

2023 Ohio Law Review

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State of Ohio Board of Pharmacy



OPA Annual Conference & Trade Show
Reimagining Pharmacy

April 14-16, 2023



Disclosure Statement

- Sheri Zapadka has no relevant financial relationship(s) with ineligible companies to disclose.

and

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

1. Identify recent changes in state and federal laws and rules which impact pharmacy practice in Ohio.
2. Describe the effect of recent law and rule changes on the practice of pharmacy.
3. Discuss implementation strategies for law and rule compliance.
4. Review relevant board notices and publications.

Workload Advisory Committee Updates



**July 2020: First
Workload
Survey**



**July 2021:
Appointments
made to the
Pharmacist
Workload
Advisory
Committee**



**November 2021:
Follow-up
Survey
Conducted
Pharmacists and
technicians**

Workload Advisory Committee Updates

Proposed
Rule OAC
4729:5-3-21

Prohibition on the use of Quotas in the Practice of Pharmacy

- Prohibition of quotas related to duties of pharmacy personnel
- Quota = fix numbers or formulas evaluating
 - Prescriptions filled
 - Services rendered
 - Programs offered
 - Revenue obtained
- Does not include competencies or performance standards

Workload Advisory Committee Updates

Proposed Rule
4729:5-3-22

Mandatory
Rest Breaks

If working longer than 6 hours must be allowed a 30-minute uninterrupted break

Pharmacy is not required to close

Pharmacist must remain on the premises and available for emergencies

Continued supervision of staff

Similar/same time each day

Cannot require shifts longer than 12-hours

Must allow 6-hours time off between shifts

House Bill 193- ORC
3719.05 & ORC 3719.06

Schedule II controlled substances

- Electronic prescription required
- Exceptions:
 - Oral emergency Rx
 - Written Rx
 - Technical, electrical, internet failure
 - Written in accordance with ORC 3719.06
 - Pharmacist is **NOT** required to verify a prescription was issued under an exception to electronic prescribing

Electronic Prescribing for Controlled Substances

ORC 3719.05

Electronic Prescribing for Controlled Substances

- Medicare Part D:
- Effective 1/1/2023
 - Electronic Prescribing required for all controlled substances
 - LTC Facility compliance = 1/1/2025
 - All compliance requirements are limited to prescribers
 - Pharmacist is not required to verify prescriber waiver or exemption
 - Does not limit or impede dispensing controlled substances from valid oral, written or faxed Rx

Telehealth Rules

ORC 4743.09 & OAC 4731-37-01

Effective 2/28/2023

- Applies to patients located in Ohio
- Same standards as in-person visit
- Synchronous or asynchronous communication (21 CFR 410.78)
- In-person visit required if standards of care cannot be met by telehealth
- Allows use of remote monitoring devices
- Allows prescribing, personally furnishing of non-controlled Rx drugs, and controlled substances pursuant to OAC 4731-11-09

Telehealth Rules

ORC 4743.09
&
OAC 4731-37-01

- Comply with federal laws for prescribing/personally furnishing controlled substances and OAC 4731-37-01
- Physical examination prior to prescribing CII for new patients
 - Exceptions:
 - Hospice or palliative care
 - Substance use disorder – FDA approved drug
 - Mental health condition- FDA approved drug
 - Emergency situation- 3-day supply or less, no re-prescribing
 - Federal law exemptions

Telehealth Rules

ORC 4743.09 & OAC 4731-37-01

FAQ:

- Telehealth = services provide by a health care professional licensed in Ohio
- Prescriber may be physically in another state
- Patient is physically in Ohio
- **Ohio DEA registration is required**



Telehealth- DEA

Proposed Rules for Permanent Telemedicine Flexibilities

- Expand access beyond COVID-19 public health emergency
- 30-day public comments ended 3/31/2023
- Will expand induction of buprenorphine via telemedicine
- Will allow for controlled substance prescribing when the practitioner and patient have not had a prior in-person medical evaluation



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Pharmacist Telehealth Services

ORC 4729.285

ORC 4743.09: A pharmacist may provide telehealth services.



In the case of dispensing a drug:

Pharmacist may NOT use telehealth mechanisms or virtual means to dispensed dangerous drug.

DATA 2000/ X-Waiver Effective 12/29/2022

DATA 2000 Waiver
registration no longer
required

Buprenorphine Rx =
standard DEA

No patient limits

Prescriber training
requirements – June 21,
2023

Act does not impact
existing state laws

Substance- Use Data Dashboards

New Ohio dashboards to track and report data

- Overdose deaths
- Substance-use related measures
- 88 Counties
- Real-time research focusing on prevention, treatment and recovery programs
- Transparent, public platform

<https://data.ohio.gov/wps/portal/gov/data/view/ohio-ibhd>



Substance-Use Data Dashboards

- 55 opioid related measures
 - Overdose deaths
 - High-risk prescribing
 - ED overdose cases
 - Naloxone distribution
 - Individuals receiving/enrolled in treatment programs
 - EMS naloxone administrations

State of Ohio Integrated Behavioral Health Dashboard

Last Refreshed: March 6, 2023

Details

Visualize

Export Data  Share 

Select measurement period

(x-axis)

☐ monthly

☐ quarterly

☒ yearly

Select county

(AID)

(AII)

Adams

Allen

Ashland

Ashtabula

C Athens

h Auglaize

Belmont

at Brown

at Butler

Carrol

& Cham

Clark

Clermont

Clinton

Columbiana

Select measure name

○ Drug OD deaths

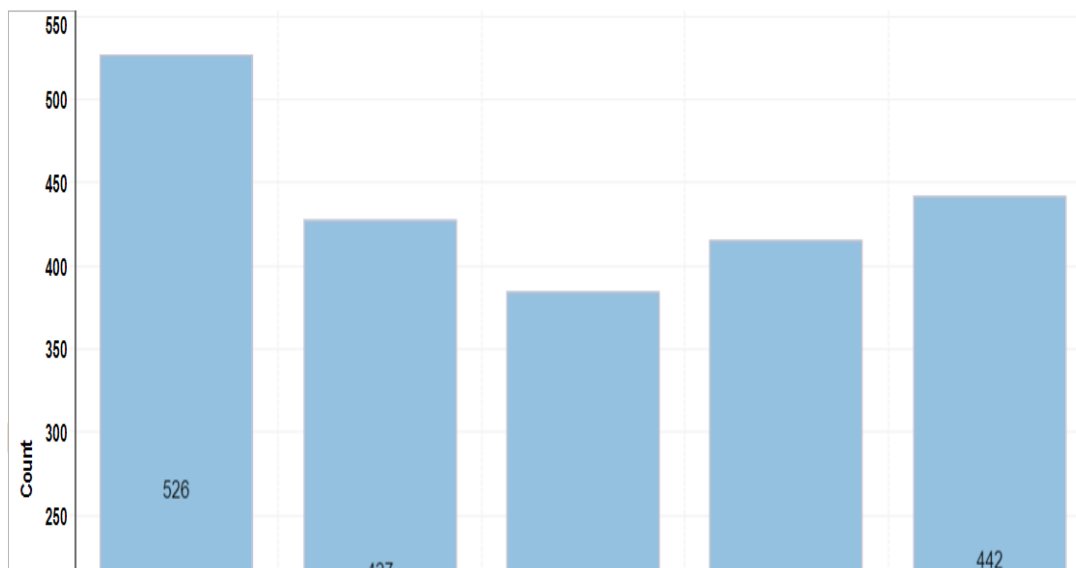
☒ Drug OD deaths involving any benzodiazepine

☐ Drug OD deaths involving any form of cocaine

☐ Drug OD deaths involving any non-cocaine psychostimulant

State of Ohio Integrated Behavioral Health Dashboard

Drug OD deaths involving any benzodiazepine



Nicotine Replacement Therapy

OAC 4729:1-3-07

Does not include
nicotine cessation
medications (e.g.,
varenicline, bupropion,
etc.)

Includes: patch, gum,
lozenge (OTC) and
inhaler, nasal sprays (Rx)

Physician authorized
protocol (MD/DO)
onsite

Complete ACPE or SOBP
accredited course

May not delegate
authority

Nicotine
Replacement
Therapy
OAC 4729:1-3-07



- Protocol signed by MD/DO
- Renewed every 2 years
- Treatment guidelines
- Locations
- Types of nicotine replacement products
- CDC recommended screening procedure
- Records onsite x 3 years (screening, dispensing, follow-up care plan)

Nicotine Replacement Therapy

OAC 4729:1-3-07



Follow-up care plan:

- Ohio Tobacco Quit Line
- Pt. to notify prescriber
- Psychological aspects of addiction
- Side effects
- Duration of treatment
- Patient follow-up timeline
- Relapse plan
- Smoking cues/triggers
- Coping strategies
- When to seek Rx treatment

Dispensing Overdose Reversal Drugs

ORC 4729.44, ORC 4729.541

- Effective 4/6/2023
 - New Ohio law authorizes anyone in the state to order, possess, and distribute naloxone with few requirements
- Effective 2/8/2023:
 - Board suspended all patient-specific record keeping requirements for selling or personally furnishing naloxone from a licensed TDDD.

ON 2/15/2023: FDA unanimously voted to recommend naloxone nasal spray be sold and distributed without a prescription.

Dispensing Overdose Reversal Drugs

ORC 4729.44, ORC 4729.541

Prescribing/Personally Furnishing

- May prescribe without examination
- Must supply instructions re: emergency administration
- Must instruct to call 911
- Civil, Criminal, Professional Immunity

Pharmacy Dispensing

- Rx or protocol
- Eliminates authority for boards of health to authorize protocols
- Expands protocols to PA and APRNs

Dispensing
Overdose
Reversal
Drugs

ORC 4729.44
ORC 4729.541

- What is still required?

- Records of receipt
- Records of disposal
- Records of transfer or sale.



Law expands general and emergency access, and automated distribution

Law exempts persons and government entities from TDDD licensure

Adding Drug
Delivery
Devices to
Prescriptions
ORC 4729.391



Effective 4/6/2023

- RPh may modify a prescription to include a drug delivery device
- The device is necessary for drug administration
- For reimbursement by health plans/insurers, modified prescriptions are deemed a valid prescription for drug delivery devices

Consult Agreements

ORC 4729.39, OAC 4729:1-6



Consult agreements between:

Physicians (MD/DO)

Physician Assistants (PA)

Clinical Nurse Specialists (CNS)

Certified Nurse Midwives (CNM)

Certified Nurse Practitioners (CNP)



NO Consult Agreements with:

Podiatrist (DPM)

Certified Nurse Anesthetist (CRNA)

Consult Agreements

ORC 4729.39, OAC 4729:1-6

- Consult with APRN or PA requires authorization from the collaborating physician:



Ohio Board of Nursing



Ohio Medical Board

- In writing
 - Standard Care Agreement
 - Other written document
- In writing
 - In the supervision agreement

Consult Agreements

ORC 4729.39, OAC 4729:1-6

- Pharmacist Changes:
 - Can now order and evaluate
 - Blood Tests
 - Urine Tests
 - Other laboratory tests
 - Diagnostic tests

* Tests must be related to the drug therapy being managed



Consult Agreements

ORC 4729.39, OAC 4729:1-6

Pharmacist Management of Controlled Substances

- CS Registration issued by the board
- Apply using your elicense account
- No charge to apply
- Then apply to DEA for a mid-level DEA registration

*Per Federal Regulations: RPh may NOT use a facility DEA

*DEA permits management of opioid use disorder by RPh
(e.g., buprenorphine)

Controlled Substances for the Treatment of Obesity

OAC 4731-11-04

CIII-V with approved FDA indication

Assess patient once in the first 3-months

Patient must lose 5% of initial weight
during the first 3-months of treatment

Continued treatment beyond 3-months

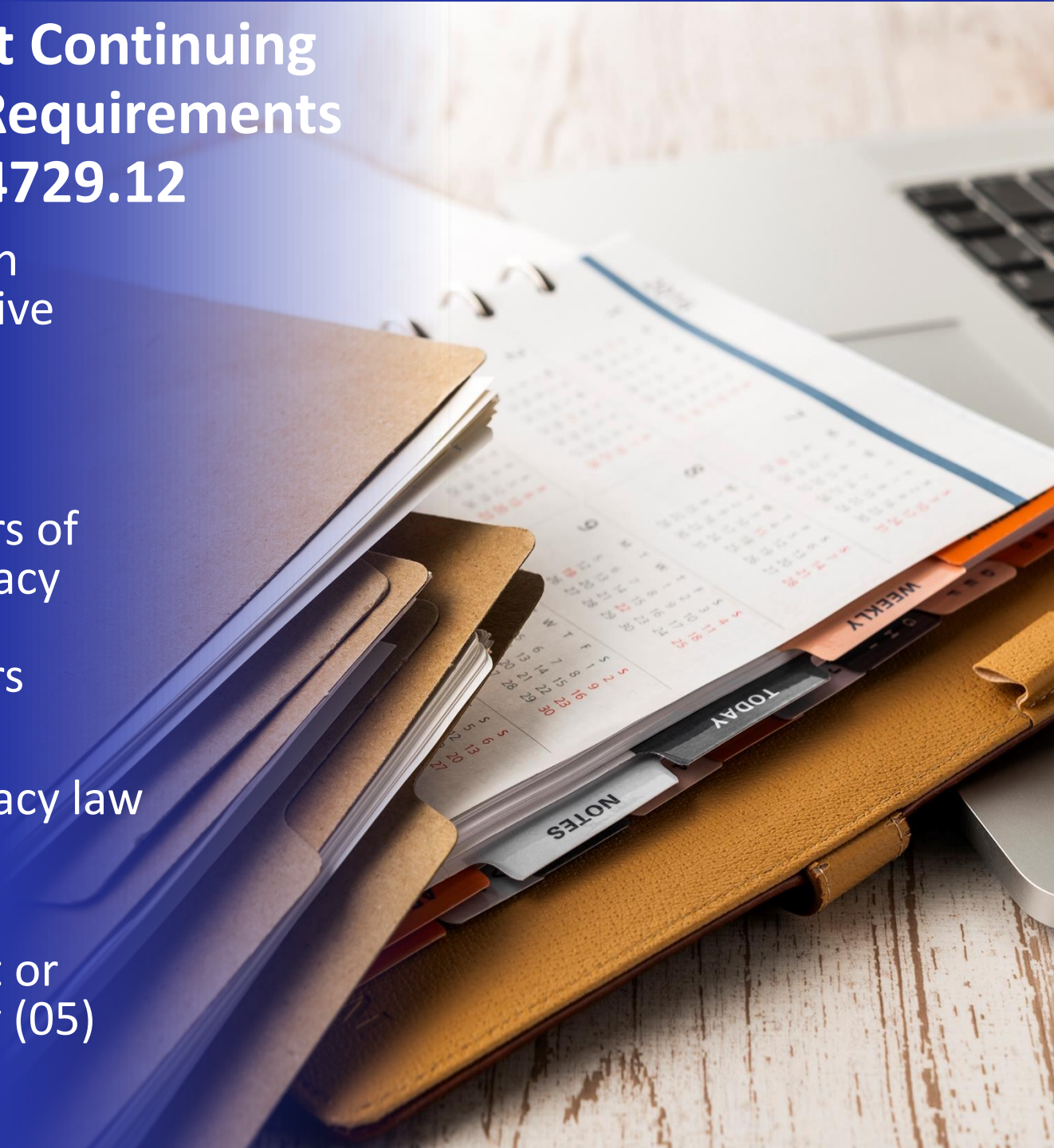
- Patient significantly benefits from treatment
- Weight is reduced, or
- Weight loss is maintained, and comorbidities are reduced



Pharmacist Continuing Education Requirements ORC 4729.12

Continuing Education
Requirements Effective
April 6, 2023:

- Pharmacist must complete 30-hours of continued pharmacy education in the previous two years
- 2 hours of pharmacy law (03)
- 2 hours of patient or medication safety (05)



2023 Law and Responsible Person Virtual Presentations

2023 Law Review

- Federal law changes
- State law and rule changes
- Pharmacy technician updates

2023 Responsible Person Roundtable

- Diversion trends
- Common issues found during inspection
- Federal and state law/rule updates

2023 Responsible Person 101

- Duties of a responsible person
- General TDDD requirements
- Resources for responsible person

Dates posted at www.pharmacy.ohio.gov

State of Ohio Board of Pharmacy | pharmacy.ohio.gov

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