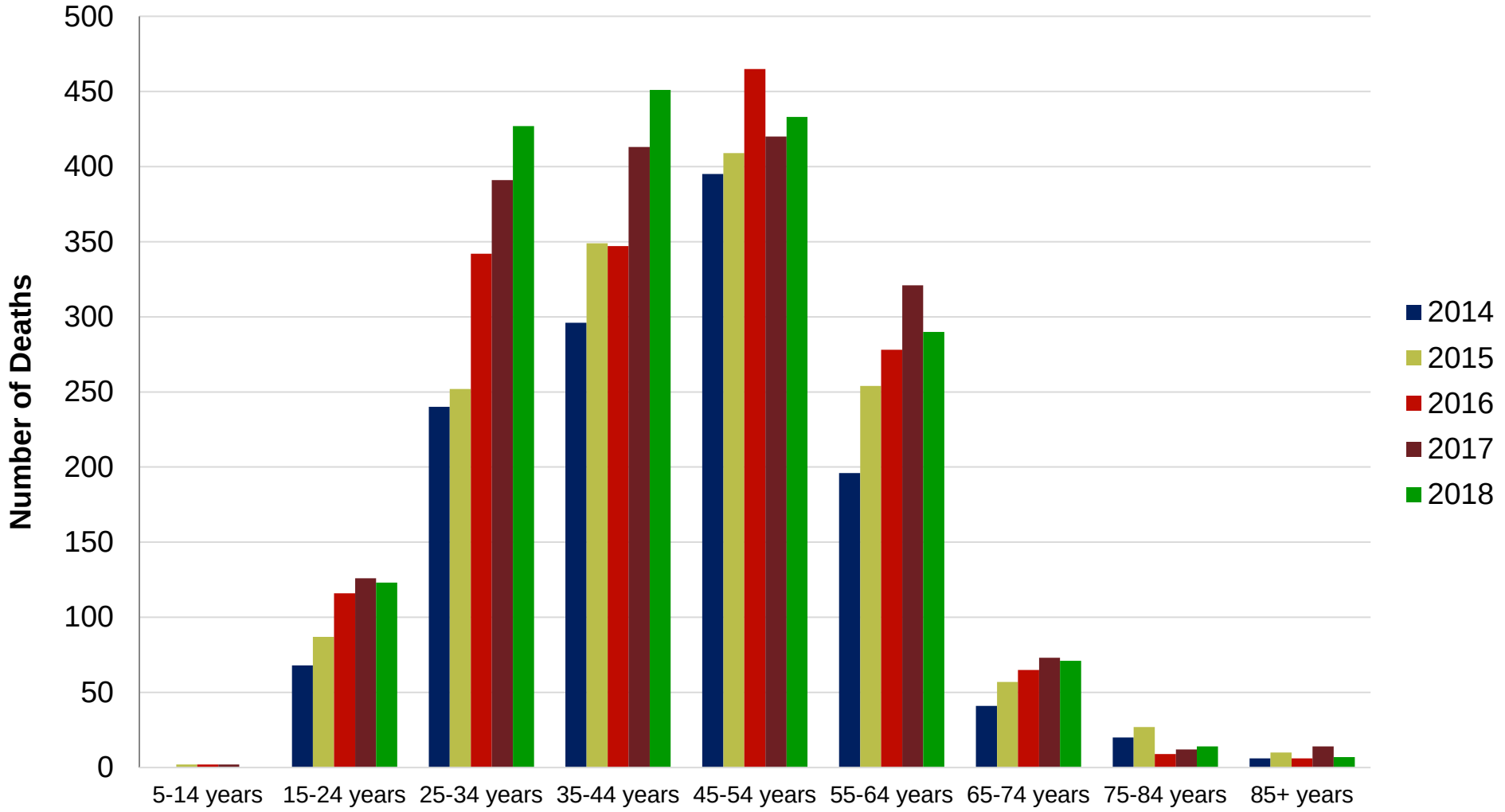


3 Waves of the Rise in Opioid Overdose Deaths



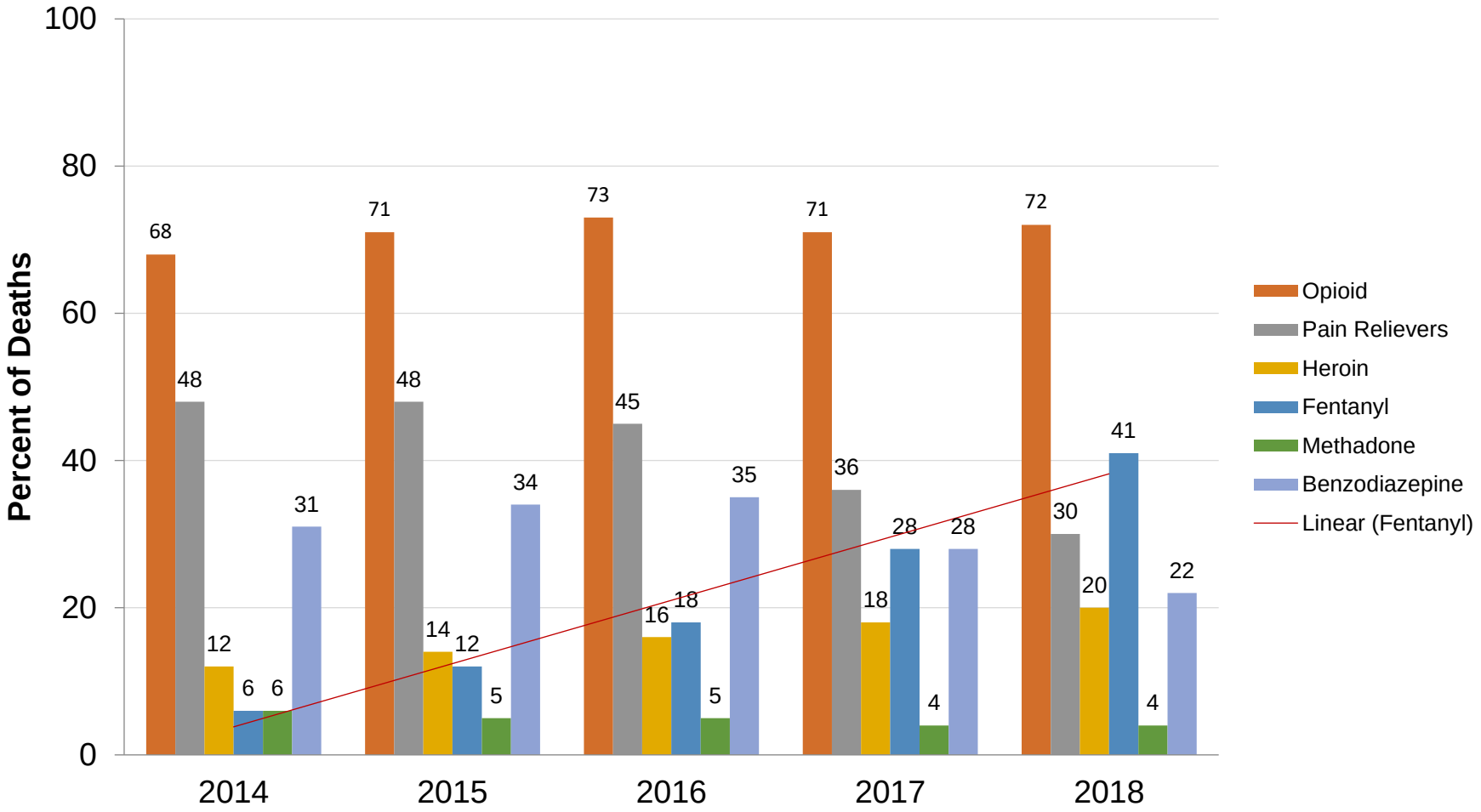
SOURCE: National Vital Statistics System Mortality File.

OD Deaths by Age Distribution



Source: Tennessee Department of Health, Office of Informatics and Analytics

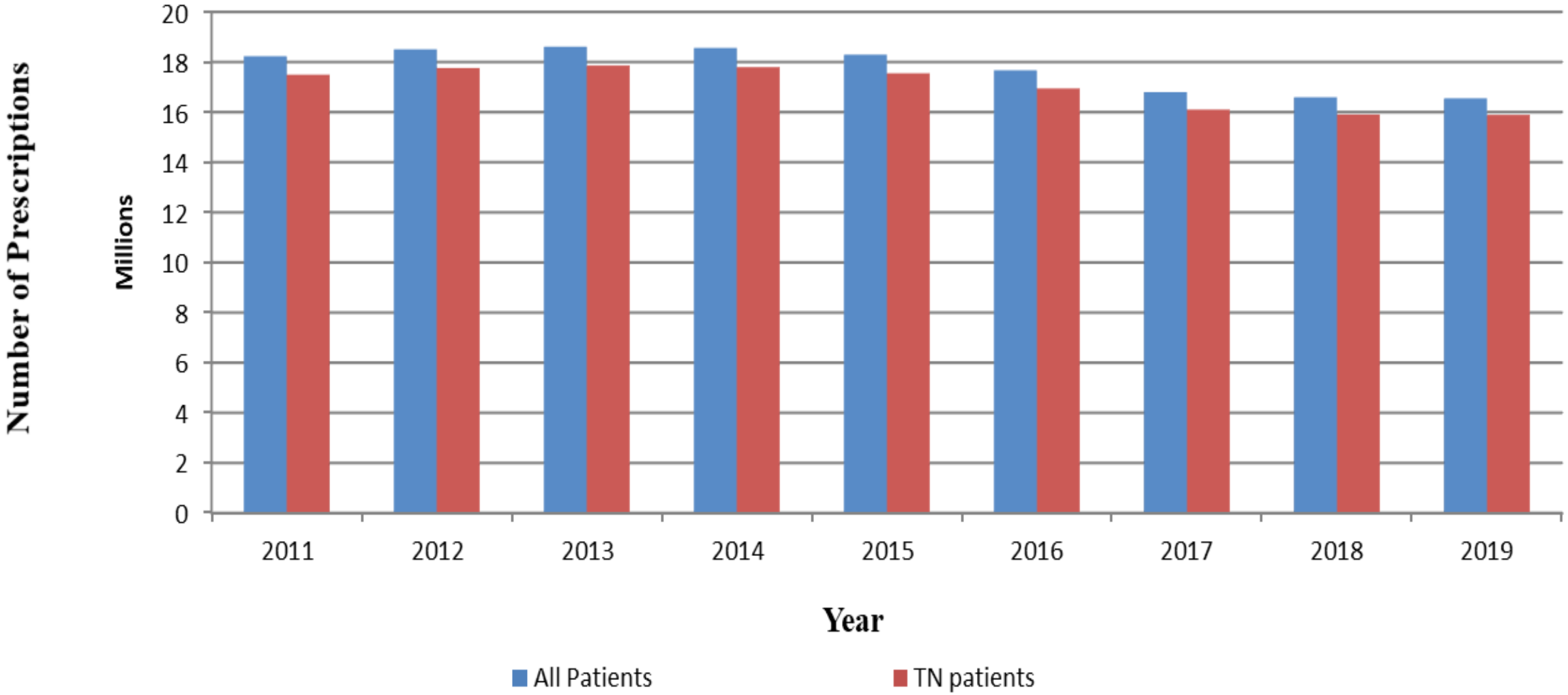
Trends in overdose deaths by drug type



Drug types are not mutually exclusive, so will not sum to 100%

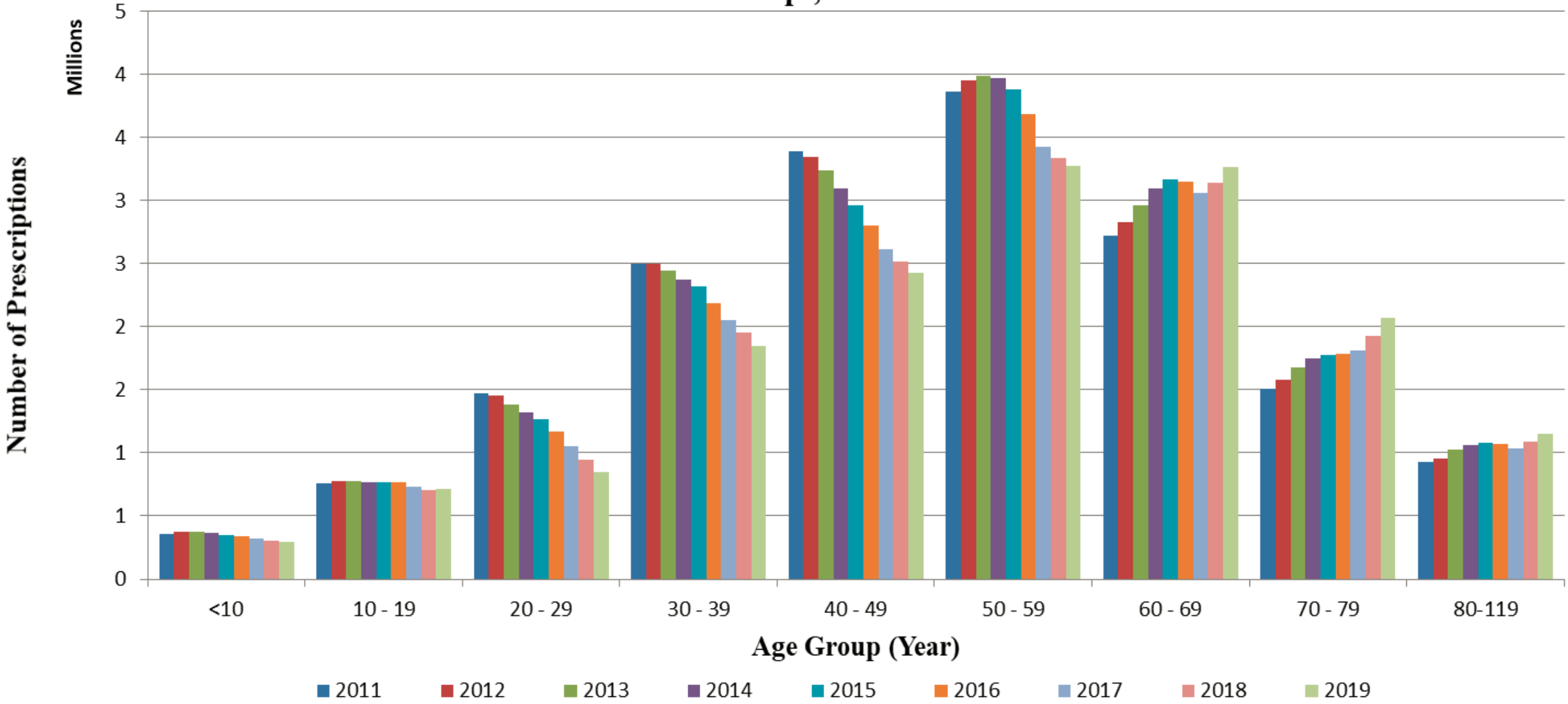
Source: Tennessee Department of Health, Office of Informatics and Analytics

Number of Prescriptions Dispensed in TN and Reported to TN CSMD, 2011-2019*



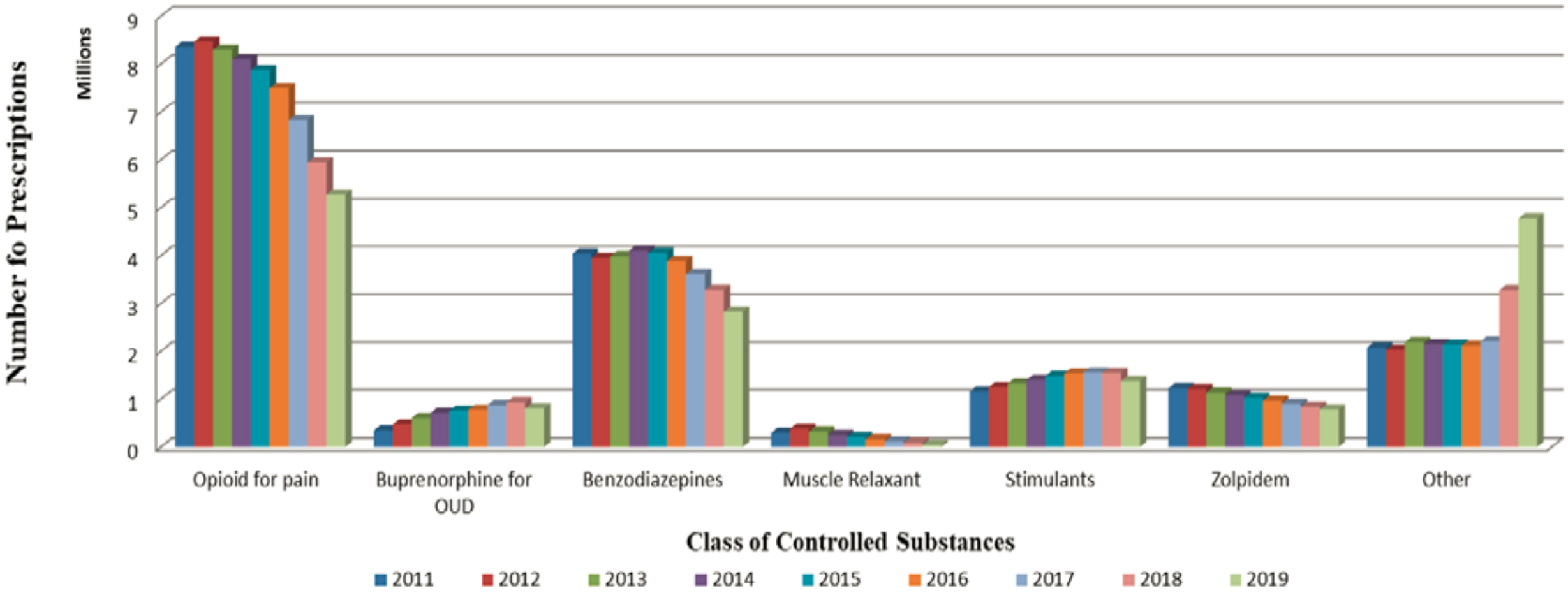
*Excluding prescriptions reported from VA pharmacies; Gabapentin reporting started July 1, 2018

Number of Prescriptions Dispensed among TN Patients and Reported to TN CSMD by Age Group , 2011-2019*



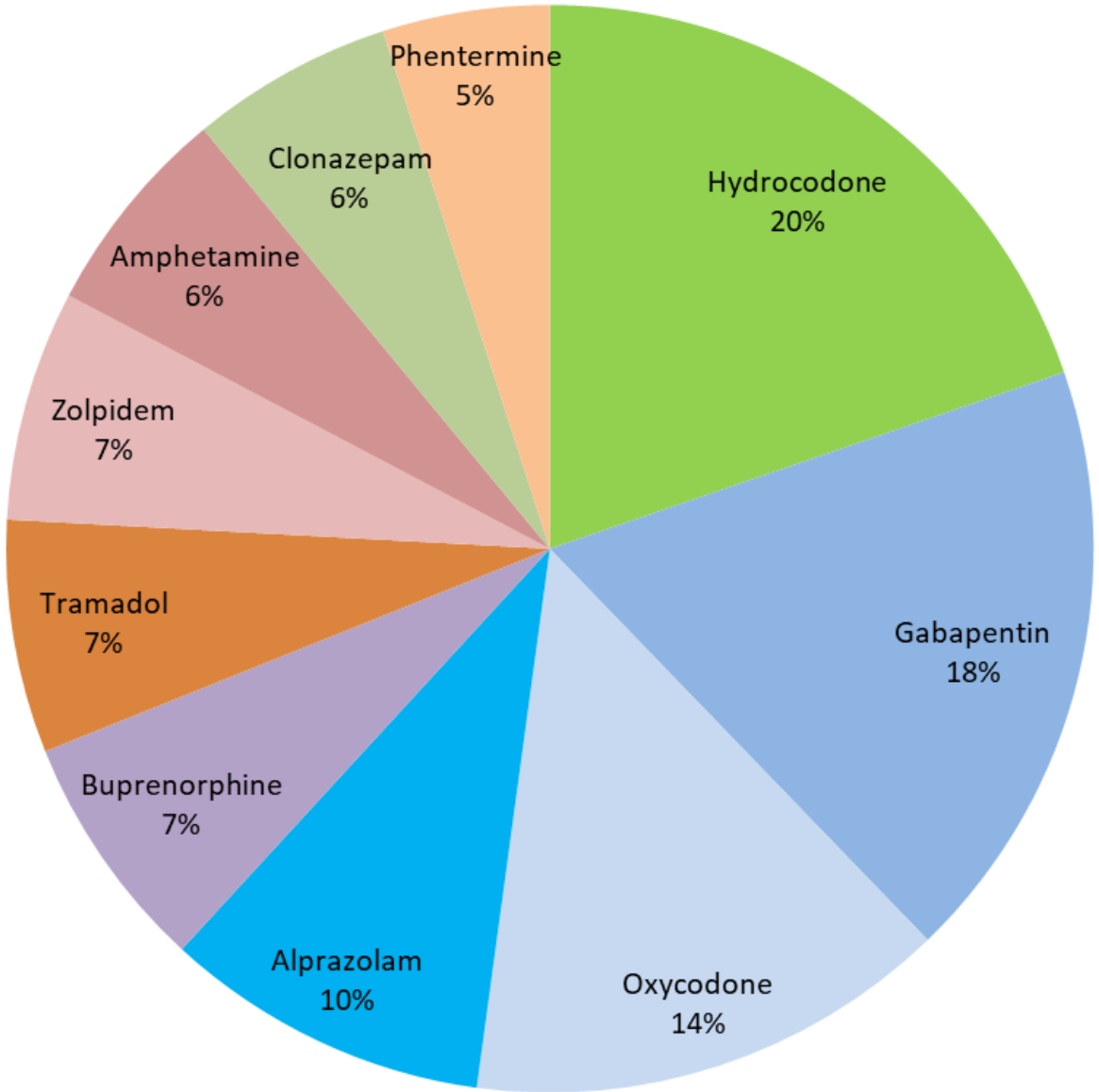
*Excluding prescriptions reported from VA pharmacies.

Number of Prescriptions Dispensed among TN Patients and Reported to TN CSMD by the Class of Controlled Substances, 2011-2019*



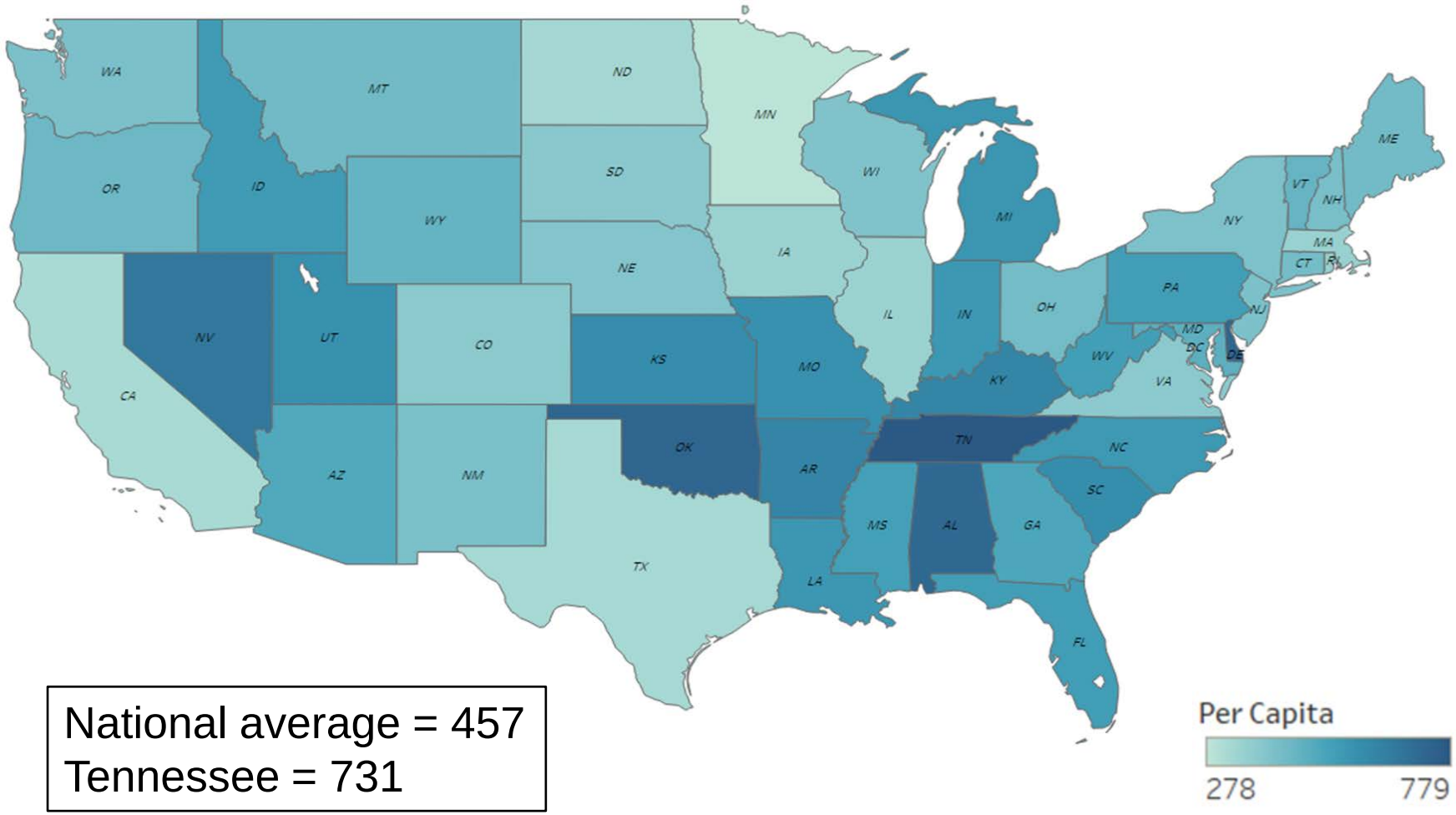
* The class of controlled substances was defined based on a CDC document. If a drug was not on the document, the drug was grouped into the 'Other'; Excluding prescriptions reported from VA pharmacies.

Distribution of the Top 10 Most Frequently Prescribed Controlled Substances Products in TN CSMD in 2019*



* Excluding prescriptions reported from VA pharmacies.

Opioid Morphine Milligram Equivalents per Capita, 2019



National average = 457
Tennessee = 731

Source: IQVIA *Xponent*, 2019

MME for Long Acting Opioids Reported to the CSMD

Amount of MME for Long Acting Drugs Dispensed in TN and Reported to the CSMD, 2011-2019*			
Year	Overall patients in CSMD	TN patients	Change among TN patients (%)
2011	3,254,786,743	3,121,293,556	-
2012	3,285,062,156	3,148,353,468	0.9
2013	3,238,216,544	3,106,161,557	-1.3
2014	2,924,795,127	2,806,107,045	-9.7
2015	2,552,291,111	2,454,148,868	-12.5
2016	2,124,916,097	2,045,899,859	-16.6
2017	1,630,298,000	1,568,894,509	-23.3
2018	1,204,793,575	1,162,067,475	-25.8
2019	861,215,258	831,818,929	-28.6
2011 - 2019			-73

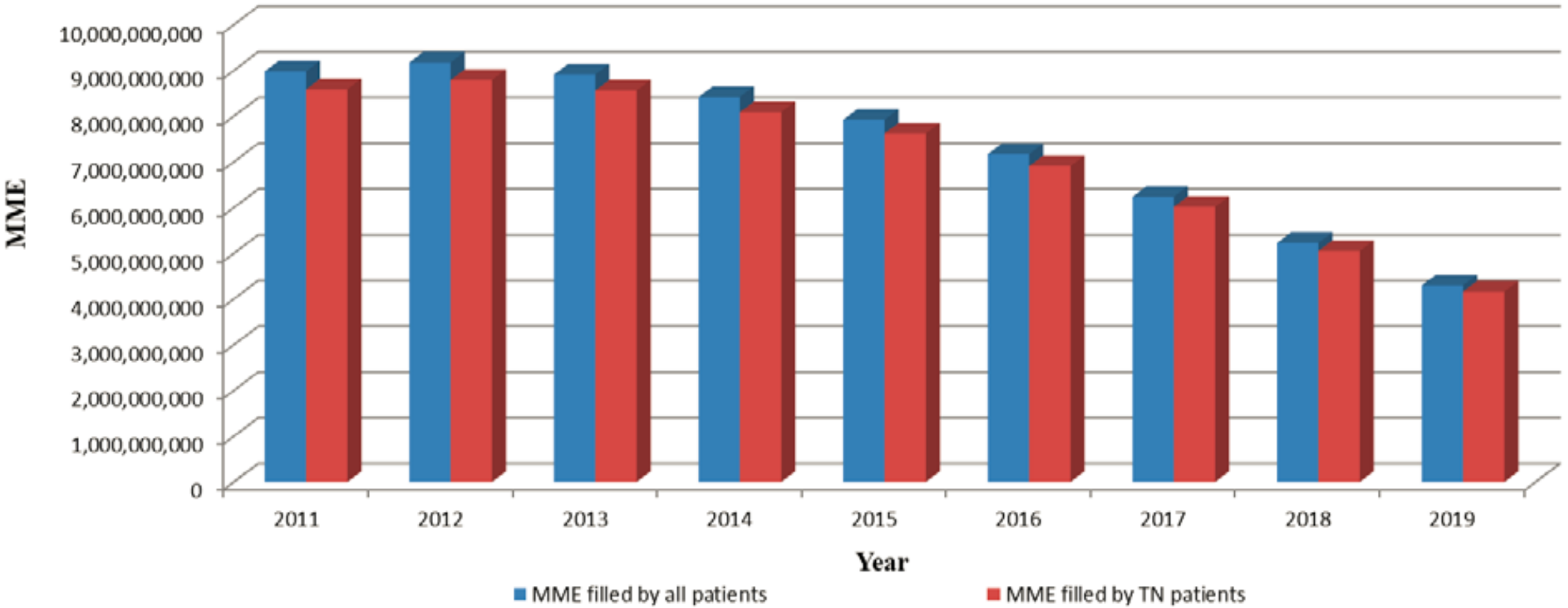
* 1) The classes of controlled substances were defined based on a CDC document;
  2) Excluding prescriptions reported from VA pharmacies.
  3) Excluding buprenorphine products.

MME for Short Acting Opioids Reported to the CSMD

Amount of MME for Short Acting Drugs Dispensed in TN and Reported to the CSMD, 2011-2019*			
Year	Overall patients in CSMD	TN Patients	Change among TN Patients (%)
2011	5,727,903,926	5,469,306,918	-
2012	5,891,039,406	5,645,050,796	3.2
2013	5,676,117,306	5,459,300,461	-3.3
2014	5,495,823,563	5,283,695,020	-3.2
2015	5,371,326,766	5,168,525,477	-2.2
2016	5,046,357,775	4,863,320,231	-5.9
2017	4,606,843,191	4,448,492,750	-8.5
2018	4,025,049,294	3,890,868,224	-12.5
2019	3,438,870,781	3,331,205,043	-14.3
2011 - 2019			-39.1

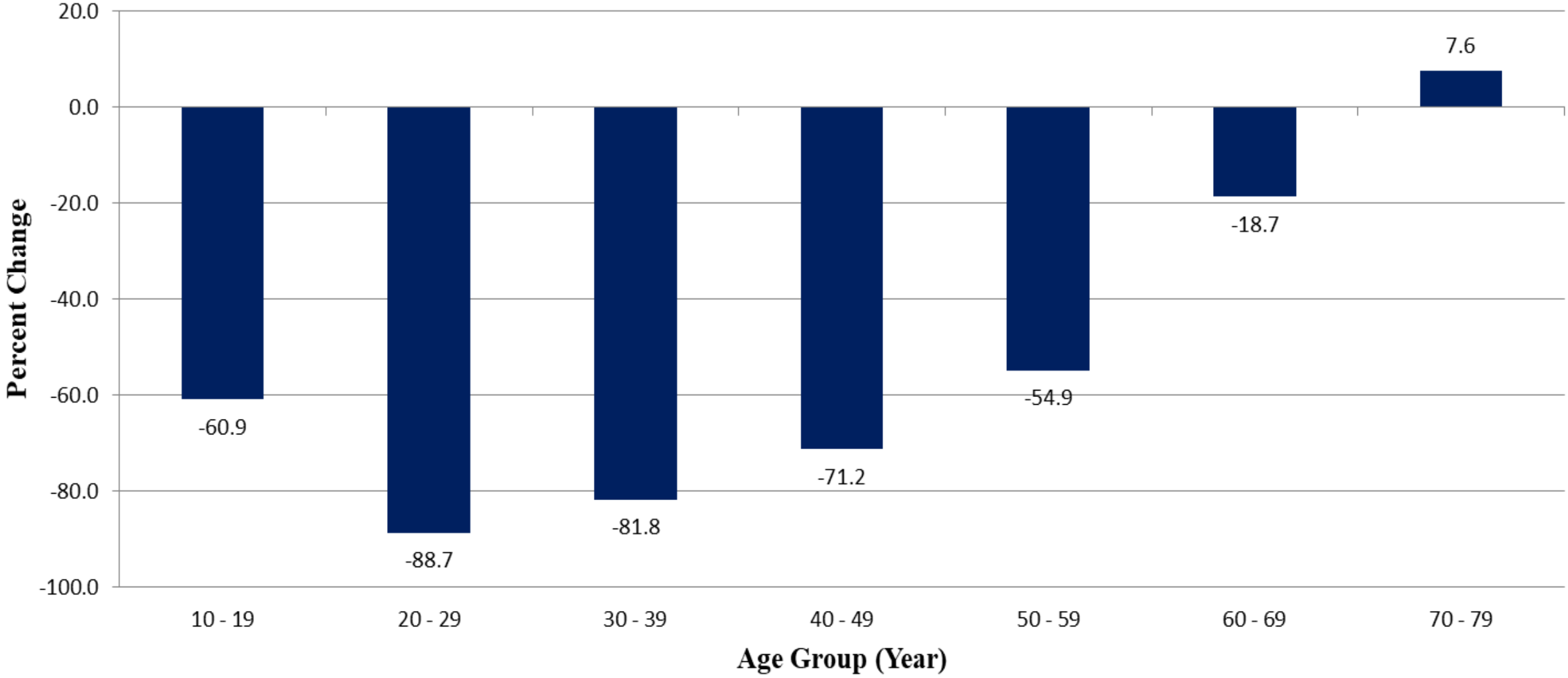
* 1) The classes of controlled substances were defined based on a CDC document;
2) Excluding prescriptions reported from VA pharmacies.
3) Excluding buprenorphine products.

MME of Opioids Reported to TN CSMD, 2011-2019*



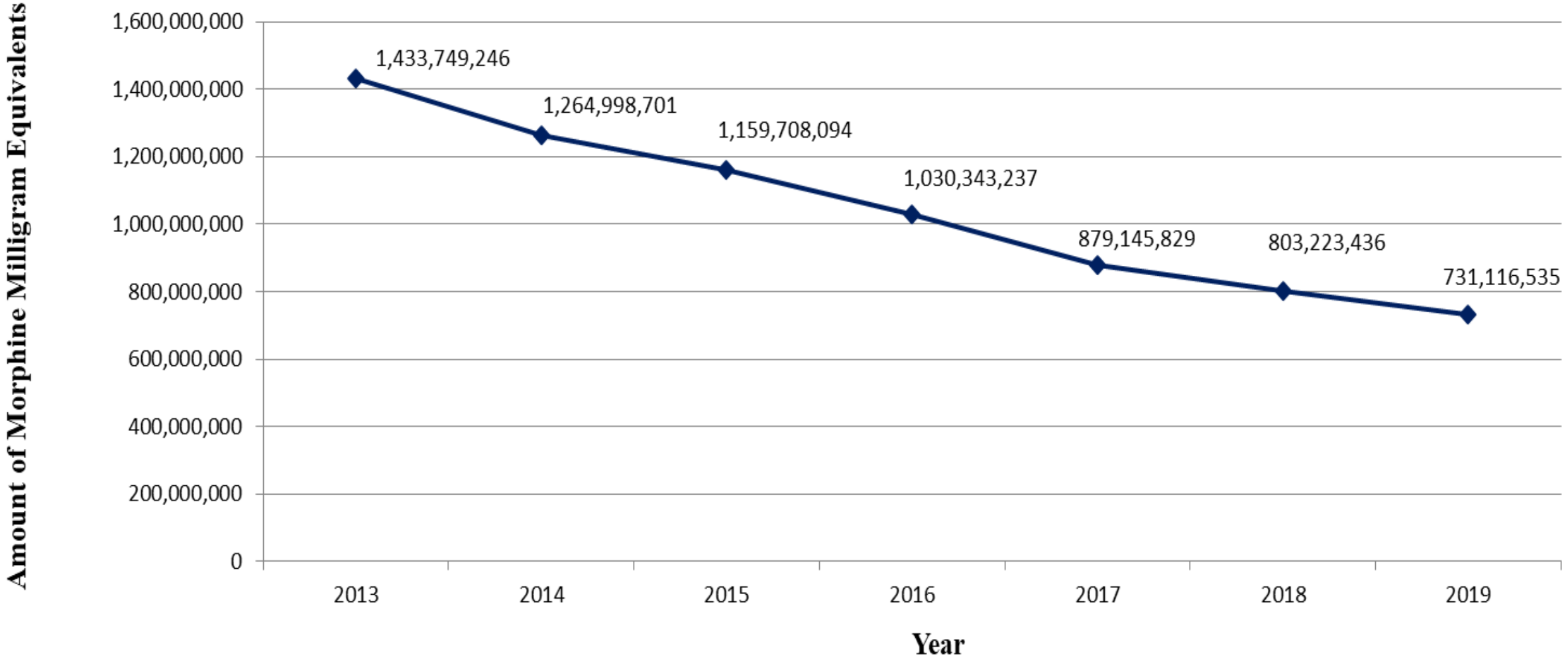
* Excluding prescriptions reported from VA pharmacies; Excluding buprenorphine products.

Change in Morphine Milligram Equivalents Dispensed among TN Patients by Age Group, 2011 VS. 2019*



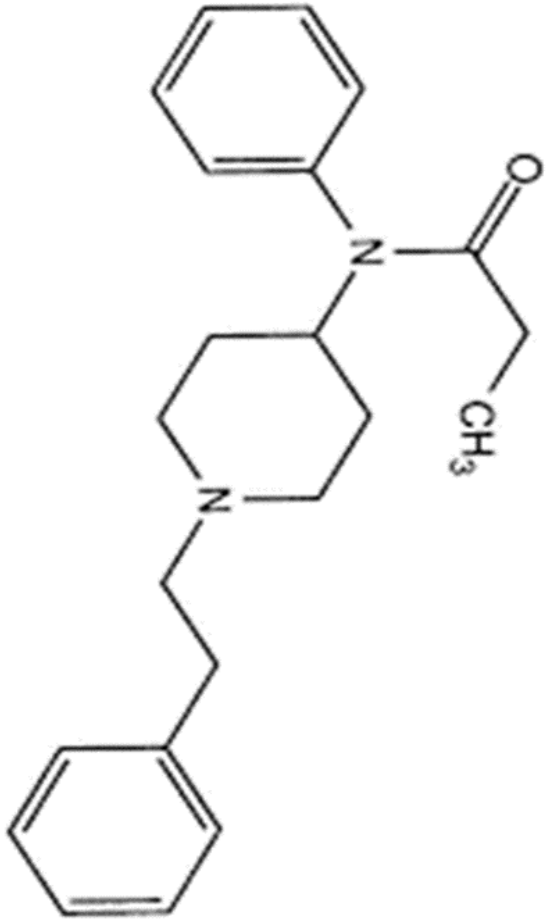
* Excluding prescriptions reported from VA pharmacies; Excluding buprenorphine products.

MMEs Prescribed by Top 50 Prescribers*

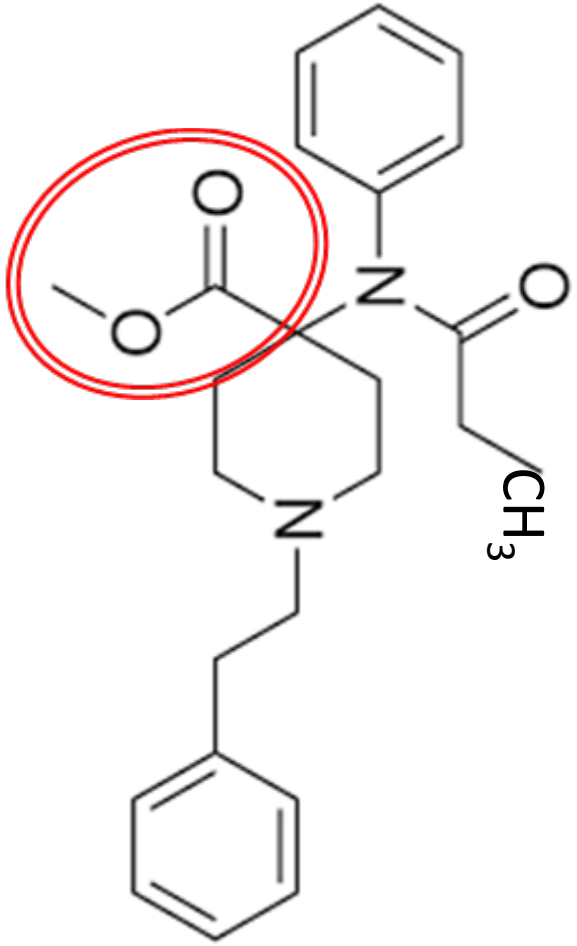


*MME in 2013 and 2014 covered 12-month opioid prescriptions written by the top 50 prescribers from April 1 of preceding year to March 31 of current year; MME in 2015, 2016, 2017, 2018 and 2019 covered opioid prescriptions filled by the patients of the top 50 prescribers in each preceding calendar year .

Fentanyl

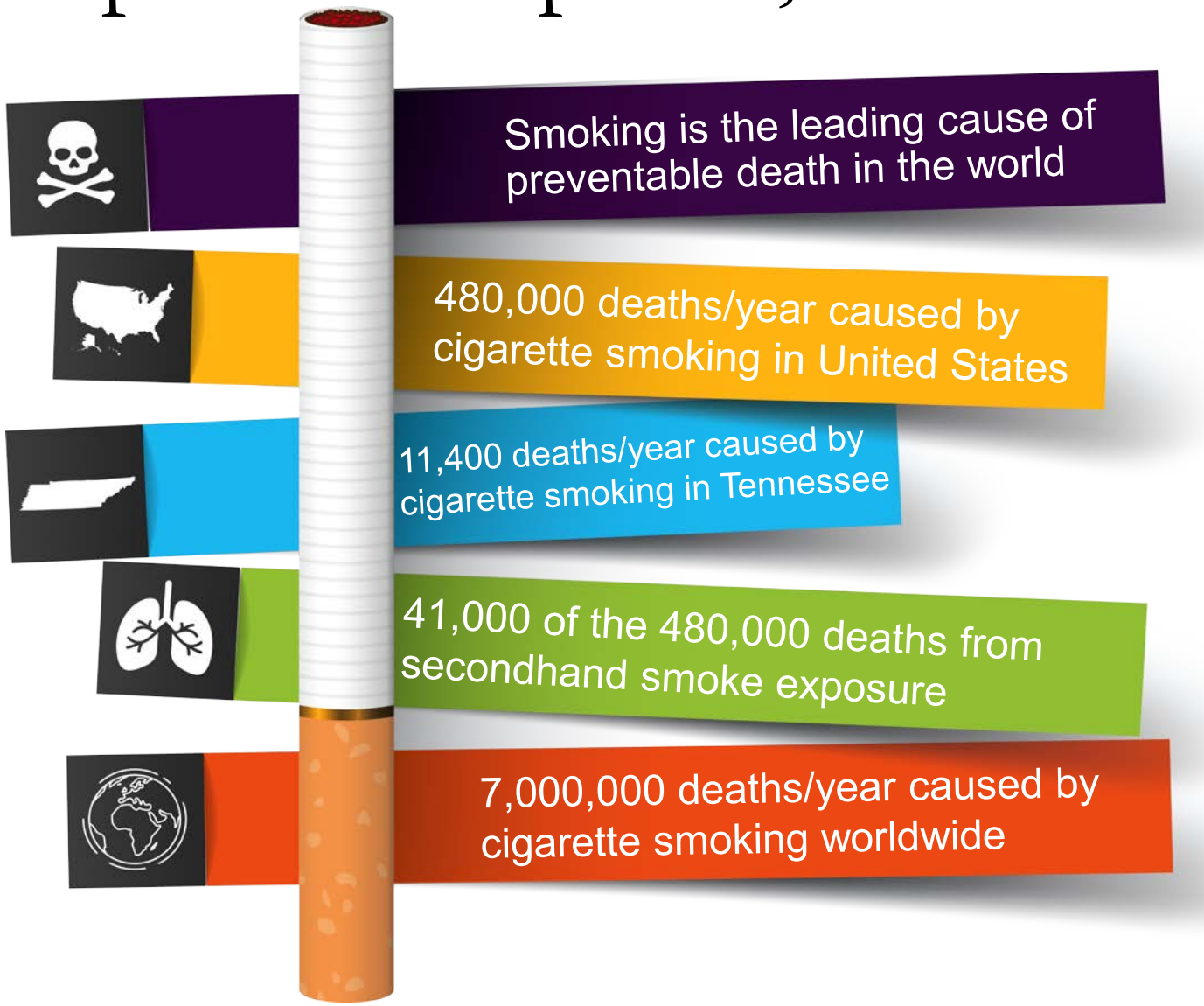


Carfentanil



Lethal Doses of Fentanyl & Carfentanil

Compared to Opioids, Nicotine…



Dangers of Fentanyl

Direct substitute for heroin or opioid addiction

Dose required for euphoric effect also induces respiratory depression

Requires an “accurate cut” which is almost impossible clandestinely

Utilized as cutting agent for heroin, methamphetamine, cocaine, and counterfeit

Physical characteristics present significant hazards

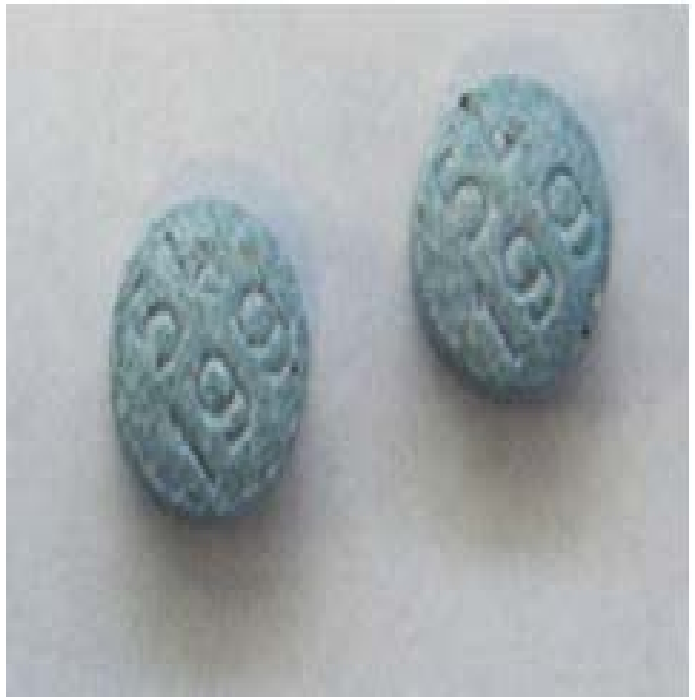
Source: Tennessee Bureau of Investigation

Alprazolam or Fentanyl

Counterfeit Fentanyl Laced

Genuine Alprazolam

Can You Tell the Difference?



Counterfeit Fentanyl Laced

Oxycodone 30 mg

Mobile Pill Manufacturing Plant

Morphine Milligram Equivalents

Opioid conversion factor to Morphine	Dosage	Frequency	MME/Day	Total MME from a 3-day Rx
Oxycodone 1.5 = 1	5 mg	TID	22.5 MME	67.5 MME
	10mg	TID	45 MME	135 MME
Hydrocodone 1 = 1	5 mg	TID	15 MME	45 MME
	10 mg	QID	40 MME	120 MME
Hydromorphone 4 = 1	4 mg	QID	64 MME	192 MME

What about Tramadol?

The U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH) classify Tramadol as an opioid analgesic used for the therapy of mild-to-moderate pain. It is now considered a controlled substance for purposes of reporting to the CSMD.

Tramadol	100mg = 10mg of Morphine (10MME)

Legislative Mandates

2010 PC 663 Dr. Shopping reporting

2011 PC 340 Pain clinic rules

2012 PC 880 TN Rx Safety Act. All Rx'ers with DEA # must register in CSMD (PMP)

2012 PC 961 Interventional Pain Management

2013 PC 430 Requires two hour CME related to controlled substance prescribing, limits Rx's for Opioids and Benzodiazepines to 30 days, requires the BME to develop the Chronic Pain Guidelines.

2013 PC 840 CSMD (PMP)

2016 PC 1002 TN Prescription Safety Act of 2016 – Must query the CSMD at least yearly

2016 PC 1033 Pain clinics require license held by Medical Director, no pharmacy present

2017 PC 112 Non residential Buprenorphine Treatment guidelines

2017 PC 355 Disposal of Rx Drugs

2018 PC 901 Requirements for > 3 day supply or 180MME

2018 PC 978 Revises Non residential Buprenorphine Treatment

2018 PC 1007 Partial Fill of opioid prescription

2018 PC 901 Requires education for women of child bearing age prior to Rx'ing an opioid

2018 PC 1039 TN Together: Time and MME limits & Opioid Rx'ing requirements.

2019 PC 124 **Electronic prescribing requirements, drop 20 day option.**

RED = Major Influence on decreasing MME

CHAPTER NO. 327
HOUSE BILL NO. 1896
By Representative Maddox
Substituted for: Senate Bill No. 1869 By Senator Herron

AN ACT to amend Tennessee Code Annotated, Title 39, Title 53, Title 63 and Title 68, relative to intractable pain.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, is amended by adding Sections 2 through 11, inclusive as a new part to be appropriately designated.

SECTION 2. This part may be known and cited as the "Intractable Pain Treatment Act".

…Passed May 21, 2001

2010 Tennessee Code
Title 63 - Professions Of The Healing Arts
Chapter 6 - Medicine and Surgery
Part 11 - Intractable Pain Treatment

- 63-6-1101 - Short title.
- 63-6-1102 - Part definitions.
- 63-6-1103 - Legislative declarations.
- 63-6-1104 - Pain patient's bill of rights.
- 63-6-1105 - Physician authorized to write prescriptions.
- 63-6-1106 - Disciplinary action against physicians.
- 63-6-1107 - Treatment of chemically dependent individuals.
- 63-6-1108 - Physician discipline for inappropriate use.
- 63-6-1109 - Use of physician assistants or other personnel Licensing Continued education.
- 63-6-1110 - Violation of federal law is not authorized.
- 63-6-1111 - Authorization for rules and regulations.

https://law.justia.com/codes/tennessee/2010/title-63/chapter-6/part-11/

Tennessee Code
Title 63 - Professions Of The Healing Arts, Chapter 6 - Medicine and Surgery, Part 11 – Intractable Pain Treatment 63-6-1104 - Pain patient's bill of rights.

63-6-1104. Pain patient's bill of rights.

(a) This section may be known and cited as the Pain Patient's Bill of Rights.

b) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve such patient's severe chronic intractable pain.

(c) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve severe chronic intractable pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the provisions of this part.

(d) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

(e) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain, as long as that prescribing physician is in conformance with this part.

(f) A patient may voluntarily request that such patient's physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(g) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in this chapter or the regulations adopted thereunder; or

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

[Acts 2001, ch. 327, § 5.]

2015 Tennessee Code
Title 63 - Professions Of The Healing Arts
Chapter 6 - Medicine and Surgery

Part 11 - Intractable Pain Treatment Act [Repealed]
§ 63-6-1104 - [Repealed]

HISTORY: Acts 2001, ch. 327, § 5; repealed by Acts 2015, ch. 26, § 1, effective July 1, 2015

Tennessee Chronic Pain Guidelines

- Indicated for primary care, not pain specialists
- Are accepted medical practice
- Available online at Tennessee Department of Health website

https://www.tn.gov/content/dam/tn/health/documents/ChronicPainGuidelines.pdf

Disclosure: Dr. Baron is on the Steering Committee for CPG

Tennessee Chronic Pain Guidelines

- SECTIONS I, II, III
- APPENDICIES
  - CORE COMPETENCIES
  - TN TOGETHER
  - PAIN MEDICINE SPECIALIST
  - MENTAL HEALTH ASSESSMENT TOOLS
  - MEDICATION ASSISTED TREATMENT PROGRAM
  - WOMEN'S ISSUES: WOMEN OF CHILD BEARING AGE
  - PREGNANT WOMEN
  - RISK ASSESSMENT TOOLS
  - CSMD:
  - SAMPLE INFORMED CONSENT: Controlled Substance Agreement
  - SAMPLE PATIENT AGREEMENT: Controlled Substance Treatment
  - URINE DRUG TESTING
  - TAPERING PROTOCOL
  - MORPHINE EQUIVALENT DOSE
  - NALOXONE
  - SAFETY NET
  - PRESCRIPTION DRUG DISPOSAL
  - USE OF OPIOIDS IN WORKERS' COMPENDSATION MEDICAL CLAIMS
  - MEDICAL TREATMENT GUIDELINES FOR PAIN MANAGEMENT FOR WORKERS' COMPENSATION
  - CHRONIC PAIN GUIDLINE ALGORITHYM WOMEN'S HEALTH
  - CHRONIC PAIN GUIDLEINE ALGORYTHYM OPIOID THERAPY
  - NON-OPIOID THERAPIES
  - ACUTE PAIN
  - PERIOPERATIVE PAIN MANAGEMENT
  - TENNESSEE EMERGENCY DEPARTMENT OPIOID PRESCRIBING GUIDELINES
  - PEDIATRIC PAIN
  - TERMS/DEFINITIONS
  - LINKS
  - REFERENCES

Tennessee Chronic Pain Guidelines

Section	
I	**Prior to Initiating** Opioid Therapy for Chronic Non-Malignant Pain
II	**Initiating** Opioid Therapy for Chronic Non-Malignant Pain
III	**Ongoing** Opioid Therapy for Chronic Non-Malignant Pain

PC 1039 and PC 124 Requirements

"Tennessee Together" Bill and update

4 categories for prescribing opioids:

I. Up to 3 days or up to 180 MME
II. Up to 10 days or up to 500 MME
III. Up to 30 days or up to 1200 MME – more than minimally invasive surgery
IV. Up to 30 days or up to 1200 MME – Medical Necessity

Exemptions

- Treated with an opioid ≥ 90 days in the last year
- Active Cancer, Palliative Care, Hospice Care
- Sickle Cell Disease
- Treated by a pain management specialist
- Treated for OUD with MAT – Buprenorphine or Methadone
- Patients with “Severe Burns” or “Major Physical Trauma”
- Administration in a licensed healthcare facility

PC 124

Effective January 1, 2021 - All Schedule II, III, IV & V **must** be electronically prescribed

Defined

- Severe Burn
- Major Physical Trauma
- Palliative Care
- Serious Illness

May prescribe up to 14 days for the treatment of upper respiratory infection (URI)

(codeine preparations for cough)

PC 124

Palliative Care	Specialized treatment for patients facing serious illness, which focuses on providing relief of suffering through a multidisciplinary approach to maximize quality of life
Serious Illness	Health condition that carries a high risk of mortality and negatively impacts a patient's daily bodily functions
Severe Burn	Injury sustained from thermal or chemical causes resulting in second degree or third-degree burns
Major Physical Trauma	Serious injury sustained due to blunt or penetrating force resulting in serious blood loss, fracture, significant temporary or permanent impairment, or disability

Evidence-Based Medicine

Opioids:

No prospective study has clearly demonstrated long-term safety or long-term efficacy in terms of analgesia or functional improvement.

Long-term Opioid Therapy for Neuropathy

“Long-term opioid therapy did not improve functional status but rather was associated with a higher risk of subsequent opioid dependency and overdose.”

AMA Neurol. 2017;74(7):773-779. doi:10.1001/jamaneurol. 2017. 0486
Published online May 22, 2017.

Thank you

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