Oklahoma State Board of Osteopathic Examiners

Proper Prescribing

2024

LEARNING OBJECTIVES

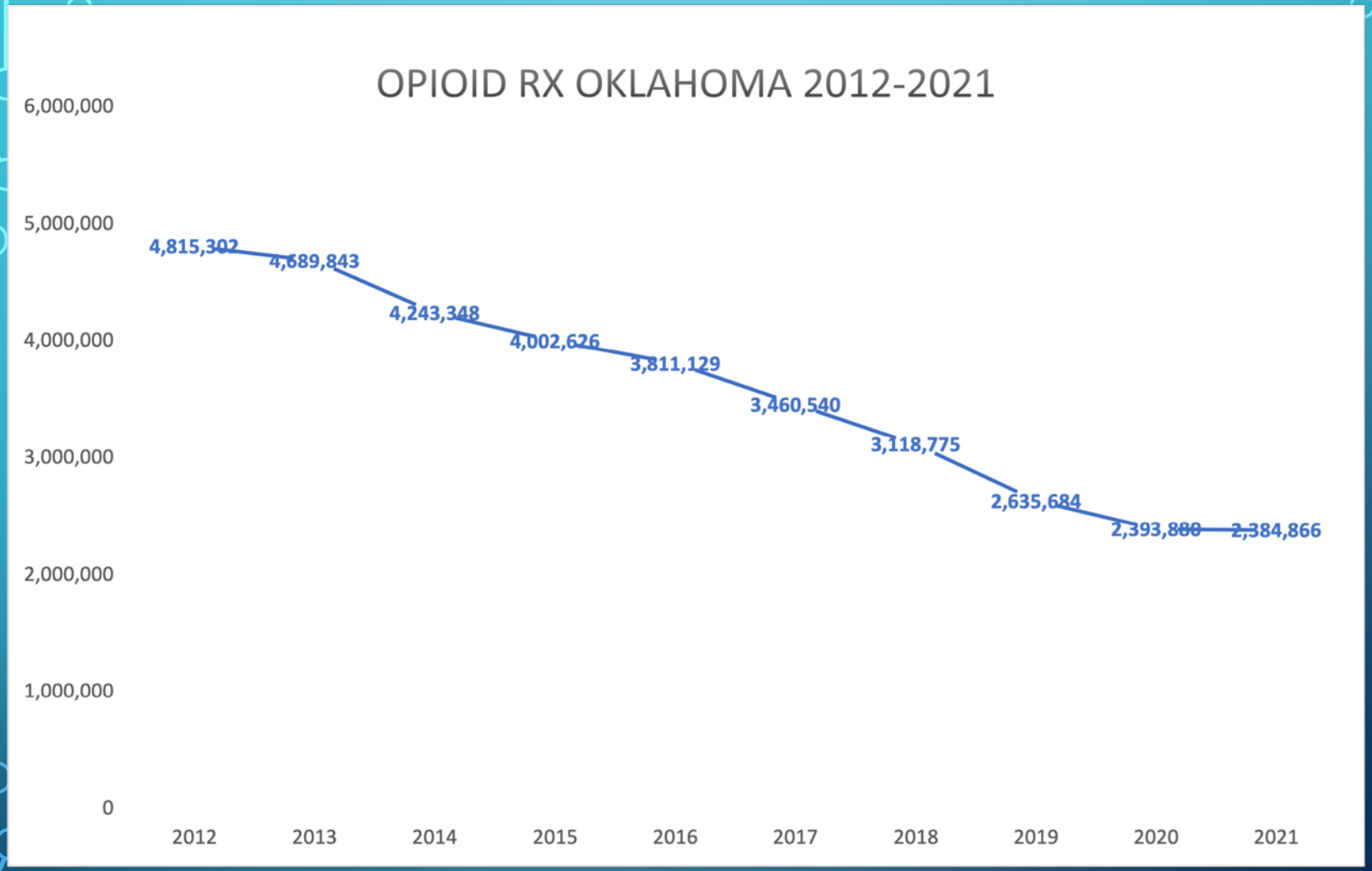
Learn	The statutory requirements for prescribing controlled medications in Oklahoma.
Learn	The “Red flags” that investigators notice when reviewing medical charts.
Learn	How the Oklahoma State Board of Osteopathic Examiners evaluates complaints and conducts investigations.

IN THE NEWS…

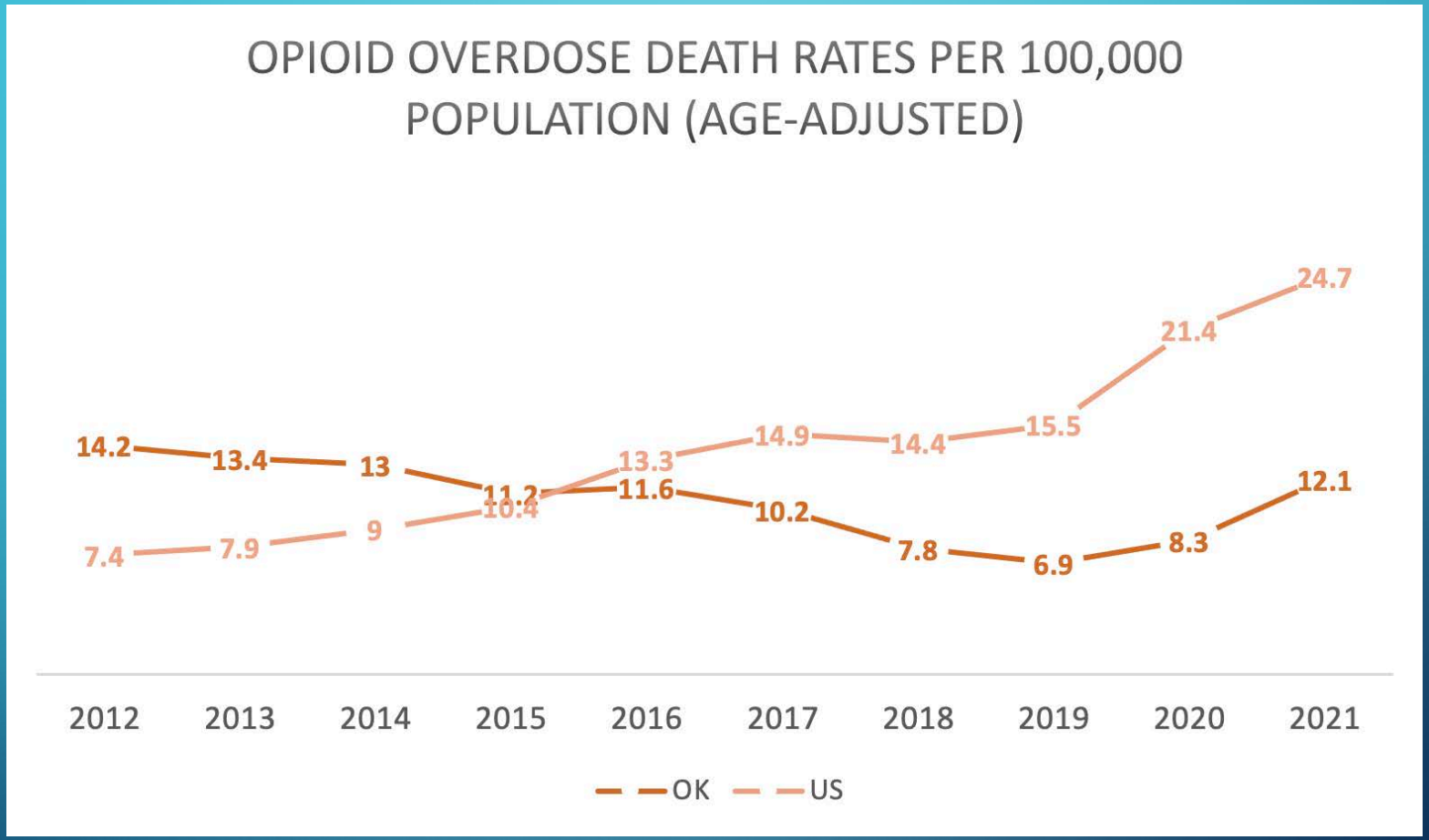
CONSOLIDATED APPROPRIATIONS ACT OF 2023

- Requires new or renewing Drug Enforcement Administration (DEA) registrants, as of June 27, 2023, to have completed at least 8 hours of training on opioid or other substance use disorders, as well as the safe pharmacological management of dental pain.
- Practitioners can meet this requirement in one of three ways:
  1. A total of 8 hours of training from various training entities on opioid or other substance use disorders.
  2. Board certification in addiction medicine or addiction psychiatry.
  3. Graduation within 5 years and in good standing from a medical, advanced practice nursing, or physician assistant school in the United States that included successful completion of an opioid or other substance use disorder curriculum of at least 8 hours.

SAMHSA. Recommendations for Curricular Elements in Substance Use Disorders Training. Retrieved from https://www.samhsa.gov/medications-substance-use-disorders/provider-support-services/recommendations-curricular-elements-substance-use-disorders-training

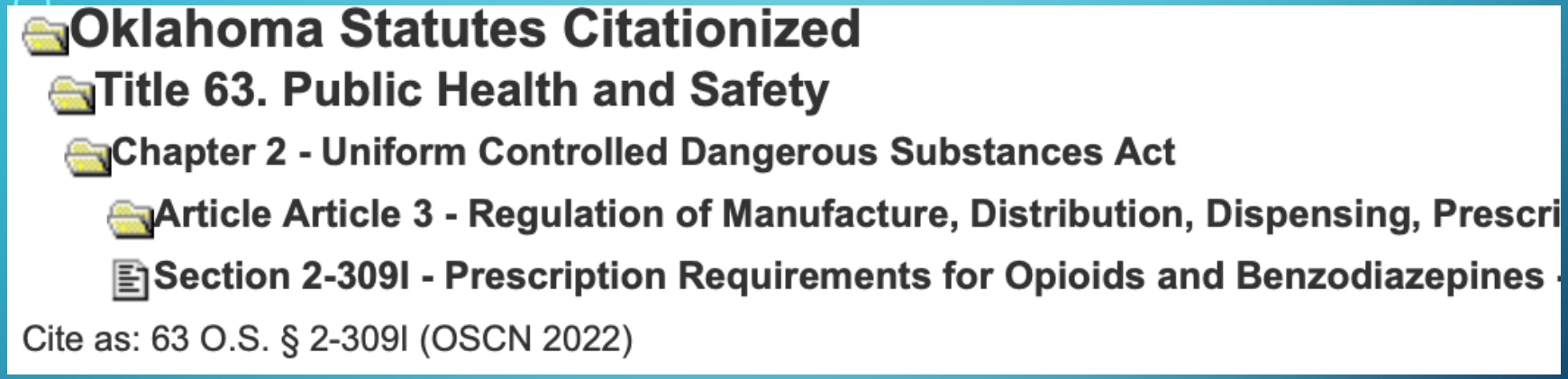


"2022 Overdose Epidemic Report." AMA End the Epidemic. American Medical Association, September 8, 2022. https://end-overdose-epidemic.org/highlights/ama-reports/2022-report/.



https://www.kff.org/other/state-indicator/opioid-overdose-death-rates. Accessed 4-14-23.

PRESCRIBING CONTROLLED MEDICATIONS IN OKLAHOMA



63 O.S. § 2-309I (OSCN 2022)

63 O.S. § 2-411 (OSCN 2022)

Oklahoma Statutes Citationized

Title 63. Public Health and Safety

Chapter 2 - Uniform Controlled Dangerous Substances Act

Article Article 4 - Penalties - Offenses

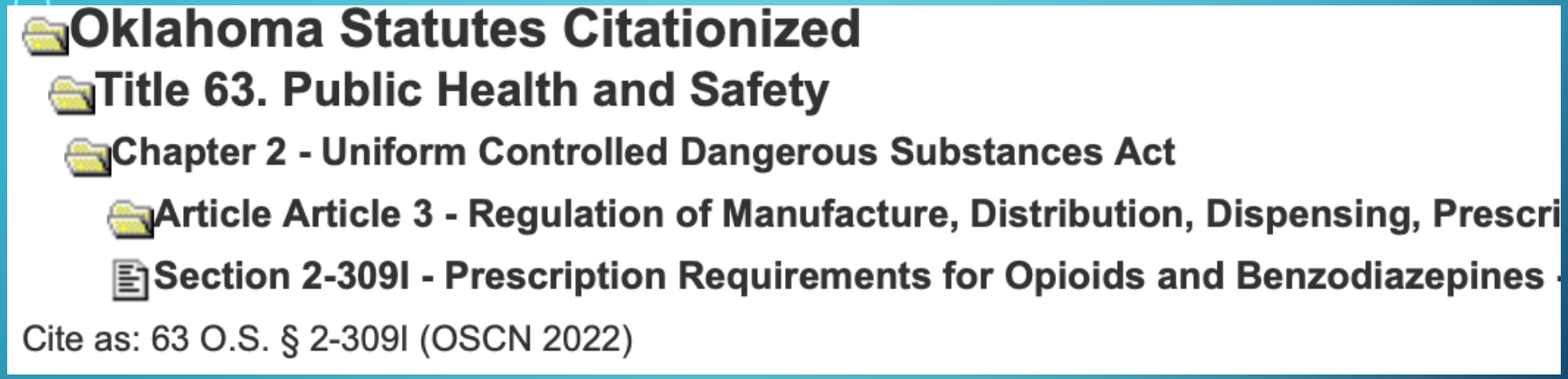
Section 2-411 - General Penalty Clause

Cite as: O.S. §, __ __

63 O.S. § 2-411

- Any person who violates any provision of this act not subject to a specific penalty provision is guilty of a misdemeanor punishable by imprisonment in the county jail for not more than one (1) year, or by a fine of not more than One Thousand Dollars ($1,000.00), or by both such fine and imprisonment.

CHRONIC OPIOID THERAPY



63 O.S. § 2-309I (OSCN 2022)

63 O.S. § 2-309I-H

- This section shall not apply to a prescription for a patient who is in treatment for cancer or receiving aftercare cancer treatment, receiving hospice care from a licensed hospice, or palliative care in conjunction with a serious illness, 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.

63 O.S. § 2-309I-K

- Nothing in the Anti-Drug Diversion Act shall be construed to require a practitioner to limit or forcibly taper a patient on opioid therapy. The standard of care requires effective and individualized treatment for each patient as deemed appropriate by the prescribing practitioner without an administrative or codified limit on dose or quantity that is more restrictive than approved by the Food and Drug Administration (FDA).

FDA APPROVED DOSING ON PDR.NET

- 7.5 to 10 mg of hydrocodone and 300 to 660 mg of acetaminophen: 1 tablet every 4 to 6 hours as needed, not to exceed 6 tablets/day.
- 2.5—10 mg of oxycodone 1-2 tablets PO every 6 hours as needed.
- The maximum acetaminophen dose is 4 g/day. (2g)

FDA-approved labeling defines adult opioid-tolerant patients as those who take the following per day for a minimum of 1 week: oral morphine 60 mg or more; oral oxycodone 30 mg or more; oral hydromorphone 8 mg or more; oral oxymorphone 25 mg or more; 60 mg oral hydrocodone or more; transdermal fentanyl 25 mcg or more per hour; or another opioid at an equivalent dose.

"PDR Search." Morphine Sulfate Tablets (morphine sulfate) dose, indications, adverse effects, interactions... from PDR.net. Accessed September 22, 2022.

63 O.S. § 2-309I-J

- Any practitioner authorized to prescribe 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 practitioner and qualifying opioid therapy patient. For the purposes of this section, "qualifying opioid therapy patient" means:
- 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.

63 O.S. § 2-309I-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.

63 O.S. § 2-309I-F (SLIDE 1/2)

- When 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;
- 2. 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 an opioid use disorder as defined by the American Psychiatric Association 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;

63 O.S. § 2-309I-F (SLIDE 2/2)

- 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 an opioid use disorder as defined by the American Psychiatric Association and document with specificity the efforts undertaken;
- 4. Review the central repository information in accordance with Section 2-309D of this title; and
- 5. Monitor compliance with the patient-provider agreement and any recommendations that the patient seek a referral.

ACUTE OPIOID THERAPY

THE INITIAL PRESCRIPTION

44. "Initial prescription" means a prescription issued to a patient who:

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

63 O.S. § 2-309I-A

- A practitioner shall not issue an initial prescription for an opioid drug in a quantity exceeding a seven-day supply for treatment of acute pain.
- Any opioid prescription for acute pain shall be for the lowest effective dose of an immediate-release drug.

63 O.S. § 2-309I-B (SLIDE 1/3)

- Prior to issuing an initial prescription for an opioid 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;
- 4. Access relevant prescription monitoring information from the central repository pursuant to Section 2-309D of this title;

63 O.S. § 2-309I-B (SLIDE 2/3)

- 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
- d. the subsequent prescription is dispensed no more than five (5) days after the "do not fill until" date indicated on the prescription;

63 O.S. § 2-309I-B (SLIDE 3/3)

- 6. In the case of a patient under the age of eighteen (18) years, 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.

63 O.S. § 2-309I-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:
- 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.

63 O.S. § 2-309I-CE

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

PRESCRIBING OPIOIDS TO MINORS

63 O.S. § 2-309I-D (SLIDE 1/2)

- Prior to issuing the initial prescription of an opioid 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:
- 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

63 O.S. § 2-309I-D (SLIDE 2/2)

- 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.
- The practitioner shall include a note in the medical record of the patient that the patient or the parent or guardian of the patient, as applicable, has discussed with the practitioner the risks of developing a physical or psychological dependence on the controlled dangerous substance and alternative treatments that may be available. The applicable state licensing board of the practitioner shall develop and make available to practitioners guidelines for the discussion required pursuant to this subsection.

ANTI-DIVERSION

TITLE 475: OBNDD PRESCRIBING RULES

Only a **registered practitioner** may issue a **prescription for a Schedule II, III, IV and V** Controlled Dangerous Substance (CDS)

It is the **responsibility of the registered practitioner** to guard against diversion of CDS by authorized employees

A prescription for a CDS must be issued for a **legitimate medical purpose** by a registered practitioner

A **prescription may not** be issued for a CDS to a drug dependent person for **the purpose of continuing his/her dependence** on such drugs

CFR TITLE 21: DEA RULES

1301.71 Security Requirements Generally

- **All applicants and registrants shall provide effective controls and procedures to guard against . . . diversion of controlled substances**

1301.76 Other Security Controls for Practitioners

- **The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances**

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

XIULU RUAN *v.* UNITED STATES

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

No. 20–1410. Argued March 1, 2022—Decided June 27, 2022*


RED FLAGS

RED FLAGS FOR INVESTIGATORS

- Multiple patients come from distant geographical locations
- Individual patients use multiple drug stores to fill prescriptions
- Multiple prescriptions issued to many individual patients
- Poor medical charting, over-reliance on generic templates
- Out-of-the-ordinary patient volume
- Lack of attention to medication misuse and other signs of problems

RED FLAGS FOR INVESTIGATORS, PART 2

- Unusual number of patients receiving higher dose opioid therapy. (>100 MME)
- Unusual number of Rx for specialty
- High numbers of dosage units per month
- Multiple prescribers for the same patient
- Patient's friends and family receiving the same CDS regimen
- Multiple overdose deaths
- Cash payments

HOW PROVIDERS GET INTO TROUBLE PRESCRIBING FOR CHRONIC PAIN

Scammed by 'professional' patients

Failure to implement adequate screening procedures and office policies

Failure to engage patient monitoring techniques

Guarding against drug diversion and abuse

Ignoring aberrant behavior and clinical impairment

Failure to properly document patient charts

No Pain Management Agreement (MAJOR VIOLATION)

Inadequate H&P, lab, imaging, and other diagnostic indicators

Treatment plans, assessments, records, referrals, consults

THE OKLAHOMA OSTEOPATHIC MEDICINE ACT

HEALTH OVERSIGHT AGENCIES ARE ESTABLISHED BY LAW AND SHARE ONE COMMON MISSION: **PROTECT THE PUBLIC.**

HOW DO AGENCIES PROTECT THE PUBLIC?

- State and Federal Statutes
- State Administrative Rules & Regulations
- Enforcement
- Screening and Licensing qualified applicants
- Educate

THE STATUTES (LAW) – TITLE 59 WHAT DOES IT SAY?

Investigators may investigate and inspect the records to ensure compliance with any State or Federal law or rule affecting the practice of osteopathic medicine.

Licensee shall be deemed to have given consent.

Refusal to allow such access may constitute grounds for non-renewal, suspension, or revocation of license. Refusal will guarantee an appearance before the Board for non-compliance.

WHAT INITIATES AN INVESTIGATION BY THE BOARD?

- Complaints from the public
- Other physicians
- Family members of patients
- Pharmacists
- Citizens of a community
- Oklahoma Attorney General
- Oklahoma Bureau of Narcotics
- Drug Enforcement Administration

THE PROCESS


Report comes into Office where it is reviewed by Executive Director & Investigators for Emergency Action
Medical Review Committee: Executive Director, Investigators (2x), Investigative Assistant, Medical Advisors (2x), and Prosecutor
Case opened or closed with letter to complainant
If opened, assigned to an investigator as Preliminary or Full
Based upon the results of the investigation, the physician is cleared, or the prosecution process begins
If prosecution occurs, case is heard by the Board
An Order from the Board is issued

MEDICAL REVIEW COMMITTEE

Executive Director
Prosecuting Attorney
Investigators (x2)
Investigation Assistant
Medical Advisors (x2)

Review Complaints for:

- Violation of Oklahoma Osteopathic Medicine Act
- Violation of OAC 510- State Board of Osteopathic Examiners
- Violation of other State or Federal Law – especially violation of OBN or DEA Statutes/Rules

Possible Outcomes:

- No Jurisdiction, No Clear and Convincing Evidence, No Violation, Preliminary Investigation, Full Investigation

HOW A VERIFIED COMPLAINT IS FILED

Case goes to Board's executive director & prosecuting attorney to draft a Verified Complaint

Charges (Verified Complaint) are drafted

Respondent served with Citation, Notice of Hearing and Complaint

Hearing before the Board

KEEPING YOUR LICENSE

OSTEOPATHIC BOARD
59 O.S. § 637

§59-637. Refusal to issue or reinstate, suspension or revocation of license – Hearing, witnesses and evidence – Judicial review.

A. The State Board of Osteopathic Examiners may refuse to admit a person to an examination or may refuse to issue or reinstate or may suspend or revoke any license issued or reinstated by the Board upon proof that the applicant or holder of such a license:

1. Has obtained a license, license renewal or authorization to sit for an examination, as the case may be, through fraud, deception, misrepresentation or bribery; or has been granted a license, license renewal or authorization to sit for an examination based upon a material mistake of fact;

2. Has engaged in the use or employment of dishonesty, fraud, misrepresentation, false promise, false pretense, unethical conduct or unprofessional conduct, as may be determined by the Board, in the performance of the function or duties of an osteopathic physician, including but not limited to the following:

a. Obtaining or attempting to obtain a fee, charge, tuition or other compensation by fraud, deception or misrepresentation; willfully and continually overcharging or overtreating patients; or charging for visits to the physician's office which did not occur or for services which were not rendered,

b. using intimidation, coercion or deception to obtain or retain a patient or discourage the use of a second opinion or consultation,

c. willfully performing inappropriate or unnecessary treatment, diagnostic tests or osteopathic medical or surgical services,

d. **delegating professional responsibilities to a person who is not** qualified by training, skill, competency, age, experience or **licensure** to perform them, noting that delegation may only occur within an appropriate doctor/patient relationship, wherein a proper patient record is maintained including, but not limited to, at the minimum, a current history and physical,

e. misrepresenting that any disease, ailment, or infirmity can be cured by a method, procedure, treatment, medicine or device,

f. acting in a manner which results in final disciplinary action by any professional society or association or hospital or medical staff of such hospital in this or any other state, whether agreed to voluntarily or not, if the action was in any way related to professional conduct, professional competence, malpractice or any other violation of the Oklahoma Osteopathic Medicine Act,

g. **signing a blank prescription form**; or **dispensing**, **prescribing**, **administering** or otherwise distributing any drug, controlled substance or other treatment **without sufficient examination or the establishment of a physician/patient relationship**, or for other than medically accepted therapeutic or experimental or investigational purpose duly 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**,

WHAT ARE THE POSSIBLE CONSEQUENCES OF A BOARD ACTION?

- Revocation of license
- Suspension of license
- Surrender of license
- Multi-year probation

OTHER CONSEQUENCES…

- Competency evaluation (out-of-state)
- Prescribing course (out-of-state)
- Ethics course (out-of-state)
- Long-term treatment (out-of-state)
- Probation appearances (Board)
- Cost assessment of investigation and Board Hearing
- Action to National Practitioner Databank
- Action on Board website
- Action to OBN – loss of narcotic permit
- Action to DEA – loss of narcotic permit
- Possible criminal charges
- Show-cause hearings OLegal fees (enormous)
- Loss of provider status – insurance
- Loss of hospital privileges
- Loss of specialty board certification
- Substantial personal embarrassment
- Catastrophic financial losses

HOW DO I STAY OUT OF TROUBLE WITH THE LICENSING BOARD, OBN AND DEA?

DOCUMENTATION!

"While the prescribing healthcare professional is obligated to treat pain, he or she must appreciate the importance of complete documentation . . ."

(Pain Medicine News, Special Report, December 2004)

"Curtailing drug abuse and drug diversion can be accomplished without unduly impeding the compassionate use of narcotic analgesics . . ."

(Journal of Medical Licensure and Discipline, Vol 91,No. 2, 2005, David G. Greenberg, MD, MPH)

SCREENING, MONITORING, AND DOCUMENTATION

ACCESSIBILITY TO THE OKLAHOMA STATE BOARD OF OSTEOPATHIC EXAMINERS

- Contact the Board by Mail:

  OSBOE

  4848 N. Lincoln Blvd., Suite 100

  Oklahoma City, OK 73105

- Contact the Board's website:

  www.osboe.ok.gov

- Contact the Board by telephone:

  405.528.8625 (M-F) 8:00 a.m. – 4:30 p.m.

- **Contact the Executive Director 24/7 by telephone at 405/543-8877**

- Contact the Board by fax:

  405.557.0653