

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	05/21/2015	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 6/26/2015

2. COMAR Codification

Title Subtitle Chapter Regulation

10 25 17 02, .03, .04, and .05

3. Name of Promulgating Authority

Maryland Health Care Commission

4. Name of Regulations Coordinator

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5. Name of Person to Call About this Document

Suellen Wideman

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6. Check applicable items:

- New Regulations
 - Amendments to Existing Regulations
 - Date when existing text was downloaded from COMAR online: January 30, 2015.
 - 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 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 Suellen Wideman, Assistant Attorney General, (telephone #4107643326) on May 21, 2015. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Craig P. Tanio, M.D.

Title

Chairman

Telephone No.

4107643460

Date

May 21, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

10.25.17 Benchmarks for Preauthorization of Health Care Services

Authority: Health-General Article §§19-101 and 19-108.2 Annotated Code of Maryland

Notice of Proposed Action

[]

The Maryland Health Care Commission proposes to amend Regulation .02, .03, .04, and .05 under COMAR 10.25.17 Benchmarks for Preauthorization of Health Care Services.

This action was considered by the Commission at an open meeting on May 21, 2015, notice of which was given through publication in the Maryland Register, pursuant to State Government Article, §10-506, Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to amend the regulations to reflect changes made to Md. Code Ann., Health-Gen. §19-108.2, effective July 1, 2015, and make other appropriate changes. The law added a fourth benchmark requiring certain State-regulated insurers, nonprofit health service plans, health maintenance organizations and pharmacy benefit managers (collectively, “payors”) to establish an electronic process to allow a prescriber to override the step therapy or fail-first protocol (protocol) for pharmaceutical preauthorization requests by July 1, 2015. The proposed amendments include language that payors must notify providers about the online process available to override the protocol and must inform their members about the protocol. A reporting requirement related to the fourth benchmark was added. The amendments remove expired payor reporting requirement dates pertaining to their attainment of the first three benchmarks. A provision was added stating that payors must maintain their electronic preauthorization processes and demonstrate continued compliance with all four benchmarks upon request from the Commission. The proposed amendments change the length of time a waiver is valid from one to two years and require payors to submit a renewal of their waiver request 30 days prior to its expiration; the current regulations require that renewal waiver requests be submitted 45 days prior to expiration.

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 David Sharp, Director, Center for Health Information Technology & Innovative Care Delivery, Maryland Health Care Commission, 4160 Patterson Avenue, Baltimore, MD 21215, or call 410-764-3578, or email to dsharp@maryland.gov, or fax to 410-358-1236. Comments will be accepted through 4:30 p.m. July 27, 2015. A public hearing has not been scheduled.

Open Meeting

Final action on the proposal will be considered by the Commission during a public meeting to be held on September 17, 2015 at 1:00 p.m., at 4160 Patterson Avenue, Baltimore, MD 21215.

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?

Yes

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

Maryland Health Care Commission
Special Funds

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:

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

G. Small Business Worksheet:

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

Chapter 17 Benchmarks for Preauthorization of Health Care Services

Authority: Health-General Article, §§19-101 and 19-108.2, Annotated Code of Maryland

10.25.17.02 (January 30, 2015)

.02 Definitions.

A. (Text unchanged).

B. Terms Defined.

(1) - (5) (Text unchanged)

(6) "Prescriber" means a health care practitioner who has the required license and, if necessary, scope of practice or delegation agreement that permits the health care practitioner to prescribe drugs to treat medical conditions or diseases.

(7) "Step therapy or fail-first protocol" is a protocol established by an insurer, a nonprofit health service plan, a health maintenance organization, or a pharmacy benefits manager that requires a certain prescription drug or sequence of prescription drugs to be used by an insured individual or an enrollee before another specific prescription drug ordered by a prescriber is covered.

(8) "Supporting Medical Information" means:

(a) A paid claim from a payor that requires a step therapy or fail-first protocol for an insured or an enrollee;

(b) A pharmacy record that documents that a prescription has been filled and delivered to an insured or enrollee, or to a representative of an insured or enrollee; or

(c) Other information mutually agreed to that constitutes sufficient supporting medical information by an insured's or enrollee's prescriber and a payor that requires a step therapy or fail-first protocol.

10.25.17.03 (January 30, 2015)

.03 Benchmarks.

A. [On or before October 1, 2012, each] Each payor shall establish and maintain online access for a provider to the following:

(1) - (2) (Text unchanged)

B. [On or before March 1, 2013, or another date established by the Commission, in consultation with its multistakeholder workgroup and published in the Maryland Register, each] Each payor shall establish and maintain an online process for:

(1) - (2) (Text unchanged)

C. [On or before July 1, 2013, or another date established by the Commission, in consultation with its multistakeholder workgroup and published in the Maryland Register, each] Each payor shall establish and maintain an online preauthorization system that meets the requirements of [Insurance Article,] Health General §19-108.2(e), Annotated Code of Maryland, to [approve]:

(1) [In] Approve in real time, electronic preauthorization requests for pharmaceutical services:

(a) - (b) (text unchanged)

(2) [Within] Render a determination within 1 business day after receiving all pertinent information on requests not approved in real time, electronic preauthorization requests for pharmaceutical services that:

(a) - (b) (text unchanged)

(3) [Within] Render a determination within 2 business days after receiving all pertinent information, electronic preauthorization requests for health care services, except pharmaceutical services, that are not urgent.

D. On or before July 1, 2015, a payor that requires a step therapy or fail-first protocol shall:

(1) Establish and shall thereafter maintain an online process to allow a prescriber to override the step therapy or fail-first protocol if:

(a) The step therapy drug has not been approved by the U.S. Food and Drug Administration for the medical condition being treated; or

(b) A prescriber provides supporting medical information to the payor that a prescription drug covered by the payor:

- (i) Was ordered by the prescriber for the insured or enrollee within the past 180 days; and
 - (ii) Based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition;
- (2) Provide notice to prescribers regarding the availability of its online process; and
 - (3) Provide information to insureds or enrollees on the availability of the step therapy or fail-first protocol within its network.

E. A payor that becomes authorized to provide benefits or services within the State of Maryland after October 1, 2012, shall meet each benchmark within [Regulation .03B of] this chapter within [3] three months of the payor's offering of services or benefits within the State and shall thereafter maintain the processes or actions required by each benchmark.

10.25.17.04 (January 30, 2015)

.04 Reporting.

A. On or before [March 1, 2013] August 1, 2015, a payor that requires a step therapy or fail-first protocol shall report to the Commission in a form and manner specified by the Commission on its attainment of the benchmark in Section .03D.

- [(1) The status of the payor's attainment of the benchmarks in Regulation .03A and B of this chapter; and
- (2) An outline of the payor's plans for attaining the benchmark in Regulation .03C of this chapter.]

B. [On or before December 1, 2013, a payor shall report to the Commission in a form and manner specified by the Commission on the payor's attainment of the benchmarks in Regulation .03C.] A payor that becomes authorized to provide benefits or services within the State of Maryland after October 1, 2012, shall report to the Commission in a form and manner specified by the Commission on its attainments of each benchmark in Regulation .03 of this chapter within 3 months of the payor's offering of services or benefits within the State.

C. If requested by the Commission, a payor shall demonstrate continued compliance with the benchmarks in Regulation .03.

10.25.17.05 (January 30, 2015)

.05 Waiver from Benchmark Requirement.

A. A payor may request that the Commission issue or renew a waiver from the requirement to meet a benchmark in Regulation .03[B] of this chapter by the demonstration of extenuating circumstances, including:

- (1) – (3) (Text unchanged)

B. Submission of Request for Waiver or Renewal of Waiver.

- (1) A request for a waiver or renewal of waiver shall be in writing and shall include:

- (a) [A description] An identification of each preauthorization benchmark for which a waiver is requested; and
- (b) (text unchanged)

- (2) A request for a waiver shall be filed with the Commission in accordance with the following:

- (a) For [the benchmark in Regulation .03A of] benchmarks in this chapter, [no later than 30 days after the effective date of this chapter;
- (b) For benchmarks in Regulation .03B and C of this chapter,] no later than 60 days prior to the compliance date; or

- [(c)] (b) For renewal of a waiver, no later than [45] 30 days prior to its expiration.

- (3) (Text unchanged)

C. Issuance of Waiver[s].

- (1) – (2) (Text unchanged)

(3) A waiver or renewal of a waiver shall be valid for [1 year] two years, unless withdrawn by the Executive Director[,] after notice to the payor.

D. Review of Denial of Waiver.

- (1) - (2) (text unchanged)

(3) The payor may address the Commission before [the Commission determines] a determination is made by the Commission as to whether or not to issue a waiver after a request for review of denial of waiver by the Executive Director.

E. (Text unchanged)

