ASSEMBLY HEALTH COMMITTEE

STATEMENT TO

ASSEMBLY, No. 4815

STATE OF NEW JERSEY

DATED: OCTOBER 21, 2020

The Assembly Health Committee reports favorably Assembly Bill No. 4815.

This bill requires health insurance carriers and utilization review organizations to meet certain guidelines in the administration and review of step therapy protocols. The bill defines "step therapy protocol" as a protocol, policy, or program that establishes the specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular patient, are covered by a health benefits plan.

The bill provides that clinical review criteria used to establish a step therapy protocol is to be based on clinical practice guidelines that:

(1) recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol;

(2) are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by following certain procedures outlined in the bill;

(3) are based on high quality studies, research, and medical practice;

(4) are created by an explicit and transparent process that minimizes biases and conflicts of interest, explains the relationship between treatment options and outcomes, rates the quality of the evidence supporting recommendations, and considers relevant patient subgroups and preferences; and

(5) are continually updated through a review of new evidence, research and newly developed treatments.

In addition, the bill provides guidelines for the review of step therapy exceptions. Under the bill, "step therapy exception" means the overriding of a step therapy protocol in favor of immediate coverage of the health care provider's selected prescription drug.

The bill provides that when coverage of a prescription drug for the treatment of any medical condition is restricted for use by a carrier or utilization review organization through the use of a step therapy protocol, the carrier or utilization review organization is to provide the covered person and prescribing practitioner a clear, readily accessible, and convenient process to request a step therapy exception. Under the bill, a carrier or utilization review organization may use its existing medical exceptions process to satisfy this requirement. An explanation

of the process is to be made available on the carrier or utilization review organization's website.

A step therapy exception is to be granted if:

(1) the required prescription drug is contraindicated or is likely to cause an adverse reaction or physical or mental harm to the patient;

(2) the required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;

(3) the patient has tried the required prescription drug while under their current or a previous health insurance or health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) the required prescription drug is not in the best interest of the patient, based on medical necessity; or

(5) the patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan.

Under the bill, when a step therapy exception is granted, the carrier or utilization review organization is to authorize coverage for the prescription drug prescribed by the patient's treating health care provider.

The bill provides that any step therapy exception is to be eligible for appeal by a covered person. The carrier or utilization review organization is to grant or deny a step therapy exception request or an appeal of a step therapy exception request within 72 hours of receipt of the request or appeal. In cases where exigent circumstances exist, the carrier or utilization review organization is to respond within 24 hours of receipts. If a response by a carrier or utilization review organization is not received within the time allotted, the exception or appeal is to be deemed granted.

The bill also provides that a carrier or utilization review organization is to report to the Commissioner of Banking and Insurance certain information concerning the number and nature of step therapy exceptions requested, appealed, denied, and granted.