



TO: The Honorable Joseline A. Pena-Melnyk, Chair
 Members, House Health and Government Operations Committee
 The Honorable Steve Johnson

FROM: Danna L. Kauffman
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RE: **SUPPORT** – House Bill 785 – *Health Insurance – Step Therapy or Fail-First Protocol – Revisions*

On behalf of the Maryland State Medical Society, the Maryland Chapter of the American Academy of Pediatrics, the Maryland Academy of Family Physicians, the Maryland Society of Eye Physicians and Surgeons, the Maryland Section of the American College of Obstetricians and Gynecologists, the Mid-Atlantic Association of Community Health Centers, and the Maryland Clinical Social Work Coalition, we submit this letter of **support** for House Bill 785.

Bill Rationale

Maryland has fallen behind other states in protecting patients from restrictive step-therapy or fail-first protocols (“step therapy”). Step therapy is a form of prior authorization where a health insurance carrier or pharmacy benefits manager (PBM) requires a patient to “fail-first” on certain medications, which are typically older and less-expensive, before the patient can take the medication recommended by the treating prescriber. While over two dozen states have added robust exemption policies into their laws, Maryland still only allows a patient to avoid an insurer’s step therapy protocol if the patient has been on a drug for 180 days and the prescriber attests that the patient is doing well on the drug.¹ This typically occurs when a patient changes health insurers or health plans or there is a change to the patient’s health plan.

¹ States with similar provisions of Senate Bill 515 are: North Dakota, Louisiana, Maine, New York, Pennsylvania (as of January 1, 2024), Kentucky, West Virginia, Virginia, Iowa, Minnesota, Kansas, Minnesota, Oklahoma, Colorado, New Mexico, Arizona, Oregon, Washington and California.

While carriers may have their own exemption process, it is not consistent or uniformly applied. The only exemption process in the law for requesting a drug outside of the carrier's requirements is when the carrier either does not have a drug on its' formulary, removes a drug from its' formulary, or moves the drug to a different cost tier (Section 15-831 of the Insurance Article). It does not address situations as outlined in House Bill 785 – when the carrier has a drug on its formulary but is requiring the patient to use another drug and the 180-day exception does not apply.

Step therapy prevents patients from accessing treatments recommended by their treating prescriber in a timely manner. When a patient is required to try what is often the “lesser” medication for treating his/her condition, patients suffer serious negative consequences, compromising treatment decisions and the patient's health. As pointed out by the Maryland/DC Society of Clinical Oncologists, “step therapy or fail first policies can be particularly problematic for patients with cancer because they can significantly delay a patient's access to the best treatment available for their condition. While waiting to complete a “step,” a patient with cancer may experience disease progression and irreversible damage to their overall health.” This is true for those also suffering from other chronic care diseases.

Bill Summary

Therefore, House Bill 785 makes the necessary changes to ensure that patients have access to the most appropriate and necessary drugs in a timely manner. While there may be times that a patient can handle a “step” medication, there needs to be safeguards built into the law to protect patients when the “step” medication may result in poor health outcomes.

House Bill 785 requires a health insurance carrier to establish a process for requesting an exception to a step therapy protocol if, based on the professional judgement of a prescriber:

- the prescription drug required to be used under a step therapy protocol is either:
 - contraindicated or will likely cause an adverse reaction, physical harm, or mental harm to the patient; or
 - is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or
- the patient is stable on a prescription drug selected by their health care provider; or
- the patient has already tried a prescription drug in the same pharmacologic class or has the same mechanism of action as the step therapy drug and was discontinued by the prescriber due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

This legislation also exempts from step therapy protocols a prescription drug that is used to treat the insured or enrollee's mental disorder or condition under certain conditions.

Lastly, the bill requires that the exemption process be clearly described, including the specific information and documentation that must be submitted by the prescriber to be considered a complete step therapy exception request; easily accessible to the prescriber; and posted on the entity's website.

On behalf of the above-referenced organizations and our patients, we urge a favorable vote on House Bill 785.