ASSEMBLY, No. 2010

STATE OF NEW JERSEY

220th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2022 SESSION

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SYNOPSIS

Establishes certain guidelines for health insurance carriers concerning step therapy protocols.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.

(Sponsorship Updated As Of: 3/30/2023)

AN ACT concerning health insurance and supplementing Title 26 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. The Legislature finds and declares that:

a. Health insurance plans are increasing the use of step therapy protocols that require patients to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider.

b. Step therapy protocols, if based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of patients, can play an important role in controlling health care costs.

c. In some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous consequences for the patient who may either not realize a benefit from taking a prescription drug or may suffer harm from taking an inappropriate drug.

d. Without uniform policies in the State for step therapy protocols, all patients may not receive the equivalent or most appropriate treatment.

e. It is imperative that step therapy protocols in the State preserve the heath care provider's right to make treatment decisions in the best interest of the patient.

f. The Legislature declares, therefore, that it is a matter of public interest that health insurance carriers be required to base step therapy protocols on appropriate clinical practice guidelines or published peer-reviewed data developed by independent experts with knowledge of the condition or conditions under consideration; that patients be exempt from step therapy protocols when those protocols are inappropriate or otherwise not in the best interest of the patients; and that patients have access to a fair, transparent and independent process for requesting an exception to a step therapy protocol when the patient's physician deems appropriate.

2. As used in this act:

"Carrier" means an insurance company, health service corporation, hospital service corporation, medical service corporation, or health maintenance organization authorized to issue health benefits plans in this State.

"Clinical practice guidelines" means a systematically developed statement to assist decision making by health care providers and patient decisions about appropriate healthcare for specific clinical circumstances and conditions.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and practice

guidelines used by a carrier or utilization review organization to determine the medical necessity and appropriateness of health care services.

"Commissioner" means the Commissioner of Banking and Insurance.

"Covered person" means a person on whose behalf a carrier offering the plan is obligated to pay benefits or provide services pursuant to the health benefits plan.

"Health benefits plan" means a benefits plan which pays or provides hospital and medical expense benefits for covered services, and is delivered or issued for delivery in this State by or through a carrier. Health benefits plan includes, but is not limited to, Medicare supplement coverage and risk contracts to the extent not otherwise prohibited by federal law. For the purposes of this act, health benefits plan shall not include the following plans, policies, or contracts: accident only, credit, disability, long-term care, CHAMPUS supplement coverage, coverage arising out of a workers' compensation or similar law, automobile medical payment insurance, personal injury protection insurance issued pursuant to P.L.1972, c.70 (C.39:6A-1 et seq.), or hospital confinement indemnity coverage.

"Health care provider" means an individual or entity which, acting within the scope of its licensure or certification, provides a covered service defined by the health benefits plan. Health care provider includes, but is not limited to, a physician and other health care professionals licensed pursuant to Title 45 of the Revised Statutes, and a hospital and other health care facilities licensed pursuant to Title 26 of the Revised Statutes.

"Medically necessary" means health services and supplies that, under the applicable standard of care, are appropriate:

(1) to improve or preserve health, life, or function;

(2) to slow the deterioration of health, life, or function; or

(3) for the early screening, prevention, evaluation, diagnosis or treatment of a disease, condition, illness or injury.

"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.

"Step therapy protocol" means 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 required to be administered in order to be covered by a health benefits plan.

"Utilization review organization" means an entity that conducts utilization review, other than a carrier performing utilization review for its own health benefit plans.

3. a. Clinical review criteria used to establish a step therapy protocol shall 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:

(a) requiring members to disclose any potential conflict of interests with entities, including carriers and pharmaceutical manufacturers, and recuse themselves from voting if they have a conflict of interest;

(b) using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; and

(c) offering opportunities for public review and comments; and

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

(4) are created by an explicit and transparent process that:

(a) minimizes biases and conflicts of interest;

(b) explains the relationship between treatment options and outcomes;

(c) rates the quality of the evidence supporting recommendations; and

(d) considers relevant patient subgroups and preferences; and

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

b. In the absence of clinical guidelines that meet the requirements in subsection a. of this section, peer-reviewed publications may be substituted.

c. When establishing a step therapy protocol, a utilization review agent shall also consider the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

d. A carrier shall:

(1) upon written request, provide specific written clinical review criteria relating to a particular condition or disease, including clinical review criteria relating to a step therapy protocol exception determination; and

(2) make available the clinical review criteria and other clinical information on its internet website and to a health care professional on behalf of an insured person upon written request.

e. This section shall not be construed to require carriers or the State to establish a new entity to develop clinical review criteria used for step therapy protocols.

4. Notwithstanding the provisions of any law, rule, or regulation to the contrary:

a. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a carrier or utilization review organization pursuant to a step therapy protocol, the carrier

or utilization review organization shall provide the covered person and prescribing practitioner a clear, readily accessible, and convenient process to request a step therapy exception. A carrier or utilization review organization may use its existing medical exceptions process to satisfy this requirement. An explanation of the process shall be made available on the carrier or utilization review organization's website. A carrier or utilization review organization shall disclose all rules and criteria related to the step therapy protocol upon request to all prescribing practitioners, including the specific information and documentation required to be submitted by a prescribing practitioner or patient for an exception request to be complete.

b. A step therapy exception shall 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 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.

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

d. Any step therapy exception shall be eligible for appeal by a covered person. The carrier or utilization review organization shall 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 shall respond within 24 hours of receipt. If a request for a step therapy exception is incomplete or if additional clinically relevant information is required, the carrier or utilization review organization shall notify the prescribing practitioner within 72 hours of submission, or 24 hours in exigent circumstances, what additional or clinically relevant information is required in order to approve or deny the step therapy exception request or appeal pursuant to the criteria disclosed pursuant to subsection a. of this section. Once the requested information is submitted, the applicable time period to grant or deny a step therapy exception request or appeal shall apply. If a response by a carrier

or utilization review organization is not received within the time allotted, the exception or appeal shall be deemed granted. In the event of a denial, the carrier or utilization review organization shall inform the patient of the appeal process.

e. Any step therapy exception pursuant to this section shall be eligible for appeal by a covered person.

f. This section shall not be construed to prevent:

(1) a carrier or utilization review organization from requiring a patient to try an AB-rated generic equivalent or interchangeable biological product prior to providing coverage for the equivalent branded prescription drug;

(2) a carrier or utilization review organization from requiring a pharmacist to effect substitutions of prescription drugs consistent with the laws of this State; or

(3) a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

5. Annually, a carrier or utilization review organization shall report to the commissioner, in a format prescribed by the commissioner:

a. the number of step therapy exception requests received, by reason for the exception;

b. the type of health care providers or the medical specialties of the health care providers submitting step therapy exception requests;

c. the number of step therapy exception requests that were denied, by reason for the exception, and the reasons for the denials;

d. the number of step therapy exception requests that were approved, by reason for the exception;

e. the number of step therapy exception requests that were initially denied and then appealed, by reason for the exception;

f. the number of step therapy exception that were initially denied and then subsequently reversed by internal appeals or external reviews, by reason for the exception; and

g. the medical conditions for which patients are granted exceptions due to the likelihood that switching from the prescription drug will likely cause an adverse reaction by or physical or mental harm to the insured.

6. The commissioner shall adopt, pursuant to the "Administrative Procedure Act" P.L.1968, c.410 (C.52:14B-1 et seq.), rules and regulations to effectuate the purposes of this act.

7. This act shall take effect on the 60th day after enactment and apply to all contracts and policies delivered, issued, executed, or renewed on or after January 1, 2021.

STATEMENT

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.