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TO: The Honorable Melony Griffith
Chair, Senate Finance Committee

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

RE: SB0515 – Health Insurance – Step Therapy or Fail-First Protocol – Revisions – **Support with Amendments**

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, appropriates 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.

But the HEAU does have some technical concerns.

1. On page 4, line 22, the HEAU suggests substituting "THE" with "A" to account for any of the patient's providers having discontinued a drug due to lack of efficacy or effectiveness, diminished effect, or an abuse event.

2. On page 4, line 25, the term "appeal" is introduced without definition. It 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 10A. Introduction of the term "appeal" without definition or reference to 15-10A, which does not use the term "appeal," introduces unnecessary ambiguity regarding the process that is due.

It is possible the bill's step therapy exception denial process is intended to be a precursor to the carrier's internal grievance process given the real-time and one business day turnaround times, but this should be clarified.

In any event, to avoid confusion, we believe it would be appropriate to state that a decision by an entity subject to this section to deny a step therapy exception request constitutes an adverse decision as defined under Subtitle 10A of this title.

Lastly, the HEAU objects to Page 5, line 10, which appears to state that the step therapy exceptions process does not apply if the issuer mandates use of generics/biologics first; this exception could swallow the rule with respect to generics/biologics. Consumers who have previously tried and failed on generics/biologics, or for whom a generic/biologic is contraindicated, should not lose the protections afforded by this bill.

We support this well-intentioned bill and look forward to working with all stakeholders to strengthen consumer protections regarding step therapy without inadvertently reducing or hindering consumer rights under existing law.

cc: Senator Clarence Lam