



**STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES**

Margaret M. O'Neill Bldg., Suite 1
Dover, Delaware 19901
302-739-3621

The Honorable John Carney
Governor

John A. McNeal
Director

MEMORANDUM

DATE: April 29, 2019

TO: All Members of the Delaware State Senate
and House of Representatives

FROM: Mr. J. Todd Webb, Chairperson
State Council for Persons with Disabilities

RE: H.B. 105 (Creating a Step Therapy Exception Process)

The State Council for Persons with Disabilities (SCPD) has reviewed H.B. 105 which would create a Step Therapy Exception Process that allows patients who are required by their insurance company to go through step therapy protocols to, under certain circumstances, bypass step therapy to obtain the initially-prescribed medication. SCPD realizes H.S. 1 for H.B. 105 has been introduced. Council endorses the proposed legislation and has the following observations.

Step therapy requires patients to try less expensive drug therapies before coverage is provided for a drug selected by the patient's health care provider. The process is intended to control costs associated with prescription drugs, but can often undermine the judgment of physicians and can cause adverse or dangerous consequences for patients.

The bill provides that "when coverage of a prescription drug for the treatment of any medical condition is restricted for use by an insurer, health plan, or utilization review entity through the use of a step therapy protocol, the patient and prescribing practitioner shall have access to a clear, readily accessible and convenient process to request a step therapy exception determination." The bill then lists the circumstances in which a step therapy shall be expeditiously granted, including when: the required drug will likely cause an adverse reaction by or harm to the patient; the drug is expected to be ineffective based on known clinical characteristics of the patient and the known characteristics of the drug regimen; the patient has tried the required drug while under the patient's current or previous insurance or benefit plan and such drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; the required drug is not

in the best interest of the patient based on medical necessity, and; the patient is stable on a drug selected by the patient's health care provider or while the patient was insured by the patient's current or a previous benefit plan.

The bill further provides the criteria to establish a step therapy protocol and requires that such protocols be based on clinical criteria that are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups and are based on peer reviewed studies, research, and medical practice.

Again, SCPD endorses the proposed legislation given its effort to limit insurers' ability to require step therapy. Step therapy places significant burdens on physicians and patients, and has been shown to have a negative impact on patients, including delayed access to the most effective treatment. This bill is an effective first step toward prioritizing patient care over insurer profit.

Thank you for your consideration and please contact SCPD if you have any questions regarding our position or observations on the proposed legislation.

cc: Ms. Laura Waterland, Esq.
Governor's Advisory Council for Exceptional Citizens
Developmental Disabilities Council

P&L/H.B. 105 creating a step therapy exception process 4-18-19