Controlled Substance Issues in Geriatric Patients, Including Palliative Care

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Disclosures

- Director of Palliative Medicine - Princeton and Brookwood Baptist Medical Centers
- Chairman - Medical Ethics Committee, Princeton and Brookwood Medical Centers
- Regional Medical Director for Alabama - Kindred Hospice
- Alabama State Committee of Public Health - Chair
- Alabama State Board of Medical Examiners - Board Member
- Medical Association of the State of Alabama - Board Member
- Cadenza Health, partner
- Physician Reviewer, Carelon Post Acute Services/Elevance Health

Objectives

- Discuss prescribing issues in geriatric patients
- Improve awareness of the Beers Criteria
- Describe some common problems with controlled substances in hospice and palliative medicine
- Improve communication skills

"When you're retired, you'll have plenty of time to do more reading...mostly prescription labels."

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Geriatric Prescribing

- 87% were prescribed at least one medication
- 36% were prescribed 5 or more medications
- 38% also took OTC medications
- In one sample of Medicare nursing home patients, patients were prescribed an average of 14 medications
- Use of herbal and dietary supplements is rising
- 30% of geriatric hospital admissions are related to medication-related adverse events

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Geriatric Prescribing

- Individuals >65 years account for 1/3 of all prescription medications (but, they only represent approximately 13% of the population)
- Polypharmacy is common (generally defined as the use of at least 5 medications)
- Drug misuse and abuse in the elderly can cause cognitive and physical impairment: increases risk for falls, MVAs, and may result in a declining ability to perform ADLs
- Substance abuse: abusers are stereotyped as being young, so we miss it in this population

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Polypharmacy

- Geriatric population is at greater risk for adverse drug events (ADEs) - metabolic changes and decreased drug clearance associated with aging
- Increases the potential for drug-drug interactions
- Independent risk factor for hip fractures
- At risk of developing "prescribing cascades" (an ADE is misinterpreted as a new medical condition and additional pill(s) is/are prescribed to treat this problem
- Use of multiple medications is associated with medication noncompliance

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Beers Criteria

» Medications considered potentially inappropriate for use in older patients, mostly due to high risk for adverse events

» Some are available as over-the-counter products

» These are medications to avoid, and they fall into 5 categories:

1. Most older adults
2. Older adults with certain conditions
3. In combination with other treatments because of the risk for harmful "drug-drug" interactions
4. Use with caution because of the potential for harmful side effects
5. Drug dose adjustment or avoidance based on kidney function

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Beers Criteria

» Evidence-based
» Updated periodically
» American Geriatrics Society website: www.americangeriatrics.org

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From THE AMERICAN GERIATRICS SOCIETY

A POCKET GUIDE TO THE

2023 AGS BEERS CRITERIA®

This clinical tool, based on the 2023 AGS Updated Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults (AGS Beers Criteria®), has been developed to assist healthcare providers in improving medication safety in older adults. Our purpose is to inform clinical decision-making concerning the prescribing of medications for older adults in order to improve safety and quality of care.

Originally conceived of in 1991 by the late Mark Beers, MD, a geriatrician, the Beers Criteria catalogues medications that cause side effects in the elderly due to the physiologic changes of aging. The 2023 American Geriatrics Society (AGS) Beers Criteria® (AGS Beers Criteria®) for Potentially Inappropriate Medication (PIM) Use in Older Adults is the seventh overall update and fourth since AGS became the criteria's steward in 2011. As with previous updates, the AGS and its expert panel have attempted to preserve the spirit and intent of the original Beers Criteria by providing an explicit list of PIMs that are best avoided by older adults in most circumstances or under specific situations, such as certain diseases, conditions, or care settings.

The full document, along with accompanying resources and an appendix of medications removed from the criteria tables, can be found in its entirety online at geriatricscareonline.org.

INTENDED USE

The criteria are intended to be applied to adults 65 years old and older in all ambulatory, acute, and institutionalized settings of care, except hospice and end-of-life care settings.

The intention of the AGS Beers Criteria® is to: (1) reduce older adults' exposure to Potentially Inappropriate Medications (PIMs) by improving medication selection; (2) educate clinicians and patients; and (3) serve as a tool for evaluating quality of care, cost, and patterns of drug use in older adults.

- This should be viewed as a guideline for identifying medications for which the risks of use in older adults often outweigh the benefits.
- The criteria are a blunt instrument, and we are unable to delineate all specialized use cases and possible exceptions to the criteria.
- This list is not meant to supersede clinical judgment or an individual patient's values and needs.
- Prescribing for older adults is often a complex endeavor involving the consideration of many factors, particularly the preferences and goals of the patient and family.
- These criteria are not meant to be applied in a punitive manner.
- These criteria also underscore the importance of using a team approach to prescribing and the use of non-pharmacological approaches and of having economic and organizational incentives for this type of model.
- The criteria are not applicable in all circumstances (i.e., patients receiving palliative and hospice care). If a provider is not able to find an alternative and chooses to continue to use a drug on this list in an individual patient, designation of the medication as potentially inappropriate can serve as a reminder for close monitoring and periodic review.

The primary target audience is the practicing clinician. Although the AGS Beers Criteria® may be used internationally, it is specifically designed for use in the United States and there may be additional considerations for certain drugs in specific countries.

AGS THE AMERICAN GERIATRICS SOCIETY Geriatrics Health Professionals. Leading change. Improving care for older adults.

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Table 1 Continued

Organ System, Therapeutic Category, Drug(s)[a]	***Recommendation***, Rationale, *Quality of Evidence (QE[b])*, *Strength of Recommendation (SR[b])*
Benzodiazepines ■Alprazolam ■Chlordiazepoxide (alone or in combination with amitriptyline or clidinium) ■Clobazam ■Clonazepam ■Clorazepate ■Diazepam ■Estazolam ■Lorazepam ■Midazolam ■Oxazepam ■Temazepam ■Triazolam	***Avoid*** The use of benzodiazepines exposes users to risks of abuse, misuse, and addiction. Concomitant use with opioids may result in profound sedation, respiratory depression, coma, and death. Older adults have increased sensitivity to benzodiazepines and decreased metabolism of long-acting agents; the continued use of benzodiazepines may lead to clinically significant physical dependence. In general, all benzodiazepines increase risk of cognitive impairment, delirium, falls, fractures, and motor vehicle crashes in older adults. May be appropriate for seizure disorders, rapid eye movement sleep behavior disorder, benzodiazepine withdrawal, ethanol withdrawal, severe generalized anxiety disorder, and periprocedural anesthesia. *QE = Moderate; SR = Strong*
Nonbenzodiazepine benzodiazepine receptor agonist hypnotics ("Z-drugs") ■Eszopiclone ■Zaleplon ■Zolpidem	***Avoid*** Nonbenzodiazepine benzodiazepine receptor agonist hypnotics ("Z-drugs") have adverse events similar to those of benzodiazepines in older adults (e.g., delirium, falls, fractures, increased emergency room visits/hospitalizations, motor vehicle crashes); minimal improvement in sleep latency and duration. *QE = Moderate; SR = Strong*
Meprobamate	***Avoid*** High rate of physical dependence; very sedating. *QE = Moderate; SR = Strong*

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Organ System, Therapeutic Category, Drug(s)[a]	***Recommendation,*** Rationale, *Quality of Evidence (QE[b]), Strength of Recommendation (SR[b])*
Megestrol	***Avoid*** Minimal effect on weight; increases risk of thrombotic events and possibly death in older adults. *QE = Moderate; SR = Strong*
Meperidine	***Avoid*** Oral analgesic not effective in dosages commonly used; may have higher risk of neurotoxicity, including delirium, than other opioids; safer alternatives available. *QE = Moderate; SR = Strong*

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TABLE 4. 2023 American Geriatrics Society Beers Criteria® for Potentially Clinically Important Drug–Drug Interactions That Should Be Avoided in Older Adults

Object Drug or Class	Interacting Drug or Class	***Recommendation,*** Risk Rationale, *Quality of Evidence (QE[a]), Strength of Recommendation (SR[a])*
RAS inhibitor (ACEIs, ARBs, ARNIs, aliskiren) or potassium-sparing diuretics (amiloride, triamterene)	Another RAS inhibitor or potassium-sparing diuretic	***Avoid routinely using 2 or more RAS inhibitors, or a RAS inhibitor and potassium sparing diuretic, concurrently in those with chronic kidney disease Stage 3a or higher.*** Increased risk of hyperkalemia. *QE = Moderate; SR = Strong*
Opioids	Benzodiazepines	***Avoid*** Increased risk of overdose and adverse events. *QE = Moderate; SR = Strong*
Opioids	Gabapentin Pregabalin	***Avoid; exceptions are when transitioning from opioid therapy to gabapentin or pregabalin, or when using gabapentinoids to reduce opioid dose, although caution should be used in all circumstances.*** Increased risk of severe sedation-related adverse events, including respiratory depression and death. *QE = Moderate; SR = Strong*

This table is not a comprehensive list of all drug-drug interactions relevant for older adults.

[a]Quality of evidence and strength of recommendation ratings apply to all drugs and recommendations within each criterion unless stated otherwise.

[b]Data are limited for selective peripheral alpha-1 blockers (e.g., tamsulosin, silodosin, and others) but may apply as well.

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Disease or Syndrome	Drug(s)[a]	***Recommendation,*** Rationale, *Quality of Evidence (QE[b]), Strength of Recommendation (SR[b])*
Central nervous system		
Delirium	Anticholinergics* Antipsychotics[c] Benzodiazepines Corticosteroids (oral and parenteral)[d] H2-receptor antagonists ■Cimetidine ■Famotidine ■Nizatidine Nonbenzodiazepine benzodiazepine receptor agonist hypnotics ("Z-drugs") ■Eszopiclone ■Zaleplon ■Zolpidem Opioids	***Avoid, except in situations listed under rationale statement.*** Avoid in older adults with or at high risk of delirium because of potential of inducing or worsening delirium. Antipsychotics: avoid for behavioral problems of dementia or delirium unless nonpharmacologic options (eg, behavioral interventions) have failed or are not possible and the older adult is threatening substantial harm to self or others. If used, periodic deprescribing attempts should be considered to assess ongoing need and/or lowest effective dose. Corticosteroids: if needed, use lowest possible dose for the shortest duration and monitor for delirium. Opioids: emerging data highlights an association between opioid administration and delirium. For older adults with pain, use a balanced approach, including use of validated pain assessment tools and multimodal strategies that include nondrug approaches to minimize opioid use. *QE = H2-receptor antagonists: Low. All others: Moderate; SR = Strong*
Dementia or cognitive impairment	Anticholinergics* Antipsychotics, chronic use or persistent as-needed use[c] Benzodiazepines Nonbenzodiazepine benzodiazepine receptor agonist hypnotics ("Z-drugs") ■Eszopiclone ■Zaleplon ■Zolpidem	***Avoid*** Avoid because of adverse CNS effects. See criteria on individual drugs for additional information. Antipsychotics: increased risk of stroke and greater rate of cognitive decline and mortality in people with dementia. Avoid antipsychotics for behavioral problems of dementia or delirium unless documented nonpharmacologic options (e.g., behavioral interventions) have failed and/or the patient is threatening substantial harm to self or others. If used, periodic deprescribing attempts should be considered to assess ongoing need and/or lowest effective dose. *QE = Moderate; SR = Strong*

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Beers Criteria

» **Avoid the concurrent use of opioids with either benzodiazepines or gabapentinoids - increased risk of overdose, severe sedation, respiratory depression, and death**

» **Updates for 2023**

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Prescribing in Geriatrics

Medical decision-making is of greater complexity:

- Determine that a dangerous drug is indicated
- Choose the best drug
- Determine a dose and schedule appropriate for the patient's physiologic status
- Monitor for effectiveness and toxicity
- Educate the patient about possible side effects
- Know indications for seeking consultation

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Prescribing in Geriatrics

Unique challenges

- Drug trials often exclude those with advanced age
- Pharmacokinetics changes with age:
  - increased volume of distribution
  - Decreased drug clearance/metabolism (renal and hepatic function declines)

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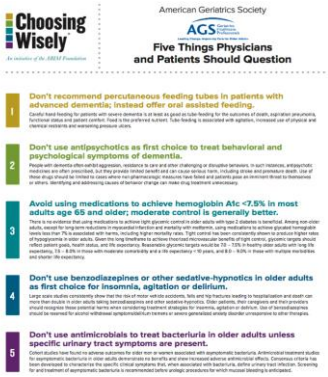
Adverse Reaction Predictors

- >4 prescription medications
- >4 active medical problems
- Hospital admission
- Alcohol use
- Lower MMSE scores
- Greater number of medications added during a hospital admission



Choosing Wisely

An initiative of the ABIM Foundation

American Geriatrics Society

AGS

Five Things Physicians and Patients Should Question

1 **Don't recommend percutaneous feeding tubes in patients with advanced dementia; instead offer oral assisted feeding.**

Careful hand-feeding for patients with severe dementia is at least as good as tube-feeding for the outcomes of death, aspiration pneumonia, functional status and patient comfort. Food is the preferred nutrient. Tube-feeding is associated with agitation, increased use of physical and chemical restraints and worsening pressure ulcers.

2 **Don't use antipsychotics as first choice to treat behavioral and psychological symptoms of dementia.**

People with dementia often exhibit aggression, resistance to care and other challenging or disruptive behaviors. In such instances, antipsychotic medicines are often prescribed, but they provide limited benefit and can cause serious harm, including stroke and premature death. Use of these drugs should be limited to cases where non-pharmacologic measures have failed and patients pose an imminent threat to themselves or others. Identifying and addressing causes of behavior change can make drug treatment unnecessary.

3 **Avoid using medications to achieve hemoglobin A1c <7.5% in most adults age 65 and older; moderate control is generally better.**

There is no evidence that using medications to achieve tight glycemic control in older adults with type 2 diabetes is beneficial. Among non-older adults, except for long-term reductions in myocardial infarction and mortality with metformin, using medications to achieve glycated hemoglobin levels less than 7% is associated with harms, including higher mortality rates. Tight control has been consistently shown to produce higher rates of hypoglycemia in older adults. Given the long timeframe to achieve theorized microvascular benefits of tight control, glycemic targets should reflect patient goals, health status, and life expectancy. Reasonable glycemic targets would be 7.5 – 7.5% in healthy older adults with long life expectancy, 7.6 – 8.0% in those with moderate comorbidity and a life expectancy ~ 10 years, and 8.0 – 8.5% in those with multiple morbidities and shorter life expectancy.

4 **Don't use benzodiazepines or other sedative-hypnotics in older adults as first choice for insomnia, agitation or delirium.**

Large scale studies consistently show that the risk of motor vehicle accidents, falls and hip fractures leading to hospitalization and death can more than double in older adults taking benzodiazepines and other sedative-hypnotics. Older patients, their caregivers and their providers should recognize these potential harms when considering treatment strategies for insomnia, agitation or delirium. Use of benzodiazepines should be reserved for alcohol withdrawal symptoms/delirium tremens or severe generalized anxiety disorder unresponsive to other therapies.

5 **Don't use antimicrobials to treat bacteriuria in older adults unless specific urinary tract symptoms are present.**

Cohort studies have found no adverse outcomes for older men or women associated with asymptomatic bacteriuria. Antimicrobial treatment studies for asymptomatic bacteriuria in older adults demonstrate no benefits and show increased adverse antimicrobial effects. Consensus criteria has been developed to characterize the specific clinical symptoms that, when associated with bacteriuria, define urinary tract infection. Screening for and treatment of asymptomatic bacteriuria is recommended before urologic procedures for which mucosal bleeding is anticipated.

4 **Don't use benzodiazepines or other sedative-hypnotics in older adults as first choice for insomnia, agitation or delirium.**

Large scale studies consistently show that the risk of motor vehicle accidents, falls and hip fractures leading to hospitalization and death can more than double in older adults taking benzodiazepines and other sedative-hypnotics. Older patients, their caregivers and their providers should recognize these potential harms when considering treatment strategies for insomnia, agitation or delirium. Use of benzodiazepines should be reserved for alcohol withdrawal symptoms/delirium tremens or severe generalized anxiety disorder unresponsive to other therapies.

Question:

Due to the heightened risk of anxiety in chronic pain patients, benzodiazepines should always be considered as an adjuvant to opioid therapy to improve pain and anxiety control.

A. True
B. False

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FALSE

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Board Rule 540-X-4-.09 Risk and Abuse Mitigation Strategies

1. All controlled substances have a risk of addiction, misuse, and diversion
2. Provide patients with risk education prior to initiation and continuation of controlled substances
3. Utilize medically appropriate risk and abuse mitigation strategies
4. Utilize the "Morphine Milligram Equivalency" ("MME") and "Lorazepam Milligram Equivalency" ("LME") standard for calculations. Examples of conversion tools are on the ALBME website. The Board does not endorse any particular tool.
5. PDMP query requirements
6. Exemptions
7. **Avoid concomitant benzodiazepine therapy with opioids**
8. Two (2) AMA PRA Category 1 credits continuing medical education (CME) in controlled substance prescribing every two (2) years
9. A violation of this rule is grounds for the assessment of a fine and for the suspension, restriction, or revocation of a physician's Alabama Controlled Substances Certificate or license to practice medicine.

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Another Question:

An 86-year-old man with metastatic lung cancer was given lorazepam by the intern on call because neither she nor the patient could sleep. The patient then became agitated shortly after getting the medication. He has now refused all other medications, cussed out the chaplain, and slapped a nurse in the face.

What is your first course of treatment?

a. Double the lorazepam dose

b. Add quetiapine

c. Increase the morphine

d. Add diphenhydramine

e. Stop the lorazepam

f. Tell the nurse to duck next time

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Follow-up question:

The patient remains agitated and is a threat to himself and others. You need an additional agent to relieve his symptoms of agitated delirium. After stopping the lorazepam, you should initiate which treatment for terminal agitated delirium?

a. Haloperidol
b. Quetiapine
c. Risperidal
d. Ambien
e. Propofol

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Some Issues with Controlled Substances in Hospice Care

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Myth

"Roxanol" (concentrated morphine) is given and absorbed sublingually.

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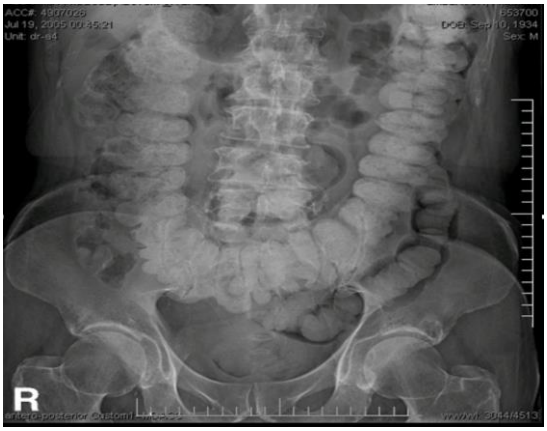

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Opioid-induced Constipation (OIC): Mechanisms

1. Suppress forward peristalsis
2. Increase ileocecal and anal sphincter tone
3. Reduce sensitivity to distention
4. Increase fluid absorption
5. Reduce intestinal secretions

Treatment

- Softeners
  - Docusate - cheap, but a waste of time and money
- **Osmotics**
  - **Lactulose**
  - **Sorbitol**
  - **Polyethylene glycol**
  - **MOM**
- Bulk/Fiber - cause cement-like bowel casts. Do NOT use.

- **Stimulating**

Senna > bisacodyl

Metoclopramide

- Opioid antagonists
  - last choice, but very effective if needed
  - **$$$$$!!!**

*A Combination of a stimulant + osmotic is first-line

**** Don't forget prevention!**

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Opioid Induced Neurotoxicity

Opioid induced neurotoxicity/neuroexcitability (accumulation of active metabolites (e.g. morphine-3-G):

- Hallucinations
- Delirium
- Agitation
- Myoclonus
- Hyperalgesia
- Rarely, seizures

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An 82 y/o woman with end-stage CHF and evidence of cardiorenal syndrome (Cr 3.17) is hospitalized. The family wants to focus on making the patient comfortable. She already has a PICC line, so a morphine drip was started for comfort and hospice discharge planning was begun. Two days later, the patient becomes agitated. The nurse reports that the patient was initially very comfortable and pain-free but slowly became more agitated.

She is now confused, agitated, thrashing around in her bed, and moaning. There is frequent twitching of her eyebrows and arms. Vitals are normal. The morphine infusion is now at 4 mg/hour. Her urine output is negligible (<30cc over the past 24 hours). The patient's daughter is in the room and is very upset. She asks you whether you can increase the morphine to better manage her mother's suffering.

What do you do next?

a. Stop the morphine and start Ativan.

b. Increase the morphine infusion by 50% to 6 mg/hour.

c. Give some Haldol.

d. Continue the morphine drip and start Ativan with a goal of heavy sedation

e. Change the morphine to a different opioid and add Ativan.

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Opioids in Renal Failure

- Avoid: (because of toxic metabolites)
  - **Morphine**
  - **Meperidine**
  - **Codeine**
- Use, but be careful:
  - Hydromorphone
  - Oxycodone
- Considered safe:
  - Fentanyl
  - Methadone

What about Methadone in Hospice and Palliative Care?

- Less opioid escalation with methadone
- **NMDA receptor antagonist**
- μ agonist with some δ agonist activity
- Inhibits reuptake (weak) of norepinephrine and serotonin
- Less affinity for μ receptors = less side effects
- Can reverse tolerance from other opioids
- Effective for neuropathic pain (NMDA)
- Cheap

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What about Methadone in Hospice and Palliative Care?

- Lipophilic; excellent oral absorption (80%)
- Lacks active metabolites
- Safe in renal failure
- Hepatic metabolization
- Dirt cheap

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Methadone

- Excellent choice in patients with:
  - Morphine allergy.
  - Neuropathic pain.
  - Problems with adverse effects of other opioids.
  - Pain refractory to other opioids.
  - Uncontrolled pain.
  - Hyperalgesia.
  - Diversion issues.
  - Drug cost problems.

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CAUTION

- **Use should be very limited:**
  - Long and unpredictable half-life - titrate very slowly (every 5-7 days)
  - Dose increases should be limited to 10% OR 2.5mg increments every 8 hours.
  - The dose of methadone varies inversely with the previously required morphine dose: be EXTREMELY careful with rotation from other opioids
  - Need to dose reduce methadone by **80-90%** due to incomplete cross-tolerance with other opioids

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Journal of Clinical Oncology, 1998

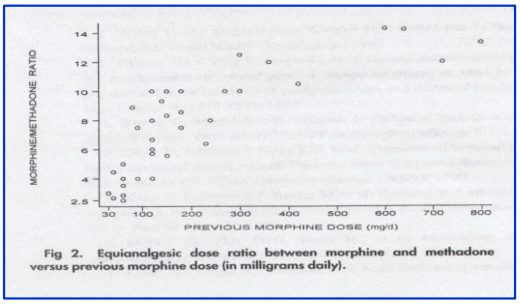

Fig 2. Equianalgesic dose ratio between morphine and methadone versus previous morphine dose (in milligrams daily).

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Methadone conversion ratios

Total MME	Conversion ratio
<90 mg	**1:4**
90-300mg	**1:8**
300-1000mg	**1:12**
>1000mg	**1:20**

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CAUTION: Methadone

- QTc prolongation at high doses
- Drug interactions: many! CP450
  - Methadone inhibits its own metabolism at higher doses
- **NEVER use for breakthrough (PRN) dosing!!!**

methadone 5 mg = 1 tab, Tab, Oral, Q8hr, PRN, For: Pain, Start date 10/26/19 20:32:00 CDT Ordered

- Use as a TID regimen **for pain (not for SUD)**
- **Never use in opioid naïve patients**
- Half-life is much longer than duration of analgesia

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Drug interactions

CP-450 inhibitors: (raise methadone levels)

Macrolides (erythromycin)
Imidazoles (ketoconazole)
Quinolones (ciprofloxacin)
SSRI (fluvoxamine)
Benzodiazepines (diazepam)
Protease inhibitors (ritonavir)
Acute alcohol ingestion

CP 450 inducers: (lower methadone levels)

Anticonvulsants (phenobarb, dilantin)
Rifampin
Corticosteroids
Chronic alcoholism

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Drug Disposal

» What happens to controlled substances after a patient's death?
» Who may dispose of controlled substances after a patient's death?

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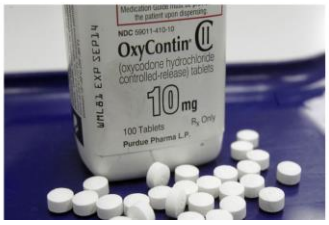
"That's my inheritance": When hospice patients die, their opioid pills remain

By KATHERINE HAFNER
THE VIRGINIAN-PILOT | JAN 25, 2018 | 11:02 AM



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Responsibility

- Hospices have a duty to educate patients and families about the importance of safe disposal of unwanted controlled substances, and how to use the options available to them.
- New law now permits (but does not require) a qualified hospice program's licensed physicians, physician assistants, and nurses to dispose of controlled substances which were lawfully dispensed to the person receiving hospice care in the following situations:
  - » **After death of the patient**
  - » **The hospice patient no longer requires the controlled substance because the plan of care of the hospice patient has been modified**

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Strategies

- Make a plan for disposal with the family at the outset of care
- Provide a limited supply of pills
- Perform PDMP checks
- Perform routine pill counts during home visits
- Utilize a lock box, if necessary
- Utilize urine drug screens
- Facilitate destruction of unused medications

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Disposal Education

- Flushing or dumping down a drain is not the best way to dispose of medication.
- Disposal in Household Trash

  Remove the medicine from its original container and mix it with an undesirable substance, such as used coffee grounds or kitty litter.

  Place the mixture in a sealable bag, empty bag, or other container to prevent medicine from leaking or breaking out of a garbage bag.
- Medication "Take-Back" Programs

  Collection boxes overseen by law enforcement or pharmacies

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Communication with Patients and Families

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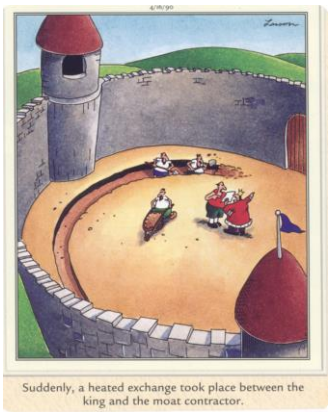

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Benefits

- Improve patient-provider interactions
- Improve patient satisfaction
- Reduce the risk of medical errors
- Improve patient perception of the quality of healthcare received
- Decrease patient complaints
- Improve teamwork and collaboration

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Needed for Diagnostic Accuracy

- Most diagnostic decisions come from the history-taking component of the visit
- Interruptions by the clinician may reduce accuracy
- History-taking can become too structured (think medical students)
- Physicians conduct thousands of patient interviews over a typical career - extensive experience teaches diagnostic pattern recognition

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Patient Satisfaction

- Improves as the length of the visit increases
- Improves compliance with treatment
- Improves outcomes
- Quality of time spent NOT quantity, is a factor
- Improves with the demonstration of empathy by the provider
- **Breakdown in communication is a root cause of many malpractice claims (>80%)**

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Delivering the news…

- Sit down
- Use open-ended questions
- Avoid medical jargon
- Pay close attention to the tone/inflection of your voice
- Ask targeted "How" or "What" questions. Avoid "Why".
- Force correction - very powerful
- Communicate using empathy
  - Mirroring (repeat their last 1-3 words)
  - Always label any observed emotions
  - Observe for nonverbal communication

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Question

In our interactions with patients (and families), empathy helps us communicate our appreciation of patients' problems and issues. Empathy is the art of seeing the world as someone else sees it. When you have empathy, it means you attempt to understand why other people's actions and feelings make sense to them. A useful strategy during your patient visit that will convey empathy to your patients includes:

A. Sitting down
B. Asking open-ended questions
C. Avoiding medical jargon
D. Labeling observed emotions
E. Using the forced correction technique

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Examples

- Tell me about how you take your current medications.
- What else can you think of that might show up in your urine on a drug screen?
- How did ____ end up in your urine?
- How did ____ not show up in your urine?
- So, it sounds like you probably drink 2 cases of beer per day?

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Examples

- I've got some bad/terrible news for you…
- I'm sorry, but I can no longer write pain medications for you.
- Seems like this will put you in a tough spot…
- Sounds like you're upset over this news…
- You probably think that I'm just looking for a reason to stop your _____.
- You probably think the only reason we test your urine is…
- It seems that you don't think I'm treating you fairly…

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More examples

- How am I supposed to keep you safe if I continue to write this dangerous medicine?
- How can I continue to prescribe these dangerous medications to you when….
- How can I continue to prescribe you a medication that could end up putting you in the hospital or killing you?

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Ask for help!!!

Alabama Board of Medical Examiners
P.O. Box 946
Montgomery AL 36101-0946

www.albme.gov
(334) 242-4116
Toll Free: 1-800-227-2606

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Navigating the Prescription Drug Monitoring Program (PDMP)

Alabama Department of Public Health

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Financial Disclosures

Neither Scott Harris, M.D., M.P.H., nor Nancy Bishop, R.Ph., has financial relationships with a commercial interest to disclose.

Objectives

- Describe opioid prescribing trends since 2018.
- Explain accessing the PDMP and how it can be used as a clinical tool.
- Explain specific features of the Alabama PDMP.

Prescription Drug Monitoring Programs

- Have existed in some form for over 100 years.
  - New York, 1918
  - California, 1939
- First electronic PDMP in Oklahoma, 1991.
- Most recent was Missouri, 2023.

The Basics of the Alabama PDMP

- Legislation creating the controlled substance database in Alabama was signed into law in 2004.
- Began collecting prescription information in 2006.
- Database includes Schedules II, III, IV, and V, per the Alabama Controlled Substance List
  - Not Cannabis
- There are substances scheduled in Alabama but not federally: gabapentin, all products containing butalbital, codeine cough syrups, and others.

How Substances are Scheduled in Alabama

- At the federal level, by DEA.
- Within Alabama, by the State Committee of Public Health.
- Within Alabama, by statute enacted by the Legislature.
- Within Alabama, at the request of the Alabama Department of Forensic Sciences.

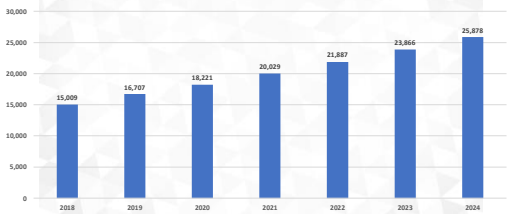
The Basics of the Alabama PDMP (continued)

- Pharmacies and dispensing prescribers are required to submit dispensations within 24 hours of dispensing (daily on business days).
- Alabama data shares with 37 states (all surrounding states), the District of Columbia, military services, and Puerto Rico.
- Contains 5 years plus current year of prescription information.
- Most common error is incorrect Drug Enforcement Administration (DEA) number entered by pharmacies, such as DEA of another prescriber or a fake DEA number.

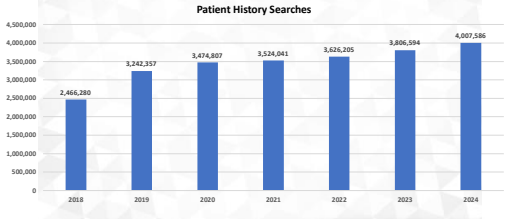
Access to Alabama's PDMP

- Prescribers and prescribing boards.
  - Physicians
  - Dentists
  - Optometrists
  - Podiatrists
  - NOT veterinarians
- Pharmacists and pharmacy boards.
- Medical examiners and coroners.
- Law enforcement agencies.
- Alabama Medicaid.
- Certain research requests.

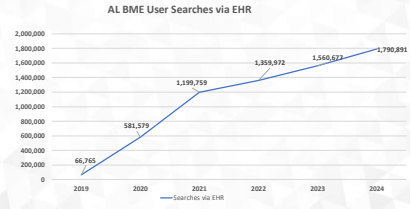
Number of ALBME Licensees with an Alabama PDMP Account: 2018 through 2024 (includes Delegates)



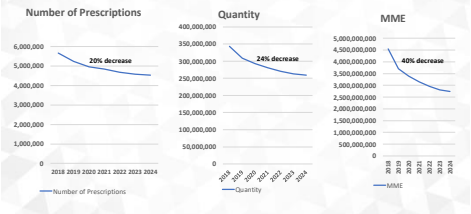
Number of Patient History Searches by ALBME Licensees 2018 through 2024 (includes Delegates)



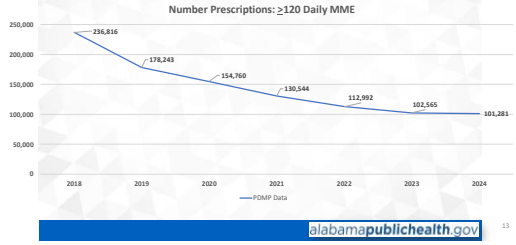
Number of Searches by ALBME licensees via Electronic Health Record (EHR)



Opioids: Number of Prescriptions, Quantity, and Morphine Milligram Equivalents (MME) 2018 through 2024



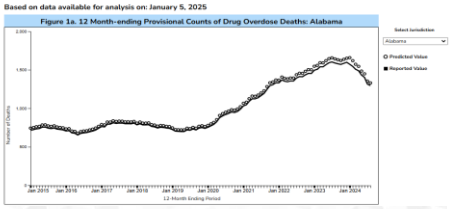
Number of Prescriptions: 120 or Greater Daily Morphine Milligram Equivalents (MME)



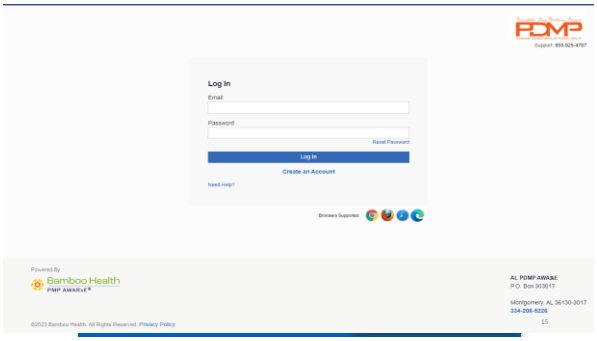
Provisional Drug Overdose Death Counts

12 Month-ending Provisional Number and Percent Change of Drug Overdose Deaths

Based on data available for analysis on: January 5, 2025



CDC National Center for Health Statistics



Alabama PDMP

Website: alabama.pmpaware.net

- Log in to existing account.
- Create an account.
  - Email address will be the account ID and can be personal email address or one associated with employer.
  - Requires email verification.
- Reset password.
  - Two methods:
    - Email with link will be sent to address affiliated with account.
    - Code sent to mobile number if one is listed in the user's profile.
  - System requires password reset every 90 days.

Appropriate Use of PDMP Data

- Any person who intentionally makes an unauthorized disclosure of information contained in the controlled substances prescription database shall be guilty of a Class A misdemeanor. Any person or entity who intentionally obtains unauthorized access to or who alters or destroys information contained in the controlled substances database shall be guilty of a Class C felony. (Act 2004-443, p. 781, § 7)
- The reports generated from the controlled substances database contain confidential information, including patient identifiers, and are not public records. The information should not be provided to any other persons or entity.

Best Practices

- PDMP reports should not be placed in the patient's medical record (paper or electronic) or given to the patient.
- PDMP information is not subject to subpoena or discovery in civil proceedings.
- The prescriber/pharmacist can state in the medical record that a PDMP report was reviewed.
- The patient's prescriber/pharmacist can discuss PDMP results with the patient's other prescribers/pharmacists.
- Multiple state queries are limited to exact match on last name, first name, and date of birth (DOB).

PDMP Report Disclaimer

ADPH makes no claims, promises, or guarantees the accuracy, completeness, or adequacy of the contents of the Recipient Query Report, and expressly disclaims liability for errors and omissions in the contents. The records herein are based on information submitted by pharmacies and dispensing health care practitioners. Records on this report should be verified before any clinical decisions are made or actions taken.

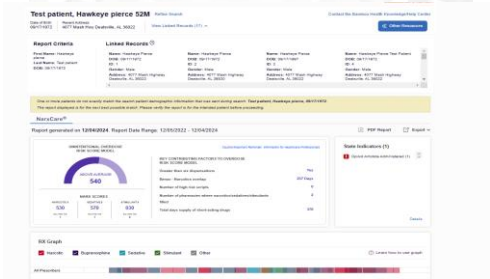
Program Features

- Overdose risks scores provided for all patients.
- Prescribers can search for prescriptions dispensed under his/her DEA number (MyRx).
- Quarterly Prescriber Reports.
- EHR Integration: Allows prescribers to access PDMP directly from the EHR.

Overdose Risk Scores

- Scores range from 000-999.
- Overall Unintentional Overdose Risk Score.
- Scores for three different drug types:
  - Narcotics.
  - Sedatives.
  - Stimulants.
- Calculation based on the number of:
  - Providers.
  - Pharmacies.
  - MME.
  - Overlapping prescriptions.
  - Other parameters.
- Last number is the number of active prescriptions for that drug type.

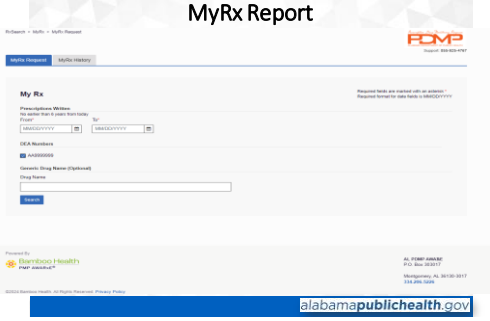
Overdose Risk Scores



MyRx Report

- DEA numbers displayed include the user's DEA number(s) and the collaborating mid-level prescriber's DEA number.
- Shows all prescriptions dispensed under the user's DEA number(s).
- Feature that allows physicians to monitor collaborating mid-level prescribers.
- Located under RxSearch (Click on Menu, then MyRx).
- MyRx History: MyRx Reports requested by user.

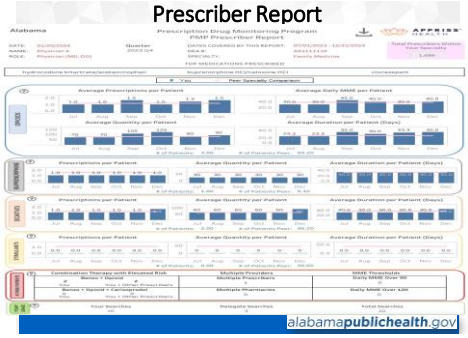
MyRx Report



Prescriber Reports

- Prescriber reports are issued quarterly to all who have prescribed at least one controlled substance in the previous 6 months.
- Can be accessed when the user logs into his/her PDMP account (via Aware). No one except the user has access to his/her Prescriber Report. PDMP staff will access the report only upon the prescriber's request when clarification is needed.
- Reports are now interactive with features that allow the prescriber to drill down to see specific patient information.

Prescriber Report



EHR Integration

- PDMP integration is available for most EHRs and pharmacy management software. Check with your vendor or go to: https://www.alabamapublichealth.gov/pdmp/ehr_integration.html
- Funding has been secured for Fiscal Year 2025 (through September 2025).
- Saves time and improves workflow.
- As of January 31, 2025, 960 entities have integrated the PDMP into their EHR/pharmacy management software system, and 250 are pending.

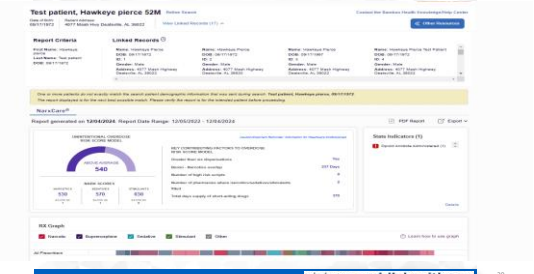
EHR Integration

- Searches include Georgia, Mississippi, Florida, Louisiana, and others as requested by the entity. Must access through Aware for other states. Hopefully, Tennessee will be added soon.
- The other states' PDMP must approve each entity for data sharing via EHR access. Let PDMP staff know if GA, MS, FL, and/or LA have not approved EHR request.

New Feature

- Notification: Patient was administered an opioid overdose reversal agent (naloxone or nalmefene) by EMS on [date].
- Disclaimer: Does not necessarily indicate an overdose occurred.
- Is not used in overdose risk score calculation.

Overdose Risk Scores



Helpful Hints

- The patient's last name, first name, and DOB are required fields.
- May enter partial first and last name:
  - At least three letters.
  - Common names may generate multiple patients (example: Wil for Williams, Williamson, etc.).
- May enter a DOB range. Helps find patients who may have been entered with a different DOB but, again, be careful with common names.
- Hyphenated names can be tricky. Using the Partial Name feature may be helpful.
- Liquid quantities are measured per ml which can make quantities look high.

More Helpful Hints

- Let PDMP staff know if two patients are consolidated in error.
- Multiple state searches via Aware: **Matches only same first and last name and DOB** so common names may include more than one patient. Important to discuss with patient before making assumptions.
- Password resets: Sometimes fire walls block PDMP emails. There is an option to reset your password via text when a cell number is listed in your PDMP profile.
- Mid-level prescribers: Inform PDMP staff when new collaborating practice agreement is approved by AL BME. Mid-level prescribers must have an active QACSC to qualify for PDMP access as NP or PA.

PDMP Continuing Education Opportunities

- Online PDMP townhall available at https://aub.ethosce.com/.
  - No cost
  - 2 hours CE
- Program focusing on state and federal laws pertaining to the PDMP and controlled substances.
  - August 19, 2025 in Huntsville
  - Three hours of CE (6:00 PM – 9:00 PM)
  - No cost, but no dinner
  - Registration: https://aub.ethosce.com/

AlaHOPE Curriculum

- Partnership with JCDH, Department of Health Services Administration at UAB School of Health Professions, and ALBME.
- Funded by CDC Overdose Data to Action grant and goal of Prescriber/Dispenser Committee of Opioid Overdose and Addiction Council.
- "Alabama Health Professionals' Opioid and Pain Management Education" = AlaHOPE.
  - https://aub.ethosce.com/alahope/group/alahope
  - Multi-disciplinary opioid and pain management curriculum for AL Health Professional Schools and current health professionals.
  - Continuing education credit.
  - No cost.

ALAHOPE

alabamapublichealth.gov

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Connect Alabama App: Information and Resources Locator

alabamapublichealth.gov

35

alabamapublichealth.gov

36

Contact Information

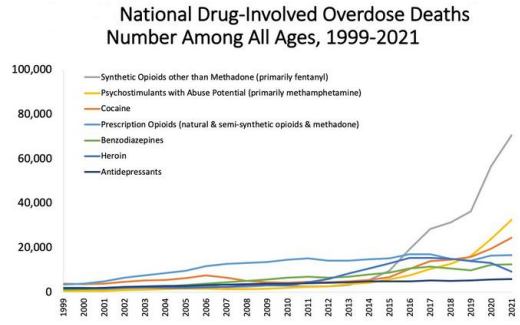
Alabama PDMP
Email address: pdmp@adph.state.al.us
Phone: 334-290-6707
Website: alabamapublichealth.gov/pdmp

Pharmacy Division Team:

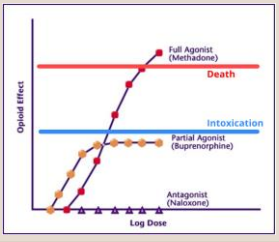
Nancy Bishop, RPh, Pharmacy Director and PDMP Director
Rachel Kiefer, Pharm D., Assistant Pharmacy Director and OD2A Prevention Manager
Brittany Stewart, CPhT, PDMP Administrator
Vicki Walker, CPhT, PDMP Compliance Program Administrator
Lacey Peacock, CPhT, 340B Program Coordinator and Naloxone Distribution

Buprenorphine: Managing Opioid Use Disorder

J. Luke Engeriser, MD, DFAPA, DFASAM
Residency Program Director, Psychiatry
Fellowship Program Director, Addiction Medicine
Associate Professor
USACOM, Department of Psychiatry
Deputy Chief Medical Officer
AltaPointe Health

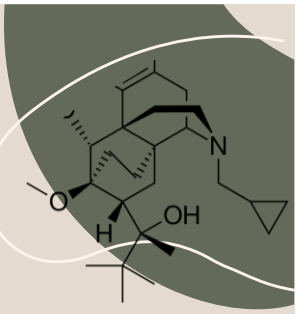


What is buprenorphine?



Regulatory History

- Approved by FDA 2002 to be prescribed for OUD under the Drug Addiction Treatment Act of 2000 (DATA 2000)
- Physicians needed to apply for a DEA waiver after completing an 8-hour course
- Comprehensive Addiction and Recovery Act (CARA) in 2016 extended prescribing authority to NPs and Pas who obtain waiver
- In 2023, Consolidated Appropriations Act eliminated the waiver program
- All providers with DEA registration can now prescribe buprenorphine for OUD



Mono-product → Buprenorphine

vs.

Combination Product → Buprenorphine + Naloxone

Formulations

- Sublingual tablets/films
- Transdermal
- Long-acting injection
- Subcutaneous implant

High Receptor Affinity

+

Partial mu-opioid agonism

⇩

Buprenorphine Precipitated Opioid Withdrawal (BPOW)

7

Managing Withdrawal/BPOW

Joint pain	Nausea/vomiting	Diarrhea	Hot/cold flashes Restlessness	Anxiety
Ibuprofen	Ondansetron	Loperamide	Clonidine	Gabapentin
Acetaminophen				Benzodiazepines
		All of the above		
		Ketamine?		

Assessment

HISTORY
Include substance use assessment, pregnancy test, lab testing including HIV, Hep B and C

URINE DRUG SCREEN
Including fentanyl

CHECK PDMP
Before every refill

SIGNED CONSENT
Include expectations

Diagnosing Opioid Use Disorder (OUD)

- Opioids are often taken in larger amounts or over a longer period of time than intended.
- There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
- A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
- Craving, or a strong desire to use opioids.

Diagnosing Opioid Use Disorder (OUD)

- Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home.
- Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
- Important social, occupational or recreational activities are given up or reduced because of opioid use.
- Recurrent opioid use in situations in which it is physically hazardous
- Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids.

Diagnosing Opioid Use Disorder (OUD)

- Tolerance, as defined by either of the following:
  - (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect
  - (b) markedly diminished effect with continued use of the same amount of an opioid
- Withdrawal, as manifested by either of the following:
  - (a) the characteristic opioid withdrawal syndrome
  - (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms

QUESTIONS TO ASK ABOUT OPIOID USE

1. Type and amount of opioid(s) used recently
2. Route of administration
3. Last use
4. Treatment history
5. Problems resulting from drug use.
6. Experiences with buprenorphine

Opioid Intoxication vs. Withdrawal

Intoxication

- Drooping eyelids
- Constricted pupils
- Reduced respiratory rate
- Scratching (due to histamine release)
- Head nodding

Withdrawal

- Restlessness
- Irritability/anxiety
- Yawning
- Abdominal cramps, nausea, diarrhea
- Dilated pupils
- Sweating
- Piloerection

How should I react to a positive UDS?

- Buprenorphine is a risk reduction strategy
- A positive drug screen in itself should not be a reason to deny/stop treatment
- Drug screens positive for fentanyl or methadone require caution
- Benzodiazepines, barbiturates, and alcohol can increase risk of overdose
- Continued positive UDS on follow-up appointments may require a change in treatment strategy

Induction Steps

- **HOW LONG SINCE LAST USE** — Time to wait depends on drug of choice
- **URINE DRUG SCREEN** — Presence or absence of opioids, fentanyl
- **COWS SCORE** — Should be at least moderate withdrawal
- **GIVE BUPRENORPHINE** — Sublingual
- **WAIT** — Look for BPOW vs. inadequate relief from opioid withdrawal

Clinical Opiate Withdrawal Scale (COWS)

Resting Pulse Rate: _____beats/minute
Measured after patient is sitting or lying for one minute
0 pulse rate 80 or below
1 pulse rate 81-100
2 pulse rate 101-120
4 pulse rate greater than 120

Sweating: *over past 1/2 hour not accounted for by room temperature or patient activity.*
0 no report of chills or flushing
1 subjective report of chills or flushing
2 flushed or observable moistness on face
3 beads of sweat on brow or face
4 sweat streaming off face

Restlessness *Observation during assessment*
0 able to sit still
1 reports difficulty sitting still, but is able to do so
3 frequent shifting or extraneous movements of legs/arms
5 unable to sit still for more than a few seconds

Pupil size
0 pupils pinned or normal size for room light
1 pupils possibly larger than normal for room light
2 pupils moderately dilated
5 pupils so dilated that only the rim of the iris is visible

Bone or Joint aches *If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored*
0 not present
1 mild diffuse discomfort
2 patient reports severe diffuse aching of joints/muscles
4 patient is rubbing joints or muscles and is unable to sit still because of discomfort

Runny nose or tearing *Not accounted for by cold symptoms or allergies*
0 not present
1 nasal stuffiness or unusually moist eyes
2 nose running or tearing
4 nose constantly running or tears streaming down cheeks

GI Upset. *over last 1/2 hour*
0 no GI symptoms
1 stomach cramps
2 nausea or loose stool
3 vomiting or diarrhea
5 multiple episodes of diarrhea or vomiting

Tremor *observation of outstretched hands*
0 no tremor
1 tremor can be felt, but not observed
2 slight tremor observable
4 gross tremor or muscle twitching

Yawning *Observation during assessment*
0 no yawning
1 yawning once or twice during assessment
2 yawning three or more times during assessment
4 yawning several times/minute

Anxiety or Irritability
0 none
1 patient reports increasing irritability or anxiousness
2 patient obviously irritable or anxious
4 patient so irritable or anxious that participation in the assessment is difficult

Gooseflesh skin
0 skin is smooth
3 piloerection of skin can be felt or hairs standing up on arms
5 prominent piloerection

Total Score _____
The total score is the sum of all 11 items
Initials of person completing assessment: _____

Source: Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). J Psychoactive Drugs, 35(2), 253–9

Opioid Withdrawal Severity

Severity Category	Associated COWS Range
Mild	COWS < 13
Moderate	COWS 13-24
Moderately severe	COWS 25-36
Severe	COWS > 36

MD+CALC

Induction Settings

INPATIENT FACILITY
- Easiest setting
- Allows constant monitoring
- May be unavailable geographically and may not be affordable

OFFICE
- Original protocols developed for in office
- Has generally been not practical for most ambulatory settings
- Emergency Departments

HOME
- Comfortable for patient
- Requires a lot of education
- Provider not available if BPOW

Home Induction

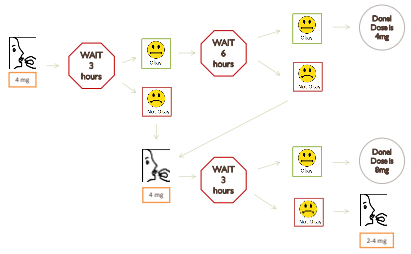
Buprenorphine - Beginning Treatment at Home

Before taking a buprenorphine tablet you want to feel lousy from your withdrawal symptoms. Very lousy! It should be at least 12 hours since you used heroin or pain pills (Roxicet, Vicodin, Lortab, etc.) and at least 24 hours since you used methadone or fentanyl.

Wait it out as long as you can. The worse you feel when you begin the medication, the better it will make you feel and the more satisfied you will be with the whole experience.

You should have a least 3 of the following feelings:
- twitching, tremors or shaking
- joint and bone aches
- bad chills or sweating
- anxious or irritable
- goose pimples
- very restless, can't sit still
- heavy yawning
- enlarged pupils
- runny nose, tears in eyes
- stomach cramps, nausea, vomiting, or diarrhea

Adapted from: Lee JD, Grossman E, DiRocco D, Gourevitch MN. Home buprenorphine/naloxone induction in primary care. *J Gen Intern Med*. 2009;24(2):226-232.



Adapted from: Lee JD, Grossman E, DiRocco D, Gourevitch MN. Home buprenorphine/naloxone induction in primary care. *J Gen Intern Med.* 2009;24(2):226-232.

Typical dosing

- Goal is to eliminate severe cravings that may lead to relapse
- Typical dose 8-16 mg per day
- Dose does not need to be divided, but many patients prefer to take BID or TID
- Doses > 24 mg rarely effective, BUT this may be different with fentanyl
- Suboxone 8/2mg = Zubsolv 5.7/1.4 mg

Always prescribe naloxone

- Available over the counter, but may be expensive
- Free through Vital

https://vitalalabama.com/free-naloxone-and-fentanyl-test-strips/

Contingency Management

- Induction Phase
- Stabilization Phase
  Weekly visits/refills
- Maintenance Phase
  Monthly visits/refills
- Increase intensity of treatment
  Therapy/12 step meeting frequency

Patients can move back to Stabilization Phase when needed

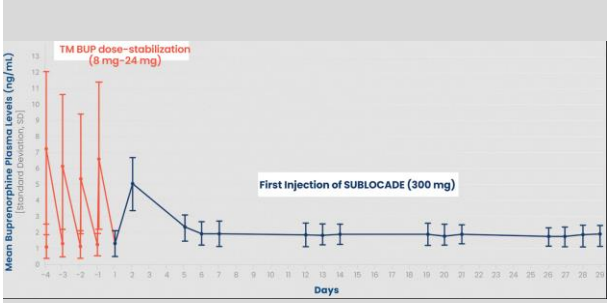
Reducing buprenorphine diversion

Visit Frequency	**Weekly visits/medication fills early in treatment**
Dosing	**Use lowest effective dose**
Drug testing	**Look for buprenorphine and metabolites**
Medication & wrapper counts	**Random call-ins**

Long-Acting Injectible Buprenorphine

Sublocade® (buprenorphine extended-release) injection for subcutaneous use® 100mg·300mg

Brixadi® (buprenorphine) extended-release injection for subcutaneous use CIII
Weekly 8 • 16 • 24 • 32 mg Monthly 64 • 96 • 128 mg



Pregnant patients

- Buprenorphine is recommended in pregnancy and should be started as early as possible
- Mono-product vs. Combination Product
- Coordinate treatment with OB/Gyn
- Dose may need to be increased during pregnancy – are cravings being controlled?
- Neonatal opioid withdrawal syndrome possible, but not a reason to withhold treatment
- Can (should) continue buprenorphine with lactation

Acute pain & surgery

- Continue usual dose of buprenorphine
- Buprenorphine alone is a very effective pain medication, but in tolerant individuals will not be enough to control acute pain
- Coordinate with surgeon/anesthesiologist
- Add short-acting full agonist opioids in supervised settings until acute pain relief
- Doses of full-agonist opioids may need to be higher than in opioid-naïve patients
- Use adjunctive medications for pain (ibuprofen, acetaminophen, gabapentin)

How long should I treat?

- employment and financial stability
- housing stability
- engagement in mutual-help programs, or involvement in other meaningful activities
- sustained abstinence from opioid and other drugs during treatment
- positive changes in the psychosocial environment;
- evidence of additional psychosocial supports
- persistent engagement in treatment for ongoing monitoring past the point of medication discontinuation

Fentanyl

HIGH POTENCY

- Much greater risk of overdose
- Counterfeit pills
- Fentanyl test strips

HIGH LIPOPHILICITY

- Stays in system much longer than expected
- Greater risk of BPOW

Fentanyl - Prevention of BPOW

48-72 hours	Cross taper from full agonist to buprenorphine	Start 8mg and repeat every 30-60 minutes until comfortable	Low-dose IM ketamine
WAIT	**LOW-DOSE BUPRENORPHINE WITH OPIOID CONTINUATION (LDB-OC)**	**RAPID HIGH-DOSE BUPRENORPHINE (HDB)**	**"MOBILE METHOD"**
Clonidine, gabapentin, etc. to help	Very hard/illegal to do outside of inpatient setting	Hard to do outside of inpatient setting	Suitable for inpatient, ED, possibly office

Cohen SM, Weimer MB, Lexander KA, et al. Low dose initiation of buprenorphine: a narrative review and practical approach. J Addict Med. 2022;16(4):399-406.
Herring AA, Vosoughi AA, Luftig J, et al. High-dose buprenorphine induction in the emergency department for treatment of opioid use disorder. JAMA Netw Open. 2021;4(7):e2117128.

Behavioral Health Crisis Center (BHCC) Protocol AKA "Mobile Method"

AltaPointe Health

ASAM Annual Conference April 2023

LUCINDA GRANDE, MD

- At-home induction
- 8mg oral ketamine when starting to feel uncomfortable
- Up to 32mg during any 8-hour period (for relief from withdrawal symptoms

ANDREW HERRING, MD

- Use in Emergency Department
- 0.5 mg / kg IV target dose

TOM HUTCH, MD

- Potential use in outpatient settings

Potential Mechanisms

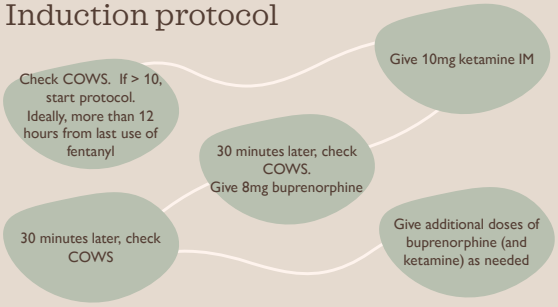
- Direct reduction of opioid withdrawal symptoms
- Potentiates effectiveness of buprenorphine μOR signaling
- Resensitizes μOR in face of fentanyl desensitization
- Inhibits descending pathways of hyperalgesia and central sensitization
- Addresses co-morbid symptoms of depression

- Hallozian C, Luftig J, Lang A, et al. *J Addict Med.* 2022;16(4):483-487.
- Christian NJ, Bumier JL, Evarts MS, Weimer MB. *J Addict Med.* 2023;17(4):488-490.
- Mizobuchi Y, Miyano K, Manabe S, et al. *Biomolecules.* 2022;12(3):426.

Our burning question

Could low-dose intramuscular ketamine assist in preventing BPOW when transitioning from fentanyl to buprenorphine?

Induction protocol



Results

Initial COWS	COWS score 30 minutes after ketamine	COWS score 30 minutes after buprenorphine 8mg	Total buprenorphine given first 4 hours
13.7	5.9	4.0	9.6

INITIAL CONCLUSIONS

Low-dose intramuscular ketamine was well tolerated, safe, and appears to have been successful in decreasing the frequency of BPOW

Transition from Methadone

1. Taper dose to 30mg daily
2. Wait 24-48 hours from last use of methadone (the longer the better)
3. Patient should be in at least moderate withdrawal (COWS>10)
4. Start with 2-4 mg buprenorphine. If withdrawal improves, give additional 2-8 mg until withdrawal symptoms relieved

Summary

Buprenorphine is a safe and potentially life-saving medication for individuals with opioid use disorder.

Alabama is in desperate need for more providers to be comfortable prescribing this medication.


Thank you
Lengeriser@altapointe.org

Gas station pharmacology

Commonly Used Drugs in the Gray Zone of Legality and Safety

J. Luke Engeriser, MD, DFAPA, DFASAM

Residency Program Director, Psychiatry
Fellowship Program Director, Addiction Medicine
Associate Professor
USACOM, Department of Psychiatry
Deputy Chief Medical Officer
AltaPointe Health
President
Alabama Society of Addiction Medicine

I have no financial relationships with an ineligible company/ commercial interest. I will discuss community use of multiple off-label/unapproved products but will not endorse their use for treatment of any medical condition.

What is a "gas station drug"?

- Legal ambiguity
- Addictive potential
- No FDA oversight

Common gas station drugs

Tianeptine (Tianaa, Za Za)	Kratom	Delta-8-THC, delta-10-THC	Nitrous oxide
Phenibut	Poppers	Cold/flu medicines	Sexual enhancers

Opioid-like

Kratom

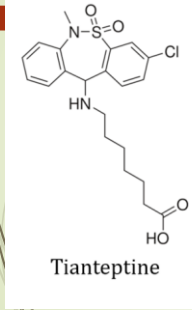
- Mu-opioid partial agonist
- Use for self-withdrawal management

thang, kakuam, thom, ketum, biak

Trakulsrichai S, Sathirakul K, Auparakkitanon S, et al. Pharmacokinetics of mitragynine in man. Drug Des Devel Ther. 2015;9:2421-2429.

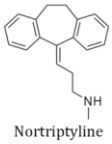
Tianeptine

- Structurally similar to tricyclics
- Mu-Opioid partial agonism
- Withdrawal syndrome

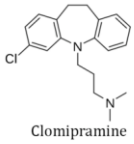


Tianteptine

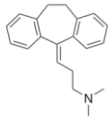
Typical TCAs



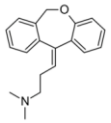
Nortriptyline



Clomipramine



Amitriptyline

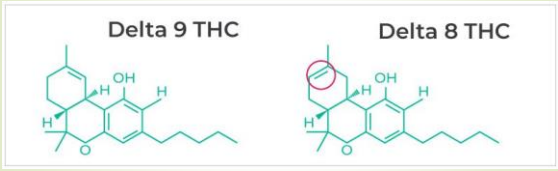


Doxepin

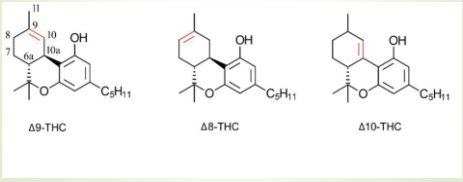
Loperamide

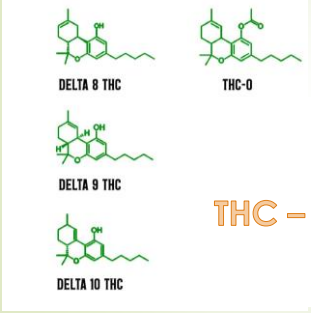
- Peripheral mu-opioid agonist
- Crosses blood brain barrier at high dose

Cannabis-like



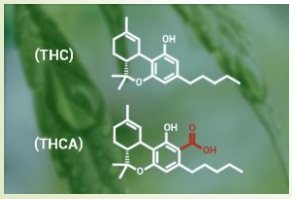
Delta-10-THC





THC – O (-acetate)

Tetrahydrocannabinolic Acid (THCA)



HB445 – In effect January 1, 2026

- 3rd Party Testing
- Serving size restrictions
- Cannot sell beverages also containing alcohol or another intoxicating compound
- Packaging needs to be less appealing to children
- Prohibit selling to anyone under age 21
- Store needs a license to sell, and under 21 not allowed in store
- Bans online sales

Synthetic cannabinoids/Mojo

Common brands:

Spice
K2
Scooby snax
Ninja
Yucatan
****many others****

- PSYCHOTOGENIC
- VAPING
- CHEMICAL VARIATION

Sedative/hypnotic-like

phenibut

- Gaba-B agonist and gabapentinoid
- "nootropic"

COMMON BRANDS:

SLEEP WALKER

RED DAWN

ANVIFEN

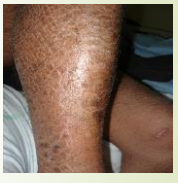
FENIBUT

NOOFEN

LIFTMODE

Kava

- From Piper methisticum shrub
- Potentiates gaba-a receptor



Amanita muscaria

- AKA Fly agaric and fly aminita

Alcohol

Stimulant-like

Synthetic cathinones (Bath salts)

- Khat plant
- Psychotogenic
- Excited delirium

Caffeine/energy drinks

- 85% of us population consumes daily
- Safe amount- up to 400mg
- Tolerance varies

Pseudoephedrine

- Stimulates alpha and beta adrenergic receptors

Ephedrine inhalers/tablets

Stimulates alpha and beta adrenergic receptors

Nicotine

PCP/ketamine-like

OTC cough

- Dextromethorphan (DXM)
- NMDA antagonist
- Street names: CCC, Dex, DXM, Poor Man's PCP, Robo, Rojo, Skittles, Triple C, Velvet

Nitrous oxide

LSD-like

Salvia Divinorum

Other

Sexual enhancement

- Royal Honey
- Rhino products

Diphenhydramine

Amyl Nitrites "Poppers"

BUG SPRAY

Paper route, wasping, KD, Katie, zombie

Questions?

Prescribing Dilemmas: Case Studies from the Alabama Board of Medical Examiners
Part 1

J. MATTHEW HART, JD
SPECIAL COUNSEL TO THE EXECUTIVE DIRECTOR

MISSION

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William M. Perkins,
Executive Director

Prescribing Dilemma #1

"The patients just came to me this way!"

Prescribing Dilemma # 1

Presentation: Patient comes to a prescriber with a reported lengthy history of chronic conditions and multiple controlled substance prescriptions with high doses

- The patient wants the prescriber to continue the medications "just like the other doctor did it"
- The prescriber knows the dosages are too high, that the combinations are risky, but the patient is very averse to change

Should you continue the patients on the medications, or make changes?

A) CONTINUE

B) MAKE CHANGES

Prescribing Dilemma # 1

Dilemma: continue the patients on the medications, or make changes?

- Is the prescriber aware of titration methodologies?
- Is the prescriber willing to say "No?" and mean it?

Risks to the prescriber: Patient harm, transformation of the practice into a pill mill, and Board intervention.

Prescribing Dilemma #2

"He prescribes the opioids. I just prescribe the benzodiazepine."

The prescriber should remain in his or her silo.

A) TRUE

B) FALSE

Prescribing Dilemma # 2

Presentation: A patient is being prescribed a controlled substance by one prescriber, and another prescriber is managing another condition with a controlled substance. The combination poses a risk of harm to the patient.

Dilemma: Can the prescriber remain in his or her silo? What are his/her responsibilities? What can he/she do about the risks?

Prescribing Dilemma # 2

Review: Dr. Parran's Presentation

- Benzodiazepines are very "STICKY" drugs because short-term prescribing commonly becomes long term
- Problems with chronic (daily) benzo exposure:
  - TACHYPHYLAXIS (INSOMNIA)
  - PHYSICAL DEPENDENCE AND WITHDRAWAL (withdrawal symptoms are identical to indications for the drug)
  - LIKELY IMPAIR HELP SEEKING BEHAVIOR
  - FDA INDICATION ARE ALL FOR SHORT TERM USE
  - EFFICACY STUDIES ARE ALMOST ALL SHORT DURATION

Prescribing Dilemma # 2

Review: Dr. Parran's Presentation

- To Taper Off the benzodiazepine
  - **Short** – switch to intermediate onset, long T1/2 agent administered **nightly** and taper.
  - **Long** – switch to intermediate onset, long T1/2 **nightly** and taper.
- Start NON-benzo TX Plan for mental health issues
- The Taper (Outpatient setting)
  - 10% / month = NON - urgent taper
  - 10% / week = Urgent taper
- Avoid PRN benzos entirely

Prescribing Dilemma #3

"My patient has severe pain, but she is also probably abusing/misusing the prescriptions."

Prescribing Dilemma # 3

Presentation: There is a legitimate diagnosis supporting the prescribing of a controlled substance, such as an opioid for chronic pain, but the prescriber has reason to believe that the patient may misuse, abuse, or divert the medication.

Dilemma: Prescribe the controlled substance or withhold it? Are there any risk mitigation measures the prescriber can take? Is there a third option?

Prescribing Dilemma # 3

Review: Dr. Parran's Presentation

- January 2016 Annals of Intl Med: 90% of patients continued to receive prescription opioids after an accidental overdose was recorded in the chart
- March 2016 JGIM – Benzos are prescribed more frequently to patients with risk factors for benzo-related adverse events

Prescribing Dilemma # 3

Review: Dr. Engeriser's Presentation on Buprenorphine Management

- How should I react to a positive UDS?
  - Buprenorphine is a risk reduction strategy
  - A positive drug screen in itself should not be a reason to deny/stop treatment
  - Drug screens positive for fentanyl or methadone require caution
  - Benzodiazepines, barbiturates, and alcohol can increase risk of overdose
  - Continued positive UDS on follow-up appointments may require a change in treatment strategy

Prescribing Dilemma #4

"What risk and abuse mitigation strategies do you want me to use?"

Prescribing Dilemma # 4

Presentation: The Board requires the use of risk and abuse mitigation strategies tailored to the individual patient.

Dilemma: There are many strategies to choose from. Which one does the Board want me to use?

Prescribing Dilemma # 4

Review: PDMP Presentation

- Overdose risks scores provided for all patients.
- Prescribers can search for prescriptions dispensed under his/her DEA number (MyRx).
- Quarterly Prescriber Reports.
- EHR Integration: Allows prescribers to access PDMP directly from the EHR.
- Application: How to use these reports?

Who should utilize risk and abuse mitigation strategies?

A) COLLABORATING/SUPERVISING PHYSICIAN ONLY

B) THE PHARMACIST

C) EVERY PRACTITIONER

D) THE PRACTITIONER THAT SAW THE PATIENT FIRST

Prescribing Dilemma #5

"An investigator just came to my office. Am I going to lose my license?"

Prescribing Dilemma # 5

Presentation: A Board investigator comes to your office with a subpoena or communication from the Board about your controlled substance prescribing.

Dilemma: What is going to happen next? Should I change anything I'm doing?

Prescribing Dilemma # 5

- Self-audit questions:
  - Are my licenses in order?
  - Am I following the rules? Did the investigator just educate me on a rule?
  - Are my medical records and documentation up to date?
- Possible outcomes:
  - Nothing happens
  - Educational letter
  - Interview with the Board
  - Mandated CME
  - Discipline

Prescribing Dilemma #6

"What's the deal with testosterone?"

Prescribing Dilemma # 6

Review: Dr. Koulianos on Testosterone

- Most men who need testosterone don't receive treatment, while those who don't need it, do. Low testosterone becomes increasingly common as men age.
- According to the American Urology Association, a diagnosis should rely on both blood tests and clear, persistent symptoms
- A.U.A. guideline: healthy testosterone levels in men fall between 300 and 800 nanograms per deciliter. However, testosterone can fluctuate widely. Levels are highest in the morning
- There is also a "plateau effect" with testosterone. Once a patient reaches his personal threshold, taking more of the hormone isn't going to do very much.

Is an Advanced Practice Provider required to have a controlled substance certificate to prescribe testosterone?

A)YES

B)NO

Resources

Board Website: www.albme.gov

- Rules page: Rules and Laws | Alabama Board of Medical Examiners & Medical Licensure Commission
- Practice Issues & Opinions | Alabama Board of Medical Examiners & Medical Licensure Commission (albme.gov)
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Prescribing Dilemmas: Case Studies from the Alabama Board of Medical Examiners Part 2

EFFIE HAWTHORNE, JD, ASSOCIATE GENERAL COUNSEL

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William M. Perkins,
Executive Director

Prescribing Dilemma #7

"What do you mean when you say I have to rotate prescriptions?"

Who is required to rotate controlled substance prescriptions?

A) FIRST PRESCRIBER AND SECOND PRESCRIBER

B) COLLABORATING/SUPERVISING PHYSICIAN AND APP

C) NO ONE

D) OFFICE MANAGER

Prescribing Dilemma # 7

Presentation: The Board audits a collaborative practice between a physician and a CRNP. The Board auditor checks the controlled substance prescribing of the CRNP and finds that the CRNP is not alternating prescriptions with the physician as required by the QACSC protocol.

Dilemma: There are special protocols for the use of a QACSC by a CRNP or PA.

QACSC Protocols

- If the **physician initiates** the medication, and the patient is well-maintained, the APP may prescribe a 30-day supply with 2 reissues up to 90 days. (3 separate scripts) DEAs will alternate every 90 days.
- If **APP initiates** the medication, they are limited to a 30-day supply. The physician must prescribe the next 30-days under his/her own DEA. Once well-maintained, prescriptions will alternate every 90 days.
- Physician must have an established and on-going relationship with the patient! Must see the patient at least once per year.
- The collaborating/ supervising physician must check the APP's prescribing on a quarterly basis by logging into his/her own PDMP using their name and password.

NP/PA Initiates a Schedule 4 Drug for a Patient

- He/she may prescribe a 30-day supply.
- Next visit: The physician must write the follow up prescription under his/her DEA.
- If the patient is well-maintained, the NP/PA may write the next 30-day prescription with 2 reissues (up to 90 days).
- The physician should write the next 90-day prescription under his/her own DEA/ACSC.
- The PDMP should reflect the alternations every 90 days.
- You can see this information under the patient in the PDMP.
- The physician should see the patient at least once per year.
- If the physician initiates the medication, the NP/PA may write a 30-day prescription with 2 reissues if well-maintained.

"I prescribe electronically and send my physician the prescriptions to review. Does this count?"

The PDMP must show alternating prescribers.

The prescriptions must be **signed** by the NP/PA or physician- not just "reviewed".

Check your PDMP regularly. Call the pharmacy if you find discrepancies.

Prescribing Dilemma #8

"What do I do with all these pills my patient just brought me?"

The patient should take them back home and flush them or dump them down the drain.

A) TRUE

B) FALSE

Prescribing Dilemma # 8

Presentation: A patient or family member of a patient has unused controlled substances and brings them to you for disposal.

Dilemma: How do we educate patients and families about the disposal of unwanted controlled substances, and how do we use the options available to them?

Prescribing Dilemma # 8

Review: Dr. Ayers on Palliative Medicine

- Make a plan for disposal with the family at the outset of care
- Provide a limited supply of pills
- Perform PDMP checks
- Perform routine pill counts during home visits
- Utilize a lock box, if necessary
- Utilize urine drug screens
- Facilitate destruction of unused medications

Prescribing Dilemma # 8

Review: Dr. Ayers on Palliative Medicine

- Flushing or dumping down a drain is not the best way to dispose of medication.
- Disposal in Household Trash
  - Remove the medicine from its original container and mix it with an undesirable substance, such as used coffee grounds or kitty litter.
  - Place the mixture in a sealable bag, empty bag, or other container to prevent medicine from leaking or breaking out of a garbage bag.
- Medication "Take-Back" Programs
  - Collection boxes overseen by law enforcement or pharmacies

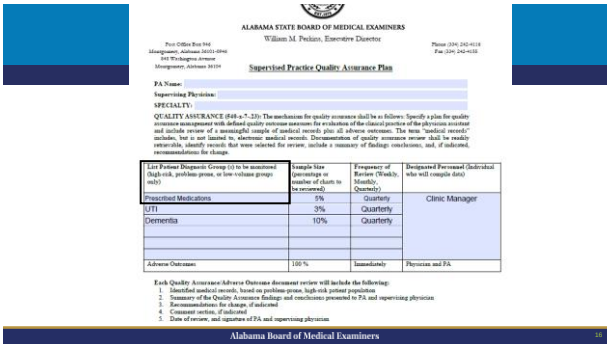
Prescribing Dilemma #9

"What does QA for prescribing controlled substances look like? Isn't it just chart review?"

Quality Assurance for Controlled Prescribing

Controlled substance prescribing can be a part of your quarterly QA.

Data can be compiled by office staff and reviewed by physician/CRNP/CNM/PA.



ALABAMA STATE BOARD OF MEDICAL EXAMINERS

William M. Perkins, Executive Director

Post Office Box 946
Montgomery, Alabama 36101-0946
848 Washington Avenue
Montgomery, Alabama 36104

Phone: (334) 242-4116
Fax: (334) 242-4155

Supervised Practice Quality Assurance Plan

PA Name:
Supervising Physician:
SPECIALTY:

QUALITY ASSURANCE (648-x-7-.23): The mechanism for quality assurance shall be as follows: Specify a plan for quality assurance management with defined quality outcome measures for evaluation of the clinical practice of the physician assistant and include review of a meaningful sample of medical records plus all adverse outcomes. The term "medical records" includes, but is not limited to, electronic medical records. Documentation of quality assurance review shall be readily retrievable, identify records that were selected for review, include a summary of findings conclusions, and, if indicated, recommendations for change.

List Patient Diagnosis Group (s) to be monitored (high-risk, problem-prone, or low-volume group only)	Sample Size (percentage or number of charts to be reviewed)	Frequency of Review (Weekly, Monthly, Quarterly)	Designated Personnel (Individual who will compile data)
Prescribed Medications	5%	Quarterly	Clinic Manager
UTI	3%	Quarterly	
Dementia	10%	Quarterly	
Adverse Outcomes:	100 %	Immediately	Physician and PA

Each Quality Assurance/Adverse Outcome document review will include the following:
1. Identified medical records, based on problem-prone, high-risk patient population
2. Summary of the Quality Assurance findings and conclusions presented to PA and supervising physician
3. Recommendations for change, if indicated
4. Comment section, if indicated
5. Date of review, and signature of PA and supervising physician

COLLECTIVE QA REPORT: PRESCRIBED MEDICATIONS

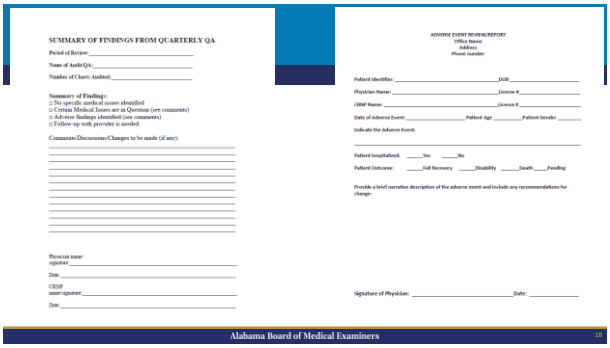
Review Period: ____Weekly ___Monthly ____Quarterly Date of Review: _____

Total # of patients seen: _____ Adverse Outcomes: _____ Y _____ N
SUMMARY STATEMENT: On the above date, _____ (insert #) charts, identifiers listed below were chosen at random and reviewed for quality monitoring. The charts were reviewed for the following Prescribed Medication indicators:

1. Medications are prescribed per FDA guidelines (per PDR, NP Manual, or Product Insert)
2. Proper chart documentation of medication name, dosage, and directions for use and are legible
3. Medications prescribed are appropriate for the patient dx according to practice protocol
4. Controlled medications were ordered according to regulations of BME and ABN
5. No medications were ordered or refilled due to nature of visit

Chart #/Identifier			
Date of Service			
D=Discussed –noted changes which are needed **?** = Appropriate **NA**=Not applicable	1. 2. 3. 4. 5.		

Chart #/Identifier			
Date of Service			
D=Discussed –noted changes which are needed **?** = Appropriate **NA**=Not applicable	1. 2. 3. 4. 5.		



SUMMARY OF FINDINGS FROM QUARTERLY QA

Period of Review:_____
Name of Audit/QA:_____
Number of Charts Audited:_____

Summary of Findings:
□ No specific medical issues identified
□ Certain Medical Issues are as Question (see comments)
□ Adverse findings identified (see comments)
□ Follow-up with provider is needed

Comments/Discussions/Changes to be made (if any):
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Physician name/
signature _____
Date:_____
CRNP
name/signature:_____
Date:_____

ADVERSE EVENT REVIEW/REPORT
Office Name
Address
Phone number

Patient Identifier: _____DOB _____
Physician Name: _____License #_____
CRNP Name: _____License #_____
Date of Adverse Event: _____ Patient Age _____Patient Gender _____
Indicate the Adverse Event:
_____
Patient hospitalized: _____Yes _____No
Patient Outcome: _____Full Recovery _____Disability _____Death _____Pending

Provide a brief narrative description of the adverse event and include any recommendations for change:

Signature of Physician: _____Date: _____

If the physician and APP work in the same office with each other, QA is not required.

A) TRUE

B) FALSE

Prescribing Dilemma #10

"Can my PA or CRNP prescribe weight loss and testosterone medications via telehealth while I work on my farm?"

Prescribing Dilemma # 10

Issues:

- Is this a bona fide collaboration?
- Are appropriate risk and abuse mitigation strategies being used?
- Are the QACSC protocols being followed?
- Are conflicts of interest being addressed?
- Is the patient receiving appropriate care?

Can an APP prescribe controlled substances for weight loss?

A) YES

B) NO

Resources

Board Website: www.albme.gov

- Rules: Rules and Laws | Alabama Board of Medical Examiners & Medical Licensure Commission
- Practice Issues & Opinions | Alabama Board of Medical Examiners & Medical Licensure Commission (albme.gov)
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Prescribing Controlled Substances by Telehealth: Legal FAQs

EFFIE HAWTHORNE, JD, ASSOCIATE GENERAL COUNSEL

MISSION

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William M. Perkins,
Executive Director

Key Laws

Alabama's telehealth laws are codified at: Section 34-24-700, et seq.

- Section 34-24-701 – Definitions
- Section 34-24-702 – Licensure Requirements
- Section 34-24-703 – Duties of the physician
- Section 34-24-704 – Issuance of Legend and Controlled Prescriptions
- Section 34-24-705 – Compliance with State and Federal Laws

BME Declaratory Rulings

The Board has issued declaratory rulings since the passage of the state's telehealth laws interpreting its application to specific situations.

- April 27, 2023: Provision of Telehealth by Limited Licensees
- June 22, 2023: VA System Clinical Video Telehealth Protocol
- August 17, 2023: Contrast Injection under Remote Supervision

Section 34-24-701 - Definitions

Originating site. The physical location of a patient at the time in which telehealth medical services are provided.

Distant site. The physical location of a physician at the time in which telehealth medical services are provided.

Telehealth. The use of electronic and telecommunications technologies, including devices used for digital health, asynchronous and synchronous communications, or other methods, to support a range of medical care and public health services

Telemedicine. A form of telehealth referring to the provision of medical services by a physician at a distant site to a patient at an originating site via asynchronous or synchronous communications, or other devices that may adequately facilitate and support the appropriate delivery of care. The term includes digital health but does not include incidental communications between a patient and a physician.

Frequently Asked Questions #1

Is there a special license just for telehealth?

Answer: No.

Section 34-24-702 – Licensure Requirements

Physicians who engage in the provision of telehealth medical services to any individual in Alabama must possess a full and active license to practice medicine in Alabama - this is the same license that every physician is issued.

The provision of telehealth medical services is deemed to occur at the patient's physical location (the "Originating Site") within Alabama at the time telehealth medical services are provided.

Frequently Asked Questions #2

Are there exemptions to the licensure requirement?

Answer: Yes.

Section 34-24-702 – Licensure Requirements

Telehealth services that may not require an Alabama license:

(1) The physician is licensed in another state or D.C., and services are irregular or infrequent (telehealth medical services occurring fewer than ten days in a calendar year or involving fewer than ten patients in a calendar year); or

(2) Services are provided in consultation with an Alabama licensed physician, limited to ten days in a calendar year, or necessary medical care is provided to a patient being transported into Alabama.

Practitioners should consult an attorney with additional questions about when a license is required.

Frequently Asked Questions #3

If the entire practice is telehealth, does someone have to physically see the patient?

Answer: It depends.

Section 34-24-703 – Duties of the Physician

A physician has the same duty to exercise reasonable care, diligence, and skill whether providing services in-person or via telehealth, including when appropriate, to:

- Establish a diagnosis.
- Disclose the diagnosis and evidence for it.
- Discuss the risks and benefits of treatment options.
- Provide a visit summary to the patient and information on how to obtain appropriate follow-up and emergency care if needed.
- A physician-patient relationship must be established either at the initiation of the patient or referral by the patient's established physician.

Section 34-24-703 – Duties of the Physician

Before providing telehealth medical services, the physician must:

- Verify the patient's identity;
- Require the patient to identify his or her physical location, including city and state;
- Disclose the identity and credentials of the physician and any other personnel; and
- Obtain the patient's consent for the use of telehealth and document it in the patient's medical record.

Frequently Asked Questions #4

Are in-person visits necessary?

Answer: It depends.

Section 34-24-703 – Duties of the Physician

In-Person Visit Requirement

If a physician or practice group provides telehealth services more than four times in a 12-month period to the same patient for the same medical condition without resolution, the physician shall either:

(1) See the patient in person within a reasonable amount of time, which shall not exceed 12 months; or

(2) Appropriately refer the patient to a physician who can provide the in-person care within a reasonable amount of time, which shall not exceed 12 months.

The provision of telehealth services that includes video communication to a patient at an originating site with the **in-person** assistance of a licensed physician, physician assistant, certified registered nurse practitioner, certified nurse midwife, or other person licensed by the Alabama Board of Nursing shall constitute an in-person visit for this purpose. An LPC or LSW at the originating site does not meet this requirement.

Mental Health Exemption to the In-Person Req

However, this provision shall not apply to the provision of mental health services as defined in Section 22-50-1. Ala. Code § 34-24-703(f)(5).

Definition of Mental Health Services:

Diagnosis of, treatment of, rehabilitation for, follow-up care of, prevention of and research into the causes of all forms of mental or emotional illness, including, but not limited to, alcoholism, drug addiction, or epilepsy in combination with mental illness or an intellectual disability.

Declaratory Ruling of April 27, 2023: Provision of Telehealth by Limited Licensees

Question Presented: Where a teaching physician licensed under Ala. Code § 34-24-75(a) engages in telehealth services exclusively on behalf of the employing academic medical center and does not receive reimbursement outside his or her employment with the academic medical center for the service, may the limited licensed teaching physician provide telehealth services to an outside health care facility that has contracted with the academic medical center for those services?

Declaratory Ruling of April 27, 2023: Provision of Telehealth by Limited Licensees

Answer: A teaching physician licensed under Ala. Code § 34-24-75(a) *may* provide telehealth services to an outside health care facility that has contracted with the teaching physician's employing academic medical center for those services *if* the physician is providing the telehealth services exclusively on behalf of the employing academic medical center and does not receive reimbursement outside of his or her employment with the academic medical center for the services.

Declaratory Ruling of August 17, 2023: Contrast Injection under Remote Supervision

Question Presented: May a radiologic technologist who holds ARRT certification and registration administer contrast media via an intravenous injection to a patient in Alabama undergoing a Computed Tomography ("CT") or Magnetic Resonance Imaging ("MRI") diagnostic test pursuant to the order of a physician while (a) such radiologic technologist is under the remote supervision of an Alabama-licensed, board-certified radiologist who is virtually present in the office suite through audio/video ("A/V") real-time communications technology that enables the radiologist to be immediately available to furnish assistance and direction throughout the performance of the procedure and (b) an Alabama-licensed Registered Nurse ("RN") is physically present at the facility to accept real-time instructions from the supervising radiologist in order to provide appropriate treatment to the patient in the event patient experiences an adverse reaction to the contrast media?

Declaratory Ruling of August 17, 2023: Contrast Injection under Remote Supervision

Answer: A radiologic technologist who holds ARRT certification and registration *may* administer contrast media via an intravenous injection to a patient at an originating site in Alabama undergoing a Computed Tomography ("CT") or Magnetic Resonance Imaging ("MRI") diagnostic test pursuant to the order of a physician *only when* (a) such radiologic technologist is under the real-time supervision of an Alabama-licensed, board-certified radiologist who is virtually present in the office suite utilizing synchronous audio and visual real-time communications technology that enables the radiologist to observe, direct, and furnish assistance and direction to the radiologic technologist throughout the performance of the procedure; (b) an Alabama-licensed Registered Nurse ("RN"), Certified Registered Nurse Practitioner ("CRNP"), Physician Assistant ("PA"), or non-radiologist physician who is appropriately trained to treat adverse reactions to contrast media is physically present at the originating site whenever contrast media is being administered by intravenous injection to a patient; (c) the originating site facility's policy and procedures includes a modality for the supervising radiologist to provide real-time instructions to the RN, CRNP, PA, or other physician assigned to treat contrast-media reactions; and (d) the originating site facility is equipped with the emergency supplies, equipment, and drugs necessary to treat a contrast media reaction.

Frequently Asked Questions #5

Can I initiate controlled substance prescribing via telehealth if I am a MD/DO?

Answer: Yes.

Section 34-24-704 – Issuance of Legend and Controlled Prescriptions

A prescriber may prescribe a legend drug, medical supplies, or a controlled substance via telehealth if the prescriber is authorized to do so under state and federal law. A prescription for a controlled substance may only be issued via telehealth if:

(1) The telehealth visit includes synchronous audio or audio-visual communication using HIPAA-compliant equipment with the prescriber;

(2) The prescriber has had at least one in-person encounter with the patient within the preceding 12 months; and

(3) The prescriber has established a legitimate medical purpose for issuing the prescription within the preceding 12 months.

Section 34-24-704 – Issuance of Legend and Controlled Prescriptions

The in-person encounter may be satisfied by the in-person assistance of personnel licensed by the Board of Medical Examiners or Board of Nursing at the originating site when the prescriber is evaluating the patient from a distant site using video communication.

- An LPC or LSW at the originating site does not meet this requirement.

Declaratory Ruling of June 22, 2023: VA System Clinical Video Telehealth Protocol

Question Presented: Whether the Clinical Video Telehealth (CVT) protocol utilized by the Birmingham VA HealthCare System (BVAHCS) meets the "in-person" requirement found under Ala. Code § 34-24-704(b)(1)b? This provision governs when a controlled substance may be prescribed following a telehealth visit and requires, in pertinent part, the prescriber to have had "at least one in-person encounter with the patient within the preceding 12 months." Ala. Code § 34-24-704(b)(1)b.

Declaratory Ruling of June 22, 2023: VA System Clinical Video Telehealth Protocol

Answer: The "in-person" requirement found at Ala. Code § 34-24-704(b)(l)b may be satisfied by the in-person assistance of personnel licensed by the Board of Medical Examiners or the Board of Nursing at the originating site when the prescriber is evaluating the patient from a distant site using video communication. Therefore, the Board opines that the CVT protocol is an acceptable approach to meeting the requirement, as stated in Ala. Code § 34-24-704(b)(l)b, for an in-person encounter between a prescriber and the patient to whom a controlled substance is being prescribed if the staff member who is physically present with the patient for the appointment check-in and check-out is a licensee of the Board of Medical Examiners or the Board of Nursing.

Guidance Letter Issued August 2024

Question Posed to the Board:

"Whether the "in-person" encounter that has been conducted for a patient by an initial prescriber as required under Ala. Code § 34-24-704(b)(1)b must be repeated by a subsequent prescriber in order to continue to prescribe that patient a controlled substance via a telemedicine visit within the same 12-month period, when the latter prescriber, like the former, is treating the patient under the auspices of our company and within our offices?"

Answer:

The Board is of the opinion that a subsequent prescriber in the same practice or physician group, of the same or similar specialty as the previous prescriber in that practice group, may continue to prescribe a controlled substance to a patient based upon an "in-person" examination by the previous prescriber.

Guidance Letter Issued August 2024

Caveats:

- Each provider has full access to the records of the patients they are seeing, including all documentation from any previous encounters with other providers.
- The covering or subsequent prescriber would have full access to the documentation of the "in-person" evaluation that was performed for the same patient with the same condition(s) within the preceding 12 months.
- Protocols are in place for patients who will be seen via telemedicine to continue receiving treatment in the event that their original prescriber is unable to see them.
- The Board acknowledges the apparent conflict between Ala. Code § 34-24-704(b)(1)b and established, safe medical practice and issues this guidance as a temporary accommodation.

Telehealth is a Modality, not a Different Standard of Care

Question: I write controlled substance prescriptions to my patient. Does Federal law require that I see the patient every 30 days?

Answer: No. Neither the CSA nor DEA regulations require a practitioner to see a patient every 30 days. Nonetheless, the CSA and DEA regulations do require that a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. See 21 CFR 1306.04(a). As DEA has previously stated, 'practitioners who prescribe controlled substances must see their patients in an appropriate time and manner so as to meet their obligation to prescribe only for a legitimate medical purpose in the usual course of professional practice and to thereby minimize the likelihood that patients will abuse, or become addicted to, the controlled substances.' *Issuance of Multiple Prescriptions for Schedule II Controlled Substances*, 72 FR 64921, 64928 (2007). **EO-DEA093, June 23, 2020**

Telehealth is a Modality, not a Different Standard of Care

Ala. Code Section 34-24-703(a)

A physician providing telehealth medical services shall owe to the patient the same duty to exercise reasonable care, diligence, and skill as would be applicable if the service or procedure were provided in person. Telehealth medical services shall be governed by the Medical Liability Act of 1987, codified in Sections 6-5-540 through 6-5-552, and shall be subject to the exclusive jurisdiction and venue of the circuit courts of the State of Alabama, regardless of the citizenship of the parties.

Frequently Asked Questions #6

Can I prescribe controlled substances via telehealth if I am a CRNP/CNM/PA?

Answer: Yes.

Frequently Asked Questions #7

Can I prescribe to my existing patient while they are in another state?

Answer: Probably not.

Licensure Requirements in Other States

All states require a physician to be licensed in that state in order to practice medicine there. Because most states define the practice of medicine to occur where the *patient* is physically located, if your patient is in another state when the telemedicine visit occurs, you must be licensed in that state unless the state provides for a limited exception.

Florida, Georgia, Tennessee, and Mississippi all require a physician to be licensed in that state to perform a telemedicine visit while a person is in that state. The residency of the person does not alter this requirement.

Florida provides an exception for a true emergency. All four states permit an unlicensed physician to consult with a physician licensed in that state via telehealth, but this consult exception does not permit the unlicensed physician to treat the patient.

Florida issues a free telehealth registration to permit physicians to practice via telehealth only. A holder of this free registration may not issue a prescription for a Schedule II controlled substance.

Georgia issues a telehealth license that prohibits physical practice in GA, chronic pain practice, and the issuance of prescriptions for Schedule II controlled substances.

Frequently Asked Questions #8

Can I prescribe controlled weight loss medications via telemedicine?

Answer: Probably not.

Ala. Admin. Code R. 540-X-17-.03

(2) A written prescription or a written order for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity shall be signed by the prescribing physician on the date the medication is to be dispensed or the prescription is provided to the patient. If an electronic prescription is issued for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity, the prescribing physician must sign and authorize the transmission of the electronic controlled substance prescription in accordance with federal law and must comply with all applicable requirements for Electronic Prescriptions for Controlled Substances (See 21 CFR Parts 1300, 1304, 1306 and 1311, as amended effective June 1, 2010). Such prescriptions or orders shall not be called into a pharmacy by the physician or an agent of the physician.

(3) The prescribing/ordering physician shall be present at the facility when he or she prescribes, orders or dispenses a controlled substance for a patient for the purpose of weight reduction or treatment of obesity.

Ala. Admin. Code R. 540-X-17-.03

(1) Only a doctor of medicine or doctor of osteopathy licensed by the Medical Licensure Commission of Alabama may order, prescribe, dispense, supply, administer or otherwise distribute a controlled substance in Schedule III, IV or V to a person for the purpose of weight control, weight loss, weight reduction, or treatment of obesity, except that a Physician Assistant, Certified Registered Nurse Practitioner or Certified Nurse Midwife may prescribe non-controlled drugs for such purpose. If a Physician Assistant, Certified Registered Nurse Practitioner or Certified Nurse Midwife prescribes non-controlled drugs for weight reduction or the treatment of obesity, the prescriber shall comply with the guidelines and standards of this Chapter which apply to MDs and DOs.

Frequently Asked Questions #9

Can I prescribe testosterone via telemedicine?

Answer: Should you?

Ala. Admin. Code R. 540-X-17-.03

Frequently Asked Questions #10

Does the Federal DEA waiver permit an out of state physician to prescribe controlled substances to an Alabama patient without possessing an ACSC/QACSC/LPSP ?

Answer: No.

Section 34-24-705 – Compliance with State and Federal Laws

(a) A physician who provides a telehealth medical service shall comply with all federal and state laws, rules, and regulations applicable to the provision of telehealth medical services, including the Health Insurance Portability and Accountability Act (HIPAA), and shall use devices and technologies in compliance with these laws, rules, and regulations. A physician who provides telehealth medical services shall also take reasonable precautions to protect the privacy and security of all verbal, visual, written, and other communications involved in the delivery of telehealth medical services.

Section 34-24-705 – Compliance with State and Federal Laws

Requirement to Maintain Medical Records:

- A physician who provides telehealth services must maintain complete and accurate medical records, must have access to the patient's medical records, and must be able to produce records upon demand by the patient, the Board of Medical Examiners, or the Medical Licensure Commission.

Medical Licensure Commission Rule 545-X-4-.08(2)(e):

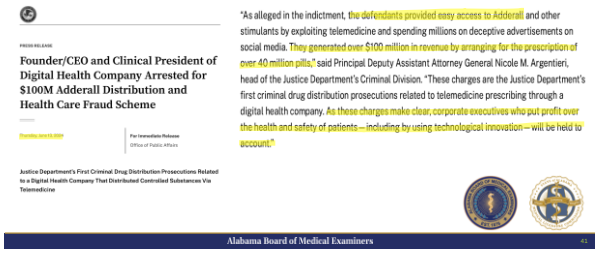
- (e) Retention and Access by Physicians Practicing Telemedicine. Physicians who practice medicine via telemedicine have the same duty as all other physicians to adhere to these rules relating to medical records. Physicians who provide care via telemedicine must retain access to the medical records which document their delivery of health care services via telemedicine. A physician who is unable to access and produce the medical records documenting his or her practice of medicine via telemedicine upon demand for inspection or review by the Board of Medical Examiners or Medical Licensure Commission shall be in violation of Code of Ala. 1975, §34-24-360(2) and (23).

Frequently Asked Questions #11

What is the DEA doing with telehealth?

Answer: The FBI, DEA, and HHS have task forces focused on health care fraud. The DEA has rules published for comment addressing telehealth.

Frequently Asked Questions # 11



PRESS RELEASE

Founder/CEO and Clinical President of Digital Health Company Arrested for $100M Adderall Distribution and Health Care Fraud Scheme

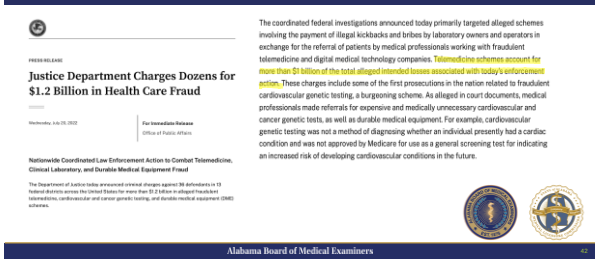
Thursday, June 13, 2019

For Immediate Release
Office of Public Affairs

Justice Department's First Criminal Drug Distribution Prosecutions Related to a Digital Health Company That Distributed Controlled Substances Via Telemedicine

"As alleged in the indictment, the defendants provided easy access to Adderall and other stimulants by exploiting telemedicine and spending millions on deceptive advertisements on social media. They generated over $100 million in revenue by arranging for the prescription of over 40 million pills," said Principal Deputy Assistant Attorney General Nicole M. Argentieri, head of the Justice Department's Criminal Division. "These charges are the Justice Department's first criminal drug distribution prosecutions related to telemedicine prescribing through a digital health company. As these charges make clear, corporate executives who put profit over the health and safety of patients – including by using technological innovation – will be held to account."

Frequently Asked Questions # 11



PRESS RELEASE

Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud

Wednesday, July 28, 2021

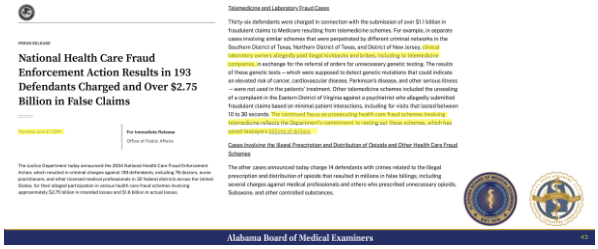
For Immediate Release
Office of Public Affairs

Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

The Department of Justice today announced criminal charges against 36 defendants in 13 federal districts across the United States for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment (DME) schemes.

The coordinated federal investigations announced today primarily targeted alleged schemes involving the payment of illegal kickbacks and bribes by laboratory owners and operators in exchange for the referral of patients by medical professionals working with fraudulent telemedicine and digital medical technology companies. Telemedicine schemes account for more than $1 billion of the total alleged intended losses associated with today's enforcement action. These charges include some of the first prosecutions in the nation related to fraudulent cardiovascular genetic testing, a burgeoning scheme. As alleged in court documents, medical professionals made referrals for expensive and medically unnecessary cardiovascular and cancer genetic tests, as well as durable medical equipment. For example, cardiovascular genetic testing was not a method of diagnosing whether an individual presently had a cardiac condition and was not approved by Medicare for use as a general screening test for indicating an increased risk of developing cardiovascular conditions in the future.

Frequently Asked Questions # 11



PRESS RELEASE

National Health Care Fraud Enforcement Action Results in 193 Defendants Charged and Over $2.75 Billion in False Claims

Thursday, June 27, 2024

For Immediate Release
Office of Public Affairs

The Justice Department today announced the 2024 National Health Care Fraud Enforcement Action, which resulted in criminal charges against 193 defendants, including 76 doctors, nurse practitioners, and other licensed medical professionals in 32 federal districts across the United States, for their alleged participation in various health care fraud schemes involving approximately $2.75 billion in intended losses and $1.6 billion in actual losses.

Telemedicine and Laboratory Fraud Cases

Thirty-six defendants were charged in connection with the submission of over $1 billion in fraudulent claims to Medicare resulting from telemedicine schemes. For example, in separate cases involving similar schemes that were perpetrated by different criminal networks in the Southern District of Texas, Northern District of Texas, and District of New Jersey, clinical laboratory owners allegedly paid illegal kickbacks and bribes, including to telemedicine companies, in exchange for the referral of orders for unnecessary genetic testing. The results of these genetic tests — which were supposed to detect genetic mutations that could indicate an elevated risk of cancer, cardiovascular disease, Parkinson's disease, and other serious illness — were not used in the patients' treatment. Other telemedicine schemes included the unsealing of a complaint in the Eastern District of Virginia against a psychiatrist who allegedly submitted fraudulent claims based on minimal patient interactions, including for visits that lasted between 10 to 30 seconds. The continued focus on prosecuting health care fraud schemes involving telemedicine reflects the Department's commitment to rooting out these schemes, which has saved taxpayers billions of dollars.

Cases Involving the Illegal Prescription and Distribution of Opioids and Other Health Care Fraud Schemes

The other cases announced today charge 14 defendants with crimes related to the illegal prescription and distribution of opioids that resulted in millions in false billings, including several charges against medical professionals and others who prescribed unnecessary opioids, Suboxone, and other controlled substances.

Frequently Asked Questions # 11

DEA announced 3 new rules to make permanent some temporary telemedicine flexibilities established during the COVID-19 public health emergency while also establishing new patient protections.

- These rules do not apply to telemedicine visits in which a patient has already been seen in-person by a medical provider. Once a patient has had an in-person visit with a medical provider, the medical provider may prescribe any medications through telemedicine indefinitely. Also, if a telemedicine visit does not involve a patient being prescribed medications, then the telemedicine rules do not apply. Patients can always have telemedicine visits with medical providers. These rules only apply if a patient has never been seen in-person by the medical provider and the patient is being prescribed controlled medication.

Frequently Asked Questions # 11

DEA Rule on Buprenorphine delayed with a new effective date of December 31, 2025.

- Addresses situations where a prescriber is issuing an Rx to a patient to treat OUD by telemedicine where the prescriber has not previously conducted an in-person medical evaluation.
- Prescriber must review the patient's PDMP for the state in which the patient is located during the telemedicine encounter.
- May only prescribe an initial six-month supply of buprenorphine (split amongst several prescriptions totaling six calendar months) through audio-only means.

Frequently Asked Questions # 11

DEA Rule on Buprenorphine delayed with a new effective date of December 31, 2025.

- Additional prescriptions can be issued under other forms of telemedicine as authorized under the Controlled Substances Act, or after an in-person medical evaluation is conducted.
- The pharmacist must verify the identity of the patient prior to filling a prescription.
- This regulation does not affect practitioner-patient relationships in cases where an in-person medical evaluation has previously occurred.

Frequently Asked Questions # 11

DEA Rule on Telehealth Registration (Comment period ended March 18, 2025)

The rule proposes to create three types of Special Registration:

(1) Telemedicine Prescribing Registration, authorizing qualified clinician practitioners to prescribe Schedule III-V controlled substances.

(2) Advanced Telemedicine Prescribing Registration, authorizing qualified specialized clinician practitioners to prescribe Schedule II-V controlled substances.

(3) Telemedicine Platform Registration authorizing qualified covered online telemedicine platforms, in their capacity as platform practitioners, to dispense Schedule II-V controlled substances.

The rule also provides heightened prescription, recordkeeping, and reporting requirements.

Frequently Asked Questions # 11

DEA Rule for Prescribing Controlled Substances within the VA System

- Effective February 18, 2025
- This rule authorizes Department of Veterans Affairs (VA) practitioners acting within the scope of their VA employment to prescribe controlled substances via telemedicine to a VA patient with whom they have **not** conducted an in-person medical evaluation. VA practitioners are permitted to prescribe controlled substances to VA patients if another VA practitioner has, at any time, previously conducted an in-person medical evaluation of the VA patient, subject to certain conditions.

Resources

Board Website: www.albme.gov

- Rules: Rules and Laws | Alabama Board of Medical Examiners & Medical Licensure Commission
- Practice Issues & Opinions | Alabama Board of Medical Examiners & Medical Licensure Commission (albme.gov)
- Investigations & Misconduct | Alabama Board of Medical Examiners & Medical Licensure Commission (albme.gov)
- Reporting | Alabama Board of Medical Examiners & Medical Licensure Commission (albme.gov)

X: Follow @AlaMedBd

- Receive alerts for new rules, agendas, newsletters, etc.
- We are also on Facebook and LinkedIn

Resources

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AN ADVANCED PRACTICE PROVIDER'S PERSPECTIVE ON PRESCRIBING IN A COLLABORATIVE/SUPERVISORY PRACTICE

Adam Kinsaul, DNP, ACNP-BC, CRNP, RNFA

DISCLOSURE

1. I have no financial disclosures
2. I have no corporate / sponsorship disclosures

BACKGROUND

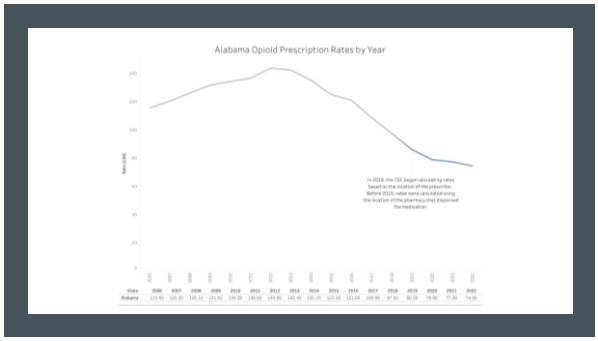
- Graduated from Bevill State Community College 2006
- Graduated from UNA 2008 with my BSN
- Practice as RN at St.Vincent's & UAB 2006-2010
- Graduated from UAB 2010 with MSN Acute Care NP
- Practicing as NP at Southern Orthopedics Precision Sports Medicine in Jasper,AL 2010-Present
- Assistant Professor UAB School of Nursing Acute, Chronic, Continuing Care – Current

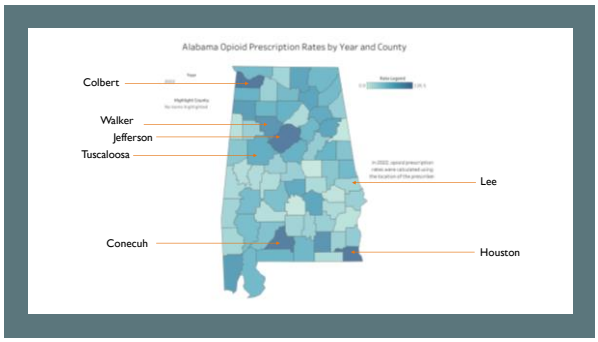
OBJECTIVES

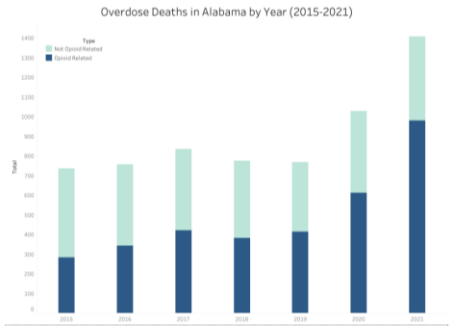
1. Explore the Scope of Prescriptive Authority
2. Examine Challenges and Opportunities In Collaborative Prescribing
3. Promote Effective Collaboration for Patient-Centered Care

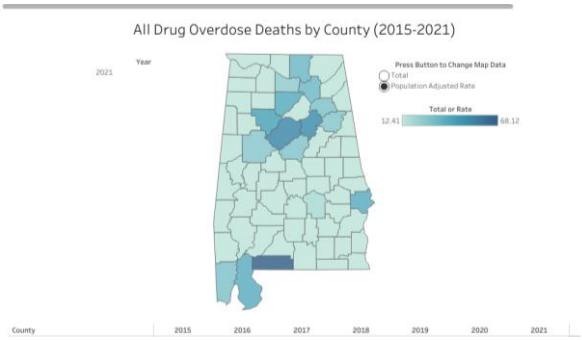
AGENDA

1. Review The Rules
2. Prescribing Practices
3. Special Considerations
4. Risk and Abuse Mitigation
5. Collaborative Strategies









REVIEW THE RULES

QUALIFIED ALABAMA CONTROLLED SUBSTANCE CERTIFICATE

1. Be in collaborative practice with a physician who has an unrestricted Alabama Controlled Substance Certificate (ACSC)
2. Complete total 12 hours approved CME regarding controlled substances one year prior to applying
3. Have at least 12 months active clinical practice in Alabama
4. Apply for QACSC License
5. Apply for DEA Registration

"To prescribe, administer, authorize for administration a Schedule III, IV, or V controlled substance in Alabama, Certified Nurse Practitioners (CRNP) and Certified Nurse Midwives (CNM) must obtain annually a Qualified Alabama Controlled Substances Certificate (QACSC)."

- Schedules III-V Controlled Substances
- Specific to each collaborative practice agreement
- Must be renewed annually

SPECIFIC RULES - QACSC

- Collaborating / Supervising MD/DO must complete an audit of PDMP for prescriber every quarter
- Verbal orders permissible by NP/PA

	Quantity	Provider	Reissue
Initial	30 day supply	NP/PA	None
Established*	30 day supply	NP/PA	2 (90 day)
Dispensing	None	NP/PA	None

*Initial Prescription by MD/DO

SPECIFIC RULES - LPSP

- Long-Acting Schedule II – must be started by MD/DO, can be continued by NP/PA without dosage change – only permitted in Hospice/Palliative Care; Nursing Homes; Oncology
- Schedule II/N – Non-narcotic medications (Amphetamine, Amobarbitol, Pentobarbitol, Secobarbitol)
- Must alternate between NP/PA and MD/DO on subsequent scripts

Short Acting

	Quantity	Provider	Reissue
Initial	30 day supply	NP/PA	None
Established*	30 day supply	NP/PA	None**
Dispensing	None	NP/PA	None
Dose Change (Increase)		MD/DO	

*Initial Prescription by MD/DO
**Schedule II/IIN can have 2 refills

PRESCRIBING PRACTICES

PRESCRIBING PRACTICES

CDC 2022 Guidelines

- *Nonopioid therapies "are at least as effective" as opioids for many acute pain conditions, including low back pain, neck pain, pain related to other musculoskeletal injury (e.g., sprains, strains, tendonitis, and bursitis), pain related to minor surgery…*
- *Maximize the use of nonopioid pharmacology therapies and nonpharmacologic therapies*
- *Nonopioid therapies are preferred for subacute and chronic pain*
- *Prescribe immediate-release opioids, at lowest effective dose, as-needed only, and no more frequent than every 4 hours*
- *Avoid co-prescribing with benzodiazepines*

(AAGMS, 2022)

PRESCRIBING PRACTICES – NP/PA

NPs in Alabama: 9,607

- Offices of Physicians: 48.9%
- Hospitals (state, local, and private): 22%.
- Outpatient Care Centers: 9.1%
- Offices of Other Health Practitioners: 4.1%
- Home Health Care Services: 2.6%

(ABN, 2025; BLS, 2023)

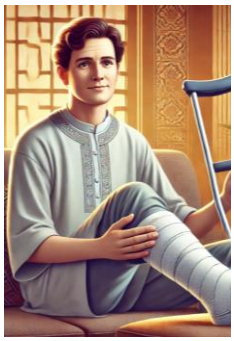
PAs in Alabama: 1,414

- Physician Offices or Clinics: 54.5%
- Hospital Settings: 37.7%
- Urgent Care Centers: 6.5%
- Other Setting: 1.3%

(ALBME, 2023; AAPA, 2020)

PRESCRIBING PRACTICES – NP/PA

- NP/PA practicing in an Orthopedic clinic: Acute Fracture
  - Tylenol Arthritis Strength 650 mg q8 hours
  - Ibuprofen 800 mg q8 or q12 – short course
  - Tramadol or Hydrocodone 5 mg / 7.5 mg q8 hours #21



PRESCRIBING PRACTICES – NP/PA

- NP/PA practicing in an Orthopedic clinic: Post-TKA
  - Tylenol Arthritis Strength 650 mg q8 hours
  - Celebrex 200 mg daily
  - Oxycodone 5 mg q8 hours #21
  - Tizanidine 4 mg qHS
  - Gabapentin 100 mg qHS or BID

PRESCRIBING PRACTICES – NP/PA

- NP/PA practicing in an Urgent Care: Low Back Pain
  - PT for Low Back
  - Tylenol Arthritis Strength 650 mg q8 hours
  - Meloxicam 7.5 mg / 15 mg daily
  - Tizanidine 4 mg qHS or Robaxin 750 mg TID
  - Gabapentin 100 mg qHS or BID*
  - Paraspinous / Trigger Point muscle injections
  - Narcotics ***ONLY*** in extreme situation: Hydrocodone 7.5 mg q8 hours #21

RISK MITIGATION STRATEGIES

1. PDMP
2. Communication
3. Quality Assurance

As part of your QACSC / LPSP rules you are required to:

- Get a PDMP account – the PDMP is your best friend!
- Communication – Keep the collaboration going
- Quality Assurance – It goes both ways

RISK MITIGATION STRATEGIES – PDMP

1. PDMP

- Get a PDMP account – the PDMP is your best friend!
  - Check it ***every time*** before your write a narcotic
  - EMR integration
  - http://alabama.pmpaware.net

RISK MITIGATION STRATEGIES

II. Communication

- Be the communicator – For your Patient
- Be the communicator – For your Collaborator / Supervisor
- Be the communicator – For your Profession

RISK MITIGATION STRATEGIES

III. Quality Assurance

- Keep the quality ***high***
- Don't get lazy

PROMOTING EFFECTIVE COLLABORATION

- Bring Awareness
- Reach Out
- Stay Consistent

REFERENCES

- American Association of Oral and Maxillofacial Surgeons [AAOMS]. (2022). Summary of 2022 CDC practice guideline for prescribing opioids for pain. https://aaoms.org/wp-content/uploads/2024/07/AAOMS_Summary_of_CDC_guideline.pdf
- Alabama Board of Nursing [ABN]. (2025). Daily Statistics. https://www.abn.alabama.gov/9774/statistics-posted-daily-by-the-alabama-board-of-nursing?utm_source=chatgpt.com
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- American Academy of Physician Associates [AAPA]. (2020). Alabama PA practice profile. https://www.aapa.org/wp-content/uploads/2016/12/PAs_In_Alabama.pdf
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THANK YOU

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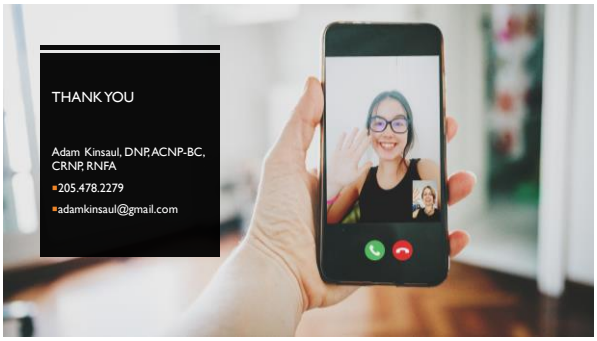


Testosterone: Prescribing Issues

GEORGE T. KOULIANOS, MD, FACOG

Introduction

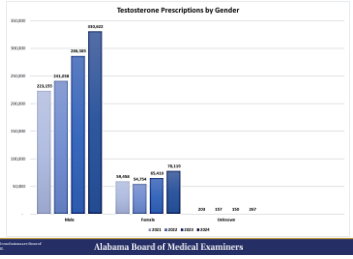
- Nationally, testosterone prescriptions have increased from 7.3 million to more than 11 million between 2019 and 2024. Conservative estimate IQVIA.com
- Increased awareness
- Fueled the rise of questionable clinics selling testosterone and other treatments as a cure all to those who don't need it
- According to the American Urological Association, up to a third of men taking testosterone have never been diagnosed with a deficiency
- 25% of testosterone therapy patients have never had a serum testosterone level checked before starting treatment
- 50% of patients on testosterone therapy have never had a serum testosterone level checked after starting treatment

New York Times, Jan 25, 2025, American Urologic Association 2024

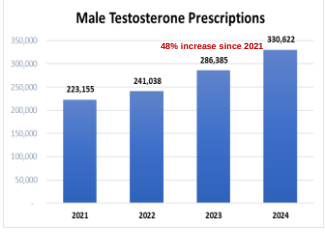
Introduction

- Testosterone is a schedule III-controlled substance with the potential to cause significant adverse effects if prescribed for inappropriate indications and without proper medical supervision

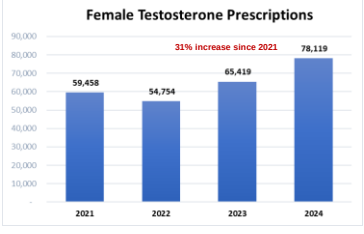
Testosterone Prescriptions by Gender*



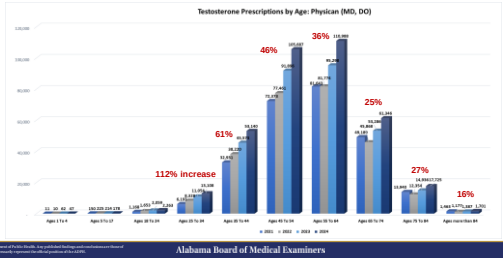
Male Testosterone Prescriptions*



Female Testosterone Prescriptions*

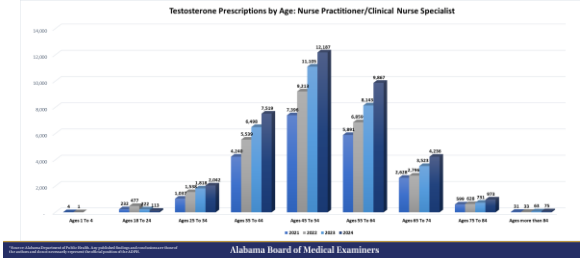


Testosterone Prescriptions by Age: Physician (MD, DO)*



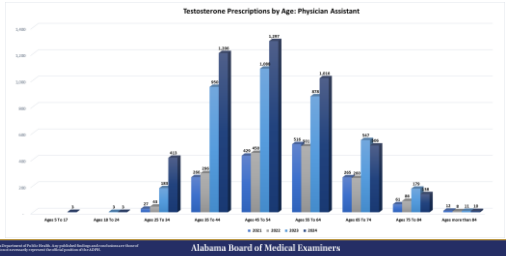
Alabama Board of Medical Examiners

Testosterone Prescriptions by Age: NP/Clinical Nurse Specialist*



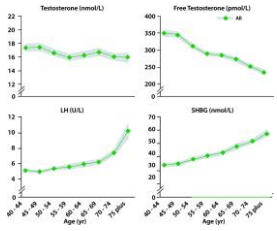
Alabama Board of Medical Examiners

Testosterone Prescriptions by Age: Physician Assistant*



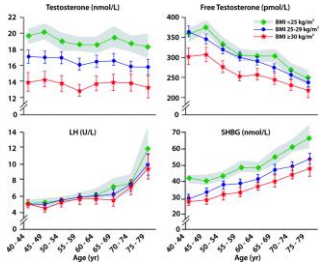
Alabama Board of Medical Examiners

Relationship between age and testosterone



J Clin Endocrinol Metab 2008;93:2737

Relationship between age, BMI and hormones



Clin Endocrinol Metab 2008;93:2737

Who is a candidate for androgen supplementation?

- Men with abnormal testosterone below 300 ng/dl
- Confirmed on subsequent AM lab evaluation
- Exclusion of other related conditions
- Valid symptoms

Valid Symptoms and Low Testosterone < 300 ng/dl

- Persistent fatigue after lifestyle and medical workup
- Decline in muscle mass
- Decline in libido
- Erectile dysfunction
- Depression
- Sleep disturbance
- Idiopathic anemia
- Osteopenia/osteoporosis
- Persistent sleep disturbance with ongoing treatment for sleep apnea

Evaluation

- History and physical exam including genitourinary
  - Penis, scrotum, testes, prostate
  - Breasts
  - General body habitus
- Confirmatory laboratory including fasting early morning serum total testosterone, LLH, Hemoglobin, Hematocrit, Prolactin and PSA

Contraindications to Treatment

- Future fertility
- Active prostate cancer
- Uncertain serum PSA status
- Major cardiac or thromboembolic events in past 6 months
- Cardiac arrhythmia
- Undiagnosed or unmanaged sleep apnea
- Primary or secondary polycythemia
- Active liver and or gallbladder disease

Counseling on Risks of Testosterone Replacement

- Loss of testicular volume and function
- Impaired fertility
- Small increase in risk of thrombotic events (cardiac & cerebral)
- Small increase in risk of cardiac arrhythmia
- Significant risk of secondary polycythemia/erethrocytosis
- Possible risk of major cardiac or thrombotic event if testosterone levels are too high
- Elevated estrogen levels, gynecomastia and mood alteration
- Increase in prostate size and lower urinary tract symptoms

Counseling on Potential Benefits of Testosterone Replacement

Libido	Erectile function	Body composition
Insulin sensitivity	Mood	Bone density

Additional Counseling

All men should be counseled on the importance of a high-quality diet, exercise, sleep quality, stress management, avoidance of marijuana and alcohol, and general medical evaluation

Optimizing these variables will often help patients normalize testosterone levels without needing replacement

Origins of Testosterone Replacement Therapy

- First isolated and synthesized in 1935
- Initial formulations had negligible oral bioavailability and a very short duration of action due to extensive hepatic metabolism
- Testosterone therapy has evolved considerably since the days of the 19th century French physiologist Charles Brown-Sequard, who extolled the virtues of a guinea pig testicular extract in restoring waning potency and virility

Hoyes, FJ, JCEM 2000,3020

Treatment Options

Transdermal gel

Intramuscular

Pellets

Oral

3 Month Follow Up Information

- Repeat serum testosterone, hemoglobin, hematocrit and PSA level
- Physical exam by physician
- Evaluate response
- If no benefit is confirmed, testosterone should be discontinued
- Consider referral at any time to urologist or medical endocrinologist
- Adhere to the philosophy of: lowest effective dose
- Consider checking PDMP to identify potential testosterone abuse

Ongoing Treatment Follow Up

- Repeat labs every 6 months
  - Serum testosterone over 800 ng/dl should be considered excessive
- Consider checking PDMP at initiation and annually to identify potential testosterone abuse
- Refer challenging patients to a urologist or medical endocrinologist
- Patients should be seen by their physician at least once per year after steady state has been established
  - Telehealth is not an acceptable visit

Conclusions

- Testosterone replacement therapy is a useful tool in managing the symptomatic testosterone deficient male, but also one that can easily be abused with detrimental health risks to our patients.

Testosterone Therapy for Women

- Current data supports the short-term efficacy and safety of testosterone treatment in post menopausal women with sexual dysfunction due to hypoactive sexual desire disorder (HSDD), after an evaluation has excluded other causes such as relationship, psychological and medication related.
- Limited data supports the use in perimenopausal women.
- Combined hormonal and psychosexual approaches may be beneficial in some cases with mixed etiologies.

Changes in Circulating Hormone Levels at Menopause

	Premenopause	Postmenopause
Estradiol	40 – 400 pg/ml	10 – 20 pg/ml
Estrone	30 – 200 pg/ml	30 – 70 pg/ml
Testosterone	20 – 80 pg/ml	15 – 70 pg/ml
Androstenedione	60 – 300 ng/dl	30 – 150 ng/dl

Speroff: Clinical Endocrinology and Infertility 9th Ed

Hypoactive Sexual Desire Disorder

- Defined as the absence of sexual fantasies and thoughts and/or desire for or receptivity to, sexual activity that causes the personal distress or difficulties in the relationship lasting for at least 6 months.
- Causes can be multifactorial and can include central processes (i.e. neuroendocrine imbalance, medication, hypogonadism, psychological distress) and cultural factors (religious or cultural emphasis on sexual purity).
- Can be associated with profound negative effects on mood, self esteem, and partner relationships and can cause significant decrease in quality of life.

Uloko et al: 2022 J Sexual Med

HSDD Diagnosis and Evaluation

- Use of a validated self report screening and diagnostic instrument
  - Decreased Sexual Desire Screener (Panay N: Sept 2022 Post Reprod Health;28(3):158)
  - Lab evaluation
    - Total serum testosterone
      - Mid to high range level may not need additional supplementation
    - Sex Hormone Binding Globulin
      - Women with levels above normal range are less likely to benefit from testosterone therapy

HSDD Evaluation and Monitoring

- Checking a free testosterone may provide an insight into the lack of response in women not experiencing an improvement of symptoms with testosterone treatment.

When Testosterone Therapy is Not Recommended

- Infertility
- Sexual dysfunction other than HSDD
- Improvement of cardiovascular, metabolic or bone health
- Depression
- General wellbeing
- Enhance cognitive performance
- Delay cognitive decline
- Treatment of low androgen levels due to hypopituitarism, adrenal insufficiency, surgical menopause, pharmacologic glucocorticoid administration

Testosterone Therapy Contraindications

Hepatic disease

Hyperlipidemia

Treatment Methods

Aim for testosterone concentrations in the physiologic postmenopausal range

Consider a trial of conventional hormone replacement therapy first

No FDA approved products for women

When using male approved products use 1/10th the recommended starting dose for men

Options: Gel, cream, patch (transference risk)

Not recommended: Testosterone implants, IM injections, oral preparations (includes buccal lozenges and troches)

General Concerns: Safety & Efficacy of Custom Compounded Hormone Therapy

- There is a lack of high quality data on the safety and efficacy of custom compounded bioidentical hormone therapy for the management of menopausal symptoms
- Compounded bioidentical menopausal therapy should not be prescribed routinely when FDA approved formulations exist
- Due to lack of regulation, the amount of active medication can be highly variable within a specific dose
- There are no requirements for adverse event reporting, which hinders a definitive evaluation of safety
- Patients requesting the use of compounded bioidentical menopausal hormone therapy should be counseled on the lack of FDA approval of these preparations and their potential risks and benefits

Committee on Clinical Consensus-Gynecology. Compounded Bioidentical Menopausal Hormone Therapy. Obstetrics and Gynecology;142:1266-1273

Testosterone Pellets: Safety Concerns

- The FDA released a letter referencing the lack of reporting of more than 4,200 adverse events, including endometrial cancers, by the BioTE Medical company based in Irving, TX that provides bioidentical hormone pellet therapy
- The global consensus on the use of testosterone in women (which is endorsed by multiple international societies) is clear that the use of these pellets does not represent appropriate care
- We have to tell women that their new mustache, deepened voice, or clitoromegaly is permanent

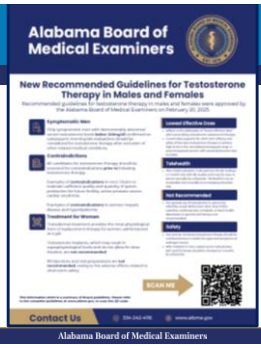
Dunsmoor-Su R. Testosterone Therapy in Women. Obstetrics and Gynecology 2021;138:809-812

Duration and Monitoring of Treatment

- Serum testosterone, liver function and fasting lipids should be measured at baseline
- Serum testosterone should be measured 3-6 weeks after treatment has started (levels do not always predict response to therapy)
- Evaluate response at 3 to 6 months after treatment start and then every 6 months thereafter
- Discontinue treatment if no response at 6 months

Safety Information

- No safety and efficacy data for testosterone therapy available after 24 months
- Long term effects on cardiovascular risk and breast cancer incidence are not known
- Women on testosterone therapy should be monitored for signs and symptoms of androgen excess every 6 months



Conclusions

- There has been a marked increase in testosterone utilization in both men and women over the past several years.
- Risks have been underappreciated and can be significant
- Patients require careful monitoring
- Long term impacts of therapy in women are not fully appreciated

ADDICTION and Substance Use Disorders

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Disclosures & LO's

Disclosures: None

Learning Objectives:

1) Identify the common pharmacologic effect between each of the five (?six) families of controlled drugs
2) Describe the basics of safe clinical reasoning with respect to prescribing ANY medication, and ESPECIALLY CRX
3) Outline a prudent approach to the longitudinal prescribing of controlled drugs

Terms

- Tolerance
  - The development of a need to take increasing doses of a medication to obtain the same effect; tachyphylaxis is the term used when this process happens quickly
- Dependence
  - The development of substance specific symptoms of withdrawal after the abrupt stopping of a medication; these symptoms can be physiological only (ie, absence of psychological or behavioral maladaptive patterns)

Substance Use Disorder DSM-V

- Tolerance*
- Withdrawal*
- More use than intended
- Craving for the substance
- Unsuccessful efforts to cut down
- Spends excessive time in acquisition
- Activities given up because of use
- Uses despite negative effects
- Failure to fulfill major role obligations
- Recurrent use in hazardous situations
- Continued use despite consistent social or interpersonal problems

* ? not counted if prescribed by a physician

Severity measured by number of symptoms:
2-3 mild, 4-6 moderate, 7-11 severe

Substance abusing or addictive brains = High Risk Brains **(I am sorry but they just are!!!)**

- Substance use disorder mild (Substance Abuse) = planned binge – type use patterns
  - Higher risk
  - Phase or time of life
  - Behavior not a disease
- Substance use disorder moderate or severe = intermittent, inconsistent, unpredictable, *repeated loss of control* over the use of a euphoria producing drug / "high risk" drug / controlled prescription drug; resulting in *repeated adverse consequences* and *craving* when not using
  - Highest risk
  - Chrinic brain disease, 60% genetic, 30% environment, 10-14% life time prevalence
  - Higher in some groups (major trauma / psychiatric patient / chronic pain patient populations)

Substance Use Disorder Moderate to Severe: predictable ***natural history***

- A cascade of increasing dysfunction and disability in the following domains:
  1. ***Self image***
  2. ***Interpersonal***
  3. ***Social***
  4. ***Financial***
  5. ***Legal***
  6. ***Work***
  7. ***Physical***

SUD: from natural history to ***morbidity and mortality***: the unspeakable toll

- Tobacco dependence – contributes to 20% USA annual mortality
- Tobacco dependence kills 1/3 and maims 1/3 of users

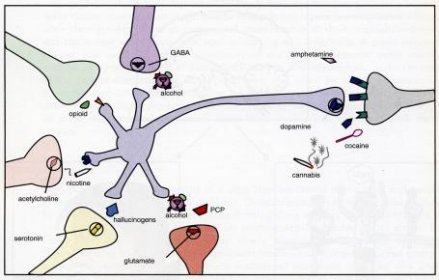
- Other addictions-
  - ***DEATH***: 700% increased annual mortality risk
  - ***FAMILIES***: 50% divorce, 70% domestic violence, 75% child abuse/neglect, >80% childhood sexual abuse.
  - ***SELF HARM***: 40-50% of successful suicides, 40-80% of level I trauma
  - ***FINANCIAL***: productivity
  - Not to mention all of the other medical complications / organ damage

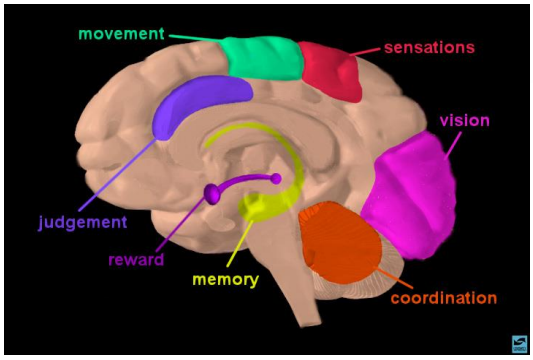
Euphoria Producing Drugs or EPD's

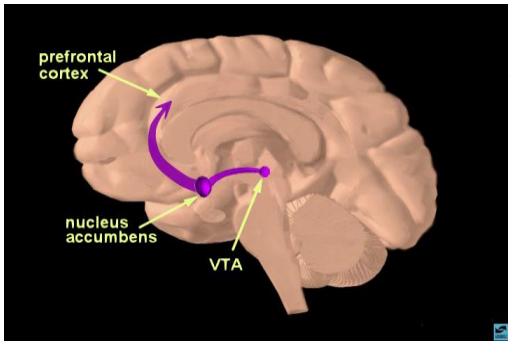
- EPD's include: opioids, stimulants, sedative-hypnotics, cannabinoids, Psychedelics (PCP / ketamine / psilocybin)
- Very different substances
- Totally different primary brain effects
- ALL produce an acute surge of dopamine from the mid brain to the fore-brain
- ***Dopamine surges mediate addictive disease***
- High Risk Medications (***sorry***, but they just are!)

Neuroanatomic substrates

Mesolimbic Dopamine Neuron and Drugs of Abuse



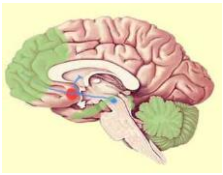




The Pleasure Centers Affected by: Cocaine / Methamphetamine / Ecstasy **& ALL RX stimulants**

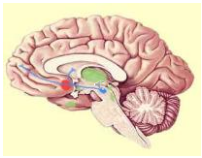
- Cocaine and amphetamines (methamphet / ecstasy / Ritalin / Adderall / Vivanse / Adipex / etc / etc all concentrate in the central link of the reward circuit (the ventral tegmental area and the nucleus accumbens). These areas contain especially high concentrations of dopaminergic synapses, which are the preferred target of these drugs.

The Pleasure Centers Affected by:
Alcohol **& ALL *Benzos, Barbs and Gabapentinoids***



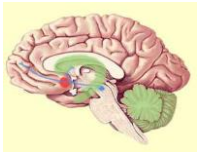
- Alcohol and other sedative-hypnotic drugs affect not only the basic structures of the reward circuit, but also several other structures that use GABA as a neurotransmitter. GABA is one of the most widespread neurotransmitters in several parts of the brain, including the cortex, the cerebellum, the hippocampus, the amygdala, and the superior and inferior colliculi.

The Pleasure Centers Affected by Drugs:
Opioids (from fentanyl to tramadol)



- Opioids act not only on the central structures of the reward circuit (the ventral tegmental area and the nucleus accumbens), but also on other structures that are naturally modulated by endorphins. These structures include the amygdala, the locus coeruleus, the arcuate nucleus, and the periaqueductal grey matter, which also influence dopamine levels, though indirectly. Opiates also affect the thalamus, which would explain their analgesic effect.

The Pleasure Centers Affected by:
Cannabis, "medicinal MJ", synthetics



- The active ingredient in cannabis is THC, which concentrates chiefly in the ventral tegmental area and the nucleus accumbens, but also in the hippocampus, the caudate nucleus, and the cerebellum.
- THC's effects on the hippocampus might explain the memory problems that can develop with the use of cannabis, while its effects on the cerebellum might explain the loss of coordination and balance experienced by people who indulge in this drug.

Controlled drugs ARE Euphoria Producing Drugs: **CRx = EPD's**

- So why do you have to put your DEA # on it?????
- So why do controlled drug RXs cause such a high risk of triggering a relapse of addictive disease?

- So … what does this mean for clinical practice … … …
  - High Risk Brains + High Risk Drugs = ***High Risk Behaviors*** … ***OR IN OTHER WORDS***
  - SUD patients + *chronic* CRX = high risk of problem patient behaviors … causing patient, family, community & Rxer ***harm***.
  - (Hypocritic oath – first do no harm)

So … isn't this just ***obvious***?
(and why spend a lovely day going over it)

- "*Like … don't prescribe long term outpatient addictive and abuse-able medications to patients who are abusers or addicted*"

- Perhaps it is obvious … but haven't you seen it done?

- Several data points: 1992 / 1998 / 2007 / 2016 / today

1992 Inner City Medical Clinic

- "Physician Failure to Record Alcohol Use History When Prescribing Benzodiazepines."

Graham AV, Parran TV: Journal of Substance Abuse 1992. 4:179-185

- ***Little evidence of SUD screening*** in medical records prior to initiating long term benzodiazepine prescription

(FAILURE TO SCREEN FOR CONTRAINDICATIONS)

1998 University Affiliated Large County Teaching Hospital

1. > 7000 Outpatients interviewed for SUD (alcohol problems)
2. Inpatient & Outpatient Medical Record Review for SUD DX
3. Outpatient Medical Record Review for prescribing of CRX: ***patients with SUD DX were THE MOST LIKELY to get OPT CRX***

- Second strongest predictor of receiving a CRX = having SUD documented in the medical record and having a Resident Physician as the doctor
- *Strongest predictor* of receiving a CRX = having a SUD documented in the medical record and having an ***Attending Physician*** as the doctor

- This is why this problem goes on and on and on and on over decades

January *2016 – Annals of Int Med*

- *90% of patients **continued to receive** prescription opioids **after** an accidental overdose was recorded in the chart*
- >20% received a higher dose within 6 months
- Opioid discontinuation after overdose was associated with lower risk for repeated OD

Annals of Internal Medicine • Vol. 164 No. 1 • 5 January 2016

(FAILURE TO RESPOND WHEN CONTRAINDICATIONS EMERGE DURING RXING)

March 2016 - JGIM

- Benzodiazepines are Prescribed More Frequently to Patients Already at Risk for Benzodiazepine-Related Adverse Events in Primary Care.
- J Gen Intern Med. 2016;31(9):1027-1034 March 2016

(ID CONTRAINDICATIONS AND RX ANYWAY)

Controlled drug prescribing trends 1989 - 2019

- 1985-2013 > 500% increase in opioid prescribing in the US
- 2013 – 2024 ~ 50% decrease in opioid prescribing from peak in 2013 (*still **200+%** > than 1980s*)
- 2013-2023 > 30% increase in benzodiazepine prescribing
- 2013-2023 ~40% increase in psychostimulant prescribing

HOW COULD THIS BE? Perpetuation of status quo: FAILURES

- **HRB's** REALLY REALLY REALLY **want** high risk drugs = RXer-Pt relationship / communication challenge
- Screening for HRB **poorly & rarely** done
  - Good Screens are incompletely / rarely used
- Un-appreciated contraindications (death/jail/etc)
- Blurring of basic ethical tenants of doctoring
  - Above all, first do no harm … **then** comfort always
- Lack of knowledge of *SUD dopamine surge nexus*

THIS WOULD ***NEVER*** HAPPEN IN CARDIOLOGY or ID!!!

CRx Prescribing Decisions: ***Remember:*** *Avoid High-Risk Drugs with High-Risk Brains*

- Any prescribing decision involves:
  - Indications – establishing the reason to RX
  - Contraindication – screening for reasons not to RX
  - Clinical reasoning – comparing risks v. benefits
- Contraindication screening requires K,A,S.
  - K=clinically *understanding* contraindications
  - A=*respecting the gravity* of contraindications
  - S=*using screening tools* to ID contraindications **and** communication skills to maintain your boundaries
- ***These*** K,A,S are ***ALL*** needed for safe CRx prescribing

SOLUTIONS: Towards more prudent OPT Prescribing of CRx

- Who **TO** prescribe long term CRx?
  - **Presence** of **Indications** – patient specific and disease specific
    AND
  - **Lack** of **Contraindications**
- Who **NOT TO** prescribe long term CRx?
  - Lack of **indications**
    OR
  - Presence of **contraindications** **(even if indications exist)**

Decisions re: ***possible*** chronic CRX

ASK THE FIVE QUESTIONS: **Universal Precautions**

1. Is there a clear diagnosis?
   1. *In your area of expertise and scope of practice*?
   2. *Of a severity to indicate a potential CRX?*
2. Is there documentation of an adequate work-up?
3. Is there impairment of function or quality of life?
4. Has non-CRX multi modal therapy failed / inappropriate?
5. Are contraindications to CRX therapy ruled out?

- ***Begin CRX therapy AS A TRIAL…Document! Monitor!***
- **Avoid poly-pharmacy *of controlled substances***

Contraindications to ***chronic*** CRX TX

- High Risk Brains (HRB)***:
  - **Current addictive disease = strong contraindication**
  - **Past addictive disease = strong contraindication**
  - **History of diversion = strong contraindication**
- History of significant nonadherence = relative contraindication
- Allergy to C RX medications = relative contraindication
- Severe COPD = relative contraindication (opioids / benzos)
- Obst Sleep Apnea = emerging contraindication (opioids / benzos)

***** Prescribe chronic C RX to HRB's only with expert advice and support (i.e. a methadone or suboxone clinic)**

Prescribing Controlled Drugs: How do you rule out addiction?

- Perform an AUDIT (EMR) and CAGE-AID (in person).
- Ask family or S.O. the f-CAGE (Informed Consent & ROI).
- Consider one or more toxicology tests.
- Inquire of prior prescribers re: use of CRx and Adherence.
- Check the PMP report before ANY CRx (short or long-term)
- If history of current or prior addiction, what class?
  - i.e. sedative hypnotics / opioids / stimulants / cannabinoids

SUD Mod-Severe and long-term CRX

- *Patients who have SUD **have already demonstrated the inability to consistently control their use of euphoria producing drugs**, and that these substances trigger behaviors on the patients' part that produce harm.*
- SUD mod – severe is a life-long diagnosis
- Therefore, ***ruling out current or past H/O SUD*** is an essential step in trying to ensure that a patient is safe when exposed to CRX.

Monitoring strategy when prescribing OPT controlled drugs – ***"universal precautions"***

- Informed Consent Form – AND require / document adherence to it
- Document functional / quality of life improvement – pt and family
- ROI for ANYONE & EVERYONE you think is needed
- Titrate RX to improved function / quality of life
- Referrals / consults / studies / work-up – document adherence
- Monitor medications (opt pharmacy profile printout & PMP).
- Avoid non-planned escalation – "nonadherence"
- Monitor for scams (NO early refills – they are dangerous)
- Periodic toxicology tests, occasional metabolite checks (& levels if high dose)
- Document, document, document! (USE a CRX Flow Sheet)

Prescribing Controlled Drugs: Where troubles come from….The PRESCRIBERS

- The AMA has described mechanisms by which prescribers become involved in RxDA – "the 4-D's + 1 +1"
  - Dated
  - Duped
  - Disabled
  - Dishonest
  - Defiant
  - Distracted

Prescribing Controlled Drugs
The Doctors (PRESCRIBERS)

- Beyond the 4 D's + 1 + 1 – the CWRU experience
  - Medication mania
  - Confrontation phobia
  - Hypertrophied enabling

(makes it is SO hard to say "I am sorry but no")

Diagnosing Aberrant RXer-Pt Relationships

- Assess Behavior
  - The "HEART SINK" Patient interview
- Differential Diagnosis
  - Borderline personality disorder
  - Somatiform disorder
  - Addiction with your CRX (Scams)
  - Family disturbances
  - Criminal intent – "a true capitalist!"

Passik SD, et al. *Oncology*. 1998;12:517-22.
Portenoy RK, Savage SR. *J Pain Symptom Manage*. 1997;14:S27-35.
Passik SD, Weinreb HJ. *Adv Ther*. 2000;17:70-83.
Portenoy RK, Payne R. In: *Substance Abuse: A Comprehensive Textbook*. 3rd Edition. Baltimore, MD: Williams & Wilkins; 1997:563-89.

Prescription Drug Abuse
Scams

- Strategies to increase frequency, number, potency of controlled prescriptions
- Efforts to increase drug supply by stressing/pressuring the doctor-patient relationship

Prescription Drug Abuse
Scams #1

- Spilled the bottle
- The dog ate it
- Lost the prescription
- Washed in laundry
- Medications stolen
- Left somewhere
- The Pharmacist "shorted" me
- "Oh by the way"
- Etc, etc, etc … … …

Dealing with Scams
Principles

- Cops v. Docs attitudes
- No offense but...
- Learn to recognize common scams
- Just say no and mean it – "say no when you mean no and yes when you mean yes"
- Avoid being "coy" – when "no becomes yes"
- Turn the tables

Discuss Your Concerns: (problem behaviors and CRX)

- Explain why the behaviors raise your concerns about patient safety and possible SUD.
- State that the benefits of CRX no longer outweigh the risks.
  - "I cannot responsibly continue prescribing CRX, as I feel it will cause you more harm than good."
- Always offer a referral for detox or addiction treatment
- Stay in the "Risk/Benefit" mindset, not the "bad behavior = bad pt." mindset

Giving Bad News

- Prepare the patient to receive the news:
- Tell the Bad News (no early refills, need to change RX, etc)
- Use the ***OPEN*** mnemonic:
  - **O**ptimism Statement
  - **P**artnership Statement
  - **E**licit the Patient's Response
  - **N**o More talking, just listen
- Allow space / time for reaction / emotion
- Use ***PEARLS*** statements

Giving Bad News: ***"I am SO sorry … but no"***

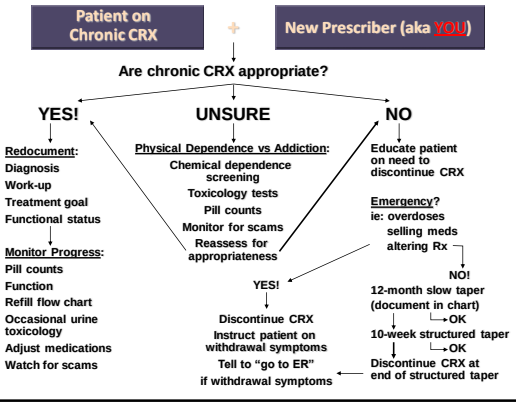
- *"Unfortunately, I have some difficult news for you."*
- "Based on what you have been nice enough to tell me, and your PMP report, I can not continue to RX …"
- THEN Use PEARLS Statements: **P**artnership / **E**mpathy / **A**pology / **R**espect / **L**egitimization / **S**upport
- Then "this can be really hard to hear … I am wondering what your thoughts are?
- Allow space / time for reaction / emotion
- Answer questions, use more PEARLS statements
- Then close

Additional "**words that make a difference**"

- "I wish things were different … and I know that you do too, but they aren't …"
- I thought you had one DX, but now I know you have two DX (including SUD) … and I ***must*** change the TX plan.
- I don't want you sick … but I ***must*** have you safe, and continued prescribing is not safe

Avoid Common Pitfalls

- "But I really, really need the _____"
- "Don't you trust me?" / "I thought we had a good relationship" / "I thought you cared about me?"
- "If you don't give them to me, I will drink / use drugs / hurt myself / go to the street / lose my job / my children will starve!! / … / … / …"
- "Can you just give me enough to find a new doc?"
- "You did this to me" / "I will go into withdrawal"
- ***Remember*** … it is unsafe and thus not allowed … and "I am so sorry … and still want to work with you"



Prescribing Controlled Drugs
Solutions

- Improve skills to ID a **H/O or CURRENT SUD**
- Approach these patients as if they have a relative, if not absolute, **contraindication** to long-term controlled prescriptions!!!!!
- Aggressively pursue skills in DDx and management of:
  - Acute vs chronic vs malignant pain
  - Anxiety vs depression
  - Insomnia

Prescribing Drugs
Solutions (cont'd)

- Use an Informed Consent Form with ***ANY/ALL*** chronic CRX
- Carefully **document** in progress note the rationale, diagnosis, anticipated time course, and symptom endpoint when initiating a controlled drug prescription
- Use a Chronic CRX Monitoring Flow Chart
- Establish a cross-coverage prescription policy
- Do not prescribe CII-CIV to family or close associates

Prescribing Controlled Drugs
Solutions (cont'd)

- Know the pharmacology and abuse potential of all drugs prescribed
- Medical letter, AHFS > PDR, industry reps
- Careful prescription writing and management habits
- Recognize and deal with scams
- ***GET COMFORTABLE PRESCRIBING BUPRENORPHINE-NX IF YOU PRESCRIBE OPIOIDS FOR CHRONIC PAIN (and maybe acute pain)!!!***

Prescribing Controlled Drugs
A Question of Balance

- Implementing RxDA solutions can
  - Avoid being DATED / DUPED / DISTRACTED
  - Increase comfort with prescribing controlled drugs
  - Markedly decrease ill-advised prescribing
  - Achieve better balanced and improved patient care
  - Maintaining better Prescriber-Pt Boundaries in this high(est) risk area for boundary confusion.

Prescribing Controlled Drugs Benzodiazepines & stimulants:

Balancing SAFE Practice Principals

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Disclosures

None

The Sed Hypnotic Family

- Benzos
- Non-benzo hypnotics (e.g. zolpidem)
- Barbiturates (e.g. butalbital)
- Barbiturate-like (e.g. Soma)
- Gabapentinoids (e.g. gabapentin & pregabalin)

Overview of Benzodiazepine Pharmacology

- Mechanism of action
- Receptor activity
- Pharmacokinetics
- Adverse effects
- Drug interactions
- Use in clinical practice

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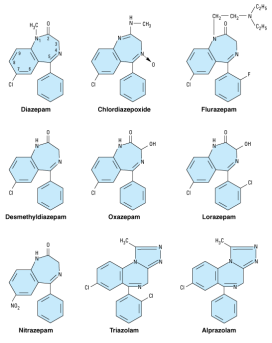
Benzodiazepines Chemical Classification



Source: Katzung BG: *Basic & Clinical Pharmacology*, 10th Edition: http://www.accessmedicine.com

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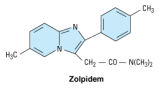
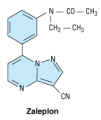
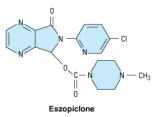
NON-Benzodiazepine Selective Agonists at α_1 BZ receptors







Source: Katzung BG: *Basic & Clinical Pharmacology*, 10th Edition: http://www.accessmedicine.com

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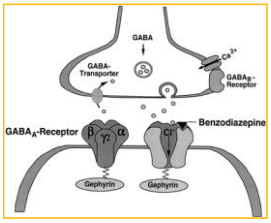
Mechanism of Action

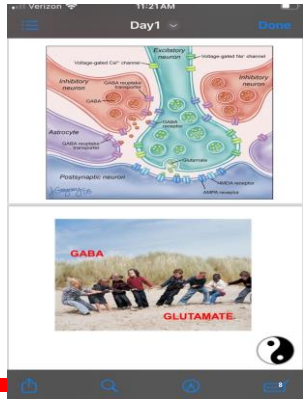
- BZ receptors on the postsynaptic GABA neuron
- Enhance the inhibitory effect of GABA on neuronal excitability by increasing neuronal membrane permeability to Chloride ions



BZ (benzodiazepines)

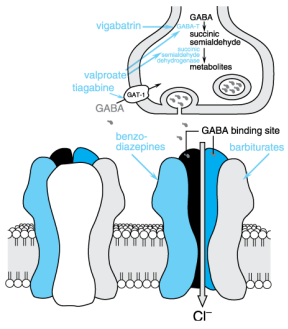
Pediatric Conception of the Gaba-Glutamate "balance"

- GABA: inhibitory
- Glutamate: excitatory
- Brain state: dynamic "balance" (or imbalance) between the two



Mechanism of Action

- Benzodiazepines and Barbiturates and Alcohol and *probably* Gabapentinoids ***multiply*** each other's effects.



Source: Brunton LL, Lazo JS, Parker KL: *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 11th Edition: http://www.accessmedicine.com

Receptors

- GABA-A & GABA-B
- BZ receptors are located on GABA-A
  - α_1-GABA-A: sedative and amnestic effects; most abundant
  - α_2-GABA-A : anxiolytic effects
  - α_3-GABA-A: noradrenergic, serotonergic and cholinergic neurons produce depressant effects
- Currently available BZ have no specificity for BZ receptor subtypes
- Investigational compounds selective for α_2 and α_3 (***potentially*** anxioselective)
- Selective α_1-GABA-A receptor agonists: zolpidem etc

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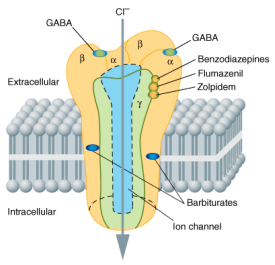
Pentameric structure of the $GABA_A$ receptor



Source: Katzung BG, Masters SB, Trevor AJ: *Basic & Clinical Pharmacology, 12th Edition*; http://www.accessmedicine.com

- Benzo area of action
- Zolpidem will only bind $GABA_A$ receptors containing an α1 subunit
- Propofol only binds to $GABA_A$ receptors containing β_2 and β_3 subunits
- Barbiturates – more of a direct effect to open the Cl ion channel, thus a narrower toxic/therapeutic ratio.
- BZ antagonist: flumazenil blocks actions of BZ and zolpidem ***BUT NOT*** barbiturates or ethanol

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Organ level effects

- Sedation
  - Calming effect with concomitant reduction of anxiety and some depressed effects on psychomotor and cognitive functions (disinhibition)
  - Dose dependent anterograde amnesia
- Hypnosis
  - Effects of BZ on normal sleep: TOTALLY DISRUPTIVE
    - Latency of sleep onset is decreased
    - Duration of stage 2 NREM is increased
    - Duration of REM is decreased
    - Duration of stage 4 NREM slow-wave is decreased
  - New hypnotics decrease the latency to persistent sleep
  - Use for more than 1-2 weeks leads to some tolerance to their effects on sleep patterns

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Organ level effects

- Anticonvulsant Effects (acute NOT chronic)
  - *Primarily if IV or IM (lorazepam)*
  - *NOT for long-term OPT seizure control*
- Muscle Relaxation (Mythical)
  - *ONLY at HIGH DOSE, and SHOULD NO LONGER BE USED*
- Effects on Respiration and Cardiovascular Function (Minimal)
  - Some respiratory depression (esp. pts with pulmonary disease or OSA)
  - Dose related effects
  - May affect the medullary vasomotor center → cardiovascular depression
  - May depress the gag reflex = increased risk of aspitation at high dose

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Pharmacokinetics: Absorption

- Readily absorbed following oral administration
- Diazepam is the most rapidly absorbed orally
- Temazepam is slowly absorbed
- Chlordiazepoxide and Diazepam are poorly and erratically absorbed after IM administration
- Lorazepam and Midazolam are rapidly and completely absorbed after IM administration

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Pharmacokinetics: Distribution

- BZ are all relatively lipophilic
  - Lipophilicity is important in determining the duration of clinical effect after single dose administration
  - Diazepam and clorazepate have the highest lipid solubility → quickest onsets of action
- CNS is the central compartment of BZ distribution
- After a single dose, BZ will redistribute rapidly out of the CNS to other lipophilic tissues (more frequent dosing until steady state then T ½ life dosing)
- BZ are widely distributed into body tissues, cross the blood-brain-barrier and EASILY cross the placenta
- BZ are highly bound to plasma proteins (70-99%)

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Pharmacokinetics: Elimination

- All BZ are hepatically metabolized and renally excreted
  - Oxidation (P450 3A4)
  - Glucuronide conjugation
- Lorazepam, Oxazepam, & Temazepam are conjugated only
- Clonazepam undergoes nitroreduction and is relatively unstable in urea

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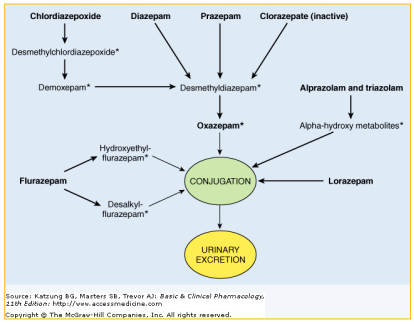
Metabolic Pathways of Benzodiazepines



Source: Katzung BG, Masters SB, Trevor AJ: *Basic & Clinical Pharmacology*, 11th Edition: http://www.accessmedicine.com

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Pharmacokinetics of Benzodiazepines & Newer Hypnotics

Drug	Peak Blood Level (hours)	Elimination Half-Life (hours)	Comments
Alprazolam**	1–2	12–15	Second most potent, rapid oral absorption
Chlordiazepoxide	2–4	15–40	Active metabolites; erratic bioavailability from IM injection
Clorazepate	1–2 (nordiazepam)	50–100	Prodrug; hydrolyzed to active form in stomach
Clonazepam	2	24-50	**Most potent** of benzodiazepaines, 0.5 mg ~ equal to at least 5 and prob 10 mg diaz
Diazepam	1–2	20–80	Active metabolites; erratic bioavailability from IM injection
Flurazepam	1–2	40–100	Active metabolites with long half-lives
Lorazepam**	1–6	10–20	No active metabolites
Oxazepam**	2–4	10–20	No active metabolites
Temazepam*	2–3	10–40	Slow oral absorption
Triazolam*	1	2–3	Rapid onset; short duration of action
Zolpidem*	1–3	1.5–3.5	No active metabolites

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Adverse Effects-CNS: TYPICALLY TRANSIENT*

- Sedation* & Drowsiness*
- Amnesia*
- Psychomotor impairment*
- Ataxia*
- Disorientation* / confusion*
- ***Depression***
- Aggression / Irritability / Excitement*
- Cognitive impairment (memory)*
- Paradoxical disinhibition*

* EXCEPT IN OLDER PATIENTS

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Drug-drug interactions of Benzos

- Pharmacodynamic: please avoid mixing together in the same brain!
  - **Other CNS depressants**
    - ***EtOH***
    - ***Other sedative hypnotics like barbiturates OR gabapentinoids***
    - ***OR non-benzo sleepers,***
    - ***Opioids*)**
- Pharmacokinetic
  - CYP P 450 3A4 metabolism

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Generic Name	Brand Name	Approximate Equivalent Dosages (mg)	Approved Dosage Range (mg/day)
Alprazolam	Xanax	**0.5 – 1.0**	0.75-4; 1.5-8
Chlordiazepoxide	Librium	25	25-100
Clonazepam	Klonopin	**0.5**	1-4
Clorazepate	Tranxene	15	7.5-60
Estazolam	ProSom	4	0.5-1
Flurazepam	Dalmane	30	15-30
Diazepam	**Valium**	**10**	2-40
Lorazepam	Ativan	**2**	0.5-10
Midazolam	Versed	4	N/A
Oxazepam	Serax	30	30-120
Quazepam	Doral	30	7.5-15
Temazepam	Restoril	30	15-30
Triazolam	Halcion	0.5	0.125-0.5

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Physical Dependence / Withdrawal

- Benzodiazepine dependence **&** ETOH dependence
  - With long term use of BZ (or/and ethanol) there is a decrease in efficacy of GABA A receptors
    - BZ receptors reduced by 30% in the hippocampus and by 25% in the frontal cortex
  - When high-dose BZ or/and ethanol are abruptly discontinued → "down-regulated" state of inhibitory transmission is unmasked = not enough inhibitory transmission = increased excitatory transmission → *characteristic withdrawal* symptoms and *worsening of underlying anxiety / insomnia* symptoms.

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Tolerance

- Result of down-regulation of brain BZ receptors
- Tolerance most pronounced at the α_1-GABA-A receptor: sedative and amnestic effects
- *Usually develops to the disinhibition, sedation, euphoria and drowsiness* seen initially with BZ
  - Problematic when used for insomnia
- ***Tolerance to the anxiolytic effect is rare***
  - SO … PATIENTS WHO CONTINUE TO ESCALATE DOSE ARE CONCERNING!

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BENZODIAZEPINE **CONTRAINDICATIONS** #1

- Current of Past SUD Moderate-Severe
- History of Diversion
- SUD Mild (binge type behavior)
- If they don't take them (legitimate medical purpose)
- The ELDERLY
- Obst. Sleep Apnea
- Severe COPD
- Non-adherence

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BENZODIAZEPINE **CONTRAINDICATIONS** #2

- Opioid RX
- METHADONE OR BUPRENORPHINE CLINIC
  - DOUBLE contraindication
- Continued low risk "social" alcohol use
- Other Sedative-Hypnotic RX (Barbs / Benz / Sleepers / ?gabapentinoids)
- Specific diagnosis to try to avoid chronic daily benzos:
  - Fibromyalgia
  - Most anxiety disorders … especially PTSD
  - Chronic insomnia

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LONG TERM BENZODIAZEPINE PRESCRIBING:
Commonly done, not well supported by data

- Benzodiazepines are very "STICKY" drugs
  - Short-term RX commonly becomes long term RX
- Problems with chronic (daily) benzo exposure:
  - TACHYPHYLAXIS (increased INSOMNIA)
  - PHYSICAL DEPENDENCE AND WITHDRAWAL (W/D sx are identical to indications)
  - LIKELY IMPAIR HELP SEEKING BEHAVIOR
  - FDA INDICATIONS ARE ALL FOR SHORT TERM USE
  - EFFICACY STUDIES ARE ALMOST ALL SHORT DURATION

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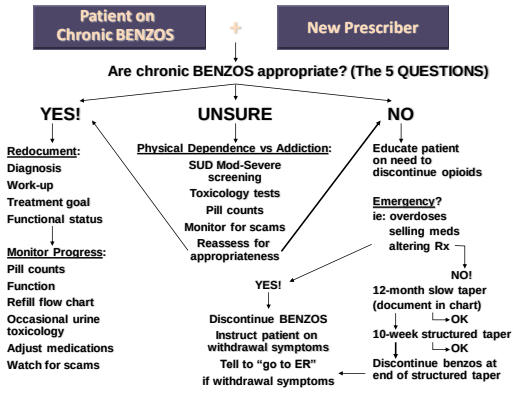


TAPERING off of Sedative-Hypnotics

- To Taper Off the benzodiazepine
  - Switch to intermediate onset, long T1/2 agent administered **nightly** and taper (aka Librium).
  - Start NON-benzo TX Plan for mental health issues
- Two Potential Tapers (Outpatient setting)
  - 5% to 10% / month = ***NON - urgent taper***
  - 10% / week = ***Urgent taper*** (W/D sx in week 4-10)

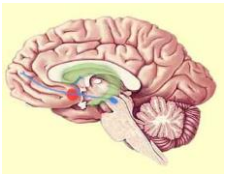
Benzodiazepine W/D: **OPT** options

- Short T ½ drug – see daily, Long T ½ drug – see QOD
- Short T ½ = 7 days, Long T ½ = 14-21 days duration
- START IMMEDIATELY:
  - Tegretol 200 BID up to TID OR Depakote 500 BID up to QID
- Add in if needed:
  - PRN Topiramate 25 BID and titrate as needed up to 50 QID
  - OR Lamictal or Trileptal
- After primary W/D, continue one agent for 6 - 12 months
- Also give SSRI's / high dose buspirone / prn hydroxyzine / clonidine - prazosin / beta blockers / etc for TX of the underlying anxiety sx.

More on Psychostimulants

The Pleasure Centers Affected by Drugs

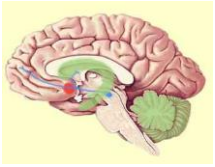
Cocaine and stimulants – methamphetamine / ecstasy / bath-salts / **ALL prescribed stimulants (ADD/ADHD/Obesity/Narcolepsy)**



- Cocaine and amphetamines concentrate in the central link of the reward circuit (the ventral tegmental area and the nucleus accumbens). These areas contain especially high concentrations of dopaminergic synapses, which are the preferred target of these drugs.

The Pleasure Centers Affected by Drugs

Cannabinoids / marijuana / "medical" marijuana / THC / Marinol / synthetic cannabinoids ("spice", "K2", etc)



- The active ingredient in cannabis is THC, which concentrates chiefly in the ventral tegmental area and the nucleus accumbens, but also in the hippocampus, the caudate nucleus, and the cerebellum.
- THC's effects on the hippocampus might explain the memory problems that can develop with the use of cannabis, while its effects on the cerebellum might explain the loss of coordination and balance experienced by people who indulge in this drug.

A Brief Diversion: **clinical implications of THC & Stimulant RX**

- THC produces the ***opposite*** effect of psychostimulants with regards to the "therapeutic actions" (sorry but THC antagonizes their "legitimate medical purpose") … so stimulants should not be Rxed in THC users
- THC use mimics the SX of ADD and ADHD … so in a THC user even making a DX of ADD / ADHD is problematic
- THC INTENSIFIES the "high" from stimulants (not a legitimate medical purpose)
- ALL patients receiving RX stimulants should be regularly screened for THC use

Stimulant Use, Abuse, Addiction: The US History

- Opioids – stimulants – opioids – stimulants … … …
- 1865 – O, 1880 – C, 1900 – O, 1920 – C, 1930 – O, 1950s-1960s – S*, 1970s – O, 1988-1994 – C, 1995-2013 – O
- Today (decreasing opioids, increasing stimulants)
- Increasing stimulants: cocaine, crack, RX stimulants, methamphetamine

- * 1950s & 60s stimulant addiction epidemic = CII for most RX Stimulants

The Harris Interactive Study

- A self-administered, anonymous online questionnaire of subjects between the ages of 18 and 24 currently enrolled in a 2 or 4 year college.
- Administered between March 30th and April 2nd, 2014
- 2,087 Respondents of whom 110 ***(5.3%)*** **had ever used methylphenidate nonmendically**
- 30% of RX stimulants were used intermittently (i.e. during parties and exam weeks) and these students were in the bottom third of class GPA

So … what are the family members of the STIMULANT Family?

- Cocaine HCL, cocaine HCO3 (Crack)
- RX Stimulants: Ritalin, Adderall, Vivanse, Cylert, phentermine, Dexedrine, Concerta
- Ecstasy (MDMA)
- Methamphetamine
- Bath salts
- Caffeine

The prescribed stimulants

- Mixed amphetamine salts (Adderall)
- Methylphenidate
- Phentermine (Adipex etc)
- Others (Belviq or lorcaserin / Bontril or phendimetrazine / Didrex or benzphetamine / Qsymia or phentermine and topirimate)
- Tamper resistant: Concerta (gel-like matrix)
- Pro-drugs: lis-dexamfetamine (Vyvanse)
- There is ***no*** *low abuse potential* CRX stimulant

Psychostimulant Pharmacology: 2 ***ACTIONS***

1. Systemic effect - block the re-uptake of nor-epinephrine.

2. Central nervous system effect - block the re-uptake of dopamine.

3. (cocaine also blocks the Na-K pump in peripheral nerves)

Stimulants - acute pharmacologic ***effects***

- Local anesthetic (ONLY COCAINE)
- Stimulant (PRIMARY MEDICAL EFFECTS)
  - increase heart rate, blood pressure, reflexes, tremor, concentration, energy, smooth muscle spasm
  - decrease appetite, need for sleep
- Euphoriant (UNWANTED SIDE-EFFECT) -
  - increase in mood, excitement, disinhibition
- SEs/AEs: Anxiety / Tics / SZ / ?Psychosis (& above)

Stimulants - more pharmacologic ***effects***

- RAPID tolerance to the Euphoric effect
  - The "High" disappears after several days / few weeks
- SLOW PARTIAL TOLERANCE re: Stimulant effect
  - The same dose maintains its efficacy over long periods of time = low dose long-term use less concerning
- Little (if any) need for dose increases over time
- "Rapid escalators" are a *REALLY* bad sign – high risk for a SUD

Mechanism of Stimulant Psychoactive Effect: **Basic Science** RESEARCH

Binding to dopamine transporter correlates best with *behavioral potency* in animals = **Dopamine Levels in NA**

Lesions of mesolimbic dopamine circuit ("reward" circuit) abolish cocaine self-administration

So … it **is** the dopamine surge causing the psychoactive effect after all!!!

"IV Ritalin Abuse: prototype for RXDA"

Stimulant Prescribing

- Drug-drug interactions:
  - Pharmacologic – very few OTT MAOIs
  - Pharmacodynamic – other controlled drugs
- Contraindications:
  - Current or H/O SUD Mod – Severe
  - Regular THC users (decreased / loss of efficacy)
  - Medical – HTN / hyperthyroid / tachyarrhythmias / ?SZ / unstable angina / closed-angle glaucoma

https://doi.org/10.2165/00003088-200140100-00004

Stimulant Prescribing

- ID an indication: using careful, well documented H&P skills and validated instruments
- Rule out contraindications: using careful, well documented H&P skills and validated tools
- Start with low dose / monitor
- Expect long-term efficacy at stable low doses
- Re-evaluate if transient efficacy & escalating dose

So … who should get long term Benzos / Stimulants?

- Who **TO** prescribe them to?
  - **Presence** of **Indications** – patient specific and disease specific
    AND
  - **Lack** of **Contraindications**
- Who **NOT TO** prescribe to?
  - Lack of **indications**
    OR
  - Presence of **contraindications** **(even if indications exist)**
- "DON'T RX long-term controlled drugs to patients with current or past SUD" … say *I'm so sorry but no*

So … what are the alternatives?

- Non-controlled drugs and therapy (of course)
  - Benzodiazepines: ("none of that #@!& works" = SUD HRB)
    - SSRIs / buspirone / anti-seizure meds (**if** gabapentin use LOW DOSE) / alpha agonists / beta blockers / CBT / meditation / aerobic exercise / stretching
  - Psychostimulants: ("none of that #@!& works" = SUD HRB)
    - SNRIs / Strattera / alpha agonists / behavioral therapy
- Remember … when CRX it is essential to maintain boundaries!

Alabama Board of Medical Examiners

Controlled Substance Prescribing in Collaborative/Supervisory Relationships: Roles and Responsibilities

SUZANNE POWELL, BSN, RN
DIRECTOR OF ADVANCED PRACTICE PROVIDERS

MISSION OF THE ALABAMA STATE BOARD OF MEDICAL EXAMINERS AND MEDICAL LICENSURE COMMISSION

"The Alabama Board of Medical Examiners and the Medical Licensure Commission of Alabama are charged with protecting the health and safety of the citizens of the state of Alabama."

William M. Perkins
Executive Director

What's New?

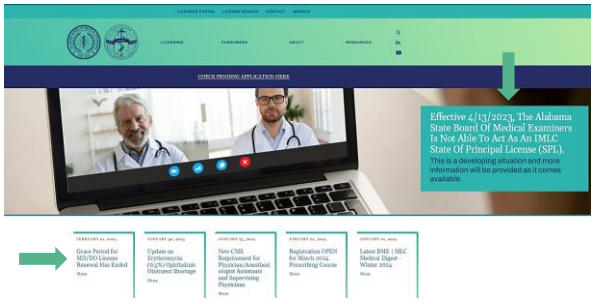
- Modified Applications
- Online Payments and Gateway Licensee Portal
- New Rule for PAs– Alternative to the requirement of completing 12 months of active clinical practice in Alabama to qualify for a QACSC

Processed QACSC Applications: PA and CRNP

2022: 473 2023: 569 2024: 514

Processed LPSP Applications: PA and CRNP

2022: 284 2023: 330 2024: 303



RESOURCES > LEGAL > ADMINISTRATIVE RULES

Administrative Rules

Administrative Rules are published by the Legislative Reference Service

Click here for Board of Medical Examiners Administrative Rules

Click here for Medical Licensure Commission Administrative Rules

Chapter 540-X-1	Organization and Administration	6	The Practice of Medicine or Osteopathy Across State Lines (Repealed 10/15/22)
Chapter 540-X-2	Definitions	7	Guidelines and Standards for the Utilization of Controlled Substances for Weight
Chapter 540-X-3	Certificate of Qualification	8	Qualified Alabama Controlled Substances Registration Certificate (QACSC) for C Nurse Practitioners (CRNP) and Certified Nurse Midwives (CNM)
Chapter 540-X-4	Controlled Substances Certificate	9	Pain Management Sevices
Chapter 540-X-5	Hearings and Appeals	0	Limited Purpose Schedule II Permit (LPSP)
Chapter 540-X-6	Conduct of Hearings in Contested Cases	1	Policy on Data 2000: Guidelines for the Treatment of Opioid Addiction in the Me (Repealed 10/15/2023)
Chapter 540-X-7	Assistants to Physicians	2	Joint Rules of the Alabama Board of Medical Examiners and the Medical Licensu Alabama Concerning the Interstate Medical Licensure Compact
Chapter 540-X-8	Advanced Practice Nurses: Collaborative Practice	3	Physician Reentry Into Practice
Chapter 540-X-9	Miscellaneous	4	Physician Assistant Reentry Into Practice
Chapter 540-X-10	Office-Based Surgery	5	Physician Recommendation of the Use of Medical Cannabis
Chapter 540-X-11	Guidelines for the Use of Lasers and Other Modalities Affecting Living Tissue	6	Collaborative Pharmacy Practice
Chapter 540-X-12	Qualified Alabama Controlled Substances Registration Certificate (QACSC)	8	Physician Supervision of Athletic Trainers
Chapter 540-X-13	Alabama Physician Health Program	A	Appendices
Chapter 540-X-14	Continuing Medical Education		
Chapter 540-X-15	Telehealth (Repealed 12/23/15)		

In the Controlled Prescribing Rules, you will find.....

- Important definitions for prescribing of standard, specialty, and controlled medications
- Qualifications of the CRNP/CNM/**PA** to apply
- Physician responsibilities
- Renewal Information
- Protocols for prescribing

Prescriptions and Medication Orders by CRNPs, CNMs, and PAs

May not sign prescriptions for controlled substances without a Qualified Alabama Controlled Substances Certificate and a DEA.

- May call and/or write a verbal order for a controlled substance provided….
- Collaborating physician has approved the medication and either signed the Rx or given a verbal order which is written in the medical record
- The CRNP/CNM/PA verbal order must be signed by the physician within 7 business days

Controlled Substance Prescribing

- Define separate policies in your practice for prescribing legend drugs and controlled drugs
- Check Medical Staff Bylaws and facility policies prior to writing inpatient orders for Controlled Substances
- You will need a QACSC and your own DEA if writing prescriptions for discharge that will be filled at an outside pharmacy

Qualified Alabama Controlled Substance Certificate

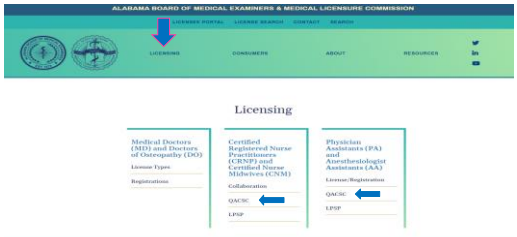
Obtaining a QACSC

- Eligibility Requirements to obtain a QACSC
- Collaborative Agreement(s) or Registration Agreement(s) with Final Approval by the ABN/BME totaling at least 12 months in the State of Alabama
- Attended the controlled prescribing seminar presented by the Medical Association State of Alabama to obtain the 12 AMA PRA Category 1 credits offered (Register at www.albme.gov)
- Send in application for QACSC within one (1) year of completing the prescribing course. Application must be approved by the Board. The Board meets once a month

The 12 months of collaboration or supervision is a cumulative total. It does not need to be completed with a single physician, nor must it be with the physician for whom you are applying for the QACSC.

Where do I find the Applications?

www.albme.gov



Next step: Click on FORMS or Application Forms

A QACSC is specific to each collaborative practice agreement.

How to Apply/What Happens Next | Eligibility Requirements | Forms | Fees | Renewal Requirements | FAQ

How to Apply/What Happens Next

Complete the application forms and submit with fee payment.

- The application will be placed on the next Board agenda for approval.
- After the Board meeting, approved applicants will be notified of approval/non-approval.

Forms

- Prescribing Protocols for QACSC and LPSP
- Initial QACSC Application for CRNPs/CNMs Application and Instructions
- Additional QACSC Application for CRNPs/CNMs Application and Instructions

Fees

- Initial QACSC: $110
- Additional QACSC: $60
- QACSC renewal: $60

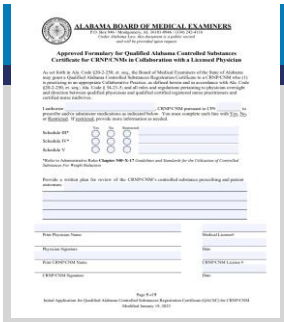
Print receipts at the Licensee Portal.

Initial QACSC versus Additional QACSC

The Initial QACSC is the FIRST QACSC that you apply for and receive. The fee is $110.00 and includes a PDMP fee.

The Additional QACSC is ANY SUBSEQUENT QACSC that you may apply for after you have been issued the Initial QACSC. The fee is $60.00.

*If you apply for an Initial QACSC and withdraw the application or are not granted approval, then you will be required to pay the $110.00 initial fee again.



ALABAMA BOARD OF MEDICAL EXAMINERS

Approved Formulary for Qualified Alabama Controlled Substances Certificate for CRNP/CNMs in Collaboration with a Licensed Physician

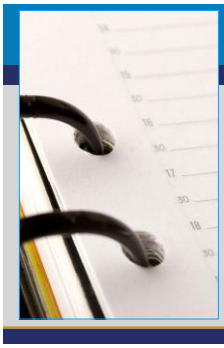
QACSC Application

- The **CP#** is the collaborative practice number assigned to your CP once you have been given final approval. It is found on the CP certificate in the physician's licensee portal
- Must state "yes", "no", or "restricted"
- Written plan for review must be completed. This explains how the physician will monitor the NP/ PAs prescribing
- You can always have a more restrictive policy in your practice!

Example of Written Plan for Review

"The collaborating physician will monitor 10% of the CRNP/PA's patient records for controlled substance prescribing for accuracy. Patient outcomes will also be reviewed. All patients with adverse outcomes will be thoroughly reviewed and appropriate plan of action will be determined by the physician."

- 10% is not required, but it should be a meaningful sample.
- 100% adverse events must be reviewed.
- **Controlled prescribing can be part of the quarterly QA review!



QACSC

- ❖The QACSC is linked to a specific Collaborative/Registration Agreement. It is NOT transferrable
- ❖To add a covering physician to the QACSC the physician **must first** be an approved covering physician on the Collaborative Practice or Registration Agreement
- ❖Doesn't stand alone. If the Collaborative Practice or Registration Agreement linked to the QACSC terminates, then the QACSC also terminates
- ❖QACSC covers schedules 3, 3N, 4, and 5

Which license do I apply for first?

A) QACSC

B) DEA

Applying for the DEA

- **Do not apply** for the DEA until you have approved for and have been issued a QACSC
- Apply for DEA Registration at www.deadiversion.usdoj.gov and then send a copy of the certificate to the BME
- Your QACSC status will be "Active Pending DEA" until we receive a copy of the DEA. You cannot print your certificate or renew the QACSC for the next calendar year with this status!

You are not authorized to write a prescription for a controlled substance in Alabama without both the QACSC and the DEA

Do I Need Multiple QACSCs?

- NP/PA works with the physician in his/her primary practice site Monday thru Friday.

On the weekends, they also work together at the ER in their town. Does the NP/PA need a QACSC for each site?

Answer: NO

- If **all** practice sites are listed on the Collaborative Practice Agreement and the physician can walk into any listed site and see patients and records, only one QACSC is required.
- *If NP/PA works at Urgent Care on the weekends under a different collaborating physician, then 2 QACSCs would be required. One for each physician/site.
- **If a PA has multiple registration agreements with the same physician, the PA may be required to have a QACSC for each registration agreement.

Controlled Substances for Weight Reduction… Can I Prescribe?

540-X-17-.02 Schedule II Controlled Substances.

"A physician shall not order, prescribe, dispense, supply, administer or otherwise distribute any Schedule II amphetamine or Schedule II amphetamine-like anorectic drug, or Schedule II sympathomimetic amine drug or compound thereof or any salt, compound, isomer, derivative or preparation of the foregoing which is chemically equivalent thereto or other non-narcotic Schedule II stimulant drug, which drugs or compounds are classified under Schedule II of the Alabama Uniform Controlled Substances Act, to any person for the purpose of weight control, weight loss, weight reduction or treatment of obesity."

540-X-17-.03 Schedule III, IV And V Controlled Substances for Weight Reduction:

(1) Only a doctor of medicine or doctor of osteopathy licensed by the Medical Licensure Commission of Alabama may order, prescribe, dispense, supply, administer or otherwise distribute a controlled substance in Schedule III, IV or V to a person for the purpose of weight control, weight loss, weight reduction, or treatment of obesity, except that a *Physician Assistant, Certified Registered Nurse Practitioner or Certified Nurse Midwife may prescribe* ***non-controlled drugs*** *for such purpose*. If a Physician Assistant, Certified Registered Nurse Practitioner or Certified Nurse Midwife prescribes non-controlled drugs for weight reduction or the treatment of obesity, the prescriber shall comply with the guidelines and standards of this Chapter which apply to MDs and DOs.

(2) A written prescription or a written order for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity **shall be signed by the prescribing physician on the date the medication is to be dispensed, or the prescription is provided to the patient**

If an electronic prescription is issued for any controlled substance for a patient for the purpose of weight reduction or treatment of obesity, the prescribing physician **must sign and authorize** the transmission of the electronic controlled substance prescription in accordance with federal law and must comply with all applicable requirements for Electronic Prescriptions for Controlled Substances

Such prescriptions or orders **shall not** be called in to a pharmacy by the physician or an agent of the physician

(3) The prescribing/ordering physician shall be present at the facility when he or she prescribes, orders or dispenses a controlled substance for a patient for the purpose of weight reduction or treatment of obesity

Author: Alabama Board of Medical Examiners Statutory Authority: Code of Ala. 1975, §34-24-53.History: New Rule: Filed December 16, 2011; effective January 20, 2012. Amended: Filed June 18, 2015; effective July 23, 2015. Amended: Published August 31, 2020; effective October 15, 2020

Know the Rules of Prescribing Controlled Medications

Code of Alabama 20-2-260

- A PA, CRNP or CNM authorized to prescribe…. shall not prescribe, administer, or dispense any controlled substance to:
  - ❖ his or her own self
  - ❖ spouse
  - ❖ child
  - ❖ parent

What are the QACSC & LPSP Protocols?

The Protocols govern how you prescribe controlled medications!

QACSC Protocols

If the **physician initiates** the medication, and the patient is well-maintained, the APP may prescribe a 30-day supply with 2 reissues up to 90 days. (3 separate scripts) DEAs will alternate every 90 days

If **APP initiates** the medication, they are limited to a 30-day supply. The physician must prescribe the next 30-days under his/her own DEA. Once well-maintained, prescriptions will alternate every 90 days

Physician must have an established and on-going relationship with the patient! Must see the patient at least once per year. **A lot of people choose for the physician to see patients in their birth month to achieve this**!

The collaborating/ supervising physician must check the APP's prescribing on a quarterly basis by logging into his/her own PDMP using their name and password to utilize the My Rx report(*see video in later slide)

NP/PA Initiates a Schedule 4 Drug for a Patient

- He/she may prescribe a 30-day supply.
- Next visit: the physician must write the follow up prescription under his/her DEA.
- If the patient is well-maintained, the NP/PA may write the next 30-day prescription with 2 reissues (30/30/30) not to exceed 90 days.
- The physician should write the next 90-days under their own DEA/ACSC.
- The PDMP should reflect the alternations every 90 days.
- You can see this information under the patient in the PDMP.
- Physician should see the patient at least once per year.
- **If physician initiates the medication, the NP/PA may write a 30-day prescription with 2 reissues if well-maintained**.

"I prescribe electronically and send my physician the prescriptions to review. Does this count?"

The PDMP must show alternating prescribers.

The prescriptions must be **signed** by the NP/PA or physician- not just "reviewed".

Check your PDMP regularly. Call the pharmacy if you find discrepancies.

Medication Assisted Treatment (MAT) is the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders

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Can I Become a Data-Waivered Practitioner in Alabama?

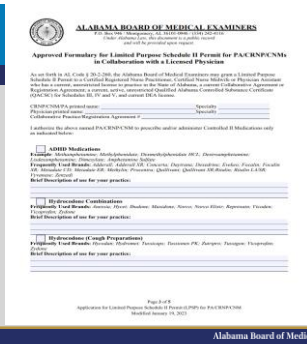
- On **December 29, 2022**, with the signing of the Consolidated Appropriations Act of 2023, otherwise known as the Medication Access and Training Expansion(MATE)Act, Congress eliminated the "Data-Waiver Program"
- A Data Waiver registration is no longer required to treat patients with buprenorphine for opioid use disorder
- Going forward, all prescriptions for buprenorphine only require a standard DEA registration number. Prescriptions no longer require the X DEA number
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine
- The Act does not impact existing state laws or regulations that may be applicable **QACSC protocols still apply!**
- The Act also introduced new training requirements for all prescribers. These requirements went into effect on **June 27, 2023,** for initial and renewal applicants

Practitioners Can Meet This Requirement in One of Three Ways:

- A total of 8-hours of one-time training* from a range of training entities on opioid or other substance use disorders. (Practitioners who previously took training for the DATA-2000 waiver to prescribe buprenorphine can count this towards their 8-hour training requirement)
- 2) Board certification in addiction medicine or addiction psychiatry from the American Board of Medical Specialties, American Board of Addiction Medicine, or the American Osteopathic Association
- 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. This curriculum must have included teaching on the treatment and management of patients with opioid and other substance use disorders, including the appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of a substance use disorder
- **See SAMHSA's website for a complete list of approved accredited CME organizations/providers & additional details. **The 8-hour portion of this course meets the requirement**!

Limited Purpose Schedule 2 Permit

	Requirements	Important
Limited Purpose Schedule 2 Permit (LPSP)	Current /Active QACSC	Covering physicians must first be on the QACSC
	Current/Active DEA	LPSP will terminate along with the QACSC if the Collaborative Agreement Terminates
	Submit Application to include the drug groups need for your practice	Long-Acting Schedule 2 medications are historically **only approved** for Hospice/ Palliative Care under the umbrella of Hospice/ Oncology/ Rehab clinical practices/ nursing homes
	Submit explanation for the need of each drug group requested	Not just the drug name



ALABAMA BOARD OF MEDICAL EXAMINERS

Approved Formulary for Limited Purpose Schedule II Permit for PA/CRNP/CNMs in Collaboration with a Licensed Physician

As set forth in AL Code § 20-2-260, the Alabama Board of Medical Examiners may grant a Limited Purpose Schedule II Permit to a Physician Assistant (PA), Certified Registered Nurse Practitioner (CRNP), or Certified Nurse Midwife (CNM) who has a current, unrestricted license to practice in the State of Alabama, a current Collaborative Agreement or Registration Agreement, a current, active, unrestricted Qualified Alabama Controlled Substance Certificate (QACSC) for Schedules III, IV and V, and current DEA license.

CRNP/CNM/PA printed name: _____ Specialty: _____
Physician printed name: _____ Specialty: _____
Collaborative Practice/Registration Agreement # _____

I authorize the above named PA/CRNP/CNM to prescribe and/or administer Controlled II Medications only as indicated below:

☐ **ADHD Medications**
Examples: *Methamphetamine; Methylphenidate; Dexmethylphenidate HCL; Dextroamphetamine; Lisdexamphetamine; Dimesylate; Amphetamine Sulfate*
Frequently Used Brands: *Adderall; Adderall XR; Concerta; Daytrana; Dexadrine; Evekeo; Focalin; Focalin XR; Metadate CD; Metadate ER; Methylin; Procentra; QuilliVant; QuilliVant XR;Ritalin; Ritalin LA/SR; Vyvanse; Zenzedi*
Brief Description of use for your practice:

☐ **Hydrocodone Combinations**
Frequently Used Brands: *Anexsia; Hycet; Ibudone; Maxidone; Norco; Norco Elixir; Reprexain; Vicodan; Vicoprofen; Zydone*
Brief Description of use for your practice:

☐ **Hydrocodone (Cough Preparations)**
Frequently Used Brands: *Hycodan; Hydromet; Tussigon; Tussionex PC; Tussprex; Tussigon; Vicoprofen*
Brief Description of use for your practice:

Page 2 of 5
Application for Limited Purpose Schedule II Permit (LPSP) for PA/CRNP/CNM
Modified January 19, 2023

LPSP Application

***Specific drug groups**

***Frequently Used Brands - not an exhaustive list, just examples**

***Brief Indication – not a list of medications**

NEW!! APPs may now request to treat Narcolepsy with stimulants IF:

1) Medications are FDA approved for Narcolepsy
2) The patient has undergone a sleep study and received a diagnosis of Narcolepsy by a physician
3) The practice site has been approved by the Board of Medical Examiners

(This may require individual review)

Long-Acting Schedule 2 Medications

These should only be requested if providing primary care in the areas of

- **Hospice**
- **Palliative Care (under the umbrella of hospice)**
- **Oncology**
- **Nursing Homes**

Medications in this list are considered to be long acting and are subject to the following standard: "Initial dose and any subsequent escalation of the dose must be written by the physician with CRNP/CNM/PA writing maintenance doses only".

These medications should only be requested for Hospice/Palliative Care, Nursing Homes, or Oncology.

Fentanyl-Long Acting
Frequently Used Brands: *Duragesic*
Brief Description of use for your practice:

Hydromorphone-ER/LA
Frequently Used Brands: *Dilaudid-ER, Hysingla, Exhydro*
Brief Description of use for your practice:

Hydromorphone
Frequently Used Brands: *Dilaudid, Dilaudid-HP, Exalgo*
Brief Description of use for your practice:

Page 4 of 5
Application for Limited Purpose Schedule II Permit (LPSP) for PA/CRNP/CNM
Modified January 19, 2023

May I Apply for the QACSC and the LPSP at the Same Time?

What If I Only Need an LPSP to Write Stimulants?

IF you have a current Alabama DEA registration, you may apply for the QACSC and the LPSP at the same time

IF this is your initial QACSC, you must wait to apply for the LPSP until AFTER you have received the DEA and the BME has made the QACSC "Active"

You cannot have an LPSP without a QACSC, therefore, you must first receive the QACSC and subsequently the DEA before applying for the LPSP

What If I Need to Add a Drug Class?

PA/NP requested ADHD Medications, Hydrocodone Cough Preps and Hydrocodone Combinations on LPSP application.

- PA/NP needs to **add** Oxycodone IR medications.

PA/NP may submit a request for an **LPSP Expansion**. This may be done at any time for no additional fee. The request will still go before the Board of Medical Examiners for review and approval.

If the expansion request is for **ADHD Medications**, the DEA will need to be updated to reflect the addition of **2N** medications.

Helpful Hints

Historically, the Board will not approve Hydrocodone Cough Preps for children under the age of 18 or for **chronic** cough.

Historically, the Board will not approve ADHD medications for: Hypersomnia (IH), obstructive sleep apnea, or Binge-Eating Disorder.

ADHD medications are historically approved for ADD/ADHD only.

Historically, the Board will not approve ADHD meds for urgent care. Only primary care.

Historically, the Board will not approve long-acting schedule 2 medications for **chronic pain** or any primary care specialty other than **oncology, hospice, palliative care within hospice, or nursing homes.**

After receiving approval from the BME, you will need to **update** the DEA with the new approved drug schedules to include 2 and/or 2N

You cannot utilize the LPSP until this has been completed, and you have received the updated DEA certificate

Scan/email or upload a copy of the updated DEA certificate once received

LPSP Protocols

Schedule 2N- Stimulants

- If the physician initiates a **stimulant (2N)** and the patient is well-maintained, the CRNP/CNM/PA may prescribe a 30-day supply with two reissues not to exceed a 90-day supply.
- If the CRNP/CNM/PA initiates a **stimulant (2N)**, the PA/NP/CNM may write a 30-day supply.
- The **physician must SEE the patient** before medication is continued, and the physician must prescribe the next 30 days under his/her own DEA and ACSC.
- Once the patient is well-maintained, the PDMP should reflect alternation of prescribing DEAs every 90 days.

PA/NP Initiates a 30-day supply of an ADHD medication

- Next visit: Physician must physically see the patient AND write the next 30/60/90-day prescription under his/her DEA and ACSC
- If the patient is well-maintained, the PA/NP may continue the medication with a 30-day prescription and 2 reissues up to 90 days
- If an **escalation** is needed, the PHYSICIAN must prescribe under his/her DEA
- Prescriptions alternate every 90 days in PDMP

Schedule 2

If the physician **initiates** a short acting Schedule **2** medication, the CRNP/CNM/PA may write the next 30-day prescription. Then the prescriptions would alternate between DEA's **every 30 days**

If the CRNP/CNM/PA **initiates** a short acting Schedule **2** medication, the CRNP/CNM/PA may write a 30-day supply. The **physician must physically SEE the patient** before medication is continued. Physician must prescribe the next 30 days under his/her own DEA and ACSC

PA/NP Initiates a 30-day supply of Hydrocodone Combination medication for a patient that has back pain

- Next visit: Physician must physically see the patient and write the next 30-day prescription under his/her own DEA and ACSC
- PA/NP may continue the medication with a **30-day** prescription if well-maintained alternating with the physician. **NO reissues!**
- PDMP should show alternation between prescribers every 30-days
- All escalations written by the physician

LPSP Protocols Continued

- All schedule **2/2N** escalations must be prescribed by the physician under his/her DEA and ACSC
- Only a **physician** may initiate/escalate **long-acting** schedule **2** meds.
- CRNP/CNM/PA may write **maintenance doses only** in oncology, hospice, palliative care within hospice, and nursing home/rehabilitation facilities
- Must be approved on LPSP application
- A QACSC and/or LPSP holder is **NOT ALLOWED** to dispense controlled substances in any schedule

Physician **initiates** a long-acting schedule **2** medication for an oncology patient.

- ✓Physician MUST initiate medication
- ✓PA/NP may write a 30-day maintenance dose only
- ✓Physician must write the escalation, if needed
- ✓PDMP should reflect the prescriptions alternating every 30 days

Scheduled 2 and 2N Medications

Cannot be verbally called into a pharmacy

Must either be written or sent in electronically

"Electronic Prescription for Controlled Substances" (EPCS)

EPCS: Why is This Important?

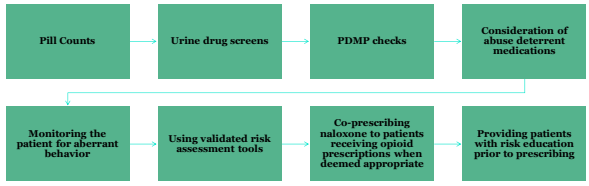
***EPCS is one and the same as a practitioner physically signing a prescription**

***Do not send a controlled medication via EPCS unless you are physically registered appropriately with your own signature**

***If you do not have an LPSP and DEA, you should never send in a controlled medication for another prescriber via EPCS**

***If you have an LPSP and DEA, but you are not authenticated by the DEA-required process, you should also never send in a controlled medication via EPCS**

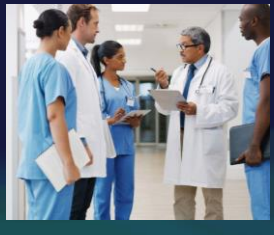
Risk Mitigation Includes:



What if the Pharmacy says I am not authorized to write controlled substances?

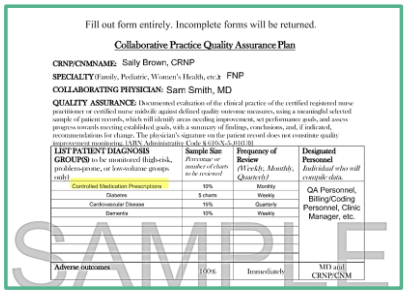
- Medicaid does require that you submit a copy of your DEA certificate directly to them.
- Prescribers of controlled substances are mandated to re-register their DEA License every three years. To ensure your DEA is on file at Medicaid, upload a copy of the provider's DEA Registration Certificate to the Medicaid Interactive Web Portal or fax to (334) 215-7416 with the barcode cover sheet that is provided in the Interactive Web Portal at the end of the Enrollment Updates request. Please be sure to include the provider's name, NPI number, and license number on the certificate. Medicaid will apply the DEA to all service locations based on the provider's NPI and license number. Melissa.gill@gainwelltechnologies.com
- Call and speak with a pharmacist about a specific patient with a medication that was denied
- Ask specifically for the reasons why. Many times, it has to do with the pharmacy not being able to access your QACSC and DEA information through their third-party vendors (This is usually the case!!)
- Make sure you have added the appropriate schedules to your DEA!
- It can be an insurance issue where they are denying the medication because there is something specific that needs to be addressed as far as being a credentialed provider for that specific insurance company
- Go to our website at www.albme.gov ; Click on "License Search"; Search for Licenses; Enter your first and last names only; Click Search. Please click on your name to view the details that we have listed for your QACSC and/or LPSP. Make sure all of this is appropriate

Quality Assurance for Controlled Prescribing



Controlled substance prescribing can be a part of your quarterly QA

Data can be compiled by office staff and reviewed by physician/CRNP/CNM/PA



Fill out form entirely. Incomplete forms will be returned.

Collaborative Practice Quality Assurance Plan

CRNP/CNMNAME: Sally Brown, CRNP

SPECIALTY (Family, Pediatric, Women's Health, etc.): FNP

COLLABORATING PHYSICIAN: Sam Smith, MD

QUALITY ASSURANCE: Documented evaluation of the clinical practice of the certified registered nurse practitioner or certified nurse midwife against defined quality outcome measures, using a meaningful selected sample of patient records, which will identify areas needing improvement, set performance goals, and assess progress towards meeting established goals, with a summary of findings, conclusions, and, if indicated, recommendations for change. The physician's signature on the patient record does not constitute quality improvement monitoring. (AAC Administrative Code §410-X-5-.01(1)(l)

LIST PATIENT DIAGNOSIS GROUPS) to be monitored (high-risk, problem-prone, or low-volume groups only)	**Sample Size** *Percentage or number of charts to be reviewed*	**Frequency of Review** *(Weekly, Monthly, Quarterly)*	**Designated Personnel** *Individual who will compile data.*
Controlled Medication Prescriptions	10%	Monthly	QA Personnel, Billing/Coding Personnel, Clinic Manager, etc.
Diabetes	5 charts	Weekly	
Cardiovascular Disease	15%	Quarterly	
Dementia	10%	Weekly	
Adverse outcomes	100%	Immediately	MD and/or CRNP/CNM

SAMPLE

COLLECTIVE QA REPORT: PRESCRIBED MEDICATIONS

Review Period: ____Weekly ___Monthly ____Quarterly Date of Review: _____

Total # of patients seen: _____ Adverse Outcomes: _____ Y _____ N

SUMMARY STATEMENT: On the above date, _____ (insert #) charts, identifiers listed below were chosen at random and reviewed for quality monitoring. The charts were reviewed for the following Prescribed Medication indicators:

1. Medications are prescribed per FDA guidelines (per PDR, NP Manual, or Product Insert)
2. Proper chart documentation of medication name, dosage, and directions for use and are legible
3. Medications prescribed are appropriate for the patient dx according to practice protocol
4. Controlled medications were ordered according to regulations of BME and ABN
5. No medications were ordered or refilled due to nature of visit

Chart #/Identifier			
Date of Service			
D=Discussed –noted changes which are needed **?** = Appropriate **NA**=Not applicable	1. 2. 3. 4. 5.		

Chart #/Identifier			
Date of Service			
D=Discussed –noted changes which are needed **?** = Appropriate **NA**=Not applicable	1. 2. 3. 4. 5.		

SUMMARY OF FINDINGS FROM QUARTERLY QA

Period of Review:_____

Name of Audit/QA:_____

Number of Charts Audited:_____

Summary of Findings:

□ No specific medical issues identified

□ Certain Medical Issues are in Question (see comments)

□ Adverse findings identified (see comments)

□ Follow-up with provider is needed

Comments/Discussions/Changes to be made (if any):

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Physician name:

signature _____

Date:_____

CRNP

name/signature_____

Date:_____

ADVERSE EVENT REVIEW/REPORT

Office Name

Address

Phone number:

Patient Identifier:_____DOB_____

Physician Name: _____License #_____

CRNP Name: _____License #_____

Date of Adverse Event: _____Patient Age _____Patient Gender _____

Indicate the Adverse Event:

_____

Patient hospitalized: _____Yes _____No

Patient Outcome: _____Full Recovery _____Disability _____Death _____Pending

Provide a brief narrative description of the adverse event and include any recommendations for change:

Signature of Physician: _____Date: _____

Prescription Drug Monitoring Program (PDMP)

PDMP: Registration

1

Register

- Register as a **Prescriber Delegate-Licensed** if you do not have personal controlled prescribing certificates but are a licensed LPN, RN, NP, or PA

2

Register

- Register as a **Prescriber Delegate-Non-Licensed** if you are not a licensed health care professional (example: office administrator, medical assistant)

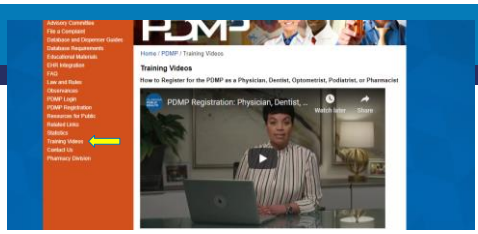
3

Register

- Register as a **Nurse Practitioner or Physician Assistant** if you are a Nurse Practitioner or Physician Assistant and you have your own state controlled prescribing certificates and DEA

Information Needed When Registering for the PDMP

- Email address
- DEA Number
- NPI Number
- State License Number (QACSC)
- Last 4 digits of SS#
- Health Care Specialty
- Primary contact phone number
- Cell phone number
- Email associated with your collaborating/supervising physician's PDMP account



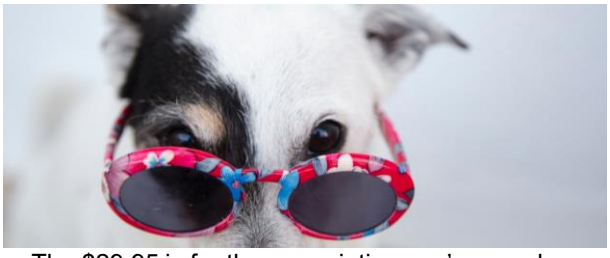
Training Videos Available on the PDMP Website:
www.alabamapublichealth.gov/pdmp/

Prescription Drug Monitoring Program (PDMP)

Upon receipt of the QACSC and DEA you are **required** to register for the Prescription Drug Monitoring Program at https://alabamapmpaware.net/login

PDMP allows you and the Collaborating/ Supervising physician to check your prescribing on a regular basis

Always contact the pharmacy if you see any errors when you review the PDMP



The $29.95 is for the prescription, ma'am, and the $15.00 surcharge is a little gift for our handwriting expert!

Example of How a Prescription Gets Logged Into the PDMP Under the Wrong Prescriber

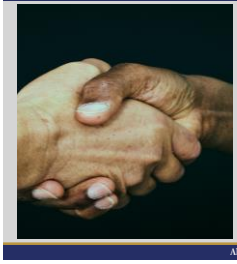
- Both the physician and the NP are listed on the prescription pad
- The prescriber does not circle their name nor indicate who is the actual prescriber
- The pharmacy cannot read the illegible signature on the prescription
- Prescription gets logged into the PDMP under whomever the pharmacy personnel entering the information chooses or logs it under who wrote the previous prescription

*My Rx Report

HOW PRESCRIBERS CAN VIEW PRESCRIPTIONS FILLED UNDER THEIR DEA NUMBER

- A training video is located on the PDMP website: www.alabamapublichealth.gov/pdmp/
- Completing this process fulfills the obligation of the physician to check CRNP/CNM/PA's prescribing quarterly as it will show the CRNP/CNM/PA's prescribing
- A log should be maintained in the office; in the event an audit is done, and proof is requested. You can document on the QA form! **If you find any discrepancies, you should notify the dispensing pharmacy**

PDMP CONTRACT AGREEMENT



- Agree to check current patients and/or potential patients of your practice only
- Privacy Statement: Any person who intentionally obtains unauthorized access.....shall be guilty of a Class C Felony
- **Unlawful Disclosure: Any reproduction or copy of the information is privileged and confidential.....not subject to subpoena or discovery in civil proceedings**
- MAT may require more frequent PDMP checks!

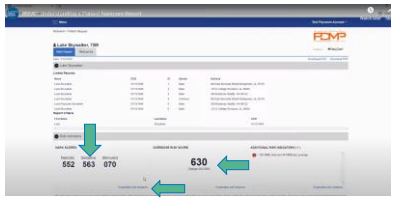
PDMP: Tool and Resource

NarxCare is a software platform imbedded in your PDMP report

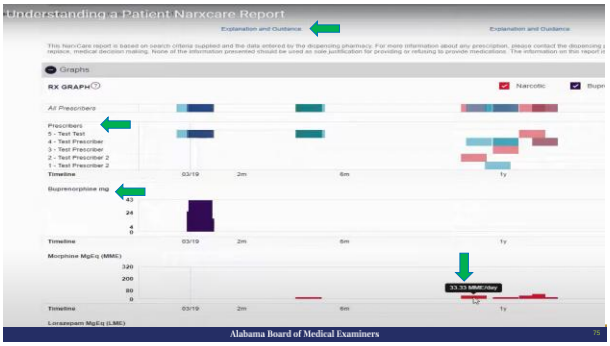
Information assists providers when making prescribing decisions

The NarxCare provider application is divided into 4 regions:

1. **Header** – patient information and tutorials
2. **Scores and Indicators** – Narx, Overdose Risk Score (ORS) and Additional Risk Indicators
3. **Graphs** – important details of prescription use
4. **Full Prescription Detail** - add detail for each prescription dispensed



- This report reveals **Risk Indicators** and will show how many prescriptions are active in a specific drug type
- The **Risk Score** should be used to trigger discussion and draw awareness to the presence of significant PDMP data
- It should be used to guide decision making**. It should NOT be used as a single factor in clinical decisions.**
- **Explanation & Guidance** offers excellent information!



Updated CDC Guidelines

- Based on updated CDC Guidelines released in November 2022, adjustments have been made to the morphine milligram equivalency (MME) calculation in the Prescription Drug Monitoring Program database.
- Specifically, the CDC made changes to commonly prescribed opioids for pain management resulting in changes to MME conversion calculations. An example of this includes Tramadol:

  Example of Previous MME Conversion Calculation:

  Tramadol 50 mg * (180 qty/30-day supply) *0.1 = 30 MME

- **Example of Updated MME Conversion Calculation:**

  Tramadol 50 mg *(180 qty/30-day supply) *0.2 - 60 MME

For a full list of opioids with updated conversion factors, please visit the CDC Guidelines document at https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w.

How Often Do I Need to Check the PDMP?

****Nursing homes, hospice prescriptions, treatment of active malignant pain, intra-op are EXEMPT**

- For prescriptions totaling less than 30 MME/day or 3 LME/day, practitioners are expected to use the PDMP in a manner consistent with good clinical practice
- MME greater than 30/day or LME greater than 3/day requires a PDMP check at least twice annually
- MME greater than 90/day or LME greater than 5/day requires a PDMP check with every prescription written on the same day that it is written

PDMP Contact Information

Password Reset/ Creating an Account/ Technical Support: #1-855-925-4767

Deactivated Account/ Not Tech Support/ Other Questions: #1-877-703-9869

For questions regarding linking or deleting the collaborating physician:

Nancy Bishop: nancy.bishop@adph.state.al.us

Vicki Walker: vicki.walker@adph.state.al.us

For general PDMP questions:

- **#334-206-5226**
- 1-800-703-9869 or 1-800-925-4767

Highest Ranking States for Prescribing Opioids in 2023 CDC

Highest opioid dispensing rates per 100 persons in 2023:

1) Arkansas (71.5)

2) Alabama (71.4)

3) Mississippi (63.1)

4) Louisiana (62.7)

(Tennessee had the highest opioid prescription rate for every 100 persons at 94.4)

Alabama has the highest downward trend (50%) for prescribing opioids in the nation!

From 140 Rx per 100 patients in 2017-2018
to
71 Rx per 100 patients in 2023

While this is great news, we are still second highest in the nation for dispensing opioids

Lowest States in the Nation for Dispensing Opioids in 2023 CDC

Lowest dispensing rates per 100 persons in 2023:

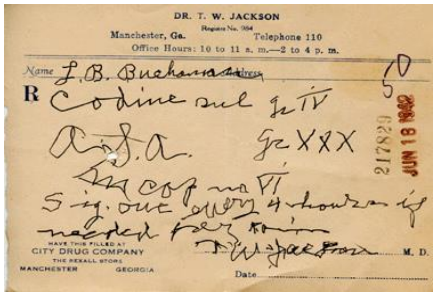
1) Hawaii (22.6)

2) California (23.8)

3) New Jersey (26.3)

4) New York (26.3)

**We are dispensing 45.1- 48.8 per 100 persons higher!


DR. T. W. JACKSON
Manchester, Ga. Telephone 110
Office Hours: 10 to 11 a. m.—2 to 4 p. m.
Name L.B. Buchanan
R Codine sul gr IV
A.J.A. gr XXX
Sig. one every 4 hours if needed for pain
HAVE THIS FILLED AT CITY DRUG COMPANY THE REXALL STORE MANCHESTER GEORGIA
T.W. Jackson M. D.
Date
JUN 18 1930
21782

Federal Prescription Requirement

- **Title 21-Part 1306 (a) Code of Federal Regulation:**

(a) All prescriptions for controlled substances shall:

- Be dated as of, and signed on, the day they are issued
- Bear the full name and address of the patient

Prescription Format

Name, Practice Address, Phone # for Collaborating Physician
Name and License #
QACSC#, LPSP#, and DEA#, if medication is controlled
Demographic information if different from Collaborating Physician
Date prescription is written
Two signature lines: "Dispense as Written" and "Product Selection Permitted"
May use "Notes" section if unable to fit all necessary information required
Make sure the pharmacist can see what you, the prescriber, are seeing! Sometimes it is NOT the same

John Doe, MD
123 Anywhere St.
Any town, AL 33333
Telephone 334-123-4567

Jane Doe CRNP/ Lic # 1-000000
QACSC #12345/ LPSP #12345
DEA # MD1234567
Address if different from physician

Patient Name _____ **Date** _____

Patient Address _____
_____

Rx

_____ _____

Dispense as written **Product Selection Permitted**

RENEWALS: QACSC, LPSP, and DEA

- Any QACSC and/or LPSP obtained during the calendar year must be renewed annually before 12/31 for the next calendar year
- Renewals for the QACSC and/or LPSP are processed **online** between **10/01-12/31** www.albme.gov
- The fees are $60.00 for each QACSC and $10.00 for each LPSP
- **Obtain 4 AMA PRA Category 1 credits every 2 years through a Board approved course/courses**
- DEA renewals are processed on the DEA website: www.deadiversion.usdoj.gov every 2-3 years. The DEA will send one email reminder 30 days in advance. The fee is $888. Please send the BME a copy

Renewal is Required for Both the QACSC and LPSP

- ✓ QACSC is renewed FIRST. You will see RENEW to the right of the license
- ✓ At the end of the QACSC renewal, you will see an Alert! message that says,

"Your renewal has been submitted. Click **yes** to continue renewing more registrations", if applicable. Click **no** to go back to your profile.

- ✓ If you have a Limited Purpose Schedule 2 Permit (LPSP), you should click **YES** – it will take you directly to the LPSP Renewal
- ✓ If you click **NO, you will need to renew the LPSP in the profile.**
- ✓ **If you fail to renew the QACSC or the LPSP, you will not have the ability to write controlled substances after December 31st!**
- ✓ You may print your renewal receipt and certificate in the profile.

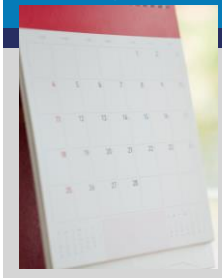
December or January Issue

If this is your **FIRST** (Initial) QACSC and your application is approved in December, the QACSC will be issued **JANUARY 1***

***The DEA takes 2-4 weeks to receive.** If the DEA is not received in time to renew the QACSC by December 31, you could incur late fees/penalty fees

Any **Additional QACSC or LPSP** license issued in November or December will have to be renewed by **December 31** to remain active for the following year!!

If the QACSC is Not Renewed by December 31, it Will EXPIRE….



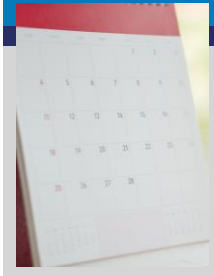
If the **QACSC** is reissued between **January 1- January 31**, a **LATE FEE of $75.00** will be added to the **$60** renewal fee

A paper renewal form must be completed after January 31

If the **QACSC** is reissued **after** January 31, and **NO PRESCRIBING** has occurred, a **PENALTY FEE of $110.00** will be added to the **$60** renewal fee

If the **QACSC** is reissued after January 31, and there is evidence of prescribing, a **PENALTY FEE of $150.00** will be added to the **$60** renewal fee

If the LPSP is Not Renewed by December 31, it Will EXPIRE….



If the **LPSP** is reissued between **January 1 – January 31**, a **LATE FEE** of **$50.00** will be added to the **$10** renewal fee

A paper renewal form must be completed after January 31

If the **LPSP** is reissued **after** January 31, and **NO PRESCRIBING** has occurred, a **PENALTY FEE of $95.00** will be added to the **$10** renewal fee

If the **LPSP** is reissued after January 31, and there is evidence of prescribing, a **PENALTY FEE of $125.00** will be added to the **$10** renewal fee

Make sure to complete your evaluation! Without it, you will not receive your CME credits from the Medical Association!

Advanced Practice Department

Suzanne Powell, BSN, RN Director of Advanced Practice Providers, spowell@albme.gov	Sandi Kirkland, BSN, RN Advanced Practice Nurse Consultant, skirkland@albme.gov	Leslie Roberts, BSN, RN Advanced Practice Nurse Consultant lroberts@albme.gov	Tonya Vice, BSN, RN Advanced Practice Nurse Consultant, tvice@albme.gov
Jaime Friday APP Specialist jfriday@albme.gov	Chekaylah Bradley, MHS APP Specialist cbradley@albme.gov	Hannah Paulk APP Specialist hpaulk@albme.gov	Shemika Whetstone, BIS APP Specialist swhetstone@albme.gov

Questions?