

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	07/07/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 8/19/2016

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	09	08	10
10	09	49	01-.08 and .10-.12

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator	Telephone Number
Michele Phinney	410-767-5623

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5. Name of Person to Call About this Document	Telephone No.
Alison Donley	410-767-6541

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6. Check applicable items:

- New Regulations

- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: May 17, 2016.

- 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 - 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 General Provisions Article, §3-302(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 24, 2016. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title

Secretary

Telephone No.

410-767-6500

Date

July 7, 2016

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 09 MEDICAL CARE PROGRAMS
10.09.08 Freestanding Clinics
Subtitle 09 MEDICAL CARE PROGRAMS
10.09.49 Telehealth Services

Authority: See proposal.

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to :

- (1) Amend Regulation .10 under COMAR 10.09.08 Freestanding Clinics; and
- (2) Amend Regulations .01, .02, .04—.09, repeal Regulation .03 and adopt new Regulation .03, repeal Regulation .10, and amend and recodify Regulations .11 and .12 to be Regulations .10 and .11 respectively, under COMAR 10.09.49 Telehealth Services.

Statement of Purpose

The purpose of this action is to :

- 1) Clarify and update the telehealth chapter based on administrative simplifications to register as a telehealth provider;
- 2) Permit providers who are fluent in American Sign Language (ASL) to engage in telehealth directly with a deaf or hard of hearing recipient from the recipient's home or other secure agreed upon location in an effort to increase access for deaf or hard of hearing recipients; and
- 3) Update the language in the Freestanding Clinics' chapter to stay consistent with the amendments made to the telehealth chapter.

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, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmfh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through September 19, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2017

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. This proposal intends to clarify and update the telehealth chapter based on administrative simplifications to register as a telehealth provider and to permit providers who are fluent in American Sign Language (ASL) to engage in telehealth directly with a deaf or hard of hearing recipient from the recipient's home or other secure agreed upon location in an effort to increase access for deaf or hard of hearing recipients, which will not result in an economic impact.

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. above.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.08 Freestanding Clinics

10.09.08.10 (5/23/16)

.10 Payment Procedures.

A.—E. (text unchanged)

F. The provider may not bill the Program for:

(1)—(2) (text unchanged)

(3) Professional services rendered by mail or telephone [with the exception of telemedicine services];

[(4) Services which are provided at no charge to the general public;]

[(5)] (4)—[(7)] (6) (text unchanged)

G.—I. (text unchanged)

10.09.49 Telehealth Services

Authority: Health-General Article, §§2-104(b) and 15-105.2(b), Annotated Code of Maryland; Ch. 280, Acts of 2013

10.09.49.01 (5/17/16)

.01 Scope.

A. This chapter applies to telehealth programs reimbursed by the Maryland Medicaid Program [effective October 1, 2015].

B. The purpose of providing medically necessary services via telehealth is to improve:

(1) Access to [outpatient specialty care and psychiatric] *somatic and behavioral health* services, thus reducing preventable hospitalizations and reducing barriers to health care access;

(2) Access to outpatient and inpatient [psychiatric] subspecialty [consultation] *services*, thus improving diagnostic clarification, treatment recommendations, and planning for the individual;

(3) (text unchanged)

(4) Capacity and choice for ongoing [outpatient] treatment in underserved areas of the State.

10.09.49.02 (5/17/16)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(4) (text unchanged)

(5) "Distant site" means a site [approved by] *registered with the Department* to provide telehealth services, at which the licensed distant site provider is located at the time the service is provided via technology-assisted communication.

(6) "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.

(7) (text unchanged)

(8) "*GT modifier*" means the *Healthcare Common Procedure Coding System (HCPCS) service code modifier indicating that the provider rendered a healthcare service via an interactive audio and video telecommunications system.*

[(8)] (9)—[(9)] (10) (text unchanged)

[(10)] (11) "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] *registered with the Department* to provide telehealth services.

[(11)] (12) "Professional fee" means:

(a) For [telemedicine] *somatic* services, the Departmental fee schedule for clinical somatic services, that is incorporated by reference in COMAR 10.09.02.07; or

(b) For [telemental] *behavioral* health services, the Departmental fee schedule for clinical behavioral health services, that is incorporated by reference in COMAR 10.09.59.09.

[(12)] (13) "Provider" means:

(a) (text unchanged)

(b) An agent, employee, or related party of a person identified in [§B(10)(a)] *§B(12)(a)* of this regulation;

(c) An individual or any other person with an ownership interest in a person identified in [§B(10)(a)] *§B(12)(a)* of this regulation.

[(13)] (14)—[(17)] (18) (text unchanged)

[(18)] (19) "Telehealth" means the delivery of medically necessary *somatic or behavioral health* services to a patient at an originating site by distant site provider, through the use of technology-assisted communication.

[(19)] (20) “Telehealth Program” means the program by which medically necessary *somatic or behavioral health* services are authorized to be delivered via technology-assisted communication between originating and distant site providers.

[(20)] “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.

(21) “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.]

[(22)] (21) “Transmission fee” means the amount the Department reimburses [an approved] *a registered* originating site for the telehealth transmission.

.03 Registration.

An eligible originating and distant site provider shall register with the Department before providing telehealth services.

10.09.49.04 (5/17/16)

.04 Service Model.

A. Telehealth improves access to distant site providers [from other areas of the State, the District of Columbia, or a contiguous state].

B. (text unchanged)

C. Medical [Assistance-approved] *Assistance-registered* originating site providers shall engage in agreements with *registered* distant site providers for telehealth services.

D. (text unchanged)

10.09.49.05 (5/17/16)

.05 Covered Services.

Under the 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 telehealth services provided by a distant site provider;]

[B.] A. Medically necessary services covered by the Maryland Medical Assistance Program rendered by [an approved] *a registered* distant site provider that [can] *shall* be:

(1) *Distinct from services provided by the originating site provider; and*

(2) *Able to be delivered using technology-assisted communication.*

[C. An approved originating site for the transmission fee;]

B. The transmission fee paid to a registered originating site, except when the originating site is not a Medicaid payable provider.

[D. The professional fee for an approved distant site provider for initial telehealth services furnished before, during, and after communicating with the Medical Assistance participant presenting in a hospital emergency department setting if:

(1) The distant site provider is not the physician of record or the attending physician; and

(2) The initial telehealth service is distinct from the care provided by the physician of record or the attending physician; and

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.]

10.09.49.06 (5/17/16)

.06 Participant Eligibility.

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

A.—C. (text unchanged)

D. [Is] *When treated for behavioral health services, 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.

10.09.49.07 (5/17/16)

.07 Provider Conditions for Participation.

A. To participate in the Program, the provider shall:

(1) [Be] *Except when the originating site is not a Medicaid payable provider, be enrolled as a Medical Assistance Program provider on the date of the service is rendered;*

(2) [Meet] *Except when the originating site is not a Medicaid payable provider, meet the requirements for participation in the Medical Assistance Program as set forth in:*

(a)—(c) (text unchanged)

(3) [Apply] *Register for participation in the Program [using the application form designated by the Department];*

[(4) Be approved for participation by the Department;]

(4) *Engage in telehealth with a permitted telehealth provider registered with the Department, except when the originating site is not a Medicaid payable provider; and*

[(5) Have a written contingency plan when telehealth is unavailable; and]

[(6)] (5) (text unchanged)

B. Medical Record Documentation. An originating and distant site provider shall:

(1) *Maintain documentation in the same manner as during an in-person visit, using either electronic or paper medical records;*

(2) *Retain telehealth records according to the provisions of Health-General Article, §4-403, Annotated Code of Maryland; and*

(3) *Include the participant's consent to participate in telehealth or an explanation as to why consent was not available.*

[B. Approved] *C. Permitted Originating [Site] Sites. The following sites may [be approved] register as an originating site for Telehealth Program service delivery:*

(1)—(2) (text unchanged)

(3) *A deaf or hard of hearing participant's home or any other secure location as approved by the participant and the provider;*

[(3)] (4)—[(12)] (13) (text unchanged)

[C. Approved] *D. Permitted Distant Site Rendering Providers. The following provider types [who practice within the State, the District of Columbia, or a contiguous state] may [be approved] register as distant site providers [for Telehealth Program consultation] to render behavioral or somatic services via telehealth:*

(1)—(2) (text unchanged)

(3) *A psychiatric nurse practitioner; [or]*

(4) *A physician[.]; or*

(5) *A provider fluent in American Sign Language providing telehealth services to a deaf or hard of hearing participant.*

10.09.49.08 (5/17/16)

.08 Technical Requirements.

A. (text unchanged)

B. A provider of health services delivered through telehealth shall, at a minimum, meet the following technology requirements:

(1) A camera that has the ability to manually or under remote control provide multiple views of a patient with the capability of altering the resolution, focus, and zoom requirements according to the [consultation] service;

(2) *Unless engaging in a telehealth communication with a participant who is deaf or hard of hearing, [Audio] audio equipment that ensures clear communication and includes echo cancellation;*

(3) (text unchanged)

(4) Display monitor size sufficient to support diagnostic needs used in the [telemedicine] telehealth services; and

(5) (text unchanged)

10.09.49.09 (5/17/16)

.09 Confidentiality.

The originating and distant site providers:

A.—C. (text unchanged)

D. May not store at originating and distant sites the video images or audio portion of the [telemedicine] telehealth service for future use.

10.09.49.11 (5/17/16)

[.11] .10 Limitations.

A. A service provided through telehealth is subject to the same program restrictions, preauthorizations, limitations, and coverage that exist for the service when provided [other than through telehealth] *in person.*

B.—D. (text unchanged)

E. The Department may not reimburse [for consultation that occurs during an ambulance transport.] *a provider for the following:*

(1) *Services that occur during an ambulance transport;*

- (2) *Communications between providers where the participant is not physically present at the originating site; or*
- (3) *Telehealth services delivered where either:*
 - (a) *The distant site is not a registered distant site provider as set forth in Regulation .07 of this chapter; or*
 - (b) *The originating site is not a permitted originating site provider as set forth in Regulation .07 of this*

chapter.

F.—J. (text unchanged)

10.09.49.12 (5/17/16)

[.12] .II Reimbursement.

A. To receive reimbursement for [telemedicine] *telehealth* services, [providers] *a provider* shall [be]:

(1) *Be* actively enrolled with Maryland Medical Assistance; *and*

(2) *Participate with a telehealth partner that meets provider conditions for participation as set forth in Regulation .07 of this chapter.*

B. There are two categories of fees that the Department shall reimburse [an approved] *a registered telehealth* provider, as applicable:

(1) (text unchanged)

(2) [Professional] *Distant site professional fee performed via telehealth.*

C. Originating Site Transmission Fee.

(1) (text unchanged)

[(2) Originating sites shall use the appropriate telehealth service modifier.]

[(3)] (2) (text unchanged)

D. [Professional] Distant Site Professional Fee.

(1) The *distant site* professional fee shall be:

(a) For [telemedicine services, for both originating and distant site providers] *somatic services provided via telehealth*, 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] *behavioral health services provided via telehealth*, as set forth in the Departmental fee schedule for [clinical services] *Public Mental Health System Reimbursement*, 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 –*GT* service modifier.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene