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TO: The Honorable Joseline Peña-Melnyk, Chair and
Members of the House Health and Government Operations Committee

FROM: Office of the Attorney General, Health Education and Advocacy Unit

RE: SB0515 (on Crossover) – Health Insurance – Step Therapy or Fail-
First Protocol – Revisions – **Support**

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) supports the goal of curtailing the unjustifiably negative effects of step therapy by carriers that increasingly deny claims for prescribed drugs. The HEAU supports eliminating unnecessary step therapy requirements and streamlining the step therapy process when appropriately utilized. The changes this bill proposes should help eliminate dangerous delays in care, reduce inappropriate denials of medically necessary care, and reduce administrative costs.

The HEAU assists consumers in mediating and filing a grievance or appeal of carrier adverse decisions (denials based on medical necessity, appropriateness or efficiency) or coverage decisions (other non-coverage decisions). In fiscal year 2022, the HEAU closed nearly 600 appeals and grievances cases, mediating 436 of those cases. Of the 436 cases, 26% were adverse decision cases, 56% were coverage decision cases, and 18% were eligibility cases. The HEAU mediation process resulted in 65% of the medical necessity cases and 56% of the coverage decision cases being overturned or modified. The HEAU mediation process resulted in 72% of pharmacy-related denials being overturned or modified. In the same fiscal year, 50% of grievances the MIA investigated were pharmacy-related grievances, and 84% of the denials were modified or overturned during the grievance process.

Over the years the HEAU has assisted many consumers impacted by step therapy protocols including:

- A 42-year-old woman diagnosed with psoriatic arthritis had been stable on Remicade infusions every 6 weeks with a dosage of 7 mg/kg since 2017. In July 2021, the carrier abruptly denied the Remicade claim, declaring “you will be held to FDA dosing guidelines not to exceed [6 mg/kg every 8 weeks].” In her internal appeal letter, the rheumatologist said “I have been made aware that the new policy at [the carrier] is to automatically deny any medication for a patient that is a higher dose or more frequent schedule than what the FDA product insert guide lists; even if it is a proven dose and schedule that has had significant benefit for a particular patient. This policy will jeopardize my patient’s treatments and cause disease relapse, unnecessary pain, loss of income from not being able to work and irreversible damage to her joints.” With the HEAU’s intervention, the denial was overturned, and the prior dosage and frequency resumed. Several other patients filed complaints about the same carrier, which was denying medication claims notwithstanding each patient’s established need for medically necessary treatments tailored to their disease progression and symptoms. The HEAU also obtained reversals of those denials.

- A 62-year-old consumer had been taking a brand name medication for a thyroid condition consistently since 2014. When she attempted to obtain a refill, her carrier denied coverage because the brand name drug was off-formulary and the plan required her to try and fail a generic drug first. The consumer’s physician provided records stating that the consumer had tried the on-formulary generic drug prior to 2014 and that it was unsuccessful in controlling her TSH level. The carrier continued to deny coverage. The HEAU sought external review resulting in the carrier overturning the denial and approving the medication for one year.

- A 35-year-old resident suffered from psoriatic arthritis. After trying several medications without success, he was prescribed Enbrel which significantly improved his health. When he switched jobs and employer-based insurance, his new carrier denied coverage of Enbrel because it was off-formulary and required step-therapy. The consumer unsuccessfully appealed the denial twice with the carrier. The carrier’s plan documents were unclear suggesting on the one hand that step therapy was required, but also suggesting that continuation of Enbrel therapy required proof of a positive clinical response. The HEAU obtained his medical records and appealed the denial, resulting in the carrier overturning the denial and approving the medication for one year.

These stories are not unique and highlight the problems faced by consumers and providers daily. The data shows that denials of coverage are overturned or modified at a high rate, so the current process only prevents or delays access to timely and appropriate care, jeopardizing patient health and well-being and burdening healthcare providers.

The technical concerns raised by the HEAU have been ameliorated by the amendments and follow up conversations with the proponents and the Maryland Insurance Administration. Notably, the amendments make clear what has long been the HEAU and the MIA's position that a carrier's denial of coverage based on step therapy is a medical necessity denial and subject to the appeals and grievances process under Title 15, Subtitle 10. And consumers who have previously tried and failed on generics or biologics, or for whom a generic/biologic is contraindicated will not lose the protections afforded by this bill.

The HEAU also supports the amendment that requires more immediate turn-around times on exception requests.

For all of these reasons, we urge a favorable report on SB515.