

HOUSE BILL 185

56TH LEGISLATURE - STATE OF NEW MEXICO - SECOND SESSION, 2024

INTRODUCED BY

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AN ACT

RELATING TO HEALTH COVERAGE; ENACTING NEW SECTIONS OF THE
HEALTH CARE PURCHASING ACT, THE PUBLIC ASSISTANCE ACT, THE NEW
MEXICO INSURANCE CODE, THE HEALTH MAINTENANCE ORGANIZATION LAW
AND THE NONPROFIT HEALTH CARE PLAN LAW TO ESTABLISH GUIDELINES
RELATING TO STEP THERAPY FOR PRESCRIPTION DRUG COVERAGE AND
ELIMINATE STEP THERAPY REQUIREMENTS FOR CERTAIN CONDITIONS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. A new section of the Health Care Purchasing
Act is enacted to read:

"[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY
PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

A. Group health coverage, including any form of
self-insurance, offered, issued or renewed under the Health
Care Purchasing Act that provides coverage for prescription

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1 drugs for which any step therapy protocols are required shall
2 establish clinical review criteria for those step therapy
3 protocols. The clinical review criteria shall be based on
4 clinical practice guidelines that:

5 (1) recommend that the prescription drugs
6 subject to step therapy protocols be taken in the specific
7 sequence required by the step therapy protocol;

8 (2) are developed and endorsed by an
9 interdisciplinary panel of experts that manages conflicts of
10 interest among the members of the panel of experts by:

11 (a) requiring members to: 1) disclose
12 any potential conflicts of interest with group health plan
13 administrators, insurers, health maintenance organizations,
14 health care plans, pharmaceutical manufacturers, pharmacy
15 benefits managers and any other entities; and 2) recuse
16 themselves if there is a conflict of interest; and

17 (b) using analytical and methodological
18 experts to work to provide objectivity in data analysis and
19 ranking of evidence through the preparation of evidence tables
20 and facilitating consensus;

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

23 (4) are created pursuant to an explicit and
24 transparent process that:

25 (a) minimizes bias and conflicts of

1 interest;

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

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

6 (d) considers relevant patient subgroups
7 and preferences; and

8 (5) take into account the needs of atypical
9 patient populations and diagnoses.

10 B. In the absence of clinical guidelines that meet
11 the requirements of Subsection A of this section, peer-reviewed
12 publications may be substituted.

13 C. When a group health plan restricts coverage of a
14 prescription drug for the treatment of any medical condition
15 through the use of a step therapy protocol, an enrollee and the
16 practitioner prescribing the prescription drug shall have
17 access to a clear, readily accessible and convenient process to
18 request a step therapy exception determination. A group health
19 plan may use its existing medical exceptions process in
20 accordance with the provisions of Subsections D through I of
21 this section to satisfy this requirement. The process shall be
22 made easily accessible for enrollees and practitioners on the
23 group health plan's publicly accessible website.

24 D. A group health plan shall expeditiously grant an
25 exception to the group health plan's step therapy protocol,

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1 based on medical necessity and a clinically valid explanation
2 from the patient's prescribing practitioner as to why a drug on
3 the plan's formulary that is therapeutically equivalent to the
4 prescribed drug should not be substituted for the prescribed
5 drug, if:

6 (1) the prescription drug that is the subject
7 of the exception request is contraindicated or will likely
8 cause an adverse reaction by or physical or mental harm to the
9 patient;

10 (2) the prescription drug that is the subject
11 of the exception request is expected to be ineffective based on
12 the known clinical characteristics of the patient and the known
13 characteristics of the prescription drug regimen;

14 (3) while under the enrollee's current health
15 coverage or previous health coverage, the enrollee has tried
16 the prescription drug that is the subject of the exception
17 request or another prescription drug in the same pharmacologic
18 class or with the same mechanism of action as the prescription
19 drug that is the subject of the exception request and that
20 prescription drug was discontinued due to lack of efficacy or
21 effectiveness, diminished effect or an adverse event; or

22 (4) the prescription drug required pursuant to
23 the step therapy protocol is not in the best interest of the
24 patient, based on clinical appropriateness, because the
25 patient's use of the prescription drug is expected to:

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1 (a) cause a significant barrier to the
2 patient's adherence to or compliance with the patient's plan of
3 care;

4 (b) worsen a comorbid condition of the
5 patient; or

6 (c) decrease the patient's ability to
7 achieve or maintain reasonable functional ability in performing
8 daily activities.

9 E. Upon the granting of an exception to a group
10 health plan's step therapy protocol, the group health plan
11 administrator shall authorize continuing coverage for the life
12 of the enrollee for the prescription drug that is the subject
13 of the exception request.

14 F. A group health plan shall respond with its
15 decision on an enrollee's exception request within seventy-two
16 hours of receipt. In cases where exigent circumstances exist,
17 a group health plan shall respond within twenty-four hours of
18 receipt of the exception request. In the event the group
19 health plan does not respond to an exception request within the
20 time frames required pursuant to this subsection, the exception
21 request shall be granted.

22 G. A group health plan administrator's denial of a
23 request for an exception for step therapy protocols shall be
24 subject to review and appeal pursuant to the Patient Protection
25 Act.

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1 H. After an enrollee has made an exception request
2 in accordance with the provisions of this section, a group
3 health plan shall authorize continued coverage of a
4 prescription drug that is the subject of the exception request
5 pending the determination of the exception request.

6 I. The provisions of this section shall not be
7 construed to prevent a:

8 (1) group health plan from requiring a patient
9 to try a generic equivalent of a prescription drug before
10 providing coverage for the equivalent brand-name prescription
11 drug; or

12 (2) practitioner from prescribing a
13 prescription drug that the practitioner has determined to be
14 medically necessary.

15 J. The provisions of this section shall apply only
16 to a group health plan delivered, issued for delivery or
17 renewed on or after January 1, 2025.

18 K. As used in this section, "medical necessity" or
19 "medically necessary" means health care services determined by
20 a practitioner, in consultation with the group health plan
21 administrator, to be appropriate or necessary according to:

22 (1) any applicable, generally accepted
23 principles and practices of good medical care;

24 (2) practice guidelines developed by the
25 federal government or national or professional medical

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1 societies, boards or associations; or

2 (3) any applicable clinical protocols or
3 practice guidelines developed by the group health plan
4 consistent with federal, national and professional practice
5 guidelines. These standards shall be applied to decisions
6 related to the diagnosis or direct care and treatment of a
7 physical or behavioral health condition, illness, injury or
8 disease."

9 SECTION 2. A new section of the Public Assistance Act is
10 enacted to read:

11 "[NEW MATERIAL] MEDICAL ASSISTANCE--PRESCRIPTION DRUG
12 COVERAGE--STEP THERAPY PROTOCOLS--CLINICAL REVIEW CRITERIA--
13 EXCEPTIONS.--

14 A. By January 1, 2025, the secretary shall require
15 any medical assistance plan for which any step therapy
16 protocols are required to establish clinical review criteria
17 for those step therapy protocols. The clinical review criteria
18 shall be based on clinical practice guidelines that:

19 (1) recommend that the prescription drugs
20 subject to step therapy protocols be taken in the specific
21 sequence required by the step therapy protocol;

22 (2) are developed and endorsed by an
23 interdisciplinary panel of experts that manages conflicts of
24 interest among the members of the panel of experts by:

25 (a) requiring members to: 1) disclose

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1 any potential conflicts of interest with health care plans,
2 medical assistance plans, health maintenance organizations,
3 pharmaceutical manufacturers, pharmacy benefits managers and
4 any other entities; and 2) recuse themselves if there is a
5 conflict of interest; and

6 (b) using analytical and methodological
7 experts to work to provide objectivity in data analysis and
8 ranking of evidence through the preparation of evidence tables
9 and facilitating consensus;

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

12 (4) are created pursuant to an explicit and
13 transparent process that:

14 (a) minimizes bias and conflicts of
15 interest;

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

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

20 (d) considers relevant patient subgroups
21 and preferences; and

22 (5) take into account the needs of atypical
23 patient populations and diagnoses.

24 B. In the absence of clinical guidelines that meet
25 the requirements of Subsection A of this section, peer-reviewed

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1 publications may be substituted.

2 C. When a medical assistance plan restricts
3 coverage of a prescription drug for the treatment of any
4 medical condition through the use of a step therapy protocol, a
5 recipient and the practitioner prescribing the prescription
6 drug shall have access to a clear, readily accessible and
7 convenient process to request a step therapy exception
8 determination. A medical assistance plan may use its existing
9 medical exceptions process in accordance with the provisions of
10 Subsections D through I of this section to satisfy this
11 requirement. The process shall be made easily accessible for
12 recipients and practitioners on the medical assistance plan's
13 publicly accessible website.

14 D. A medical assistance plan shall expeditiously
15 grant an exception to the medical assistance plan's step
16 therapy protocol, based on medical necessity and a clinically
17 valid explanation from the patient's prescribing practitioner
18 as to why a drug on the plan's formulary that is
19 therapeutically equivalent to the prescribed drug should not be
20 substituted for the prescribed drug, if:

21 (1) the prescription drug that is the subject
22 of the exception request is contraindicated or will likely
23 cause an adverse reaction by or physical or mental harm to the
24 patient;

25 (2) the prescription drug that is the subject

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

4 (3) while under the recipient's current
5 medical assistance plan, or under the recipient's previous
6 health coverage, the recipient has tried the prescription drug
7 that is the subject of the exception request or another
8 prescription drug in the same pharmacologic class or with the
9 same mechanism of action as the prescription drug that is the
10 subject of the exception request and that prescription drug was
11 discontinued due to lack of efficacy or effectiveness,
12 diminished effect or an adverse event; or

13 (4) the prescription drug required pursuant to
14 the step therapy protocol is not in the best interest of the
15 patient, based on clinical appropriateness, because the
16 patient's use of the prescription drug is expected to:

17 (a) cause a significant barrier to the
18 patient's adherence to or compliance with the patient's plan of
19 care;

20 (b) worsen a comorbid condition of the
21 patient; or

22 (c) decrease the patient's ability to
23 achieve or maintain reasonable functional ability in performing
24 daily activities.

25 E. Upon the granting of an exception to a medical

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1 assistance plan's step therapy protocol, a medical assistance
2 plan shall authorize continuing coverage for the life of the
3 patient for the prescription drug that is the subject of the
4 exception request.

5 F. A medical assistance plan shall respond with its
6 decision on a recipient's exception request within seventy-two
7 hours of receipt. In cases where exigent circumstances exist,
8 a medical assistance plan shall respond within twenty-four
9 hours of receipt of the exception request. In the event the
10 medical assistance plan does not respond to an exception
11 request within the time frames required pursuant to this
12 subsection, the exception request shall be granted.

13 G. A medical assistance plan's denial of a request
14 for an exception for step therapy protocols shall be subject to
15 review and appeal pursuant to department rules.

16 H. After a recipient has made an exception request
17 in accordance with the provisions of this section, a medical
18 assistance plan shall authorize continued coverage of a
19 prescription drug that is the subject of the exception request
20 pending the determination of the exception request.

21 I. The provisions of this section shall not be
22 construed to prevent:

23 (1) a medical assistance plan from requiring a
24 patient to try a generic equivalent of a prescription drug
25 before providing coverage for the equivalent brand-name

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1 prescription drug; or

2 (2) a practitioner from prescribing a
3 prescription drug that the practitioner has determined to be
4 medically necessary.

5 J. As used in this section, "medical necessity" or
6 "medically necessary" means health care services determined by
7 a practitioner, in consultation with the medical assistance
8 plan, to be appropriate or necessary, according to:

9 (1) any applicable, generally accepted
10 principles and practices of good medical care;

11 (2) practice guidelines developed by the
12 federal government or national or professional medical
13 societies, boards or associations; or

14 (3) any applicable clinical protocols or
15 practice guidelines developed by the medical assistance plan
16 consistent with federal, national and professional practice
17 guidelines. These standards shall be applied to decisions
18 related to the diagnosis or direct care and treatment of a
19 physical or behavioral health condition, illness, injury or
20 disease."

21 SECTION 3. A new section of Chapter 59A, Article 22 NMSA
22 1978 is enacted to read:

23 "[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY
24 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

25 A. Each individual health insurance policy, health
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1 care plan and certificate of health insurance delivered or
2 issued for delivery in this state that provides a prescription
3 drug benefit for which any step therapy protocols are required
4 shall establish clinical review criteria for those step therapy
5 protocols. The clinical review criteria shall be based on
6 clinical practice guidelines that:

7 (1) recommend that the prescription drugs
8 subject to step therapy protocols be taken in the specific
9 sequence required by the step therapy protocol;

10 (2) are developed and endorsed by an
11 interdisciplinary panel of experts that manages conflicts of
12 interest among the members of the panel of experts by:

13 (a) requiring members to: 1) disclose
14 any potential conflicts of interest with insurers, health
15 maintenance organizations, health care plans, pharmacy benefits
16 managers and any other entities; and 2) recuse themselves if
17 there is a conflict of interest; and

18 (b) using analytical and methodological
19 experts to work to provide objectivity in data analysis and
20 ranking of evidence through the preparation of evidence tables
21 and facilitating consensus;

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

24 (4) are created pursuant to an explicit and
25 transparent process that:

- 1 (a) minimizes bias and conflicts of
2 interest;
- 3 (b) explains the relationship between
4 treatment options and outcomes;
- 5 (c) rates the quality of the evidence
6 supporting recommendations; and
- 7 (d) considers relevant patient subgroups
8 and preferences; and
- 9 (5) take into account the needs of atypical
10 patient populations and diagnoses.

11 B. In the absence of clinical guidelines that meet
12 the requirements of Subsection A of this section, peer-reviewed
13 publications may be substituted.

14 C. When a health insurance policy, health care plan
15 or certificate of insurance restricts coverage of a
16 prescription drug for the treatment of any medical condition
17 through the use of a step therapy protocol, an insured and the
18 practitioner prescribing the prescription drug shall have
19 access to a clear, readily accessible and convenient process to
20 request a step therapy exception determination. An insurer may
21 use its existing medical exceptions process in accordance with
22 the provisions of Subsections D through I of this section to
23 satisfy this requirement. The process shall be made easily
24 accessible for insureds and practitioners on the insurer's
25 publicly accessible website.

1 D. An insurer shall expeditiously grant an
2 exception to the health insurance policy's, health care plan's
3 or certificate of insurance's step therapy protocol, based on
4 medical necessity and a clinically valid explanation from the
5 patient's prescribing practitioner as to why a drug on the
6 health insurance policy's, health care plan's or certificate of
7 insurance's formulary that is therapeutically equivalent to the
8 prescribed drug should not be substituted for the prescribed
9 drug, if:

10 (1) the prescription drug that is the subject
11 of the exception request is contraindicated or will likely
12 cause an adverse reaction by or physical or mental harm to the
13 patient;

14 (2) the prescription drug that is the subject
15 of the exception request is expected to be ineffective based on
16 the known clinical characteristics of the patient and the known
17 characteristics of the prescription drug regimen;

18 (3) while under the insured's current health
19 insurance policy, health care plan or certificate of insurance,
20 or under the insured's previous health coverage, the insured
21 has tried the prescription drug that is the subject of the
22 exception request or another prescription drug in the same
23 pharmacologic class or with the same mechanism of action as the
24 prescription drug that is the subject of the exception request
25 and that prescription drug was discontinued due to lack of

1 efficacy or effectiveness, diminished effect or an adverse
2 event; or

3 (4) the prescription drug required pursuant to
4 the step therapy protocol is not in the best interest of the
5 patient, based on clinical appropriateness, because the
6 patient's use of the prescription drug is expected to:

7 (a) cause a significant barrier to the
8 patient's adherence to or compliance with the patient's plan of
9 care;

10 (b) worsen a comorbid condition of the
11 patient; or

12 (c) decrease the patient's ability to
13 achieve or maintain reasonable functional ability in performing
14 daily activities.

15 E. Upon the granting of an exception to a health
16 insurance policy's, health care plan's or certificate of
17 insurance's step therapy protocol, an insurer shall authorize
18 continuing coverage for the life of the insured for the
19 prescription drug that is the subject of the exception request.

20 F. An insurer shall respond with its decision on an
21 insured's exception request within seventy-two hours of
22 receipt. In cases where exigent circumstances exist, an
23 insurer shall respond within twenty-four hours of receipt of
24 the exception request. In the event the insurer does not
25 respond to an exception request within the time frames required

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1 pursuant to this subsection, the exception request shall be
2 granted.

3 G. An insurer's denial of a request for an
4 exception for step therapy protocols shall be subject to review
5 and appeal pursuant to the Patient Protection Act.

6 H. After an insured has made an exception request
7 in accordance with the provisions of this section, an insurer
8 shall authorize continued coverage of a prescription drug that
9 is the subject of the exception request pending the
10 determination of the exception request.

11 I. The provisions of this section shall not be
12 construed to prevent:

13 (1) a health insurance policy, health care
14 plan or certificate of insurance from requiring a patient to
15 try a generic equivalent of a prescription drug before
16 providing coverage for the equivalent brand-name prescription
17 drug; or

18 (2) a practitioner from prescribing a
19 prescription drug that the practitioner has determined to be
20 medically necessary.

21 J. The provisions of this section shall apply only
22 to a health insurance policy, health care plan or certificate
23 of insurance delivered, issued for delivery or renewed on or
24 after January 1, 2025.

25 K. The superintendent shall promulgate rules as may

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1 be necessary to appropriately implement the provisions of this
2 section.

3 L. Nothing in this section shall be interpreted to
4 interfere with the superintendent's authority to regulate
5 prescription drug coverage benefits under other state and
6 federal law.

7 M. As used in this section, "medical necessity" or
8 "medically necessary" means health care services determined by
9 a practitioner, in consultation with the insurer, to be
10 appropriate or necessary, according to:

11 (1) any applicable, generally accepted
12 principles and practices of good medical care;

13 (2) practice guidelines developed by the
14 federal government or national or professional medical
15 societies, boards or associations; or

16 (3) any applicable clinical protocols or
17 practice guidelines developed by the insurer consistent with
18 federal, national and professional practice guidelines. These
19 standards shall be applied to decisions related to the
20 diagnosis or direct care and treatment of a physical or
21 behavioral health condition, illness, injury or disease."

22 SECTION 4. Section 59A-22B-8 NMSA 1978 (being Laws 2023,
23 Chapter 114, Section 13) is amended to read:

24 "59A-22B-8. PRIOR AUTHORIZATION FOR PRESCRIPTION DRUGS OR
25 STEP THERAPY FOR ~~[SUBSTANCE USE DISORDER]~~ CERTAIN CONDITIONS

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1 PROHIBITED.--

2 A. Coverage for medication approved by the federal
3 food and drug administration that is prescribed for the
4 treatment of an autoimmune disorder, a behavioral health
5 condition, cancer or a substance use disorder, pursuant to a
6 health care provider's medical necessity determination, shall
7 not be subject to prior authorization, except in cases in which
8 a generic version is available.

9 B. A health insurer shall not impose step therapy
10 requirements before authorizing coverage for medication
11 approved by the federal food and drug administration that is
12 prescribed for the treatment of an autoimmune disorder, a
13 behavioral health condition, cancer or a substance use
14 disorder, pursuant to a health care provider's medical
15 necessity determination, except in cases in which a generic
16 version is available."

17 SECTION 5. A new section of Chapter 59A, Article 23 NMSA
18 1978 is enacted to read:

19 "[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY
20 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

21 A. Each group or blanket health insurance policy,
22 health care plan and certificate of health insurance delivered
23 or issued for delivery in this state that provides a
24 prescription drug benefit for which any step therapy protocols
25 are required shall establish clinical review criteria for those

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1 step therapy protocols. The clinical review criteria shall be
2 based on clinical practice guidelines that:

3 (1) recommend that the prescription drugs
4 subject to step therapy protocols be taken in the specific
5 sequence required by the step therapy protocol;

6 (2) are developed and endorsed by an
7 interdisciplinary panel of experts that manages conflicts of
8 interest among the members of the panel of experts by:

9 (a) requiring members to: 1) disclose
10 any potential conflicts of interest with insurers, health
11 maintenance organizations, health care plans, pharmacy benefits
12 managers and any other entities; and 2) recuse themselves if
13 there is a conflict of interest; and

14 (b) using analytical and methodological
15 experts to provide objectivity in data analysis and ranking of
16 evidence through the preparation of evidence tables and
17 facilitating consensus;

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

20 (4) are created pursuant to an explicit and
21 transparent process that:

22 (a) minimizes bias and conflicts of
23 interest;

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

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

3 (d) considers relevant patient subgroups
4 and preferences; and

5 (5) take into account the needs of atypical
6 patient populations and diagnoses.

7 B. In the absence of clinical guidelines that meet
8 the requirements of Subsection A of this section, peer-reviewed
9 publications may be substituted.

10 C. When a health insurance policy, health care plan
11 or certificate of insurance restricts coverage of a
12 prescription drug for the treatment of any medical condition
13 through the use of a step therapy protocol, an insured and the
14 practitioner prescribing the prescription drug shall have
15 access to a clear, readily accessible and convenient process to
16 request a step therapy exception determination. An insurer may
17 use its existing medical exceptions process in accordance with
18 the provisions of Subsections D through I of this section to
19 satisfy this requirement. The process shall be made easily
20 accessible for insureds and practitioners on the insurer's
21 publicly accessible website.

22 D. An insurer shall expeditiously grant an
23 exception to the health insurance policy's, health care plan's
24 or certificate of insurance's step therapy protocol, based on
25 medical necessity and a clinically valid explanation from the

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1 patient's prescribing practitioner as to why a drug on the
2 health insurance policy's, health care plan's or certificate of
3 insurance's formulary that is therapeutically equivalent to the
4 prescribed drug should not be substituted for the prescribed
5 drug, if:

6 (1) the prescription drug that is the subject
7 of the exception request is contraindicated or will likely
8 cause an adverse reaction by or physical or mental harm to the
9 patient;

10 (2) the prescription drug that is the subject
11 of the exception request is expected to be ineffective based on
12 the known clinical characteristics of the patient and the known
13 characteristics of the prescription drug regimen;

14 (3) while under the insured's current health
15 insurance policy, health care plan or certificate of insurance,
16 or under the insured's previous health coverage, the insured
17 has tried the prescription drug that is the subject of the
18 exception request or another prescription drug in the same
19 pharmacologic class or with the same mechanism of action as the
20 prescription drug that is the subject of the exception request
21 and that prescription drug was discontinued due to lack of
22 efficacy or effectiveness, diminished effect or an adverse
23 event; or

24 (4) the prescription drug required pursuant to
25 the step therapy protocol is not in the best interest of the

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1 patient, based on clinical appropriateness, because the
2 patient's use of the prescription drug is expected to:

3 (a) cause a significant barrier to the
4 patient's adherence to or compliance with the patient's plan of
5 care;

6 (b) worsen a comorbid condition of the
7 patient; or

8 (c) decrease the patient's ability to
9 achieve or maintain reasonable functional ability in performing
10 daily activities.

11 E. Upon the granting of an exception to a health
12 insurance policy's, health care plan's or certificate of
13 insurance's step therapy protocol, an insurer shall authorize
14 continuing coverage for the life of the insured for the
15 prescription drug that is the subject of the exception request.

16 F. An insurer shall respond with its decision on an
17 insured's exception request within seventy-two hours of
18 receipt. In cases where exigent circumstances exist, an
19 insurer shall respond within twenty-four hours of receipt of
20 the exception request. In the event the insurer does not
21 respond to an exception request within the time frames required
22 pursuant to this subsection, the exception request shall be
23 granted.

24 G. An insurer's denial of a request for an
25 exception for step therapy protocols shall be subject to review

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1 and appeal pursuant to the Patient Protection Act.

2 H. After an insured has made an exception request
3 in accordance with the provisions of this section, an insurer
4 shall authorize continued coverage of a prescription drug that
5 is the subject of the exception request pending the
6 determination of the exception request.

7 I. The provisions of this section shall not be
8 construed to prevent:

9 (1) a health insurance policy, health care
10 plan or certificate of insurance from requiring a patient to
11 try a generic equivalent of a prescription drug before
12 providing coverage for the equivalent brand-name prescription
13 drug; or

14 (2) a practitioner from prescribing a
15 prescription drug that the practitioner has determined to be
16 medically necessary.

17 J. The provisions of this section shall apply only
18 to a health insurance policy, health care plan or certificate
19 of insurance delivered, issued for delivery or renewed on or
20 after January 1, 2025.

21 K. The superintendent shall promulgate rules as may
22 be necessary to appropriately implement the provisions of this
23 section.

24 L. Nothing in this section shall be interpreted to
25 interfere with the superintendent's authority to regulate

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1 prescription drug coverage benefits under other state and
2 federal law.

3 M. As used in this section, "medical necessity" or
4 "medically necessary" means health care services determined by
5 a practitioner, in consultation with the insurer, to be
6 appropriate or necessary, according to:

7 (1) any applicable, generally accepted
8 principles and practices of good medical care;

9 (2) practice guidelines developed by the
10 federal government or national or professional medical
11 societies, boards or associations; or

12 (3) any applicable clinical protocols or
13 practice guidelines developed by the insurer consistent with
14 federal, national and professional practice guidelines. These
15 standards shall be applied to decisions related to the
16 diagnosis or direct care and treatment of a physical or
17 behavioral health condition, illness, injury or disease."

18 SECTION 6. A new section of the Health Maintenance
19 Organization Law is enacted to read:

20 "[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY
21 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

22 A. Each individual or group health maintenance
23 organization contract delivered or issued for delivery in this
24 state that provides a prescription drug benefit for which any
25 step therapy protocols are required shall establish clinical

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1 review criteria for those step therapy protocols. The clinical
2 review criteria shall be based on clinical practice guidelines
3 that:

4 (1) recommend that the prescription drugs
5 subject to step therapy protocols be taken in the specific
6 sequence required by the step therapy protocol;

7 (2) are developed and endorsed by an
8 interdisciplinary panel of experts that manages conflicts of
9 interest among the members of the panel of experts by:

10 (a) requiring members to: 1) disclose
11 any potential conflicts of interest with carriers, insurers,
12 health care plans, pharmaceutical manufacturers, pharmacy
13 benefits managers and any other entities; and 2) recuse
14 themselves if there is a conflict of interest; and

15 (b) using analytical and methodological
16 experts to work to provide objectivity in data analysis and
17 ranking of evidence through the preparation of evidence tables
18 and facilitating consensus;

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

21 (4) are created pursuant to an explicit and
22 transparent process that:

23 (a) minimizes bias and conflicts of
24 interest;

25 (b) explains the relationship between

1 treatment options and outcomes;

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

4 (d) considers relevant patient subgroups
5 and preferences; and

6 (5) take into account the needs of atypical
7 patient populations and diagnoses.

8 B. In the absence of clinical guidelines that meet
9 the requirements of Subsection A of this section, peer-reviewed
10 publications may be substituted.

11 C. When a health maintenance organization contract
12 restricts coverage of a prescription drug for the treatment of
13 any medical condition through the use of a step therapy
14 protocol, an enrollee and the practitioner prescribing the
15 prescription drug shall have access to a clear, readily
16 accessible and convenient process to request a step therapy
17 exception determination. A carrier may use its existing
18 medical exceptions process in accordance with the provisions of
19 Subsections D through I of this section to satisfy this
20 requirement. The process shall be made easily accessible for
21 enrollees and practitioners on the carrier's publicly
22 accessible website.

23 D. A carrier shall expeditiously grant an exception
24 to the health maintenance organization contract's step therapy
25 protocol, based on medical necessity and a clinically valid

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1 explanation from the patient's prescribing practitioner as to
2 why a drug on the health maintenance organization contract's
3 formulary that is therapeutically equivalent to the prescribed
4 drug should not be substituted for the prescribed drug, if:

5 (1) the prescription drug that is the subject
6 of the exception request is contraindicated or will likely
7 cause an adverse reaction by or physical or mental harm to the
8 patient;

9 (2) the prescription drug that is the subject
10 of the exception request is expected to be ineffective based on
11 the known clinical characteristics of the patient and the known
12 characteristics of the prescription drug regimen;

13 (3) while under the enrollee's current health
14 maintenance organization contract, or under the enrollee's
15 previous health coverage, the enrollee has tried the
16 prescription drug that is the subject of the exception request
17 or another prescription drug in the same pharmacologic class or
18 with the same mechanism of action as the prescription drug that
19 is the subject of the exception request and that prescription
20 drug was discontinued due to lack of efficacy or effectiveness,
21 diminished effect or an adverse event; or

22 (4) the prescription drug required pursuant to
23 the step therapy protocol is not in the best interest of the
24 patient, based on clinical appropriateness, because the
25 patient's use of the prescription drug is expected to:

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1 (a) cause a significant barrier to the
2 patient's adherence to or compliance with the patient's plan of
3 care;

4 (b) worsen a comorbid condition of the
5 patient; or

6 (c) decrease the patient's ability to
7 achieve or maintain reasonable functional ability in performing
8 daily activities.

9 E. Upon the granting of an exception to a health
10 maintenance organization contract's step therapy protocol, a
11 carrier shall authorize continuing coverage for the lifetime of
12 the enrollee for the prescription drug that is the subject of
13 the exception request.

14 F. A carrier shall respond with its decision on an
15 enrollee's exception request within seventy-two hours of
16 receipt. In cases where exigent circumstances exist, a carrier
17 shall respond within twenty-four hours of receipt of the
18 exception request. In the event the carrier does not respond
19 to an exception request within the time frames required
20 pursuant to this subsection, the exception request shall be
21 granted.

22 G. A carrier's denial of a request for an exception
23 for step therapy protocols shall be subject to review and
24 appeal pursuant to the Patient Protection Act.

25 H. After an enrollee has made an exception request

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1 in accordance with the provisions of this section, a carrier
2 shall authorize continued coverage of a prescription drug that
3 is the subject of the exception request pending the
4 determination of the exception request.

5 I. The provisions of this section shall not be
6 construed to prevent:

7 (1) a health maintenance organization contract
8 from requiring a patient to try a generic equivalent of a
9 prescription drug before providing coverage for the equivalent
10 brand-name prescription drug; or

11 (2) a practitioner from prescribing a
12 prescription drug that the practitioner has determined to be
13 medically necessary.

14 J. The provisions of this section shall apply only
15 to a health maintenance organization contract delivered, issued
16 for delivery or renewed on or after January 1, 2025.

17 K. The superintendent shall promulgate rules as may
18 be necessary to appropriately implement the provisions of this
19 section.

20 L. Nothing in this section shall be interpreted to
21 interfere with the superintendent's authority to regulate
22 prescription drug coverage benefits under other state and
23 federal law.

24 M. As used in this section, "medical necessity" or
25 "medically necessary" means health care services determined by

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1 a practitioner, in consultation with the carrier, to be
2 appropriate or necessary, according to:

3 (1) any applicable, generally accepted
4 principles and practices of good medical care;

5 (2) practice guidelines developed by the
6 federal government or national or professional medical
7 societies, boards or associations; or

8 (3) any applicable clinical protocols or
9 practice guidelines developed by the carrier consistent with
10 federal, national and professional practice guidelines. These
11 standards shall be applied to decisions related to the
12 diagnosis or direct care and treatment of a physical or
13 behavioral health condition, illness, injury or disease."

14 SECTION 7. A new section of the Nonprofit Health Care
15 Plan Law is enacted to read:

16 "[NEW MATERIAL] PRESCRIPTION DRUG COVERAGE--STEP THERAPY
17 PROTOCOLS--CLINICAL REVIEW CRITERIA--EXCEPTIONS.--

18 A. Each individual or group nonprofit health care
19 plan contract delivered or issued for delivery in this state
20 that provides a prescription drug benefit for which any step
21 therapy protocols are required shall establish clinical review
22 criteria for those step therapy protocols. The clinical review
23 criteria shall be based on clinical practice guidelines that:

24 (1) recommend that the prescription drugs
25 subject to step therapy protocols be taken in the specific

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1 sequence required by the step therapy protocol;

2 (2) are developed and endorsed by an
3 interdisciplinary panel of experts that manages conflicts of
4 interest among the members of the panel of experts by:

5 (a) requiring members to: 1) disclose
6 any potential conflicts of interest with health care plans,
7 insurers, health maintenance organizations, pharmaceutical
8 manufacturers, pharmacy benefits managers and any other
9 entities; and 2) recuse themselves if there is a conflict of
10 interest; and

11 (b) using analytical and methodological
12 experts to work to provide objectivity in data analysis and
13 ranking of evidence through the preparation of evidence tables
14 and facilitating consensus;

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

17 (4) are created pursuant to an explicit and
18 transparent process that:

19 (a) minimizes bias and conflicts of
20 interest;

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

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

25 (d) considers relevant patient subgroups

1 and preferences; and

2 (5) take into account the needs of atypical
3 patient populations and diagnoses.

4 B. In the absence of clinical guidelines that meet
5 the requirements of Subsection A of this section, peer-reviewed
6 publications may be substituted.

7 C. When a health care plan restricts coverage of a
8 prescription drug for the treatment of any medical condition
9 through the use of a step therapy protocol, a subscriber and
10 the practitioner prescribing the prescription drug shall have
11 access to a clear, readily accessible and convenient process to
12 request a step therapy exception determination. A health care
13 plan may use its existing medical exceptions process in
14 accordance with the provisions of Subsections D through I of
15 this section to satisfy this requirement. The process shall be
16 made easily accessible for subscribers and practitioners on the
17 health care plan's publicly accessible website.

18 D. A health care plan shall expeditiously grant an
19 exception to the health care plan's step therapy protocol,
20 based on medical necessity and a clinically valid explanation
21 from the patient's prescribing practitioner as to why a drug on
22 the health care plan's formulary that is therapeutically
23 equivalent to the prescribed drug should not be substituted for
24 the prescribed drug, if:

25 (1) the prescription drug that is the subject

1 of the exception request is contraindicated or will likely
2 cause an adverse reaction by or physical or mental harm to the
3 patient;

4 (2) the prescription drug that is the subject
5 of the exception request is expected to be ineffective based on
6 the known clinical characteristics of the patient and the known
7 characteristics of the prescription drug regimen;

8 (3) while under the subscriber's current
9 health care plan, or under the subscriber's previous health
10 coverage, the subscriber has tried the prescription drug that
11 is the subject of the exception request or another prescription
12 drug in the same pharmacologic class or with the same mechanism
13 of action as the prescription drug that is the subject of the
14 exception request and that prescription drug was discontinued
15 due to lack of efficacy or effectiveness, diminished effect or
16 an adverse event; or

17 (4) the prescription drug required pursuant to
18 the step therapy protocol is not in the best interest of the
19 patient, based on clinical appropriateness, because the
20 patient's use of the prescription drug is expected to:

21 (a) cause a significant barrier to the
22 patient's adherence to or compliance with the patient's plan of
23 care;

24 (b) worsen a comorbid condition of the
25 patient; or

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1 (c) decrease the patient's ability to
2 achieve or maintain reasonable functional ability in performing
3 daily activities.

4 E. Upon the granting of an exception to a health
5 care plan's step therapy protocol, a health care plan shall
6 authorize continuing coverage for the lifetime of the
7 subscriber for the prescription drug that is the subject of the
8 exception request.

9 F. A health care plan shall respond with its
10 decision on a subscriber's exception request within seventy-two
11 hours of receipt. In cases where exigent circumstances exist,
12 a health care plan shall respond within twenty-four hours of
13 receipt of the exception request. In the event the insurer
14 does not respond to an exception request within the time frames
15 required pursuant to this subsection, the exception request
16 shall be granted.

17 G. A health care plan's denial of a request for an
18 exception for step therapy protocols shall be subject to review
19 and appeal pursuant to the Patient Protection Act.

20 H. After a subscriber has made an exception request
21 in accordance with the provisions of this section, a health
22 care plan shall authorize continued coverage of a prescription
23 drug that is the subject of the exception request pending the
24 determination of the exception request.

25 I. The provisions of this section shall not be

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1 construed to prevent:

2 (1) a health care plan from requiring a
3 patient to try a generic equivalent of a prescription drug
4 before providing coverage for the equivalent brand-name
5 prescription drug; or

6 (2) a practitioner from prescribing a
7 prescription drug that the practitioner has determined to be
8 medically necessary.

9 J. The provisions of this section shall apply only
10 to a health care plan delivered, issued for delivery or renewed
11 on or after January 1, 2025.

12 K. The superintendent shall promulgate rules as may
13 be necessary to appropriately implement the provisions of this
14 section.

15 L. Nothing in this section shall be interpreted to
16 interfere with the superintendent's authority to regulate
17 prescription drug coverage benefits under other state and
18 federal law.

19 M. As used in this section, "medical necessity" or
20 "medically necessary" means health care services determined by
21 a practitioner, in consultation with the health care plan, to
22 be appropriate or necessary, according to:

23 (1) any applicable, generally accepted
24 principles and practices of good medical care;

25 (2) practice guidelines developed by the

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1 federal government or national or professional medical
2 societies, boards or associations; or

3 (3) any applicable clinical protocols or
4 practice guidelines developed by the health care plan
5 consistent with federal, national and professional practice
6 guidelines. These standards shall be applied to decisions
7 related to the diagnosis or direct care and treatment of a
8 physical or behavioral health condition, illness, injury or
9 disease."

10 SECTION 8. EXCEPTIONS.--The provisions of Section 1 and
11 Sections 3 through 7 of this 2024 act do not apply to
12 short-term plans subject to the Short-Term Health Plan and
13 Excepted Benefit Act.

14 SECTION 9. COMPLIANCE.--Beginning in July 2026, and
15 annually thereafter, the office of superintendent of insurance
16 or a contracting party shall perform an audit to ensure
17 compliance with the provisions of this 2024 act.

18 SECTION 10. APPLICABILITY.--The provisions of this act
19 apply to group health insurance policies, health care plans or
20 certificates of health insurance, other than small group health
21 plans, that are delivered, issued for delivery or renewed in
22 this state on or after January 1, 2025.