Z91.83

Wandering in diseases not classified elsewhere

The Oklahoma Opioid Crisis and SB848

Layne Subera, DO, MA, FACOFP

Oklahoma State Board of
Medical Licensure and
Supervision
Guidelines for providing onehour CME required for SB 1446

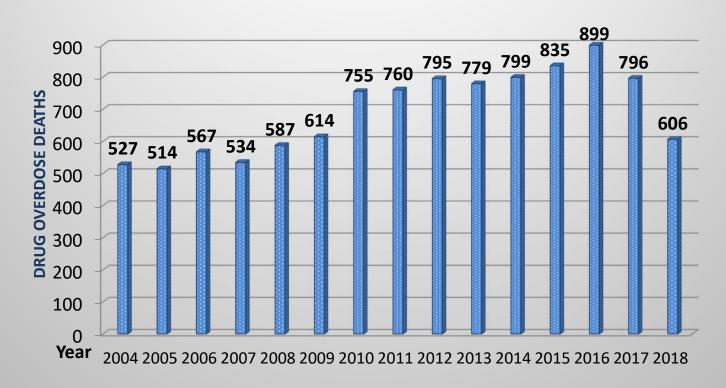
Adopted March 7, 2019

Objective: Review the new prescribing requirements outlined in SB 1446 848

- 1. Initial 7 day prescription
- 2. Subsequent 7 day prescription
- 3. Requirements for a 3rd prescription
- 4. Requirements for monthly assessments and 3 month prescriptions
- 5. Opioid Qualifying Patients

OBN

STATE OF OKLAHOMA DRUG DEATHS 15 YEAR COMPARISON



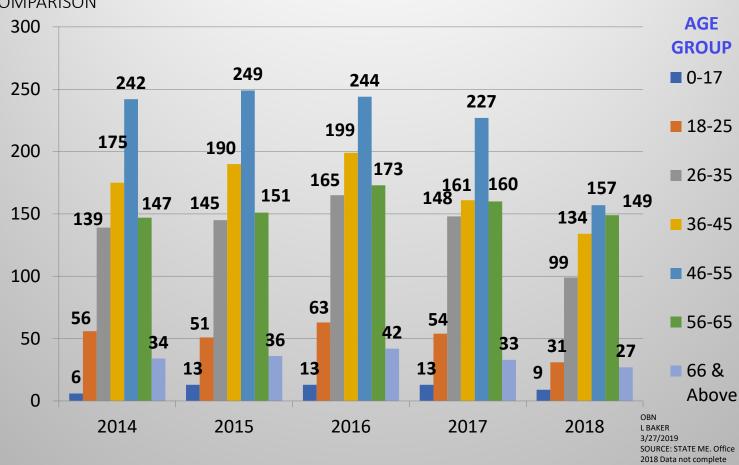
OBN L Baker 3/4/2019 Source: State ME 2018 Data is not complete.

OBN

STATE OF OKLAHOMA

DRUG DEATHS
BY AGE GROUP

5 YEAR COMPARISON

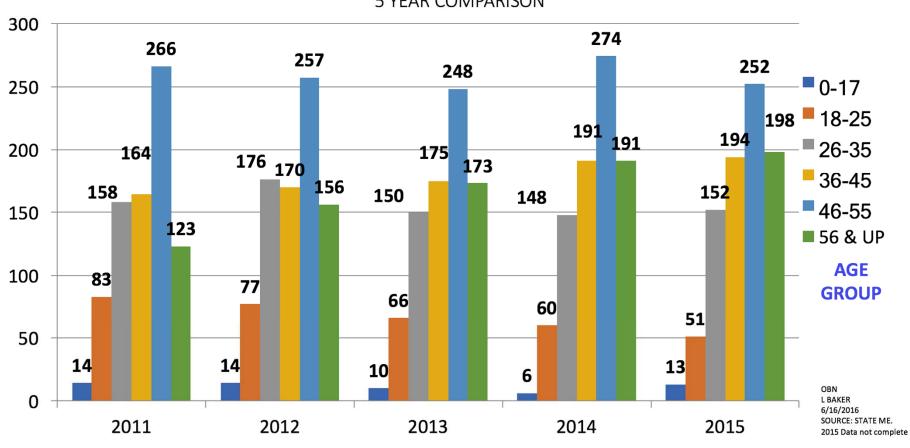


STATE OF OKLAHOMA

DRUG OVERDOSE DEATHS

BY AGE GROUP

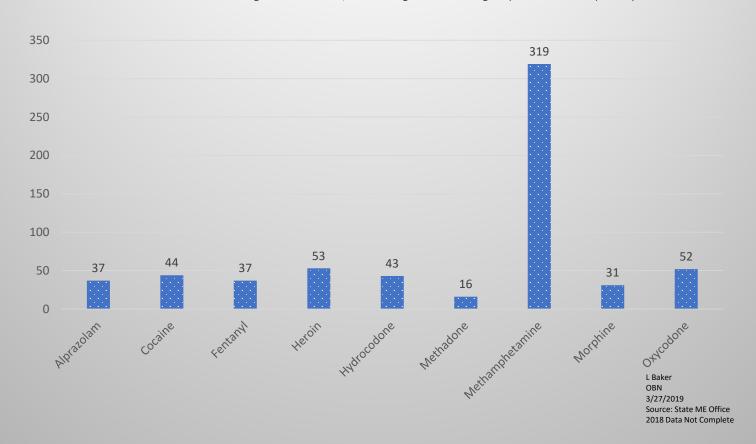
5 YEAR COMPARISON



OBN

STATE OF OKLAHOMA 2018 DRUG DEATHS INVOLVING THE TOP 9 ABUSED DRUGS

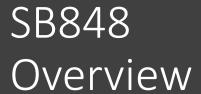
The majority of all drug overdose deaths are due to a combination "cocktail" of drugs rather than just one specific drug. This chart reflects the total number of deaths each drug was involved in, even though another drug may have been the primary cause of death.



SB848

An Act relating to the regulation of opioid drugs

Rader and Sharp of the Senate and Echols of the House





Improves SB1446.



83 pages (SB1446 was 35 pages.)



Uniform Controlled Substances Act.



Some violations involve criminal law.

Deborah J. Bruce, J.D., CMBE, Executive Director, Oklahoma Board of Osteopathic Examiners

FOR THE FIRST TIME IN OKLAHOMA HISTORY THERE IS A STATUTE THAT SPECIFICALLY **CRIMINALIZES** THE CONDUCT OF "PHYSICIANS" WHO MAY BE EXERCISING APPROPRIATE MEDICAL JUDGMENT.

Fake News? Pages 1-7 of SB1446 amends ONLY the Allopathic Medical Act, 59 O.S. § 495.1. No other regulatory agency is affected in any way. SB1446, pages 7-34, amend or add new regulations to the Uniform Controlled Dangerous Substances Act [UCDSA], 63 O.S. § 2-101. This act provides penalties including fines and incarceration for physicians who violate its provisions. And, it can be enforced by any Oklahoma peace officer. 63 O.S. § 2-501.

This means that ANY police officer from any Oklahoma town or city...any county sheriff or deputy...any of the more than 50 Oklahoma District Attorneys "may arrest without warrant" any physician **suspected** of violating SB1446.

Title 63. Public Health and Safety §63-2-501. Powers of enforcement personnel.

Any peace officer may:

- 1. Carry firearms;
- 2. Execute search warrants, arrest warrants, subpoenas, and summonses issued under the authority of this state;
- 3. Make an arrest without warrant of any person the officer has probable cause for believing has committed any felony under the Uniform Controlled Dangerous Substances Act or a violation of Section 2-402 of this title;
- 4. Make seizures of property pursuant to the provisions of the Uniform Controlled Dangerous Substances Act;
- 5. Perform such other lawful duties as are required to carry out the provisions of the Uniform Controlled Dangerous Substances Act;
- 6. Conduct investigations and make an arrest of any person the officer has probable cause to believe is involved in money laundering activities, as otherwise set forth by laws of this state; and

https://law.justia.com/codes/oklahoma/2014/title-63/section-63-2-501/

SB848: Sections 1-15

Amends 59 O.S. 2011

Continuing Medical Education



The Board shall require that the licensee receive not less than:

One (1) hour of education in pain management or addiction every one (1) year of licensure.



The CME is needed preceding an application for renewal of a license.



Required UNLESS the licensee does not hold a valid DEA number.



Reference: SB848 p. 4

SB848: Sections 5, 6, and 13

Amends 59 O.S. 2011

Unprofessional Conduct Additions - MDs

- Over-prescribing opioids.
 - Prescribing, dispensing or administering controlled substances or narcotic drugs without medical need in accordance with:
 - Published standards,
 - Pertinent licensing board standards and,
 - Prescribing, dispensing or administering opioid drugs in excess of the maximum dosage authorized under Section 5 of this act limits authorized in Section 2- 309I of Title 63 of the Oklahoma Statutes;
- Failure to check Prescription Monitoring Program (PMP) database.

authorized by a state or federal agency, or not in good faith to relieve pain and suffering, or not to treat an ailment, physical infirmity or disease, or violating any state or federal law on controlled dangerous substances <u>including</u>, but not limited to, prescribing, dispensing or administering opioid drugs in excess of the maximum limits authorized in Section 2-309I of Title 63 of the Oklahoma Statutes,

Unprofessional Conduct Additions - DOs

For DOs: Title 510:5-9-2 PRESCRIBING FOR CHRONIC PAIN

- 1. Allows treatment of a patient's intractable pain, as long as the benefit of the expected relief outweighs the risk, even if the use of the drug increases the risk of death.
- 2. Requires complete medical history and physical examination which includes an assessment of the patient's pain, physical and psychological function, substance abuse history, underlying or co-existing diseases or conditions and the presence of a recognized medical indication for the use of an analgesic.
- 3. The treatment plan must state objectives by which treatment success can be evaluated, such as pain relief and or improved physical and psychological function.
- 4. The course of treatment must be reviewed periodically, at least annually, with consideration given to referral for a current second opinion.
- 5. The management of intractable pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists.
- 6. Obtain informed consent prior to proceeding if treatment substantially increases the risk of death.
- 7. Accurate and complete records documenting these requirements must be kept.
- 8. The physician must be licensed in Oklahoma, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions.
- 9. Expert clinical testimony may be used to prove a violation of this rule. As used herein, a "clinical expert" is a physician who, by reason of specialized education or substantial relevant experience in pain management.
- 10. Nothing in this rule shall limit a physician's authority to prescribe or administer prescription drug products beyond the customary indications as noted in the manufacturer's package insert for use in treating intractable pain, provided the drug is recognized for treatment of intractable pain in standard reference compendia or medical literature.

TITLE 510. STATE BOARD OF OSTEOPATHIC EXAMINERS http://www.ok.gov/osboe/documents/RULES.pdf Accessed 9/11/18.

Unprofessional Conduct Additions - Pharmacists

- Upon receipt of a valid Schedule II opioid prescription issued pursuant to the provisions of Section 2-309I of Title 63 of the Oklahoma Statutes,
 - a pharmacist shall fill the prescription to the specified dose, and
 - shall not be permitted to fill a different dosage than what is prescribed.
- However, the pharmacist maintains the right not to fill the valid opioid prescription.

SB1446: Section 16

Amends 63 O.S. 2011, Section 2-101, as last amended by Section 1, Chapter 43, O.S.L. 2017 (63 O.S. Supp. 2017, Section 2-101)

27. "Opiate" or "opioid" means any Schedule II, III, IV or V substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does The terms do not include, unless specifically designated as controlled under the Uniform Controlled Dangerous Substances Act, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts (dextromethorphan). It does The terms do include its the racemic and levorotatory forms;

Opiate, opioid, etc.

(6) a physician assistant <u>or Advanced Practice</u>

<u>Registered Nurse</u> under the supervision of a licensed medical doctor or osteopathic physician,

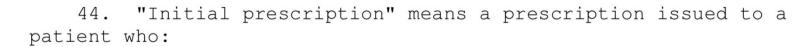
APRNs

42. "Acute pain" means pain, whether resulting from disease, accidental or intentional trauma or other cause, that the practitioner reasonably expects to last only a short period of time. "Acute pain" does not include chronic pain, pain being treated as part of cancer care, hospice or other end-of-life care, or pain being treated as part of palliative care;

Acute Pain

43. "Chronic pain" means pain that persists beyond the usual course of an acute disease or healing of an injury. "Chronic pain" may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years;

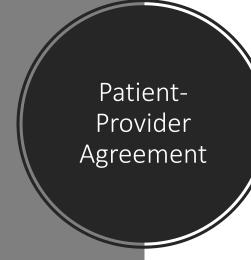
Chronic Pain





- a. has never previously been issued a prescription for the drug or its pharmaceutical equivalent in the past year, or
- b. requires a prescription for the drug or its pharmaceutical equivalent due to a surgical procedure or new acute event and has previously had a prescription for the drug or its pharmaceutical equivalent within the past year.
 - When determining whether a patient was previously issued a prescription for a drug or its pharmaceutical equivalent, the practitioner shall:
 - consult with the patient,
 - review the medical record and,
 - review the PMP.

SB848, p64-65



- "Patient-provider agreement" means a written contract or agreement that is executed between a practitioner and a patient, prior to the commencement of treatment for chronic pain... as a means to:
 - explain the possible risk of development of physical or psychological dependence in the patient and prevent the possible development of addiction,
 - document the understanding of both the practitioner and the patient regarding the pain-management plan of the patient,
 - establish the rights of the patient in association with treatment and the obligations of the patient in relation to:
 - the responsible use,
 - · discontinuation of use, and
 - storage of Schedule II controlled dangerous substances,
 - any restrictions on the refill of prescriptions
 - or the acceptance of Schedule II prescriptions from practitioners,
 - identify the specific medications and other modes of treatment... that are included as a part of the pain-management plan,
 - specify the measures the practitioner may employ to monitor the compliance of the patient:
 - including, but not limited to, random specimen screens and pill counts,
 - delineate the process for terminating the agreement.
- Compliance with the "consent items" shall constitute a valid, informed consent for opioid therapy.

with the terms of the agreement. Compliance with the "consent items" shall constitute a valid, informal informed consent for opioid therapy. The provider practitioner shall be held harmless from civil litigation for failure to treat pain if the event occurs because of nonadherence by the patient with any of the provisions of the patient-provider agreement;

Hold Harmless

46. "Serious illness" means a medical illness or physical injury or condition that substantially affects quality of life for more than a short period of time. "Serious illness" includes, but is not limited to, Alzheimer's disease or related dementias, lung disease, cancer, heart failure, renal failure, liver failure or chronic, unremitting or intractable pain such as neuropathic pain;

Serious Illness

47. "Surgical procedure" means a procedure that is performed for the purpose of structurally altering the human body by incision or destruction of tissues as part of the practice of medicine. This term includes the diagnostic or therapeutic treatment of conditions or disease processes by use of instruments such as lasers, ultrasound, ionizing, radiation, scalpels, probes or needles that cause localized alteration or transportation of live human tissue by cutting, burning, vaporizing, freezing, suturing, probing or manipulating by closed reduction for major dislocations or fractures, or otherwise altering by any mechanical, thermal, light-based, electromagnetic or chemical means.

Surgical Procedure

SB848: Section 18

Amends 63 O.S. 2011, Section 2-309D, as last amended by Section 35, Chapter 210, O.S.L. 2016 (63 O.S. Supp. 2017, Section 2-309D)

4. The failure of a registrant to access and check the central repository as required under state or federal law or regulation shall may, after investigation, be grounds for the licensing board of the registrant to take disciplinary action against the registrant.

Failure to Access the PMP

Prior to prescribing or authorizing for refill, if one hundred eighty (180) days have elapsed prior to the previous access and check, of opiates, synthetic opiates, semisynthetic opiates, benzodiazepine or carisoprodol to a patient of record, registrants or members of their medical or administrative staff shall be required until October 31, 2020, to access the information in the central repository to assess

PMP Must be checked every 180 days.

- F. When a Schedule II controlled dangerous substance or any prescription an opioid drug is continuously prescribed for three (3) months or more for chronic pain, the practitioner shall:
- 1. Review, at a minimum of every three (3) months, the course of treatment, any new information about the etiology of the pain,
- 4. Review the central repository information in accordance with Section 2-309D of this title; and

PMP Must be checked every 90 days?

M. The Oklahoma State Bureau of Narcotics and Dangerous Drugs is authorized to provide unsolicited notification to the licensing board of a pharmacist or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of safe practice or if a practitioner or prescriber has exhibited prescriptive behavior consistent with generally recognized standards indicating potentially problematic prescribing patterns. An

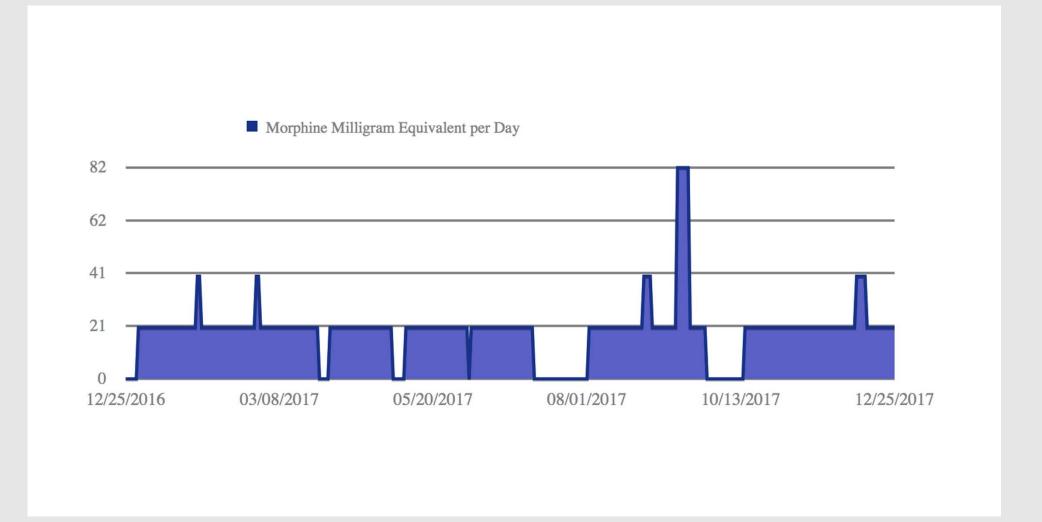
Unsolicited Notifications from OBNDD

SB848: Section 19

A new section of law to be codified in the Oklahoma Statutes as Section 2-3091 of Title 63

Section 2-309I. A. A practitioner shall not issue an initial prescription for an opioid drug which is a prescription drug in a quantity exceeding a seven-day supply for treatment of acute pain for an adult patient, or a seven-day supply for treatment of acute pain for a patient under the age of eighteen (18) years old. Any opioid prescription for acute pain pursuant to this subsection shall be for the lowest effective dose of an immediate-release opioid drug.

Seven day Limit on Initial Opioid Rx



- B. Prior to issuing an initial prescription of a Schedule II controlled dangerous substance or any for an opioid drug that is a prescription drug in a course of treatment for acute or chronic pain, a practitioner shall:
- 1. Take and document the results of a thorough medical history, including the experience of the patient with nonopioid medication and nonpharmacological pain-management approaches and substance abuse history;
- 2. Conduct, as appropriate, and document the results of a physical examination;
- 3. Develop a treatment plan with particular attention focused on determining the cause of pain of the patient;

Issuing An Initial Prescription, Part 1

- 4. Access relevant prescription monitoring information from the central repository pursuant to Section 2-309D of this title;
- 6. In the case of a patient under the age of eighteen (18) years old, enter into a patient-provider agreement with a parent or guardian of the patient; and
- 7. In the case of a patient who is a pregnant woman, enter into a patient-provider agreement with the patient.

Issuing An Initial Prescription, Part 2

D. Prior to issuing the initial prescription of a Schedule II controlled dangerous substance or any an opioid drug that is a prescription drug in a course of treatment for acute or chronic pain and again prior to issuing the third prescription of the course of treatment, a practitioner shall discuss with the patient or the parent or guardian of the patient if the patient is under eighteen (18) years of age and is not an emancipated minor, the risks associated with the drugs being prescribed, including but not limited to:

Prescriptions for Minors, Part 1

- 1. The risks of addiction and overdose associated with opioid drugs and the dangers of taking opioid drugs with alcohol, benzodiazepines and other central nervous system depressants;
 - 2. The reasons why the prescription is necessary;
 - 3. Alternative treatments that may be available; and
- 4. Risks associated with the use of the drugs being prescribed, specifically that opioids are highly addictive, even when taken as prescribed, that there is a risk of developing a physical or psychological dependence on the controlled dangerous substance, and that the risks of taking more opioids than prescribed or mixing sedatives, benzodiazepines or alcohol with opioids can result in fatal respiratory depression.

Prescriptions for Minors, Part 2

C. No less than seven (7) days after issuing the initial prescription pursuant to subsection A of this section, the practitioner, after consultation with the patient, may issue a subsequent prescription for the drug to the patient in a quantity not to exceed seven (7) days, provided that:

The Second Seven Day Prescription, Part 1

- 1. The subsequent prescription would not be deemed an initial prescription under this section;
- 2. The practitioner determines the prescription is necessary and appropriate to the treatment needs of the patient and documents the rationale for the issuance of the subsequent prescription; and
- 3. The practitioner determines that issuance of the subsequent prescription does not present an undue risk of abuse, addiction or diversion and documents that determination.

The Second Seven Day Prescription, Part 2

SB848, p77-78

Second Seven Day Prescription Compromise 5. Limit the supply of any opioid drug prescribed for acute pain to a duration of no more than seven (7) days as determined by the directed dosage and frequency of dosage; provided, however, upon issuing an initial prescription for acute pain pursuant to this section, the practitioner may issue one (1) subsequent prescription for an opioid drug in a quantity not to exceed seven (7) days if:

- a. the subsequent prescription is due to a major surgical procedure or "confined to home" status as defined in 42 U.S.C., Section 1395n(a),
- b. the practitioner provides the subsequent prescription on the same day as the initial prescription,
- c. the practitioner provides written instructions on the subsequent prescription indicating the earliest date on which the prescription may be filled, otherwise known as a "do not fill until" date, and
- the subsequent prescription is dispensed no more than five (5) days after the "do not fill until" date indicated on the prescription;

Provider Compliance Tips for Home Health Services (Part A non DRG) MLN Fact Sheet

An individual is considered "confined to the home" (homebound) if the following two criteria are met:

Criterion One

- a. The beneficiary must either:
 - i. Because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person to leave their place of residence.
 - ii. Have a condition such that leaving his or her home is medically contraindicated.

If the beneficiary meets one of the Criterion One conditions, then the beneficiary must **also** meet two additional requirements defined in Criterion Two below.

Criterion Two

a. In determining whether the patient meets Criterion Two of the homebound definition, the clinician needs to take into account the illness or injury for which the patient met Criterion One and consider the illness or injury in the context of the patient's overall condition. The clinician is not required to include standardized phrases reflecting the patient's condition (for example, repeating the words "taxing effort to leave the home") in the patient's chart, nor are such phrases sufficient, by themselves, to demonstrate that Criterion Two has been met. For example, longitudinal clinical information about the beneficiary's health status is typically needed to sufficiently demonstrate a normal inability to leave the home and that leaving home requires a considerable and taxing effort. Such clinical information about the beneficiary's overall health status may include, but is not limited to, such factors as the beneficiary's diagnosis, duration of the beneficiary's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc.

Page 2 of 5 ICN 909413 February 2018

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ProviderComplianceTipsforHomeHealthServices-ICN909413.pdf

E. At the time of the issuance of the third prescription for a prescription an opioid drug, the practitioner shall enter into a pain-management patient-provider agreement with the patient.

The Third Opioid Prescription

- F. When a Schedule II controlled dangerous substance or any prescription an opioid drug is continuously prescribed for three (3) months or more for chronic pain, the practitioner shall:
- 1. Review, at a minimum of every three (3) months, the course of treatment, any new information about the etiology of the pain, and the progress of the patient toward treatment objectives and document the results of that review;

Chronic Opioid Therapy, Part 1

2. Assess In the first year of the patient-provider agreement, assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence an opioid use disorder and document the results of that assessment. Following one (1) year of compliance with the patient-provider agreement, the practitioner shall assess the patient at a minimum of every six (6) months;

Chronic Opioid Therapy, Part 2

3. Periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence an opioid use disorder as defined by the American Psychiatric Association and document with specificity the efforts undertaken;

Chronic Opioid Therapy, Part 3

- 4. Review the central repository information in accordance with Section 2-309D of this title; and
- 5. Monitor compliance with the pain-management patient-provider agreement and any recommendations that the patient seek a referral.

Chronic Opioid Therapy, Part 4

- G. 1. Any prescription for acute pain pursuant to this section shall have the words "acute pain" notated on the face of the prescription by the practitioner.
- 2. Any prescription for chronic pain pursuant to this section shall have the words "chronic pain" notated on the face of the prescription by the practitioner.

Prescription Labeling

 $\underline{\text{H.}}$ This section shall not apply to a prescription for a patient who is currently in active treatment for cancer, receiving hospice care from a licensed hospice or palliative care, or is a resident of a long-term care facility, or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence.

Exclusions

I. J. Any provider practitioner authorized to prescribe opioids an opioid drug shall adopt and maintain a written policy or policies that include execution of a written agreement to engage in an informed consent process between the prescribing provider practitioner and qualifying opioid therapy patient. For the purposes of this section, "qualifying opioid therapy patient" means:

Qualifying Opioid Therapy Patients, Part 1

- 1. A patient requiring opioid treatment for more than three (3) months;
- 2. A patient who is prescribed benzodiazepines and opioids together for more than one twenty-four-hour period; or
- 3. A patient who is prescribed a dose of opioids that exceeds one hundred (100) morphine equivalent doses.

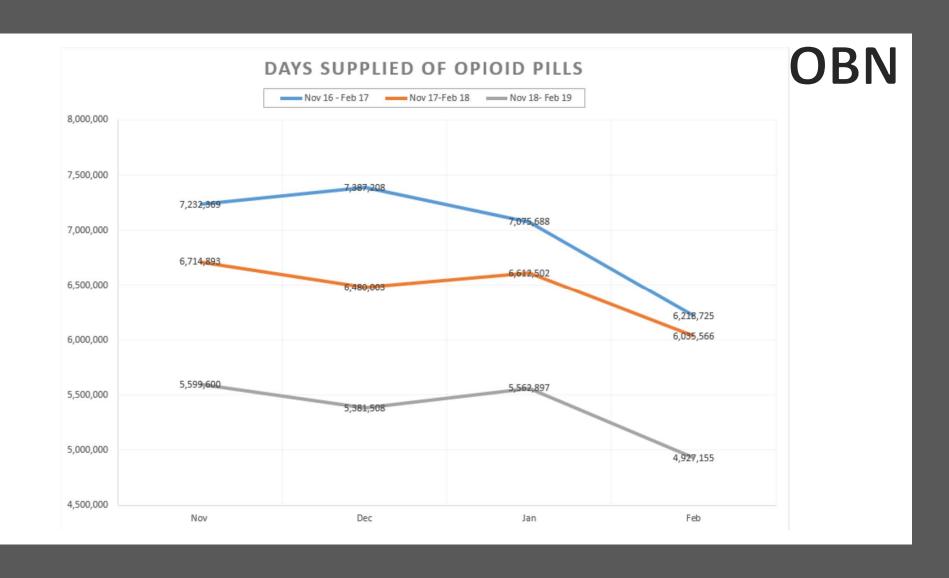
Qualifying Opioid Therapy Patients, Part 2

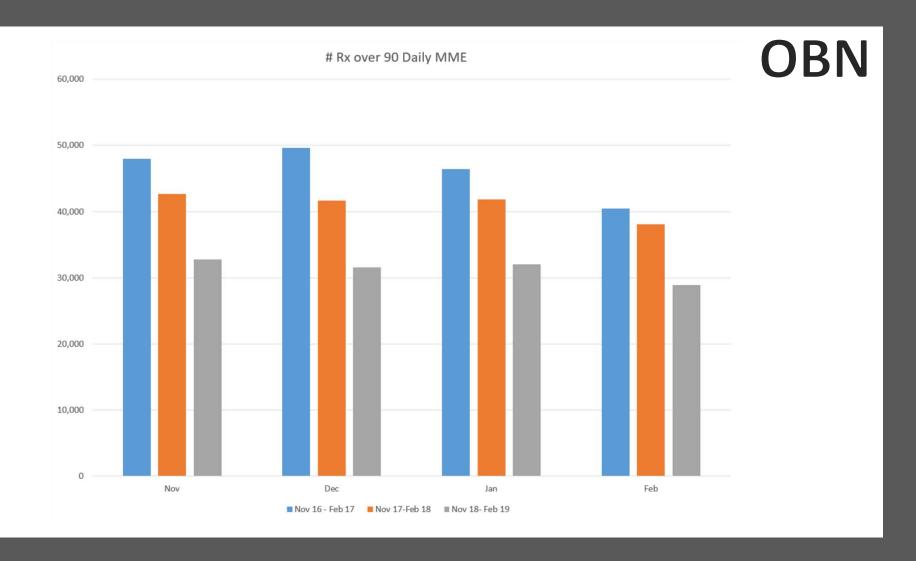
The Morphine Milligram Equivalent Controversy

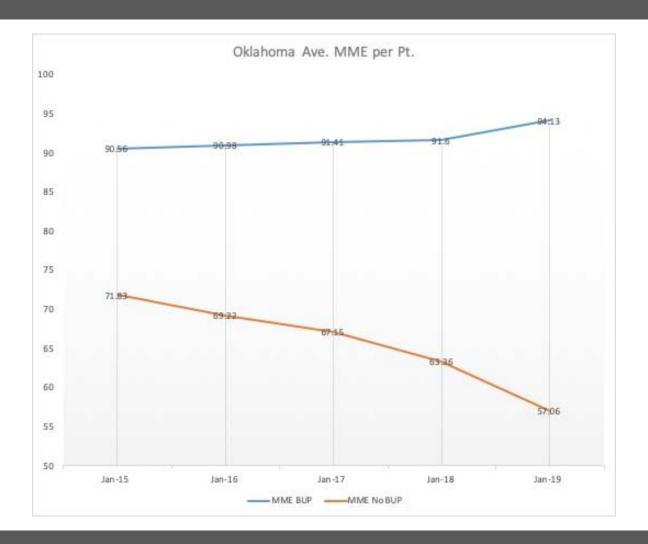
- The law references 100 MME as a safe patient threshold.
 - Attorney General's Office disagreed at March OOC Meeting.
- "If you choose to prescribe greater than 100 MME, document the rationale thoroughly."

nic has a policy of limiting dosing to 100mg eatment Guidelines and state law. You agre

Best Practice For An Act Regulating Of Opioid Drugs document. October 26, 2018.







Journal of Substance Abuse Treatment

Opioid medication discontinuation and risk of adverse opioid-related health

Tami L. Mark*, William Parish

Budgrund: Between 2012 and 2017, the United States dramatically reduced opioid prescribing rates. While this may be appropriate given the opioid epidemic, there has been little research to paich the clinical practice of the properties of the 2013-2014 to 2013-201

sures: 126 outcome was an opione-teated asverte reven centure as an emergency department vast or daton with a primary or secondary disponsis of opiolo glossoning or substance we disorder. The median length of time to discontinuation was 1 day indicating that half of parlients had no dose prior to discontinuation. 86% of patients discontinued within 2 days (considered rapid tapering in nical guidelines). 49% of members had an opiolé-related hospitalization or emergency department.

Irelated deaths which reached (2,000 in 2016 Contents for contents and reversions), 2015, To reduce good prescribing, and of contents and Prevention, 2015, To reduce good prescribing, and the contents and prevention reporting misses of prescribed guidelines and initiated preceptions drug mon-deflorts, and located awareness of the dangers of epiolois, the end alpoid precenting me electrical from 2017, falling to all guideline growther me electrical from 2018 to 2017, falling to missing double, has reduced from the contents and produce for the contents and produce for the contents and produce for the high rare of epiold use, long-term use, misses and dependent and produce for the contents and produce for the high rare of epiold use, long-term use, misses and dependent on the contents and produce for the high rare of epiold use, long-term use, misses and dependent on the produce of the contents and produce for the high rare of epiold use, long-term use, misses and dependent on the contents and produce for the high rare of epiold use, long-term use, misses and dependent on the produce of the high rare of epiold use, long-term use and dependent on the produce of the high rare of epiold use, long-term use and dependent on the produce of the high rare of the high rare of epiold use, long-term use and dependent on the produce of the high rare of the hi

The United States opioid prescribing rate grew steadily from 2006 https://doi.org/10.2109/14.1091/14.1

Corresponding author at: RTI International, 9110 Executive Blvd. Suite 920, Rockville, MD 20857, United States of America E-mail address: tmark@rti.org (T.i., Mark).

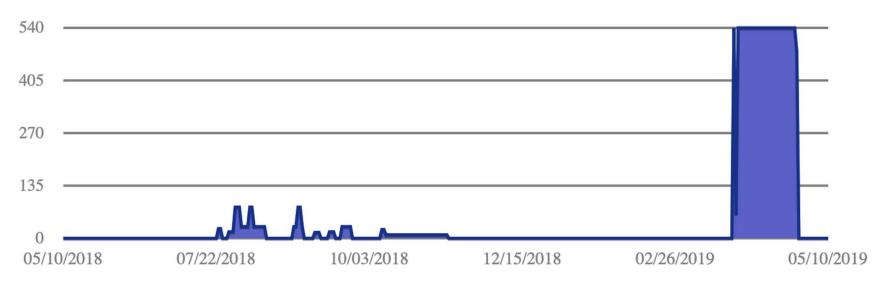
cecived 26 January 2019; Received in revised form 29 April 2019; Accepted 1 May 2019 740-5472/ © 2019 Elsevier Inc. All rights reserved.

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Opioid discontinuation and the risk of adverse opioid-related healthcare events

- Journal of Substance Abuse Treatment.
- Accepted May 1, 2019.
- Studied people @ >120 MME only.
- ~5% had a taper >90 days.
- ~50% experienced a hospitalization or ER visit.
- 68% for concerns of medication misuse.
- 60% met criteria for OUD.
- <1% were transitioned to an opioid use disorder medication.





SB848: Section 23

Effective Date

SECTION 23. It being immediately necessary for the preservation of the public peace, health or safety, an emergency is hereby declared to exist, by reason whereof this act shall take effect and be in full force from and after its passage and approval.

Enactment