



## **Draft Amendments**

### **COMAR 10.25.17, *Preauthorization of Health Care Services***

October 16, 2025

The Maryland Health Care Commission seeks public comment to informal draft amendments to COMAR 10.25.17. The draft amendments align with federal policy, strengthen transparency, and support the implementation of Chapter 848 (Senate Bill 791) and Chapter 847 (House Bill 932), *Health Insurance - Utilization Review - Revisions* (2024).

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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) *A payor that [R]requires preauthorization, concurrent authorization, or step therapy for health care services or imposes quantity limits on 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) *"Adverse decision" has the meaning stated in Insurance Article, § 15-10A-01(b)(1), Annotated Code of Maryland.*

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

(3) *"Commission" means the Maryland Health Care Commission.*

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

[(3)](5) *"Concurrent authorization" means the process of a payor choosing whether to allow, deny, or otherwise limit coverage of a course of treatment, in whole or in part, while a patient is actively undergoing treatment.*

(6) *"Clinical criteria requirement" means criteria based on current evidence in widely used treatment guidelines or clinical literature.*

(7) *"Health Care [Service]Provider" has the meaning stated in Health-General Article, § 19–108.3, Annotated Code of Maryland.*

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

[(4)] (9) *"Internal coverage criteria" means the specific clinical criteria reviewed or updated for all reviews used by a payor to make coverage determinations, including preauthorization, concurrent authorization, step therapy, or quantity limits.*

(10) *"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.*

(11) *"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)](12) *"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)](13) *"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)](14) *"Quantity limits" means restrictions by a payor on the amount, dosage, or frequency of a drug, device, or service that the payor will cover within a specified time period, including but not limited to:*

(a) *Limits based on clinical guidelines or safety protocols;*

(b) *Maximum units allowed per prescription or per time interval;*

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- (c) *Frequency caps on refills or administrations; and*
- (d) *Requirements tied to utilization management criteria.*

(15) *“Publicly accessible” means the general public can access the material on the payor’s website without the need to:*

- (a) *Pay a fee;*
- (b) *Establish a user account or password;*
- (c) *Submit personal identifying information; or*
- (d) *Navigate numerous pages*

(16) *“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)](17) *“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.*

(18) *“Widely used treatment guidelines” means nationally recognized organizations that represent clinical medical specialties as described in § 15-10B-05(a)(11)(iv), Annotated Code of Maryland.*

**.03 [Benchmarks.] Online Process Requirements.**

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] *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.*

*B. A payor’s online process shall:*

- (1) *[Accepting electronically a preauthorization request]Accept electronic preauthorization 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 track the request, including any out-of-pocket costs and more affordable medication alternatives or preauthorization requirements;*
- (5) *Provide the information required under §B(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]health care 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[,] 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)]B(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]C. *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.

B.] *D. 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.] Information about Preauthorization, Concurrent Authorization, Step Therapy, and Quantity Limits.**

[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.]

*A. By September 30, 2026, a payor shall make the following information publicly accessible in a clear, searchable online format determined by the Commission:*

(1) *A comprehensive list by product offered by the payor of health care services that require preauthorization, concurrent authorization, step therapy, and quantity limits;*

(2) *Contact information for inquiries related to preauthorization, concurrent authorization, step therapy, or quantity limits;*

(3) *Links to the individual internal coverage criteria corresponding to each health care service, and the summary of clinical standards and evidence-based practices that support each internal coverage criteria; and*

(4) *A list of internal coverage criteria for each health care service that is subject to a preauthorization, concurrent authorization, or step therapy requirement, along with the current clinical standards and evidence-based practices used in their development that shall include:*

(a) *A list of the citations of sources of clinical evidence, which shall only include widely accepted treatment guidelines and peer-reviewed literature that justify the coverage criteria;*

(b) *An explanation of the rationale supporting the adoption of the coverage criteria, describing how the clinical evidence was evaluated and applied to the specific health care service, with each claim cited;*

(c) *Identification of the clinical specialty organizations responsible for developing any referenced widely used treatment guidelines; and*

(d) *A description of how the coverage criteria align with current standards of care and evidence-based practice.*

*B. Peer-reviewed literature used to justify internal coverage criteria shall be specifically designed to answer the clinical questions most relevant to the coverage criteria, published in peer-reviewed journals, and demonstrate clear and consistent findings, which meet rigorous standards of quality and relevance from acceptable sources using the following methods:*

(a) *All or none studies with definitive outcomes;*

(b) *Large, randomized controlled trials or cohort studies;*

(c) *Non-randomized prospective studies; and*

(d) *Systematic reviews or meta-analyses that summarize the literature using transparent methodology.*

*C. A payor shall include a txt file in the root directory of the website domain that includes a direct link to the information required by §A of this regulation.*

*D. A payor may not issue an adverse determination decision if:*

(1) *The requirements listed in §A-C of this regulation are not fulfilled;*

(2) *The payor has not complied with the requirements of Insurance Article, Title 15, Subtitle 10, Annotated Code of Maryland; or*

(3) *The payor or a private review agent acting on the carrier's behalf has not complied with the requirements of Insurance Article, Title 15, Subtitle 10b, Annotated Code of Maryland.*

*E. A payor shall annually review and update its internal coverage criteria based on the following:*

(1) *The health care services to which preauthorization, concurrent authorization, step therapy, and quantity limits apply;*

(2) *Coverage decisions and guidelines; and*

(3) *Relevant current clinical guidelines.*

*F. A payor shall revise its policies as necessary to comply with this regulation or upon request of the Commission, including the removal of requirements for health care services that no longer warrant preauthorization, concurrent authorization, step therapy, and quantity limits.*

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G. A payor shall make the information in §A of this regulation available to the Commission within 30 days of a written request.

H. A payor shall post on its website in a manner that is publicly accessible:

(1) The name(s) of the private review agent(s) used in conducting a preauthorization review, concurrent review, step therapy, and quantity limits;

(2) A copy of the private review agent's internal grievance process if a carrier delegates its internal grievance process to the private review agent in accordance with Insurance Article, § 15–10A–02(l), Annotated Code of Maryland; and

(3) The procedures and policies to ensure that a representative of the private review agent is reasonably accessible to patients and health care providers seven days a week, 24 hours a day.

**.05 Reporting.**

A. If requested by the Commission, a payor shall demonstrate continued compliance with the [benchmarks in] preauthorization requirements in Regulation .03 and .04 of this [chapter]Chapter.

B. Preauthorization Utilization Summary.

(1) Beginning in calendar year 2027, by June 30 each year, a payor shall submit to the Commission for the prior calendar year, or more frequently at the request of the Commission, a Preauthorization Utilization Summary of the use of preauthorization, concurrent authorization, step therapy, and quantity limits.

(2) A payor shall minimally submit the following metrics regarding coverage of health care services in aggregate and stratified by each health care service that requires preauthorization, concurrent authorization, step therapy, or quantity limits:

(a) The percentage of standard requests that were approved;

(b) The percentage of standard requests that were denied;

(c) The percentage of standard requests that were approved after appeal;

(d) The percentage of standard requests for which the timeframe for review was extended, and the request was approved;

(e) The percentage of expedited requests that were approved;

(f) The percentage of expedited requests that were denied;

(g) The average time that elapsed between the submission of a request and a determination by the payor, for standard preauthorization, concurrent authorization, step therapy, or quantity limits; and

(h) The average time that elapsed between the submission of a request and a decision by the payor for expedited preauthorization, concurrent authorization, step therapy, and quantity limits.

(3) At the request of the Commission, a payor shall break down the metrics identified in § B(2) by demographic, medical and social risk, or other factors.

(4) A payor shall annually post the results of the Preauthorization Utilization Summary on the payor's website in a manner that is publicly accessible.

C. Annual Coverage Compliance Review.

(1) Beginning in calendar year 2026, by November 30 each year, a payor shall submit to the Commission an Annual Coverage Compliance Review of Regulation .04 for the prior year.

(2) A payor shall:

(a) Use an accredited independent review organization recognized by the Commission and listed on the Commission's website to complete the Annual Coverage Compliance Review; and

(b) Post a summary of the findings on the payor's website in a manner that is publicly accessible.

[C.]D. A payor that has been granted a waiver under Regulation .06 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].06 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]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.

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(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 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 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.

## **.07 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 Online Process 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;*

*(c) Prescribing less than 100 prescriptions annually; or*

*(d) 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 Commission using the form on the Commission's website.*

## **[.06].08 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:*

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- (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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