State Medical Board of Ohio
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Supreme Court of Ohio

Specialized Dockets Annual Conference

Oct. 11, 2018

State Medical Board of Ohio

1

About the Medical Board

The Medical Board is the state agency charged with regulating the practice of medicine and selected other health professions.

- 12 persons appointed by the governor to 5-year terms; may be reappointed
- 9 doctors: 7 MDs, 1 DO, and 1 DPM
- 3 consumer members
- Monthly meetings, open to public

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2

MAT: Treatment for Those Affected by the Opioid Epidemic

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3

MEDICATIONS TO TREAT OPIOID USE DISORDER

- Methadone (full opioid agonist, controlled substance)
- Buprenorphine (partial opioid agonist, controlled substance)
- Naltrexone (full opioid antagonist, non-controlled substance)

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4

MEDICATIONS TO TREAT OPIOID USE DISORDER

- Buprenorphine may be prescribed by a "waivered prescriber" under the Drug Addiction Treatment Act of 2000 (DATA 2000)
- DATA 2000 allowed office-based opioid therapy or "OBOT"

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5

PRACTITIONER REQUIREMENTS UNDER DATA 2000

"Qualifying physician"

- Board certified in addiction psychiatry
- Completed 8 hours of training in an approved course

Comprehensive Addiction and Recovery Act of 2016

- Allowed nurse practitioners and physician assistants obtain a waiver to prescribe buprenorphine

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6

PATIENT LIMITS

- Prescribers have a limit on the number of patients who may be prescribed buprenorphine
- 30 patients per physician during the first year of the waiver
- After the first year, physician may prescribe to 100 patients
- After 1 year at 100 patients, the physician can treat up to 275 patient if they meet certain criteria.
- Waivered NPs and PAs may prescribe to up to 30 patients

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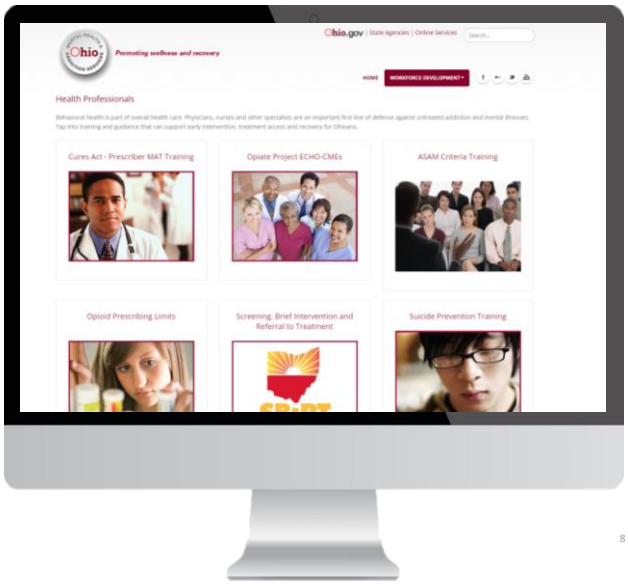
7

21st Century Cures Act:

Efforts to develop a workforce that can prescribe buprenorphine for medication assisted treatment is under way in Ohio. Physicians, physician assistants or advanced nurse practitioners can access training through Ohio Department of Mental Health and Addiction Services.

The Ohio Dept. of Medicaid:

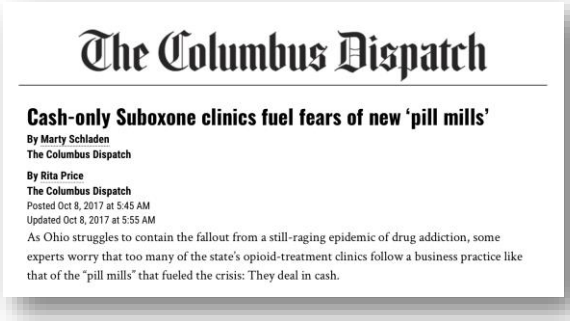
Pays for a range of treatment options, including methadone, buprenorphine & naltrexone (Vivitrol®)



8

THE NEED FOR STATE REGULATION

- Cash & Carry business model developing
  - "They would give you $50 for referrals."
- For too many addicts, "Their primary use is not 'treatment' but as a way to ward off symptoms of withdrawal until the next shipment of heroin or Fentanyl hits the streets"
  - Street demand for buprenorphine
- However, a realization that flexibility is needed (e.g., jails)



The Columbus Dispatch

Cash-only Suboxone clinics fuel fears of new 'pill mills'

By Marty Schladen
The Columbus Dispatch

By Rita Price
The Columbus Dispatch
Posted Oct 8, 2017 at 5:45 AM
Updated Oct 8, 2017 at 5:55 AM

As Ohio struggles to contain the fallout from a still-raging epidemic of drug addiction, some experts worry that too many of the state's opioid-treatment clinics follow a business practice like that of the "pill mills" that fueled the crisis: They deal in cash.

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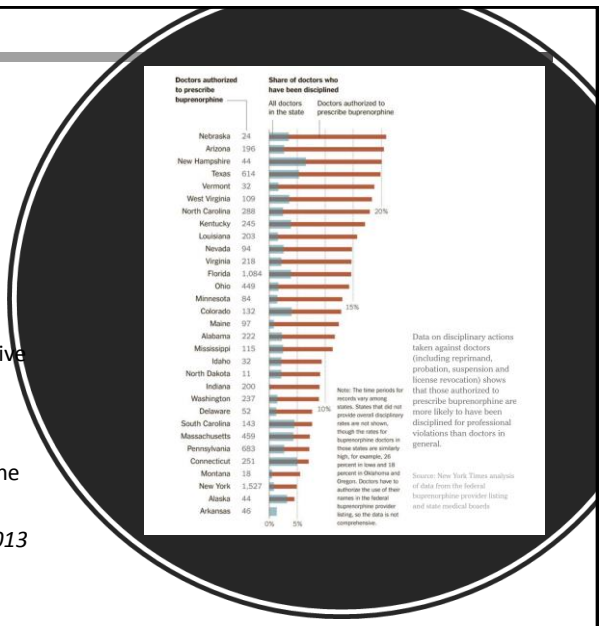
THE NEED FOR STATE REGULATION

"A relatively high proportion of buprenorphine doctors have troubled records, a *[NY] Times* examination of the federal 'buprenorphine physician locator' found."

"Nationally, at least 1,350 of 12,780 (10.5%) buprenorphine doctors have been sanctioned for offenses that include excessive narcotics prescribing, insurance fraud, sexual misconduct and practicing medicine while impaired."

"Some have been suspended or arrested, leaving patients in the lurch."

- *"Addiction Treatment With a Dark Side" NY Times Nov. 16, 2013*



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MEDICAL BOARD RULES

- In 2015, the State Medical Board developed a rule establishing additional requirements for physicians prescribing buprenorphine
- The rule was created to decrease diversion and inappropriate prescribing of buprenorphine
- The rule requires prescribers to follow a treatment protocol approved by SAMHSA or the Ohio Department of Mental Health and Addiction Services
- Ensures access to treatment provided by legitimate health care professionals

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11

MEDICAL BOARD RULES

OBOT Rules OAC 4731-11-12

- No more than 30-day supply at a time during first 12 months
- 16 milligram per day limit unless exceptions are met
- Physician shall personally meet with and evaluate the patient at each visit during the first 12 months of OBOT, and shall document an assessment and plan for continuing treatment

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12

MEDICAL BOARD RULES

OBOT Rules OAC 4731-11-12 (continued)

- After 1 year, physician shall personally meet with and evaluate the patient at least every 3 months, unless more frequent meetings are indicated
- The physician shall not provide OBOT to a patient that is receiving other CS for more than 12 consecutive weeks, without having consulted with a board-certified addictionologist or addiction psychiatrist, who has recommended the patient receive OBOT

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13

MEDICAL BOARD RULES

Sections 4730.55 and 4731.056, Ohio Revised Code, adopted in 2017, require the Medical Board to adopt rules that establish standards and procedures to be followed by PAs and physicians in the use of all drugs approved for medication assisted treatment, including buprenorphine.

The rules must address the following:

- Detoxification
- Relapse prevention
- Patient assessment
- Individual treatment planning
- Counseling and recovery supports
- Diversion control and any other topics selected by the Medical Board

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14

RULE UPDATES IN PROCESS

- The Medical Board is also required to work with the Board of Nursing so that the rules for physicians, physician assistants and nurse practitioners are consistent.
- Medical Board rules regulating medication assisted treatment are currently pending at the Common Sense Initiative
- Some key differences in the new office based opioid treatment rules 4730-4-01 and 4731-33-03 and the current rule 4731-11-12:
  - Certain institutional facilities are exempt from the rule, such as correctional facilities, hospitals, opioid treatment programs and youth services facilities
  - The proposed rules add a requirement for prescribers to offer naloxone kit, including ensuring that the patient receives instructions on the kit's use, recognition of signs and symptoms or overdose and Calling 911 in an overdose situation

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15

RULE UPDATES IN PROCESS

The proposed rules requires the prescriber to take steps to reduce chance of diversion through:

- Use of the lowest effective dose (must not exceed 24mg; any doses over 16 mg must have a rationale for the dose in the patient record
- Appropriate frequency of office visits
- Pill counts
- OARRS checks
- Drug screens at least 2 times per quarter for the first year/
- Once per quarter thereafter

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16

RULE UPDATES IN PROCESS

- The proposed rules address the use of extended release, injectable or implanted buprenorphine
- Must follow FDA labeling
- The proposed rules also include a rule on the use of Naltrexone (4730-4-04 and 4731-33-04)

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17

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State of Ohio Board of Pharmacy

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STATE OF OHIO BOARD OF PHARMACY

19

BUPRENORPHINE

- Methadone clinics operate under strict federal and state protocols and rules.
- Buprenorphine can be prescribed for office-based settings.
  - Person may feel more comfortable and may already be receiving treatment for other medical problems.
- Different approaches to treatment work for different people.
- Drugs containing buprenorphine (Suboxone®) contain an opioid blocker called naloxone.
  - When taking appropriately, it prevents a person in recovery from feeling the effects of opiates, or feeling "high."

20

RECENT STUDY

- In a study of opioid overdose survivors in Massachusetts,
  - Methadone and buprenorphine were found to reduce subsequent overdose deaths by 59% and 38%, respectively, compared with outcomes for survivors receiving no medication treatment after overdose.
  - Fewer than one-third of overdose survivors receive medication within a year due to accessibility.

Knopf, A (2018) ***Study: Methadone, buprenorphine after overdose improve survival rates.*** **Retrieved from https://www.addictionpro.com**

NEED FOR LICENSURE

- Capitalizing on individuals suffering from addiction, suboxone clinic owners along with unscrupulous physicians seek to exploit addiction as a method of reaping sizable profits.
- Similar pattern as "pill mills":
  - ✓ Non-physician owners with a criminal history;
  - ✓ Long patient lines or patient's loitering around building;
  - ✓ Cash-only;
  - ✓ Lack of adherence to standards of care.
- Undermines use of buprenorphine as an effective treatment option.

FACILITY LICENSURE

- Worked closely with Department of Mental Health and Addiction Services to raise the standard of care.
- After November 30, 2017, facilities where prescribers more than 30 individuals with a controlled substances for opioid abuse at any given time will be subject to licensure.
  - Terminal distributor of dangerous drugs with a office-based opioid treatment (OBOT) classification;
  - Failure to obtain proper licensure may be fined up to $5,000.

23

FACILITY LICENSURE

- Treatment of opioid dependence or addiction using a controlled substance does not necessarily mean that such medication must be on-site.
- It can also apply to practices where prescriptions for controlled substances are issued for opioid addiction/dependence and the patient receives medication at a pharmacy.
  - Received a total of 70 applications (as of Aug. 29, 2017).
  - Received a total of 253 applications (as of Sept.26, 2018).
- Exemptions include facilities owned or operated by a hospital or clinics are already certified by the Department of Mental Health and Addiction Services.

24

COMPLIANCE

- Licensure requires office-based opioid treatment facilities to comply with the following:
  - Mandatory background checks for the owners and employees of these facilities and prohibiting those convicted or serious criminal offenses from engaging in OBOT;
  - Facilities must be physician-owned, unless otherwise approved by the Board;
  - Adherence to prescriber limits set forth by federal regulations.
  - An applicant for an OBOT classification licensure shall not be licensed as a pain management clinic classification unless approved by the board.

25

RESPONSIBLE PERSON

- May be a physician or advanced practice nurse.
- Must possess a waiver to prescribe or personally furnish buprenorphine under the Drug Addiction Treatment Act of 2000 (DATA 2000).
- Must be physically present at the location for at least fifteen hours per week.
- If the facility is not open more than fifteen hours per week, the minimum amount of on-site supervision shall be at least fifty per cent of the total hours the facility is open.

26

EMPLOYEES

- The Board recognizes that those providing office-based opioid treatment (including prescribers, nurses and counselors) may have a history of substance-use disorder.
- Such a history does not automatically preclude a provider from practicing/working at a facility or serving as the responsible person for the facility (i.e. physician):
  - Complies with the terms of the provider's applicable probation or consent agreement;
  - Demonstrates a pattern of sustained recovery.

27

INSPECTIONS

- Field staff conducts annual inspections on all licensed OBOT.
  - Security and storage of dangerous drugs and documents
  - Recordkeeping
  - Monitor adherence to patient limits (Federal regulations depending on prescriber's waiver issued by SAMHSA, NPs and PAs -30 patients)
  - Adherence to applicable state and federal laws and regulations

28

HELPFUL DOCUMENTS

- Frequently asked questions document: www.pharmacy.ohio.gov/OBOT
- Application: www.pharmacy.ohio.gov/OBOTapplication
- Legal questions: www.pharmacy.ohio.gov/LegalOBOT

29

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30