# **Proposed Action on Regulations**

|                           | Date Filed with AELR<br>Committee | TO BE COMPLETED BY DSD                      |
|---------------------------|-----------------------------------|---|
| Transmittal Sheet         | 06/05/2015                        | Date Filed with Division of State Documents |
| PROPOSED<br>OR REPROPOSED |                                   | Document Number                             |
| Actions on Regulations    |                                   | Date of Publication in MD<br>Register       |

410-767-5623

- 1. Desired date of publication in Maryland Register: 7/10/2015
- 2. COMAR Codification

**Title Subtitle Chapter Regulation** 

10 09 49 01-.12

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator Telephone Number

Michele Phinney

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# 6. Check applicable items:

- X- New Regulations
- **X-** Amendments to Existing Regulations

  Date when existing text was downloaded from COMAR online: April 15, 2015.
- X- Repeal of Existing Regulations
- \_ Recodification
- \_ Incorporation by Reference of Documents Requiring DSD Approval
- \_ Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: -- P.

# 7. Is there emergency text which is identical to this proposal:

\_ Yes X- No

### 8. Incorporation by Reference

\_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

# 9. Public Body - Open Meeting

\_ OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland. \_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

### 10. Children's Environmental Health and Protection

\_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

## 11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by David Lapp, Assistant Attorney General, (telephone #410-767-5292) on May 14, 2015. A written copy of the approval is on file at this agency.

# Name of Authorized Officer

Van T. Mitchell

TitleTelephone No.Secretary410-767-6500

Date

June 4, 2015

# Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

# **Subtitle 09 MEDICAL CARE PROGRAMS**

# 10.09.49 [Telemedicine] Telehealth Services

Authority: Health-General Article, §2-104(b), Annotated Code of Maryland; Ch. 280, Acts of 2013

# **Notice of Proposed Action**

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The Secretary of Health and Mental Hygiene proposes to amend Regulations .01—.11 and repeal and adopt new Regulation .12 under COMAR 10.09.49 Telehealth Services.

# **Statement of Purpose**

The purpose of this action is to combine the Maryland Medicaid Telemedicine Program and the Maryland Medicaid Telemental Health Program under the same chapter. The Behavioral Health Administration will maintain the Telemental Health Program regulations (COMAR 10.21.30) but a future proposal will amend the chapter to remove references to Medicaid-covered by services and address only non-Medicaid populations and services.

# **Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

# **Estimate of Economic Impact**

The proposed action has no economic impact.

# **Economic Impact on Small Businesses**

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

# Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

# **Opportunity for Public Comment**

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through August 10, 2015. A public hearing has not been scheduled.

# **Economic Impact Statement Part C**

- A. Fiscal Year in which regulations will become effective: FY 2016
- B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?
- 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:

No service delivery changes occur as a result of this proposal; the proposal intends to make two separate programs subject to the same chapter.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

See E.

G. Small Business Worksheet:

Attached Document:

# Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

# **Subtitle .09 MEDICAL CARE PROGRAMS**

# 10.09.49 [Telemedicine] Telehealth Services

Authority: Health-General Article, §2-104(b), Annotated Code of Maryland; Ch. 280, Acts of 2013

10.09.49.01 (4/15/15)

### .01 Scope.

- A. This chapter applies to [telemedicine] *telehealth* programs reimbursed by the Maryland Medicaid Program effective October 1, [2014] 2015.
  - B. The purpose of providing medically necessary services via [telemedicine] telehealth is to improve:
- (1) Access to outpatient specialty care *and psychiatric services*, thus reducing preventable hospitalizations and reducing barriers to health care access;

- (2) [Patient compliance with treatment plans] Access to outpatient and inpatient psychiatric subspecialty consultation, thus improving diagnostic clarification, treatment recommendations, and planning for the individual;
  - (3) (text unchanged)
  - (4) Capacity and choice for [outpatient] ongoing outpatient treatment in underserved areas of the State.

### .02 Definitions.

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms Defined.
- [(1) "Campus" means the physical area immediately adjacent to the provider's main buildings, other areas, and structures that are not strictly contiguous to the main buildings but are located on the same property, and any other areas determined on an individual-case basis by the Department to be part of the provider's campus
- (2) "Consulting provider" means the licensed provider at the distant site who provides medically necessary consultation services to the patient at the originating site via telemedicine upon request from the originating site provider]
- (1) "Administrative services organization (ASO)" means an entity that manages the Public Behavioral Health System on behalf of the Department.
- (2) "Campus" means the physical area immediately adjacent to the provider's main buildings, other areas, and structures that are not strictly contiguous to the main buildings but are located on the same property, and any other areas determined on an individual-case basis by the Department to be part of the provider's campus.
- (3) "Department" means the Department of Health and Mental Hygiene, which is the single State agency designated to administer the [telemedicine] *telehealth* program.
- (4) "Distant site" means a site approved by the Department to provide [telemedicine] *telehealth* services, at which the licensed [consulting] *distant site* provider is located at the time the service is provided via technology-assisted communication.
- [(5) "Federally qualified health center (FQHC)" has the meaning stated in Health-General Article, §24-1301, Annotated Code of Maryland.
  - (6) "Medically necessary" means that the service or benefit is:
- (a) Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;
  - (b) Consistent with currently accepted standards of good medical practice;
  - (c) The most cost-efficient service that can be provided without sacrificing effectiveness or access to care; and
  - (d) Not primarily for the convenience of the consumer, family, or provider.
- (7) "Originating site" means the location of an eligible Medicaid participant at the time the service being furnished via technology-assisted communication occurs, which is a site approved by the Department to provide telemedicine services.
- (8) "Originating site transmission fee" means the amount the Department reimburses an approved originating site for the telemedicine transmission.
- (9) "Professional fee" means the Departmental fee schedule for clinical services which is incorporated by reference in COMAR 10.09.02.07.
  - (10) "Provider" means:
- (a) An individual, association, partnership, corporation, unincorporated group, or any other person authorized, licensed, or certified to provide services for Medical Assistance participants and who, through appropriate agreement with the Department, has been identified as a Maryland Medical Assistance Provider by the issuance of an individual account number;
  - (b) An agent, employee, or related party of a person identified in §B(10)(a) of this regulation; or
- (c) An individual or any other person with an ownership interest in a person identified in B(10) of this regulation.
- (11) "Security" means the protection of information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction.
- (12) "Store and Forward technology" means the transmission of medical images or other media captured by the originating site provider and sent electronically to a distant site provider, who does not physically interact with the patient located at the originating site.
- (13) "Technology-assisted communication" means multimedia communication equipment permitting two-way real-time interactive communication between a patient at an originating site and a consulting provider at a distant site.
- (14) "Telemedicine" means the delivery of medically necessary services to a patient at an originating site by a consulting provider, through the use of technology-assisted communication.]
- (5) "Distant site provider" means the licensed provider at the distant site who provides medically necessary consultation services to the patient at the originating site via telehealth upon request from the originating site provider.
- (6) "Federally qualified health center (FQHC)" has the meaning stated in Health-General Article, \$24-1301, Annotated Code of Maryland.
  - (7) "Medically necessary" means that the service or benefit is:

- (a) Directly related to diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition;
  - (b) Consistent with currently accepted standards of good medical practice;
  - (c) The most cost-efficient service that can be provided without sacrificing effectiveness or access to care; and
  - (d) Not primarily for the convenience of the consumer, family, or provider.
- (8) "Originating site" means the location of an eligible Medicaid participant at the time the service being furnished via technology-assisted communication occurs, which is a site approved by the Department to provide telehealth services.
  - (9) "Professional fee" means:
- (a) For telemedicine services, the Departmental fee schedule for clinical somatic services, that is incorporated by reference in COMAR 10.09.02.07; or
- (b) For telemental health services, the Departmental fee schedule for clinical behavioral health services, that is incorporated by reference in COMAR 10.09.59.09.
- (10) "Psychiatric nurse practitioner" means an advanced practice registered nurse whose certification and licensing indicates CRNP-PMH.
  - (11) "Provider" means:
- (a) An individual, association, partnership, corporation, unincorporated group, or any other person authorized, licensed, or certified to provide services for Medical Assistance participants and who, through appropriate agreement with the Department, has been identified as a Maryland Medical Assistance Provider by the issuance of an individual account number;
  - (b) An agent, employee, or related party of a person identified in §B(11)(a) of this regulation; or
- (c) An individual or any other person with an ownership interest in a person identified in §B(11)(a) of this regulation.
- (12) "Public Behavioral Health System" means the system that provides medically necessary behavioral health services for Medical Assistance participants and certain other uninsured individuals, including mental health and substance use disorder services.
- (13) "Residential crisis services site" means a facility that provides intensive mental health and support services that are:
- (a) Provided to a child or an adult with mental illness who is experiencing or is at risk of a psychiatric crisis that would impair the individual's ability to function in the community; and
- (b) Designed to prevent a psychiatric inpatient admission, provide an alternative to psychiatric inpatient admission, shorten the length of inpatient stay, or reduce the pressure on general hospital emergency departments.
- (14) "Store and Forward technology" means the transmission of medical images or other media captured by the originating site provider and sent electronically to a distant site provider, who does not physically interact with the patient located at the originating site.
- (15) "Technology-assisted communication" means multimedia communication equipment permitting two-way real-time interactive communication between a patient at an originating site and a distant site provider at a distant site
- (16) "Telehealth" means the delivery of medically necessary services to a patient at an originating site by distant site provider, through the use of technology-assisted communication.
- (17) "Telehealth Program" means the program by which medically necessary services are authorized to be delivered via technology-assisted communication between originating and distant site providers.
- (18) "Telemedicine" means the delivery of medically necessary somatic services to a patient at an originating site by a distant site provider, through the use of technology-assisted communication.
- (19) "Telemental health" means the delivery of medically necessary behavioral health services to a patient at an originating site by a distant site provider, through the use of technology-assisted communication.
- (20) "Transmission fee" means the amount the Department reimburses an approved originating site for the telehealth transmission.

### .03 Approval.

The Department shall grant approval to allow originating and [consulting] *distant* site providers to receive State and federal funds for providing [telemedicine] *telehealth* services if the [telemedicine] *telehealth* provider meets the requirements of this chapter.

### .04 Service Model.

- A. [Telemedicine] *Telehealth* improves access to [consulting] *distant site* providers from other areas of the State, the District of Columbia, or a contiguous state.
  - B. [Telemedicine] Telehealth providers may be part of a private practice, hospital, or other health care system.
- C. Medical Assistance-approved originating site providers shall engage in agreements with [consulting] *distant site* providers for telehealth services.
- D. [Fee-for-service reimbursement for professional services shall be in accordance with the Maryland Medical Assistance Program Physicians' Services Provider Fee Manual, which is incorporated by reference in COMAR 10.09.02.07.] *Professional services rendered via telehealth are reimbursed on a fee-for-service basis.*

### .05 Covered Services.

Under the [Telemedicine] Telehealth Program, the Department shall cover:

- A. Medically necessary services covered by the Maryland Medical Assistance Program rendered by an originating site provider that are distinct from the [telemedicine] *telehealth* services provided by a [consulting] *distant site* provider:
- B. Medically necessary consultation services covered by the Maryland Medical Assistance Program rendered by an approved [consulting] *distant site* provider that can be delivered using technology-assisted communication;
  - C. An approved originating site for the [originating site] transmission fee;
- D. The professional fee for an approved [consulting] *distant site* provider for initial [telemedicine] *telehealth* consultation for services furnished before, during, and after communicating with the Medical Assistance participant presenting in a hospital emergency department setting if:
  - (1) The [consulting] distant site provider is not the physician of record or the attending physician; and
- (2) The initial [telemedicine] *telehealth* consultation is distinct from the care provided by the physician of record or the attending physician;
  - E. The following mental health services:
    - (1) Diagnostic interview;
    - (2) Individual therapy, with or without medication evaluation and management;
    - (3) Family therapy, with or without the identified patient;
    - (4) Outpatient evaluation and management for a new or established patient;
    - (5) Outpatient office consultation for a new or established patient;
    - (6) Initial inpatient consultation for a new or established patient; and
    - (7) Emergency department services.

### .06 Participant Eligibility.

A participant is eligible to receive [telemedicine] telehealth services if the individual:

- A. Is enrolled in the Maryland Medical Assistance Program on the date the service is rendered;
- B. Consents to [telemedicine] *telehealth* services unless there is an emergency that prevents obtaining consent, which the originating site shall document in the participant's medical record; [and]
  - C. Is present at the originating site at the time the [telemedicine] telehealth service is rendered; and
- D. Is authorized to receive behavioral health treatment services through the Public Behavioral Health System, except for behavioral health services provided in a hospital emergency department.

### .07 Provider Conditions for Participation.

- A. To participate in the Program, the provider shall:
  - (1) Be enrolled as a Medical Assistance Program provider on the date the service is rendered;
  - (2)—(4) (text unchanged)
  - (5) Have a written contingency plan when [telemedicine] telehealth is unavailable; and
- (6) If a behavioral health service provider, be registered as a provider through the ASO on the date the service is rendered.
- B. Approved Originating Site. The following sites may be approved as an originating site for [Telemedicine] *Telehealth* Program service delivery:
  - [(1) A FQHC;
  - (2) A hospital, including the emergency department;
  - (3) The office of a physician, nurse practitioner, or nurse midwife;
  - (4) A renal dialysis center;
  - (5) A local health department; and
  - (6) A nursing facility.]
  - (1) A college or university student health or counseling office;
  - (2) An elementary, middle, high, or technical school with a supported nursing, counseling or medical office;
  - (3) A local health department;
  - (4) A FQHC;
  - (5) A hospital, including the emergency department;
  - (6) A nursing facility;
  - (7) The office of a physician, psychiatric nurse practitioner, nurse practitioner, or nurse midwife;
  - (8) An outpatient mental health center;
  - (9) A renal dialysis center; or
  - (10) A residential crisis services site.
- C. Approved Distant Site. The following provider types who practice within the State, the District of Columbia, or a contiguous state may be approved as [consulting] *distant site* providers for [Telemedicine] *Telehealth* Program consultation services:
  - (1) [A physician] A nurse midwife;
  - (2) A nurse practitioner; [and]
  - (3) [A nurse midwife.] A psychiatric nurse practitioner; or

(4) A physician.

### .08 Technical Requirements.

- A. A provider of health care services delivered through [telemedicine] *telehealth* shall adopt and implement technology in a manner that supports the standard of care to deliver the required service.
- B. A provider of health services delivered through [telemedicine] *telehealth* shall, at a minimum, meet the following technology requirements:
  - (1)—(2) (text unchanged)
- (3) Bandwidth speed *and image resolution* sufficient to provide quality video to meet a minimum of 15 frames per second, *or higher, as industry standards change;* 
  - (4)—(5) (text unchanged)

### .09 Confidentiality.

The originating and [consulting] distant site providers:

A—D (text unchanged)

### .10 Medical Records.

- A. The originating and [consulting] *distant site* providers shall maintain documentation in the same manner as during an in-person visit or consultation, using either electronic or paper medical records.
- B. [Telemedicine] *Telehealth* records shall be retained according to the provisions of Health-General Article, §4-403, Annotated Code of Maryland.
  - C. (text unchanged)

### .11 Limitations.

- A. A service provided through [telemedicine] *telehealth* is subject to the same program restrictions, preauthorizations, limitations, and coverage that exist for the service when provided other than through [telemedicine] *telehealth*.
  - B. A [telemedicine] telehealth service does not include:
    - (1)—(3) (text unchanged)
- (4) A telephone conversation, electronic mail message, or facsimile transmission between the originating and [consulting] distant site providers without interaction between the [consulting] distant site provider and the patient.
- C. "Store and Forward technology" does not meet the Maryland Medical Assistance Program's definition of [telemedicine] *telehealth*.
- D. [Telemedicine] *Telehealth*-delivered services may not bill to the Maryland Medical Assistance Program *or to the ASO* when technical difficulties preclude the delivery of part or all of the [telemedicine] *telehealth* session.
  - E. (text unchanged)
  - [F. Telemental health services are not covered under this regulation but are covered under COMAR 10.21.30.
- G. The Department may not reimburse for services that require in-person evaluation or that cannot be reasonably delivered via telemedicine.
  - H. The Department may not reimburse consulting providers for a facility fee.]
  - F. The Department may not reimburse for services that:
    - (1) Require in-person evaluation; or
    - (2) Cannot be reasonably delivered via telehealth.
  - G. The Department may not reimburse distant site providers for a facility fee.
- H. The Department may not reimburse for originating site transmission fees billed using both the physicians' services fee and the Health Services Cost Review Commission fee.
  - I. (text unchanged)
- J. The Department may not reimburse for [telemedicine] *telehealth* services delivered by an originating and distant site provider located in different facilities in the same [hospital] campus.

### .12 Reimbursement.

- A. To receive reimbursement for telemedicine services, providers must be actively enrolled with Maryland Medical Assistance.
- B. There are two categories of fees that the Department shall reimburse an approved telehealth provider, as applicable:
  - (1) Originating site transmission fee; and
  - (2) Professional fee.
  - C. Originating site transmission fee.
    - (1) The telehealth transmission fee is set:
- (a) In the Maryland Medical Assistance Program Physicians' Services Provider Fee Manual, which is incorporated by reference in COMAR 10.09.02.07; or
  - (b) By the Health Services Cost Review Commission for sites located in regulated space.
  - (2) Originating sites shall use the appropriate telehealth service modifier.
  - (3) Transmission fees paid to the originating site may be used to pay for:

- (a) Line or per minute usage charges, or both; and
- (b) Any additional programmatic, administrative, clinical, or contingency support at the originating site. D. Professional Fee.
  - (1) The professional fee shall be:
- (a) For telemedicine services, for both originating and distant site providers, as set forth in the Maryland Medical Assistance Program Physicians' Services Provider Fee Manual, which is incorporated by reference in COMAR 10.09.02.07; or
- (b) For telemental health services, for both originating and consulting site providers, as set forth in the Departmental fee schedule for clinical services, which is incorporated by reference in COMAR 10.09.59.09.
- (2) Professional fees charged for telehealth services shall be billed with the appropriate telehealth service modifier.

# VAN T. MITCHELL

Secretary of Health and Mental Hygiene