

Preventing Unlawful Prescribing and Controlled Substance Diversion and Abuse A Perspective from the ALBME

> E. Wilson Hunter General Counsel Alabama Board of Medical Examiners

> > www.albme.org



#### **Purpose and mission**

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.



#### **Defining the problem**

		1
	ATTENTION PATIENTS:	
PLEASE IMMED ANY OF DRUG 1 1.TES1 SCH 2.TES MEI 3.TES OTH HER DISI THANH	DUE TO HAVING TO BE CLOSED TO ATTEND A CONFERNECE ON TO ATTEND A CONFERNECE ON THURSDAY AND FRIDAY, TODAY WILL BE A <b>RAPID FIRE</b> <b>DATIENT DAY</b> . PLEASE HAVE YOUR PAYMENT READY, AND <u>ALSO BE READY</u> <b>D PROVIDE A URINE</b> <b>SPECIMEN</b> . DUE TO THE HEAVY VOLUME, I KINDLY ASK THAT CONVERSATIONS BE KEPT TO A MINIMUM AND ANY MEDICATION CHANGE REQUESTS BE HELD UNTIL	,
	THANK YOU,	one
	8:00 will be	∃ir ve >re A. M.

### **Defining the Problem**

	Rx Count	Total Quantity (Pills)	Days Supply
1	31131	2477387	830231
2	30819	2398679	852734
3	37224	2316444	1140761
4	34543	2202004	921976
5	23989	2147714	714428
6	29814	2126940	766265
7	39725	2084043	1132050
8	25629	1908321	734974
9	28648	1887241	819695
10	22648	1878007	608554

# Alabama had the highest opioid prescribing rate in the nation in 2017



#### 2017 CDC Map

#### U.S. County Prescribing Rates, 2017



U.S. County Prescribing Rates, 2016

U.S. Prescribing Rate Maps



#### **ALBME Initiatives**

- Alabama Pain Management Act (2013)
- Risk and Abuse Mitigation Strategies for Prescribing Physicians (2017)
- Enforcement

- Ala. Code § 34-24-600, et seq.,
- Ala. Admin. Code 540-X-19
- Provisions:
  - Pain management providers must register with the Board
  - Limits ownership and operation
  - Requires oversight by a medical director
  - Authorizes Board to conduct investigations and inspections
  - All ACSC and PM holders must register with the PDMP

Current number of registrations in Alabama:

- Approximately 600 registrations
- Who has to register:
  - Anyone who intends to run a "pain clinic"
  - Anyone who dispenses opioids
  - A practice where any physician is ranked in the top three percent of controlled substance prescribers in the state
- 2019 revisions to rules include limiting medical directors to physicians without significant disciplinary history within the preceding 5 years

#### Enforcement tools:

- The Board can initiate investigations
- The Board can inspect a pain management clinic at any time (Rule 540-X-19-.06)
- Practicing pain management without a registration can be punished with a \$10,000 fine (per violation) and/or with revocation of the ACSC (Rule 540-X-19-.08(3)(a))
- Medical Director can be held accountable (540-X-19-.08(3)(b))

#### Successes:

- Identification of pain management providers
- Enhanced enforcement tools
- Medical director requirement prevents underqualified physicians from setting up a pain clinic
- Weaknesses:
  - Non-physician ownership of facilities
  - No one to report to/No one to shut down repeat, nonphysician offenders

### **Risk and Abuse Mitigation Rule**

Board rule made effective March 9, 2017

#### Requires:

- Use of CDC-based Morphine Milligram Equivalency ("MME") standard to measure opioid dosing
- Use of risk and abuse mitigation strategies when prescribing opioids and other controlled substances
- Use of PDMP when prescribing certain amounts of opioids
- Continuing medical education in controlled substances prescribing every two years

# **Risk and Abuse Mitigation Rule**

Emulation of this rule is recommended to all health care licensing boards that regulate controlled substances per the Alabama Opioid Overdose and Addiction Council's 2018 Annual Report

#### Successes:

- Heightened awareness of opioid overprescribing problem
- Required PDMP use
- Education of prescribers
- Weakness: only applies to prescribers

# **Risk and Abuse Mitigation Rule**

#### 2019 Revision

- All controlled substances have a risk of use, misuse, and diversion.
- Today, we are focused on opioids. Historically, widespread opioid misuse has been followed by widespread amphetamine misuse
- Education is needed to help prescribers understand that all controlled substances carry some risk
- The Board has recalibrated the Risk and Abuse Mitigation rule to make it generally applicable to all controlled substances
- Adoption of Lorazepam Milligram Equivalence standard and required PDMP use for benzodiazepine prescriptions

# **Enforcement: Sources of Information**

#### Complaints from other physicians

- "any person making any report or rendering any opinion or supplying any evidence or information or offering any testimony to the board or to the commission in connection with an investigation or hearing conducted by the board or the commission as authorized in this article shall be immune from suit..." Ala. Code § 34-24-361(i).
- Complaints from pharmacists
- Patient Complaints
- Other state and federal agencies
- Board-initiated investigations

Tools for disciplining and educating licensees:

- Voluntary Agreements
- Board-ordered Continuing Medical Education
  - Up to 50 hours per year
  - Ala. Code § 34-24-61
- Restriction, Suspension, or Revocation of ACSC
  Ala. Code § 20-2-54
- Restriction, Suspension, or Revocation of medical license
  Ala. Code §§ 34-24-360 and -361

- Example 1: Investigation resulting in a voluntary agreement
  - Facts: Pain management physician ranked in top 150 of Alabama prescribers; reported by local physician; climbing in the rankings year over year; no specialty training
  - Numerous patients being prescribed cocktail of opioid, benzodiazepine, and carisoprodol
  - Many patients being prescribed chronic opioid regimens in excess of 200 MME/day

It is a straight to be a straight to

#### Board concerns:

- Primary concern is failure to maintain a medical record which meets the minimum standards for prescribing controlled substances.
- In some cases practicing medicine in such a manner as to endanger the health of the patients of the practitioner by excessive prescribing of controlled substances and amount of controlled substance not reasonably related to proper medical management of patient's illnesses or conditions.

Board concerns (continued)

- Limited use of risk mitigation strategies.
  - No PDMP check documented.
  - No Pill count documented.
  - No discussion of presence or absence of aberrant behavior.
- Board action: Invite
- Board conclusion: Unsafe prescribing is a product of knowledge and training deficit

#### Board Action

- Board-ordered to CME (Intensive Prescribing Course and Medical Records Keeping Course)
- Voluntary agreement signed by physician
  - Example Terms of the Agreement:
    - MME cap for prescribing controlled substances to treat chronic pain
    - Referral to pain specialist for patients needing more than 90 MME/day
    - Mandatory use of certain risk and abuse mitigation strategies
    - Restriction on co-prescribing of opioids and central nervous system depressing medications
- Violation of terms may result in discipline

- Example 2 Investigation resulting in Probation
- Facts: Complaint from pharmacist; pain clinic with physician ranked in top 850 prescribers; numerous patients with prescriptions for opioids in excess of 200 MME/day; physician NOT registered to do pain management; no specialty training
- Physician interviewed by investigator; a month later, he still has not registered
- Physician has not accessed the PDMP

- It is a straight to be a straight to
- Board action: Invite
  - Fails to articulate medical decision-making
  - No objective data in medical records
  - States the norm for chronic pain is 200 MME/day
  - Claims to be titrating patients down but no evidence to support
  - Practicing weight-loss with use of controlled substances but expresses ignorance that Board has any rules regulating this
  - Obtained zero hours of CME the previous year

- Board action: Summary Suspension of ACSC
- Independent Expert review obtained
  - Conclusions:
    - Excessive dosages and amounts of opioids and controlled substances
    - Inadequate documentation
    - Inadequate use of risk/abuse/diversion mitigation strategies
    - Lack of attention or use of non-pharmacologic modalities
    - Inadequate attention to co-prescribing of highly addictive and CNS-depressing medications

- Result: Joint Stipulation and Consent Order
- Physician admitted to violations
- ACSC Revoked; Revocation Suspended; ACSC placed on Probation for 24 months, with conditions; \$10,000 fine
- Probation terms restrict prescribing with MME cap, required use of risk/abuse mitigation strategies, coprescribing restrictions and use of protocols
- Compliance monitored by the Board

- Example 3 Investigation resulting in surrender of license
- Facts: Non-physician owned pain management clinic; prior medical director's ACSC summarily suspended and revoked; target physician replaces soon thereafter
- Target physician applies for pain management registration but is not registered with PDMP; pays \$2000 fine

- Facts: Physician practices pain management at location without a registration for 6 months
- Investigation: 10 charts subpoenaed; interviews of non-physician owners and staff

#### Board Findings:

- Physician practiced pain management for 6 months without a registration
- Clinic is cash only and does not have a medical director
- Physician has been dispensing phentermine without a registration
- Physician denied dispensing phentermine; PDMP and staff contradict

#### Board findings:

- Insufficient or no objective data in medical records
- Patients prescribed high doses of narcotics with other commonly diverted drugs
- Husband and Wife team of patients receiving 870 pills a month with daily MME (if they were taking them) of 1275 MME/day and 1425 MME/day, respectively
- Clinic ownership is straw man because real owner is a convicted felon
- Board conclusion: Pill Mill

- Board Action: Summary Suspension of ACSC and Pain Management Registration
- Independent Expert Review obtained (Supports Board findings)
- Result: Physician surrendered his Alabama Medical License, his Pain Management Registration, and his ACSC
- Location reported by Board to law enforcement













- A physician who loses his ACSC or medical license is, in most cases, going to lose it for a minimum of two years because both the Board and MLC can summarily deny petitions for reinstatement for up to 24 months before they are required to either grant the petition or set a hearing at which the reinstatement petition will be contested
  - Ala. Code § 34-24-61(b) (Authority for Board to deny ACSC reinstatement petitions)
  - Ala. Code § 34-24-361(h)(9) (Authority for MLC to deny license reinstatement petition)
- After five years, a revoked or surrendered license is gone forever (Ala. Code § 34-24-361(h)(9))

- A physician who loses his ACSC or medical license can be required to pay a fine (up to \$10,000 per violation) AND he/she can be required to pay the administrative costs of the Board, including:
  - The costs of the Board's expert witnesses
  - Attorney's fees
  - Deposition costs
  - Other actual expenses
  - (Source: Ala. Code § 34-24-380 and -381)

- A physician who is assessed an administrative fine or who is ordered to pay the Board's administrative costs CANNOT renew his/her medical license until those fines/costs are paid in full (Ala. Code § 34-24-383)
- Appeals of Board or MLC actions must be filed, commenced, and maintained in the Alabama Court of Civil Appeals (Ala. Code § 34-24-380 and Ala. Code § 34-24-367)

#### PDMP use and access

- All physicians who have an ACSC must be registered with the state's Prescription Drug Monitoring Program
- Board Rule 540-X-4-.09 REQUIRES physicians to access the PDMP in certain circumstances
  - Physicians should not only access the PDMP, but they should make treatment decisions based on what they find there
  - Example 1: they might find that a patient is receiving a CNS-depressing drug from another physician that complicates the physician's planned therapy
  - Example 2: the "low-risk" elderly patient is doctor-shopping
  - Example 3: a physician should periodically run himself through the PDMP. Many physicians have found a staff member who has stolen a prescription pad that way

### **Looking Ahead**

Areas of misuse, abuse, and diversion identified by the ALBME:

- The deadly combination of benzodiazepines and opioids
  - Alprazolam is a major culprit, but the combination of opioids and any other central nervous system depressing substance creates an even greater risk of overdose and death than opioids alone

#### – Buprenorphine

- Treating an addict is not easy; buprenorphine is frequently abused, misused, and diverted
- A buprenorphine "pill mill" is not any better than an opioid pill mill

### **Looking Ahead**

Rule changes

- Amendment to Board Rule 540-X-19-.03
  - Added grounds for denial of a pain management registration
  - Can deny registration at locations with multiple offenders
- Amendment to Board Rule 540-X-19-.05
  - Closing enforcement gaps by tightening requirements for a physician to serve as medical director at a pain clinic
- MAT Act of 2019



#### Board Website: <a href="http://www.albme.org">www.albme.org</a>

- Rules page: https://www.albme.org/rules.html
- FAQs for Physicians:

https://www.albme.org/practicematterslnks.html#prescr

- Twitter: Follow @AlaMedBd
  - Receive alerts for new rules, public actions, agendas, newsletters, etc.

#### **Contact Information**

#### Edwin Rogers, Chief Investigator

Direct: (334) 833-0179 E-mail: erogers@albme.org **Robert Steelman, Investigator** Direct: (334) 833-0198 E-mail: <u>bsteelman@albme.org</u> Wilson Hunter, General Counsel Direct: (334) 833-0188 E-mail: <u>whunter@albme.org</u> Matt Hart, Associate General Counsel Direct: (334) 833-0192 E-mail: <u>mhart@albme.org</u> Virginia Reeves, Associate General Counsel Direct: (334) 833-0167 E-mail: vreeves@albme.org

