



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.