



Proposed Amendments

COMAR 10.25.17

Preauthorization Regulations

March 19, 2026

Please note: Text in italics and brackets reflect proposed amendments. Proposed amendments incorporate feedback Commission staff received during an informal comment period in October and November 2025.

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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]103, [and]19-108.2, 19-108.5, and 19-109 Annotated Code of Maryland

.01 Scope.

A. This chapter applies to[a payor that]:

(1) [Requires]A *payor that requires preauthorization or step therapy* for health care services; and

(2) [Is required to report to the Maryland Health Care Commission on its attainment and plans for attainment of certain preauthorization benchmarks.]A *health care provider*.

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, Title 9, Annotated Code of Maryland; or

(2) Personal injury protection claims pursuant to Insurance Article, Title 19, Annotated Code of Maryland.

.02 Definitions.

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

B. Terms Defined.

(1) "*Carrier*" has the meaning stated in the Insurance Article, §15–1301, Annotated Code of Maryland.

[(1)](2) "Commission" means the Maryland Health Care Commission.

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

(4) "*Health care provider*" has the meaning stated in Health-General Article, §19–108.3, Annotated Code of Maryland.

[(3)](5) "Health care service" has the meaning stated in Insurance Article, §15-10A-01, Annotated Code of Maryland.

(6) "*Online process*" means the process established by carriers that meets the requirements outlined in Health-General Article, § 19-108.5(b)(1), Annotated Code of Maryland.

[(4)](7) "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;]A *carrier*; or

(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, Title 9, Annotated Code of Maryland; or

(ii) Personal injury protection claims pursuant to Insurance Article, Title 19, Annotated Code of Maryland.

[(5)](8) "Preauthorization" means the process of obtaining approval *for coverage* from a payor by meeting certain criteria before a certain health care service [can be]is rendered by the health care provider.

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

[(7)](10) "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]a payor 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)](11) "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.]Online Process Requirements.

A. [Each]A 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]A payor shall establish and maintain an online process [for:]that meets the requirements of §§19-108.2 and 19-108.5 of the Health General Article, Annotated Code of Maryland.

C. A payor's online process shall:

- (1) [Accepting electronically a]Accept electronic preauthorization [request]requests from a health care provider; [and]
- (2) [Assigning to a preauthorization request]Assign a unique electronic identification number [that a provider may use to track the request during the preauthorization process, whether the request is tracked electronically, through a call center, or by fax]to each preauthorization request;
- (3) Link directly to all e-prescribing systems and electronic health record systems that use the National Council for Prescription Drug Programs SCRIPT standard and the National Council for Prescription Drug Programs Real-Time Benefit Standard;
- (4) Provide accurate, real-time patient-specific benefit information to insureds, enrollees, and contracted health care providers, including any:
 - (a) Copayment, deductible, coinsurance, or other out-of-pocket costs;
 - (b) More affordable medication alternatives; and
 - (c) Preauthorization requirements;
- (5) Provide the information required under §C(4) of this regulation at the point of prescribing in an accessible and understandable format;

[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)](6) 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) For which no clinical review is required; and

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

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

(a) Are not urgent; and

(b) Do not meet the standards for real-time approval under §C[(1)](6) of this regulation;

and

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

D. [Each]A payor that requires a step therapy or fail-first protocol shall:

(1) *Comply with Insurance Article, §15-142(e), Annotated Code of Maryland;*

(2) Establish and 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 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)](3) Provide notice to prescribers regarding the availability of its online process; and

[(3)](4) 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.]A payor may not:

(1) *Impose a fee or charge a person for accessing its online process; or*

(2) *Access, without health care provider consent, health care provider data via the online process other than for the insured or enrollee.*

.04 Reporting

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 of each benchmark in Regulation .03 of this chapter within 3 months of the payor's offering of services or benefits within the State.

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

[C.]B. A payor that has been granted a waiver under Regulation .05 of this chapter 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 Payor Waiver from [Benchmark]Requirement.

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

(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]preauthorization 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]requirement 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 renewal of a waiver, no later than 30 days prior to its expiration; or

(b) For a payor that becomes authorized to provide [benefits or]services within the State of Maryland after October 1, 2012, within [3]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]requirement to a payor that demonstrates extenuating circumstances within this chapter.

(2) The Executive Director will review and provide a decision to approve or deny all waiver requests within a reasonable time frame.

(3) A waiver or renewal of a waiver shall be valid for [2]two years, unless withdrawn by the Executive Director.

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 shall submit a plan to the Executive Director within 30 days that includes a timeline for attaining each [benchmark]requirement in Regulation .03 of this chapter in a format approved by the Commission.

E. Review of Denial or Withdrawal of Waiver.

(1) If the Executive Director has denied or withdrawn a waiver, a payor may seek Commission review of 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 a waiver, which shall:

(a) State with particularity the grounds and factual basis for a payor's disagreement with the denial or withdrawal decision;

(b) Specify the remedy requested; and

(c) If desired, include a written request to orally address the Commission, which shall be scheduled if requested.

(2) The full Commission may review the written request for review of a denial or withdrawal of a waiver directly or, at the discretion of the Chair of the Commission, appoint a Commissioner to review the request submitted under §E(1) of this regulation, who will make a recommendation to the full Commission.

(3) If a written request was submitted under §E(1)(c) of this regulation, a payor may orally address the Commission before a determination is made by the Commission as to whether or not to issue or withdraw a waiver.

(4) After reviewing and considering a payor's written request for review of the denial or withdrawal decision and any oral argument, if applicable, the full Commission shall issue a written decision affirming, reversing, or modifying the decision reviewed.

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

G. A payor that has been granted a waiver under this regulation 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.

.06 Provider Requirements and Waiver.

A. On or before July 1, 2026, a health care provider shall ensure that each e-Prescribing system or electronic health record system owned or contracted for by the health care provider to maintain a health record of an insured or enrollee has the ability to access, at the point of prescribing:

- (1) The electronic preauthorization process established by a payor; and*
- (2) The real-time patient out of pocket cost information and available medication alternatives.*

B. Health Care Provider Waiver Requirements.

(1) A health care provider may request that the Commission issue or renew a waiver from the requirements in §A of this regulation by demonstration of the following extenuating circumstances:

- (a) Economic hardship;*
- (b) Technology limitations; or*
- (c) Other circumstances determined by the Commission to be extenuating.*

(2) A health care provider seeking a waiver from the requirements of § A of this regulation shall submit an attestation to the Commission using the form on the Commission's website.

[.06].07 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.]A. A payor that becomes authorized to provide services within the State after the effective date of a requirement in this chapter shall meet each requirement within this chapter within three months of offering services.

B. A person that fails to meet a requirement of this chapter may be subject to a financial penalty based on:

- (1) The person's ability to pay;*
- (2) The willfulness of the improper conduct;*
- (3) The extent of actual or potential public harm caused by the violation;*
- (4) The cost of auditing or investigating the matter; and*
- (5) The person's history of any previous violation.*

C. A person assessed a fine may challenge the assessment in accordance with the procedure outlined in COMAR 10.25.12.02.

Administrative History

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