OKLAHOMA STATE BOARD OF OSTEOPATHIC EXAMINERS

OKLAHOMA PROPER PRESCRIBING 2022

OKLAHOMA STATE BOARD OF OSTEOPATHIC EXAMINERS

Established 1921

****

Michael T. Leake Jr., J.D. – Executive Director

Layne Subera, D.O. – Medical Advisor

DISCLOSURE NOTICE

- No conflicts to disclose
- Employed by State of Oklahoma.

LEARNING OBJECTIVES

Learn	How the Oklahoma State Board of Osteopathic Examiners approaches investigations.
Learn	Key requirements for prescribing controlled medications in Oklahoma.
Learn	"Red flags" that the Oklahoma State Board of Osteopathic Examiners notices when reviewing a physician's prescribing practices.

STAFF

- Michael Leake, J.D., Executive Director
- Richard Zimmer, CMBI, Chief Investigator
- John Mobley, CMBI, Investigator
- Christi Aquino, Director of Licensing
- Kelsey Devinney, Business Manager
- Kimberly Contreras, Investigative Assistant
- Janis Womack, Administrative Technician II
- Daniel Gamino, J.D. – General Counsel (Contractor)
- Patrick Quillian, J.D. – Special Prosecutor (Contractor)

OKLAHOMA STATE BOARD OF OSTEOPATHIC EXAMINERS

Katie Templeton, J.D. –*President*	Bret Langerman, D.O. –*Vice President*	Catherine Taylor, J.D. – *Secretary/Treasurer*	Jay D. Cunningham, D.O. –*Member*	LeRoy E. Young, D.O. –*Member*
	Duane Koehler, D.O. –*Member*	Dale Derby, D.O. –*Member*	C. Michael Ogle, D.O. - *Member*	

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

HOW DO WE PROTECT THE PUBLIC, AND THE OSTEOPATHIC PROFESSION, FROM THE UNETHICAL PRACTITIONER?

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

PRESCRIBING CONTROLLED MEDICATIONS IN OKLAHOMA

OBNDD PRESCRIBING RULES
OAC TITLE 475

- 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

DEA TITLE 21
CODE OF FEDERAL REGULATIONS (CFR)

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**

SENATE BILLS 1446 & 848

- **Excluded**: SB 1446 & 848 do not apply to patients receiving active treatment for cancer, hospital, palliative care, residents of long-term care facility, or medication for treatment of substance abuse or opioid dependence.
- **CMEs**: All Oklahoma physicians (DOs/MDs) who hold an OBN and DEA registration must take one (1) hour of Proper Prescribing every single year. The one (1) course must be approved by the DO Board or it will not count—see the Agency's website for all approved courses.
- **PMP**: All Oklahoma physicians (DOs/MDs) are required to check the PMP at the time of the initial prescription for opioids, synthetic opioids, semi-synthetic opioids, benzos, and carisoprodol and then at least every 180 days. You must document that your checked PMP—you may include a copy of the PMP in the record (but this is not required).
  - It is recommended, but not required, that you check PMP every time you order a CDS.
- **MME**: If you choose to prescribe greater than 100 MME, it is very important that the patient's records clearly show documentation for your rationale.

SENATE BILLS 1446 & 848 PATIENT-PROVIDER AGREEMENT & WRITTEN POLICIES

- **Pain Management Agreement**: Practitioner shall enter into an Agreement with a patient: (1) at the time of the third prescription for opioid drug; (2) if the patient requires more than three months of pain management; (3) if the patient is receiving benzos and opioids together (even if it is only a one-time script); (4) if the patient requires more than 100 MMEs; (5) the patient is pregnant; or (6) with the parent or legal guardian if patient is a minor.
- **Written Policies**: Any provider authorize to prescribe opioids shall adopt and maintain a written policy including execution of written contract between practitioner and a "qualifying opioid therapy patient."
  - "Qualifying Opioid Therapy Patient": (1) a patient requiring opioid therapy for more than three (3) months; (2) a patient who is prescribed benzos and opioids together (even it if is only one time); or (3) a patient who is prescribed a dose that exceeds 100 MMEs.

SENATE BILLS 1446 & 848 INITIAL SCRIPT & INFORMED CONSENT

- **Prior to Initial Script**: Practitioner shall: (1) take and document a thorough medical history; (2) conduct and document a physical exam; (3) develop a treatment plan; (4) access the PMP; (5) limit supply to no more than seven (7) days for acute pain; and (6) if patient is under the age of eighteen (18), enter into a Patient-Provider Agreement with the parent or legal guardian.
- **Informed Consent**: Prior to initial prescription and again prior to third prescription, practitioner must discuss risk including: (1) risk of addiction and overdose, dangerous of taking opioids with alcohol, benzos, and other CNS depressants; (2) reason the prescription is necessary; (3) alternative treatment available; and that (4) risks can include fatal respiratory depression. Practitioner shall document in the patient's record each time that the informed consent discussion occurs.

New Rules From OBNDD That Apply to Schedule II Prescriptions

December 11, 2020

Part 1 - Issuance of Multiple Prescriptions

A single prescription for a Schedule II drug does not have a limit on quantity or day's supply.

Doctors can now issue multiple prescriptions on the same day to a patient provided that the prescriptions do not exceed a total of up to a 90-day supply for a Schedule II CDS.

A prescription for a Schedule II CDS becomes invalid 30 days after the earliest date on which a pharmacy may fill the prescription, with day 1 being the first day after the earliest date on which a pharmacy may fill the prescription.

"New Rules From OBNDD That Apply to Schedule II Prescriptions," December 11, 2020. Oklahoma State Board of Pharmacy. https://www.ok.gov/pharmacy/.

Part 2 — Partial Filling of Schedule II Prescriptions

A pharmacy can now partial fill a Schedule II CDS prescription for a patient for up to 30 days after the earliest date on which a pharmacy may fill the prescription. This would not include emergency oral prescriptions which would have to be filled not later than 72 hours after the earliest date on which a pharmacy may fill the prescription.

This does not affect partial filling of Schedule II CDS prescriptions for Long Term Care Facility patients or patients with a medical diagnosis documenting a terminal illness which can be partial filled for up to 60 days from the issue date unless sooner terminated by discontinuance of the prescription.

Please keep in mind that if you partial fill a Schedule II prescription due to the fact that the pharmacy does not have enough medication in stock, then you must fill the remainder within 72 hours of the first partial filling.

"New Rules From OBNDD That Apply to Schedule II Prescriptions," December 11, 2020. Oklahoma State Board of Pharmacy. https://www.ok.gov/pharmacy/.

This is due to the fact that the DEA rule 21 CFR 1306.13(a) requires this situation to be handled this way currently, The OSBP anticipates that this will be changed in the future to 30 days to fill the remainder.

DEA 21 USC §829(f)(1)(C) allows a pharmacy to partial fill a Schedule II prescription for up to 30 days if the initial partial fill is requested by the patient or the practitioner that issued the prescription.

"New Rules From OBNDD That Apply to Schedule II Prescriptions," December 11, 2020. Oklahoma State Board of Pharmacy. https://www.ok.gov/pharmacy/.

SENATE BILLS 1446 & 848 ACUTE vs. CHRONIC

Acute	Chronic
• **<u>Shall not</u>** issue an initial prescription for an opioid drug in a quantity that exceeds seven (7) day supply. • **<u>Shall</u>** be for the lowest effective dose of immediate-release opioid drug • **<u>Must</u>** state “acute pain” on face of Rx. • Following initial seven (7) day script, and after an in-person or by telemedicine, a second seven (7) days script may be ordered by the provider if: (1) it is determined the script is necessary/appropriate, rationale is documented, and a determination (with documentation) is made that additional script does not present undue risk of abuse, addiction or diversion.	• **If continuing opioid treatment for three (3) months or longer,** provider **<u>shall</u>**: (1) review every three (3) months course of treatment, any new information regarding etiology of pain, and the progress toward treatment objectives; (2) assess patient prior to every renewal to determine if patient is experiencing dependency and document assessment; (3) periodically make reasonable efforts, unless clinically contraindicated to stop, decrease dosage or try other treatment modalities; (4) review PMP; (5) monitor compliance with patient provider agreement; and (6) state “chronic pain” on the face of the script. • After one (1) year of compliance with provider agreement, the physician may review treatment plan and assess patient at six (6) month intervals. • Assessment may be performed by a mid-level providers (PA/APRN). • Face-to-face assessment is recommended by not required; however, an in-person visit is required to start a CDS.

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).

WITHOUT AN ADMINISTRATIVE LIMIT

SB57, p12

STATE STATUTES, RULES, AND REGULATIONS

- **The Oklahoma Osteopathic Medicine Act**
  - Oklahoma Statute (O.S) Title 59
    - Sections 626 (3) (D), 637 (A) (2) (g) (3)

- **OAC Title 510 – State Board of Osteopathic Examiners**
  - Subchapter 9. Prescribing for Chronic Pain
    - Requirements for osteopathic physicians who prescribe for chronic, intractable pain

(visit our website – www.osboe.ok.gov)

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

- **… Investigators may investigate and inspect the records**
- **… To ensure compliance with any State of 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 a visit before the Board for non-compliance.

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

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

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

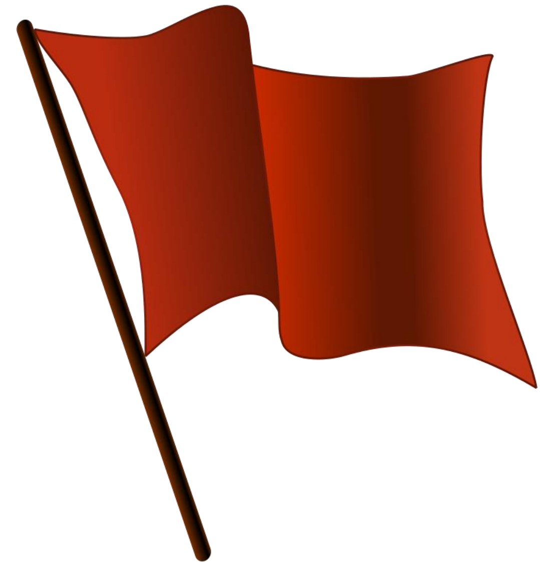
PREMLINARY CONSIDERATIONS

During the investigation

- Volume > CDS dosage units per month, year
- Number CDS scripts per day
- Class of CDS / combination of CDS "cocktails"
- Ignoring or failing to check PMP
- Patient Deaths
- MME – Morphine Milligram Equivalents

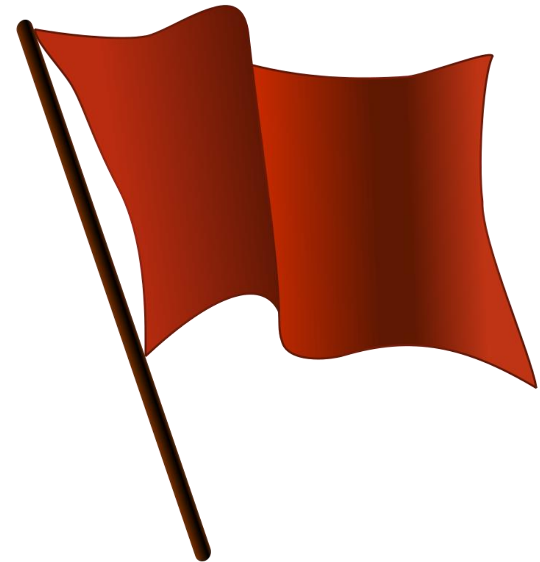
RED FLAGS FOR INVESTIGATORS

- Patients come from everywhere
- Individual patients use multiple drug stores to fill prescriptions
- Multiple prescriptions to single patient
- Poor medical chart/records
- Excessive patient volume
- Early Refills



RED FLAGS FOR INVESTIGATORS, CONT'D

- High number of Rx for specialty
- High number of dosage units per month
- Multiple prescribers for same patient
- Friends and Family receiving same CDS Rx
- Multiple Overdose deaths
- Cash payments
- Excessive number of patients receiving high dose opioid therapy. (>100 MME)



THE VIOLATIONS

59 O.S. § 637 (A)

59 O.S. § 637 (A)

§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**,

- **h.** **engaging in any sexual activity within a physician/patient relationship,**

- **i.** terminating the care of a patient without adequate notice or without making other arrangements for the continued care of the patient,

- **j.** **failing to furnish a copy of a patient's medical records** upon a proper request from the patient or legal agent of the patient or another physician; or failing to comply with any other law relating to medical records,

- **k.** failing to comply with any subpoena issued by the Board,

- **l.** **<u>violating a probation agreement</u>** or order with this Board or any other agency, and

- **m.** failing to keep complete and accurate records of purchase and disposal of controlled drugs or narcotic drugs;

- **3.** Has engaged in **<u>gross negligence</u>**, **<u>gross malpractice</u>** or **<u>gross incompetence</u>**;

- **4.** Has engaged in **<u>repeated acts</u>** of **<u>negligence</u>**, **<u>malpractice</u>** or **<u>incompetence</u>**;

- **5.** Has been **<u>finally adjudicated</u>** and **<u>found guilty</u>**, or **<u>entered a plea of guilty or nolo contendere</u>** in a **<u>criminal prosecution</u>**, for any offense reasonably related to the qualifications, functions or duties of an osteopathic physician, or for any offense involving moral turpitude, whether or not sentence is imposed, and regardless of the pendency of an appeal;

- **6. Has had <u>the authority to engage in the activities regulated by the Board</u>** revoked, suspended, restricted, modified or limited, or has been reprimanded, warned or censured, probated or otherwise disciplined **<u>by any other state or federal agency whether or not voluntarily</u>** agreed to by the physician including, but not limited to, the denial of licensure, surrender of the license, <u>permit or authority</u>, allowing the license, permit or authority to expire or lapse, or discontinuing or limiting the practice of osteopathic medicine pending disposition of a complaint or completion of an investigation;

- **7.** Has violated, or failed to comply with provisions of any act or regulation administered by the Board;

- **8.** Is incapable, for **medical or psychiatric** or any other good cause, of **discharging the functions of an osteopathic physician** in a **manner consistent with the public's health**, **safety** and **welfare**;

- **9.** Has been guilty of advertising by means of knowingly false or deceptive statements;

- **10.** Has been guilty of advertising, practicing, or attempting to practice under a name other than one's own;

- **11.** Has violated or refused to comply with a lawful order of the Board;

- **12.** **Has been guilty of habitual drunkenness**, or **habitual addiction** to the use of morphine, cocaine or other habit-forming drugs;

- **13.** Has been **guilty of personal offensive behavior**, which would include, but not be limited to obscenity, lewdness, molestation and other acts of moral turpitude; and

- **14.** Has been **adjudicated** to be **insane**, or **incompetent**, or admitted to an institution for the treatment of psychiatric disorders.

HOW IS A VERIFIED COMPLAINT FILED?

Case goes to Board's 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

WHAT ARE THE CONSEQUENCES OF BOARD ACTION?

- Revocation
- Suspension
- Usually, emergency suspension or surrender of license
- Multi-year probation upon reinstatement

CONSEQUENCES CONT'D

- 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

CONSEQUENCES CONT'D

- Action to National Practitioner Databank
- Action to FSMB
- Action on Board website
- Action to OBN – loss of narcotic permit
- Action to DEA – loss of narcotic permit
- Possible criminal charges
- Show-cause hearings OBN / DEA

CONSEQUENCES CONT'D

- Legal 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 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

RESPONSIBLE PRESCRIBING AND DOCUMENTATIO N

Documentation (OAC 510:5-9-1)

- Complete H & P
- Pain Assessment
- Physical and psychological function
- History of substance abuse
- Co-existing conditions
- Treatment of Objectives
- Risk/Benefit Discussion
- Other modalities
- PMP Search

HOW – AND WHY – DO DOCTORS 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, other diagnostic indicators
- Treatment plans, assessments, records, referrals, consults

Sometimes considered 'passive mistakes' resulting in non-punitive remedial action as opposed to punitive action (Board Order)

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