Proper Prescribing
OK SB 1446

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National Issues

- CMS actions with a "soft stop" at 90, "hard stop" at 200 MME's in 2019?
- DEA reduced manufacturing of opioids 25% in 2017 and a further 20% in 2018 and more in 2019
- Pharmacy chains and payor policies
- Numerous states capping at <90-100 MME's
- Numerous laws regarding initial prescriptions
- Increased investigations of providers and pharmacies and pharmaceutical manufacturers

Why Opioids?

- Chronic pain is a complex problem, no single answer
- Opioids alone are usually insufficient
- Opioid therapy can be highly beneficial in select patients who demonstrate compliance and function
- Many times the only remaining option
- Overall nationwide reduction of opioid prescriptions
- Oklahoma has had roughly 20% reduction in opioids

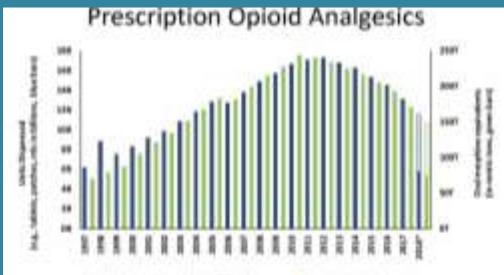
Increasing Opioid Mortality

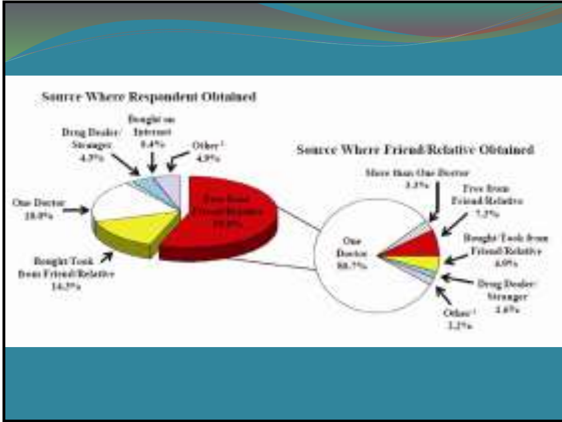
- 72,000 plus overdose deaths in 2017
- Significant escalation in illicit opioids
- Diversion: most deaths are from "non-prescribed" opioids
- Lethal combinations
- Illicit opioids outnumber prescribed opioids
- The number one excuse for governmental intrusion

CDC Enhanced Opioid Overdose Surveillance 2017

- 11 states participated including Oklahoma
- 59% of deaths due to illicit opioids
- 18.5% combined prescription and illicit opioids
- 18% positive for only prescription opioids
  - 50% of these deaths also positive for benzodiazepine
  - "Findings indicate that illicit opioids were a major driver of deaths... and were detected in approximately three of four deaths"

Prescription Opioid Reduction





Required CME

- 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.

SB1446 Addresses:

- Addiction and abuse
- CME requirement
- Dose reduction and cessation
- Lowering MME's
- Other therapies
- Decreasing the risks of acute pain treatment leading to chronic opioid therapy
- ***Need for assessing, documenting and specifying your treatment plan of the opioid patient***

Initial 7 Day Prescription

- Acute pain, no opioids in last year
- Acute pain episode due to surgery or new condition in a patient on opioids.
  - Fracture
  - Kidney stone
  - ER visit for unrelated pain complain
- Shall be for the lowest effective dose
- Must check PMP
- Failure to check PMP shall be grounds for discipline

Initial 7 Day Prescription

- Perform and document a thorough medical history
- Including experience of the patient with non-opioid medication and non-pharmacological pain management
- Screen for substance abuse and addiction
- Perform and ***document*** a physical examination
- PMA required for under 18 and pregnancy

Prior to Issuing an Initial Prescription

- Practitioner shall discuss and ***document*** with a note in medical record of the risks not limited to
  - Risks of addiction and overdose and risks of combining alcohol and or benzodiazepines
  - The reasons why the prescription is necessary
  - Alternative treatments that may be available
  - Risks associated with the drug being prescribed such as physical and psychological dependence, that "opioids are highly addictive" and overutilization can lead to death

Subsequent 7 Day Prescription

- Practitioner determines that the prescription is necessary
- ***Document*** rational for subsequent prescription
- Practitioner determines the the subsequent script does not present a risk of abuse, addiction or diversion and ***documents*** in the chart
- In office visit vs "after consultation" with the practitioner?

Prior to Issuing a 3rd Prescription

- Similar to issuing the initial prescription
- Practitioner shall discuss and ***document*** with a note in medical record of the risks not limited to
  - Risks of addiction and overdose and risks of combining alcohol and or benzodiazepines
  - The reasons why the prescription is necessary
  - Alternative treatments that may be available
  - Risks associated with the drug being prescribed such as physical and psychological dependence, that "opioids are highly addictive" and overutilization can lead to death

Pain Management Agreement

- Provides informed consent
- Essentially an opioid "contract"
- Needed before the 3rd prescription and for chronic pain treatment
- Needed at initial prescription for under 18 and pregnancy
- The Boards will provide an approved agreement for use

Pain Management Agreement

- Explain the possible risks
- Document the understanding of patient and physician
- Establish the rights and obligations of the patient
- Storage of opioids
- Establish specific medications and other treatments
- Specify the measures used by the physician to monitor the patient
- Delineate the process for termination of agreement
- Compliance shall constitute valid informed consent

Chronic Utilization of Opioids

- When an opioid is continuously prescribed for 3 months or more the practitioner shall
  - Assess patient prior to every renewal to determine if the patient is experiencing problems with physical or psychological dependence *and* ***document*** the results of that assessment
    - What constitutes assessment?
    - In office? By phone? Telemedicine?
    - Refills of Schedule III?
    - Mid level providers?
    - "The" practitioner

Chronic Utilization of Opioids

- Review at a minimum every 3 months
  - The course of treatment
  - Any new information about the etiology of the pain
  - Progress of the patient toward treatment objectives
  - Monitor the compliance with the pain management agreement and any recommendations that the patient seek a referral
  - Check PMP (and save in the chart?)
  - ***Document the results***

Chronic Utilization of Opioids

- Periodically make reasonable efforts, unless clinically contraindicated, to
  - Stop use of controlled substance
  - Decrease the dosage
  - Try other medications and treatment modalities in an effort to reduce the potential for abuse or development of physical or psychological dependence
  - DOCUMENT and SPECIFY the efforts undertaken

Further Requirements

- "Any provider authorized to prescribe opioids 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".
- PMA in combination with written policy

Qualifying Opioid Therapy Patient

- ***A patient requiring opioid treatment for more than 3 months***
  - Does not matter if low dose or high dose
- ***A patient who is prescribed a benzodiazepine and opioid together***
  - What about different doctors prescribing each?
  - Psychiatrist and PCP
- ***A patient prescribed a dose of opioids of 100 MME's or more***

The OBNDD is Authorized To….

- Provide unsolicited notification to the licensing board
  - If a patient has received one or more prescriptions for CDS in quantities or frequency inconsistent with recognized standards or safe practice
  - If a practitioner has exhibited prescriptive behavior indicating potentially problematic prescribing patterns
  - Failure to check PMP as required under law shall be grounds for licensing board to take disciplinary action

OBNDD Shall Report:

- Registration of prescribers and dispensers in the central repository (PMP)
- Data regarding the checking and using of the PMP
- Data from boards regarding continuing education
- Effects on the prescriber work force
- Changes in the number of patients taking more than 100 MME's
- Data regarding quantity of opioid medications prescribed in MME's

Further Points

- Shall not apply to patients with active cancer pain, end of life, palliative, hospice care or long term care facility
- Shall not apply to medications for the treatment of substance abuse or opioid dependence
- "The provider shall be held harmless from civil litigation for failure to treat pain if the event occurs because of the non-adherence by the patient with any of the provisions in the patient-provider agreement".