SB 791

Department of Legislative Services

Maryland General Assembly
2024 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 791 (Senator Klausmeier)

Finance Health and Government Operations

Health Insurance - Utilization Review - Revisions

This bill, among other things, (1) requires carriers, by July 1, 2026, to establish and maintain an online process for prior authorizations that meets specified parameters; (2) alters current requirements for the prior authorization of specified prescription drugs; (3) requires carriers to comply with certain requirements when rendering adverse decisions; (4) alters timelines for certain adverse decisions; (5) alters and adds to the criteria and standards that must be used by private review agents; and (6) requires existing benchmarks for standardizing and automating preauthorization of health care services and payors' online preauthorization systems to include certain utilization criteria. The bill includes study and reporting requirements involving the Maryland Health Care Commission (MHCC) and the Maryland Insurance Administration (MIA). The bill also repeals obsolete provisions and makes conforming changes. **The bill generally takes effect January 1, 2025; the bill's study and reporting requirements take effect July 1, 2024.**

Fiscal Summary

State Effect: Minimal increase in MIA special fund revenues in FY 2025 from the $125 rate and form filing fee. Any additional workload on MHCC and MIA can likely be absorbed within existing budgeted resources. Expenditures for the State Employee and Retiree Health and Welfare Benefits Program likely increase by $1.75 million in FY 2025 (but may increase by as much as $12.5 million), increasing to $3.5 million (or as much as $25.0 million) annually thereafter, as discussed below.

Local Effect: To the extent health insurance costs increase under the bill, health care expenditures for local governments that purchase fully insured health benefit plans may increase. Revenues are not affected.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary:

Definitions

The definition of "health care service" is expanded to include a health or medical care procedure or service rendered by a health care provider that provides any other care, service, or treatment of disease or injury, the correction of defects, or the maintenance of physical or mental well-being of human beings. Additionally, the definition of "adverse decision" is expanded to include a utilization review determination based on a prior authorization or step therapy requirement.

"Course of treatment" means treatment that (1) is prescribed to treat or ordered for the treatment of an insured with a specific condition; (2) is outlined and agreed to by the insured and the health care provider before the treatment begins; and (3) may be part of a treatment plan.

"Active course of treatment" means a course of treatment for which an insured is actively seeing a health care provider and following the course of treatment.

Establishment of Online Processes

By July 1, 2026, carriers must establish and maintain an online process that can (1) link directly to all e-prescribing systems and electronic health record systems that use specified standards; (2) accept electronic prior authorization requests from a health care provider; (3) approve electronic prior authorization requests, as specified; and (4) link directly to real-time patient out-of-pocket costs and more affordable medication alternatives made available by the carrier. A carrier may not impose a fee or charge on a person for accessing the online process. Additionally, a carrier may not access health care provider data via the online process other than for the insured or enrollee, without consent.

By July 1, 2025, a carrier must (1) post the contact information for each third-party vendor or other entity that the carrier will use to establish the online process on its website and (2) on the request of a health care provider, provide the contact information for each third-party vendor or other entity.

By July 1, 2026, each health care provider must ensure that the e-prescribing system or electronic health record system they use has the ability to access, at the point of prescribing, (1) the electronic prior authorization process established by a carrier and (2) the real-time patient out-of-pocket cost information and available medication alternatives.

By July 1, 2026, each carrier, or pharmacy benefits manager (PBM) on behalf of the carrier, must provide real-time patient specific benefit information to insureds and enrollees and contracted health care providers. A carrier or PBM must ensure the information provided is accurate and delivered in an accessible and understandable format, as specified.

Prior Authorization for Prescription Drugs

The bill requires that, on receipt of information documenting a prior authorization from the insured or the insured's health care provider, a carrier must honor a prior authorization granted from a previous entity for at least the *lesser of 90 days or the length of the course of treatment*.

A carrier may not require a health care provider to submit a request for another prior authorization for a prescription drug if (1) the insured changes health benefit plans that are both covered by the same carrier and the prescription drug is a covered benefit under the current health benefit plan or (2) the dosage for the approved prescription drug changes and the change is consistent with U.S. Food and Drug Administration (FDA) label dosages (the prohibition does not apply for a dosage change for an opioid).

The bill repeals the requirement that a carrier, when issuing an adverse decision denying coverage for a prescription drug, must provide a detailed written explanation for the denial of coverage.

Restrictions on Issuing an Adverse Decision: Except for a provider employed by a group health maintenance organization (HMO), a carrier may not issue an adverse decision on a reauthorization for the same prescription drug or request additional documentation from the prescriber for the reauthorization request if the following is true:

- the prescription drug is a biological product used for immunotherapy or for the treatment of a mental disorder, as specified;
- the carrier previously approved a prior authorization for the prescription drug for the insured;
- the insured has been treated with the prescription drug without interruption since the initial approval of the prior authorization; and
- the prescriber attests that, based on the prescriber's professional judgment, the prescription drug continues to be necessary to effectively treat the insured.

Notice Requirements: If the prescription drug that is being requested has been removed from the formulary or moved to a higher deductible, copayment, or coinsurance tier, the carrier must provide the insured and the insured's health care provider with notice of the

change at least 30 days in advance. The notice must include the process for requesting an exemption, as specified.

If a carrier implements a new prior authorization requirement for a prescription drug, the carrier must provide notice at least *60 days* before implementation of the new requirement. The carrier's notice must indicate that the insured may remain on the prescription drug at the time of reauthorization if the conditions specified above exist.

Prior Authorization of a Course of Treatment

Specified entities must approve a request for the prior authorization of a course of treatment that is (1) for a period of time that is as long as necessary to avoid disruption in care and (2) determined in accordance with applicable coverage criteria, the insured's medical history, and the health care provider's recommendation. For new enrollees, specified entities may not disrupt or require reauthorization for an active course of treatment for covered services until at least 90 days after the enrollment date.

These provisions apply to (1) an insurer, nonprofit health service plan, or HMO that provides hospital, medical, or surgical benefits; (2) an insurer, nonprofit health service plan, or HMO that contracts with a private review agent; and (3) an insurer, nonprofit health service plan, or HMO that contracts with a third party to dispense medical devices, appliances, or goods.

Internal Grievance Procedures

Emergency Cases: The bill repeals a provision requiring that regulations issued by the Insurance Commissioner are the basis for whether a grievance is considered an emergency case. Instead, a carrier must initiate the expedited procedures required for an emergency case if (1) the member or the member's representative requests the expedited review or (2) the health care provider, or the member or the member's representative, attests that the adverse decision was rendered for health care services that are proposed but have not been provided and the services are necessary to treat a condition or illness that, without immediate medical attention, would seriously jeopardize a member's life or health, cause the member to be a danger to the member's self or others, or cause the member to continue using intoxicating substances in an imminently dangerous manner.

Nonemergency Cases: For nonemergency cases, when a carrier renders an adverse decision, the carrier's written notice to the member, the member's representative, and the health care provider acting on behalf of the member must include the reasoning used to determine that the health care service is not medically necessary and did not meet the carrier's criteria and standards used in conducting the utilization review. The written notice must also provide the specific *reference, language, or requirements* from the criteria and

standards on which the decision was based and may not solely use language directing the member to review the additional coverage criteria in the member's policy or plan documents. Finally, the business telephone number provided in the written notice must be a dedicated number for adverse decisions. Similar requirements apply when a carrier issues a nonemergency grievance decision.

Incomplete Grievances: If a member, a member's representative, or a health care provider on behalf of the member files a grievance with a carrier and the carrier lacks sufficient information to complete its internal grievance process, the carrier must take specified actions within five working days of the grievance being filed. In addition to other actions required under current law, after confirming through a complete review of any information already submitted by the health care provider, the carrier must (1) request the specific information that must be submitted to complete the internal grievance process and (2) provide the specific reference, language, or requirements from the criteria and standards used by the carrier to support the need for the additional information.

Additional Reporting Requirements

In its quarterly reports to the Commissioner describing its activities regarding grievance decisions, a carrier must, in addition to complying with existing reporting requirements, include the following information: (1) whether an adverse decision issued by the carrier involved a prior authorization or step therapy protocol; (2) the number of adverse decisions overturned after a reconsideration request; and (3) the number of requests made and granted for nonformulary prescription drugs.

The Commissioner, when compiling an annual summary report for the Governor and General Assembly from the information provided by carriers, must report any violations by a private review agent.

Private Review Agents

Certificate of Registration: A private review agent applying for a certificate of registration from the Commissioner must attest that the criteria and standards to be used in conducting utilization review are generally recognized by health care providers practicing in the relevant clinical specialties and are:

- objective and clinically valid (as specified under current law);
- reflected in published peer-reviewed scientific studies and medical literature;
- developed by specified entities;
- recommended by federal agencies;
- approved by FDA as part of drug labeling;

- taking into account the needs of atypical patient populations and diagnoses;
- sufficiently flexible to allow deviations from norms when justified on a case-by-case basis;
- ensuring quality of care of health care services;
- reviewed, evaluated, and updated at least annually and as necessary to reflect any changes; and
- in compliance with any other criteria and standards required for coverage, as specified.

A private review agent applying for a certificate of registration must submit (1) if applicable, any provisions by which patients, *or* physicians, hospitals, *or other health care practitioners* may seek reconsideration; and (2) a list of the persons involved in establishing the specific criteria and standards to be used in conducting utilization review, including each person's *board certifications or practice specialty, licensure category, and title within the person's organization*.

Posting a Copy of Utilization Review Criteria and Standards: A private review agent must post the specific criteria and standards to be used in conducting utilization review, as well as any subsequent revisions, modifications, or additions, on its website or the carrier's website. A private review agent may not charge a fee to provide this information, with the exception of a reasonable fee to provide the information in hard copy format.

Making Determinations: The bill alters or adds the following requirements for a private review agent:

- A private review agent must make all initial determinations on whether to authorize or certify a nonemergency course of treatment or *health care service, including pharmaceutical services not submitted electronically,* within two working days after receipt of the information necessary to make the determination.
- A private review agent must make all determinations to authorize or certify a request for additional visits or days of care submitted as part of an existing course of treatment or treatment plan within one working day after receipt of the information necessary to make the determination.
- If after receipt of an initial request for health care services, and confirming through a complete review of information already submitted by the health care provider, a private review agent does not have sufficient information to make a determination, the private review agent must promptly, and within three calendar days after receipt of the initial request, inform the health care provider that additional information must be provided by specifying the information that must be submitted to complete the request and the criteria and standards to support the need for additional information.

- If a private review agent needs additional information to determine whether to authorize or certify an inpatient admission, or an admission for residential crisis services, for the treatment of a mental, emotional, or substance abuse disorder, the private review agent *must promptly request the specific information needed*.
- For electronic submissions of a step therapy exception request or a prior authorization request for pharmaceutical services, if a private review agent does not have sufficient information to make a determination, the private review agent, after confirming through a complete review of the information submitted by the health care provider, must request the information promptly, within three calendar days of receiving the initial request, by specifying the information that must be submitted to complete the request and the criteria and standards to support the need for additional information.
- Except as specified, a private review agent must make initial determinations on whether to authorize or certify an emergency course of treatment or health care service for a member within 24 hours of the initial request after receipt of the information necessary to make the request. If the private review agent needs additional information after confirming through a complete review of the information already submitted by the health care provider, the private review agent must promptly request the specific information needed and within 2 hours after receipt of the information, notify the health care provider of the authorization or certification determination.
- A private review agent must initiate the expedited procedure for an emergency case if the patient or the patient's representative requests or if the health care provider attests that the services are necessary to treat a condition or illness that, without immediate medical attention, would seriously jeopardize a member's life or health, cause the member to be a danger to the member's self or others, or cause the member to continue using intoxicating substances in an imminently dangerous manner.

If a private review agent fails to make a determination within the time limits required, the request is deemed approved.

Health Care Provider Access to Physician That Rendered Adverse Decision: The bill specifies that if an initial determination is made by a private review agent not to authorize or certify a health care service and the health care provider believes the determination warrants immediate reconsideration, the private review agent *must* give the health care provider the opportunity to speak with the physician that rendered the determination, by telephone on an expedited basis, within 24 hours of the health care provider seeking the reconsideration.

If the physician is unable to immediately speak with the health care provider seeking the reconsideration, the physician must provide the health care provider with specified contact information that the health care provider can use to contact the physician.

Qualification of Physician on Panel Who Renders Adverse Decisions: The bill specifies that at least one *licensed* physician on the panel who renders an adverse decision, in addition to being board certified or eligible in the same specialty as the treatment under review, must be *knowledgeable about the requested health care service or treatment through actual clinical experience*. When the health care service under review is a dental service, the adverse decision must be made by a licensed dentist, or a panel of other appropriate health care service reviewers with at least one licensed dentist on the panel *who is knowledgeable about the required health care service or treatment through actual clinical experience*.

Reports, Studies, and Workgroups Required under the Bill

Development of Standards for Payor Programs: Uncodified language requires MHCC and MIA, in consultation with health care practitioners and payors, to jointly conduct a study on the development of standards for the implementation of payor programs to modify prior authorization requirements for prescriptions drugs, medical care, and other health care services based on health care practitioner-specific criteria. The study must include an analysis of (1) adjustments to payor prior authorization requirements based on a health care practitioner's prior approval rates, ordering and prescribing patterns, and participation in a payor's two-sided incentive arrangement or a capitation program and (2) any other information or metrics necessary to implement the payor programs.

By December 1, 2024, MHCC and MIA must submit a report to the General Assembly that details their findings and recommendations from the study, including recommendations for legislative initiatives necessary for the establishment of payor programs modifying prior authorization requirements based on health care practitioner-specific criteria.

Assessment of Implementation of an Online Electronic Process for Prior Authorization: Uncodified language requires MHCC, in consultation with MIA, to monitor the progress toward implementing the bill's requirements regarding an online electronic process for prior authorization (including monitoring any federal or State developments relating to the requirements) and review issues or recommendations from other states that are implementing a real-time benefit requirement. By December 1, 2025, MHCC must inform the General Assembly of any findings and recommendations relating to the implementation of the bill's requirements regarding an online electronic process for prior authorization.

Current Law:

Definitions

"Adverse decision" means a utilization review determination made by a private review agent, carrier, or health care provider that a proposed or delivered health care service is or was not medically necessary, appropriate, or efficient and may result in noncoverage of the health care service. An adverse decision does not include a decision concerning a subscriber's status as a member.

"Grievance decision" means a final determination by a carrier or private review agent that arises from a grievance filed with the carrier or private review agent under its internal grievance process regarding an adverse decision concerning a member or patient.

"Health care service" means a health or medical care procedure or service rendered by a health care provider that (1) provides testing, diagnosis, or treatment of a human disease or dysfunction or (2) dispenses drugs, medical devices, medical appliances, or medical goods for the treatment of a human disease or dysfunction.

A "private review agent" means a (1) nonhospital-affiliated person or entity performing utilization review that is either affiliated with, under contract with, or acting on behalf of a Maryland business entity or a third party that pays for, provides, or administers health care services to citizens of the State or (2) any person or entity performing utilization review for the purpose of making claims or payment decisions for health care services on behalf of the employer's or labor union's health insurance plan under an employee assistance program for employees other than the employees employed by the hospital or a business wholly owned by the hospital.

"Utilization review" means a system for reviewing the appropriate and efficient allocation of health care resources and services given or proposed to be given to a patient or group of patients.

Benchmarks for Standardizing and Automating Preauthorization of Health Care Services

MHCC must work with payors and providers to attain specified benchmarks for standardizing and automating the process required by payors for preauthorizing health care services and overriding a payor's step therapy or fail-first protocol, including an online preauthorization system, as specified.

Prior Authorization for Prescription Drugs

Chapter 549 of 2019 established requirements for prior authorization for a prescription for a chronic condition and requires specified entities to (1) maintain a database of information

relating to prior authorization requests filed electronically; (2) provide a detailed written explanation when denying a prior authorization; (3) honor prior authorizations granted to an insured from a previous entity for at least the initial 30 days of an insured's prescription drug benefit coverage under the new entity's health benefit plan; and (4) provide written notice of any new prior authorization requirement the entity implements for a prescription drug at least 30 days prior to implementation.

If a carrier requires a prior authorization for a prescription drug, the prior authorization request must allow a health care provider to indicate whether a prescription drug is to be used to treat a chronic condition. If a health care provider indicates as such, a carrier may not request a reauthorization for a repeat prescription for one year or for the standard course of treatment for the chronic condition, whichever is less.

Internal Grievance Procedures

Each carrier must establish for its members an internal grievance process, which must meet specified requirements.

A carrier must render a final decision in writing on a grievance within 30 working days after the date on which the grievance is filed unless a specified exception applies. For a grievance that involves a retrospective denial, a carrier must render a final decision in writing within 45 working days after the date on which the grievance is filed. A carrier may extend the 30-day or 45-day period required for making a final grievance decision with the written consent of the member, the member's representative, or the health care provider who filed the grievance.

A member, a member's representative, or a health care provider may file a complaint with the Commissioner if a grievance decision is not received from the carrier by the thirtieth working day on which the grievance is filed.

If a carrier does not have sufficient information to complete its internal grievance process, the carrier must, within five working days after a grievance has been filed, notify the member, the member's representative, or the health care provider who filed the grievance that it cannot proceed with reviewing the grievance unless additional information is provided. Additionally, the carrier must assist the member, the member's representative, or the health care provider in gathering the necessary information without further delay.

For nonemergency cases, when a carrier renders an adverse decision, the carrier must document the decision in writing after the carrier has provided oral communication of the decision to the member, the member's representative, or the health care provider acting on behalf of the member. The written notice must be sent to the member, the member's representative, or the health care provider acting on behalf of the member within five working days after the decision has been made. The written notice must state in

detail – using clear, understandable language – the specific factual basis for the carrier's decision and reference the specific criteria and standards on which the grievance decision was based. Additionally, the notice must state the name, business address, and business telephone number of the designated employee or representative who has responsibility for the carrier's internal grievance process (or the medical director who made the grievance decision if the carrier is an HMO).

In an emergency case, a carrier must include an expedited procedure that can be used to render a grievance decision within 24 hours of the date the grievance is filed with the carrier. A carrier must provide written notice of a grievance decision to the member, the member's representative, or the health care provider within one day after orally communicating the decision to that individual. The notice must include the same information that is provided for a grievance decision rendered in a nonemergency case.

On a quarterly basis, each carrier must submit a report to the Commissioner that describes specified activities, including the number of adverse decisions issued by the carrier and the type of service at issue in those adverse decisions.

Private Review Agents

Certificate of Registration: A private review agent may not conduct utilization review in the State unless the Commissioner has granted the private review agent a certificate of registration. When applying for a certificate, a private review agent must certify that the criteria and standards to be used in conducting utilization review are objective, clinically valid, compatible with established principles of health care, and flexible enough to allow deviations from norms when justified on a case-by-case basis.

A private review agent may not use criteria and standards for utilization review that do not meet these requirements. A person who knowingly uses criteria and standards to conduct utilization review that do not meet these requirements is guilty of a misdemeanor and on conviction is subject to specified penalties.

A private review agent applying for a certificate of registration must also submit specified information that the Commissioner requires, including a list of the persons involved in establishing the specific criteria and standards to be used in conducting utilization review. The Commissioner may establish reporting requirements to evaluate the effectiveness of private review agents and determine if utilization review programs are in compliance with applicable State law and regulations.

Providing a Copy of Utilization Review Criteria and Standards: On the written request of any person or health care facility, a private review agent must provide one copy of the specific criteria and standards to be used in conducting utilization review of proposed or

delivered services and any subsequent revisions, modifications, or additions to the specific criteria and standards to be used in conducting utilization review of such services. A private review agent is entitled to charge a reasonable fee to furnish a copy of the utilization review criteria and standards.

Making Determinations: A private review agent must comply with the following timelines and requirements:

- make all initial determinations on whether to authorize or certify a nonemergency course of treatment for a patient within two working days after receipt of the information necessary to make the determination;
- make all determinations on whether to authorize or certify an extended stay in a health care facility or additional health care services within one working day after receipt of the information necessary to make the determination;
- if within three calendar days after receipt of the initial request for health care services the private review agent does not have sufficient information to make a determination, the private review agent must inform the health care provider that additional information must be provided;
- if a private review agent requires prior authorization for an emergency inpatient admission, or an admission for residential crisis services, for the treatment of a mental, emotional, or substance use disorder, the private review agent must make all determinations within two hours after receipt of the information necessary to make the decision and must promptly notify the health care provider of the determination; and
- for electronic submissions of a step therapy exception request or a prior authorization request for pharmaceutical services, a private review agent must make a determination in real time if no additional information is needed to process the request and the request meets the private review agent's criteria for approval. If additional information is required to make a determination, a private review agent must make the determination within one working day of receiving that information and must promptly notify the health care provider of the determination.

If a private review agent makes an initial determination not to authorize or certify a health care service and the health care provider believes the determination warrants an immediate reconsideration, the private review agent may grant the health care provider an opportunity to speak with the physician that rendered the determination. The health care provider and physician must speak within 24 hours of the provider seeking the reconsideration.

Adverse Decisions: Except as otherwise specified, all adverse decisions must be made by a physician or a panel of other appropriate health care service reviewers with at least

one physician on the panel who is board certified or eligible in the same specialty as the treatment under review.

State Expenditures: The State Employee and Retiree Health and Welfare Benefits Program is largely self-insured for its medical contracts and, as such, except for the one fully insured integrated health model medical plan (Kaiser), is not subject to this bill. However, the program generally provides coverage as otherwise required under State law.

The Department of Budget and Management (DBM) advises that the bill's requirements increase annual costs to the program by $3.5 million to $25.0 million. According to DBM, annual costs increase by $3.5 million assuming that the bill only requires coverage of prior authorizations for qualifying mental disorders and biologics for immunotherapy. However, DBM advises that, if the bill is interpreted as requiring coverage of prior authorizations for qualifying mental disorders and the entire autoimmune therapeutic class, annual costs increase by an estimated $25.0 million.

The Department of Legislative Services advises that, if DBM elects to comply with the bill's requirements, program costs likely increase by $1.75 million (and as much as $12.5 million) in fiscal 2025. Beginning in fiscal 2026, annual expenditures likely increase by $3.5 million, but potentially as much as $25.0 million.

Small Business Effect: Small business health care providers experience reduced administrative burdens under the bill. Due to the bill's changes to the utilization review process, premiums for small businesses that purchase fully insured health benefit plans may increase.

Additional Information

Recent Prior Introductions: Similar legislation has been introduced within the last three years. See HB 305 and SB 308 of 2023.

Designated Cross File: HB 932 (Delegate Cullison, *et al.*) - Health and Government Operations.

Information Source(s): Department of Budget and Management; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

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