

TO: Health Care Clients

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RE: MIA Life and Health Bulletin 24-13

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On May 24, 2024, the Maryland Insurance Administration (“MIA”) released Bulletin 24-13 “Insurers, Nonprofit Health Service Plans, Health Maintenance Organizations, and Private Review Agents” to “clarify and explain the interplay between step therapy, prior authorization, and other utilization review protocols for prescription drugs” and “to provide guidance on how and when it is permitted to consider prescription drug costs as a factor any utilization review determination.” This memo supplements the bulletin by providing additional information on the applicability of Maryland’s insurance law and the process for filing a complaint as well as highlighting key provisions from the bulletin. This memo is not a substitute for the bulletin. We strongly encourage all clients to fully read the bulletin (link below).

As background, the need to reform Maryland’s prior authorization and utilization review processes has been fueled by patients being denied the continued use of prescription drugs at reauthorization despite the prescription drug effectively treating the patient’s condition. This bulletin addresses this and other issues by specifically stating when an insurance carrier or pharmacy benefit manager (“PBM”) **may not** deny a patient the right to remain on a prescription drug as well as other procedural elements that must be satisfied by the insurance carrier or PBM in order to issue a prescription drug denial. Coupled with the provisions passed during the 2024 Session (*Senate Bill 791/House Bill 932: Health Insurance – Utilization Review – Revisions<sup>1</sup>*), this bulletin provides strong and needed protections for both prescribers and patients.

1. With some exceptions, the provisions in this bulletin generally apply to health care plans in Maryland’s fully insured marketplace, which is typically Maryland’s individual and small group market (approximately 18% of the marketplace). To determine if a patient is in a Maryland regulated plan, the patient’s insurance card should indicate “MIA” or “Maryland Insurance Administration.” Please note that patients may be using an older insurance card, so the lack of this notation is not fully indicative of whether the patient is covered by Maryland law. Patients that have a self-insured health plan or that are

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<sup>1</sup> House Bill 932/Senate Bill 791 was signed into law by Governor Moore on May 16, 2024.

enrolled in Medicaid, a Medicaid managed care organization, Medicare Fee-for-Service, or a Medicare Advantage Plan are not covered by Maryland law.

2. Key provisions:

- Pages 3 and 4: Therapeutic Interchanges - Therapeutic interchange is when PBM requests that a patient change from one prescription drug to another, either for medical reasons that benefit the patient, or because the change will result in financial savings and benefits to the carrier or patient. However, it does not apply to a drug utilization review. If requested by the PBM, the key issue is that the prescriber **must agree** to the change and the interchange must be disclosed to the patient. The patient may decline to change prescription drugs and remain on the original drug if the original drug is still on the PBM's formulary, and the patient pays any cost difference in the copayment or coinsurance. If a drug is removed from the PBM's formulary, the prescriber or patient may request a formulary exception to remain on the originally prescribed drug. A decision not to approve a formulary exception is an adverse decision if the decision is based on a finding that the proposed drug is not medically necessary, appropriate, or efficient and may be appealed to the PBM and/or the MIA.
- Page 4: Step Therapy – Regarding drug utilization review, carriers/PBMs may use “step therapy” during utilization review. Regardless of whether the carrier uses the terminology “step therapy” to describe its process, if the prescriber has ordered a specific drug for a patient within the past 180 days and provides the required documentation that the drug has been effective, the carrier is prohibited from requiring the patient to use or try a less expensive alternative drug before agreeing to cover or authorize the requested drug. This includes any new drugs that may have first come to market after the member was originally authorized to use the current drug. Simply stated, during utilization review, a carrier or PBM may not deny a patient who has already been effectively treated with a drug because the patient has not “failed” on formulary alternatives or documented contraindications to the formulary alternatives.
- Pages 4 and 5: Prior Authorization – Any denial of a prescription drug based on prior authorization must be supported by the specific utilization review criteria and standards used by the carrier or PBM in conducting utilization review. A denial of a prior authorization request for a prescription drug based on the existence of lower cost alternative will be considered an adverse decision under Maryland law; therefore, such denial is required to be supported by specific criteria and standards from the utilization review plan that was submitted to the Insurance Commissioner. Furthermore, if a prior authorization request is denied on the grounds that less costly drugs were not used before the prescribed drug, this is a step therapy denial, which is subject to the restrictions described above.

3. If a prescriber or patient has received a denial and believes that the denial violates Maryland law, it is strongly encouraged that the prescriber or patient file a complaint with the Maryland Insurance Administration. Historically, the MIA finds in favor of the prescriber or patient 70% of the time. In addition, a complaint(s) can trigger a market conduct audit of the insurance carrier or other enforcement mechanisms. You may also seek assistance from the Attorney General's Health Education and Advocacy

Unit (“HEAU”) with filing a complaint. However, it is encouraged to always file with the Maryland Insurance Administration due to its regulation of insurance carriers and PBMs.

**Additional Information:**

MIA Bulletin 24-13 - [24-13-Prescription-Drug-Utilization-Review.pdf \(maryland.gov\)](#)

MIA Complaint Form - <https://insurance.maryland.gov/Consumer/Documents/lh-agcomplaintform08-17rev.pdf>

Information on MIA Appeals and Grievances - [Appeals and Grievance \(maryland.gov\)](#)

Attorney General HEAU - [HEAU Complaint Chooser \(marylandattorneygeneral.gov\)](#)

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