

ASSEMBLY COMMITTEE SUBSTITUTE FOR  
ASSEMBLY COMMITTEE SUBSTITUTE FOR  
**ASSEMBLY, No. 1825**

**STATE OF NEW JERSEY**  
**221st LEGISLATURE**

ADOPTED MARCH 20, 2025

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**SYNOPSIS**

Establishes certain guidelines for SHBP, SEHBP, and Medicaid concerning step therapy protocols.

**CURRENT VERSION OF TEXT**

Substitute as adopted by the Assembly Appropriations Committee.

(Sponsorship Updated As Of: 3/24/2025)

1 AN ACT concerning step therapy protocols and supplementing  
2 Titles 30 and 52 of 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. To address the increasingly high cost of prescription drug  
9 utilization and to address patient safety, health insurance carriers  
10 and other plan sponsors use step therapy protocols that require  
11 patients to try one or more prescription drugs before coverage is  
12 provided for a drug selected by the patient's health care provider.

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

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

21 d. It is imperative that step therapy protocols in the State  
22 preserve the health care provider's right to make medically  
23 necessary treatment decisions in the best interest of the patient.

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

36

37 2. As used in sections 2 through 6 of this act:

38 "Division" means the Division of Medical Assistance and Health  
39 Services in the Department of Human Services.

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

1 “Managed care organization” means a health maintenance  
2 organization contracted with the division to provide benefits to  
3 Medicaid beneficiaries.

4 “Medicaid” means the program established pursuant to P.L.1968,  
5 c.413 (C.30:4D-1 et seq.).

6 “Medical necessity” or “medically necessary” means the same as  
7 those terms are defined in section 4 of P.L.2023, c.296 (C.17B:30-  
8 55.3).

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

12 “Step therapy protocol” means a protocol, policy, or program  
13 that establishes the specific sequence in which prescription drugs  
14 for a specified medical condition, and medically appropriate for a  
15 particular patient, are required to be administered in order to be  
16 covered by the division or a managed care organization.

17

18 3. a. The division or a managed care organization shall require  
19 that clinical review criteria used to establish a step therapy protocol  
20 under Medicaid are based on clinical practice guidelines developed  
21 by the division, or a managed care organization that:

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

24 (2) are developed and endorsed by a multidisciplinary panel of  
25 experts that:

26 (a) relies on objective data; and

27 (b) manages conflicts of interest among the members by  
28 requiring members to disclose any potential conflict of interests  
29 with entities, including managed care organizations, carriers, and  
30 pharmaceutical manufacturers and recuse themselves from voting if  
31 they have a conflict of interest;

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

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

35 (a) minimizes biases and conflicts of interest;

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

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

40 (d) considers relevant patient subgroups and preferences; and

41 (5) are reviewed annually or quarterly if there is a new  
42 indication or new clinical information available and updated when  
43 such review reveals new evidence necessitating modification.

- 1       b. In the absence of clinical guidelines that meet the  
2 requirements in subsection a. of this section, peer-reviewed  
3 publications may be substituted.
- 4       c. When establishing a step therapy protocol, the division or  
5 managed care organization shall also consider the needs of atypical  
6 patient populations and diagnoses when establishing clinical review  
7 criteria.
- 8       d. A managed care organization shall:
- 9       (1) upon written request, provide written clinical review criteria  
10 relating to a particular condition or disease, including clinical  
11 review criteria relating to a step therapy protocol exception  
12 determination; and
- 13       (2) make available the clinical review criteria and other clinical  
14 information on its internet website and to a health care professional  
15 on behalf of an insured person upon written request.
- 16       e. This section shall not be construed to require managed care  
17 organizations or the State to establish a new entity to develop  
18 clinical review criteria used for step therapy protocols.
- 19
- 20       4. Notwithstanding the provisions of any law, rule, or  
21 regulation to the contrary:
- 22       a. When coverage of a prescription drug for the treatment of  
23 any medical condition is restricted for use by a managed care  
24 organization pursuant to a step therapy protocol, the managed care  
25 organization shall provide the enrollee and prescribing practitioner  
26 a clear, readily accessible, and convenient process to request a step  
27 therapy exception. A managed care organization may use its  
28 existing medical exceptions process to satisfy this requirement. An  
29 explanation of the process shall be made available on the managed  
30 care organization's website. A managed care organization shall  
31 disclose all rules and criteria related to the step therapy protocol  
32 upon request to all prescribing practitioners, including the specific  
33 information and documentation required to be submitted by a  
34 prescribing practitioner or patient for an exception request to be  
35 complete.
- 36       b. A step therapy exception shall be granted if the prescribing  
37 health care provider determines that:
- 38       (1) the required prescription drug is contraindicated or is likely  
39 to cause an adverse reaction or physical or mental harm to the  
40 patient;
- 41       (2) the required prescription drug is expected to be ineffective  
42 or less effective than an alternative based on the known clinical  
43 characteristics of the patient and the known characteristics of the  
44 prescription drug regimen; or

1 (3) all formulary drugs used to treat each disease state have been  
2 ineffective or less effective than an alternative in the treatment of  
3 the enrollee's disease or condition, or all such drugs have caused or  
4 are reasonably expected to cause adverse or harmful reactions in the  
5 enrollee.

6 If requested by a managed care organization, the prescribing  
7 health care provider shall provide documentation to support the  
8 determinations made by the provider pursuant to paragraphs (1)  
9 through (3) of this subsection.

10 c. When a step therapy exception is granted, the managed care  
11 organization shall authorize coverage for the prescription drug  
12 prescribed by the patient's treating health care provider at least 180  
13 days or the duration of therapy if less than 180 days, provided that  
14 the prescription drug is covered under the managed care  
15 organization's formulary.

16 d. Any step therapy exception shall be eligible for appeal by an  
17 enrollee. The managed care organization shall grant or deny a step  
18 therapy exception request or an appeal of a step therapy exception  
19 request within a time frame appropriate to the medical exigencies of  
20 the case but no later than 24 hours for urgent requests and 72 hours  
21 for non-urgent requests after obtaining all necessary information to  
22 make the approval or adverse determination.

23 e. Any step therapy exception pursuant to this section shall be  
24 eligible for appeal by an enrollee.

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

26 (1) a managed care organization from requiring a patient to try  
27 an AB-rated generic equivalent, biosimilar, or interchangeable  
28 biological product prior to providing coverage for the equivalent  
29 branded prescription drug;

30 (2) a managed care organization from requiring a pharmacist to  
31 effect substitutions of prescription drugs consistent with the laws of  
32 this State; or

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

35

36 5. A managed care organization shall make statistics available  
37 regarding step therapy exception request approvals and denials on  
38 its Internet website in a readily accessible format, as determined by  
39 the Commissioner of Human Services, or the commissioner's  
40 designee. The commissioner shall determine by regulation the  
41 statistics and format of the statistics that are made available.

42

43 6. The Commissioner of Human Services shall apply for such  
44 State plan amendments or waivers as may be necessary to  
45 implement the provisions of this act and secure federal financial

1 participation for State Medicaid expenditures under the federal  
2 Medicaid program. Prior to the implementation of this act, the  
3 Commissioner of Human Services shall provide a separate rate  
4 certification for this program and benefit change within the acute  
5 care and managed long-term services and supports programs in  
6 compliance with federal standards including but not limited to 42  
7 C.F.R. 438.4. Implementation of this program and benefit change  
8 during the course of a state fiscal year shall require a mid-year  
9 managed care rate adjustment for the acute care and managed long  
10 term services and supports program.

11

12 7. As used in sections 7 through 10 of this act:

13 "Covered person" means a person on whose behalf the State  
14 Health Benefits Program or the School Employees' Health Benefits  
15 Program is obligated to pay benefits or provide services pursuant to  
16 the health benefits plan.

17 "Health benefits plan" means a plan providing health care  
18 benefits coverage for public employees and their dependents offered  
19 by the State Health Benefits Program or the School Employees'  
20 Health Benefits Program.

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

28 "Medical necessity" or "medically necessary" means the same as  
29 those terms are defined in section 4 of P.L.2023, c.296 (C.17B:30-  
30 55.3).

31 "Step therapy exception" means the overriding of a step therapy  
32 protocol in favor of immediate coverage of the health care  
33 provider's selected prescription drug.

34 "Step therapy protocol" means a protocol, policy, or program  
35 that establishes the specific sequence in which prescription drugs  
36 for a specified medical condition, and medically appropriate for a  
37 particular patient, are required to be administered in order to be  
38 covered by a health benefits plan.

39 "Utilization review organization" means an entity that contracts  
40 with a vendor to conduct utilization review.

41 "Vendor" means a third-party administrator that conducts claims  
42 administration, network management, claims processing, or other  
43 related services for the State Health Benefits Commission or the  
44 School Employees' Health Benefits Commission.

- 1       8. a. A contract entered into by the State Health Benefits  
2 Commission or the School Employees' Health Benefits Commission  
3 with a vendor shall require that clinical review criteria used to  
4 establish a step therapy protocol are based on clinical practice  
5 guidelines developed by the vendor that:
- 6       (1) recommend that the prescription drugs be taken in the  
7 specific sequence required by the step therapy protocol;
- 8       (2) are developed and endorsed by a multidisciplinary panel of  
9 experts that:
- 10      (a) relies on objective data; and
- 11      (b) manages conflicts of interest among the members by  
12 requiring members to disclose any potential conflict of interests  
13 with entities, including vendors, carriers, and pharmaceutical  
14 manufacturers and recuse themselves from voting if they have a  
15 conflict of interest;
- 16      (3) are based on high quality studies, research, and medical  
17 practice;
- 18      (4) are created by an explicit and transparent process that:
- 19      (a) minimizes biases and conflicts of interest;
- 20      (b) explains the relationship between treatment options and  
21 outcomes;
- 22      (c) rates the quality of the evidence supporting  
23 recommendations; and
- 24      (d) considers relevant patient subgroups and preferences; and
- 25      (5) are reviewed annually or quarterly if there is a new  
26 indication or new clinical information available and updated when  
27 such review reveals new evidence necessitating modification.
- 28       b. In the absence of clinical guidelines that meet the  
29 requirements in subsection a. of this section, peer-reviewed  
30 publications may be substituted.
- 31       c. When establishing a step therapy protocol, a utilization  
32 review agent shall also consider the needs of atypical patient  
33 populations and diagnoses when establishing clinical review  
34 criteria.
- 35       d. A vendor shall:
- 36      (1) upon written request, provide written clinical review criteria  
37 relating to a particular condition or disease, including clinical  
38 review criteria relating to a step therapy protocol exception  
39 determination; and
- 40      (2) make available the clinical review criteria and other clinical  
41 information on its internet website and to a health care professional  
42 on behalf of an insured person upon written request.
- 43       e. This section shall not be construed to require vendors or the  
44 State to establish a new entity to develop clinical review criteria  
45 used for step therapy protocols.

- 1 9. Notwithstanding the provisions of any law, rule, or  
2 regulation to the contrary:
- 3 a. When coverage of a prescription drug for the treatment of  
4 any medical condition is restricted for use by a vendor or utilization  
5 review organization pursuant to a step therapy protocol, the vendor  
6 or utilization review organization shall provide the covered person  
7 and prescribing practitioner a clear, readily accessible, and  
8 convenient process to request a step therapy exception. A vendor or  
9 utilization review organization may use its existing medical  
10 exceptions process to satisfy this requirement. An explanation of  
11 the process shall be made available on the vendor or utilization  
12 review organization's website. A vendor or utilization review  
13 organization shall disclose all rules and criteria related to the step  
14 therapy protocol upon request to all prescribing practitioners,  
15 including the specific information and documentation required to be  
16 submitted by a prescribing practitioner or patient for an exception  
17 request to be complete.
- 18 b. A step therapy exception shall be granted if the prescribing  
19 health care provider determines that:
- 20 (1) the required prescription drug is contraindicated or is likely  
21 to cause an adverse reaction or physical or mental harm to the  
22 patient;
- 23 (2) the required prescription drug is expected to be ineffective  
24 or less effective than an alternative based on the known clinical  
25 characteristics of the patient and the known characteristics of the  
26 prescription drug regimen; or
- 27 (3) all formulary drugs used to treat each disease state have been  
28 ineffective or less effective than an alternative in the treatment of  
29 the covered person's disease or condition, or all such drugs have  
30 caused or are reasonably expected to cause adverse or harmful  
31 reactions in the covered person.
- 32 If requested by a vendor, the prescribing health care provider  
33 shall provide documentation to support the determinations made by  
34 the provider pursuant to paragraphs (1) through (3) of this  
35 subsection.
- 36 c. When a step therapy exception is granted, the vendor or  
37 utilization review organization shall authorize coverage for the  
38 prescription drug prescribed by the patient's treating health care  
39 provider at least 180 days or the duration of therapy if less than 180  
40 days, provided that the prescription drug is covered by the patient's  
41 health benefits plan.
- 42 d. Any step therapy exception shall be eligible for appeal by a  
43 covered person. The vendor or utilization review organization shall  
44 grant or deny a step therapy exception request or an appeal of a step  
45 therapy exception request within a time frame appropriate to the

1 medical exigencies of the case but no later than 24 hours for urgent  
2 requests and 72 hours for non-urgent requests after obtaining all  
3 necessary information to make the approval or adverse  
4 determination.

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 vendor or utilization review organization from requiring a  
9 patient to try an AB-rated generic equivalent, biosimilar, or  
10 interchangeable biological product prior to providing coverage for  
11 the equivalent branded prescription drug;

12 (2) a vendor 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.

17

18 10. A vendor or utilization review organization shall make  
19 statistics available regarding step therapy exception request  
20 approvals and denials on its Internet website in a readily accessible  
21 format, as determined by the State Treasurer, or the State  
22 Treasurer's designee. The State Treasurer shall determine by  
23 regulation the statistics and format of the statistics that are made  
24 available.

25

26 11. This act shall take effect on, and apply to all contracts and  
27 policies delivered, issued, executed, or renewed on or after, January  
28 1, 2026.