30:4D-7uu to 30:4D-7zz et al
LEGISLATIVE HISTORY CHECKLIST

Compiled by the NJ State Law Library

LAWS OF: 2025 **CHAPTER:** 50

NJSA: 30:4D-7uu to 30:4D-7zz et al Establishes certain guidelines for SHBP, SEHBP, and Medicaid concerning step therapy protocols.

BILL NO: A1825 (Substituted for S3533 (SCS))

SPONSOR(S) Verrelli, Anthony S. and others

DATE INTRODUCED: 1/9/2024

COMMITTEE: **ASSEMBLY:** Health
Financial Institutions & Insurance
Appropriations

SENATE: --

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** 03/24/2025

SENATE: 03/24/2025

DATE OF APPROVAL: 5/8/2025

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (A1825 AcaAcsAcs (ACS) enacted)

ADVANCE LAW Yes

PAMPHLET LAW Yes

A1825

INTRODUCED BILL: (Includes sponsor(s) statement) Yes

REPRINT(S): Yes AHE 3/14/24
AFI 1/27/25 ACS
AAP 3/20/25 ACS ACS

TECHNICAL REVIEW OF BILL: No

COMMITTEE STATEMENT: **ASSEMBLY**: Yes Health
Financial Institutions & Insurance
Appropriations

SENATE: No

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: Yes 03/27/2025 ACS
03/27/2025 ACS ACS

S3533 (SCS)

INTRODUCED BILL: (Includes sponsor(s) statement)		Yes	
REPRINT(S):		Yes	SBA 3/17/25 SCS
TECHNICAL REVIEW OF BILL:		No	
COMMITTEE STATEMENT:	**ASSEMBLY**:	No	
	SENATE:	Yes	Commerce Budget & Appropriations

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT:	No	
LEGISLATIVE FISCAL ESTIMATE:	Yes	11/25/2024 03/24/2025

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: Yes

LEGISLATOR STATEMENT: No

FOLLOWING WERE PRINTED:

To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext.103 or mailto:refdesk@njstatelib.org

REPORTS:	No
HEARINGS:	No
NEWSPAPER ARTICLES:	No

CL/MMcB

§§1-6
C.30:4D-7uu
to 30:4D-7zz
§§7-10
C.52:14-17.28h
to 52:14-17.28k
§1
Note to §7
§11
Note to all
sections

P.L. 2025, CHAPTER 50, ***approved May 8, 2025***
Assembly Committee Substitute for
Assembly Committee Substitute for
Assembly, No. 1825

AN ACT concerning step therapy protocols and supplementing Titles 30 and 52 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. To address the increasingly high cost of prescription drug utilization and to address patient safety, health insurance carriers and other plan sponsors use 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. 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. It is imperative that step therapy protocols in the State preserve the heath care provider's right to make medically necessary treatment decisions in the best interest of the patient.

e. The Legislature declares, therefore, that it is a matter of public interest that the State Health Benefits Program, the School Employers Health Benefits Program, and NJ FamilyCare 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 sections 2 through 6 of this act:

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

"Health care provider" means an individual or entity which, acting within the scope of its licensure or certification, provides a covered service. 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.

"Managed care organization" means a health maintenance organization contracted with the division to provide benefits to Medicaid beneficiaries.

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

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

"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 the division or a managed care organization.

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

(a) relies on objective data; and

(b) manages conflicts of interest among the members by requiring members to disclose any potential conflict of interests

with entities, including managed care organizations, carriers, and pharmaceutical manufacturers and recuse themselves from voting if they have a conflict of interest;

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

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, the division or managed care organization shall also consider the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

d. A managed care organization shall:

(1) upon written request, provide 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 managed care organizations 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 managed care organization pursuant to a step therapy protocol, the managed care organization shall provide the enrollee and prescribing practitioner a clear, readily accessible, and convenient process to request a step therapy exception. A managed care organization may use its existing medical exceptions process to satisfy this requirement. An explanation of the process shall be made available on the managed

care organization's website. A managed care 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 the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

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

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

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

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

f. This section shall not be construed to prevent:

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

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

6. The Commissioner of Human Services shall apply for such State plan amendments or waivers as may be necessary to implement the provisions of this act and secure federal financial participation for State Medicaid expenditures under the federal Medicaid program. Prior to the implementation of this act, the Commissioner of Human Services shall provide a separate rate certification for this program and benefit change within the acute care and managed long-term services and supports programs in compliance with federal standards including but not limited to 42 C.F.R. 438.4. Implementation of this program and benefit change during the course of a state fiscal year shall require a mid-year managed care rate adjustment for the acute care and managed long term services and supports program.

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

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

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

"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.

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

"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 contracts with a vendor to conduct utilization review.

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

8. a. A contract entered into by the State Health Benefits Commission or the School Employees' Health Benefits Commission with a vendor shall require that clinical review criteria used to establish a step therapy protocol are based on clinical practice guidelines developed by the vendor 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:

(a) relies on objective data; and

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

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

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 vendor shall:

(1) upon written request, provide 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 vendors or the State to establish a new entity to develop clinical review criteria used for step therapy protocols.

9. 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 vendor or utilization review organization pursuant to a step therapy protocol, the vendor 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 vendor 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 vendor or utilization review organization’s website. A vendor 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 the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

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

c. When a step therapy exception is granted, the vendor or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient’s treating health care provider at least 180 days or the duration of therapy if less than 180 days, provided that the prescription drug is covered by the patient’s health benefits plan.

d. Any step therapy exception shall be eligible for appeal by a covered person. The vendor or utilization review organization shall grant or deny a step therapy exception request or an appeal of a step therapy exception request within a time frame appropriate to the medical exigencies of the case but no later than 24 hours for urgent requests and 72 hours for non-urgent requests after obtaining all necessary information to make the approval or adverse determination.

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

(2) a vendor 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.

10. A vendor or utilization review organization shall make statistics available regarding step therapy exception request approvals and denials on its Internet website in a readily accessible format, as determined by the State Treasurer, or the State

Treasurer's designee. The State Treasurer shall determine by regulation the statistics and format of the statistics that are made available.

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

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

CHAPTER 50

AN ACT concerning step therapy protocols and supplementing Titles 30 and 52 of the Revised Statutes.

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

C.30:4D-7uu Findings, declarations.

1. The Legislature finds and declares that:

a. To address the increasingly high cost of prescription drug utilization and to address patient safety, health insurance carriers and other plan sponsors use 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. 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. It is imperative that step therapy protocols in the State preserve the heath care provider's right to make medically necessary treatment decisions in the best interest of the patient.

e. The Legislature declares, therefore, that it is a matter of public interest that the State Health Benefits Program, the School Employers Health Benefits Program, and NJ FamilyCare 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.

C.30:4D-7vv Definitions.

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

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

"Health care provider" means an individual or entity which, acting within the scope of its licensure or certification, provides a covered service. 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.

"Managed care organization" means a health maintenance organization contracted with the division to provide benefits to Medicaid beneficiaries.

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

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

"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 the division or a managed care organization.

C.30:4D-7ww Clinical review criteria, guidelines, step therapy protocol, Medicaid.

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

(a) relies on objective data; and

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

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

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, the division or managed care organization shall also consider the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

d. A managed care organization shall:

(1) upon written request, provide 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 managed care organizations or the State to establish a new entity to develop clinical review criteria used for step therapy protocols.

C.30:4D-7xx Prescription drug coverage restriction, step therapy protocol, exception process, managed care organization.

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 managed care organization pursuant to a step therapy protocol, the managed care organization shall provide the enrollee and prescribing practitioner a clear, readily accessible, and convenient process to request a step therapy exception. A managed care organization may use its existing medical exceptions process to satisfy this requirement. An explanation of the process shall be made available on the managed care organization's website. A managed care 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 the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

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

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

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

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

f. This section shall not be construed to prevent:

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

(2) a managed care 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.

C.30:4D-7yy Statistics made available, step therapy exception request approvals, denials, managed care organization.

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

C.30:4D-7zz State plan amendments, waivers, apply as necessary for implementation, step therapy.

6. The Commissioner of Human Services shall apply for such State plan amendments or waivers as may be necessary to implement the provisions of this act and secure federal financial participation for State Medicaid expenditures under the federal Medicaid program. Prior to the implementation of this act, the Commissioner of Human Services shall provide a separate rate certification for this program and benefit change within the acute care and managed long-term services and supports programs in compliance with federal standards, including, but not limited to, 42 C.F.R. 438.4. Implementation of this program and benefit change during the course of a state fiscal year shall require a mid-year managed care rate adjustment for the acute care and managed long term services and supports program.

C.52:14-17.28h Definitions.

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

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

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

"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.

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

"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 contracts with a vendor to conduct utilization review.

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

C.52:14-17.28i Clinical review criteria, guidelines, step therapy protocol, State Health Benefits Commission, School Employees' Health Benefits Commission.

8. a. A contract entered into by the State Health Benefits Commission or the School Employees' Health Benefits Commission with a vendor shall require that clinical review criteria used to establish a step therapy protocol are based on clinical practice guidelines developed by the vendor 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:

(a) relies on objective data; and

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

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

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 vendor shall:

(1) upon written request, provide 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 vendors or the State to establish a new entity to develop clinical review criteria used for step therapy protocols.

C.52:14-17.28j Prescription drug coverage restriction, step therapy protocol, exception process, vendor, utilization review organization.

9. 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 vendor or utilization review organization pursuant to a step therapy protocol, the vendor 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 vendor 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 vendor or utilization review organization's website. A vendor 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 the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

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

c. When a step therapy exception is granted, the vendor or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider at least 180 days or the duration of therapy if less than 180 days, provided that the prescription drug is covered by the patient's health benefits plan.

d. Any step therapy exception shall be eligible for appeal by a covered person. The vendor or utilization review organization shall grant or deny a step therapy exception request or an appeal of a step therapy exception request within a time frame appropriate to the medical

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

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

(2) a vendor 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.

C.52:14-17.28k Statistics made available, step therapy exception request approvals, denials, vendor, utilization review organization.

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

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

Approved May 8, 2025.

ASSEMBLY, No. 1825

STATE OF NEW JERSEY

221st LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2024 SESSION

Sponsored by:
Assemblyman HERB CONAWAY, JR.
District 7 (Burlington)
Assemblyman ANTHONY S. VERRELLI
District 15 (Hunterdon and Mercer)

Co-Sponsored by:
Assemblywomen Murphy, Swain, Assemblyman Tully, Assemblywoman Speight, Assemblymen Danielsen, Karabinchak, Assemblywomen Quijano, Lampitt, Lopez, N.Munoz, Tucker, Reynolds-Jackson, Dunn, Assemblymen Stanley, Sauickie, Clifton, Assemblywomen Haider, Swift, Assemblyman DeAngelo, Assemblywoman Carter, Assemblymen Bergen, Guardian and Azzariti Jr.

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: 2/8/2024)

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.

[First Reprint]

ASSEMBLY, No. 1825

STATE OF NEW JERSEY

221st LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2024 SESSION

Sponsored by:
Assemblyman HERB CONAWAY, JR.
District 7 (Burlington)
Assemblyman ANTHONY S. VERRELLI
District 15 (Hunterdon and Mercer)

Co-Sponsored by:
Assemblywomen Murphy, Swain, Assemblyman Tully, Assemblywoman Speight, Assemblymen Danielsen, Karabinchak, Assemblywomen Quijano, Lampitt, Lopez, N.Munoz, Tucker, Reynolds-Jackson, Dunn, Assemblymen Stanley, Sauickie, Clifton, Assemblywomen Haider, Swift, Assemblyman DeAngelo, Assemblywoman Carter, Assemblymen Bergen, Guardian, Azzariti Jr. and Assemblywoman Matsikoudis

SYNOPSIS

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

CURRENT VERSION OF TEXT

As reported by the Assembly Health Committee on March 14, 2024, with amendments.

(Sponsorship Updated As Of: 5/2/2024)

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

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1]Assembly AHE committee amendments adopted March 14, 2024.

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 [1], biosimilar,[1] 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 [1]**[**January 1, 2021**]** July 1, 2024[1].

ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 1825

STATE OF NEW JERSEY

221st LEGISLATURE

ADOPTED JANUARY 27, 2025

Sponsored by:
Assemblyman ANTHONY S. VERRELLI
District 15 (Hunterdon and Mercer)

Co-Sponsored by:
Assemblywomen Murphy, Swain, Assemblyman Tully, Assemblywoman Speight, Assemblymen Danielsen, Karabinchak, Assemblywomen Quijano, Lopez, N.Munoz, Tucker, Reynolds-Jackson, Dunn, Assemblymen Stanley, Sauickie, Clifton, Assemblywomen Haider, Swift, Assemblyman DeAngelo, Assemblywoman Carter, Assemblymen Bergen, Guardian, Azzariti Jr., Assemblywoman Matsikoudis, Assemblymen Sampson and Rodriguez

SYNOPSIS

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

CURRENT VERSION OF TEXT

Substitute as adopted by the Assembly Financial Institutions and Insurance Committee.

(Sponsorship Updated As Of: 3/20/2025)

AN ACT concerning step therapy protocols 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. To address the increasingly high cost of prescription drug utilization and to address patient safety, health insurance carriers and other plan sponsors use 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. 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. It is imperative that step therapy protocols in the State preserve the heath care provider's right to make medically necessary treatment decisions in the best interest of the patient.

e. 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.

"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. For the purpose of this act, "health benefits plan" shall include the School Employees Health Benefits Plan, the State Employees' Health Benefits Plan, and Medicaid, and shall not include the following plans, policies, or contracts: commercial market plans including individual, small and large group plans, Medicare, Medicare Advantage, Medicare supplement, accident only, credit, disability, long-term care, TRICARE 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.), and 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.

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

"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 developed by the carrier 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:

(a) relies on objective data; and

(b) manages conflicts of interest among the members by 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;

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

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 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 of a particular drug on the provider portal of the Internet website of the carrier and upon written request to non-profit health care organizations, subject to redaction as may be necessary. When releasing to non-profit health care organizations, a carrier may redact information as may be permitted by the Department of the Treasury for the State Health Benefits Program or the Department of Human Services for the New Jersey FamilyCare Program.

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 the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

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

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 at least 180 days or the duration of therapy if less than 180 days, provided that the prescription drug is covered by the patient's health care plan.

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 a time frame appropriate to the medical exigencies of the case but no later than 24 hours for urgent requests and 72 hours for non-urgent requests after obtaining all

necessary information to make the approval or adverse determination.

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. A carrier or utilization review organization shall make statistics available regarding step therapy exception request approvals and denials on its Internet website in a readily accessible format, as determined by the Commissioner of Human Services. The Commissioner of Human Services shall determine by regulation the statistics and format of the statistics that are made available.

6. The Commissioner of Banking and Insurance and the Commissioner of Human Services 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. The Commissioner of Human Services shall apply for such State plan amendments or waivers as may be necessary to implement the provisions of this act and secure federal financial participation for State Medicaid expenditures under the federal Medicaid program. Prior to the implementation of this act, the Commissioner of Human Services shall provide a separate rate certification for this program and benefit change within the acute care and managed long-term services and supports programs in compliance with federal standards including but not limited to 42 C.F.R. 438.4. Implementation of this program and benefit change during the course of a State Fiscal Year shall require a mid-year managed care rate adjustment for the acute care and managed long term services and supports program.

8. 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, 2026.

ASSEMBLY COMMITTEE SUBSITUTE FOR

ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 1825

STATE OF NEW JERSEY

221st LEGISLATURE

ADOPTED MARCH 20, 2025

Sponsored by:
Assemblyman ANTHONY S. VERRELLI
District 15 (Hunterdon and Mercer)
Senator ANGELA V. MCKNIGHT
District 31 (Hudson)
Senator JON M. BRAMNICK
District 21 (Middlesex, Morris, Somerset and Union)

Co-Sponsored by:
Assemblywomen Murphy, Swain, Assemblyman Tully, Assemblywoman Speight, Assemblymen Danielsen, Karabinchak, Assemblywomen Quijano, Lopez, N.Munoz, Tucker, Reynolds-Jackson, Dunn, Assemblymen Stanley, Sauickie, Clifton, Assemblywomen Haider, Swift, Assemblyman DeAngelo, Assemblywoman Carter, Assemblymen Bergen, Guardian, Azzariti Jr., Assemblywoman Matsikoudis, Assemblyman Sampson, Assemblywoman Park, Assemblyman Rodriguez, Assemblywomen Hall, Bagolie, Peterpaul, Donlon, Senators Wimberly and Greenstein

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)

AN ACT concerning step therapy protocols and supplementing Titles 30 and 52 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. To address the increasingly high cost of prescription drug utilization and to address patient safety, health insurance carriers and other plan sponsors use 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. 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. It is imperative that step therapy protocols in the State preserve the heath care provider's right to make medically necessary treatment decisions in the best interest of the patient.

e. The Legislature declares, therefore, that it is a matter of public interest that the State Health Benefits Program, the School Employers Health Benefits Program, and NJ FamilyCare 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 sections 2 through 6 of this act:

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

"Health care provider" means an individual or entity which, acting within the scope of its licensure or certification, provides a covered service. 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.

"Managed care organization" means a health maintenance organization contracted with the division to provide benefits to Medicaid beneficiaries.

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

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

"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 the division or a managed care organization.

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

(a) relies on objective data; and

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

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

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, the division or managed care organization shall also consider the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

d. A managed care organization shall:

(1) upon written request, provide 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 managed care organizations 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 managed care organization pursuant to a step therapy protocol, the managed care organization shall provide the enrollee and prescribing practitioner a clear, readily accessible, and convenient process to request a step therapy exception. A managed care organization may use its existing medical exceptions process to satisfy this requirement. An explanation of the process shall be made available on the managed care organization's website. A managed care 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 the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

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

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

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

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

f. This section shall not be construed to prevent:

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

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

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

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

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

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

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

"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.

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

"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 contracts with a vendor to conduct utilization review.

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

8. a. A contract entered into by the State Health Benefits Commission or the School Employees' Health Benefits Commission with a vendor shall require that clinical review criteria used to establish a step therapy protocol are based on clinical practice guidelines developed by the vendor 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:

(a) relies on objective data; and

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

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

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 vendor shall:

(1) upon written request, provide 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 vendors or the State to establish a new entity to develop clinical review criteria used for step therapy protocols.

9. 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 vendor or utilization review organization pursuant to a step therapy protocol, the vendor 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 vendor 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 vendor or utilization review organization's website. A vendor 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 the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

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

c. When a step therapy exception is granted, the vendor or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider at least 180 days or the duration of therapy if less than 180 days, provided that the prescription drug is covered by the patient's health benefits plan.

d. Any step therapy exception shall be eligible for appeal by a covered person. The vendor or utilization review organization shall grant or deny a step therapy exception request or an appeal of a step therapy exception request within a time frame appropriate to the

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

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

(2) a vendor 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.

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

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

ASSEMBLY HEALTH COMMITTEE

STATEMENT TO

ASSEMBLY, No. 1825

with committee amendments

STATE OF NEW JERSEY

DATED: MARCH 14, 2024

The Assembly Health Committee reports favorably and with committee amendments Assembly Bill No. 1825.

As amended, 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 are 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 receipt of the request or appeal. 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.

This bill was pre-filed for introduction in the 2024-2025 session pending technical review. As reported, the bill includes the changes required by technical review, which has been performed.

COMMITTEE AMENDMENTS:

The committee amendments:

1) provide that section 4 of the bill is not to be construed to prevent a carrier or utilization review organization from requiring a patient to

try a biosimilar prior to providing coverage for the equivalent branded prescription drug; and

2) make a technical change to update the effective date.

ASSEMBLY FINANCIAL INSTITUTIONS AND INSURANCE COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR
ASSEMBLY, No. 1825

STATE OF NEW JERSEY

DATED: JANUARY 27, 2025

The Assembly Financial Institutions and Insurance Committee reports favorably an Assembly Committee Substitute for Assembly Bill No. 1825.

This substitute 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 required to be administered in order to be covered by a health benefits plan.

The bill provides that clinical review criteria used to establish a step therapy protocol will be based on clinical practice guidelines developed by the carrier 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 rely on objective data and manages conflicts of interest among the members by 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;

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

The bill further 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 pursuant to a step therapy

protocol, the carrier or utilization review organization must 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 will be made available on the carrier or utilization review organization's website.

A step therapy exception will be granted if the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

If requested by a carrier, the prescribing health care provider is to provide documentation to support the determinations made by the provider.

Additionally, the bill provides that when a step therapy exception is granted, the carrier or utilization review organization will authorize coverage for the prescription drug prescribed by the patient's treating health care provider at least 180 days or the duration of therapy if less than 180 days, provided that the prescription drug is covered by the patient's health care plan.

The bill provides that any step therapy exception is eligible for appeal by a covered person. The carrier or utilization review organization must grant or deny a step therapy exception request or an appeal of a step therapy exception request within a time frame appropriate to the medical exigencies of the case but no later than 24 hours for urgent requests and 72 hours for non-urgent requests after obtaining all necessary information to make the approval or adverse determination.

The bill finally provides that a carrier or utilization review organization is to make available on its Internet website certain information regarding step therapy exception request approvals and denials, as determined by the Commissioner of Human Services.

ASSEMBLY APPROPRIATIONS COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY COMMITTEE SUBSTITUTE FOR
ASSEMBLY, No. 1825

STATE OF NEW JERSEY

DATED: MARCH 20, 2025

The Assembly Appropriations Committee reports favorably an Assembly Committee Substitute for Assembly Bill No. 1825 ACS.

As reported, this substitute bill establishes certain guidelines for the State Health Benefits Program, the School Employees Health Benefits Program, and the State Medicaid program concerning step therapy protocols. The bill also applies to: vendors that contract with the State Health Benefits Program and the School Employees Health Benefits Program; managed care organizations that administer the State Medicaid program; and utilization review organizations that work with these entities.

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 required to be administered in order to be covered by a health benefits plan. "Vendor" means a third-party administrator that conducts claims administration, network management, claims processing, or other related services for the State Health Benefits Commission or the School Employees' Health Benefits Commission.

The bill provides that clinical review criteria used to establish a step therapy protocol will 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 rely on objective data and manages conflicts of interest among the members;

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

The bill further provides that when coverage of a prescription drug for the treatment of any medical condition is restricted for use pursuant to a step therapy protocol, the vendor or managed care organization must provide the covered person and prescribing practitioner a clear, readily accessible, and convenient process to request a step therapy exception. An existing medical exceptions process may be used to satisfy this requirement.

A step therapy exception will be granted if the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

If requested by a vendor or managed care organization, the prescribing health care provider is to provide documentation to support the determinations made by the provider.

Additionally, the bill provides that when a step therapy exception is granted, the vendor or managed care organization will authorize coverage for the prescription drug prescribed by the patient’s treating health care provider at least 180 days or the duration of therapy if less than 180 days, provided that the prescription drug is covered by the patient’s health care plan.

The bill provides that any step therapy exception is eligible for appeal by a covered person. The vendor or managed care organization must grant or deny a step therapy exception request or an appeal of a step therapy exception request within a time frame appropriate to the medical exigencies of the case but no later than 24 hours for urgent requests and 72 hours for non-urgent requests after obtaining all necessary information to make the approval or adverse determination.

The bill finally provides that the vendor or managed care organization is to make available on its Internet website certain information regarding step therapy exception request approvals and denials.

FISCAL IMPACT:

The Office of Legislative Services concludes that this bill would increase annual State expenditures for prescription drugs under the

New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program (the State's Medicaid and Children's Health Insurance Program) by an indeterminate amount. Generally, the expenditure increase would result as the bill would regulate the use of prescription drug step therapy protocols for patients covered under these plans and ease the overriding of protocols in favor of drugs selected by health care providers.

The bill would result in indeterminate increases in annual expenditures for local government employers that provide employee coverage through the State Health Benefits Program or the School Employees' Health Benefits Program, and NJ FamilyCare program.

There is the potential for annual costs savings to the State Health Benefits Program, School Employees' Health Benefits Program, and NJ FamilyCare program if the bill's regulations were to result in positive health outcomes that reduce future treatment costs.

Higher NJ FamilyCare expenditures would increase annual State revenue by an indeterminate amount from federal Medicaid and Children's Health Insurance Program matching funds.

LEGISLATIVE FISCAL ESTIMATE

ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 1825

STATE OF NEW JERSEY
221st LEGISLATURE

DATED: MARCH 4, 2025

SUMMARY

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

Type of Impact: Annual State expenditure and revenue increase; annual local expenditure increase.

Agencies Affected: Division of Pensions and Benefits-Department of the Treasury; Department of Human Services; local entities.

Office of Legislative Services Estimate

Fiscal Impact	Annual
State Expenditure Increase	Indeterminate
Local Expenditure Increase	Indeterminate
State Revenue Increase	Indeterminate

- The Office of Legislative Services (OLS) concludes that this bill would increase annual State expenditures for prescription drugs under the New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program (the State's Medicaid and Children's Health Insurance Program) by an indeterminate amount. Generally, the expenditure increase would result as the bill would regulate the use of prescription drug step therapy protocols for patients covered under these plans and ease the overriding of the protocols in favor of drugs selected by health care providers.

- The bill would result in indeterminate increases in annual expenditures for local government employers that provide employee coverage through the State Health Benefits Program or the School Employees' Health Benefits Program.

- There is the potential for annual cost savings to the State Health Benefits Program, School Employees' Health Benefits Program, and NJ FamilyCare program if the bill's regulations were to result in positive health outcomes that reduce future treatment costs.

- Higher NJ FamilyCare expenditures would increase annual State revenue by an indeterminate amount from federal Medicaid and Children's Health Insurance Program matching funds.

BILL DESCRIPTION

This bill requires health insurance carriers and utilization review organizations to meet certain guidelines in the administration and review of step therapy protocols. These protocols establish 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.

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

Health benefits plan under the bill includes the New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and Medicaid.

The Department of Human Services is required to apply for any State plan amendments or waivers necessary to implement the provisions of the bill and secure federal financial participation for State Medicaid expenditures under the federal Medicaid program.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS concludes that this bill would increase annual State expenditures for prescription drugs under the New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program by an indeterminate amount. Generally, the expenditure increase would result as the bill would regulate the use of prescription drug step therapy protocols and ease the overriding of the protocols in favor of drugs selected by health care providers. Additionally, the fiscal impact of the bill would be affected by several unknown variables, such as: the number of enrollees currently using step therapy drugs, the cost differentials between first line drugs and second line drugs; and the current impact of step therapy protocols, by drug, on expenditures. The OLS notes that the Department of Human Services may also incur additional annual costs related to its administrative responsibilities under the bill.

The bill would result in indeterminate increases in annual expenditures for local government employers that provide employee coverage through the State Health Benefits Program or the School Employees' Health Benefits Program.

Increased NJ FamilyCare program expenditures would result in an annual, indeterminate increase in State revenue in the form of federal Medicaid and Children's Health Insurance Program matching funds. For reference, on average, the federal government provides $0.64 in matching funds for every $1.00 in qualifying State NJ FamilyCare expenditures.

There is the potential for annual cost savings to the State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program if the bill's regulations were to result in positive health outcomes that reduce future treatment costs.

The OLS notes that health benefits plans purchased in the commercial market are exempt under the bill, so local government employers that procure these plans for their employees would not be affected by the bill's provisions.

Sections:	*Commerce, Labor and Industry Section & Human Services Section*
Analysts:	*John Gaudioso* *Assistant Fiscal Analyst*
	Sarah Schmidt *Lead Research Analyst*
Approved:	*Thomas Koenig* *Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

LEGISLATIVE FISCAL ESTIMATE

ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 1825

STATE OF NEW JERSEY
221st LEGISLATURE

DATED: MARCH 27, 2025

SUMMARY

Synopsis:	Establishes certain guidelines for SHBP, SEHBP, and Medicaid concerning step therapy protocols.
Type of Impact:	Annual State expenditure and revenue increase; annual local expenditure increase.
Agencies Affected:	Division of Pensions and Benefits-Department of the Treasury; Department of Human Services; local entities.

Office of Legislative Services Estimate

Fiscal Impact	Annual
State Expenditure Increase	Indeterminate
Local Expenditure Increase	Indeterminate
State Revenue Increase	Indeterminate

- The Office of Legislative Services (OLS) concludes that this bill would increase annual State expenditures for prescription drugs under the New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program (the State's Medicaid and Children's Health Insurance Program) by an indeterminate amount. Generally, the expenditure increase would result as the bill would regulate the use of prescription drug step therapy protocols for patients covered under these plans and ease the overriding of the protocols in favor of drugs selected by health care providers

- The bill would result in indeterminate increases in annual expenditures for local government employers that provide employee coverage through the State Health Benefits Program or the School Employees' Health Benefits Program.

- There is the potential for annual cost savings to the State Health Benefits Program, School Employees' Health Benefits Program, and Medicaid program if the bill's regulations were to result in positive health outcomes that reduce future treatment costs.

- Higher NJ FamilyCare expenditures would increase annual State revenue by an indeterminate amount from federal Medicaid Program matching funds.

BILL DESCRIPTION

This bill requires the New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and the State Medicaid program to meet certain guidelines in the administration and review of step therapy protocols. These protocols establish 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.

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

The Department of Human Services is required to apply for any State plan amendments or waivers necessary to implement the provisions of the bill and secure federal financial participation for State Medicaid expenditures under the federal Medicaid program

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS concludes that this bill would increase annual State expenditures for prescription drugs under the New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program by an indeterminate amount. Generally, the expenditure increase would result as the bill would regulate the use of prescription drug step therapy protocols and ease the overriding of the protocols in favor of drugs selected by health care providers. Additionally, the fiscal impact of the bill would be affected by several unknown variables, such as: the number of enrollees currently using step therapy drugs, the cost differentials between first line drugs and second line drugs; and the current impact of step therapy protocols, by drug, on expenditures. The OLS notes that the Department of Human Services may also incur additional annual costs related to its administrative responsibilities under the bill.

The bill would result in indeterminate increases in annual expenditures for local government employers that provide employee coverage through the State Health Benefits Program or the School Employees' Health Benefits Program.

Increased NJ FamilyCare program expenditures would result in an annual, indeterminate increase in State revenue in the form of federal Medicaid and Children's Health Insurance Program matching funds. For reference, on average, the federal government provides $0.64 in matching funds for every $1.00 in qualifying State NJ FamilyCare expenditures.

There is the potential for annual cost savings to the State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program if the bill's regulations were to result in positive health outcomes that reduce future treatment costs.

The OLS notes that health benefits plans purchased in the commercial market are exempt under the bill, so local government employers that procure these plans for their employees would not be affected by the bill's provisions.

Section:	*Commerce, Labor and Industry*
Analyst:	*John Gaudioso* *Associate Fiscal Analyst*
Approved:	*Thomas Koenig* *Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

SENATE, No. 3533

STATE OF NEW JERSEY

221st LEGISLATURE

INTRODUCED SEPTEMBER 12, 2024

Sponsored by:
Senator ANGELA V. MCKNIGHT
District 31 (Hudson)
Senator JON M. BRAMNICK
District 21 (Middlesex, Morris, Somerset and Union)

Co-Sponsored by:
Senators Wimberly and Greenstein

SYNOPSIS

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

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 3/17/2025)

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, biosimilar, 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 July 1, 2024.

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 are 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 receipt of the request or appeal. 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.

SENATE COMMITTEE SUBSTITUTE FOR

SENATE, No. 3533

STATE OF NEW JERSEY

221st LEGISLATURE

ADOPTED MARCH 17, 2025

Sponsored by:
Senator ANGELA V. MCKNIGHT
District 31 (Hudson)
Senator JON M. BRAMNICK
District 21 (Middlesex, Morris, Somerset and Union)

Co-Sponsored by:
Senators Wimberly and Greenstein

SYNOPSIS

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

CURRENT VERSION OF TEXT

Substitute as adopted by the Senate Budget and Appropriations Committee.

AN ACT concerning step therapy protocols and supplementing Titles 30 and 52 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. To address the increasingly high cost of prescription drug utilization and to address patient safety, health insurance carriers and other plan sponsors use 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. 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. It is imperative that step therapy protocols in the State preserve the heath care provider's right to make medically necessary treatment decisions in the best interest of the patient.

e. The Legislature declares, therefore, that it is a matter of public interest that the State Health Benefits Program, the School Employers Health Benefits Program, and NJ FamilyCare 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 sections 2 through 6 of this act:

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

"Health care provider" means an individual or entity which, acting within the scope of its licensure or certification, provides a covered service. 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.

"Managed care organization" means a health maintenance organization contracted with the division to provide benefits to Medicaid beneficiaries.

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

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

"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 the division or a managed care organization.

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

(a) relies on objective data; and

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

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

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, the division or managed care organization shall also consider the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

d. A managed care organization shall:

(1) upon written request, provide 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 managed care organizations 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 managed care organization pursuant to a step therapy protocol, the managed care organization shall provide the enrollee and prescribing practitioner a clear, readily accessible, and convenient process to request a step therapy exception. A managed care organization may use its existing medical exceptions process to satisfy this requirement. An explanation of the process shall be made available on the managed care organization's website. A managed care 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 the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

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

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

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

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

f. This section shall not be construed to prevent:

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

(2) a managed care 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. A managed care organization shall make statistics available regarding step therapy exception request approvals and denials on its Internet website in a readily accessible format, as determined by the Commissioner of Human Services, or the commissioner’s

designee. The commissioner shall determine by regulation the statistics and format of the statistics that are made available.

6. The Commissioner of Human Services shall apply for such State plan amendments or waivers as may be necessary to implement the provisions of this act and secure federal financial participation for State Medicaid expenditures under the federal Medicaid program. Prior to the implementation of this act, the Commissioner of Human Services shall provide a separate rate certification for this program and benefit change within the acute care and managed long-term services and supports programs in compliance with federal standards including but not limited to 42 C.F.R. 438.4. Implementation of this program and benefit change during the course of a state fiscal year shall require a mid-year managed care rate adjustment for the acute care and managed long term services and supports program.

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

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

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

"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.

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

"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 contracts with a vendor to conduct utilization review.

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

8. a. A contract entered into by the State Health Benefits Commission or the School Employees' Health Benefits Commission with a vendor shall require that clinical review criteria used to establish a step therapy protocol are based on clinical practice guidelines developed by the vendor 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:

(a) relies on objective data; and

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

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

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 vendor shall:

(1) upon written request, provide 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 vendors or the State to establish a new entity to develop clinical review criteria used for step therapy protocols.

9. 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 vendor or utilization review organization pursuant to a step therapy protocol, the vendor 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 vendor 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 vendor or utilization review organization’s website. A vendor 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 the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

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

c. When a step therapy exception is granted, the vendor or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider at least 180 days or the duration of therapy if less than 180 days, provided that the prescription drug is covered by the patient's health benefits plan.

d. Any step therapy exception shall be eligible for appeal by a covered person. The vendor or utilization review organization shall grant or deny a step therapy exception request or an appeal of a step therapy exception request within a time frame appropriate to the medical exigencies of the case but no later than 24 hours for urgent requests and 72 hours for non-urgent requests after obtaining all necessary information to make the approval or adverse determination.

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

(2) a vendor 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.

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

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

SENATE COMMERCE COMMITTEE

STATEMENT TO

SENATE, No. 3533

STATE OF NEW JERSEY

DATED: OCTOBER 10, 2024

The Senate Commerce Committee reports favorably Senate Bill No. 3533.

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 are 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 benefits 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 benefits 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 receipt of the request or appeal. 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.

SENATE BUDGET AND APPROPRIATIONS COMMITTEE

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 3533

STATE OF NEW JERSEY

DATED: MARCH 17, 2025

The Senate Budget and Appropriations Committee reports favorably a Senate Committee Substitute for Senate Bill No. 3533.

As reported, the bill establishes certain guidelines for the State Health Benefits Program, the School Employees Health Benefits Program, and the State Medicaid program concerning step therapy protocols. The bill also applies to: vendors that contract with the State Health Benefits Program and the School Employees Health Benefits Program; managed care organizations that administer the State Medicaid program; and utilization review organizations that work with these entities.

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 required to be administered in order to be covered by a health benefits plan. "Vendor" means a third-party administrator that conducts claims administration, network management, claims processing, or other related services for the State Health Benefits Commission or the School Employees' Health Benefits Commission.

The bill provides that clinical review criteria used to establish a step therapy protocol will 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 rely on objective data and manages conflicts of interest among the members;

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

The bill further provides that when coverage of a prescription drug for the treatment of any medical condition is restricted for use pursuant to a step therapy protocol, the vendor or managed care organization is to provide the covered person and prescribing practitioner a clear, readily accessible, and convenient process to request a step therapy exception. An existing medical exceptions process may be used to satisfy this requirement.

A step therapy exception will be granted if the prescribing health care provider determines that:

(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 or less effective than an alternative based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

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

If requested by a vendor or managed care organization, the prescribing health care provider is to provide documentation to support the determinations made by the provider.

Additionally, the bill provides that when a step therapy exception is granted, the vendor or managed care organization will authorize coverage for the prescription drug prescribed by the patient’s treating health care provider at least 180 days or the duration of therapy if less than 180 days, provided that the prescription drug is covered by the patient’s health care plan.

The bill provides that any step therapy exception is eligible for appeal by a covered person. The vendor or managed care organization is to grant or deny a step therapy exception request or an appeal of a step therapy exception request within a time frame appropriate to the medical exigencies of the case but no later than 24 hours for urgent requests and 72 hours for non-urgent requests after obtaining all necessary information to make the approval or adverse determination.

The bill finally requires certain information regarding step therapy exception request approvals and denials to be made available to the public.

FISCAL IMPACT:

The Office of Legislative Services (OLS) concludes that this bill would increase annual State expenditures for prescription drugs under the New Jersey State Health Benefits Program, the School Employees’ Health Benefits Program, and the NJ FamilyCare program (the State’s Medicaid and Children’s Health Insurance Program) by an indeterminate amount. Generally, the expenditure increase would

result as the bill would regulate the use of prescription drug step therapy protocols for patients covered under these plans and ease the overriding of the protocols in favor of drugs selected by health care providers.

The bill would result in indeterminate increases in annual expenditures for local government employers that provide employee coverage through the State Health Benefits Program or the School Employees' Health Benefits Program.

There is the potential for annual cost savings to the State Health Benefits Program, School Employees' Health Benefits Program, and NJ FamilyCare program if the bill's regulations were to result in positive health outcomes that reduce future treatment costs.

Higher NJ FamilyCare expenditures would increase annual State revenue by an indeterminate amount from federal Medicaid and Children's Health Insurance Program matching funds.

LEGISLATIVE FISCAL ESTIMATE
SENATE, No. 3533
STATE OF NEW JERSEY
221st LEGISLATURE

DATED: NOVEMBER 25, 2024

SUMMARY

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

Type of Impact: Annual State expenditure and revenue increase.

Agencies Affected: Department of Human Services; Department of Banking and Insurance.

Office of Legislative Services Estimate

Fiscal Impact	Annual
State Expenditure Increase	Indeterminate
State Revenue Increase	Indeterminate

- The Office of Legislative Services (OLS) concludes that this bill would increase annual State expenditures for prescription drugs under the NJ FamilyCare program (the State's Medicaid and Children's Health Insurance Program) by an indeterminate amount. Generally, the expenditure increase would result as the bill would regulate the use of prescription drug step therapy protocols by Medicaid managed care organizations and ease the overriding of the protocols in favor of drugs selected by health care providers.

- There is the potential for annual cost savings to the NJ FamilyCare program if the bill's regulations were to cause positive health outcomes that reduce future treatment costs.

- Higher NJ FamilyCare expenditures would increase annual State revenue by an indeterminate amount from federal Medicaid and Children's Health Insurance Program matching funds.

BILL DESCRIPTION

This bill requires health insurance carriers and utilization review organizations to meet certain guidelines in the administration and review of step therapy protocols. These protocols establish 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.

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

Carriers and utilization review organization are to report to the Department of Banking and Insurance certain information concerning the number and nature of step therapy exceptions requested, appealed, denied, and granted.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS concludes that this bill would increase annual State expenditures for prescription drugs under the NJ FamilyCare program by an indeterminate amount. Generally, the expenditure increase would result as the bill would regulate the use of prescription drug step therapy protocols by Medicaid managed care organizations and ease the overriding of the protocols in favor of drugs selected by health care providers. Additionally, the fiscal impact of the bill would be affected by several unknown variables, such as: the number of enrollees currently using step therapy drugs, the cost differentials between first line drugs and second line drugs; and the current impact of step therapy protocols, by drug, on expenditures. The OLS notes that the Department of Banking and Insurance may also incur additional annual costs related to its administrative responsibilities under the bill.

Increased NJ FamilyCare program expenditures would result in an annual, indeterminate increase in State revenue in the form of federal Medicaid and Children's Health Insurance Program matching funds. For reference, on average, the federal government provides $0.64 in matching funds for every $1.00 in qualifying State NJ FamilyCare expenditures.

There is the potential for annual cost savings to the NJ FamilyCare program if the bill's regulations were to cause positive health outcomes that reduce future treatment costs.

The bill does not apply to the State Health Benefits Program or the School Employees' Health Benefits Program. As a result, the bill would not affect annual expenditures for employee health benefits by the State, local governments, or school districts participating in these plans. However, local governments and school districts that do not participate in these plans would potentially be exposed to an indeterminate annual cost increase due to the bill, all other factors being equal.

Sections: *Human Services Section & Commerce, Labor and Industry Section*

Analysts: *Sarah Schmidt*
Lead Research Analyst
John Gaudioso
Assistant Fiscal Analyst

Approved: *Thomas Koenig*
Legislative Budget and Finance Officer

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

LEGISLATIVE FISCAL ESTIMATE

SENATE COMMITTEE SUBSTITUTE FOR

SENATE, No. 3533

STATE OF NEW JERSEY
221st LEGISLATURE

DATED: MARCH 24, 2025

SUMMARY

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

Type of Impact: Annual State expenditure and revenue increase; annual local expenditure increase.

Agencies Affected: Division of Pensions and Benefits-Department of the Treasury; Department of Human Services; local entities.

Office of Legislative Services Estimate

Fiscal Impact	Annual
State Expenditure Increase	Indeterminate
Local Expenditure Increase	Indeterminate
State Revenue Increase	Indeterminate

- The Office of Legislative Services (OLS) concludes that this bill would increase annual State expenditures for prescription drugs under the New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program (the State's Medicaid and Children's Health Insurance Program) by an indeterminate amount. Generally, the expenditure increase would result as the bill would regulate the use of prescription drug step therapy protocols for patients covered under these plans and ease the overriding of the protocols in favor of drugs selected by health care providers

- The bill would result in indeterminate increases in annual expenditures for local government employers that provide employee coverage through the State Health Benefits Program or the School Employees' Health Benefits Program.

- There is the potential for annual cost savings to the State Health Benefits Program, School Employees' Health Benefits Program, and Medicaid program if the bill's regulations were to result in positive health outcomes that reduce future treatment costs.

- Higher NJ FamilyCare expenditures would increase annual State revenue by an indeterminate amount from federal Medicaid Program matching funds.

BILL DESCRIPTION

This bill requires the New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and the State Medicaid program to meet certain guidelines in the administration and review of step therapy protocols. These protocols establish 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.

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

The Department of Human Services is required to apply for any State plan amendments or waivers necessary to implement the provisions of the bill and secure federal financial participation for State Medicaid expenditures under the federal Medicaid program

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS concludes that this bill would increase annual State expenditures for prescription drugs under the New Jersey State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program by an indeterminate amount. Generally, the expenditure increase would result as the bill would regulate the use of prescription drug step therapy protocols and ease the overriding of the protocols in favor of drugs selected by health care providers. Additionally, the fiscal impact of the bill would be affected by several unknown variables, such as: the number of enrollees currently using step therapy drugs, the cost differentials between first line drugs and second line drugs; and the current impact of step therapy protocols, by drug, on expenditures. The OLS notes that the Department of Human Services may also incur additional annual costs related to its administrative responsibilities under the bill.

The bill would result in indeterminate increases in annual expenditures for local government employers that provide employee coverage through the State Health Benefits Program or the School Employees' Health Benefits Program.

Increased NJ FamilyCare program expenditures would result in an annual, indeterminate increase in State revenue in the form of federal Medicaid and Children's Health Insurance Program

matching funds. For reference, on average, the federal government provides $0.64 in matching funds for every $1.00 in qualifying State NJ FamilyCare expenditures.

There is the potential for annual cost savings to the State Health Benefits Program, the School Employees' Health Benefits Program, and the NJ FamilyCare program if the bill's regulations were to result in positive health outcomes that reduce future treatment costs.

The OLS notes that health benefits plans purchased in the commercial market are exempt under the bill, so local government employers that procure these plans for their employees would not be affected by the bill's provisions.

Section:	*Commerce, Labor and Industry*
Analysts:	*John Gaudioso* *Associate Fiscal Analyst*
	Sarah Schmidt *Lead Research Analyst*
Approved:	*Thomas Koenig* *Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

Acting Governor Way Signs Legislation Requiring Insurance Coverage for Biomarker Testing

04/23/2025

TRENTON – Acting Governor Tahesha Way today signed legislation requiring State-regulated health insurers to cover biomarker testing, putting this form of diagnostic testing in reach for more New Jerseyans.

Biomarker testing analyzes an individual's unique biological indicators to provide insights into their health status or risk of certain diseases like cancer. Biomarkers can inform certain treatment plans, making this form of testing a critical step to applying precision medicine and targeted therapies that can improve health outcomes and provide for better quality of life.

"We are continuing to advance our mission to make high-quality health care more affordable and accessible in New Jersey. By eliminating barriers to accessing biomarker testing, we are making it easier for families in our state to access personalized treatment plans," **said Acting Governor Way**. "For someone battling life-altering and potentially fatal diseases like cancer, having this testing covered by insurance could make a world of difference in their treatment plan."

Under the bill, state-regulated health insurance providers, Medicaid, and the SHBP and SEHBP are required to provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an individual's disease or condition when the test is supported by medical and scientific evidence.

"Biomarker precision medical testing helps guide health professionals with more detailed information to diagnose or provide targeted treatment options for diseases, which can lead to improved health outcomes," **said New Jersey Department of Banking and Insurance Commissioner Justin Zimmerman**. "With this law, New Jersey is increasing accessibility and affordability of this tool that can open the door to more effective care."

Primary sponsors of the legislation (A-4163/S-3098) include Senators Vin Gopal and Troy Singleton and Assembly Members Shavonda Sumter, Gary Schaer, and Shama Haider.

"With this bill now law, we are removing a major obstacle to care and providing New Jersey patients access to essential, evidence-based biomarker testing," **said Senator Vin Gopal**. "No one should be forced to choose between their health and financial struggles. This law will save lives, improve outcomes, and ultimately lower healthcare costs for families across the state."

"Acting Governor Way's signature of this legislation will add our state to the dozens of states that have expanded insurance coverage for this important form of testing," **said Senator Troy Singleton**. "Through this law, both the identification and treatment of cancers will be improved, ensuring New Jerseyans have access to the most effective healthcare possible and saving lives."

“Everyone deserves access to high-quality medical care, without being held back by financial barriers,” **said Assemblywoman Shavonda Sumter**. “This legislation is transformational. By requiring health insurers to cover biomarker testing, we are not only breaking down long-standing barriers to care but also giving patients access to potentially life-saving information. It empowers individuals to make informed decisions about their health and opens the door to more personalized, effective treatment. I’m proud to see this critical bill signed into law and remain steadfast in my commitment to the advocates who have fought tirelessly for equitable access to this essential testing.”

"It is crucial to expand access to personalized treatment through biomarker testing," **said Assemblyman Gary Schaer**. "Often times, access to patient specific treatment is not always available to patients under their insurance plan and Medicaid. By guaranteeing insurance coverage, the passage of A4163 will combat healthcare disparities and ensures that all patients receive the quality care they deserve."

“When patients are faced with uncertainty about their health, the last thing they should have to worry about is whether their insurance will cover the necessary tests that could lead to a diagnosis,” **said Assemblywoman Shama Haider**. “A4163 is about providing people with that peace of mind, ensuring they have access to the biomarker testing, regardless of their financial situation.”

“Governor Murphy and Acting Governor Tahesha L. Way have delivered hope to countless New Jerseyans who will benefit from expanded access to biomarker testing,” **said Quinton Law, Government Relations Director for the American Cancer Society Cancer Action Network (ACS CAN)**. “This is a game-changing law for New Jersey—one that will improve health outcomes and empower more patients. For those facing cancer and other serious illnesses, it could mean fewer delays, fewer barriers, and a clearer path to the right treatment at the right time. On behalf of advocates, patients, and their families, we’re deeply grateful to Senators Gopal and Singleton, Assemblymembers Sumter, Schaer, and Haider for championing this legislation, and to Governor Murphy for his support and Lieutenant Governor Way for signing it into law.”

“Biomarker testing was key to my treatment—a treatment that saved my life. My cousin was diagnosed with pancreatic cancer just weeks before me, and we lost her to the disease. She didn’t have access to biomarker testing or the precision medicine it can unlock,” **said Nick Pifani of Delran, a cancer survivor and NJ ACS CAN volunteer who benefited from biomarker testing.** “I feel incredibly fortunate that I did. My kids were seven and nine when I was diagnosed, and I credit biomarker testing with allowing me to watch them grow into adolescence. As both a survivor and a family member of someone who could have benefited, I’m deeply grateful to New Jersey’s leaders for making this life-changing resource available to more patients.”

“At present, there are more than 185,000 New Jerseyans aged 65 or older who are living with Alzheimer’s disease, a number which only continues to rise. For these individuals, and countless others, an early and accurate diagnosis can improve access to care and support services, enhance quality of life and reduce the financial impact of the disease,” **said Bruce Sisler, Director of State Government Affairs, Alzheimer’s Association Greater New Jersey Chapter**. “We applaud Governor Murphy and Acting Governor Way for providing health insurance coverage for biomarker precision medical testing. With the historic FDA-approvals of treatments that slow the progression of Alzheimer’s disease for those in the earliest stages, biomarker testing is even more critical to ensure individuals receive the most benefit at the earliest point possible in the progression of the disease. Signing this legislation will give hundreds of thousands of New Jerseyans an opportunity to extend their lives.”

"The signing of today’s bill is a major win for New Jerseyans living with multiple sclerosis (MS). We applaud the New Jersey General Assembly for passing this landmark legislation and thank Governor Murphy and Acting Governor Way

for signing A4163/S3098 into law," **said Kyle Rivers, Senior Manager, Advocacy, National Multiple Sclerosis Society**. "Thanks to continued advancements in research, the first biomarker test to predict the risk of disease activity in MS has received breakthrough status at the FDA. This legislation will ensure patients have access to precision medicine like this test, which could help accelerate diagnosis, predict and track disease progression, and monitor treatment effectiveness."

"Lung cancer continues to take a heavy toll on families across New Jersey, with an estimated 2,670 lung cancer deaths in 2025 alone. Access to comprehensive biomarker testing is critical to ensuring patients get the most effective, personalized treatment," **said Michael Seilback, AVP, Nationwide Advocacy, State Public Policy for the American Lung Association**. "We are proud to have supported Bill A4163/ S3098 and applaud the Murphy-Way Administration for signing this lifesaving bill into law. By requiring insurance coverage for comprehensive biomarker testing, New Jersey will take the important steps to improve lung cancer treatment outcomes—this law represents hope and impactful change for lung cancer patients."

"The New Jersey State Society of Physician Assistants (NJSSPA) extends our sincere gratitude to Governor Phil Murphy and Lieutenant Governor Tahesha Way for signing the biomarker testing bill (A4163/S3098) into law," **said Victoria Latella, President of NJSSPA**. "This critical legislation advances timely, equitable access to precision diagnostics that are essential for identifying the most effective treatments for patients. As frontline providers in team-based care, physician assistants play a vital role in delivering these advanced diagnostic and treatment options to patients. This law empowers healthcare teams across the state to make more informed, personalized decisions that improve outcomes and enhance the quality of care. NJSSPA is proud to have stood alongside advocates and lawmakers, particularly the bill's sponsors, Senator Gopal and Assemblywoman Sumter, to make this possible."

"As an alliance of 33 leading academic cancer centers in the United States, NCCN applauds the passage of A4163/S3098 to advance access to clinically appropriate biomarker testing," **said Crystal S. Denlinger, MD, FACP, CEO, National Comprehensive Cancer Network® (NCCN®)**. "Access to guideline recommended biomarker testing is a key component of cancer care and decision-making. This law will facilitate access to evidence-based biomarker testing including those recommendations found in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) and NCCN Biomarkers Compendium®. NCCN is committed to being a resource for everyone to support the delivery of quality, effective cancer care and prevention. We thank Governor Murphy, Acting Governor Way, Senators Gopal and Singleton, and Assemblymembers Sumter, Schaer, and Haider for their commitment to people impacted by cancer in New Jersey."