MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet

PROPOSED
OR REPROPOSED
Actions on Regulations

Date Filed with AELR
Committee

09/01/2017

Date Filed with Division of State Documents

Document Number

Date of Publication in MD
Register

- 1. Desired date of publication in Maryland Register: 10/13/2017
- 2. COMAR Codification

Title Subtitle Chapter Regulation

10 09 96 01-.13

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator Michele Phinney

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

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6. Check applicable items:X- New Regulations

_ Amendments to Existing Regulations
Date when existing text was downloaded from COMAR online: .

_ 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 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 August 2, 2017. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Dennis Schrader

TitleSecretary of Health
Telephone No.
410-767-6500

Date

September 1, 2017

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.96 Remote Patient Monitoring

Authority: Health-General Article, §15-103(b), Annotated Code of Maryland

Notice of Proposed Action

П

The Secretary of Health proposes to adopt new Regulations .01—.11 under COMAR 10.09.96 Remote Patient Monitoring.

Statement of Purpose

The purpose of this action is to create a new chapter governing medically necessary services rendered via remote patient monitoring to assist Maryland Medicaid participants in managing and controlling their chronic conditions.

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, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through November 13, 2017. A public hearing has not been scheduled.

Economic Impact Statement Part C

- A. Fiscal Year in which regulations will become effective: FY 2018
- 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: These regulations have no economic impact because the remote patient monitoring service is projected to be cost neutral since additional costs will be offset by reductions in readmissions and emergency department visits.
- 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

MARYLAND DEPARTMENT OF HEALTH

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.96 Remote Patient Monitoring

Authority: Health-General Article, §15-103(b), Annotated Code of Maryland

.01 Purpose and Scope.

- A. This chapter applies to remote patient monitoring services reimbursed by the Maryland Medical Assistance Program effective January 1, 2018.
- B. The purpose of providing medically necessary services via remote patient monitoring is to assist participants in managing and controlling their chronic conditions in order to reduce readmissions, emergency department visits, and to improve quality of care
- C. The target populations are high-risk, chronically ill Maryland Medical Assistance Program participants suffering from diabetes, congestive heart failure, or chronic obstructive pulmonary disease.

.02 Definitions.

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms Defined.
- (1) "Certified nurse practitioner" means an individual who meets the licensure and conditions of participation set forth in COMAR 10.09.01.
- (2) "Department" means the Maryland Department of Health, which is the single State agency designated to administer the remote patient monitoring program.
- (3) "Episode" means the span of treatment during which remote patient monitoring services are rendered to eligible participants.

- (4) "Home" means the place of residence occupied by the participant, other than a hospital, nursing facility, or other medical or psychiatric institution.
- (5) "Home health agency" means a public or private agency or organization that meets the licensure and conditions of participation of COMAR 10.09.04.
- (6) "Maryland Medical Assistance Program" means the program of comprehensive medical, behavioral, and other health-related care for indigent and medically indigent individuals, jointly financed by the federal and state governments and administered by states under Title XIX of the Social Security Act, 42 U.S.C. §1396 et seq., as amended.
 - (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) "Participant" means an individual who is certified as eligible for, and is receiving, Medical Assistance benefits.
- (9) "Physician" means an individual who meets the licensure requirements and conditions of participation of COMAR 10.09.02.
- (10) "Physician assistant" means an individual who meets the licensure requirements and conditions of participation set forth in COMAR 10.09.55.
 - (11) "Program" means the Maryland Medical Assistance Program.
 - (12) "Provider" means an individual or an organization who:
 - (a) Meets the requirements of Regulations .03 and .04 of this chapter; and
- (b) Through an appropriate agreement with the Department, has been identified as a Program provider by the issuance of a unique provider number.
- (13) "Remote patient monitoring" means digital technologies to collect medical and other forms of health data from individuals in one location and electronically transmit that information securely to health care providers in a different location for assessment, recommendations and interventions.

.03 License Requirements.

- A. The provider shall:
 - (1) Meet all license requirements as set forth in COMAR 10.09.36.02; and
 - (2) Be licensed in the state in which the participant resides.
- B. A home health agency shall be:
 - (1) Licensed pursuant to Health-General Article, §§19-401—19-408, Annotated Code of Maryland;
- (2) Part of a hospital or related institution licensed pursuant to Health-General Article, §§19-301—19-359, Annotated Code of Maryland; or
 - (3) Legally authorized to provide home health services in the jurisdiction in which the service is provided.
- C. A doctor of medicine or osteopathy shall be licensed and legally authorized to practice medicine and surgery in the state in which the service is provided.
 - D. A certified nurse practitioner shall:
- (1) Hold a current license to practice registered nursing in Maryland, and be certified as a nurse practitioner by the Nursing Board; or
 - (2) Meet the nurse practitioner regulatory requirements of the state in which the services are provided.
 - E. A physician assistant applying for provider status shall:
- (1) Be licensed to practice as a physician assistant in Maryland or in the state or jurisdiction in which the service is provided;
 - (2) Be in compliance with requirements set forth in COMAR 10.32.03;
- (3) If practicing in Maryland, have a delegation agreement with a supervising physician that outlines the physician assistant's duties within the medical practice or facility which has been filed with and approved by the Board of Physicians; and
- (4) If practicing in Maryland, have a delegation agreement with a supervising physician that documents the specialized training, education, and experience of the physician assistant for performing advanced duties.

.04 Provider Conditions for Participation.

- A. To provide remote patient monitoring, the provider shall:
- (1) Be enrolled with an active status as a Maryland Medical Assistance Program provider on the date the service is rendered;
 - (2) Be a:
 - (a) Physician;
 - (b) Physician assistant;
 - (c) Certified nurse practitioner; or
 - (d) Home health agency when remote patient monitoring services are prescribed by a physician; and

- (3) Meet the requirements for participation in the Medical Assistance Program as set forth in:
 - (a) COMAR 10.09.36.03; and
 - (b) The COMAR chapter defining any covered service being rendered.
- B. Medical Record Documentation. A remote patient monitoring provider shall:
 - (1) Maintain documentation using either electronic or paper medical records;
- (2) Retain remote patient monitoring records according to the provisions of Health-General Article, §4-403, Annotated Code of Maryland;
 - (3) Submit the preauthorization on a form developed by the Department; and
 - (4) Include the participant's consent to participate in remote patient monitoring.
- C. Remote patient monitoring is not a substitute for delivery of care. Provider shall see patients in person periodically for follow-up care.

.05 Participant Eligibility for Services.

- A. A participant is eligible to receive remote patient monitoring services if:
 - (1) The participant is enrolled in the Maryland Medical Assistance Program on the date the service is rendered;
- (2) The participant consents to remote patient monitoring services and has the capability to utilize the monitoring tools and take actions to improve self-management of the chronic disease;
 - (3) The participant has the internet connections necessary to host the equipment in the home;
 - (4) The participant is at high risk for avoidable hospital utilization due to poorly controlled:
 - (a) Chronic obstructive pulmonary disease;
 - (b) Congestive heart failure;
 - (c) Diabetes type 1; or
 - (d) Diabetes type 2; and
- (5) The provision of remote patient monitoring may reduce the risk of preventable hospital utilization and promote improvement in control of the chronic condition.
- B. Participants with the conditions described in A(4) are eligible for an episode of remote patient monitoring if the participant had:
- (1) Two hospital admissions within the prior 12 months with the same qualifying medical condition as the primary diagnosis;
- (2) Two emergency department visits within the prior 12 months with the same qualifying medical condition as the primary diagnosis; or
- (3) One hospital admission and one separate emergency department visit within the prior 12 months with the same qualifying condition as the primary diagnosis.

.06 Covered Services.

- A. Remote patient monitoring services include:
 - (1) Installation;
 - (2) Education for the participant in the use of the equipment; and
 - (3) Daily monitoring of vital signs and other medical statistics.
- B. The remote patient monitoring provider shall establish an intervention process to address abnormal data measurements in an effort to prevent avoidable hospital utilization.
- C. Physician, nurse practitioner, and physician assistant providers who establish remote patient monitoring programs shall be responsible for:
 - (1) Establishing criteria for reporting abnormal measurements;
 - (2) Informing the participant of abnormal results; and
 - (3) Monitoring results and improvements in patient's ability to self-manage chronic conditions.
- D. Medical interventions by a physician, nurse practitioner, or physician assistant based on abnormal results shall be reimbursed according to COMAR 10.09.02.07.
 - E. A home health agency shall:
- (1) Have an order by a physician who has examined the patient and with whom the patient has an established, documented and ongoing relationship;
 - (2) Report abnormal measurements to the participant and to the ordering provider; and
- (3) Send the ordering provider a weekly summary of monitoring results, including improvement in patient's ability to self-manage chronic conditions.

.07 Limitations.

- A. Remote patient monitoring services are only covered for participants who meet the eligibility criteria specified in Regulation .05 of this chapter.
 - B. The Program does not cover:
 - (1) Remote patient monitoring equipment;
 - (2) Upgrades to remote patient monitoring equipment;
- (3) The internet connections necessary to transmit the remote patient monitoring services' results to the provider's offices; or

(4) More than:

- (a) Two months of remote patient monitoring services per episode; and
- (b) Two episodes per year per participant.
- C. Home health agencies may only be reimbursed for remote patient monitoring when the service is ordered by a physician.

.08 Preauthorization Requirements.

The Department may preauthorize services when the provider submits to the Department adequate documentation demonstrating the:

- A. Participant's condition meets the criteria listed in Regulation .05 of this chapter; and
- B. Participant has not already been preauthorized for 2 episodes during the past rolling calendar year.

.09 Payment Methodology.

- A. After providing the services outlined in Regulation .06, the remote patient monitoring provider shall submit the request for payment using the format designated by the Department.
 - B. Home health agencies shall:
 - (1) Bill on a UB04; and
 - (2) Be paid a monthly rate.
 - C. Physicians, nurse practitioners, and physician assistants who provide remote patient monitoring shall:
 - (1) Bill using a CMS 1500 or an 837P; and
 - (2) Be paid a monthly rate.
 - D. Professionals following up on abnormal results from remote patient monitoring shall be paid the lesser of:
 - (1) Provider's customary charge unless the service is free to individuals not covered by Medicaid; or
 - (2) The Department's professional fee schedule as found in COMAR 10.09.02.07.

.10 Recovery and Reimbursement.

Recovery and reimbursement shall be in accordance with COMAR 10.09.36.07.

.11 Cause for Suspension or Removal and Imposition of Sanctions.

Cause for suspension or removal and imposition of sanctions shall be in accordance with COMAR 10.09.36.08.

.12 Appeal Procedures.

Providers filing appeals from administrative decisions made in connection with these regulations shall do so in accordance with COMAR 10.09.36.09.

.13 Interpretive Regulation.

Except when the language of a specific regulation indicates an intent by the Department to provide reimbursement for covered services to Program recipients without regard to the availability of federal financial participation, State regulations shall be interpreted in conformity with applicable federal statutes and regulations.

DENNIS SCHRADER

Secretary of Health