The Opioid Crisis, the Commission and the 2018 Legislative Session

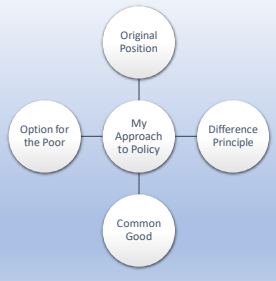
Layne Subera, DO, MA, FACOFP
PLICO Evening Rounds

Lecture Goal

- Cover new law and changes to current law.
- Discuss testimony that lead to the Commission's recommendations.

Take home points:

1. Clinic Registration Requirements.
2. Initial & Subsequent Prescriptions.
3. PPA & Informed Consents



THE OKLAHOMA COMMISSION ON OPIOID ABUSE

FINAL REPORT

Commission Legislative Recommendations

1. Enacted legislation to criminalize the trafficking of both fentanyl and its analogues.
2. Enact legislation to mandate the use of electronic prescriptions (EPCS).
3. Enacted good Samaritan law to grant limited immunity to individuals who called to report a drug overdose.
4. Enacted legislation, such as a tax on the manufacturers, wholesalers and distributors of opioids, as a funding mechanism for opioid addiction treatment.
5. Enact legislation that would require medical clinic owners to register with the Oklahoma Bureau of Narcotics and Dangerous Drugs.
6. Enact legislation that imposes maximum quantity limits on first, second and subsequent opioid prescriptions and includes formal patient notice and informed consent requirements.
7. Enact legislation that requires opioid manufacturers, wholesalers, and distributors to register with the OBM.
8. Enact legislation to create a drug overdose fatality review Board task force to study the causes of opioid overdoses and identify ways to prevent that and refer appropriate cases for criminal prosecution.

SB 1078 Trafficking of Fentanyl

- By Sen. AJ Griffin & Rep. Tim Downing

- 1 gram or more of a mixture containing fentanyl or carfentanil.
- Illegal and imposes a fine of not less than $100,000 nor more than $500,000.

HB 2931 EPCS Mandate

- By Rep. Glen Mulready & Sen. AJ Griffin

- Mandates electronic prescribing of controlled substances (EPCS).
- Effective January 1, 2020.
- Veterinarians exempted.
- OBN can grant 1 year technology exemptions to use serialized paper prescription.

SB 1367 Good Samaritan Law

- by Sen. Ervin Yen & Rep. Dale Derby

- A peace officer shall not take a person into custody based solely on the commission of an offense involving a CDS if:
  1. The individual reasonably appeared to be in need… due to the use of a CDS.
  2. The person:
     1. provided his or her full name and any other relevant information requested,
     2. remained at the scene with the individual who reasonably appeared to be in need,
     3. cooperated with emergency medical assistance personnel and peace officers.

HB XXXX Tax on Manufacturers, et al.

- by Rep. Tim Downing

- 10% tax.
- Funding source for addiction services.
- Did not move.

HB 2795 Pain Clinic Registration

- by Rep. Tim Downing & Sen. AJ Griffin
- Directs the **owners** of pain management clinics to register with the Oklahoma Bureau of Narcotics and Dangerous Drugs Control.
- Applies if >50% of patients receive an opioid, benzodiazepine or carisoprodol on a month-to-month basis.
- Plan yearly on-site inspections.

OBNDD Registration Fees in HB 2795

• Practitioners and mid-levels	• $140.00 per year of registration
• Home Care, Hospices, etc.	• $140.00 annually
• Wholesaler, Distributor, etc.	• $300.00 annually
• **Medical Facility Owners**	• **$300.00 annually**
• Manufacturers	• $500.00 annually

HB 2796 Out of State Suppliers

- by Rep. Tim Downing & Sen. AJ Griffin
- Requires out-of-state manufacturers and distributors to register with OBNDD.
- OBNDD did not have access to wholesale shipment information.
- Bill allows identification of “hotspots”.

HB 2798 Opioid Overdose Fatality Review Board

- by Rep. Tim Downing & Sen. AJ Griffin
- *"to study causes of opioid overdoses and identify ways to prevent death and refer appropriate cases for criminal prosecution."*
- Chaired by the Attorney General.
- Members:
  - Heads of the relevant state agencies.
  - Presidents of the medical associations.
  - Specified physician members.
  - Lay members.

SB 1446

An Act relating to the regulation of opioid drugs
by Sen. Anthony Sykes & Rep. Dale Derby

SB 1446 Overview

- Quantity Limits, Informed Consent, Substance Abuse Assessment.
- 7 sections, 35 pages.
- The word "shall" appears 25 times.
- Changes the Uniform Controlled Substances Act.
- Violations involve criminal law.

SB 1446: Section 1

Amends 59 O.S. 2011, Section 495a.1

Continuing Medical Education

- **The Board shall** require that the licensee receive not less than:
  - one (1) hour of education in pain management or
  - one (1) hour of education in opioid use or addiction
- Each year preceding an application for renewal of a license.
- UNLESS the licensee does not hold a valid DEA number.

p. 4

SB 1446: Section 2

Amends 59 O.S. 2011, Section 509

Unprofessional Conduct Additions

- 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 SB 1446, Section 5
- Failure to check Prescription Monitoring Program (PMP) data base.

p. 7

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.

SB 1446: Section 3

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)

Acute Pain

- "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.

p. 21

Chronic Pain

- "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.

p. 21

Initial Prescription

- "Initial prescription" means a prescription issued to a has never previously been issued a prescription for the drug or its pharmaceutical equivalent in the past year.
- Or, 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

p. 21

Patient-Provider Agreement

- "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, informal consent for opioid therapy.

p. 21

Hold Harmless

- **The provider 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.

p. 22

Serious Illness

- "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.

p. 22

Surgical Procedure

- "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.

p. 23

SB 1446: Section 4

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)

Failure to Access the PMP

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

p26

Unsolicited Notifications from OBNDD

- 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 notification to the licensing board of the practitioner pursuant to this section:
  - Is confidential;
  - May not disclose information that is confidential pursuant to this section; and,
  - May be in a summary form sufficient to provide notice of the basis for the unsolicited notification.

p. 28

SB 1446: Section 5

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

Seven day Limit on Initial Opioid Rx

- **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 prescription for acute pain pursuant to this subsection **shall be for the lowest effective dose of immediate-release opioid drug.**

p. 28

Prior To Issuing An Initial Prescription, Part 1

- Prior to issuing an initial prescription of a Schedule II controlled dangerous substance or any opioid… **a practitioner shall:**
  - Take and document the results of a thorough medical history, including:
    - the experience of the patient with nonopioid medication,
    - nonpharmacological pain-management approaches and
    - substance abuse history.
  - Conduct, as appropriate, and document the results of a physical examination.
  - Develop a treatment plan with particular attention focused on determining the cause of pain of the patient.

p. 28

Prior To Issuing An Initial Prescription, Part 2

- Access the central repository (PMP).
- 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.
- 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.
- In the case of a patient who is a pregnant woman, enter into a patient-provider agreement with the patient.

p. 29

Required Components of a PPA Encounter

- **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:
  - 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;
  - The reasons why the prescription is necessary;
  - Alternative treatments that may be available;
  - 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 … shall develop** and make available to practitioners guidelines for the discussion required pursuant to this subsection.

p. 30

The Second Seven Day Prescription

- **No less than seven (7) days after** issuing the initial prescription … **the practitioner may,** after consultation with the patient, issue a subsequent prescription for the drug to the patient in a quantity not to exceed seven (7) days, provided that:
  - The subsequent prescription would not be deemed an initial prescription under this section,
  - **The practitioner determines** the prescription is necessary … and **documents the rationale** for the issuance of the subsequent prescription,
  - **The practitioner determines** that issuance of the subsequent prescription does not present an undue risk of abuse, addiction or diversion and **documents that determination.**

p. 30

The Third Opioid Prescription

- At the time of the issuance of the third prescription…
  - **The practitioner shall** enter into a pain management agreement with the patient.

p. 30

When Prescribing for 3 months or Longer

- Schedule II controlled dangerous substance or any prescription 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, including:
   1. any new information about the etiology of the pain,
   2. the progress of the patient toward treatment objectives,
   3. document the results of that review.
2. Assess the patient prior to every renewal to determine whether the patient is experiencing problems associated with physical and psychological dependence and document the results of that assessment.
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 and document with specificity the efforts undertaken.
4. Review the central repository information (PMP).
5. Monitor compliance with the pain-management agreement and any recommendations that the patient seek a referral.

p. 32

Exclusions

- Section 5 shall not apply to a prescription for a patient who (is):
  - In active treatment for cancer.
  - Receiving hospice or palliative care.
  - A resident of a long-term care.
  - Being prescribed controlled substances for opioid use disorder.

p. 31

Informed Consent for Qualifying Patients

- "Qualifying Opioid Therapy Patient" means:
  - A patient requiring opioid treatment for more than three (3) months;
  - A patient who is prescribed benzodiazepines and opioids together; or
  - A patient who is prescribed a dose of opioids that exceeds one hundred (100) morphine equivalent doses.
- **Any provider … 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 and qualifying opioid therapy patient.

p. 32

Rationality	Adequate Reasons
Harms & Benefits	A Public Test

Common Morality: 5 Harms

- Death
- Pain
- Loss of Ability
- Loss of Freedom
- Loss of Pleasure

Gert, Bernard, Common Morality: Deciding What to Do. Accessed 9/13/2018. https://www.youtube.com/watch?reload=9&v=enVFjAUTfI8

Rationality	Adequate Reasons
Harms & Benefits	A Public Test

SB 1446: Section 6

New Law

Insurance Department Evaluation

- The Insurance Department shall evaluate the effect of the limits on:
  - On the claims paid by health insurance carriers.
  - Out-of-pocket costs including copayments, coinsurance and deductibles paid by individual and group health insurance policyholders.
- On or before January 1, 2020
  - Submit a report on the evaluation, along with any recommended policy and regulatory options that will ensure costs for patients are not increased as a result of new prescribing limitations… to the standing committees of the Legislature.

p. 32

OBNDD Evaluation

- The Oklahoma State Bureau of Narcotics and Dangerous Drugs Control shall report… no later than January 31, 2020:

1. Registration of prescribers and dispensers in the central repository (PMP).
2. Data regarding the checking and using of the central repository by data requesters.
3. Data from professional boards regarding the CME requirements.
4. Effects on the prescriber workforce.
5. Changes in the numbers of patients taking >100 MME
6. Data regarding the total MMEs prescribed.
7. Progress on EPCS.
8. Improvements to the central repository.

p. 33

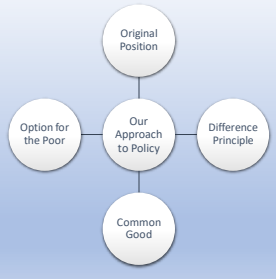
SB 1446: Section 7

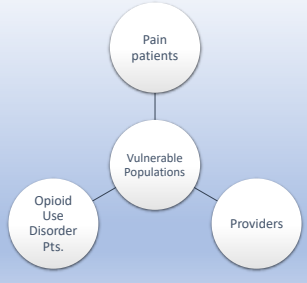
Effective Date

Effective for SB 1446

- This act shall become effective November 1, 2018.

p. 34





Thank you.