

SENATE, No. 308

STATE OF NEW JERSEY 220th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2022 SESSION

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District 19 (Middlesex)

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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: 3/20/2023)

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

3

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

6

7 1. The Legislature finds and declares that:

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

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

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

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

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

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

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38 2. As used in this act:

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

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

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

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

4 “Commissioner” means the Commissioner of Banking and
5 Insurance.

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

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

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

29 “Medically necessary” means health services and supplies that,
30 under the applicable standard of care, are appropriate:

- 31 (1) to improve or preserve health, life, or function;
32 (2) to slow the deterioration of health, life, or function; or
33 (3) for the early screening, prevention, evaluation, diagnosis or
34 treatment of a disease, condition, illness or injury.

35 “Step therapy exception” means the overriding of a step therapy
36 protocol in favor of immediate coverage of the health care
37 provider’s selected prescription drug.

38 “Step therapy protocol” means a protocol, policy, or program
39 that establishes the specific sequence in which prescription drugs
40 for a specified medical condition, and medically appropriate for a
41 particular patient, are required to be administered in order to be
42 covered by a health benefits plan.

43 “Utilization review organization” means an entity that conducts
44 utilization review, other than a carrier performing utilization review
45 for its own health benefit plans.

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47 3. a. Clinical review criteria used to establish a step therapy
48 protocol shall be based on clinical practice guidelines that:

- 1 (1) recommend that the prescription drugs be taken in the
- 2 specific sequence required by the step therapy protocol;
- 3 (2) are developed and endorsed by a multidisciplinary panel of
- 4 experts that manages conflicts of interest among the members of the
- 5 writing and review groups by:
 - 6 (a) requiring members to disclose any potential conflict of
 - 7 interests with entities, including carriers and pharmaceutical
 - 8 manufacturers, and recuse themselves from voting if they have a
 - 9 conflict of interest;
 - 10 (b) using a methodologist to work with writing groups to
 - 11 provide objectivity in data analysis and ranking of evidence through
 - 12 the preparation of evidence tables and facilitating consensus; and
 - 13 (c) offering opportunities for public review and comments; and
 - 14 (3) are based on high quality studies, research, and medical
 - 15 practice;
 - 16 (4) are created by an explicit and transparent process that:
 - 17 (a) minimizes biases and conflicts of interest;
 - 18 (b) explains the relationship between treatment options and
 - 19 outcomes;
 - 20 (c) rates the quality of the evidence supporting
 - 21 recommendations; and
 - 22 (d) considers relevant patient subgroups and preferences; and
 - 23 (5) are continually updated through a review of new evidence,
 - 24 research and newly developed treatments.
 - 25 b. In the absence of clinical guidelines that meet the
 - 26 requirements in subsection a. of this section, peer-reviewed
 - 27 publications may be substituted.
 - 28 c. When establishing a step therapy protocol, a utilization
 - 29 review agent shall also consider the needs of atypical patient
 - 30 populations and diagnoses when establishing clinical review
 - 31 criteria.
 - 32 d. A carrier shall:
 - 33 (1) upon written request, provide specific written clinical review
 - 34 criteria relating to a particular condition or disease, including
 - 35 clinical review criteria relating to a step therapy protocol exception
 - 36 determination; and
 - 37 (2) make available the clinical review criteria and other clinical
 - 38 information on its internet website and to a health care professional
 - 39 on behalf of an insured person upon written request.
 - 40 e. This section shall not be construed to require carriers or the
 - 41 State to establish a new entity to develop clinical review criteria
 - 42 used for step therapy protocols.
 - 43
 - 44 4. Notwithstanding the provisions of any law, rule, or
 - 45 regulation to the contrary:
 - 46 a. When coverage of a prescription drug for the treatment of
 - 47 any medical condition is restricted for use by a carrier or utilization
 - 48 review organization pursuant to a step therapy protocol, the carrier

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

13 b. A step therapy exception shall be granted if:

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

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

20 (3) the patient has tried the required prescription drug or another
21 prescription drug in the same pharmacologic class or with the same
22 mechanism of action and the prescription drug was discontinued
23 due to lack of efficacy or effectiveness, diminished effect, or an
24 adverse event;

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

27 (5) the patient is stable on a prescription drug selected by their
28 health care provider for the medical condition under consideration.

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

33 d. Any step therapy exception shall be eligible for appeal by a
34 covered person. The carrier or utilization review organization shall
35 grant or deny a step therapy exception request or an appeal of a step
36 therapy exception request within 72 hours of receipt of the request
37 or appeal. In cases where exigent circumstances exist, the carrier or
38 utilization review organization shall respond within 24 hours of
39 receipt. If a request for a step therapy exception is incomplete or if
40 additional clinically relevant information is required, the carrier or
41 utilization review organization shall notify the prescribing
42 practitioner within 72 hours of submission, or 24 hours in exigent
43 circumstances, what additional or clinically relevant information is
44 required in order to approve or deny the step therapy exception
45 request or appeal pursuant to the criteria disclosed pursuant to
46 subsection a. of this section. Once the requested information is
47 submitted, the applicable time period to grant or deny a step therapy
48 exception request or appeal shall apply. If a response by a carrier

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

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

7 f. This section shall not be construed to prevent:

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

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

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

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

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

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

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

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

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

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

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

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

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

STATEMENT

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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 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 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 shall 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 shall 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;

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

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

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

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

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

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

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