COMAR 10.25.17

Benchmarks for Preauthorization of Health Care Services

Informal Draft Amendments

For Public Comment

Released Friday – April 22, 2022

Health-General Article § 19-108.2 (2012, amended 2014) established four benchmarks, requiring State-regulated insurers, nonprofit health service plans, health maintenance organizations, and pharmacy benefit managers to implement, in a phased approach, electronic preauthorization processes. The MHCC adopted supporting regulations (2013, amended 2015), which includes a process by which a payor may be waived from attaining one or more of the benchmarks.

The MHCC plans to amend the regulations and seeks public comment to this informal draft. Public comments will be accepted until 4:30pm on **Friday, May 13, 2022**; comments should be submitted via email or by mail to:

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Title 10 MARYLAND DEPARTMENT OF HEALTH
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

.01 Scope.

A. This chapter applies to a payor that:

(1) Requires preauthorization for health care services; and

(2) Is required to report to the Maryland Health Care Commission [(Commission) on or before certain dates] on its attainment and plans for attainment of certain preauthorization benchmarks.

B. This chapter does not apply to a pharmacy benefits manager that only provides services for*:*

(1) workers' compensation claims pursuant to Labor and Employment Article, [§9-101, et seq.] *Title 9*, Annotated Code of Maryland [,]*;* or

(2) [for] personal injury protection claims pursuant to Insurance Article, [§19-101, et seq.] *Title 19*, Annotated Code of Maryland.

.02 Definitions.

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

B. Terms Defined.

(1) "Commission" means the Maryland Health Care Commission.

(2) "Executive Director" means the Executive Director of the Commission or the Executive Director's designee.

(3) "Health Care Service" has the meaning stated in Insurance Article, §15-10A-01, Annotated Code of Maryland.

(4) "Payor" means one of the following State-regulated entities that require preauthorization for a health care service:

(a) An insurer or nonprofit health service plan that provides hospital, medical, or surgical benefits to individuals or groups on an expense-incurred basis under health insurance policies or contracts that are issued or delivered in the State;

(b) A health maintenance organization that provides hospital, medical, or surgical benefits to individuals or groups under contracts that are issued or delivered in the State; or

(c) A pharmacy benefits manager that is registered with the Maryland Insurance Commissioner, except for a pharmacy benefits manager that only provides services for*:*

(i) workers' compensation claims pursuant to Labor and Employment Article, [§9-101, et seq.]*Title 9*, Annotated Code of Maryland;[,] or

(ii) [for] personal injury protection claims pursuant to Insurance Article, [§19-101, et seq.]*Title 19*, Annotated Code of Maryland.

(5) "Preauthorization" means the process of obtaining approval from a payor by meeting certain criteria before a certain health care service can be rendered by the health care provider.

(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.

.03 Benchmarks.

A. Each payor shall establish and maintain online access for a provider to the following:

(1) A list of each health care service that requires preauthorization by the payor; and

(2) Key criteria used by the payor for making a determination on a preauthorization request.

B. Each payor shall establish and maintain an online process for:

(1) Accepting electronically a preauthorization request from a provider; and

(2) Assigning to a preauthorization request a unique electronic identification number that a provider may use to track the request during the preauthorization process, whether [or not] the request is tracked electronically, through a call center, or by fax.

C. Each payor shall establish and maintain an online preauthorization system that meets the requirements of Health-General Article, §19-108.2(e), Annotated Code of Maryland, to:

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

(a) For which no additional information is needed by the payor to process the preauthorization request; and

(b) That meet the payor's criteria for approval;

(2) 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) Are not urgent; and

(b) Do not meet the standards for real-time approval under item (1) of this item; and

(3) 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] *Each* 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.]*United States* 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 this chapter within 3 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.

.04 Reporting.

[A. On or before 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 Regulation .03D of this chapter.]

[B]*A*. 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 attainment[s] of each benchmark in Regulation .03 of this chapter within [3]*three* months of the payor's offering of services or benefits within the State.

[C]*B*. If requested by the Commission, a payor shall demonstrate continued compliance with the benchmarks in Regulation .03 of this chapter.

C. A payor that has been granted a waiver under Regulation .05 shall notify the Executive Director if it can no longer demonstrate the extenuating circumstances for which the waiver was granted within 30 days after a payor can no longer demonstrate extenuating circumstances.

.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 of this chapter by the demonstration of *the following* extenuating circumstances[, including]:

(1) For an insurer or nonprofit health service plan, a premium volume that is less than $1,000,000 annually in the State;

(2) For a group model health maintenance organization, as defined in Health-General Article, §19-713.6, Annotated Code of Maryland, preauthorizations of health care services requested by providers not employed by the group model health maintenance organization; or

(3) Other circumstances determined by the Executive Director to be extenuating.

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) An identification of each preauthorization benchmark for which a waiver is requested; and

(b) A detailed explanation of the extenuating circumstances necessitating the waiver.

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

[(a) For benchmarks in this chapter, no later than 60 days prior to the compliance date; or]

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

([3]*b*) For a payor that becomes authorized to provide benefits or services within the State of Maryland after October 1, 2012, within [30 days] *three months* after the date the payor is authorized to provide benefits or services within the State.

C. Issuance of Waiver.

(1) The Executive Director may issue a waiver from a preauthorization benchmark to a payor that demonstrates extenuating circumstances within this chapter.

(2) The Executive Director will review and provide a decision [on] *to approve or deny* all waiver requests within a reasonable timeframe.

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

D. Withdrawal of Waiver

(1) The Executive Director may withdraw a waiver or renewal of a waiver if the Executive Director determines that the payor can no longer demonstrate extenuating circumstances.

(2) If the Executive Director withdraws a waiver or renewal of waiver, the Executive Director shall notify the payor, setting forth in writing the reasons for withdrawal.

(3) After a waiver or a renewal of a waiver is withdrawn, a payor must submit a plan to the Executive Director within 30 days that includes a timeline for attaining each benchmark in Regulation .03 in a format approved by the Commission.

[D]*E*. Review of Denial *or Withdrawal* of Waiver.

(1) *If the Executive Director has denied or withdrawn a waiver*, [A]*a* payor [that has been denied a waiver] may seek Commission review of [a]*the* denial *or withdrawal* by filing a written request for review with the Commission within 20 days of receipt of the Executive Director's *notice of* denial *or withdrawal* of waiver.

(2) The full Commission may hear the request for review directly or, at the discretion of the Chair of the Commission, appoint a Commissioner to review the request *submitted under Regulation .05B*, who will make a recommendation to the full Commission.

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

[E]*F*. A waiver or renewal of waiver from the requirements of this chapter may not be sold, assigned, leased, or transferred.

.06 Fines.

A payor that does not meet the reporting requirements of this chapter may be assessed a fine in accordance with COMAR 10.25.12.[01, et seq.]