

PROPOSED REGULATION PUBLICATION FORMS

Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 32 BOARD OF PHYSICIANS

Chapter 05 Tele[medicine]health

10.32.05

Authority: Health Occupations Article, § 14-205, 14-301, 14-601, and 14-602, Annotated

Code of Maryland

Is There Emergency Text That Is Identical To The Proposed Text:

Yes No

Is There An Incorporation By Reference Document Associated With This Proposal?

Yes No

Does This Proposal Have An Impact On Environmental Hazards Affecting The Health Of Children As Defined In Health-General Article, §13-1501(c)?

Yes (explain) No

Does This Proposal Include An Increase Or Decrease In A Fee For A License?

Yes, complete (1)—(8) No, skip (1)—(8) and proceed to Notice of Proposed Action.

(1) Explain/justify why an increase or decrease is necessary:

(2) How much money is needed to operate effectively or to eliminate an operating fund deficit?

(3) In what year was the most recent fee increase?

(4) Is the fee revenue retained by the Proposing Unit or passed through to a national organization that administers a uniform licensing exam?

(5) Describe any measures taken to mitigate the need for increased revenue:

- (6) Describe any special circumstances that have had an adverse impact on the Proposing Unit's operating expenses.
- (7) Describe any consideration given by the Proposing Unit as to the hardship a fee increase may have on the regulated profession.
- (8) Describe any efforts to solicit the opinions of licensees regarding the Proposing Unit's effectiveness and performance.

Notice of Proposed Action

The Secretary of Health proposes to revise .01,.02, .03,.04,.05,.06 and .07 under 10.32.05.

Statement of Purpose

The purpose of this proposal is to revise and re-name the Telehealth regulations to improve patient safety, authorize other health occupations under the Board's jurisdiction to do telehealth, to reflect technological innovations, and the increasing use of telehealth in more settings.

Comparison to Federal Standards

(Check one option)

No There is no corresponding federal standard to this proposed action.

or

___ There is a corresponding federal standard to this proposed action, but the proposed action **is not** more restrictive or stringent.

The corresponding federal standard is: _____

EXPLAIN why the proposed action **is not** more restrictive or stringent than the corresponding federal standard:

or

___ In compliance with Executive Order 01.01.1996.03, this proposed action **is** more restrictive or stringent than corresponding federal standards as follows:

- (1) Regulation citation and manner in which it is more restrictive than the applicable federal standard:
- (2) Benefit to the public health, safety or welfare, or the environment:
- (3) Analysis of additional burden or cost on the regulated person:
- (4) Justification for the need for more restrictive standards:

Impact Statements

Part A

(check one option)

Estimate of Economic Impact

X The proposed action has no economic impact.

Or

___ The proposed action has an economic impact. (IF this is checked, complete the following form in its entirety)

I. Summary of Economic Impact. (INSERT SHORT SUMMARY)

II.	Types of Economic Impact.	Revenue (R+/R-)	<u>Expenditure (E+/E-)</u>	<u>Magnitude</u>
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A. On issuing agency:

B. On other State agencies:

C. On local governments:

Benefit (+)

Cost (-) Magnitude

D. On regulated industries or trade groups:

E. On other industries or trade groups:

F. Direct and indirect effects on public:

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

Part B

Economic Impact on Small Businesses

(check one option)

No The proposed action has minimal or no economic impact on small businesses.

or

___ The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows.

Impact on Individuals with Disabilities

(check one option)

No The proposed action has no impact on individuals with disabilities.

or

___ The proposed action has an impact on individuals with disabilities as follows:
(Agency to complete this assessment)

Opportunity for Public Comment

Comments may be sent to Mark Woodard, Health Policy Analyst II, Maryland Board of Physicians 4201 Patterson Avenue, 4th Floor, Baltimore, MD 21215, or call 410-764-2460), or email to mark.woodard@maryland.gov, or fax to 410-358-2252. Comments will be accepted through (February 26, 2018). A public hearing has not been scheduled.

Part C
(For legislative use only; not for publication)

- A. Fiscal Year in which regulations will become effective: FY 2019
- B. Does the budget for fiscal year in which regulations become effective contain funds to implement the regulations?
 Yes No N/A
- C. If “yes”, state whether general, special (exact name), or federal funds will be used:
- D. If “no”, identify the source(s) of funds necessary for implementation of these regulations:
- E. If these regulations have no economic impact under Part A, indicate reason briefly: These regulations do not have any fees nor require any health occupation to incur any new costs.
- F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason. These regulations authorize, but do not require any health occupation under the Board of Physicians to practice their occupation through telehealth and establishes no fee.

Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 32 BOARD OF PHYSICIANS

Chapter 05 Tele[medicine]*health*

Authority: Health Occupations Article, §§14-205, 14-301, 14-601, and 14-602, Annotated

Code of Maryland

.01 Scope.

[A.] This chapter governs the practice of medicine using [telecommunication systems] *telehealth* as an adjunct to, or replacement for, traditional [face-to-face] *in-person* patient visits.

[B. This chapter does not apply to the use of an electronic means by a treating physician licensed in Maryland who is seeking consultative services of another licensed health care professional with respect to an individual patient.]

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "*Asynchronous*" means not occurring at the same time.

[(1) Consultative Service.

(a) "Consultative service" means a service provided by a physician for the sole purpose of offering an expert opinion or advising the treating physician about an individual patient.

(b) "Consultative service" does not include:

(i) Decisions that direct patient care; or

(ii) Interpretation of images, tracings, or specimens on a regular basis.]

(2) ["Face-to-face"] "*In-person*" means within [each other's sight and presence] the physical presence of the patient.

[(3) "Group practice" means a group of two or more health care practitioners legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association:

(a) In which each health care practitioner who is a member of the group provides substantially the full range of services that the practitioner routinely provides through the joint use of shared office space, facilities, equipment, and personnel;

(b) For which substantially all of the services of the health care practitioners who are members of the group are provided through the group and are billed in the name of the group, and amounts so received are treated as receipts of the group; and

(c) In which the overhead expenses of, and the income from, the practice are distributed in accordance with methods previously determined on an annual basis by members of the group.]

[(4)] (3) [Interpretive Services.

(a) “Interpretive services” means [official] reading[s] *and analyzing* [of] images, tracings, or specimens through [a telemedicine link] *telehealth or giving interpretations based on visual, auditory, thermal, ultrasonic patterns or other patterns as may evolve with technology.*

[(b) "Interpretive services" includes remote, real-time monitoring of a patient being cared for within a health care facility].

[(5) “Notice of privacy practices” means a written statement that meets the:

(a) Requirement of the Health Insurance Portability and Accountability Act of 1996; and

(b) Standards found at 45 CFR §164.520, as amended.

(6) “Physician-patient relationship” means a relationship between a physician and a patient in which there is an exchange of individual, patient-specific information.]

(4) “*Remote Patient Monitoring*” means *the use of telehealth devices to collect medical and other forms of health data from patients that are securely provided to a telehealth practitioner in a different location for assessment, recommendation, and diagnosis.*

(5) *“Store and forward technology” means the asynchronous transmission of digital images, documents and videos electronically through secure means.*

(6) *Surrogate examiner” means an individual examining a patient at the direction of a telehealth practitioner during a synchronous audio-visual telehealth encounter, and providing the telehealth practitioner with observations and information.*

(7) [“Real-time”] *“Synchronous” means simultaneously or quickly enough to allow two or more individuals to conduct a conversation.*

(8) *“Telemedicine” means the practice of medicine from a distance in which intervention and treatment decisions and recommendations are based on clinical data, documents, and information transmitted through telecommunications systems.]*

(8) *Telehealth*

(a) *“Telehealth” means the use of interactive audio, video, or other telecommunications or electronic technology by a licensed health care practitioner to deliver clinical services within the scope of practice of the health care practitioner at a location other than the location of the patient.*

(b) *Telehealth includes, but is not limited to:*

(i) *interactive audio-visual synchronous encounters;*

(ii) *store-and-forward technology;*

(iii) *interpretive services; and*

(iv) *remote patient monitoring;*

(c) *“Telehealth” does not include:*

(i) *an audio-only telephone conversation between a health care practitioner and a patient;*

(ii) *an electronic mail message between a health care practitioner and a patient; or*

(iii) a facsimile transmission between a health care practitioner and a patient;

(9) “Telehealth devices” means devices that gather visual or other data and remotely sends the images or data to a telehealth practitioner in a different location from the patient.

(10) “Telehealth Practitioner” means a Maryland licensed physician or licensed allied health practitioner performing telehealth services within their respective scope of practice.

.03 Licensure.

Except as specified in Health Occupations Article, §14-302, Annotated Code of Maryland, an individual shall be a licensed Maryland *practitioner* [physician] in order to practice telehealth if one or both of the following occurs:

A. The individual practicing telehealth is physically located in Maryland;

B. The patient is in Maryland.

.04 [Standards Related to Telemedicine] *Specific Telehealth Requirements.*

A. Prior to providing telehealth services, a telehealth practitioner shall first:

(1) Except for reviewing interpretative services, obtain oral or written acknowledgement from a patient or person in interest as defined by Health Gen. § 4-301(l), to perform telehealth services, pursuant § D of this Section. The telehealth practitioner, the telehealth practitioner’s medical practice, or facility, or school shall obtain and maintain evidence documenting appropriate patient acknowledgement to treat through telehealth technology. The telehealth practitioner shall document such acknowledgment in the patient’s records. In emergency situations an acknowledgement of telehealth services may be provided after the patient encounter;

(2) Have a procedure for handling emergencies; and

(3) Create a procedure to prevent access to data by unauthorized persons through encryption or other means, pursuant to §E of this regulation.

B. When initiating telehealth services through synchronous audio-visual communication a telehealth practitioner shall:

(1) Confirm whether the patient is in Maryland or outside of Maryland and identify the practice setting of the patient;

(2) Verify the identity of the patient through accepted patient identifiers;

(3) For an initial patient-telehealth practitioner interaction, disclose to the patient the telehealth practitioner's name, location, medical specialty, and any other relevant credentials;

(4) Identify any other individuals present at the telehealth practitioner's location;

(5) Confirm there is no one in the patient's location who is not allowed to hear or share personal health information;

(6) Inform the patient when the telehealth encounter is beginning and that sensitive medical information may be discussed; and

(7) Have a contingency procedure of re-establishing electronic or other connection if communication is terminated.

C. The requirements of §B of this regulation may be delegated.

D. An acknowledgement of telehealth services shall include:

(1) A description of the telehealth modality used by the telehealth practitioner;

(2) An statement that the telehealth practitioner may determine that telehealth is not clinically appropriate and request that a patient come for an in-person encounter;

(3) A description of telehealth privacy risks, and the telehealth practitioner's data breach policy, including the requirement to timely inform the patient of a data breach and inform the patient of the steps being taken to remediate the problem;

(4) A statement informing the patient that the patient may exclude anyone from any site during the telehealth service;

(5) A statement informing patients that they can decline telehealth service at any time without affecting their right to future care or treatment and that the patients can terminate the telehealth encounter at any time;

(6) an authorization to record the telehealth encounter and maintain and store the recording in accordance with medical retention requirements under state and federal law, if the practitioner records the telehealth encounter; and

E. The telehealth practitioner shall maintain the privacy and confidentiality of telehealth encounters in accordance with federal and state laws and regulations including:

(1) Ensure sufficient privacy and security measures through encryption, password protection, and other security measures to assure confidentiality and integrity of patient-identifiable information;

(2) Ensure a written business associate agreement between the telehealth practitioner and the business associate to appropriately safeguard and protect the privacy and security of a patient's health information; and

(3) Establish and follow processes and procedures in the event of a data breach, to notify patients about the breach of their personal health records and or electronic synchronous communications.

[A. A physician, including a physician in a group practice, who practices telehealth using a website to communicate with patients, shall:

(1) Disclose on the website the following:

(a) Licensure status and Maryland physician license number, which may be accomplished as follows:

(i) For a website sponsored by a group practice, disclosure of the licensure status and physician license number of each physician practicing within the group;

(ii) For a website sponsored by a health insurer or HMO licensed in Maryland, identification of the health plan or HMO that has credentialed the physicians, and the name, Maryland license number, and licensure status for all Maryland-licensed physicians using the website; or

(iii) Disclosure of the names, licensure status, and Maryland physician license numbers of each individual physician practicing through the website;

(b) Physician ownership of the website, if applicable;

(c) Fees for services offered on the website, to be disclosed before a patient incurs any charges;

(d) Financial interest of the physician or group practice in the products or services advertised or offered on the site, if applicable; and

(e) The notice of privacy practices used by the physician, group practice, or HMO, or a statement regarding what user data is being collected and how the data will be used;

(2) Develop a procedure to verify the identification of the individual transmitting a communication;

(3) Develop a procedure to prevent access to data by unauthorized persons through password protection, encryption, or other means; and

(4) Develop a policy on how soon an individual can expect a response from the physician to questions or other requests included in transmissions.

B. A physician, including a physician in a group practice, who practices telehealth using a website to communicate with patients, shall communicate the policies established in §A of this

regulation, via the website of the physician or group practice, or by other means, to any individual with whom the physician exchanges or intends to exchange information.]

.05 Patient Evaluation.

A. *Except when providing asynchronous telehealth services or remote patient monitoring, a [A physician] telehealth practitioner shall perform a patient evaluation adequate to establish diagnoses and identify underlying conditions or contraindications to recommended treatment options before providing treatment or prescribing medication.*

B. *A telehealth practitioner may use a surrogate examiner, telehealth devices, live synchronous audio-visual communications, and other methods of performing a medical examination remotely, as well as a patient evaluation performed by another licensed health care practitioner providing coverage, if the evaluation is adequate to comply with §A of this regulation. [A Maryland-licensed physician may rely on a patient evaluation performed by another Maryland-licensed physician if one physician is providing coverage for the other physician.]*

[C. *If a physician-patient relationship does not include prior in-person, face-to-face interaction with a patient, the physician shall incorporate real-time auditory communications or real-time visual and auditory communications to allow a free exchange of information between the patient and the physician performing the patient evaluation.*]

.06 Standard [of Quality Care] *Related to Telehealth.*

A. *A [physician] telehealth practitioner shall be held to the same standards of practice as those applicable in traditional health care settings and shall ensure that the quality and quantity of data and other information is sufficient in making medical decisions.*

[B. Except when a physician is performing interpretive services, the physician shall perform a patient evaluation that meets the requirements set forth in Regulation .05 of this chapter before providing recommendations or making treatment decisions for a patient.]

[C.] *B.* When a [physician] *telehealth practitioner* is providing interpretive services, the [physician] *telehealth practitioner* shall ensure that there is no clinically significant loss of data from image acquisition through transmission to final image display.

[D.] *C.* A [physician practicing telehealth] *telehealth practitioner* shall [:

(1) Except when providing interpretive services, obtain and document patient consent;
(2) *C]* creates and maintains adequate medical records *in accordance with Maryland and federal law and regulations.* [;]

(3) Follow requirements of Maryland and federal law and regulations with respect to the confidentiality of medical records and disclosure of medical records; and

(4) Adhere to requirements and prohibitions found in Health Occupations Article, §§1-212, 1-301—1-306, and 14-404, Annotated Code of Maryland.]

D. A telehealth practitioner may not treat a patient or prescribe medication based solely on an online questionnaire.

E. A telehealth practitioner shall not prescribe opioids for the treatment of pain through telehealth except if the patient is in a “health care facility” as defined in Section 19-114 (d)(1) of the Health General Article.

F. This section shall not be construed to authorize the delivery of health care services in a setting, or in a manner, not otherwise authorized by law.

.07 [Physician] *Telehealth Practitioner Discipline.*

The Board shall use the same standards in evaluating and investigating a complaint and disciplining a licensee who practices telehealth as it would use for a licensee who does not use telehealth technology in the licensee's practice.

(1) Telehealth practitioners shall adhere to requirements and prohibitions of the practitioner's practice act, the practitioner's regulations, the practitioner's code of ethics, and Health Occupations Article, §§1-212, 1-301—1-306.

(2) The failure of a telehealth practitioner to comply with regulation .04 or .05 of this Chapter shall constitute unprofessional conduct.

Robert R. Neall

Secretary of Health