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.