**LEARNING OBJECTIVES**

- Discuss the impact of opioid prescribing regulations on pharmacists
- Review the requirements and enactment status of the opioid prescribing regulations adopted by the Boards of Medicine, Nursing, Dentistry and Veterinary Medicine
- Describe the rationale behind new regulations regarding opioid prescribing in acute and chronic pain and use of buprenorphine in the treatment of opioid use disorder
- Apply overdose prevention education and naloxone rescue kits into pharmacy practice through REVIVE!

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**Non-opioid Treatment for Acute Pain**

- Relieve a variety of types of acute and chronic pain
  - Trauma, postoperative, cancer, arthritis pain
  - Especially effective for certain types of somatic pain
    - Muscle and joint pain
    - Bone/dental pain
    - Inflammatory pain
    - Postoperative pain
- Acetaminophen and NSAIDs, alone, often relieve mild pain, and some NSAIDs relieve certain types of moderate pain
- Non-opioids are often added to opioids for their opioid-sparing effect
- Non-opioids do not produce tolerance, physical dependence, or addiction

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**CDC Perspective Based on the Evidence**

- Opioid use for acute pain is associated with long-term opioid use
- Greater amount of early opioid exposure is associated with greater risk for long-term use
- Most guidelines on opioid prescribing for acute pain recommend prescribing ≤ 3 days, others ≤ 7 days
- Experts note that more than a few days of exposure to opioids significantly increases hazards
- Each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit
- Prescriptions with fewer days' supply will minimize the number of pills available for unintentional or intentional diversion

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**CDC Perspective on the Evidence**

- Clinicians should prescribe the lowest effective dosage
- Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day
- Avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day
- NOTE: Virginia top limit is 120 MME/day
BOARD OF MEDICINE REGULATIONS
GOVERNING PRESCRIBING OPIOIDS
AND BUPRENORPHINE

APPLICABILITY
- Regs apply to MDs, DOs, DPMs and PAs
- Excludes pain related to cancer, hospice, or palliative care
- Excludes pain treated in a hospital, nursing home, or assisted living facility as long as the facilities use a sole-source pharmacy
- Excludes patients enrolled in clinical trials authorized by state or federal law

DEFINITIONS
- Acute pain—associated with a disease or condition or is post-op pain
- Chronic pain—non-cancer pain that goes beyond 3 months
- Controlled substance—Schedules II–IV
- MME—morphine milligram equivalent
- FDA—Food and Drug Administration
- Prescription Monitoring Program—electronic system in Virginia
- SAMHSA—US Substance Abuse and Mental Health Services Administration

1) MANAGEMENT OF ACUTE PAIN
- Opioid prescriptions for acute pain shall not be for more than 7 days, unless extenuating circumstances exist and are fully documented in the record
- This restriction applies to prescriptions for opioids upon discharge from the emergency department
- Opioid prescriptions for post-op pain shall be limited to 14 days, unless extenuating circumstances are documented in the record

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MANAGEMENT OF ACUTE PAIN

Consider the MME

Document why the initial dose should exceed 50 MME/day

Prior to exceeding 120 MME/day, document the justification or consult with or refer to a pain management specialist

Why 50?

Why Co-Prescribe Naloxone?

- A strategy to mitigate risk!
- Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms
- Incorporate into the management plan strategies to decrease risk, including considering offering naloxone when factors that increase risk for opioid overdose
  - History of overdose
  - History of substance use disorder
  - Higher opioid dosages (>50 MME/day) NOTE: VIRGINIA STATES 120 MME/day
  - Concurrent benzodiazepine use

Why the concern with benzodiazepines?

- Benzodiazepines and opioids both cause central nervous system depression and can decrease respiratory drive
- Concurrent use is likely to put patients at greater risk for potentially fatal overdose
- Concurrent benzodiazepine use is noted in large proportions of opioid-related overdose deaths
- A case-cohort study found concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone

Why the concern with benzodiazepines?

- Avoid prescribing opioids and benzodiazepines concurrently whenever possible; treat anxiety or sleep with first-line pharmacotherapy
- Avoid other CNS depressants such as muscle relaxants (especially carisoprodol)
- May consider tapering opioids before benzodiazepines
- Taper benzodiazepines gradually if discontinued because abrupt withdrawal can be associated with rebound anxiety, hallucinations, seizures, delirium tremens, and, in rare cases, death
- Taper by decreasing dose by 25% every 1-2 weeks

Naloxone shall be prescribed when factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present

Other drugs that depress the central nervous system such as sedative hypnotics, carisoprodol, etc. should only be co-prescribed in extenuating circumstances, or tapered to the lowest possible effective dose
MANAGEMENT OF ACUTE PAIN

Buprenorphine products are not indicated for acute pain.

Buprenorphine can only be written by a waivered physician for acute pain in a patient who has the diagnosis of addiction.

MANAGEMENT OF CHRONIC PAIN

Evaluation prior to starting an opioid includes a history, physical and mental status.

Elements to be included:

- Nature and intensity of the pain
- Current and past treatments for pain
- Underlying coexisting diseases or conditions
- Effect of the pain on physical and psychological function, quality of life and ADL's

2) MANAGEMENT OF CHRONIC PAIN

Elements to be included in initial workup:

- Psychiatric and substance abuse history, including family history
- Urine drug screen or serum medication level
- Check of the Prescription Monitoring Program
- Assessment of patient's history and risk of substance misuse
- Records request from other practitioners and facilities

Informed consent for risks and benefits

- Securing the drug
- Proper disposal of unused drug
- Exit strategy if opioids are not effective

Evidence behind using lower doses

- Benefits of high-dose opioids for chronic pain are not established
- Many patients improve when doses are LOWERED!
- Higher opioid dosages are associated with increased risks for motor vehicle injury, opioid use disorder, and overdose
- Opioid overdose risk increases in a dose-response manner
  - Dosages of 50–100 MME/day have been found to increase risks for opioid overdose by factors of 1.9 to 4.6 compared with dosages of 1–20 MME/day
  - Dosages ≥100 MME/day are associated with increased risks of overdose 2.0–8.9 times the risk at 1–20 MME/day
  - National sample of Veterans Health Administration patients with chronic pain
    - Patients that died from an overdose - 98 MME/day
    - Non-fatal overdose - 48 MME

MANAGEMENT OF CHRONIC PAIN

Consider non-pharmacologic and non-opioid treatments

Document why the initial dose must exceed 50 MME/day

Prior to exceeding 120 MME/day, document the justification or consult with or refer to a pain management specialist
MANAGEMENT OF CHRONIC PAIN

Naloxone shall be prescribed when factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

Other drugs that depress the central nervous system such as sedative hypnotics, carisoprodol, etc. should only be co-prescribed in extenuating circumstances, or tapered to the lowest possible effective dose.

Buprenorphine mono-product tablets shall NOT be used to treat chronic pain.

MANAGEMENT OF CHRONIC PAIN

Every 3 months:
- Review the course of treatment, new information on the origin of the pain, and the patient’s overall state of health
- Document the rationale for continued prescribing of opioids
- Check the Prescription Monitoring Program
- Urine screen or serum level for the first year, every 6 months thereafter
- Regularly evaluate for opioid misuse disorder, initiate treatment, consult or refer

Why urine drug tests (UDTs)?
- Concurrent use of opioid pain medications with other opioid pain medications, benzodiazepines, or heroin can increase patients’ risk for overdose
- UDTs can provide information about drug use that is not reported by the patient
- UDTs can assist clinicians in identifying when patients are not taking opioids prescribed for them
- Diversion?
- Adverse effects?
- UDTs do not provide accurate information about how much or what dose of opioids or other drugs a patient took

Why urine drug tests (UDTs)?
- Use unexpected results to improve patient safety
  - Change in pain management strategy
  - Tapering or discontinuation of opioids
  - More frequent re-evaluation
  - Offering naloxone
  - Offering referral for treatment for substance use disorder
3) PRESCRIBING BUPRENORPHINE FOR ADDICTION TREATMENT

- Must have a waiver from SAMHSA and an X number from DEA
- Must follow all federal and state laws and regulations
- PA’s and NP’s shall only prescribe buprenorphine by practice agreement with a waived physician
- Provide or refer for counseling and document in the record
PRESCRIBING BUPRENORPHINE FOR ADDICTION TREATMENT

Assessment must include:
- Comprehensive medical, psychiatric and substance abuse history
- Family history
- Urine drug screen

Are the Buprenorphine Regulations on Mono-Product Working?

1st Quarter 2017: ~25,000 prescriptions
2nd Quarter 2017: ~15,000 prescriptions
3rd Quarter 2017: ~12,000 prescriptions

PRESCRIBING OF BUPRENORPHINE FOR ADDICTION TREATMENT

- Must check the Prescription Monitoring Program prior to initiating treatment
- Induction should begin with no more than 8 mg/day of buprenorphine
- During induction, the prescriber shall see the patient at least once a week
- During stabilization, increases shall be in safe and effective increments

Status of Opioid Regulations

- Board of Medicine
  - Applicable to MDs, DOs, DPMs and PAs
  - Replacement Emergency Regulations – Effective August 24, 2017 for up to 18 months
  - Replacement Permanent Regulations – Once Notice of Intended Regulatory Action (NOIRA) published, 30-day public comment begins
  - Once comments considered and proposed regulations published, 60-day public comment begins
  - Joint Boards of Medicine and Nursing
    - Applicable to nurse practitioners with prescriptive authority
    - Replacement Emergency Regulations – Effective August 24, 2017 for up to 18 months
    - Public comment opportunity in future during promulgation of replacement permanent regulations
**Status of Opioid Regulations, cont.**

- Board of Dentistry
  - Applicable to dentists
  - Regulations for Prescribing Opioids for Pain Management
  - Effective July 21, 2017 for up to 18 months
  - Replacement Permanent Regulations – Once Notice of Intended Regulatory Action (NOIRA) published, 30-day public comment begins
  - Once comments considered and proposed regulations published, 60-day public comment begins
  - Similar to BOM regulations for prescribing opioids for acute and chronic pain, but not quite as extensive
  - Doesn’t address buprenorphine because S4.1-3408.4 restricts prescribing of buprenorphine without naloxone to Boards of Medicine, Nursing, and Veterinary Medicine regulations, and dentists don’t treat addiction

- Board of Veterinary Medicine
  - Applicable to veterinarians
  - Emergency regulations for Prescribing of Opioids which includes buprenorphine
  - Effective June 26, 2017 for up to 18 months
  - Proposed replacement permanent regulations approved; 60-day public comment period begins
  - Once comments considered and proposed regulations published, 60-day public comment begins
  - Abbreviated version of BOM regulations for prescribing opioids, including buprenorphine, for acute and chronic pain

**Impact of Opioid Regulations on Pharmacists**

- From June 2017 Board of Pharmacy eNewsletter:
  - Boards of Medicine, Nursing, Dentistry, and Veterinary Medicine regulations do not place additional requirements on pharmacists.
  - Pharmacists should continue to evaluate the validity of prescriptions by ensuring that the prescription was issued for a legitimate medical purpose.
  - While a pharmacist may refuse to dispense any prescription, a pharmacist may not require a patient to obtain naloxone when co-prescribed by the physician or recommended by the pharmacist under a standing order.

**Impact of Addiction on Pharmacists**

- Continued need for evaluating prescriptions using a “red flags” approach;
- Increased need for educating self on:
  - Disease of addiction and ridding of stigma;
  - Proper prescribing of opioids and naloxone;
  - Identifying patients at risk of overdosing such as through Screening, Brief Intervention and Referral to Treatment (SBIRT);
  - Counseling patients on proper destruction of unwanted medications.