



Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: State Medical Board of Ohio

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Medical Board Telehealth rules

Rule Number(s): 4731-37-01, 4731-11-09, 4730-1-07, 4730-2-07, 4759-11-01, Rule 4761-15-01, and 4778-1-06

Date of Submission for CSI Review: 05/16/22

Public Comment Period End Date: 05/31/22

Rule Type/Number of Rules:

New/ 2 rules

No Change/ rules (FYR?)

Amended/ 5 rules (FYR? No)

Rescinded/ 1 rules (FYR? No)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

Please include the key provisions of the regulation as well as any proposed amendments.

The proposed rules implement the new telehealth law (Sub. HB 122) for the following Medical Board license types statutorily designated as health care professionals authorized to provide telehealth services: physicians (MD, DO, DPM), physician assistants, dietitians, respiratory care professionals, and genetic counselors. The rules are described below:

- **Rule 4731-37-01 Telehealth (new rule)**

- Defines telehealth services, synchronous communication technology, asynchronous communication technology, remote monitoring device, health care professional, consent for telehealth treatment, formal consultation, and advanced practice registered nurse.

- Requires that the standard of care for a telehealth visit is the same as the standard of care for an in-person visit.

- Provides process for selection of a telehealth services technology to meet the standard of care for a patient's medical condition, and the escalation or referral of health care services for that patient if the standard of care cannot be met with the telehealth technology selected.

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- Requires that the health care professional comply with all standard of care requirements including but not limited to those requirements listed in this rule such as the health care professional's verification of patient's name and location, documentation including patient consent for telehealth treatment, evaluation of the patient, compliance with privacy and security requirements, and transmittal of patient's medical record.
- Provides requirements for a health care professional to provide telehealth services involving a formal consultation with another health care professional.
- Explains the requirements for prescribing of non-controlled and controlled prescription drugs. A physician, or physician assistant with prescriptive authority may prescribe a drug that is a non-controlled substance through the provision of telehealth services by complying with all requirements of this general telehealth rule. For controlled substance prescriptions, a prescriber must comply with all requirements of this rule, federal law governing prescriptions for controlled drugs, and all requirements in proposed new rule 4731-11-09.
- Provides requirements for physicians and physician assistants to provide telehealth services through the use of remote monitoring devices as authorized by R.C. 4743.09(C)(5).
- Lays out the enforcement provisions for each type of health care professional for violations of this proposed rule.

● **Rule 4731-11-09 Controlled substance and telehealth prescribing**

- This is a new rule to replace a current rule. The amendments to the current rule (titled Prescribing to persons not seen by the physician) comprise more than fifty percent of that rule. So, the current rule must be rescinded, and the changed language adopted as a new rule.
- Defines hospice care, palliative care, medication assisted treatment, substance use disorder, and mental health condition.
- For a physician, or physician assistant who holds a valid prescriber number issued by the Medical Board and who has been granted physician-delegated prescriptive authority, the rule allows them to prescribe controlled substances if they comply with federal law, proposed rule 4731-37-01 if the prescribing occurs via telehealth, and the provisions of this rule.
- Requires that the physician or physician assistant shall conduct a physical examination of a new patient as part of an initial in-person visit before prescribing a schedule II controlled substance to the patient. Five exceptions to this requirement are detailed.
- Provides the enforcement provisions for each type of health care professional for violations of this proposed rule.

● **Rules 4730-1-07 Miscellaneous provisions, 4730-2-07 Standards for Prescribing, 4759-11-01 Miscellaneous Provisions, 4761- 15-01 Miscellaneous provisions, and 4778-1-06 Miscellaneous provisions**

- These amended rules incorporate proposed rule 4731-37-01 into the respective chapters for physician assistants, dietitians, respiratory care professionals, and genetic counselors.

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- 3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

4731-37-01

Authorized by Ohio Revised Code sections 4743.09, 4731.74, 4731.05. Amplifies Ohio Revised Code sections 4730.25, 4730.60, 4731.22, 4731.74, 4731.741, 4759.07, 4759.20, 4761.09, 4761.30, 4778.14, 4778.30.

4731-11-09:

Authorized by Ohio Revised Code sections 4743.09, 4731.74, R.C. 4731.05. Amplifies Ohio Revised Code sections 4731.22, 4731.74, 4731.741, 4743.09, 4730.25, 4730.60.

4730-1-07 and 4730-2-07

Authorized by Ohio Revised Code sections 4730.07, 4730.39, 4743.09. Amplifies Ohio Revised Code sections 4730.41, 4730.60.

4759-11-01

Authorized by Ohio Revised Code sections 4759.05, 4776.03, 4743.09. Amplifies Ohio Revised Code sections 1347.05, 4759.05 4776.03, 4759.20.

4761-15-01

Authorized by Ohio Revised Code sections 4761.03, 4743.09. Amplifies Ohio Revised Code sections 4761.03, 4761.30.

4778-1-06

Authorized by Ohio Revised Code sections 4778.12, 4743.09. Amplifies Ohio Revised Code sections 4778.14, 4778.30.

- 4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

If yes, please briefly explain the source and substance of the federal requirement.

While the rules do not specifically implement a federal requirement, R.C. 4731.74, which is an authorizing statute for both 4731-37-01 and 4731-11-09, requires that the Medical Board's rules shall establish standards for prescription drugs that are controlled substances "that are consistent with federal law." See R.C. 4731.74(B)(2). Accordingly, both 4731-37-01 and 4731-11-09 require that controlled substance prescribing comply with federal law.

- 5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

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The proposed telehealth rules do not exceed federal requirements, but rather include provisions authorized by Ohio law in R.C. 4743.09 and R.C. 4731.74.

6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

With the onset of the Covid-19 pandemic, the use of telehealth increased. The Ohio General Assembly in Sub. HB 122 (effective on March 23, 2022) provided a new comprehensive telehealth law for a statutorily designated list of health care professionals to provide telehealth services. The telehealth law in R.C. 4743.09(B) authorized the Medical Board to adopt rules necessary for the implementation of the new law for the health care professionals statutorily designated that are under its jurisdiction. Further, R.C. 4743.09(B) states that the health care professional licensing board shall establish in these rules “a standard of care for telehealth services that is equal to the standard of care for in-person services.”

The Medical Board’s proposed telehealth rules provides standards for the practice of telehealth by physicians, physician assistants, dietitians, respiratory care professionals, and genetic counselors, some of whom have rarely or never provided telehealth services prior to the passage of the new telehealth law.

7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of the regulations will be measured by the ability of health care professionals and patients to provide and receive telehealth services safely; licensee compliance with the rules; and minimal questions from health care professional licensees, health care practices, and health care facilities as to the meaning of the plain language of the rules.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

No, these rules are not being submitted under any of those Revised Code sections.

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The Board has engaged extensively with many of the stakeholders listed below about telehealth starting in 2020. With the definitive policy decisions provided by the passage of the new telehealth law in December of 2021, the Board ramped up its engagement with

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stakeholders with the goal of gaining their valuable input in the development of its rules implementing the legislation.

In January and February of 2022, Medical Board staff sought feedback on its preliminary draft of telehealth rules from the following stakeholders: Ohio State Medical Association, Ohio Hospital Association, Cleveland Clinic, University Hospitals, Ohio Health, Mercy Hospital system, Metro Health Systems, OSU Wexner Medical Center, Ohio Osteopathic Doctors Association, Ohio Foot and Ankle, Ohio Society for Respiratory Care, Ohio Academy for Nutrition and Dietetics, Ohio Physician Assistant Association, Ohio Psychiatric Physicians Association, Ohio Association of Community Health Centers, OneFifteen, Ohio chapter of American Academy of Pediatrics, Ohio Academy of Family Physicians, Ohio Department of Medicaid, Ohio Department of Mental Health and Addiction Services, Academy of Medicine of Cleveland and Northern Ohio, Nationwide Children's Hospital, Cincinnati Children's Hospital, Teladoc, American Telemedicine Association Action (ATA Action), hims & hers, Central Ohio Primary Care, and University Hospital of Toledo.

This included obtaining written comments as well as conducting the following videoconferences and telephone calls: three large group stakeholder videoconference calls on January 27, 2022 and January 28, 2022 that included representatives from the list above, a follow-up videoconference call with OHA on February 1, 2022, and a follow-up telephone call with Central Ohio Primary Care on February 1, 2022.

The telehealth rules were also discussed with the Physician Assistant Policy Committee on February 4, 2022 and this was reported to the Board.

At its February 9, 2022 public meeting, the Board discussed the stakeholder input and approved revised proposed rules, which incorporated many comments made by these stakeholders, for initial circulation. The proposed rules were then distributed for initial circulation and written comment as follows: (1) posted on the Board website on February 14, 2022; (2) circulated to associations and other interested parties via email on February 11, 2022; and (3) sent by email to all licensees on February 18, 2022 in the Medical Board's February 2022 eNews which included a link to proposed rules posted on the Board website. The comments were due on or before March 1, 2022.

During this initial circulation comment period of the rulemaking process, the Board received sixty-three (63) comments. Late comments were also reviewed and included in this number. Also, the Board received seven (7) written comments before initial circulation.

Additional stakeholder input was provided by videoconference meetings with the following stakeholders and groups: ATA Action on February 23, 2022, Ohio Nursing Board on March 1, 2022, and Teladoc on March 28, 2022.

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Also, the Dietetics Advisory Council and Respiratory Care Advisory Council members provided individual feedback on the proposed telehealth rules at their March 7, 2022 and March 8, 2022 meetings respectively which echoed written comments provided by the Ohio Academy of Nutrition and Dietetics and the Ohio Society for Respiratory Care.

The written comments, stakeholder input, and advisory council input were provided to the Board for its consideration at its April 13, 2022 public meeting. The Board approved the proposed rules for filing with CSI which incorporated many of the stakeholder comments.

On April 26, 2022, the Ohio Hospital Association (OHA) sent a detailed comment to the Board specific to proposed new rules 4731-37-01 and 4731-11-09. As part of the Board's continuing efforts to consider stakeholder input on these important rules, Board staff met with representatives of OHA to discuss their concerns in a videoconference meeting on May 5, 2022. The Board received a follow-up email from OHA on May 6, 2022 specific to concerns related to prescribing of controlled substances via telehealth in proposed new rule 4731-11-09.

At its May 11, 2022 meeting, the Board was presented with the additional input from OHA. The Board approved changes to proposed new rules 4731-37-01 and 4731-11-09 which incorporated many of OHA's comments, and also approved the revised telehealth rules which are attached for filing with CSI.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Attached are the Board meeting memos on the telehealth rules dated February 4, 2022 and April 7, 2022 which detail stakeholder feedback and written comments received that resulted in the recommended changes which were approved by the Board at its February 9, 2022 and April 13, 2022 public meetings. In addition, a spreadsheet summarizing comments received and their recommended disposition is attached. In approving the proposed telehealth rules for filing with CSI at the April 13, 2022 meeting, the Board accepted all recommended changes.

In addition, the recent written comments from OHA are detailed in the May 9, 2022 memo which is also attached. On May 11, 2022, the Board approved changes recommended in the memo which incorporated comments received from OHA, and also approved the attached revised telehealth rules being filed with CSI.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The rules were developed with input from Medical Board members including physicians and attorneys. Advisory councils provided input from physician assistants, respiratory care professionals, and dietitians. Also, input was received from physicians and professionals at the Department of Mental Health and Addiction Services and Ohio Board of Nursing. Board

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staff also reviewed rules and policies developed in other state and federal jurisdictions including the Code of Federal Regulations.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

Because the Board's regulations implement the new telehealth law, the Board did not consider alternative regulations.

13. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

The Board's proposed telehealth rules establish processes and standards for the practice of telehealth. However, there are provisions within the proposed telehealth rules that give the health care professional discretion on how to meet the standards and requirements.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board's proposed telehealth rules implement the recently passed telehealth law that authorizes each healthcare professional licensing board to adopt rules specific to its licensees that have been statutorily designated as healthcare professionals able to provide telehealth services. The Medical Board is the only board that licenses physicians, physician assistants, dietitians, respiratory care professionals, and genetic counselors, all of whom are authorized to provide telehealth services by the new telehealth law.

15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Medical Board's website; information concerning the rules will be included in materials emailed to licensees; and notices will be sent to associations, individuals, and groups. Medical Board staff members are available by telephone and email to answer questions. In addition, Medical Board staff members also give presentations to groups, associations, and advisory councils on regulations affecting relevant licensee types.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community; and

The scope of the impacted business community would be the following Medical Board licensee types statutorily designated as health care professionals authorized to provide

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telehealth services: physician (MD, DO, DPM), physician assistant, dietitian, respiratory care professional, and genetic counselor.

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

The health care professionals will need to be aware of the requirements for standard of care, referrals, formal consultations, prescribing non-controlled and controlled drugs, and providing telehealth through the use of remote monitoring devices. The health care professionals who are found to have violated these rules could be subject to disciplinary action, which could include a monetary fine.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

The adverse impact from additional time expended to learn and comply with proposed rules would be largely mitigated from time and opportunity cost savings in other areas such as a significant reduction in missed appointments by patients utilizing telehealth. Further, health care professionals may be able to see more patients in a day due to the efficiencies created by telehealth visits. Beyond this mitigated adverse impact of the time cost of compliance, there could be an adverse impact from noncompliance with the rules including non-monetary disciplinary action and/or a monetary fine.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The proposed rules justify the minimal adverse impact because: (1) the rules are statutorily required to implement a new (for some health care professionals) or increasingly utilized method of providing health care services; and (2) rules within the parameters set by the new telehealth law are needed to protect patient health and safety in the delivery and receipt of telehealth services.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

The requirements of the proposed telehealth rules exist for public health and safety. As such, they require consistency in their application to all licensees and therefore are not able to allow for exceptions or alternative means of compliance for small businesses.

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19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Due process requires the Medical Board to consistently apply its rules regarding the provision of telehealth services so that all licensees are treated equally.

20. What resources are available to assist small businesses with compliance of the regulation?

Medical Board staff members are available by telephone and email to answer questions.

4731-37-01

Telehealth.

(A) As used in Chapters 4730, 4731, 4759, 4761, and 4778 of the Administrative Code:

- (1) "Telehealth services" means health care services provided through the use of information and communication technology by a health care professional licensed in Ohio, within the professional's scope of practice, who is located at a site other than the site where the patient is receiving the services or the site where another health care professional with whom the provider of the services is formally consulting regarding the patient is located.
- (2) "Synchronous communication technology" means audio and/or video technology that permits two-way, interactive, real-time electronic communication between the health care professional and the patient or between the health care professional and the consulting health care professional regarding the patient.
- (3) "Asynchronous communication technology", also called store and forward technology, has the same meaning as asynchronous store and forward technologies as that term is defined in 42 C.F.R. 410.78 (effective January 1, 2022).
- (4) "Remote monitoring device" means a medical device cleared, approved, or authorized by the United States food and drug administration for the specific purpose which the health care professional is using it and which reliably transmits data electronically and automatically.
- (5) "Health care professional" means any of the following:
 - (a) A physician assistant licensed under Chapter 4730. of the Revised Code;
 - (b) A physician licensed under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;
 - (c) A dietitian licensed under Chapter 4759. of the Revised Code;
 - (d) A respiratory care professional licensed under Chapter 4761. of the Revised Code; or
 - (e) A genetic counselor licensed under Chapter 4778. of the Revised Code.
- (6) "Consent for telehealth treatment" means a process of communication between a patient or, if applicable, the patient's legal representative and the health care professional discussing the risks and benefits of, and alternatives to, treatment through a remote evaluation that results in the agreement to treatment that is documented in the medical record or signed authorization for the patient to be treated through an evaluation conducted through appropriate technology, as

specified in this rule, when the health care professional is in a location remote from the patient.

(7) "Formal consultation" means when a health care professional seeks the professional opinion of another health care professional regarding the diagnosis or treatment recommended for the patient's medical condition presented, transfers the relevant portions of the patient's medical record to the consulting health care professional, and documents the formal consultation in the patient's medical record.

(8) As used in this rule, "advanced practice registered nurse" means an individual who holds a current, valid license issued under Chapter 4723. of the Revised Code that authorizes the practice of nursing as an advanced practice registered nurse and is designated as any of the following: clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

(B) A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:

(1) The standard of care for a telehealth visit is the same as the standard of care for an in-person visit.

(2) The health care professional shall follow all standard of care requirements which include but are not limited to the standard of care requirements in paragraph (C) of this rule.

(3) The health care professional may provide the telehealth services through the use of synchronous or asynchronous communication technology provided that the standard of care for an in-person visit can be met for the patient and the patient's medical condition through the use of the technology selected. Telephone calls, as a synchronous communication technology, may only be used for telehealth services when all of the elements of a bona fide health care visit meeting the standard of care are performed. Telephone calls that are routine or simply involve communication of information do not constitute a telehealth service.

(4) If a health care professional determines at any time during the provision of telehealth services that a telehealth visit will not meet the standard of care for the medical condition of the patient or if additional in-person care is necessary, the health care professional shall do the following:

(a) If the patient must be seen immediately but not in an emergency department, the health care professional shall immediately schedule the patient for an in-person visit with the health care professional and promptly conduct that visit or refer the patient for an in-person visit with one of the following licensed health care professionals who can

provide the services in-person that are appropriate for the patient and the condition for which the patient presents:

(i) Another health care professional or an advanced practice registered nurse with whom the health care professional has a cross-coverage agreement.

(ii) In the case of a physician, a physician assistant with whom the physician has a supervision agreement or an advanced practice registered nurse with whom the physician has a standard care arrangement;

(iii) In the case of a physician assistant, a physician with whom the physician assistant has a supervision agreement; or

(iv) Any health care professional requested by the patient who is appropriate for the condition with which the patient presents.

(b) If the patient does not need to be seen immediately, the health care professional shall do one of the following:

(i) Schedule the patient for an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their condition presented; or

(ii) Refer the patient to a health care professional in the same specialty to conduct an in-person visit within an amount of time that is appropriate for the patient and their condition.

(c) If the patient must be seen by a specialist other than the health care professional, the health care professional shall make a referral to a specialist, licensed in this state, whom the healthcare professional knows has an appropriate scope of practice for the medical condition of the patient.

(d) If the patient needs emergency care, the health care professional shall help the patient identify the closest emergency department and, if necessary, in the health care professional's discretion, provide notification to the emergency department of the patient's potential arrival.

(e) The health care professional shall document the in-person visit or the referral in the patient's medical record.

(f) All referrals must be made in an amount of time that is appropriate for that patient and their condition presented.

(C) A health care professional must comply with all standard of care requirements to

provide telehealth services to a patient including but not limited to:

- (1) The health care professional shall verify the patient's identity and physical location in Ohio, and communicate the health care professional's name and type of active Ohio license held to the patient if the health care professional has not previously treated the patient. This may be done verbally as long as it is documented by the health care professional in the patient's medical record;
- (2) The health care professional shall document the consent for telehealth treatment of the patient or, if applicable, the patient's legal representative;
- (3) The health care professional shall provide the telehealth services in a manner that complies with the privacy and security requirements for the patient and their protected health information required by the law of this state and federal law. Also, the health care professional shall ensure that any username or password information and any electronic communications between the health care professional and the patient are securely transmitted and stored;
- (4) If applicable, the health care professional shall forward the medical record to the patient's primary care provider, other health care provider, or to an appropriate health care provider to whom the patient is referred as provided in paragraph (B)(4) of this rule;
- (5) The health care professional shall, through interaction with the patient, complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care for an in-person visit, which may include portions of the evaluation having been conducted by other Ohio licensed healthcare providers acting within the scope of their professional license;
- (6) The health care professional shall establish or confirm, as applicable, a diagnosis and treatment plan, which for those health care professionals designated as prescribers in section 4729.01 of the Revised Code, includes documentation of the necessity for the utilization of a prescription drug. The diagnosis and treatment plan shall include the identification of any underlying conditions or contraindications to the recommended treatment;
- (7) The health care professional shall promptly document in the patient's medical record the patient's or, if applicable, the patient's legal representative, consent for telehealth treatment, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities;
- (8) The health care professional shall provide appropriate follow-up care or recommend follow-up care with the patient's primary care provider, other appropriate health care provider, or health care facility in accordance with the

minimal standards of care:

- (9) The health care professional shall make the medical record of the visit available to the patient or if applicable, the patient's legal representative, upon request.
- (D) A health care professional must comply with the following requirements to provide telehealth services that involve a formal consultation with another health care professional:
 - (1) The health care professional who seeks a formal consultation shall document the acknowledgement of the patient or if applicable, the patient's legal representative, before seeking the telehealth services formal consultation with the consulting health care professional;
 - (2) The consulting health care professional must meet the licensure or certification requirements in division (C) of section 4743.09 of the Revised Code; and
 - (3) The health care professionals involved in the formal consultation must have received and reviewed all medical records of the patient relevant to the medical condition which is the subject of the consultation before the formal consultation occurs, unless this is not possible due to an emergency situation.
- (E) While providing telehealth services, a health care professional that is a physician or a physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority shall comply with the following requirements regarding prescription drugs:
 - (1) The physician or physician assistant may only prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is not a controlled substance to a patient through the provision of telehealth services by complying with all requirements of this rule;
 - (2) The physician or physician assistant may only prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug to a patient that is a controlled substance through the provision of telehealth services by complying with the following requirements:
 - (a) Federal law governing prescription drugs that are controlled substances;
 - (b) The requirements of this rule; and
 - (c) The requirements in rule 4731-11-09 of the Administrative Code.
- (F) A physician or physician assistant may provide telehealth services through the use of remote monitoring devices provided that:
 - (1) The patient or, if applicable, the patient's legal representative, gives consent to

the use of remote monitoring devices:

(2) The medical devices that enable remote monitoring have been cleared, approved, or authorized by the United States food and drug administration for the specific purpose for which the physician or physician assistant are using it for the patient, and the remote monitoring devices otherwise comply with all federal requirements.

(G) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following:

(1) For a physician:

(a) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;

(b) "Selling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; or

(c) "A departure from or the failure to conform to minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

(2) For a physician assistant:

(a) "A departure from, or failure to conform to, minimal standards of care of similar physician assistants under the same or similar circumstances, regardless of whether actual injury to a patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code;

(b) "Failure to comply with the requirements of this chapter, Chapter 4731. of the Revised Code, or any rules adopted by the board," as that clause is used in division (B)(2) of section 4730.25 of the Revised Code; or

(c) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter, Chapter 4731. of the Revised Code, or the rules adopted by the board," as that clause is used in division (B)(3) of section 4730.25 of the Revised Code.

(3) For a dietitian:

(a) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter or the rules adopted by the board," as that clause is used in division (A)(1) of section 4759.07 of the Revised Code; or

(b) "A departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (A)(11) of section 4759.07 of the Revised Code.

(4) For a respiratory care professional:

(a) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter or the rules adopted by the board," as that clause is used in division (A)(7) of section 4761.09 of the Revised Code; or

(b) "A departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (A)(10) of section 4761.09 of the Revised Code.

(5) For a genetic counselor:

(a) "Failure to comply with the requirements of this chapter, Chapter 4731, of the Revised Code, or any rules adopted by the board," as that clause is used in division (B)(2) of section 4778.14 of the Revised Code;

(b) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter, Chapter 4731, of the Revised Code, or the rules adopted by the board," as that clause is used in division (B)(3) of section 4778.14 of the Revised Code; or

(c) "A departure from, or failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances whether or not actual injury to the patient is established," as that clause is used in division (B)(4) of section 4778.14 of the Revised Code.

4731-11-09

Controlled substance and telehealth prescribing.

(A) As used in this rule:

- (1) "Hospice care" means the care of a hospice patient as that term is defined in section 3712.01 of the Revised Code.
- (2) "Palliative care" has the same meaning as in section 3712.01 of the Revised Code.
- (3) "Medication assisted treatment" and "substance use disorder" have the same meanings as in rule 4731-33-01 of the Administrative Code.
- (4) "Mental health condition" means any mental health condition, illness, or disorder as determined by the diagnostic criteria in the "Diagnostic and Statistical Manual of Mental Disorders Fifth Edition Text Revision" (DSM-5-TR). This is a well-known and readily available text. It may be found at libraries, bookstores, or on the internet at www.psychiatry.org.
- (5) "Emergency situation" means a situation involving an "emergency medical condition" as that term is defined in section 1753.28 of the Revised Code.

(B) A physician, or a physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority shall comply with the requirements of federal law governing prescription drugs that are controlled substances to prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is a controlled substance to a person.

(C) When the physician, or physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority prescribes, personally furnishes, otherwise provides, or causes to be provided a prescription drug that is a controlled substance during the provision of telehealth services, the physician or physician assistant shall comply with all requirements in rule 4731-37-01 of the Administrative Code.

(D) The physician, or physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority shall conduct a physical examination of a new patient as part of an initial in-person visit before prescribing a schedule II controlled substance to the patient except as provided in paragraph (E) of this rule.

(E) As an exception to paragraph (D) of this rule, a physician or physician assistant may prescribe a controlled substance to a new patient as part of the provision of telehealth services for any of the following patient medical conditions and situations:

- (1) The medical record of a new patient indicates that the patient is receiving

4731-11-09

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hospice or palliative care;

- (2) The patient has a substance use disorder, and the controlled substance is FDA approved for and prescribed for medication assisted treatment or to treat opioid use disorder.
- (3) The patient has a mental health condition and the controlled substance prescribed is prescribed to treat that mental health condition;
- (4) The physician or physician assistant determines in their clinical judgment that the new patient is in an emergency situation provided that the following occurs:
 - (a) The physician or physician assistant prescribes only the amount of a schedule II controlled substance to cover the duration of the emergency or an amount not to exceed a three-day supply whichever is shorter;
 - (b) After the emergency situation ends, the physician or physician assistant conducts the physical examination as part of an initial in-person visit before any further prescribing of a drug that is a schedule II controlled substance; or
- (5) The prescribing of a controlled substance through telehealth services is being done under an exception permitted by federal law governing prescription drugs that are controlled substances.
- (F) When prescribing a controlled substance through the provision of telehealth services under one of the exceptions in paragraph (E) of this rule, the physician or physician assistant shall document one of the reasons listed in paragraph (E) for the prescribing in the medical record of the new patient in addition to the documentation already required to meet the standard of care in rule 4731-37-01 of the Administrative Code.
- (G) Nothing in this rule shall be construed to imply that one in-person physician examination demonstrates that a prescription has been issued for a legitimate medical purpose within the course of professional practice.
- (H) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following:
 - (1) For a physician:
 - (a) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;
 - (b) "Selling, giving away, personally furnishing, prescribing, or administering

drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; or

(c) "A departure from or the failure to conform to minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

(2) For a physician assistant:

(a) "A departure from, or failure to conform to, minimal standards of care of similar physician assistants under the same or similar circumstances, regardless of whether actual injury to a patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code;

(b) "Failure to comply with the requirements of this chapter, Chapter 4731, of the Revised Code, or any rules adopted by the board," as that clause is used in division (B)(2) of section 4730.25 of the Revised Code; or

(c) "Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter, Chapter 4731, of the Revised Code, or the rules adopted by the board," as that clause is used in division (B)(3) of section 4730.25 of the Revised Code.

(I) This rule shall not apply to any prescribing situations specifically authorized by the Revised Code or Administrative Code.

4731-11-09

Prescribing to persons not seen by the physician.

TO BE RESCINDED

- (A) Except as provided in paragraph (D) of this rule, a physician shall not prescribe, personally furnish, otherwise provide, or cause to be provided, any controlled substance to a person on whom the physician has never conducted a physical examination.
- (B) Except as provided in paragraph (C) of this rule, a physician shall not prescribe, personally furnish, otherwise provide, or cause to be provided, any prescription drug that is not a controlled substance to a person on whom the physician has never conducted a physical examination.
- (C) A physician may prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is not a controlled substance to a person on whom the physician has never conducted a physical examination and who is at a location remote from the physician by complying with all of the following requirements:
 - (1) The physician shall establish the patient's identity and physical location;
 - (2) The physician shall obtain the patient's informed consent for treatment through a remote examination;
 - (3) The physician shall request the patient's consent and, if granted, forward the medical record to the patient's primary care provider or other health care provider, if applicable, or refer the patient to an appropriate health care provider or health care facility;
 - (4) The physician shall, through interaction with the patient, complete a medical evaluation that is appropriate for the patient and the condition with which the patient presents and that meets the minimal standards of care, which may include portions of the evaluation having been conducted by other Ohio licensed healthcare providers acting within the scope of their professional license;
 - (5) The physician shall establish or confirm, as applicable, a diagnosis and treatment plan, which includes documentation of the necessity for the utilization of a prescription drug. The diagnosis and treatment plan shall include the identification of any underlying conditions or contraindications to the recommended treatment;
 - (6) The physician shall document in the patient's medical record the patient's consent to treatment through a remote evaluation, pertinent history, evaluation, diagnosis, treatment plan, underlying conditions, any

contraindications, and any referrals to appropriate health care providers, including primary care providers or health care facilities;

- (7) The physician shall provide appropriate follow-up care or recommend follow-up care with the patient's primary care provider, other appropriate health care provider, or health care facility in accordance with the minimal standards of care;
 - (8) The physician shall make the medical record of the visit available to the patient;
 - (9) The physician shall use appropriate technology that is sufficient for the physician to conduct all steps in this paragraph as if the medical evaluation occurred in an in-person visit.
- (D) A physician may prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is a controlled substance to a person on whom the physician has not conducted a physical examination and who is at a location remote from the physician in any of the following situations:
- (1) The person is an active patient, as that term is defined in paragraph (D) of rule 4731-11-01 of the Administrative Code, of an Ohio licensed physician or other health care provider who is a colleague of the physician and the drugs are provided pursuant to an on call or cross coverage arrangement between them and the physician complies with all steps of paragraph (C) of this rule;
 - (2) The patient is physically located in a hospital or clinic registered with the United States drug enforcement administration to personally furnish or provide controlled substances, when the patient is being treated by an Ohio licensed physician or other healthcare provider acting in the usual course of their practice and within the scope of their professional license and who is registered with the United States drug enforcement administration to prescribe or otherwise provide controlled substances in Ohio.
 - (3) The patient is being treated by, and in the physical presence of, an Ohio licensed physician or healthcare provider acting in the usual course of their practice and within the scope of their professional license, and who is registered with the United States drug enforcement administration to prescribe or otherwise provide controlled substances in Ohio.
 - (4) The physician has obtained from the administrator of the United States drug enforcement administration a special registration to prescribe or otherwise provide controlled substances in Ohio.

- (5) The physician is the medical director, hospice physician, or attending physician for a hospice program licensed pursuant to Chapter 3712. of the Revised Code and both of the following conditions are met:
 - (a) The controlled substance is being provided to a patient who is enrolled in that hospice program, and
 - (b) The prescription is transmitted to the pharmacy by a means that is compliant with Ohio board of pharmacy rules.
- (6) The physician is the medical director of, or attending physician at, an institutional facility, as that term is defined in rule 4729-17-01 of the Administrative Code, and both of the following conditions are met:
 - (a) The controlled substance is being provided to a person who has been admitted as an inpatient to or is a resident of an institutional facility, and
 - (b) The prescription is transmitted to the pharmacy by a means that is compliant with Ohio board of pharmacy rules.
- (E) Nothing in this rule shall be construed to imply that one in-person physician examination demonstrates that a prescription has been issued for a legitimate medical purpose within the course of professional practice.
- (F) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following:
 - (1) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;
 - (2) "Selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; or
 - (3) "A departure from or the failure to conform to minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

- (G) For purposes of this rule, "informed consent" means a process of communication between a patient and physician discussing the risks and benefits of, and alternatives to, treatment through a remote evaluation that results in the patient's agreement or signed authorization to be treated through an evaluation conducted through appropriate technology when the physician is in a location remote from the patient.
- (H) This rule shall not apply to any prescribing situations specifically authorized by the Revised Code or Administrative Code.
- (I) For purposes of this rule, "patient" means a person for whom the physician provides healthcare services or the person's representative.

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, 4731-29, ~~and~~ 4731-35, [and 4731-37](#) 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.

4730-2-07

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, 4731-11, ~~and~~ 4731-35, [and 4731-37](#) 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.

4759-11-01

Miscellaneous provisions.

For purposes of Chapter 4759. of the Revised Code and rules promulgated thereunder:

- (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, 4731-8, 4731-13, 4731-15, 4731-16, 4731-26, ~~and~~ 4731-28, and 4731-37 of the Administrative Code are applicable to the holder of a license or limited permit issued pursuant to Chapter 4759. of the Revised Code, as though fully set forth in agency 4759 of the Administrative Code.

4761-15-01

Miscellaneous provisions.

For purposes of Chapter 4761. of the Revised Code and rules promulgated thereunder:

- (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, 4731-8, 4731-13, 4731-15, 4731-16, 4731-17, 4731-26, ~~and~~ 4731-28, and 4731-37 of the Administrative Code are applicable to the holder of a license or limited permit issued pursuant to Chapter 4761. of the Revised Code, as though fully set forth in agency 4761 of the Administrative Code.

4778-1-06

Miscellaneous provisions.

For purposes of Chapter 4778. of the Revised Code and rules promulgated thereunder, the provisions of Chapters 4731-13, 4731-16, 4731-26, ~~and~~ 4731-28, [and 4731-37](#) of the Administrative Code are applicable to the holder of a license to practice as a genetic counselor issued under Chapter 4778. of the Revised Code, as though fully set forth in Chapter 4778-1 or Chapter 4778-2 of the Administrative Code.



MEMORANDUM

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

FROM: Nathan T. Smith, Senior Legal and Policy Counsel

DATE: February 4, 2022

RE: Telehealth rules proposed for initial circulation

At the January 12, 2022 Medical Board meeting, Board staff presented a preliminary draft of two new telehealth rules (4731-37-01 and 4731-11-09) for Board discussion. Based on Board feedback, the following changes are proposed to OAC 4731-37-01:

- (1) Add the phrase “parent or guardian” to all paragraphs about informed consent to cover those situations where a patient’s parent or guardian would be consenting rather than the patient;
- (2) In (B)(3), to clarify when telephone calls would be appropriate as synchronous communication, add: “Telephone calls, as a synchronous communication technology, may only be used for telehealth services when all of the elements of a bona fide health care visit meeting the standard of care are performed. Telephone calls that are routine or simply involve communication of information without patient interaction do not constitute a telehealth service.”

Also, Board staff informally sought feedback on the draft of the rules from the following stakeholders: Ohio State Medical Association, Ohio Hospital Association, Cleveland Clinic, University Hospitals, Ohio Health, Mercy Health, MetroHealth, OSU Wexner Medical Center, Ohio Osteopathic Association, Ohio Foot and Ankle Medical Association, Ohio Society for Respiratory Care, Ohio Academy for Nutrition and Dietetics, Ohio Association of Physician Assistants, Ohio Psychiatric Physicians Association, Ohio Association of Community Health Centers, OneFifteen, Ohio chapter of American Academy of Pediatrics, Ohio Academy of Family Physicians, Ohio Medicaid, Ohio Department of Mental Health and Addiction Services, Academy of Medicine of Cleveland and Northern Ohio, Nationwide Children’s Hospital, Cincinnati Children’s Hospital, Teladoc, American Telemedicine Association, hims & hers, Central Ohio Primary Care, and University of Toledo Medical Center and Affiliated Hospitals.

The feedback to the proposed rules was generally very positive with most comments focused on the operability and feasibility of technical requirements. The most commented on provision from the preliminary draft was the referral provision in 4731-37-01(B)(4). Proposed changes to that provision balance comments regarding patient safety, continuity of care, feasibility for health care professionals, and access to care by providing specific requirements based on the different levels of care needed.

Feedback from these stakeholders is ongoing and will continue throughout the rulemaking process. The feedback provided from many of these stakeholders has informed the following proposed changes and additions to the proposed rules:

OAC 4731-37-01

- (1) Change to the definition of telehealth services in (A)(1) that clarifies that the rule's requirements pertaining to telehealth consultation apply to formal consulting between health care professionals.
- (2) Change to the definition of asynchronous communication in (A)(3) to make it more inclusive to audio files or video images as well as to improve readability;
- (3) Change to definition of remote monitoring device in (A)(4) and (F)(2)(b) to include medical devices that have received FDA authorization in addition to those that have received FDA clearance or approval.
- (4) Change from term "informed consent" to the broader term of "consent for treatment" in (A)(7), (C), (D), and (F) because of the specialized legal definition of informed consent pertaining to surgical or medical procedures in R.C. 2317.54.
- (5) Clarification in (A)(7), (C), and (D) that consent for treatment may be documented by the health care professional rather than require a patient signature on a form.
- (6) Changes to the continuity of care provision in (B)(4) to provide specific language addressing the varying levels of in-person care and referrals including: immediate care, non-immediate care, referral to a specialist, and emergency care.
- (7) Change to clarify a health care professional's obligation to forward a patient's medical record upon patient's authorization.
- (8) Change in (D)(3) to allow an emergency exception to the requirement that the health care professionals consulting regarding a patient have received and reviewed all of the relevant medical records of the patient.
- (9) Change in (F)(1) to eliminate the requirement for a physician or physician assistant to document that the laws of the state in which the patient is located allow for the physician or physician assistant to provide telehealth services in that state.

4731-11-09

- (1) Change to the definition of mental health condition in (A)(4) to allow flexibility in using the most current edition of the Diagnostic and Statistical Manual of Mental Disorders, instead of specifying the Fifth Edition.

Rules incorporating the new telehealth rule OAC 4731-37-01

There are no changes proposed to the following rules as proposed at the January 12, 2022 Board meeting which incorporate OAC 4731-37-01 into the respective chapters for physician assistants, dietitians, respiratory care professionals, and genetic counselors: Rule 4730-1-07 Miscellaneous provisions, 4730-2-07 Standards for Prescribing, Rule 4759-11-01 Miscellaneous Provisions, Rule 4761-15-01 Miscellaneous provisions, and Rule 4778-1-06 Miscellaneous provisions.

Enforcement of current rules in the context of new rulemaking and telehealth legislation

The new telehealth law (Sub. H.B. 122) becomes effective on March 23, 2022. R.C. 4743.09(B)(1) authorizes the Medical Board to adopt rules necessary to implement the new law. While the Board is trying to expeditiously move the telehealth rules through the rulemaking process, these rules will not be ready for adoption for at least several more months.

The Ohio General Assembly provided the following uncodified language to bridge the time period between when the statute becomes effective and when new rules implementing the law are adopted. Section 6 of Sub. HB 122 states: “Beginning on the effective date of this section, a health care professional licensing board, as defined in section 4743.09 of the Revised Code, may suspend the enforcement of any rules that the board has in effect on the effective date of this section regarding the provision of telehealth and in-person services by a health care professional under the board's jurisdiction, and requirements for the prescribing of controlled substances, while the board amends or adopts new rules that are consistent with the provisions of this act.”

This uncodified language allows the Board to launch its new rules in a less confusing manner than if it reverted to enforcing its current rules that conflict with portions of the new telehealth law for only a few months before implementing new rules. It minimizes uncertainty and confusion to patients, health care professionals, and health care systems.

Actions Requested:

- (1) Discuss and approve proposed rules with any changes for initial circulation, including referral for discussion to Physician Assistant Policy Committee, Dietetics Advisory Council, and Respiratory Care Advisory Council.
- (2) Discuss and approve a Board statement of intent regarding utilization of the statutory language allowing for Medical Board suspension of enforcement of its rules regarding telehealth, in-person services, and requirements for the prescribing of controlled substances while the Board amends or adopts new telehealth rules.



MEMORANDUM

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

FROM: Nathan T. Smith, Senior Legal and Policy Counsel

DATE: April 7, 2022

RE: Telehealth rules proposed for filing with CSI

The Board received sixty-two (62) comments on the telehealth rules approved by the Board for initial circulation at its February 9, 2022 meeting. This is in addition to seven (7) other comments received before the February Board meeting. Attached to this memo are: (1) revised proposed telehealth rules with recommended changes; (2) a spreadsheet summarizing the comments and their disposition; and (3) the actual written comments. This memo analyzes the written comments in the subject areas in which most of the comments were received. Recommendations are provided for changes to the proposed telehealth rules for filing with the Common Sense Initiative (CSI). Additional recommendations for minor or stylistic changes are contained in the spreadsheet and reflected in the revised proposed rules.

Proposed new rule 4731-37-01

Definition of asynchronous communication technology in 4731-37-01(A)(3)

Comments (ATA, Bon Secours, Cleveland Clinic, Dr. Gelles, hims & hers, MetroHealth, OHA, and OSU Wexner Medical Center) suggested revising the definition to expand the types of stored clinical information that may be transmitted through asynchronous communication. These comments differed on what should be included. **Recommendation:** define asynchronous communication technology by reference to the definition of the term in 42 CFR § 410.78 for consistency with federal law.

Add definition for formal consultation in 4731-37-01(A)(7) to clarify other parts of rule

OHA comment suggested defining formal consultation to clarify other parts of the rule in which formal consulting or consultation are referenced. University Hospital commented that inclusion of “formal” before consulting adds ambiguity to definition of telehealth services.

Recommendation: Add definition suggested by OHA except for portion involving billing:

(7) “Formal consultation” means when a health care professional seeks the professional opinion of another health care professional regarding the diagnosis or treatment recommended for the patient’s medical condition presented, transfers the relevant portions of the patient’s medical record to the consulting health professional, and documents the formal consultation in the patient’s medical record.

Out of State Practice (4731-37-01(B) and (F))

R.C. 4743.09(C)(5) states that a health care professional who is a physician, physician assistant (PA), or advance practice registered nurse (APRN) may provide the following: (a) “telehealth services to a patient located outside of this state if permitted by the laws of the state in which the patient is located” and (b) “telehealth services through the use of medical devices that enable remote monitoring, including such activities as monitoring a patient’s blood pressure, heart rate, or glucose level.” Based on this additional authority specifically granted to physicians and PAs and not granted to other health care professionals, the proposed telehealth rules include the following provisions:

(B) A health care professional may provide telehealth services to a patient located in this state. The health care professional shall comply with all of the following requirements:

(F) A health care professional that is a physician or physician assistant may provide the following additional telehealth services:

(1) A physician or physician assistant may provide telehealth services to a patient located outside of this state if permitted by the laws of the state in which the patient is located. The physician or physician assistant shall confirm and document in the medical record the location of the patient.

(2) A physician or physician assistant may provide telehealth services through the use of remote monitoring devices provided that:

Thirty-three comments (from licensed dietitians, OAND, OSRC, and Kroger Health) suggested revising the language in 4731-37-01(B) to allow dietitians, respiratory care professionals, and genetic counselors to provide telehealth services to patients located out of state.

Comments from OSMA and OPPA stated that 4731-37-01(F)(1) should be deleted as unnecessary and stated that “we do not feel the State Medical Board of Ohio’s telehealth rules should consider whether other state’s telehealth rules support an Ohio physician practicing telehealth in that state.”

Dr. Gelles’ comment raised the following questions/concerns with (F)(1): “Does the allowability of out-of-state care extend to a physician and patient dyad that does not have a pre-existing relationship? Is there a limit to how many visits across state lines can be done before an in person visit is required? There should be some restrictions on this so that corporate entities like amazon don’t start competing with Ohio physicians and try to take over the care of their patients. Also, unlimited telemedicine care across state lines (without some in person care required) can enable a patient who has moved not to establish care with a new primary care physician in their new home state. If you are providing care to a patient located in another state, is there an easy way to tell that this is allowed by law in the state where the patient is located?”

Recommendation: After consideration of the diverse comments, it is recommended to remove paragraph (F)(1) for clarity and consistency regarding the proposed rule’s regulation of telehealth services provided to patients located in this state.

Referral provisions in 4731-37-01(B)(4)

Comments (from Bon Secours, OHA, ATA, Teladoc, OSU Wexner Medical Center, and hims & hers) requested revision of the referral provisions to provide additional flexibility to whom a health care professional can refer, particularly as to the referral provision in (B)(4)(a). These comments oppose the current referral provisions because: (1) they are overly complicated; (2) impose unreasonable barriers that would limit patient access and make it difficult for some providers to offer telehealth services; and/or (3) hold telehealth services to a higher standard than in-person services.

Comments (from the OSMA and OPPA) stated that paragraph (B)(4)(b) needs to be clarified to allow a health care professional to refer the patient to another health care professional in the same specialty when the patient needs non-immediate care.

A comment from the Ohio American College of Emergency Physicians supported the provision in 4731-37-01(B)(4)(d) requiring the health care professional to notify the emergency room of a patient's potential arrival, while several other comments suggested this provision was overly burdensome and may cause confusion.

Comments (OneFifteen and Ms. Melvin) inquired about the inclusion of APRNs in the telehealth rules. We also received additional input from the Nursing Board regarding the various types of APRNs involved in telehealth, cross coverage agreements, and standard care arrangements.

Recommendation: After balancing all comments on the various components of this issue, the following changes are recommended:

- (1) 4731-37-01(A)(8) define advanced practice registered nurse for purposes of this rule to include clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.
- (2) 4731-37-01(B)(4)(a) – add APRNs as health care professionals that patients can be referred to via cross-coverage agreement or standard care arrangement.
- (3) Revise 4731-37-01(B)(4)(b)-(d) as follows:

(b) If the patient does not need to be seen immediately, the health care professional shall **do one of the following:**

(i) schedule the patient for an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their condition presented; or

(ii) **refer the patient to a health care professional in the same specialty to conduct an in-person visit within an amount of time that is appropriate for the patient and their condition.**

(c) If the patient must be seen by a specialist other than the health care professional, the health care professional shall make a referral to a specialist, licensed in this state, whom the healthcare professional knows has an appropriate scope of practice **for the medical condition of the patient** and ~~is capable of~~

~~conducting an in-person visit appropriate for the diagnosis and treatment of the patient's condition and ensure that all necessary medical files are shared upon request.~~

(d) If the patient needs emergency care, the health care professional shall help the patient identify the closest emergency room and, if necessary, in the health care professional's discretion, provide notification to the emergency room of the patient's potential arrival.

Consent for treatment (4731-37-01(A)(6) and (C))

Comments (OPPA, Bon Secours) suggested limiting consent for telehealth treatment to initial visits or revising telehealth consent to an annual requirement rather than for each visit. University Hospitals commented that consent for treatment is not needed for a formal consultation if the patient has already consented to treatment.

No change recommended - Other stakeholder input obtained in stakeholder meetings has viewed informed consent as a valuable part of each telehealth visit that does not impose an undue burden.

Cleveland Clinic requested deleting risk discussion in the definition of consent for treatment because that requires more than is required for in-person consent for treatment.

No change recommended – this consent for treatment language is in current rule 4731-11-09 and exists for patient protection.

OHA offered several suggestions for revising paragraphs related to consent for treatment including: (a) change the term “consent for treatment” to “consent for telehealth treatment”; (b) replace the term “consent for treatment” for consultation in 4731-37-01(D)(1) with the term “acknowledge”; and (c) revise the language throughout the rule for simplicity and clarity from the term “patient, parent, guardian or person designated under the patient’s health care power of attorney” to the term “patient or legal representative of the patient.”

Recommendation: Revise rule to change terms to “consent for telehealth treatment” and “patient or patient’s legal representative” in paragraph (A)(6) and references throughout the rule. **No change recommended** regarding (b) changing the term “consent for telehealth treatment” to the term “acknowledge” in paragraph (D)(1).

Standard of Care Requirements – 4731-37-01(C)

Communication of Licensure Information (4731-37-01(C)(1))

Cleveland Clinic suggested changing the requirement for a health care professional to always communicate licensure information to the patient to only requiring this when the patient requests it. Dr. Levy commented that the requirement to communicate licensure information may only be necessary in situations where patient contacts a telehealth service provider who then connects the patient with a physician unknown to the patient. OHA requested clarification that the name and location of the patient can be verified verbally.

Recommendations – In situations where the telehealth provider is unknown to the patient, the benefit of the health care professional providing their name and type of active Ohio license outweighs the minimal burden. **Revise paragraph (C)(1) to state:**

The health care professional shall verify the patient's identity and location in Ohio, and communicate the health care professional's name and licensure information type of active Ohio license held to the patient if the health care professional has not previously treated the patient. This may be done verbally as long as it is documented by the health care professional in the patient's medical record.

Transmission of Patient's Medical Records (4731-37-01(C)(4))

OHA, University Hospitals, and the Ohio Department of Mental Health and Addiction Services suggested revisions to (C)(4) to reflect current practice and for consistency with the HIPAA Privacy Rule. **Recommendation:** revise (C)(4) as follows:

If applicable, the health care professional shall request the patient's, or if applicable, the patient's parent, guardian, or person designated under the patient's health care power of attorney, authorization and, if granted, forward the medical record to the patient's primary care provider, or other health care provider designated by the patient or the patient's legal representative, or refer the patient to an appropriate health care provider or healthcare facility to whom the patient is referred as provided in paragraph (B)(4) of this rule."

Remote Monitoring (4731-37-01(A)(4) and (F))

Ms. Collins' comment asked would the Medical Board allow a clinical research exemption to the requirement that a remote monitoring device be FDA approved, cleared, or authorized.

No change recommended - paragraphs include cleared, approved, or authorized by FDA to allow for the health care professional to utilize any existing FDA pathways for clinical research.

OSU Wexner Medical Center's comment suggested that the definition of remote monitoring devices be expanded to include digital therapeutics, digital software, and digital algorithms. MetroHealth systems commented that FDA approved algorithms should be included in the definition.

No change recommended: R.C. 4743.09(C)(5) allows telehealth through the use of medical devices that enable remote monitoring." The definition of remote monitoring device in 4731-37-01(A)(4) is tied to the FDA's definition of medical device. While some software and algorithms are included under the FDA definition of medical devices, not all software and algorithms are FDA approved, cleared, or authorized medical devices.

OSRC's comment requested that RCPs be permitted to provide telehealth services through the use of remote monitoring devices.

No change recommended – R.C. 4743.09(C)(5) only authorizes a physician, PA, or APRN to provide this care through telehealth.

4731-11-09

Defining new patient

Dr. Miller suggested substituting “new patient to the practice” for “new patient” in 4731-11-09(D) so that a doctor who is covering for another doctor in the same practice group can prescribe a schedule II substance to a patient that is new to the covering physician, but not new to the practice without an in-person visit.

No change recommended - the rule follows the text of R.C. 4743.09 which already allows a significant portion of controlled substance prescribing to occur without an in-person visit.

In-person visit requirements and exceptions to that requirement

Comments by Dr. Berkowski and Dr. Reynolds objected to the in-person visit requirements. **No change recommended:** The initial in-person visit for prescribing a schedule II controlled substance to a new patient is authorized by R.C. 4743.09(B)(2).

Comments (Dr. Barker, Cleveland Clinic, OSU Wexner Medical Center, and OHA) requested additional exceptions to the in-person visit requirement.

No change recommended: The exceptions in 4731-11-09(E) are authorized by R.C. 4743.09(B)(2). The additional exceptions requested in the comments are not among those listed in the statute. Further, other exceptions requested are covered under the requirement in 4731-11-09(B) that the prescribing must comply with federal law governing prescription drugs that are controlled substances.

Other changes made to this rule for clarity include: (1) updating the definition of mental health condition in paragraph (A)(4) to reflect the recent publication of the "Diagnostic and Statistical Manual of Mental Disorders Fifth Edition Text Revision" (DSM-5-TR) and (2) removing paragraph (J) “For purposes of this rule, "patient" means a person for whom the physician or physician assistant provides healthcare services or the person's representative.” This provision is recommended to be removed because it relates to the consent for telehealth treatment provisions which are in proposed rule 4731-37-01.

Rules incorporating the new telehealth rule OAC 4731-37-01

There were no comments made to these rules and there are no changes proposed to the following rules which incorporate OAC 4731-37-01 into the respective chapters for physician assistants, dietitians, respiratory care professionals, and genetic counselors: Rule 4730-1-07 Miscellaneous provisions, 4730-2-07 Standards for Prescribing, Rule 4759-11-01 Miscellaneous Provisions, Rule 4761-15-01 Miscellaneous provisions, and Rule 4778-1-06 Miscellaneous provisions.

Other comments:

Other comments received (Carter, Craven, Lenchitz, Khan, Koznek, Melvin, West, Runyon, Neurocrine Biosciences, and Hernandez) do not require changes for at least one of the following reasons:

the comment was positive or did not suggest changes; the comment did not address the substance of the proposed rules, the comments proposed stylistic changes, and the comments requested changes that either the rules already allow or the authorizing statute (R.C. 4743.09) does not permit.

Actions Requested:

- (1) Discuss and approve revised proposed rules (4731-37-01, 4731-11-09, 4730-1-07, 4730-2-07, 4759-11-01, Rule 4761-15-01, and 4778-1-06) for filing with CSI.



MEMORANDUM

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

FROM: Nathan T. Smith, Senior Legal and Policy Counsel

DATE: May 9, 2022

RE: Recommended changes for telehealth rules after consideration of new stakeholder input

At its April 13, 2022 meeting, the Medical Board approved the telehealth rules for filing with the Common Sense Initiative (CSI). Shortly before the rules were to be filed with CSI, the Medical Board received a detailed comment from the Ohio Hospital Association (OHA). Due to the timing of the comment and as part of our continuing efforts to consider stakeholder input on these important rules, Board staff met with representatives from OHA on May 5, 2022 to discuss their concerns. On May 6, 2022, Board staff received a follow-up written comment specific to controlled substance prescribing provided through telehealth. This memo analyzes the questions and comments provided by OHA. The questions are quoted below and responses and/or recommendations for changes to the rules before filing with CSI are in bold.

OHA comment on definition of formal consultation

- 1) Definition of “formal consultation” in 4731-37-01(A)(7) – We appreciate that the rule incorporates much of a proposed definition from OHA, but it did not include the reference to the consulting physician billing for the service. We would like to understand why this piece was excluded from the definition.

No change recommended – the Board does not have jurisdiction over billing and insurance issues. Other entities such as the Ohio Department of Insurance, Ohio Department of Medicaid, and Medicare have jurisdiction of those issues. By remaining silent on the topic, the rules are consistent with the Board’s jurisdiction.

OHA comment on referral provisions in 4731-37-01(B)(4)

- 2) Section 4731-37-01(B)(4)(a) refers to patients who must be seen “immediately but not in an emergency department.” This reference is confusing because either a patient’s condition is emergent and needs to be addressed immediately, or it is non-emergent and does not need to be addressed immediately. The condition can’t be both “immediate” and “non-emergent.” This category of patient (immediate/non-emergent) is confusing to providers, who would either refer a patient to an emergency department if it is an emergency, or schedule the patient for a in-person appointment at a convenient time for the patient.

- Furthermore, as we stated in our initial comment letter, this provision establishes a standard that is different than what would be required for an in-person visit, as it may not be necessary for the in-person visit to be “immediate” in order to meet the standard of care.
- In addition, (B)(4)(i) is still overly prescriptive in terms of the type of provider to whom a patient can be referred. For example, what if the physician providing the telehealth service does not have a cross-coverage arrangement with a specialist needed to treat the patient? Can the telehealth provider not refer the patient to an appropriate provider? Or what if the patient identifies a particular specialist to whom they would like to be referred. This is a confusing limitation and one that does not exist regarding in-person visits.
- Given the above, we recommend just deleting B(4)(a) altogether, as it relates to a category of patients that don’t really exist – “immediate but non-emergent.” We believe the rest of section (B) captures the universe of patients – those in need of care from the same specialty (subsection (b)); those in need of care from a different specialty (subsection (c)); and those in need of emergency care (subsection (d)).

Response and recommendation: There are health issues and conditions that could be non-emergent, but in need of immediate evaluation. One example is a tumor that could be cancerous. In this situation, the patient does not need to go to an emergency department, but should be seen by an oncologist immediately. There are a small number of patients and their associated medical conditions that will fit into this category. Fortunately, the perceived burden of this referral provision in 4731-37-01(B)(4)(a) should then also be quite small.

Paragraph 4731-37-01(B)(4)(a) prioritizes the health and safety of Ohio patients by providing a level of continuing care commensurate with the risk to the patient in leaving the medical condition untreated. We are aware through stakeholder outreach that there are telehealth platforms where the patient does not know or know of the provider before the actual telehealth encounter starts. The provider may be based in another state, but is licensed in Ohio. The platforms are designed to offer singular episodic care in which the patient is unable to return to that provider for follow-up care or consultation. There is no establishment of a continuing relationship in which the provider could monitor the patient’s efforts to follow-up on a serious medical issue discovered during a telehealth encounter.

We have heard support from stakeholders, including those within the hospital community, for the concept of expansive telehealth in which providers whose primary focus is telehealth are linked with in-person providers through cross coverage agreements so that if escalation of care is needed for a serious medical condition it can be provided seamlessly.

In an effort to be responsive to OHA’s concerns and provide more options for patients, the following additional referral option is recommended as an addition to **4731-37-01 (B)(4)(a)**:

(iv) any health care professional requested by the patient who is appropriate for the condition with which the patient presents”

OHA additional comments to 4731-37-01(B)(4)

We believe the following clarifying language would make (B)(4)(b) and (B)(4)(c) less confusing:

- To distinguish B(4)(b) from B(4)(c), B(4)(b) should read: “If the patient does not need to be seen immediately, **and does not need to be seen by a specialist under subsection (B(4)(c))**, the health care professional shall direct the patient to schedule ~~the patient for~~ an in-person visit and conduct that visit within an amount of time that is appropriate for that patient and their condition presented.” Without this change, the limitation in (b)(ii) that the patient must be referred to someone within the same specialty is confusing. Again, what if the patient’s condition requires the patient to be seen by a different specialty than the telehealth provider?
- In (B)(4)(c), the first reference to “health care professional” is confusing – I think you mean “health care professional providing the telehealth service” – right?

No change recommended. The comments are requesting stylistic changes. The language used in these paragraphs was based on feedback provided from the Ohio State Medical Association and the Ohio Psychiatric Physicians Association.

OHA comments on 4731-37-01(D) Formal Consultation

- 3) Subsection (D) continues to be confusing. This section seems to use “referring” and “consulting” interchangeably, but they are different. A “referral” results in one provider passing a patient off to another provider to deliver care and a new patient-provider relationship occurs. In a “consult” the primary treating provider maintains the relationship with the patient and asks another provider for their opinion on a patient’s condition or course of treatment – but the physician being consulted does not establish a relationship with the patient.
 - First, in (D)(1) we recommend deleting “referring” in “**referring** health care professional who seeks a formal consultation . . .”
 - Second, it is unclear to us whether the Board views the consultations contemplated by this rule as occurring within the telehealth visit or subsequent to the telehealth visit. For example, does the Board envision Telehealth Provider A consulting with Telehealth Provider B during the telehealth interaction with the patient? Or, does the Board envision Telehealth Provider A consulting with Provider B after the telehealth interaction with the patient? We think a conversation around this issue would be helpful.
 - We remain very confused about how the Board envisions a “consent for treatment” to a consultation to occur. For in-person visits, a patient usually does not consent to a physician consulting with another physician. Why should a telehealth visit be treated differently in this regard, and if it is different, what does the Board expect such “consent” to consist of?

Response: OHA voiced concern about the use of the legal term “consent for treatment” for formal consultations. They are amenable to substituting the term “acknowledgement”. This change does not alter the intended effect of the language to ensure that the patient is aware that a formal consultation is going to occur. Further, the suggested change to delete the term “referring” helps to clarify the language. **Recommended changes to paragraph (D)(1):**

The **referring** health care professional who seeks a formal consultation shall document the **consent for treatment acknowledgement** of the patient or if

applicable, the patient's legal representative, before seeking the telehealth services formal consultation with the consulting health care professional;

OHA comment on 4731-37-01(F) remote monitoring devices

- 4) Subsection (F)(1) uses the phrase “consent to treatment to the use of remote monitoring devices.” We do not believe this is an appropriate use of the term “consent to treatment,” which is defined in the rule. If you read that definition, it does not make sense for “consent to treatment” to be followed by “to the use of remote monitoring devices.” We believe the phrase should be “consent to treatment to the use of remote monitoring devices.”

Response: OHA was concerned about the use of the legal term “consent for treatment.” The following change to paragraph (F)(1) is recommended:

The patient or, if applicable, the patient's legal representative, gives consent ~~for treatment~~ to the use of remote monitoring devices;

OHA comment on 4731-11-09

- 5) In 4731-11-09 we need to better understand the Board’s rationale for not including the numerous exceptions OHA recommended keeping that exist in the current rule but are not provided in the proposed rule. The memo to the Board seems to suggest that the Board does not have the statutory authority to include these exceptions. We do not agree with that conclusion and believe it would be detrimental to the use of telemedicine as intended by the legislature for at least a couple of those current exceptions to not be included going forward. We would like to discuss.

In its May 6th email following up on the May 5th meeting in which this rule was discussed, OHA states: “This list of exceptions [in 4731-11-09(E)] does not reference any exceptions currently permitted by Federal law (most importantly the Ryan Haight Act exception for when the patient is in a hospital).

On our call yesterday, Board staff made references to the fact that the rule requires the prescriber to comply with Federal law. The relevant provision is 4731-11-09(B) of the proposed rule, which states: “A physician or a physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority must comply with federal law governing prescription drugs that are controlled substances to prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is a controlled substance to a person.” This section does not reference (D) nor is it listed as an exception in (E). Requiring a provider to comply with Federal law alone does not grant them the ability to use all exceptions available under Federal law if it would contradict the more stringent state law. As written, the Ohio law is more stringent.

Our proposed revision would be to add a 5th exception under (E): “The telehealth services are being provided under an exception permitted by Federal law.”

Response: After consideration of OHA’s comments, the following changes to further clarify the rule for prescribers are recommended:

(B) A physician or a physician assistant who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority must **shall** comply with the requirements of federal law governing prescription drugs that are controlled substances to prescribe, personally furnish, otherwise provide, or cause to be provided a prescription drug that is a controlled substance to a person.

(C) When the physician or physician assistant, who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority, prescribes, personally furnishes, otherwise provides, or causes to be provided a prescription drug that is a controlled substance during the provision of telehealth services, the physician or physician assistant ~~must~~ **shall** comply with all requirements in rule 4731-37-01 of the Administrative Code.

(D) The physician or physician assistant, **who holds a valid prescriber number issued by the state medical board and who has been granted physician-delegated prescriptive authority**, shall conduct a physical examination of a new patient as part of an initial in-person visit before prescribing a schedule II controlled substance to the patient except as provided in paragraph (E) of this rule.

(E) As an exception to paragraph (D) of this rule, a physician or physician assistant may prescribe a controlled substance to a new patient as part of the provision of telehealth services for any of the following patient medical conditions and situations:

(1) The medical record of a new patient indicates that the patient is receiving hospice or palliative care;

(2) The patient has a substance use disorder, and the controlled substance is FDA approved for and prescribed for medication assisted treatment or to treat opioid use disorder.

(3) The patient has a mental health condition and the controlled substance prescribed is prescribed to treat that mental health condition; ~~or~~

(4) The physician or physician assistant determines in their clinical judgment that the new patient is in an emergency situation provided that the following occurs:

(a) The physician or physician assistant prescribes only the amount of a schedule II controlled substance to cover the duration of the emergency or an amount not to exceed a three-day supply whichever is shorter;

(b) After the emergency situation ends, the physician or physician assistant conducts the physical examination as part of an initial in-person visit before any further prescribing of a drug that is a schedule II controlled substance; **or**

(5) The prescribing of a controlled substance through telehealth services is being done under an exception permitted by federal law governing prescription drugs that are controlled substances.

Action Requested: Approve recommended changes to proposed rules 4731-37-01 and 4731-11-09 and approve revised proposed telehealth rules for filing with CSI.

Comments on Initial Circulation of Telehealth Rules

Name & Med Bd license Type (if applicable)	Email	Organization	Comments	Disposition of Comments
Miller, Laverne MD	drmilller@cmhosp.com		The term "new patient" in 4731-11-09 should be defined. She suggests substituting "new patient to the practice" because, when a doctor is covering for another doctor in the same practice group, the covering doctor can safely prescribe controlled substances by consulting the medical record and checking OARRS for a patient that is new to the covering doctor, but not new to the practice group.	No change recommended. The proposed rule directly implements R.C. 4743.09(B)(2) which only allows the Board to require "an initial in-person visits prior to prescribing a schedule II controlled substance to a new patient" with several exceptions.
Zebley, Kyle	kzebley@ataaction.org	ATA Action	(1) 4731-37-01(A)(3) - Definition of asynchronous communication is restrictive and could cause confusion among telehealth providers. Specifically, the transmission of stored clinical data should not be limited to video clips, sound/audio files, or photo images. This could exclude things like the transmission of patient medical histories and lab results from qualifying as asynchronous communication. (2) 4731-37-01(B)(4) - Referral provisions are impractical, restrict providers' ability to deliver telehealth services in Ohio, and hold telehealth services to a higher standard than in-person services. The provision in (B)(4)(d) requiring a telehealth provider to help the patient identify the closest emergency room and provide notification to the emergency room of the patient's potential arrival could risk patient safety by delaying their arrival to the emergency room.	(1) considered comment in revision to definition of asynchronous communication technology; (2) considered comment in revision of referral provisions.
Barker, Bruce, MD	Bruce.Barker@ohiohealth.com		4731-11-09(E) - This language is overly prescriptive and will result in the more complex patient being treated for obesity not being able to continue on treatment Anorectic therapy should be added to the list of exceptions. Also, under the proposed rule, prescribing sedative hypnotics, such as low level sleep aides like Ambien or Lunesta, during a telehealth visit is prohibited.	No changes recommended. The exceptions in 4731-11-09(E) are authorized by R.C. 4743.09(B)(2). The exceptions requested in the comment are not among those listed in the statute. As Ambien is a schedule IV drug, it is subject to the requirements of proposed 4731-11-09 (B) and (C), but is not prohibited by the proposed rule.
Berkowski, Andy, MD	BERKOWJ@ccf.org		4731-11-09(D)-(E) - opposed to these paragraphs because they require an initial in-person visit and that will be a barrier to many of his patients as he states that over 80% of his patients being treated for Restless legs syndrome (RLS) require schedule II and III opiates, are seen virtually, and live more than an hour from a Cleveland Clinic facility.	No changes recommended. The initial in-person visit for prescribing a schedule II controlled substance to a new patient is authorized by R.C. 4743.09 (B)(2)
Bestic, Anna, LD	BESTICA@ccf.org		Proposed 4731-37-01(B) restricts dietitians from providing telehealth out of state and may have negative effect on patient access to care. Requests revising 4731-37-01(B) to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Bon Secours Mercy Health	jpfishpaw@mercy.com	Bon Secours Mercy Health	(1) 4731-37-01(A)(3)- Definition of asynchronous communication should include written communication through a patient portal as part of the definition of stored clinical data or clarify that E-visits may be delivered by practitioners. (2) 4731-37-01(B)(4) - the referral provisions should include the ability to refer the patient for an in-person visit with a health care professional who is not in a cross-coverage relationship with the referring health care professional. This would prevent delays in care. (3) Consent for telehealth treatment provisions in 4731-37-01 - change these provisions to only require annual telehealth consent. As drafted this requires additional time that detracts from time spend delivering care. Suggested change would be consistent with CMS annual consent requirement for telehealth services such as e-visits and virtual check-ins.	(1) considered comment in revised definition of asynchronous communication; (2) considered comment in revised referral provisions; (3) no change recommended - stakeholder input obtained in stakeholder meetings indicates obtaining consent for treatment is a valuable part of each telehealth visit that does not impose an undue burden.
Bury, Christan, LD	BURYC@ccf.org		Proposed 4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Requests revising 4731-37-01(B) to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.

Butscher, Heather, LD	Heather.Butscher@UHHospitals.org		Proposed 4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and may have negative effect on patient care and access to care. Requests revising 4731-37-01(B) to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Cleveland Clinic - Blair Barnhart and Dr. Steven Shook	barnhab@ccf.org	Cleveland Clinic	(1) 4731-37-01(A)(3)- Definition of asynchronous communication - suggests revising the language as: "Asynchronous communication also includes bi-directional text-based communication between a provider and an established patient which is both (1) communicated via a HIPPA compliant digital platform, and (2) reviewed and responded to by a licensed medical professional for the purpose of providing medical care. Asynchronous also includes remote patient monitoring where physiologic data is reviewed by a provider who then makes a recommendation for continuing care. It does not include telephone calls, images transmitted via facsimile machines, or unidirectional text messages communicated via a non-HIPPA compliant digital platform." (2) 4731-37-01(A)(7) Definition of consent for treatment: requests deleting risk discussion in telehealth consent for treatment because that requires more than is required for in-person consent for treatment. (3) Strongly supports revised language in 4731-37-01(B)(3); (4) 4731-37-01(C)(1) - suggests revising requirement to upon request, the health care professional communicate licensure information. (5) 4731-11-09(E)(4)- urges adding two new exceptions to in-person visit requirement for prescribing schedule II controlled substances to a new patient: "patients currently being treated as inpatients in other facilities and residents of nursing home."	(1) considered comment in revised definition of asynchronous communication; (2) no change recommended - this language is in current OAC 4731-11-09 and exists for patient safety; (3) no change requested - positive comment; (4) considered comment in revising 4731-37-01(C)(1); (5) no changes recommended - the exceptions in 4731-11-09(E) are authorized by R.C. 4743.09(B)(2) and the exceptions requested in the comment are not among those provided in the statute.
Collins, Aileen	Aileen.Collins@nationwidechildrens.org	Nationwide Children's Hospital	4731-37-01 (F)(2)(b): would the Medical Board allow a clinical research exemption to requirement that remote monitoring device be FDA cleared, approved, or authorized.	No change recommended - language includes cleared, approved, or authorized by FDA to allow for health care professional to utilize any existing FDA pathways for clinical research or trials.
Craven, Deborah	debcraven06@yahoo.com		Reviewed the proposed rules and states "I am in favor."	No changes requested.
Culbertson, Gillian	CULBERG@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could negatively effect the health of her patient population. Requests rule to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
DiMarino, Anthony, LD	dimaria@ccf.org		4731-37-01(B) restricts dietitians from providing telehealth out of state and may negatively impact my patient population and our clinic . Requests revising paragraph to state: " A health care professional may provide telehealth services and shall comply with all of the following requirements: "	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Gelles, Ellen, MD	egelles@metrohealth.org		(1) 4731-37-01(A)(3) clarification needed on whether back and forth messaging over a secure patient portal is included in the definition of asynchronous communication. (2) 4731-37-01(F)(1) questions and comments include: does allowability of out of state care extend to a new patient being seen by a physician for the first time?; "is there a limit to how many visits across state lines can be done before an in-person visit is required?; There should be some restrictions on this so that corporate entities like amazon don't start competing with Ohio physicians and try to take over the care of their patients. Also, unlimited telemedicine care across state lines (without some in person care required) can enable a patient who has moved not to establish care with a new primary care physician in their new home state. If you are providing care to a patient located in another state, is there an easy way to tell that this is allowed by law in the state where the patient is located? Education might be needed so that physicians know which states don't allow this." Are you allowed to do a telehealth visit with a patient located outside of the U.S.?	(1) Comment considered in revision of definition of asynchronous communication technology. (2) Comment considered in removal of 4731-37-01(F)(1).

Goldian, Kristen Welch, LD	kgoldian@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Allowing patients full access to healthcare regardless of what state we are in is better for patient care. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Pitts, Dartesia	dpitts@forhims.com	hims & hers	(1) 4731-37-01(A)(3) definition of asynchronous communication is too restrictive in its limits on types or stored clinical data allowed. This limits patient access and does not allow providers to exercise professional discretion when determining the best modality to treat patients. (2) 4731-37-01(B)(4) - referral obligations impose unreasonable barriers that would limit patient access. Also, the barriers would make it impractical for most providers to offer any telehealth services as they would not be able to comply with the required referrals to in-person care.	(1) Comment considered in revision of definition of asynchronous communication technology. (2) Comment considered in revisions of referral provisions in 4731-37-01(B)(4).
Homan, Elyse, LD	HOMANE@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Allowing out of state patients to have access to nutrition therapy via telehealth optimizes time spent receiving adequate nutrition and also allows for more equitable health care to people in remote areas. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Kennel, Julie, LD	kennel.3@osu.edu		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Telehealth improves access to nutrition services. Limiting access to nutrition services worsens outcomes. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Kerner, Jennifer, LD	jennifer.n.kerner@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could negatively impact patients due to the travel involved in attending in-person visits. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Khan, Mukarram, DO	khan@aspm.com		Audio only calls need to be made permanent.	No change recommended - 4731-37-01(B)(3) allows for synchronous communication including audio telephone calls under conditions described in that paragraph.
Korsberg, Jane, LD	nutritionrealityllc@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could negatively affect the health of my patients who have relocated and significantly restrict my practice. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements: "	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction regulating telehealth.
Koznek, K, DO	bakerkoznek@roadrunner.com		The explosion of telemedicine would not have been necessary if pharmacies, hospitals, and state medical agencies not interfered with practice of medicines such as physician off-label prescribing.	No change requested - comment does not address proposed telehealth rules.
Lindholz, Colleen	taylor.newman@kroger.com	Kroger Health	4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and would disrupt current patient continuity of care and future opportunities to serve new patients. This provision would also limit our business opportunities. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements: "	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Lenchitz, Bernard, MD	lenchib@ucmail.uc.edu		Supports proposed rule 4731-11-09.	No change requested.
Loch, Laura, LD	Laura.Loch@thechristhospital.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and may hinder her ability to provide care to immunocompromised patients in Northern Kentucky, who prefer telehealth visits during the ongoing pandemic.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.

Ludy, Dr. Mary-Jon	mludy@bgsu.edu		4731-37-01(B) will likely affect a dietitian faculty member at Bowling Green who is involved in a pilot study about food allergy education with another dietitian in North Carolina because the faculty member is not licensed in North Carolina. Requests that wording of rule be changed to give dietitians, respiratory therapists, and genetic counselors the same telehealth practice permissions as physician and physician assistants.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Luis, Maria Garcia	GARCIA29@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and significantly impacts the patients and the services we provide. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Jamieson-Petonic, Amy, LD	Amy.Jamieson-Petonic@Uhhospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and may negatively impact my patients' health. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Match, Alie, LD	Alie.Match@UCHealth.com		4731-37-01(B) - worried that this rule would significantly hinder ability to provide equal care to patients in Indiana and Kentucky who seem to prefer a telehealth option with the ongoing pandemic.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
McKnight, Pat LD	mcknightp@aol.com		4731-37-01(B) restricts dietitians from using telehealth for patients living in states bordering Ohio and those who temporarily leave Ohio to go to Florida and Arizona for the winter. Requests removal of this limitation.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Melvin, Kelli	doxie1967@gmail.com		Inquires whether certified nurse practitioners working under the supervision of a physician are allowed to see patients via telehealth and whether that will be reflected in the rules.	Revised 4731-37-01(A)(7) and (B)(4)(a) to clarify referrals to APRN in cross coverage agreement or standard care arrangement. Proposed rules do not focus on telehealth by APRNs because they are licensed by the Nursing Board.
Menapace, Jeanette, LD	jmcout15@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could negatively affect the health of her clients and limit their access to the care and convenience of telehealth. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Nageotte, Emily, LD	Emily.Nageotte@Uhhospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Tierney, Jodie	JTierney@neurocrine.com	Neurocrine Biosciences	4731-37-01 - the proposed rule does not contemplate that telehealth visits may never be the same as in-person care for certain diseases and health conditions. Recommend aligning rules with federal policies by amending rule to state that for patient with mental health conditions, and specifically those at risk of developing a drug-induced movement disorder (DMD) such as tardive dyskinesia, the provider and patient must meet in person at least once in the six months prior to delivering the first telehealth service, and at least once annually thereafter. For subsequent visits, the in-person visit could be waived if a documented consultation between the patient and provider which concluded that an in-person visit was not necessary occurred.	No change recommended - R.C. 4743.09 does not authorize rules to mandate in-person visits for specific medical conditions or rules to require periodic in-person visits.
Nishnick, Amy, LD	nishnia@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. As a practicing dietitian, she treats patients from all over the country. These patients seek out the Cleveland Clinic and are not financially able to visit in person. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
West, Jared	acucleveland@gmail.com	Ohio Association of Acupuncture and Oriental Medicine	4731-37-01 - requests that licensed acupuncturists be included as a telehealth provider in the rule. Telehealth allows acupuncturists to perform wellness checks as well as instruct patients on how to perform self-care techniques such as acupressure and mind-body interventions.	No change recommended - acupuncturists are not authorized by R.C. 4743.09 as health care professionals allowed to provide telehealth services.

Runyon, Randy	kcarey@ohiohc.org	Ohio Association of Community Health Centers	OAHC greatly appreciates the Board's consideration to allow telemedicine and increasing access to care, and strongly supports the ability to use telehealth to serve Ohio's communities and most vulnerable populations.	No changes requested.
Mavko, Kay, LD	kmavko@columbus.rr.com	Ohio Academy of Nutrition and Dietetics	4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. OAND believes that "all health care professionals deserve continuing access to patients under the care of Ohio based providers - whether the patient lives in Ohio or outside the state." Further, "Ohio has many regional, national, and internationally renowned medical centers that provide highly specialized care to patients and once treatment is complete aftercare at home should be seamless and be provided by the team of professionals who are most familiar with the patient and the patient's treatment plan." OAND requests revising this paragraph to "A health care professional may provide telehealth services to a patient located outside of this state if permitted by the laws of the state in which the patient is located, and if they comply with the following requirements:".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
McGlone, Sean	Sean.McGlone@ohiohospitals.org	Ohio Hospital Association	(1) 4731-37-01(A)(1) - telehealth necessarily includes the term "formally consulting"; suggests defining "formal consultation" as "when a health care professional seeks the professional opinion of another health care professional regarding the diagnosis or treatment recommended, transfers the relevant portions of the medical record to the consulting health professional, documents the consult in the medical record, and the consulting health care professional bills for such consult." (2) 4731-37-01(A)(3) definition of asynchronous communication is too restrictive of the types of stored clinical data that can be transmitted; suggests revising definition to be more inclusive of other types of stored clinical data. (3) 4731-37-01(A)(7) change "consent for treatment" to "consent for telehealth treatment"; (4) 4731-37-01(D)(1) replace "consent for treatment" with "acknowledgement" - it is common for patient's to acknowledge that a consult may occur during their discussion with the health care professional rather than consent for treatment. (5) Revise language throughout from "patient or parent or guardian" to "patient or a legal representative of a patient"; (6) 4731-37-01(B)(4) - suggests revisions to provide the referring provider with greater flexibility to refer the patient and eliminating the requirement to notify the emergency room in (B)(4)(d) provision; (7) 4731-37-01(C)(1) - clarify language so that verbal verification of patient identity and physical location is sufficient; (8) 4731-37-01(C)(4) suggests eliminating the requirement for authorization of the patient before transferring record to another provider; (9) 4731-37-01(D)(3) - delete "all" in the requirement that health care professional involved in the consultation must have received and reviewed all medical records of the patient relevant to the medical condition which is the subject of the consultation before the consultation occurs, unless this is not possible due to an emergency situation"; (10) 4731-11-09 - the current version of the rule allows additional exceptions for prescribing controlled substances to patients via telehealth that are not covered by the proposed rule. Suggest revising the rule to include current exceptions in 4731-11-09(D)(1)-(4).	(1) Revised except for billing portion suggested. (2) considered comment in revised definition of asynchronous communication. (3) revised relevant paragraphs; (4) No change recommended - patient consent should be obtained; (5) revised relevant paragraphs; (6) considered comment in revising referral provisions; (7) considered comment in revising (C)(1); (8) considered comment in revising (C)(4); (9) No change recommended - the modifying phrase "relevant to the medical condition" and the inclusion of an emergency exception sufficiently address the concerns; (10) no change recommended - these additional exceptions in current 4731-11-09 are covered by the requirement that the controlled substance prescribing comply with federal law in proposed 4731-11-09(B).
Hernandez, Soley	hernandez@theohiocouncil.org	The Ohio Council of Behavioral Health and Family Service Providers	4731-37-01(A)(2) - the definition of synchronous communication should specifically include telephone calls.	No change recommended - 4731-37-01(B)(3) already states that telephone calls may be used as synchronous communication under certain circumstances.
Taylor, Marti	martit@verily.com	OneFifteen	(1) Suggests revising OBOT rules (OAC Chapter 4731-33) prior to the scheduled revision date of 2024 by clarifying that an appropriate physical exam may be conducted via telehealth with a synchronous audiovisual connection. (2) We believe that the Medical Board rules should cross-reference the categories of APRNs that the Board of Nursing approves for the practice of telehealth and include them in the definition of health care professional.	(1) No change recommended at this time - the OBOT rules will be addressed once these general telehealth rules are further along in the rulemaking process; (2) comment considered in revisions to 4731-37-01(A)(8) and (B)(4)(a).

Opher, Abigail	ado20@case.edu		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Expanding telehealth services outside of Ohio could be beneficial for my patients, including those with eating disorders who move out of state for college. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Shaw, Janet	jshaw@oppa.org	Ohio Psychiatric Physicians Association	(1) 4731-37-01(B)(4)(b) - the rule should include the situation in which a patient does not need emergency care nor to be seen by a specialist, but needs an in-person visit with a physician of the same specialty as the physician that conducted the telehealth visit. (2) 4731-37-01(C)(2) - suggests limiting the consent for treatment through telehealth to only at the initial telehealth visit. (3) 4731-37-01(F)(1) should be deleted because it is unnecessary and "we do not believe that the State Medical Board of Ohio's telehealth rules should consider whether telehealth rules from other states support a physician in Ohio practicing telehealth in another state."	(1) Considered comment in revision of referral provisions. (2) No change recommended - other stakeholder input obtained in stakeholder meetings indicated consent for telehealth treatment is a valuable part of each telehealth visit that does not impose an undue burden; (3) Removed 4731-37-01(F)(1).
Hayhurst, Jennifer	jhayhurst@osma.org	Ohio State Medical Association in consultation with the Ohio Dermatological Association and the Ohio Psychiatric Physicians Association	(1) 4731--37-01(A)(2) Definition of synchronous communication technology is not clear whether a telephone call is included. (2) 4731-37-01(B)(4)(b) - the rule fails to incorporate a scenario in which the patient does not require emergency care or care by a different specialist, but needs an in-person visit with a provider of the same specialty. (3) 4731-37-01(F)(1) should be deleted because it is unnecessary and "we do not feel that the State Medical Board of Ohio's telehealth rules should consider whether other state's telehealth rules support an Ohio physician practicing telehealth in that state."	(1) No change recommended - 4731-37-01(B)(3) allows for synchronous communication including audio telephone calls under conditions described in that paragraph; (2) comment considered in revising referral provisions; (3) Deleted 4731-37-01(F)(1).
Ciarlariello, Sue , RCP and David Corey	dpc@pacainc.com	Ohio Society for Respiratory Care	(1) 4731-37-01(B) and (F) - The OSRC believes that all health care professionals need access to patients under the care of Ohio based providers whether the patient lives in Ohio or outside the state. This rule "will prevent RCPs involved in regional programs or those working in border cities from reaching their out-of-state patients" and will "restrict the RCP's ability to use 'standard of care' remote equipment and physiologic monitoring in all patients."	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth. No change recommended for remote monitoring as R.C. 4743.09 does not authorize RCPs to provide this.
Thomas, Andrew, MD and L. Arick Forrest, MD	William.Hayes@osumc.edu	The Ohio State University Wexner Medical Center	(1) 4731-37-01(A)(3) - the definition of asynchronous communication is unnecessarily restrictive of the types of stored clinical data that may be transmitted. (2) 4731-37-01(B)(4) is overly complicated and should be simplified into one section describing the choice to see the patient in-person or make an appropriate referral. (3) 4731-37-01(C)- seek clarification that the rule allows for delegation of standard of care tasks such as obtaining consent for treatment or verifying the patient's identify and physical location. (4) 4731-37-01(F)(2) - recommend expanding the use of remote monitoring devices approved by the FDA by adding digital therapeutics, digital software, and digital algorithms. (5) 4731-11-09 - request clarifications on when an in-person visit has to occur, whether a sickle cell crisis would be captured under the emergency medical condition exception, and why this rules does not mention nurse practitioners.	(1) considered comment in revising the definition of asynchronous communication; (2) considered comment in revising referral provisions; (3) No change recommended - the current delegation rules cover this. (4) No change recommended - R.C. 4743.09(C)(5) allows telehealth through the use of medical devices that enable remote monitoring. The definition of remote monitoring device in 4731-37-01(A)(4) is tied to the FDA's definition of medical device. Not all software and algorithms are FDA approved, cleared, or authorized. (5) No change recommended - the exceptions in the rule mirror the exceptions provided in R.C. 4743.09(B)(2).
Pehling, Victoria, LD	PEHLINV@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and will significantly impact my practice and limit the care I can provide to our patients. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Poland, Laura, LD	laura@dietitianinyourkitchen.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and may have negative effect on client care and access to care. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.

Reed, Kelly	Reedk2@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could hinder patient care. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Reynolds, Thomas Lee, MD	doc@4kidhelp.com		4731-11-09 - requests to exempt children with Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) from requiring in-person sessions to receive stimulants.	No change recommended - the rule requires initial in-person visit of a new patient before prescribing a schedule II controlled substance consistent with R.C. 4743.09(B)(2).
Rodich, Melanie, LD	Melanie.Rodich@UHhospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Rood, Robin, LD	rroodrd@gmail.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. She is a dietitian that works for Teladoc and sees patients "within Ohio, but also from Maryland, Virginia, California, and Michigan to name a few." Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Shawhan, Stacy, LD	Stacy.Shawhan@UCHealth.com		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and would limit my ability to provide adequate care to my patients in Kentucky.	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Sowa, Agnieszka, LD	SOWAA@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. The ability to see our patients virtually who live outside of Ohio borders is imperative in order to be able to provide continuity of care and ensure best outcomes. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Sullivan, Lauren, LD	sullivl2@ccf.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and would limit health care to our patients who live in New York, Pennsylvania, Michigan, and West Virginia. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Carter, Tracy	cartert@summahealth.org	Summa Health	(1) clarify when an in-person visit should be conducted - is there a specific timeframe? (2) clarify how to handle non-controlled drug prescription refills for patient. (3) recommend that healthcare professionals who provide cross-coverage should not be required to see the patient in-person first before prescribing non-controlled drugs.	(1) No change recommended - 4731-37-01(B)(3)-(4) and 4731-11-09(D),(E) are consistent with R.C. 4743.09. (2)and (3) No changes recommended - 4731-37-01(E)(1) addresses the prescribing of non-controlled drugs through telehealth.
Teague, Erin, LD	Erin.Teague@UHhospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state. Requests revising paragraph to state "A health care professional may provide telehealth services and shall comply with all of the following requirements".	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.

Tucker, Claudia Duck	ctucker@teladochealth.com	Teladoc Health	(1) 4731-37-01(A)(1) - Definition of telehealth "does not track with the statutory definition in R.C. 4743.09. (2) 4731-37-01(A)(3) - Definition of asynchronous technology arbitrarily limits the types of clinical data that may be transmitted. (3) 4731-37-01(B)(4) - referral provisions place a significant burden on health care providers and may limit patient's choice of health care provider. The referral provisions for telehealth services are beyond what is required for in-person service referrals. (4) 4731-37-01(B)(4)(d) - this provision regarding referrals to the emergency room is overly prescriptive and does not reflect current best practice. (5) 4731-37-01(C)(7) - there is no definition provided for what constitutes "prompt" documentation of the patient record. (6) 4731-37-01(D)(3)- it is unreasonable to expect any health care professional to know at the time of diagnosis or treatment that they have received all the medical records of the patient relevant to the medical condition of the patient which is the subject of the consultation before the consultation occurs.	(1) No change recommended - definition is consistent with statutory definition; (2) considered comment in revising definition of asynchronous communication; (3) and (4) considered comments in revising referral provisions; (5) no change recommended; (6) no change recommended - paragraph allows for relevant medical records and provides an exception to the requirement in an emergency situation.
Sines, Amanda	amanda@gov-advantage.com	Ohio American College of Emergency Physicians	(1) 4731-37-01(A)(1) - clarify definition to include situation where physician could be on the same campus, but in a different part of the health care facility providing telehealth. (2) 4731-37-01(B)(4)(d) - "[w]e support this provision and believe it increases patient care by creating a more formalized handoff for when the patient arrives at the emergency department. (3) change references from "emergency room" to "emergency department".	(1) No change recommended; (2) positive comment - no change requested; (3) revised (B)(4)(a),(d)
Jolliff, Kinsey	kjolliff@metrohealth.org	The MetroHealth System	(1) 4731-37-01(A)(3) - the definition of asynchronous communication is unnecessarily restrictive of the types of stored clinical data that may be transmitted. (2) 431-37-01(A)(4) - definition of remote monitoring advice should be expanded to include FDA approved algorithms in the definition. (3) 4731-37-01(B)(4) - We applaud the steps the Board has taken in this section "to ensure that patients who receive telehealth services are best served when their care must be transitioned to being seen in person." Further, the rule "prioritizes the care of patients, the citizens of Ohio, rather than providers who may have no connection to Ohio who only provide care at a singular point of time." (4) 4731-37-01(B)(4)(d)- suggests revising to: If the patient needs the emergency care, the health care professional shall help the patient identify the closest emergency room."	(1) considered comment in revising the definition of asynchronous communication; (2) No change recommended - definition is tied of FDA definition of medical devices. Not all software and algorithms are FDA approved, cleared, or authorized; (3) positive comment - no change requested; (4) considered comment in revising the referral provisions.
DiBlasio, Carla	Carla.DiBlasio@UHHospitals.org	University Hospitals	(1) 4731-37-01(A)(1) - including the word "formal" before consulting adds some ambiguity in the definition of telehealth services. (2) 4731-37-01(D)(1) - does not believe that a patient needs to consent to a formal consultation if the patient has already consented to treatment. (3) We generally agree with ATA's comment letter.	(1) considered comment in adding definition for formal consultation in 4731-37-01(A)(7). (2) No change recommended - a formal consultation should have patient consent for treatment. (3) No change requested.
Wise, Julie, LD	Julie.Wise@UHHospitals.org		4731-37-01(B) improperly restricts dietitians from providing telehealth out of state and could be harmful to patients with eating disorders who rely on weekly telehealth visits regardless of their location. Requests revising paragraph to state: "A health care professional may provide telehealth services and shall comply with all of the following requirements"	Revised 4731-37-01(F) to clarify Medical Board's in state jurisdiction in regulating telehealth.
Shank, Kelly and Jeana Singleton	jmsingleton@bmdllc.com	Ohio Association of Advanced Practice Nurses	(1) 4731-37-01(A): request that definition of Advanced Practice Registered Nurse be added to include certified nurse practitioner, certified nurse midwife or certified nurse specialist; (2) 4731-37-01(B)(4)(a)(ii): add APRN with whom the physician has a standard care arrangement to the list of providers to whom a physician can refer a patient who needs immediate care.	(1) comment considered in added 4731-37-01(A)(8) definition of advanced practice registered nurse; (2) comment considered in referral provision changes in 4731-37-01(B)(4)(a).

Comments on January 20, 2022 Preliminary Draft of Telehealth Rules

Trevino, Justin, MD	Lisa.Frederick@mha.ohio.gov	Ohio Department of Mental Health and Addiction Services	(1) 4731-37-01(C)(4) - suggest "forward the medical documentation created in conjunction with performance of the telehealth service to the patient's primary care provider..." (2) 4731-37-01(C)(5) - suggest "that meets the minimal standards of care for an in-person visit, which may include the use of medical information and data gathered by other Ohio licensed healthcare providers acting within the scope of their professional license." (3) 4731-37-01(C)(7) -suggest "evaluation findings", "any contraindications to standard/indicated treatments for the identified condition(s)". (4) 4731-11-09(D) - Because there are schedule III controlled substances used for MAT that have significant abuse liability, I would consider specifying both schedules II and III in this provision.	(1) Considered comment in paragraph (C)(4) revision. (2) and (3) No changes recommended - comments suggest stylistic changes. (4) No change recommended - R.C. 4743.09 only allows for the initial in-person visit for schedule II controlled substances.
O'Reilly, Kelly	gblazer@oahp.org	Ohio Association of Health Plans	OAHF cautions implementing telehealth rules that could threaten access. Many times, a consumer will utilize telehealth because that is how they can access care. However, if a follow-up in-person appointment is required immediately after the telehealth visit it directly undermines the utility of telehealth. We believe the intent of HB 122 was to bridge access, therefore requiring an in-person visit immediately after a telehealth visit runs counter to this intent.	No changes recommended - the proposed telehealth rules do not require an in-person visit immediately after a telehealth visit. Provisions in 4731-37-01(B)(3),(4) and 4731-11-09(D),E) are consistent with R.C. 4743.09.
DiBlasio, Carla	Carla.DiBlasio@UHhospitals.org	University Hospitals	(1) 4731-37-01(C)(1) - request removal of requirement that health care professional communicate their licensure information to the patient; (2) 4731-37-01(C)(4) - remove the requirement to obtain the patient's consent to share the medical record with another health care provider; (3) concerns with the consent to consultation requirement in 4731-37-01(D)(1) articulated in the initial circulation comment above.	(1) Comment considered in paragraph (C)(1) revision; (2) revised paragraph (C)(4) consistent with comment; (3) No change recommended.
Duck Tucker, Claudia	ctucker@teladochealth.com	Teladoc	concerns with referral provisions 4731-37-01(B)(4) articulated in the initial circulation comment above.	Comment considered in changes made to referral provisions.
Levy, Alan, MD	conveyed by OSMA		(1) 4731-37-01(B)(4) - suggests another subparagraph (iv) to read "another health care professional, or medical institution, capable of conducting an in-person visit appropriate for the diagnosis and treatment of the patient's medical condition." (2) 4731-37-01(C)(1) - requirement to communicate licensure information may only be necessary in situations where patient contacts a telehealth service provider who then connects the patient with a physician unknown to the patient; (3) 4731-37-01(C)(4)-add "if applicable" to beginning of paragraph; (4) 4731-37-01(D)(3) - begin sentence with "if possible"; (5) 4731-37-01(F)(1)- it is unnecessary for the Medical Board to establish the standard of care for on Ohio provider who is providing services to a patient in another state. (6) happy with the prescribing provisions in the rules.	(1) Comment considered in revisions to referral provisions; (2) Comment considered in paragraph (C)(1) revisions; (3) and (4) changes made for initial circulation draft; (5) removed this paragraph; (6) No change requested - positive comment.
Zebley, Kyle	kzebley@ataaction.org	ATA Action	(1) 4731-37-01(A)(3) definition of asynchronous communication and 4731-37-01(B)(4) referral provisions concerns articulated in the initial circulation comment above. (2) 4731-37-03(C)(3) - "This language puts the onus of ensuring the secure username and password on the provider during patient-provider communications. ATA Action believes that this responsibility should fall on the facility or health care entity, not the provider."	(1) Comment considered in revisions made to definition of asynchronous communication and referral provisions. (2) No change recommended.
McGlone, Sean	Sean.McGlone@ohiohospitals.org	Ohio Hospital Association	(1) 4731-37-01 - the language in rule needs to appropriately differentiate between consent for treatment and informed consent. (2) Also, the rule should differentiate between "formal" consults and "informal consults". (3) 4731-37-01(B)(4) - there are differences in perspective on this issue, even within our membership - it seems the trick will be striking a balance between ensuring patient access to care and continuity of care. Some situations may not be conducive to immediately scheduling as the provider may not have control over the scheduling system. (4) Certain references to the medical record throughout the draft need to be narrowed to the relevant telehealth encounter instead of all medical records.	(1) and (2) changes were included in initial circulation draft of the rules; (3) Comment considered in revisions to referral provisions. (4) No change recommended.