Rules & Policies Agenda for Board Meeting
December 8, 2021

A. Rule Review Update
B. PA Consult Agreement Rules
C. Proposed Amendments to Rule 4731-30-03, Approval of Licensure Applications
D. Legislative Update
MEMORANDUM

TO: Betty Montgomery, President
    Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Update

DATE: November 30, 2021

Attached please find the Rule Schedule and Spreadsheet for December 2021.

**Requested Action**: No action requested.
## RULES TO DECEMBER BOARD MEETING

**For Final Adoption**
- 4731-1-07
- 4730-2-07
- 4731-35-01
- 4731-35-02

## RULES AT CSI

**Comment Deadline 10/19/20**
- 4731-11-03
- 4731-11-04
- 4731-11-04.1

## RULES SENT FOR INITIAL CIRCULATION

**Comment Deadline 12/1/21**
- 4731-18-01
- 4731-18-02
- 4731-18-03
- 4731-38-01

## RULES FOR REVIEW AT MASSAGE THERAPY ADVISORY COUNCIL

**Comment Deadline 7/2/21**
- 4731-1-01
- 4731-1-02
- 4731-1-03
- 4731-1-04
- 4731-1-05
- 4731-1-07
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- 4731-1-18
- 4731-1-19

## RULES AT JCARR

**Hearing Scheduled 12/3/21 – JCARR jurisdiction ends 1/2/22**
- 4731-6-05
- 4731-16-02
- 4731-16-05
- 4731-16-08
- 4731-22-07
- 4731-36-01

**Rules Needing Amendments Due to HB442 and HB263**

The following rules need to be amended or rescinded to remove references to cosmetic therapy and oriental medicine:

- 4731-16-01 Impaired Practitioners Definitions
- 4731-16-18 Eligibility for one-bite program
- 4731-22-02 Application

The following rules need to be amended or rescinded to address changes from HB263:

- 4731-4-02 Criminal Records Checks
- 4731-12-04 Eligibility for Licensure in Podiatric Medicine and Surgery by endorsement from Another State
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MEMORANDUM

TO: Betty Montgomery, President
    Members, State Medical Board of Ohio

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rules for Adoption, PA Consult Agreement Rules

DATE: November 29, 2021

This memo proposes adoption and amendment for rules as listed below.

The public hearing was held on October 29. No comments were received. The rules were considered at the JCARR meeting on November 8, 2021 and no comments were received. JCARR jurisdiction ended on November 26, 2021

4730-1-07  Miscellaneous Provision  Proposed to Amend
4730-2-07  Standards for Prescribing  Proposed to Amend
4731-35-01  Consult Agreements  Proposed to Amend
4731-35-02  Standards for Managing Drug Therapy  Proposed to Amend

The Hearing Examiner’s report, materials and transcript are provided to you.

Requested motion: I move to adopt and amend the rules as described in the November 29, 2021 memorandum from Ms. Anderson and to assign each rule action the effective date of December 31, 2021.
Miscellaneous provisions.

For purposes of Chapter 4730. of the Revised Code and Chapters 4730-1 and 4730-2 of the Administrative Code:

(A) An adjudication hearing held pursuant to the provisions of Chapter 119. of the Revised Code shall be conducted in conformance with the provisions of Chapter 4731-13 of the Administrative Code.

(B) The provisions of Chapters 4731-4, 4731-11, 4731-13, 4731-14, 4731-15, 4731-16, 4731-17, 4731-18, 4731-23, 4731-25, 4731-26, 4731-28, and 4731-29, and 4731-35 of the Administrative Code are applicable to the holder of a physician assistant license issued pursuant to section 4730.12 of the Revised Code, as though fully set forth in Chapter 4730-1 or 4730-2 of the Administrative Code.
Effective:

Five Year Review (FYR) Dates: 9/30/2023

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4730.07, 4730.39
Rule Amplifies: 4730.41
Prior Effective Dates: 10/31/2007, 06/30/2014, 09/30/2018, 09/30/2020
(A) A physician assistant who holds a prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician may prescribe a drug or therapeutic device provided the prescription is in accordance with all of the following:

(1) The extent and conditions of the physician-delegated prescriptive authority, granted by the supervising physician who is supervising the physician assistant in the exercise of the authority;

(2) The requirements of Chapter 4730. of the Revised Code;

(3) The requirements of Chapters 4730-1, 4730-2, 4730-4, and 4731-11, and 4731-35 of the Administrative Code; and

(4) The requirements of state and federal law pertaining to the prescription of drugs and therapeutic devices.

(B) A physician assistant who holds a prescriber number who has been granted physician-delegated prescriptive authority by a supervising physician shall prescribe in a valid prescriber-patient relationship. This includes, but is not limited to:

(1) Obtaining a thorough history of the patient;

(2) Conducting a physical examination of the patient;

(3) Rendering or confirming a diagnosis;

(4) Prescribing medication, ruling out the existence of any recognized contraindications;

(5) Consulting with the supervising physician when necessary; and

(6) Properly documenting these steps in the patient's medical record.

(C) The physician assistant's prescriptive authority shall not exceed the prescriptive authority of the supervising physician under whose supervision the prescription is being written, including but not limited to, any restrictions imposed on the physician's practice by action of the United States drug enforcement administration or the state medical board of Ohio.

(D) A physician assistant holding a prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician to prescribe
controlled substances shall apply for and obtain the United States drug enforcement administration registration prior to prescribing any controlled substances.

(E) A physician assistant holding prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician shall not prescribe any drug or device to perform or induce an abortion.

(F) A physician assistant holding prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician shall include on each prescription the physician assistant's license number, and, where applicable, shall include the physician assistant's DEA number.
Effective:

Five Year Review (FYR) Dates: 9/30/2025

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4730.07, 4730.39
Rule Amplifies: 4730.41
Prior Effective Dates: 10/31/2007, 06/30/2014, 09/30/2018, 09/30/2020
It is hereby confirmed that the State Medical Board - Physician Assistant Licensing original filed the following rule(s) pursuant to section 119.03 of the Ohio Revised Code.

Package Number: 191032
File Date and Time: 09/22/2021 4:46 PM
Confirmation Number: dd73ba718ee5f6d7c39ae0ad9af5655b

ORIGINAL FILE

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Consult agreements.

(A) For purposes of this chapter, practitioner includes the following:

(1) Physician authorized to practice medicine and surgery or osteopathic medicine and surgery under chapter 4731 of the revised code.

(2) Physician assistant who is licensed to practice as a physician assistant under chapter 4730 of the revised code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority.

(B) Requirements of a consult agreement.

(1) A consult agreement shall include all of the following:

(a) Identification of the physician practitioner(s) and pharmacist(s) authorized to enter into the agreement. They may include:

(i) Individual names of physician practitioners and pharmacists;

(ii) Physician practitioners or pharmacist practice groups; or

(iii) Identification based on institutional credentialing or privileging.

(iv) If multiple practitioners are entering the consult agreement, identification of the primary practitioner for the patient.

(b) A description of the patient’s consent to drug therapy management pursuant to the consult agreement as set forth in paragraphs (H) and (I) of rule 4729:1-06-01 of the Administrative Code.

(c) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid.

(d) A description of the drugs or drug categories managed as part of the agreement.

(e) A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement.

(f) A description of the types of blood, urine or other tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated
by the managing pharmacist as long as the tests relate directly to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated.

(g) A description of how the managing pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification pursuant to paragraph (N) of rule 4729-5-01 agency 4729 of the Administrative Code.

(h) A description of how communication between a managing pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the physician who authorized the agreement. The agreement may include a requirement that the managing pharmacist send a consult report to each consulting physician.

(i) A provision that allows a physician to override a decision made by the managing pharmacist when appropriate.

(j) An appropriate quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement.

(k) A description of a continuous quality improvement (CQI) program used to evaluate effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement.

(l) The training and experience criteria for managing pharmacists. The criteria may include privileging or credentialing, board certification, continuing education or any other training requirements. The agreement shall include a process to verify that the managing pharmacists meet the specified criteria.

(m) A statement that the physician and pharmacists shall meet minimal and prevailing standards of care at all times.

(n) An effective date and expiration date.

(o) Any other requirements contained in rules 4729:1-6-01, 4729:1-6-02 and 4729:1-6-03 of the Administrative Code.
(2) Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(c) to (A)(1)(f) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and available to an agent of the board upon request.

(3) The agreement shall be signed by the primary physician practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code, if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

(4) All amendments to a consult agreement shall be signed and dated by the primary physician practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code, if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

(c) Amendments to the consult agreement are required when the scope of the managing pharmacist's permitted procedures expands past what was contemplated withing the agreement.

(5) A consult agreement shall be valid for a period not to exceed two years.

(6) Only the following Ohio licensed physicians practitioners practicing in Ohio and Ohio licensed pharmacists may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.

(a) Physicians
(b) Physician assistants if entering into a consult agreement is authorized by one or more supervising physicians under a supervision agreement under section 4730.19 of the revised code; and

(c) Clinical nurse specialists, certified nurse-midwives, or certified nurse practitioners, if entering into a consult agreement is authorized by one or more collaborating physician

(B)(C) Recordkeeping. The primary <primary practitioner>, group or institution as defined in agency 4729 of the Administrative Code shall maintain a copy of the original consult agreement, and all amendments made thereafter, and a record of actions made in consultation with the managing pharmacist regarding each patient’s drug therapy. These records shall be maintained in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the agreement. Such consult agreements shall be considered confidential patient records.

(C)(D) Managing drug therapy.

(1) For the purpose of implementing the management of a patient’s drug therapy by an authorized managing pharmacist acting pursuant to a consult agreement, the primary <primary practitioner> must:

(a) Provide the managing pharmacist with access to the patient’s medical record; and

(b) Establish the managing pharmacist’s prescriptive authority as one or both of the following:

(i) A prescriber authorized to issue a drug order in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement. For all prescriptions issued by a pharmacist pursuant to this paragraph, the pharmacist shall comply with rules 4729:5-30 chapters 4729:5-5 of the Administrative Code for outpatient and 4729:5-13 of the Administrative Code for inpatient; and or

(ii) With respect to non-controlled dangerous drugs only, an agent of the consulting <primary practitioner>(s). As an agent of the consulting <primary practitioner>(s), a pharmacist is authorized to issue a drug order, on behalf of the consulting <primary practitioner>(s), in
writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement, and

(c) Specifically authorize the managing pharmacist’s ability to:

(i) Change the duration of treatment for the current drug therapy; adjust a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinue a drug, or to prescribe new drugs; and or

(ii) Order blood, urine and other tests related to the drug therapy being managed and to evaluate those results, and

(d) Identify the extent to which, and to whom, the managing pharmacist may delegate drug therapy management to other authorized pharmacists under the agreement.

(E) Review of consult agreements. Upon the request of the state medical board, the primary practitioner shall immediately provide a copy of the consult agreement, amendments, and any relating policies or documentation pursuant to this rule and section 4729.39 of the Revised Code. The state medical board may prohibit the execution of a consult agreement, or subsequently void a consult agreement, if the board finds any of the following:

(1) The agreement does not meet the requirements set forth in section 4729.39 of the Revised Code or this division of the administrative code; or

(2) The consult agreement, if executed, would present a danger to patient safety.
Effective:

Five Year Review (FYR) Dates: 10/31/2025

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4729.39, 4731.05
Rule Amplifies: 4729.39
Prior Effective Dates: 10/31/2020
Standards for managing drug therapy.

(A) A **physician practitioner** may elect to manage the drug therapy of an established patient by entering into a consult agreement with a pharmacist. The agreement is subject, but not limited to, the following standards:

1. The primary **physician practitioner** must ensure that the managing pharmacist has access to the patient’s medical record, the medical record is accurate, and that while transferring the medical record, the primary **physician practitioner** ensures the confidentiality of the medical record.

2. The **physician practitioner** must have an ongoing **physician practitioner**-patient relationship with the patient whose drug therapy is being managed, including an initial assessment and diagnosis by the **physician practitioner** prior to the commencement of the consult agreement.

3. With the exception of inpatient management of patient care at an institutional facility as defined in agency 4729 of the Administrative Code, the **physician practitioner**, prior to a pharmacist managing the patient’s drug therapy, shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the agreement, in such a manner that the patient or the patient’s representative understands scope and role of the managing pharmacist, which includes the following:
   
   (a) That a pharmacist may be utilized in the management of the patient's care;
   
   (b) That the patient or an individual authorized to act on behalf of a patient has the right to elect to participate in and to withdraw from the consult agreement.
   
   (c) Consent may be obtained as part of the patient's initial consent to treatment.

4. The diagnosis by the **physician practitioner** must be within the **physician practitioner**'s scope of practice.

5. The **physician practitioner** shall meet the minimal and prevailing standards of care.

6. The **physician practitioner** must ensure that the pharmacist managing the patient’s drug therapy has the requisite training, and experience related to the particular diagnosis for which the drug therapy is prescribed. **Physician Practitioners** practicing at institutional or ambulatory outpatient facilities may meet this requirement through institutional credentialing standards or policies.

7. The **physician practitioner** shall review the records of all services provided to the patient under the consult agreement.
(B) Quality assurance mechanisms. The following quality assurance mechanisms shall be implemented to verify information contained within the consult agreement, and ensure the managing pharmacist’s actions are authorized and meet the standards listed in paragraphs (A) and (B) of this rule:

1. Verification of ongoing physician-practitioner-patient relationship. A physician-practitioner-patient relationship can be established by detailing criteria set forth in paragraph (A)(2) of this rule, within the consult agreement.

2. Verification that physician-practitioner diagnosis is within the physician’s practitioner’s scope of practice. Establishing that a diagnosis is within the physician’s practitioner’s scope of practice may be established by detailing the criteria set forth in paragraph (A)(4) of this rule, within the consult agreement.

3. Verification that pharmacist’s training and experience is related to the drug therapy. Establishing that a pharmacist’s requisite training and experience with a particular drug therapy is related to the diagnosis for which the drug therapy is prescribed, may be established by detailing the criteria set forth in paragraph (A)(6) of this rule, within the consult agreement.

(C) Continuous quality improvement program. The following should be included in the development of a continuous quality improvement program in order to evaluate the effectiveness of patient care and ensure positive patient outcomes:

1. Notifications to primary physician-practitioner. The managing pharmacist must notify the primary physician-practitioner of the following situations regarding any pharmacist authorized to manage drug therapy under the agreement:

   a. A pharmacist has had their pharmacist license revoked, suspended, or denied by the state board of pharmacy;

   b. If prescribing controlled substances, a pharmacist has failed to renew their controlled substance prescriber registration;

   c. If prescribing controlled substances, a pharmacist fails to obtain or maintain a valid D.E.A. registration;

(D) Overriding decisions of managing pharmacist. Any authorized physician-practitioner identified under the consult agreement may override any decision, change, modification, evaluation or other action by any pharmacist acting pursuant to consult agreement or under the direction of the managing pharmacist, that was made with respect to the management of the patient’s drug therapy under the consult agreement.
Effective:

Five Year Review (FYR) Dates: 10/31/2025

Certification

Promulgated Under: 119.03
Statutory Authority: 4729.39, 4731.05
Rule Amplifies: 4729.39
Prior Effective Dates: 10/31/2020
It is hereby confirmed that the State Medical Board original filed the following rule(s) pursuant to section 119.03 of the Ohio Revised Code.

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MASTER COPY OF
PUBLIC RULES HEARING ON OCTOBER 29, 2021,
REGARDING PROPOSED CHANGES TO
THE OHIO ADMINISTRATIVE CODE

There are no sealed or proffered exhibits in this master copy.

- Report of Hearing

- Transcript
  - Full-Page Transcript
  - Word Index

- Exhibits

  Exhibit 1: Copy of the rules originally filed in Package 191032 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Rule-Filing System on September 22, 2021, and a copy of the confirmation of filing.

  Exhibit 2: Copy of the rules originally filed in Package 191033 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Rule-Filing System on September 22, 2021, and a copy of the confirmation of filing. Also included is a copy of the confirmation of the revised filing on October 18, 2021.

  Exhibit 3: Copy of the Notice of Public Hearing for the rules in Packages 191032 and 191033 originally filed on September 22, 2021. Also included is a copy of the hearing notice revise filed on October 18, 2021.

  Exhibit 4: Copies of the address portion of e-mails sent to persons and organizations pursuant to their standing request to be notified when the Medical Board proposes rules.
SUMMARY OF THE OCTOBER 29, 2021 PUBLIC HEARING REGARDING PROPOSED CHANGES TO THE OHIO ADMINISTRATIVE CODE

Pursuant to Section 119.03, Ohio Revised Code, a public hearing was held on October 29, 2021, to hear comments concerning proposed changes to the administrative rules of the State Medical Board of Ohio (“Board”). R. Gregory Porter, Hearing Examiner, presided.

PURPOSE OF THE HEARING

The following changes are proposed:

Physician Assistant Consult Rules

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PROCEDURAL MATTERS

1. The record was held open until 5:00 p.m. on October 29, 2021, for the purpose of receiving additional written comments concerning the proposed changes to the Ohio Administrative Code. No additional comments were received.

2. The hearing examiner marked Exhibits 1 through 4 post hearing.

TESTIMONY HEARD

Kimberly Anderson, Chief Legal Counsel for the Board

EXHIBITS EXAMINED

Exhibit 1: Copy of the rules originally filed in Package 191032 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Rule-Filing System on September 22, 2021, and a copy of the confirmation of filing.

Exhibit 2: Copy of the rules originally filed in Package 191033 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Rule-Filing System on
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Exhibit 3: Copy of the Notice of Public Hearing for the rules in Packages 191032 and 191033 originally filed on September 22, 2021. Also included is a copy of the hearing notice revise filed on October 18, 2021.

Exhibit 4: Copies of the address portion of e-mails sent to persons and organizations pursuant to their standing request to be notified when the Medical Board proposes rules.

SUMMARY OF EVIDENCE

1. Kimberly Anderson, Chief Legal Counsel for the Board, identified Exhibits 1 through 4. She further testified with respect to the notice that the Board provided to the public and interested parties regarding the proposed rule changes, and with respect to other procedural matters. Ms. Anderson further testified that no written comments were received by the Board concerning the proposed amended rules. (Hearing Transcript at 5-7)

2. No public testimony was received during the hearing.

CONCLUSION

The requirements of Chapter 119, Ohio Revised Code, have been satisfied. The Board may proceed to take action regarding the proposed amendments of Rules 4730-1-07, 4730-2-07, 4731-35-01, and 4731-35-02.
TRANSCRIPT
BEFORE THE OHIO STATE MEDICAL BOARD

In the Matter of the Proposed Rules 4730-1-07, 4730-2-07, 4731-35-01, and 4731-35-02 to be Amended.

PROCEEDINGS

before Mr. Greg Porter, Hearing Examiner, at the Ohio State Medical Board, 30 East Broad Street, Room 336, Columbus, Ohio, called at 1:32 p.m. on Friday, October 29, 2021.
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Friday Afternoon Session,

October 29, 2021.

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HEARING EXAMINER: We can go ahead and go on the record.

This public hearing for the State Medical Board of Ohio is now in session. Let the record show this public hearing is convened at 1:30 p.m. on Friday, October 29, 2021, in Room 336 of the Rhodes State Office Tower.

This public hearing was called pursuant to Section 119.03 Ohio Revised Code. I am Greg Porter, Hearing Examiner for the State Medical Board of Ohio. I am conducting this public hearing on behalf of the Board. The members of the Board will review this report concerning this hearing including any written materials submitted as evidence and have the transcript of today's hearing available for review.

The following rules are proposed, and all these are proposed to be amended, they are physician assistant consult rules and specifically 4730-1-07 titled miscellaneous provisions; 4730-2-07 standards for prescribing; 4731-35-01 consult agreements; and 4731-35-02 standards for managing drug therapy.
The purpose of this hearing today is to provide an opportunity for any person affected by the proposed rules to be heard. Any affected person may present his or her positions, arguments, or contentions orally or in writing and may present evidence tending to show that the proposed adoption of the rules as proposed will be unreasonable or unlawful.

All persons who wish to testify orally today are asked to register on the witness information sheet. If you have not done so, please do so now and list your name and any organization you may represent. If you have a written copy of your testimony, submission of a written copy will assist the Board in its review of your comments. Written statements may also be submitted today without testimony.

Please send electronic copies of your comments to my e-mail address, gregporter@med.ohio.gov. I won't read the rest of this kind of stuff because we have no witnesses here today.

I now recognize Kim Anderson, Chief Legal Counsel for the Medical Board, for the presentation of testimony on the Board's compliance with the legal
requirements in this matter.

I call Kim Anderson and ask that she's sworn in.

(Witness sworn.)

HEARING EXAMINER: Please state your name and how you are employed.

MS. ANDERSON: Kim Anderson, Chief Legal Counsel, State Medical Board of Ohio.

HEARING EXAMINER: Are you familiar with the filings and other actions taken for purposes of the rules being considered today?

MS. ANDERSON: Yes.

HEARING EXAMINER: What part did you play in the filing of the rules?

MS. ANDERSON: I participated in their filing and the distribution of the Notice of Public Hearing.

HEARING EXAMINER: Can you identify the documents that have been marked as exhibits, please.

MS. ANDERSON: Yes. Exhibit 1 is a copy of the rules originally filed in Package 191032 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Rule Filing System on September 22, 2021, and a copy of the confirmation of filing.
Exhibit 2 is a copy of the rules originally filed in Package 191033 with JCARR, Secretary of State, and the Legislative Services Commission via the Electronic Rule Filing System on September 22, 2021, and a copy of the confirmation of filing. Also included is a copy of the confirmation of the revised filing on October 18, 2021.

HEARING EXAMINER: Was public notice of the rules that are the subject of this hearing today given in the Register of Ohio at least 30 days prior to today?

MS. ANDERSON: Yes. Exhibit 3 is a copy of the Notice of Public Hearing for the rules in Packages 191032 and 191033 originally filed on September 22, 2021. Also included is a copy of the Hearing Notice Revised filed on October 18, 2021.

HEARING EXAMINER: Was notice of the proposed rules provided to any persons or organizations?

MS. ANDERSON: Yes. Exhibit 4 contains copies of the address portion of e-mails sent to persons and organizations pursuant to their standing request to be notified when the Medical Board proposes rules.

HEARING EXAMINER: Were any requests for
copies of the proposed rules received in the Board office?

MS. ANDERSON: No.

HEARING EXAMINER: Were any written comments of the proposed rules received in the Board office?

MS. ANDERSON: No.

HEARING EXAMINER: Okay. I will admit Exhibits 1 through 4 into the record.

(EXHIBITS ADMITTED INTO EVIDENCE.)

HEARING EXAMINER: Thank you, Ms. Anderson.

MS. ANDERSON: Thank you.

HEARING EXAMINER: Okay. Now would be the time to take testimony of the proposed rules from interested parties. However, we have no interested parties who are here seeking to present comments, so at this time I will simply move on to the closure of this hearing.

And I would note for the record that the record will be held open until 5 o'clock today, 5 o'clock p.m. today for the sole purpose of receiving any written -- any additional written comments on the proposed rules. Please send them to my e-mail address, gregporter@med.ohio.gov.
Thank you all for attending this public hearing. The Board will weigh the testimony and evidence presented today before considering action on those rules.

Any future action by the Board on these proposed rules will take place in the regular monthly meeting of the Board which is open to the public. Any formal action by the Board will comply with Chapter 119 of the Ohio Revised Code.

And this public hearing is concluded at approximately 20 til 2:00. Thank you very much.

(Thereupon, at 1:40 p.m., the hearing was adjourned.)

---
CERTIFICATE

I do hereby certify that the foregoing is a true and correct transcript of the proceedings taken by me in this matter on Friday, October 29, 2021, and carefully compared with my original stenographic notes.

Karen Sue Gibson, Registered Merit Reporter.

(KSG-7180)
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EXHIBITS
4730-1-07 Miscellaneous provisions.

For purposes of Chapter 4730. of the Revised Code and Chapters 4730-1 and 4730-2 of the Administrative Code:

(A) An adjudication hearing held pursuant to the provisions of Chapter 119. of the Revised Code shall be conducted in conformance with the provisions of Chapter 4731-13 of the Administrative Code.

(B) The provisions of Chapters 4731-4, 4731-11, 4731-13, 4731-14, 4731-15, 4731-16, 4731-17, 4731-18, 4731-23, 4731-25, 4731-26, 4731-28, and 4731-29, and 4731-35 of the Administrative Code are applicable to the holder of a physician assistant license issued pursuant to section 4730.12 of the Revised Code, as though fully set forth in Chapter 4730-1 or 4730-2 of the Administrative Code.

Exhibit 1
Effective:

Five Year Review (FYR) Dates: 9/30/2023

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4730.07, 4730.39
Rule Amplifies: 4730.41
Prior Effective Dates: 10/31/2007, 06/30/2014, 09/30/2018, 09/30/2020
Standards for prescribing.

(A) A physician assistant who holds a prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician may prescribe a drug or therapeutic device provided the prescription is in accordance with all of the following:

1. The extent and conditions of the physician-delegated prescriptive authority, granted by the supervising physician who is supervising the physician assistant in the exercise of the authority;

2. The requirements of Chapter 4730. of the Revised Code;

3. The requirements of Chapters 4730-1, 4730-2, 4730-4, and 4731-11, and 4731-35 of the Administrative Code; and

4. The requirements of state and federal law pertaining to the prescription of drugs and therapeutic devices.

(B) A physician assistant who holds a prescriber number who has been granted physician-delegated prescriptive authority by a supervising physician shall prescribe in a valid prescriber-patient relationship. This includes, but is not limited to:

1. Obtaining a thorough history of the patient;

2. Conducting a physical examination of the patient;

3. Rendering or confirming a diagnosis;

4. Prescribing medication, ruling out the existence of any recognized contraindications;

5. Consulting with the supervising physician when necessary; and

6. Properly documenting these steps in the patient's medical record.

(C) The physician assistant's prescriptive authority shall not exceed the prescriptive authority of the supervising physician under whose supervision the prescription is being written, including but not limited to, any restrictions imposed on the physician's practice by action of the United States drug enforcement administration or the state medical board of Ohio.

(D) A physician assistant holding a prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician to prescribe
controlled substances shall apply for and obtain the United States drug enforcement administration registration prior to prescribing any controlled substances.

(E) A physician assistant holding prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician shall not prescribe any drug or device to perform or induce an abortion.

(F) A physician assistant holding prescriber number and who has been granted physician-delegated prescriptive authority by a supervising physician shall include on each prescription the physician assistant's license number, and, where applicable, shall include the physician assistant's DEA number.
Effective:

Five Year Review (FYR) Dates: 9/30/2025

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4730.07, 4730.39
Rule Amplifies: 4730.41
Prior Effective Dates: 10/31/2007, 06/30/2014, 09/30/2018, 09/30/2020
It is hereby confirmed that the State Medical Board - Physician Assistant Licensing original filed the following rule(s) pursuant to section 119.03 of the Ohio Revised Code.

Package Number: 191032
File Date and Time: 09/22/2021 4:46 PM
Confirmation Number: dd73ba718ee5f6d7c39ae0ad9af5655b

### ORIGINAL FILE

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Consult agreements.

(A) For purposes of this chapter, practitioner includes the following:

(1) Physician authorized to practice medicine and surgery or osteopathic medicine and surgery under chapter 4731 of the revised code.

(2) Physician assistant who is licensed to practice as a physician assistant under chapter 4730 of the revised code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority.

(B) Requirements of a consult agreement.

(1) A consult agreement shall include all of the following:

(a) Identification of the practitioners and pharmacist(s) authorized to enter into the agreement. They may include:

(i) Individual names of practitioners and pharmacists;

(ii) Practitioner or pharmacist practice groups; or

(iii) Identification based on institutional credentialing or privileging.

(iv) If multiple practitioners are entering the consult agreement, identification of the primary practitioner for the patient.

(b) A description of the patient’s consent to drug therapy management pursuant to the consult agreement as set forth in paragraphs (H) and (I) of rule 4729:1-06-01 of the Administrative Code.

(c) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid.

(d) A description of the drugs or drug categories managed as part of the agreement.

(e) A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement.

(f) A description of the types of blood, urine or other tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated.
by the managing pharmacist as long as the tests relate directly to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated.

(g) A description of how the managing pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification pursuant to paragraph (N) of rule 4729:5-01 of the Administrative Code.

(h) A description of how communication between a managing pharmacist and physician practitioner acting under a consult agreement shall take place at regular intervals specified by the physician practitioner who authorized the agreement. The agreement may include a requirement that the managing pharmacist send a consult report to each consulting physician practitioner.

(i) A provision that allows a physician practitioner to override a decision made by the managing pharmacist when appropriate.

(j) An appropriate quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement.

(k) A description of a continuous quality improvement (CQI) program used to evaluate effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement.

(l) The training and experience criteria for managing pharmacists. The criteria may include privileging or credentialing, board certification, continuing education or any other training requirements. The agreement shall include a process to verify that the managing pharmacists meet the specified criteria.

(m) A statement that the physician practitioners and pharmacists shall meet minimal and prevailing standards of care at all times.

(n) An effective date and expiration date.

(o) Any other requirements contained in rules 4729:1-6-01, 4729:1-6-02 and 4729:1-6-03 of the Administrative Code.
(2) Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(c) to (A)(1)(f) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and available to an agent of the board upon request.

(3) The agreement shall be signed by the primary physician practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code, if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

(4) All amendments to a consult agreement shall be signed and dated by the primary physician practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code, if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

(c) Amendments to the consult agreement are required when the scope of the managing pharmacist's permitted procedures expands past what was contemplated withing the agreement.

(5) A consult agreement shall be valid for a period not to exceed two years.

(6) Only the following Ohio licensed physicians practitioners practicing in Ohio and Ohio licensed pharmacists may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.

(a) Physicians
(b) Physician assistants if entering into a consult agreement is authorized by one or more supervising physicians under a supervision agreement under section 4730.19 of the revised code; and

(c) Clinical nurse specialists, certified nurse-midwives, or certified nurse practitioners, if entering into a consult agreement is authorized by one or more collaborating physician

(B)(C) Recordkeeping. The primary physician practitioner, physician practitioner group or institution as defined in agency 4729 of the Administrative Code shall maintain a copy of the original consult agreement, and all amendments made thereafter, and a record of actions made in consultation with the managing pharmacist regarding each patient’s drug therapy. These records shall be maintained in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the agreement. Such consult agreements shall be considered confidential patient records.

(C)(D) Managing drug therapy.

(1) For the purpose of implementing the management of a patient’s drug therapy by an authorized managing pharmacist acting pursuant to a consult agreement, the primary physician practitioner must:

(a) Provide the managing pharmacist with access to the patient’s medical record; and

(b) Establish the managing pharmacist’s prescriptive authority as one or both of the following:

(i) A prescriber authorized to issue a drug order in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement. For all prescriptions issued by a pharmacist pursuant to this paragraph, the pharmacist shall comply with rules 4729:5-30 of the Administrative Code for outpatient and 4729:5-13 of the Administrative Code for inpatient; and or

(ii) With respect to non-controlled dangerous drugs only, an agent of the consulting physician practitioner(s). As an agent of the consulting physician practitioner(s), a pharmacist is authorized to issue a drug order, on behalf of the consulting physician practitioner(s), in
writing, orally, by a manually signed drug order sent via facsimile
or by an electronic prescribing system for drugs or combinations or
mixtures of drugs to be used by a particular patient as authorized
by the consult agreement, and

(c) Specifically authorize the managing pharmacist’s ability to:

(i) Change the duration of treatment for the current drug therapy; adjust
a drug's strength, dose, dosage form, frequency of administration,
route of administration, discontinue a drug, or to prescribe new
drugs; and or

(ii) Order blood, urine and other tests related to the drug therapy being
managed and to evaluate those results, and

(d) Identify the extent to which, and to whom, the managing pharmacist may
delegate drug therapy management to other authorized pharmacists under
the agreement.

(E) Review of consult agreements. Upon the request of the state medical board,
the primary physician shall immediately provide a copy of the consult
agreement, amendments, and any relating policies or documentation pursuant to this
rule and section 4729.39 of the Revised Code. The state medical board may prohibit
the execution of a consult agreement, or subsequently void a consult agreement, if
the board finds any of the following:

(1) The agreement does not meet the requirements set forth in section 4729.39 of the
Revised Code or this division of the administrative code; or

(2) The consult agreement, if executed, would present a danger to patient safety.
Effective:

Five Year Review (FYR) Dates: 10/31/2025

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4729.39, 4731.05
Rule Amplifies: 4729.39
Prior Effective Dates: 10/31/2020
Standards for managing drug therapy.

(A) A physician practitioner may elect to manage the drug therapy of an established patient by entering into a consult agreement with a pharmacist. The agreement is subject, but not limited to, the following standards:

1. The primary physician practitioner must ensure that the managing pharmacist has access to the patient’s medical record, the medical record is accurate, and that while transferring the medical record, the primary physician practitioner ensures the confidentiality of the medical record.

2. The physician practitioner must have an ongoing physician practitioner-patient relationship with the patient whose drug therapy is being managed, including an initial assessment and diagnosis by the physician practitioner prior to the commencement of the consult agreement.

3. With the exception of inpatient management of patient care at an institutional facility as defined in agency 4729 of the Administrative Code, the physician practitioner, prior to a pharmacist managing the patient’s drug therapy, shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the agreement, in such a manner that the patient or the patient’s representative understands scope and role of the managing pharmacist, which includes the following:

   a. That a pharmacist may be utilized in the management of the patient's care;

   b. That the patient or an individual authorized to act on behalf of a patient has the right to elect to participate in and to withdraw from the consult agreement.

   c. Consent may be obtained as part of the patient's initial consent to treatment.

4. The diagnosis by the physician practitioner must be within the physician practitioner’s scope of practice.

5. The physician practitioner shall meet the minimal and prevailing standards of care.

6. The physician practitioner must ensure that the pharmacist managing the patient’s drug therapy has the requisite training, and experience related to the particular diagnosis for which the drug therapy is prescribed. Physicians Practitioners practicing at institutional or ambulatory outpatient facilities may meet this requirement through institutional credentialing standards or policies.

7. The physician practitioner shall review the records of all services provided to the patient under the consult agreement.
(B) Quality assurance mechanisms. The following quality assurance mechanisms shall
be implemented to verify information contained within the consult agreement, and
ensure the managing pharmacist’s actions are authorized and meet the standards listed
in paragraphs (A) and (B) of this rule:

1. Verification of ongoing physician-practitioner-patient relationship. A
   physician-practitioner-patient relationship can be established by detailing
criteria set forth in paragraph (A)(2) of this rule, within the consult agreement.

2. Verification that physician-practitioner diagnosis is within the
   physician’s scope of practice. Establishing that a diagnosis is
   within the physician’s scope of practice may be established by
detailing the criteria set forth in paragraph (A)(4) of this rule, within the consult
   agreement.

3. Verification that pharmacist’s training and experience is related to the drug
   therapy. Establishing that a pharmacist’s requisite training and experience with
   a particular drug therapy is related to the diagnosis for which the drug therapy
   is prescribed, may be established by detailing the criteria set forth in paragraph
   (A)(6) of this rule, within the consult agreement.

(C) Continuous quality improvement program. The following should be included in the
development of a continuous quality improvement program in order to evaluate the
effectiveness of patient care and ensure positive patient outcomes:

1. Notifications to primary physician-practitioner. The managing pharmacist must
   notify the primary physician-practitioner of the following situations regarding
   any pharmacist authorized to manage drug therapy under the agreement:

   (a) A pharmacist has had their pharmacist license revoked, suspended, or denied
       by the state board of pharmacy;

   (b) If prescribing controlled substances, a pharmacist has failed to renew their
       controlled substance prescriber registration;

   (c) If prescribing controlled substances, a pharmacist fails to obtain or maintain
       a valid D.E.A. registration;

(D) Overriding decisions of managing pharmacist. Any authorized physician-practitioner
identified under the consult agreement may override any decision, change,
modification, evaluation or other action by any pharmacist acting pursuant to consult
agreement or under the direction of the managing pharmacist, that was made with
respect to the management of the patient’s drug therapy under the consult agreement.
Effective:

Five Year Review (FYR) Dates: 10/31/2025

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4729.39, 4731.05
Rule Amplifies: 4729.39
Prior Effective Dates: 10/31/2020
It is hereby confirmed that the State Medical Board original filed the following rule(s) pursuant to section 119.03 of the Ohio Revised Code.

Package Number: 191033  
File Date and Time: 09/22/2021 4:49 PM  
Confirmation Number: c429845e5049e4bb8f399e5edcbbc152

**ORIGINAL FILE**

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<td>Amendment</td>
<td>N</td>
<td>Y</td>
<td>11/26/2021</td>
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It is hereby confirmed that the State Medical Board revise filed the following rule(s) pursuant to section 119.03 of the Ohio Revised Code.

**Package Number:** 191033  
**File Date and Time:** 10/18/2021 2:46 PM  
**Confirmation Number:** ae1cbea5fb8102452d791ab7ff11aee

### REVISE

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</table>
The State Medical Board of Ohio, pursuant to Chapter 119, Ohio Revised Code, hereby gives notice that it will conduct a public hearing to consider the adoption of rules.

The public hearing will be conducted on **Friday, October 29, 2021 at 1:30 p.m. in Room 336 of the Rhodes State Office Tower, 30 E. Broad St., 3rd Floor, Columbus, OH 43215**. Oral or written testimony may be presented by any person affected by the proposed actions.

The following rules are proposed:

**Physician Assistant Consult Rules**

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<thead>
<tr>
<th>Rule</th>
<th>Description</th>
<th>Status</th>
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<tbody>
<tr>
<td>4730-1-07</td>
<td>Miscellaneous Provisions</td>
<td>Proposed to be Amended</td>
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<tr>
<td>4730-2-07</td>
<td>Standards for Prescribing</td>
<td>Proposed to be Amended</td>
</tr>
<tr>
<td>4731-35-01</td>
<td>Consult Agreements</td>
<td>Proposed to be Amended</td>
</tr>
<tr>
<td>4731-35-02</td>
<td>Standards for Managing Drug Therapy</td>
<td>Proposed to be amended</td>
</tr>
</tbody>
</table>

The proposed rules will be available from:

- State Medical Board of Ohio, 30 East Broad Street, 3rd Floor, Columbus, OH 43215
- Register of Ohio website: [http://www.registerofohio.state.oh.us/rules/search](http://www.registerofohio.state.oh.us/rules/search)

All interested persons will be given the opportunity to be heard at the public hearing. Those persons who wish to provide oral testimony at the hearing should preregister by contacting Kimberly Anderson at the address below. Persons providing oral testimony are encouraged to also submit a copy of the testimony to Kimberly Anderson at the email address below.

All written comments received by the Board before the close of the hearing record will be considered. **Written comments may be provided at the public hearing.** However, persons interested in providing written comments are encouraged to do so prior to October 29, 2021.

- via e-mail to: Kimberly.Anderson@med.ohio.gov
- via mail to: Kimberly Anderson, Chief Legal Counsel State Medical Board of Ohio 30 East Broad Street, 3rd Floor Columbus, OH 43215-6127

Exhibit 3
The State Medical Board of Ohio, pursuant to Chapter 119, Ohio Revised Code, hereby gives notice that it will conduct a public hearing to consider the adoption of rules.

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The following rules are proposed:

Physician Assistant Consult Rules

- 4730-1-07 Miscellaneous Provisions Proposed to be Amended
- 4730-2-07 Standards for Prescribing Proposed to be Amended
- 4731-35-01 Consult Agreements Proposed to be Amended
- 4731-35-02 Standards for Managing Drug Therapy Proposed to be amended

The proposed rules will be available from:

- State Medical Board of Ohio, 30 East Broad Street, 3rd Floor, Columbus, OH 43215
- Medical Board’s website: https://med.ohio.gov/Laws-Rules/Newly-Adopted-and-Proposed-Rules
  Under the heading “Public Rules Hearing Notices”
- Register of Ohio website: http://www.registerofohio.state.oh.us/rules/search

All interested persons will be given the opportunity to be heard at the public hearing. Those persons who wish to provide oral testimony at the hearing should preregister by contacting Kimberly Anderson at the address below. Persons providing oral testimony are encouraged to also submit a copy of the testimony to Kimberly Anderson at the email address below.

All written comments received by the Board before the close of the hearing record will be considered. Written comments may be provided at the public hearing. However, persons interested in providing written comments are encouraged to do so prior to October 29, 2021.

- via e-mail to: Kimberly.Anderson@med.ohio.gov
- via mail to: Kimberly Anderson, Chief Legal Counsel
  State Medical Board of Ohio
  30 East Broad Street, 3rd Floor
  Columbus, OH 43215-6127
<table>
<thead>
<tr>
<th>From:</th>
<th>Rodriguez, Judith</th>
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<td>To:</td>
<td>A DiPasquale; Barry T. Doyle (<a href="mailto:tdoyle@aol.com">tdoyle@aol.com</a>); Beth Bolvard; Bruce B. Whitman (<a href="mailto:bbwhitmanlaw@aol.com">bbwhitmanlaw@aol.com</a>); Cameron McNamee; Damian Clifford; Daniel Zinsmaster (<a href="mailto:daniel.zinsmaster@dinsmore.com">daniel.zinsmaster@dinsmore.com</a>); David Paragas; Deborah B. Lydon (<a href="mailto:lydon@dinslaw.com">lydon@dinslaw.com</a>); Elaine M. Hatt PhD; Eric Vinyard; Greg Warren; James Leo; James McGovern (<a href="mailto:jmcgovern@grafflaw.com">jmcgovern@grafflaw.com</a>); Jeffrey Lyurca (<a href="mailto:jlyurca@juralshuk.com">jlyurca@juralshuk.com</a>); Jennifer Armstrong; Jessica Bechtel; Joe Feltes; John R. Irwin; Ludi Hatcher; Kay Mavko; Lana Mullet; Levi Tkach; Lori Herf; M. D. Roland Benton; Mike Mathy OFMA; <a href="mailto:patrick@americanmedspa.org">patrick@americanmedspa.org</a>; Shannon Urena; Socrates Tuch; Stanley B. Dritz (<a href="mailto:sdriz@dinslaw.com">sdriz@dinslaw.com</a>); Stefanie Fratz; Steven Greer; Thomas W. Hess (<a href="mailto:thess@dinslaw.com">thess@dinslaw.com</a>); Vicki Jenkins; (<a href="mailto:roseman@sssnet.com">roseman@sssnet.com</a>); Allison Poulus; <a href="mailto:amandac8ines@sbobglobal.net">amandac8ines@sbobglobal.net</a>; Ann Spicer; Ann Warner; Belinda Jones (<a href="mailto:biones@capitol-consulting.net">biones@capitol-consulting.net</a>); Betsy Houchen; Blair Barnhart-Kinkle (<a href="mailto:barnhab@cf.org">barnhab@cf.org</a>); Bryn Hunt; Carolyn Towne; Catherine Olohan Zwissler; Doug Graff; Elizabeth Collins (E-mail); Eric Plinke (<a href="mailto:eric.plinke@dinslaw.com">eric.plinke@dinslaw.com</a>); GeoEmershaw; George Dunigan; Greg Fouche; Gregory W. Bee (E-mail); Holly Fischer; Inez 617 (<a href="mailto:inez617@msn.com">inez617@msn.com</a>); J. Richard Ludgin (E-mail); James Lindon; Jeffrey Fisher; Joel Selmeier (E-mail); John Booher; Kevin Devaney; Kevin L. Miller; Larry Wolpert; Laura Tiberi; Lisa Emrich; Lloyd DePew; M. D. Eliot Mostow (<a href="mailto:emostow@akonderm.com">emostow@akonderm.com</a>); Matt Donnelly; McGovern l/im (<a href="mailto:lamesnmcgovern@yahoo.com">lamesnmcgovern@yahoo.com</a>); Melissa Guzman; Michael Oros; Michael R. Moran; OHA - Mary Gallagher; Paul Bryson; Paul Hilderbrand; rainykgal; Ricardo del Castillo; Richard Greely; Richard Kasmer (<a href="mailto:ohiolawce@yahoo.com">ohiolawce@yahoo.com</a>); Rogers Carol (<a href="mailto:crogers65@msn.com">crogers65@msn.com</a>); Ronald House (E-mail); Scott P. Sandrock; Sean McGlone; Sharon Barnes Ph. D.; State Board of Psychology; Steve Lanier (<a href="mailto:stevelanier@yahoo.com">stevelanier@yahoo.com</a>); Teresa Lample; Terry Guzeck; Tim Cosgrove (E-mail); Tom Dilling; Victor Goodman; <a href="mailto:wfitzgibbon@cwslaw.com">wfitzgibbon@cwslaw.com</a>; Willa Ebersole; ACADEMY OF MED. OF CINCINNATI (E-mail); ACADEMY OF MEDICINE OF TOLEDO &amp; LUCAS (E-mail); Dayton Academy of Osteopathic Medicine (<a href="mailto:daytonacademy@sbcglobal.net">daytonacademy@sbcglobal.net</a>); <a href="mailto:jjohns@amcno.org">jjohns@amcno.org</a>; Lorain Co. Medical Society; MAHONING COUNTY MEDICAL SOCIETY (E-mail); Pam Fairbanks; PICKAWAY COUNTY MEDICAL SOCIETY (E-mail); Sandusky County Medical Society; Stark Medical Society</td>
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Please see attached Rules Hearing Notice and the associated rules.

Judy Rodriguez
Public Services Manager

State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215
o: 614-466-4999
w: med.ohio.gov

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FW: Rules Hearing, 10/29/21

Date: Thursday, September 23, 2021 3:21:00 PM

Attachments: Hearing Notice.pdf
image001.png
image003.png
image004.png

Judy Rodriguez
Public Services Manager
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From: Rodriguez, Judith
Sent: Thursday, September 23, 2021 3:20 PM
To: 'A DiPasquale' <ADiPasquale@nursing.ohio.gov>; 'Barry T. Doyle (tod Doyle@aol.com)'
tod Doyle@aol.com>; 'Beth Bolyard' <BBolyard@bricker.com>; 'Bruce B. Whitman (bbwhitmanlaw@aol.com)'
bb whitmanlaw@aol.com>; 'Cameron McNamee' <Cameron.McNamee@pharmacy.ohio.gov>; 'Damion Clifford' <dclifford@arnlaw.com>; 'Daniel Zinsmaster (daniel.zinsmaster@dinsmore.com)'
daniel.zinsmaster@dinsmore.com>; 'David
Subject: Rules Hearing, 10/29/21

Please see attached Rules Hearing Notice and the associated rules.

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MEMORANDUM

TO: Board Members

FROM: Joe Turek, Deputy Director

DATE: 11/30/2021

RE: Proposed Amendments to Rule 4731-30-03 (Approval of Licensure Applications)

Background

As a result of the enactment of HB 442, which eliminated the licensing of oriental medicine practitioners, internal management rule 4731-30-03 was required to be amended to remove the reference to that license type. The board approved the adoption of the rule in September of this year and it was filed with JCARR. Subsequently, it was discovered that there was an error with the filing and the rule was placed into “To Be Refiled” status. Meanwhile, licensure staff was considering potential improvements to the current process for applications that require a USMLE/COMLEX waiver, a GME equivalency determination, or a demonstration of an applicant’s fitness to practice. In light of the foregoing, the rule will be withdrawn, and the board will now be asked to consider additional amendments to the rule.

Issue

Currently, rule 4731-30-03 authorizes the Secretary/Supervising Member and the Deputy Director of Licensure to issue licenses if the applicant is not seeking a waiver or GME equivalency determination, or the applicant is not required to demonstrate fitness to resume practice due to inactivity for more than two years. Applications that are not eligible for routine authorization must come before the board for consideration. This process causes unnecessary delay, particularly considering that such applicants do not present disciplinary issues and it is extremely rare for the board to deny an applicant’s waiver/equivalency request or reject the staff’s recommendation on how to resolve concerns related to an applicant’s fitness to practice.

Recommendation

In addition to deleting the reference to oriental medicine practitioners, licensure staff recommends revising rule 4731-30-03 as delineated in the attachment to this memo.

- Paragraph (A)(2) and (3) would permit routine issuance of a license if the secretary and supervising member of the board has granted a waiver, or a determination of equivalency to, any eligibility requirement, as may be provided by law.

- New paragraph (D)(1) explicitly authorizes the Secretary and Supervising Member to grant USMLE/COMLEX waivers, determine GME equivalency, and determine whether an applicant has demonstrated fitness to resume practice.
• New paragraph (D)(2) authorizes the Secretary and Supervising Member to approve protocols for use by the deputy director of licensure whereby if the protocol is met, the waiver/equivalency is deemed granted, or it is deemed that the applicant has demonstrated fitness to resume practice.

• Per paragraph (E) applications that are ineligible for routine issuance (i.e. the Secretary and Supervising Member refuse to approve a waiver/equivalency or applications for which the Secretary and Supervising member determine that fitness to practice has not been demonstrated) will continue to be referred to the board for resolution.

In sum, these proposed amendments shift the consideration of common non-disciplinary matters to the Secretary and Supervising Member, obviating the need for them to be addressed by the full board on a monthly basis. Further, the use of approved protocols is not a new or unique concept as there are almost three dozen approved protocols currently in use that address issues related to complaint handling, affirmative answers on licensure applications, and fitness to resume practice. Lastly, the amendments will result in a more streamlined process for the board to resolve these licensure matters thereby decreasing the time to license issuance for otherwise qualified and safe practitioners.

Staff recommends a motion by the Board to:

“Approve the rule as drafted for initial circulation.”
(A) For purposes of this rule, routine authorization means issuance of a license or certificate to an individual pursuant to an application that meets the following criteria:

1. The applicant meets eligibility requirements for the license or certificate under the applicable provisions of the Revised Code and Administrative Code.

2. If applicable, the secretary and supervising member of the board has granted to the applicant is not seeking a waiver of, or a determination of equivalency to, any eligibility requirement, as may be provided for under the applicable provisions of the Revised Code and Administrative Code.

3. If applicable, the secretary and supervising member of the board has determined that the applicant has not required to demonstrated fitness to resume practice due to inactivity under the applicable provisions of the Revised Code and Administrative Code.

4. The application presents no grounds for discipline under the applicable provisions of the Revised Code or Administrative Code.

(B) The board authorizes the secretary and supervising member of the board to issue the following routine authorizations under the provisions of the Revised Code and Administrative Code, without prior consultation or approval by the board:

1. Certificate of conceded eminence pursuant to section 4731.297 of the Revised Code;
2. Clinical research faculty certificate pursuant to section 4731.293 of the Revised Code;
3. Visiting clinical professional development certificate pursuant to section 4731.298 of the Revised Code;
4. Special activity certificate pursuant to section 4731.294 of the Revised Code;
5. Special activity license to practice as a genetic counselor pursuant to section 4778.09 of the Revised Code.
(6) Expedited license to practice medicine and surgery or osteopathic medicine and surgery by endorsement pursuant to section 4731.299 of the Revised Code;  
(7) Certificate to recommend medical use of marijuana pursuant to section 4731.30 of the Revised Code;

(C) The board authorizes the deputy director of licensure, or the deputy director’s designee, to issue the following routine authorizations under the provisions of the Revised Code and Administrative Code, without prior consultation or approval by the board:

(1) License to practice as a physician assistant pursuant to section 4730.12 of the Revised Code;  
(2) License to practice medicine and surgery or osteopathic medicine and surgery pursuant to section 4731.14 of the Revised Code;  
(3) License to practice a limited branch of medicine pursuant to section 4731.17 of the Revised Code;  
(4) Training certificate pursuant to section 4731.291 of the Revised Code;  
(5) Volunteers certificate pursuant to section 4731.295 of the Revised Code;  
(6) License to practice podiatric medicine and surgery pursuant to section 4731.56 of the Revised Code;  
(7) Visiting podiatric faculty certificate pursuant to section 4731.572 of the Revised Code;  
(8) Podiatric training certificate pursuant to section 4731.573 of the Revised Code;  
(9) License to practice dietetics and limited permit to practice dietetics pursuant to section 4759.06 of the Revised Code;  
(10) Certificate to practice as an anesthesiologist assistant pursuant to section 4760.04 of the Revised Code;  
(11) License to practice respiratory care and limited permit to practice respiratory care pursuant to section 4761.05 of the Revised Code;  
(12) Certificate to practice as an oriental medicine practitioner pursuant to section 4762.03 of the Revised Code;  
(13) License to practice as an acupuncturist pursuant to section 4762.03 of the Revised Code;
License to practice as a radiologist assistant pursuant to section 4774.04 of the Revised Code;
License to practice as a genetic counselor pursuant to section 4778.05 of the Revised Code;
Supervised practice license as a genetic counselor pursuant to section 4778.08 of the Revised Code;
Temporary expedited license for members of the military and spouses who are licensed in another jurisdiction pursuant to section 4743.04 of the Revised Code.

(D)(1) The board authorizes the secretary and supervising member of the board to do the following:

(a) Grant a waiver pursuant to the provisions of rule 4731-6-05 of the Administrative Code

(b) Determine graduate medical education equivalency pursuant to section 4731.09 of the Revised Code

(c) Determine whether an applicant has demonstrated fitness to resume practice due to inactivity under the applicable provisions of the Revised Code and Administrative Code.

(2) In the interest of operational efficiency, the secretary and supervising member of the board may approve the use of protocols whereby, if the deputy director of licensure, or the deputy director’s designee, finds that the parameters of an approved protocol are met:

(a) A waiver pursuant to the provisions of rule 4731-6-05 may be deemed granted

(b) It may be deemed that an applicant’s education, post-graduate medical training, experience, or other qualifications, is equivalent to the graduate medical education requirements set forth in section 4731.09 of the Revised Code.
(c) It may be deemed that an applicant has demonstrated fitness to resume practice due to inactivity under the applicable provisions of the Revised Code and Administrative Code.

(ED) An application for a license or certificate that is ineligible for routine authorization under this rule will be referred to the board for determination of whether an applicant shall be granted a license. An affirmative vote of not fewer than six members of the board is necessary for issuance of a license or certificate pursuant to an application that is not eligible for routine authorization.

(EE) Notwithstanding the provisions of this rule, the board may designate the referral of any class of applications to the board for approval. The secretary, supervising member, or deputy director for licensure may refer any individual application to the board for approval.
134th General Assembly Legislative Update: December 8, 2021

**Actively monitoring**

**HB 122 – Telehealth (Rep. Fraizer)**
To establish and modify requirements regarding the provision of telehealth services.

**Of note:**
- Permits specified health care professionals to provide telehealth services.
- Requires telehealth services provided by health care professionals to be done so according to specified conditions and standards.
- Permits certain health care licensing boards to adopt rules as necessary to carry out the bill’s provisions regarding telehealth services provided by health care professionals.


To make changes to the laws governing massage establishments and massage therapy.

**Of note:**
- Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.


**HB 286 – Court of Common Pleas (Rep. Bill Seitz) (companion SB 189)**
To generally change the venue in which appeal from an agency order is proper to the local court of common pleas.

**Of note:**
- Modifies the current Administrative Procedure Act by generally providing that a party adversely affected by an order of an agency may appeal from the order to the court of common pleas of the county in which the place of business of the party is located or the county in which the party is a resident.
• Removes the current provision that any party adversely affected by an order of an agency issued pursuant to any other adjudication may appeal, with certain exceptions, to the Franklin County Court of Common Pleas.


**SB 189 – Change venue for appeal from an agency order (Sen. Lang and Sen. McColley)** *(companion SB 286)*

To generally change the venue in which appeal from an agency order is proper to the local court of common pleas.

**Of Note:**

• Modifies the current Administrative Procedure Act by generally providing that a party adversely affected by an order of an agency may appeal from the order to the court of common pleas of the county in which the place of business of the party is located or the county in which the party is a resident.
• Removes the current provision that any party adversely affected by an order of an agency issued pursuant to any other adjudication may appeal, with certain exceptions, to the Franklin County Court of Common Pleas.


**SB 131 – Occupational Licensing (Reciprocity) (Sen. Roegner and Sen. McColley)** *(companion HB 203)*

To require an occupational licensing authority to issue a license or government certification to an applicant who holds a license, government certification, or private certification or has satisfactory work experience in another state under certain circumstances.

**Of Note:**

• Requires automatic licensure of out of state applicants that meet certain criteria.


To require an occupational licensing authority to issue a license or government certification to an applicant who holds a license, government certification, or private certification or has satisfactory work experience in another state under certain circumstances.

**Of Note:**

• Requires automatic licensure of out of state applicants that meet certain criteria.


To Regulate the practice of surgical assistants.

**Of Note:**

- Creates a new license type for surgical assistants to be overseen by the Medical Board.


To revise the law governing the practice of anesthesiologist assistants.

**Of Note:**

- Adds anesthesiologist assistants to the list of individuals authorized to prescribe drugs or dangerous drugs or drug therapy related devices during professional practice.
- Adds anesthesiologist assistant list of practitioners from which a respiratory care therapist may receive orders or prescriptions.

**Status**: First House Health Hearing 10/12/2021.


Regards drug offenses and treatment.

**Of Note:**

- Proposes to reduce the abuse of prescription opioids, establish addiction treatment facilities, increase penalties for drug trafficking violations, modify penalties for drug possession, require an offender convicted of a drug possession or drug trafficking offense involving certain drugs to be subject to ten years of post-release control, allow a criminal defendant who has a severe substance use disorder involving certain drugs to be confined by a state detoxification provider while awaiting trial, create restitution work programs, and make an appropriation.
- Limits opioid prescriptions for acute pain to three days. Then, re-examination of the patient is required, and the prescriber may issue a new prescription for more than 3 days.
- Allows health related licensing board to adopt rules specifying circumstances under which a prescriber may issue an initial prescription for an opioid to treat acute pain in an amount that exceeds three days.
- In addition to the three-day limit, allows health related licensing board to adopt rules otherwise limiting the amount of an opioid that may be prescribed in a single prescription.

Closely monitoring


Regards emergency prescription refills.

**Of Note:**

- Increases from one to three the number of times that a pharmacist may dispense, without a prescription, certain drugs to a specific patient within a 12-month period.

**Status:** Passed out the House 5/5/2021. Third Senate Health hearing 10/6/2021.


To exempt certain mental health care providers' residential and familial information from disclosure under the Public Records Law.

**Of Note:**

- Adds forensic mental health providers, mental health evaluation providers, and regional psychiatric hospital employees to the list of professions, consolidated in continuing law into the term “designated public service worker,” whose residential and familial information is exempted from disclosure under the Public Records Law.

**Status:** Passed out the House 2/4/2021. Second Senate Health hearing 10/6/2021.


To extend certain timelines for qualified civil immunity and expand immunity to include hearing aid dealers and hearing aid fitters; to authorize emergency medical technicians to administer COVID-19 tests; to expressly cover COVID-19 vaccine injuries under the workers' compensation system.

**Of Note:**

- Sunsets June 30, 2023
- Provides vaccine mandate exemption for vaccines that have not received an FDA biologics license.
- Most public and private sector would be able to receive exemptions:
  - a) Medical contraindications; - shall provide a written statement from primary care provider
  - b) Natural immunity: - responsible for any costs or fees associated with demonstrating natural immunity to the employer.
  - c) Reasons of conscience, including religious convictions. -shall provide a written statement

SB 9 – Regulations (Sen. Mccolley and Sen. Roegner)

To reduce regulatory restrictions in administrative rules.

Of Note:

- Requires certain agencies to reduce the number of regulatory restrictions in their administrative rules.
- This applies to administrative agencies only and does not currently impact the Medical Board.


HB 138 – Emergency Medical Services (Rep. Baldridge)

Regarding the scope of emergency medical services provided by emergency medical service personnel.

Of Note:

- Eliminates the enumeration of specific services that may be provided by emergency medical services (EMS) personnel.
- Requires the State Board of Emergency Medical, Fire, and Transportation Services to establish the scope of practice for EMS personnel through rulemaking.
- Permits EMS personnel to comply with a do-not-resuscitate order issued by a physician assistant or advanced practice registered nurse.
- Requires the medical director or cooperating physician advisory board of each EMS organization to establish protocols for EMS personnel to follow when providing services at all times.


Regarding electronic prescriptions and schedule II-controlled substances.

Of Note:

- Requires that all schedule II drugs be prescribed electronically.

SB 157 – Attempted Abortions (Sen. Johnson and Sen. Steve Huffman)
Regards child born alive after attempted abortion.

Of Note:
- Requires a physician who performs or attempts an abortion in an ambulatory surgical facility or other location that is not a hospital and in which a child is born alive to immediately provide certain newborn care.
- Expands the crime of abortion manslaughter to include failure to take measures to preserve the health of a child born alive after abortion.
- Authorizes an affected woman to sue a person guilty of abortion manslaughter


SB 55 – Massage Therapy (Sen. Brenner) (companion bill HB 81)
To make changes to the laws governing massage establishments and massage therapy.

Of Note:
- Requires any individual practicing massage within the state to obtain the current massage therapy license issued by the State Medical Board.

Status: Passed out of Senate health committee 5/19/2021. Awaiting floor vote.

To authorize the use of medical marijuana for autism spectrum disorder.

Of Note:
- Allows autism spectrum disorder to be included in qualifying conditions.


SB 150 – Physician Contracts (Sen. Johnson and Sen. Williams)
To prohibit the use of noncompete provisions in physician employment contracts.

Of Note:
- Would prohibit the use of noncompete provisions in physician employment contracts.

**HB 64 – Regards fraudulent assisted reproduction (Rep. Powell)**

To create the crime of fraudulent assisted reproduction and civil actions for an assisted reproduction procedure without consent.

**Of Note:**

- Prohibits a health care professional from purposely or knowingly using human reproductive material from a donor while performing an assisted reproduction procedure if the person receiving the procedure has not expressly consented to the use of that donor’s material.
- Creates the crime of fraudulent assisted reproduction, making it a third-degree felony and allows for civil action against a fertility doctor within ten years of the offense.


**SB 151 – Infant Medical Treatment (Sen. Johnson)**

To establish standards for the medical treatment of certain infants and to name the act Emery and Elliot’s Law.

**Of Note:**

- Outlines medical treatment for mothers and infants in emergency situations or infants with a disability.


**SB 48 – Cultural Competency (Sen. Maharath and Sen. Antonio)**

To require certain health care professionals to complete instruction in cultural competency.

**Of Note:**

- Requires certain health care professionals to complete instruction in cultural competency and provide proof of completion at initial application for licensure and at renewal.
- Includes: dentists, nurses, pharmacists, physicians, psychologists, and social workers.

**Status:** Introduced in the Senate 2/3/2021. First Senate Health hearing 6/16/2021.

**HB 160 – Health Estimates (Health care price transparency) (Rep. Holmes)**

Regarding the provision of health care cost estimates.

**Of Note:**

- Authorizes the relevant regulatory boards to impose administrative remedies on a health plan issuer or health care provider who fails to comply with the bill’s health care price transparency provisions.


To authorize public bodies to meet via teleconference and video conference.

**Of Note:**
- Allows public bodies to meet and hold hearings via teleconference or video conference.
- Requires public bodies to provide the public with access to meetings and hearings commensurate with the method in which the meeting is being conducted.


**SB 123 – Abortion (Sen. Roegner and Sen. O’Brien)**

To enact the Human Life Protection Act to prohibit abortions based upon a condition precedent.

**Of Note:**
- Prohibits, as the crime of criminal abortion, a person from purposely causing or inducing an abortion by using a drug or substance or an instrument or other means.
- Provides that criminal abortion is a felony of the fourth degree.
- Provides an affirmative defense to a criminal abortion charge if the physician performed or induced the abortion, or attempted to do so, under the determination that it was necessary to prevent the woman’s death or a serious risk of the substantial and irreversible impairment of a major bodily function.
- Requires the State Medical Board to revoke a physician’s license to practice if the physician is guilty of abortion manslaughter, criminal abortion, or promoting abortion.


**SB 161 – Surgical Smoke (Sen. Brenner)**

Regards surgical smoke.

**Of Note:**
- Requires that not later than one year after the effective date of enactment, each ambulatory surgical facility shall adopt and implement a policy designed to prevent human exposure to surgical smoke during any planned surgical procedure that is likely to generate surgical smoke.
  - The policy shall include the use of a surgical smoke evacuation system.

To license and regulate art therapists and music therapists.

Of Note:
- Creates a new license type for music therapists to be regulated under the Medical Board


To modify the laws governing the practice of advanced practice registered nurses and to designate these provisions as the Better Access, Better Care Act.

Of Note:
- Would allow an APRN who has completed 2,000 clinical practice hours under a standard care arrangement the option to practice without a collaboration agreement.
- Allows an APRN who has not completed the required hours to enter into a standard care arrangement with an APRN who has completed 2,000 clinical practice hours.


To authorize a pregnant minor to consent to receive health care to maintain or improve her life or the life of the unborn child she is carrying.

Of Note:
- Allows a pregnant minor to consent to receive health care, such as prenatal health care, health care during delivery, post-delivery health care, and family planning services, to maintain or improve her life or the life of the unborn child she is carrying.
- States that the bill does not remove or limit any person’s responsibility under Ohio law to report child abuse or neglect.


To license and regulate art therapists and music therapists.

Of Note:
- Creates a new license type for music therapists to be regulated under the Medical Board

Regarding pretreatment notice about the possibility of reversing a mifepristone abortion.

Of Note:

- Prohibits a physician from performing a mifepristone abortion without both informing the patient of the possibility to reverse the mifepristone abortion if she changes her mind and providing information from the Department of Health website on assistance with reversing the effects of the of the mifepristone abortion
- Criminalizes violations of the previous requirements as a misdemeanor of the first degree.
- Allows a patient who a mifepristone abortion is performed on to file a wrongful death suit against an individual who fails to inform the patient of the possibility of reversal.


HB 388 – Vaccine Refusal (Rep. Jordan)
To prohibit taking certain actions against an individual because the individual refuses to be vaccinated against a disease.

Of Note:

- Prohibits certain discriminatory actions against unvaccinated people

Status: Introduced in the House 8/12/2021.

To regulate the practice of certified professional midwives and to name this act the Ohio Midwife Practice Act.

Of Note:

- Regulates the practice of certified professional midwives


HB 496 – Regulate the Practice of Certified Midwives (Rep. Koehler)
To regulate the practice of certified nurse-midwives, certified midwives, and certified professional midwives

Of Note:

- Regulates the practice of certified professional midwives

Operationalizing

SB 6 – Join Interstate Medical Licensure Compact (Sen. Roegner and Sen. Steve Huffman)

Of Note:
- Actively working through implementation


HB 110 – State Operating Budget (Rep. Oelslager)

Creates appropriations for FY 2022-2023.

Of Note:
- The Medical Board budget request was granted in the first version of the bill and remained in the final version.


Enacted but no operational changes needed

HB 6 – Modify laws governing certain professions due to COVID-19 (Rep. Roemer)

To modify the laws governing certain health professionals and educator preparation programs due to COVID-19.

Of Note:
- Allows pharmacists to administer immunization for influenza, COVID-19, and any other disease but only pursuant to prescription for persons seven or older.
- Allows pharmacists to administer immunizations for a disease to those 13 and older.
- Allows podiatrists to administer vaccinations for individuals seven and older for influenza and COVID-1.


To revise the law governing the practice of athletic training.

Of note:
- Makes changes to the law governing the practice of athletic training, including by requiring an athletic trainer to practice under a collaboration agreement with a physician or podiatrist.
- Amendment was included in the final version to prohibit an athletic trainer from administering intratendinous and intra-articular injections.