Draft Amendments

COMAR 10.25.17

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Presentation Overview

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Framing the Discussion

Federal policy changes in prior authorization aim to reduce administrative burden and improve timely access to care. The Centers for Medicare & Medicaid Services (CMS) recently finalized rules that include prior authorization requirements for faster timelines, communication of denials, performance metrics, and use of APIs to enable efficient data exchange. **Aligning with federal policy helps standardize prior authorization across payors and states.**

Background – State Law

- Maryland law required a phased implementation of four prior authorization benchmarks beginning in 2012; includes a requirement for payors to provide online access to a listing of all medical services and pharmaceuticals that require prior authorization and the key criteria for making a determination (see Appendix)
  - State-regulated insurers, nonprofit health service plans, health maintenance organizations, and pharmacy benefits managers have complied with the law

Background – State Law *(continued…)*

- Legislation enacted in 2024 requires payors to implement an online process to improve prior authorization at the point of prescribing*
  - Must meet specified parameters by July 1, 2026; most payors have complied with the law (as of September 2025)
    - Link to all e-prescribing and electronic health record (EHR) systems using data exchange standards**
    - Accept electronic prior authorization requests from a health care provider
    - Approve prior authorization requests when no additional information or clinical review is required, and that meet the payor's criteria for approval
    - Link directly to real-time patient out-of-pocket costs (i.e., copayment, deductible, and coinsurance) and more affordable medication alternatives at the point of prescribing

** Chapter 848 (Senate Bill 791) and Chapter 847 (House Bill 932), Health Insurance - Utilization Review – Revisions (2024) – includes several other provisions pertaining to health insurance utilization review, internal grievance and adverse decision procedures, payor reporting on adverse decisions, and the provision of patient benefit information*

*** Includes the NCPDP SCRIPT Standard and the NCPDP Real Time Benefit Standard*

Federal Policy

- April 2023: CMS finalized a rule that requires Medicare Advantage plans to implement improvements to the prior authorization process starting in 2024
  - Internal coverage criteria must be publicly available and based on current evidence in widely used treatment guidelines or clinical literature
  - Prior authorization requests must be reviewed by clinicians with relevant expertise and be valid for an entire course of approved treatment and during transitions to a new plan for at least 90 days

Federal Policy *(continued…)*

- April 2025: CMS finalized a rule that further strengthens protections for consumers enrolled in or seeking coverage from Medicare Advantage plans in 2026
  - Restricts plans from reopening and modifying previously approved prior authorizations for inpatient hospital decisions
  - Ensures the appeals process applies to any denial whether the decision is made before, during, or after care is received

See Appendix for more information on federal policy pertaining to use of APIs

A Call to Action – 2025

- In response to growing concerns that prior authorization delays patient access to care, AHIP* in collaboration with the federal government, implemented an initiative that aims to improve access to care and reduce administrative burdens for patients and providers
- More than 50 payors have voluntarily pledged a commitment to:
  - Standardize electronic prior authorization
  - Reduce the scope of claims subject to prior authorization
  - Ensure continuity of care when patients change plans
  - Enhance communication and transparency on determinations
  - Expand real-time responses
  - Ensure medical review of non-approved requests

**AHIP (America's Health Insurance Plans) is a national trade association representing numerous payers*

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Leading Objectives – Regulation Enhancements

- Support Implementation of Maryland Law*
- Increase Transparency and Enable Public Access
- Ensure Use of Evidence-Based Utilization Management
- Strengthen Accountability and Reporting

*Chapter 848 (Senate Bill 791) and Chapter 847 (House Bill 932), *Health Insurance - Utilization Review – Revisions* (2024)

Amendments – Highlights

- Adds health care provider to the Chapter's scope (for waiver provisions related to the online process under new regulation .07B) – regulation .01A

- Add new definitions for adverse decision, carrier, concurrent authorization, clinical criteria requirement, health care provider, internal coverage criteria, online process, quantity limits, publicly accessible, and widely used treatment guidelines – regulation .02B (1), (2), (5), (6), (7), (9), (10), (14), (15), and (18)

- Requires payors to implement an online process consistent with legislation enacted in 2024 (Health-General § 19-108.5) – regulation .03B

Draft Amendments – Highlights *(continued…)*

- Requires payors to make certain information available in a publicly accessible format by September 30, 2026 – regulation .04A
  - Comprehensive list by product of health care services that require preauthorization, concurrent authorization, step therapy, and quantity limits – .04A (1)
  - Contact information for inquiries related to preauthorization, concurrent authorization, step therapy, and quantity limits – .04A (2)
  - Links to internal coverage criteria corresponding to each health care service and the summary of clinical standards and evidence-based practices that support each criteria – .04A (3)

Draft Amendments – Highlights *(continued…)*

- A list of internal coverage criteria for each health care service subject to preauthorization, concurrent authorization, step therapy, and quantity limits along with the current clinical standards and evidence-based practices used in their development – .04A (4)
  - A list of citations of sources of clinical evidence…. – (a)
  - An explanation of the rationale supporting adoption of the criteria… – (b)
  - Identification of the clinical specialty organizations responsible for developing any referenced widely used treatment guidelines – (c)
  - A description of how the criteria align with current standards of care and evidence-based practice – (d)

Draft Amendments – Highlights *(continued…)*

- Requires peer-reviewed literature used to justify internal coverage criteria to be specifically designed to answer clinical questions most relevant to the 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 specific methods – regulation .04B
- Requires a payor to include a txt file on the website with a direct link to the information required under §A – regulation .04C
- Prohibits a payor from issuing and adverse determination under certain circumstances – regulation .04D
- Requires payors to annually review and update internal coverage criteria – regulation .04E

Draft Amendments – Highlights *(continued…)*

- Requires a payor to 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 – regulation .04F
- Requires a payor to make information under §A available to Commission within 30-days of a written request – regulation .04G
- Requires a payor to post on its website in a publicly accessible manner certain information related to private review agent(s) used in conducting a preauthorization review, concurrent review, step therapy, and quantity limits – regulation .04H

Draft Amendments – Highlights *(continued…)*

- Requires payors to demonstrate compliance with regulations .03 and .04 – regulation .05A

- Requires payors to submit to the Commission a Preauthorization Utilization Summary beginning 2027 on the use of preauthorization, concurrent authorization, step therapy, and quantity limits; specifies certain metrics that must be broken down by demographic, medical and social risks, and other factors, if requested by the Commission; and requires the information to be posted on payor's website in a publicly accessible manner – regulation .05B (1), (2), (3) and (4)

Draft Amendments – Highlights *(continued…)*

- Requires an annual coverage compliance review beginning 2026; payors must use an accredited Independent Review Organization recognized by the Commission and post a summary of findings on its website in a publicly accessible manner – regulation .05C

- Adds a new regulation for a waiver process for health care providers unable to access the State-mandated online process – regulation .07

- Clarifies fining authority, including when a payor may be subject to a penalty – regulation .08

Next Steps – Timeline

- Release draft amendments for a 30-day informal public comment period
- Present proposed amendments to the Commission for consideration in December
- Finalize regulations in Q2 2026 (anticipated)

The End

Appendix

Other Federal Policy

- January 2024: CMS finalized a rule that requires all federally regulated payors to implement technical and non-technical requirements, including delivering prior authorization decisions within specified timeframes, reporting certain metrics, providing reasons for a prior authorization denial, and requiring payors to connect to EHR systems via application programming interfaces (APIs)
  - Applies to medical items and services, not prescription drugs
  - Many payors are still in the early stages of implementing the APIs, with the process widely viewed as technically challenging
  - Must comply with non-technical provisions by January 1, 2026 and technical provisions (APIs) by January 1, 2027

Prior Authorization Benchmarks

- Provide online access to a listing of all medical services and pharmaceuticals that require preauthorization and the key criteria for making a preauthorization determination
- Establish an online system to receive preauthorization requests electronically and assign a unique identification number to each request for tracking purposes
- Ensure all electronic preauthorization requests for medical services and pharmaceuticals are approved within established timeframes
- Provide online access to a listing of all medical services and pharmaceuticals that require preauthorization and the key criteria for making a preauthorization determination